



STATE OFFICE FOR NUCLEAR SAFETY
Senovážné náměstí 9, 110 00 Prague 1

Prague, 12 January 2004
Ref. No.: 328/2004
File No.: 20040/2003
Responsible unit: Nuclear Materials Department

DECISION

The State Office for Nuclear Safety as a respective administrative body pursuant to § 3 par. 2 subsection c) of Act No. 18/1997 Coll., to regulate the peaceful exploitation of nuclear energy and ionizing radiation (the Atomic Law) and alteration and amendments to other laws, as amended later, decided in the administrative proceedings related to the type approval of the special-form radioactive material commenced on 27 October 2003 pursuant to the application of Isotope Products Cesio s.r.o., with its registered office at Radiová 1, 102 27 Prague 10, identification No. 45274584 (hereinafter the “applicant”), ref. No. 091/IPC/03 dated 24 October 2003, as follows:

pursuant to the provision § 23 par. 2 of Act No. 18/1997 Coll., as amended later the State Office for Nuclear Safety

approves the type

of the special-form radioactive material, type Am1.N02,

and assigns the special-form radioactive material, type Am1.N02, produced in compliance with the examined documentation, the identification designation

CZ/1009/S – 96

and for the international identification issues the decision on the type approval of the special-form radioactive material and assigns the material the code

CZ/1009/S – 96 (Rev. 0).

The special-form radioactive material with the identification designation CZ/1009/S – 96 fulfils the requirements of the recommendation of the International Atomic Energy Agency, “Edition of Security Regulations IAEA, Rules for the Safe Transport of Radioactive Materials, Edition 1996 (revised), Requirements, Sign TS-R-1, (ST-1, revised), IAEA, Vienna 2000” and international transport regulations, which refer to the cited rules of the International Atomic Energy Agency.

Description of the special-form radioactive material

The special-form radioactive material with the identification designation CZ/1009/S – 96 is depicted in the attachment, which is an integral part of this Decision. The technical drawing corresponds 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“. It has a cylindrical shape 10mm long with the diameter of 7.8mm. It consists of the external case made from stainless steel and the internal case made from the same material. The internal case containing the radionuclide source is sealed by arc welding in the shielding atmosphere (TIG) and it is inserted into the external case, which is then also sealed by arc welding in the shielding atmosphere (TIG).

Parameters of the special-form radioactive material

Type of the special-form radioactive material	Length (mm)	Diameter (mm)	Maximum activity (GBQ)
Am1.N02	10	7,8	3,7

The special-form radioactive material with the identification designation CZ/1009/S – 96 is clearly legibly and permanently designated with the following data:

- Production number
- Identification designation CZ/1009/S – 96; if it is impossible from the technical point of view to designate the identification on the case of the special-form radioactive material, this will be replaced by the decision on the type approval.

The special-form radioactive material with the identification designation CZ/1009/S – 96 is produced by Isotope Products Cesio s.r.o., Radiová 1, 102 27 Prague 10.

The special-form radioactive material with the identification designation CZ/1009/S – 96 can be used when the following conditions are fulfilled:

1. Admissible content of the special-form radioactive material

The special-form radioactive material with the identification designation CZ/1009/S – 96 and with the given production number can contain only the radionuclide source consisting of the sintered mixture of the natural powder beryllium and radionuclide ^{241}Am bound in the form of americium oxide, in the tablet with the diameter of 4,6mm and height 4,3mm, with the maximum activity of 3,7 GBq.

2. Compliance of features and parameters with the approved type

The compliance of the special-form radioactive material with the identification designation CZ/1009/S – 96 and with the given production number with the approved type must be documented by the producer in a written declaration of conformity pursuant to § 6 par. 2 subsection c) of Regulation No. 317/2002 Coll., to regulate the type approval of packaging sets for transport, stocking and storing of nuclear materials and radioactive materials, the type approval of sources of ionizing radiation and transport of nuclear materials and designated radioactive materials (the type approval and transport).

The special-form radioactive material with the identification designation CZ/1009/S – 96 and with the given production number can be launched only if its compliance with the approved type has been proved by the acceptance test of special-form radioactive material according to

the document “Compliance verification URZ, methodological procedure, QM – T – 541 Version: 0, Cesio s.r.o., revision date: 27/10/1998”.

3. Quality assurance

Every special-form radioactive material with the identification designation CZ/1009/S – 96 and the given production number must be produced in compliance with the technical drawing “Am – Be NEUTRON SOURCE Am1.N02, 1. 207.02.02 – 00:00 (4), BEBIG Isotopentechnik and Umweltdiagnostik GmbH, of 2 May/28 July 1995” and in compliance with the document “Quality Assurance Program QM –Q- 001 Version: 1, Cesio s.r.o., revision date: 21/10/1998” approved in the decision of the State Office for Nuclear Safety ref. No. 5898/4.1/98/Kod dated 28 December 1998.

4. General conditions

4.1 The Decision of the State Office for Nuclear Safety (hereinafter the “SUJB”) on the type approval of the special-form radioactive material with the identification designation CZ/1009/S – 96 is valid only together with the written declaration of conformity, proving that in compliance with the condition 2 of this Decision that special-form radioactive material with the identification designation CZ/1009/S – 96 of the given production number was produced in compliance with the submitted documentation and fulfils the parameters declared in the documentation.

