STATE OFFICE FOR NUCLEAR SAFETY

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

In Prague, on 10 October 2013
Ref. no.: SÚJB/ONRV/21067/2013
File no.: SÚJB/POD/19221/2013/2
RAW and Spent Fuel Management Division

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 Some 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 2 September 2013 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., Identification Number 45274584, Registration Number 108600 (hereinafter referred-to as "Participant in Proceedings"), of 28 August 2013 under file no. 20/EZC/13 in the matter of repeated issuance of the decision on type approval of a special form radioactive material:

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

a p p r o v e s

Construction type **Am1.N02** special form radioactive material (hereinafter referred-to as "SFRM"), this SFRM, manufactured in conformity with the documentation assessed, being assigned the identification designation

CZ/1009/S – 96

and, for the purposes of international identification, this Am1.N02 SFRM type approval decision being assigned the code designation

CZ/1009/S – 96 (Rev. 2).

The special form radioactive material under the identification designation CZ/1009/S – 96 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 (IAEA) titled "Regulations for the Safe Transport of Radioactive Material, 2009 Edition Safety Requirements Series No. TS-R-1," and the requirements of the international transportation regulations that refer to the cited IAEA's rules.

Description of the Special Form Radioactive Material

Am1.N02 special form radioactive material is a cylinder 10 mm long and the diameter of 7.8 mm. It consists of an outer capsule of stainless-steel closed with a plug of the same material welded on by welding in the protective atmosphere, an inner capsule with a plug, both of stainless steel, too, welded on using the TIG method as well, and a radionuclide emitter inside the inner capsule. A distance piece fixes the inner capsule so that the radionuclide emitter is in close contact with the outlet hole of the outer capsule, 0.2 mm thick.

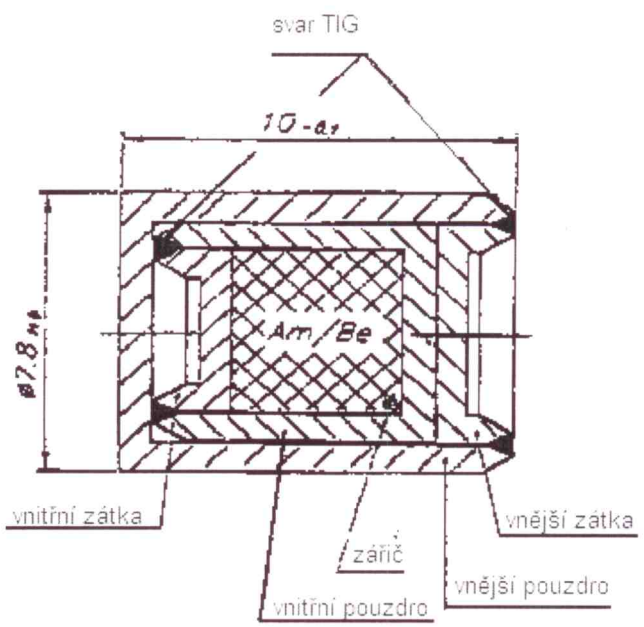
Eckert & Ziegler Cesio s. r. o., Radiová 1, 102 27 Prague 10, is the manufacturer of this SFRM.

Parameters of the Special Form Radioactive Material (SFRM)

SRFM	Outer diameter [mm]	Height [mm]	Thickness of the hole [mm]	Maximum activity [GBq]	ISO Classification
Am1.N02	**7.8**	**10**	**0.2**	**7.4**	**C 66545**

Picture of the Special Form Radioactive Material

The picture of the Am1.N02 SFRM corresponds to the technical drawing "Am – Be NEUTRON SOURCE Am1.N02, 1. 207.02.02 – 00:00 (4), BEBIG Isotopentechnik und Umweltdiagnostik GmbH, of 2 May/28 July 1995".



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

Conditions for Use of the Special Form Radioactive Material:

Type-approved SFRM Am1.N02 under identification designation CZ/1009/S - 96 may be used only subject to the compliance with the following conditions:

1. Permitted Radioactive Content

The Am1.N02 special form radioactive material under identification designation CZ/1009/S – 96 may only contain a radionuclide emitter consisting of a mixture of natural beryllium powder and a ^{241}Am radionuclide bound in the form of americium oxide, with the maximum activity of 7.4 GBq.

2. Handling, Maintenance and Inspections

Handling, maintenance and operating inspections – reviews of the Am1.N02 SFRM must be performed in compliance with the requirements given in the valid version of "Instructions for Safe Handling of Ionizing Radiation Sources (ZIZ), QM-RP-006, Eckert & Ziegler Cesio s.r.o."

Reviews of the Am1.N02 SFRM, operating stability test and long-term stability test performed in accordance with the above document under ISO 9978 "Radiation Protection – Sealed Radioactive Sources –Leakage Test Methods 1992" must be documented by an official record and archived throughout the life of the SFRM.

3. Quality Assurance

The Am1.N02 special form radioactive material under identification designation CZ/1009/S – 96 and with the given serial number must be manufactured in accordance with the technical drawing "Am – Be NEUTRON SOURCE Am1.N02, 1. 207.02.02 – 00:00 (4), BEBIG Isotopentechnik und Umweltdiagnostik GmbH, of 2 May/28 July 1995", in accordance with the approved procedures and with the document titled "Quality Assurance Programme (to meet the requirements of ISO 9001, ISO13485 and Decree no. 132/2008 Sb.), Q940-001", in the valid version.

