



State Office for Nuclear Safety

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

In Prague on: 19 January 2023
Reference No.: SÚJB/ONRV/2485/2023
File no.: SÚJB/POD/32203/2022/1
Department for RAW & SNF Handling
Handled by: Mgr. Zdeněk Venclík

DECISION

The State Office for Nuclear Safety (SÚJB), as the administrative authority competent pursuant to Section 208(b) of Act No. 263/2016 Coll., the Atomic Act (hereinafter the "Atomic Act") in the administrative proceedings concerning the approval of a product type initiated on the basis of an application by UJP PRAHA a.s., Nad Kamínkou 1345, 156 10 Prague – Zbraslav, identification number 60193247, registration number 114448 (hereinafter the "Party to the Proceedings"), pursuant to Section 27(1)(a) of Act No. 500/2004 Coll., the Administrative Procedure Code (hereinafter the "Administrative Procedure Code"), dated 19 December 2022, ref. no. 1020/05/22/Ko, received by the SÚJB on 21 December 2022, has decided as follows:

SÚJB in accordance with § 67, Section 1 AR and § 137, Section 1, paragraph a) of Atomic Act,

APPROVES THE PRODUCT TYPE

the construction type of the UK 12 S packaging container as type B(U) for ground and air transport of radioactive substances described in condition No.1 of the present Resolution, and assigned to this packaging container manufactured in compliance with the evaluated documentation the following identification:

CZ/012/B(U) – 96

and assigns the type approval decision for the UK 12 S package container for international identification purposes the code designation

CZ/012/B(U) – 96 (Rev. 4).

The UK 12 S package container (hereinafter "package container") for the transport of radioactive substances conforms to the requirements of Atomic Act., as amended, and also conforms to the relevant implementing regulations, the recommendation of the International Atomic Energy Agency (IAEA) entitled „IAEA Safety Standards, Regulations for the Safe Transport of Radioactive Material, 2012 Edition, Specific Safety Requirements No. SSR-6, International Atomic Energy Agency, Vienna, 2012”, and to the requirements of international transport regulations with reference to the cited IAEA regulations.

Description of the UK 12 S packaging container:

The UK 12 S package consists of a shielding package with a transport container as an integral part of the package. The shielding package provides special protection against the radioactivity of the substances being transported and includes a nest case. The transport container protects the shielding package from damage.

The package container is manufactured according to manufacturing documentation 846-00 00 000 and 847-00 00 000.

The shielding package consists of a cylindrical container with a central shielded nest sealed by a lid. The shielding material used is depleted uranium hermetically sealed in facing made of corrosion-resistant steel.

The shielding package is fitted with a support flange with two suspension bolts for handling purposes. The shielded lid seals the cylindrical nest compartment, which is a minimum of 41 mm diameter and 63 mm in height. The nest compartment is sealed with a metal seal at the point where the container meets the lid. The lid is attached to the container by five M8 bolts and is secured with an insert lock to prevent it from being removed. The lid has a folding handle for handling purposes. The materials to be transported must be inserted into the nest in a protective case, which forms part of the containment system of the shielding package.

The nest case consists of a cylindrical vessel that closes with a screw-on lid and is sealed with an O-ring or a flat sealing ring. Its shape may vary depending on the handling requirements.

The inner walls of the case are lined with foam to protect the radioactive materials being transported. The dimensions of the usable volume of the case are then 24 mm in diameter and 50 mm in height.

The shielding package is protected from damage by a two-part transport container. This consists of a lower and upper cylindrical vessel with a connecting flange at the end. The shielding package is clamped by its support flange between the flanges of the upper and lower part of the transport container by four M 10 bolts.

The lid of the transport container is fitted with two suspension handles for handling the packaging container and two handles for the manual handling of the lid. The transport container is secured with a padlock and a wire joint with a seal to prevent tampering. The weight of the package in this configuration is 17 kg.