4.2 The copy of the Decision on the type approval of the special-form radioactive material with the identification designation CZ/1009/S – 96 and the declaration of conformity according to the condition 2 of this Decision must be upon request submitted by the licensee to the respective competent authorities pursuant to § 9 par. 1 subsection i) of Act No. 18/1997 Coll., as amended later.

4.3 The number and validity period of this Decision must be stated in the documentation, which accompanies the special-form radioactive material with the identification designation CZ/1009/S – 96.

4.4 Pursuant to § 9 par. 1 subsection i) of Act No. 18/1997 Coll., as amended later, the licensee is responsible for the fulfillment of the conditions of this Decision with the exception of conditions No. 1, 2, and 3.

5. Validity of the Decision

5.1 The Decision on the type approval of the special-form radioactive material with the identification designation CZ/1009/S – 96 does not replace other permits of SUJB issued pursuant to § 9 par. 1 subsection i) of Act No. 18/1997 Coll., as amended later, or permits or licenses to carry out activities that have been issued by other central bodies of the state administration in compliance with special regulations.

5.2 This decision makes void and also replaces the decision of the SUJB ref. No. 16631/4.1/2001/Kod dated 11 December 2001.

This Decision is issued for the time period until: 31/12/2008.

Pursuant to § 15 par. 1 subsection a) of Act No. 18/1997 Coll., as amended later, the assigned registration number is: 108600.

The administration fees of CZK 200 were paid according to the entry No. 97 subsection b) of the schedule appendix to Act No. 368/1992 Coll., to regulate administrative fees, as amended later.

Reasoning:

The Decision is issued pursuant to the application of the producer of the special-form radioactive material with the identification designation CZ/1009/S – 96, Isotope Products Cesio s. r.o., ref. No. 091/IPC/03 dated 24 October 2003, which the State Office for Nuclear Safety received on 27 October 2003.

Pursuant to Decree No. 317/2002 Coll. the application was accompanied by the following documents and documentation:

1. Applicant's identification.
2. Copy of the entry in the Commercial Register.
3. Decision of SUJB ref. No. 16631/4.1/2001/Kod dated 11 December 2001.
4. Decision of SUJB ref. No. 16419/4.1/01/Kod dated 11 December 2001.

During the administrative proceedings SUJB will take into consideration the fact that for the issuance of the Decisions stated in the points 3 and 4 the applicant has already submitted the following documents and documentation to SUJB:

5. Type description of the closed radionuclide source Am1.N02 No. 10/01/Am, Cesio s.r.o., dated 29 March 2001.
6. Compliance verification URZ, methodological procedure, QM – T – 541 Version: 0, Cesio s.r.o., revision date: 27/10/1998.
7. APPROVAL CERTIFICATE for the design of a special-form radioactive material D/0059/S – 85 (Rev. 0) dated 20 November 1995.
8. Am – Be NEUTRON SOURCE Am1.N02, 1. 207.02.02 – 00:00 (4), BEBIG Isotopentechnik and Umweltdiagnostik GmbH, of 2 May/28 July 1995.
9. Quality Assurance Program: QM –Q- 001 Version: 1, Cesio s.r.o., revision date: 21/10/1998.

SUJB states that the assessed security documentation fulfils the provision § 23 of Act No. 18/1997 Coll., as amended later, and the requirements of Regulation No. 317/2002 Coll., and therefore it approves the type of the special-form radioactive material and assigns it the identification designation CZ/1009/S – 96.

Guidance:

According to § 61 of Act No. 71/1967 Coll., to regulate the administrative proceedings (rules of administrative procedure), you can appeal against this Decision within 15 days after the delivery to the president of the State Office for Nuclear Safety.

RNDr. Ladislav Barták
Director of the Nuclear Materials Department

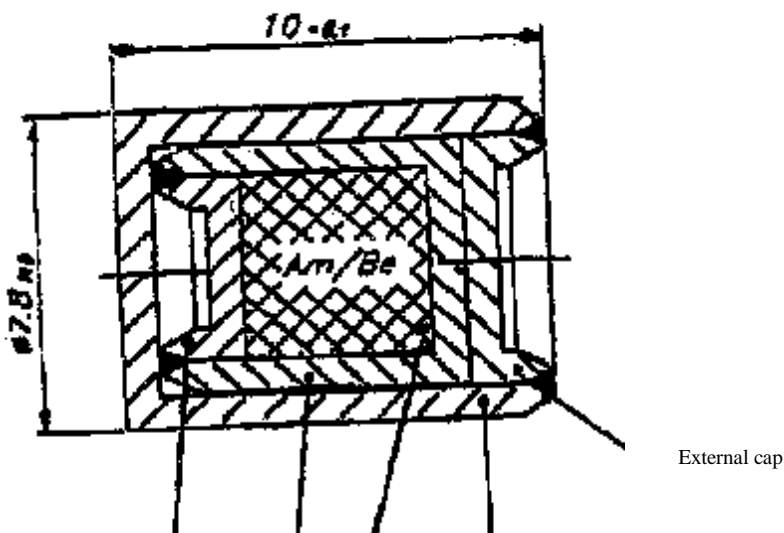
Attachment:

Technical drawing of the special-form radioactive material with the identification designation CZ/1009/S – 96.

Applicant – recipient: **Isotope Products Cesio s.r.o.**
 Radiová 1
 102 27 Prague 1

Attachment to the Decision ref. No. 328/2004

Design of the special-form radioactive material with the identification designation CZ/1009/S – 96



Internal cap Internal case Ceramic carrier External case