The manufacturer must document the conformity of the Am1.N02 special form radioactive material, under identification designation CZ/1009/S – 96 and with 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).

The Am1.N02 special form radioactive material under identification designation CZ/1009/S – 96 and with the given serial number may be put into circulation only if its conformity with the approved type was proved by the special form radioactive material acceptance test according to the valid version of the document "Closed Radionuclide Emitter (URZ) Conformity Verification, Methodology, QM – T – 541 Eckert & Ziegler Cesio s. r. o."

4. Labelling

The Am1.N02 special form radioactive material under identification designation CZ/1009/S – 96 must be labelled with the serial number and the identification designation CZ/1009/S – 96 in a clear, legible and durable manner. In case it is not technically practicable to place the identification designation onto the capsule of the special form radioactive material, it can be replaced by the type approval decision.

5. Reporting of Accidents

If any defect or accident accompanied with damage to the Am1.N02 special form radioactive material under identification designation CZ/1009/S – 96 occurs in handling it, the SFRM

must be temporarily put out of operation without unnecessary delay, in compliance with all requirements of radiation safety.

The SFRM may be put into operation only after an inspection and/or repair. At the same time, a record of the incident must be elaborated and sent by the Approval Holder pursuant to Section 9 (1) (i) of Act no. 18/1997 Sb., Atomic Act, as amended, to the State Office for Nuclear Safety within 14 days after the occurrence of the incident.

6. Validity of the Decision

a) The Decision of Type Approval of Am1.N02 SFRM does not replace other permissions of the State Office for Nuclear Safety issued pursuant to Section 9 (1) of Act no. 18/1997 Sb., as amended, and/or permissions/licenses for activities issued by other central state administration bodies pursuant to special regulations.

b) Decision ref. no. 19481/2008 of 5 September 2008 is hereby invalidated and replaced at the same time.

The validity of this Decision expires on 30 November 2023.

Justification:

The Decision is issued on the ground of the application from the Eckert & Ziegler Cesio s.r.o. Company, ref. no. 20/EZC/13 of 28 August 2013, after having assessed the documentation presented, which was submitted to the State Office for Nuclear Safety pursuant to the provision of Section 23 of Act no. 18/1997 Sb., as amended.

The Applicant submitted this application for repeated issuance of the decision on type approval of Am1.N02 SFRM for reasons of the forthcoming expiry of the above-mentioned SONS's decision ref. no. 19481/2008, of 5 September 2008, as of 31 December 2013.

The Participant in Proceedings submitted valid documentation in compliance with Sections 3 and 4 of Decree no. 317/2002 Sb., On type approval and shipment, as amended, during previous administrative procedures, the last one of which was concluded by the issuance of the Decision of the State Office for Nuclear Safety on Am1.N02 SFRM type approval, ref. no. 19481/2008 of 5 September 2008.

The Application was also supported by the following documents, in compliance with the above-cited provisions of legal regulations:

- Authenticated copy of the entry in the Register of Companies regarding the Eckert & Ziegler Cesio s. r. o. Company of 25 March 2013;
- Affirmation pursuant to Section 13 (8) of Act no. 18/1997 Sb., Atomic Act, as amended, of Eckert & Ziegler Cesio s. r. o. of 31 May 2013;
- Requirements of an application for type approval of a special form radioactive material within the meaning of Decree no. 317/2002 Sb., Eckert & Ziegler Cesio s. r. o., of 28 August 2013;
- Annex C to ref. no. 20/EZC/13, Construction types of special form radioactive materials (SFRM), Eckert & Ziegler Cesio s. r. o., of 28 August 2013;
- Copy of the document titled "Instructions for Safe Handling of Ionizing Radiation Sources (ZIZ)", QM-RP-006, Eckert & Ziegler Cesio s. r. o., copy no. 2, version no. 3, of 18 May 2011;

- Copy of the front page of the Quality Assurance Programme (to meet the requirements of ISO 9001, ISO13485 and Decree no. 132/2008 Sb.) Q940-001, Eckert & Ziegler Cesio s. r. o., version 3 of 8 April 2010, approved by SONS's Decision ref. no. SÚJB/OZ/9373/2010 of 14 April 2010;
- Digital form of the "Quality Manual" document, QM-Q-000 Eckert & Ziegler Cesio s. r. o.;
- Digital form of the "Closed Radionuclide Emitter (URZ) Conformity Verification, Methodology" document, QM – T – 541 Eckert & Ziegler Cesio s. r. o., version 1, of 27 October 1998;
- Sample of a Closed Emitter Certification, Eckert & Ziegler Cesio s. r. o., of 22 May 2013;
- Copy of the ISO 9001:2008 Quality Certificate, Certificate no. 12 100 12817 TMS, TÜV SÜD Management Service GmbH, of 30 July 2012.

SONS states that the assessed documentation complies with the relevant provisions of Act no. 18/1997 Sb., as amended, and the relevant provisions of Decree no. 317/2002 Sb., as amended, and that's why the suitability of Am1.N02 SFRM for its use in accordance with Condition 1 and subject to the other conditions hereof is proved.

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

For reasons above, SONS decided as stated in the Statement.

Advice:

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

Imprint of the official seal

RNDr. Peter Lietava
Head of the RAW and Spent Fuel Management Division

Distribution List:

Applicant

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File