The shielding package and the transport container are indelibly marked with labels, which are identical apart from the weight data, and contain:

- RADIOACTIVE warning label
- radioactivity symbol
- Description of the UK 12 S packaging container:
- type of package B(U)
- product no.
- identification number
- weight
- manufacturer name

The letters, numbers, and symbol are irremovably engraved into the material of the label.

The containment systems of the packaging container are designed for the transportation of special form radioactive material and ensure that the radioactive substance is not dispersed outside the container during transport or in the event of an accident.

The packaging container has the following containment systems:

- a) nest case sealed with an O-ring or a flat Teflon ring
- b) nest compartment sealed with a metal seal below the lid.

The packaging container is manufactured by the applicant, UJP PRAHA a. s.

Parameters and picture of the packaging container

Package container parameters:

| Parameter | |
|--------------|--------|
| Height | 335 mm |
| Diameter | 280 mm |
| Total weight | 105 kg |

Illustration of the UK 12 S packaging container



Conditions governing usage of the UK 12 S:

The type-approved UK 12 S packaging container, designation code CZ/012/B(U) – 96, may be used to transport radioactive substances only assuming compliance with the following conditions:

1. Permissible radioactive content of the packaging container

The UK 12 S type B (U) packaging container is designed for the transport of all special form radioactive materials up to the value of A1 and the listed special form radioactive materials up to the values specified in the following table:

| Radionuclide | ¹⁹² Ir | ⁶⁰ Co | ¹³⁷ Cs | ²²⁶ Ra | ⁷⁵ Se | ⁹⁰ Sr | ¹³⁷ Cs+4% ¹³⁴ Cs | ²⁴¹ Am |
|------------------------|-------------------|------------------|-------------------|-------------------|------------------|------------------|--|---------------------|
| Maximum activity (TBq) | 44 | 0.0296 | 184 | 0.0179 | 370 | 610 | 15.5 | without restriction |

2. Handling, maintenance and inspections

The UK 12 S packaging container must be handled, maintained and checked in compliance with the requirements specified in the document “UK 12 S packaging container, Operating and maintenance instructions”, packaging container number code020Cv03m01, UJP PRAHA a. s., 09/2022, as amended.

The condition and functionality of the packaging container must be checked and recorded in the form of a protocol prior to each use. The user shall submit the package container to the manufacturer for inspection after every 5 years of use. Checks on the packaging container must be recorded in a protocol and archived for the entire duration of the package’s service life.

3. Quality assurance

The UK 12 S package with the identification code CZ/012/B(U)–96 of the specified serial number must be manufactured according to the drawing documentation, in particular the assembly of the UK 12 S package, drawing number 847-00 00 000 UJP PRAHA a.s., version of the drawing documentation (V.R.) A. 0 and according to the production documentation, the parameters of which are contained in particular in the document Package container UK 12 S – description, components, specification of materials and production methods, package container file number code023Cv01m01, UJP PRAHA a.s., 01/22. Production must be carried out in a management system that complies with ISO 9001:2015 and the requirements of Decree No. 408/2016 Coll., on requirements for management systems.

Only a package container whose conformity with the approved type has been proven by a declaration of conformity drawn up in accordance with the requirements of Section 140 of the Atomic Act may be used for road transport of radioactive materials within the Czech Republic. The declaration of conformity for a newly manufactured package container must be sent to the State Office for Nuclear Safety before it is first used or marketed in accordance with the requirements of Section 140(1) of the Atomic Act.

4. Incident reporting

If a defect or an incident occurs on the PC UK 12 S package container, identification code CZ/012/B(U) – 96, when the package container is being handled, in particular if it is dropped or falls over, the package container must be temporarily put out of service without undue delay, whilst meeting all the radiation protection requirements. Such a packaging container may only be put back into service after it has been inspected or repaired, as the case may be. At the same time, a protocol will be drawn up recording the incident, which will be sent by the forwarder to the State Office for Nuclear Safety within 14 days of the incident.

5. Validity of decision

This decision on the type approval of the packaging container does not exempt the forwarder from the obligation to meet the transport requirements of any additional competent authorities, nor does it exempt the forwarder from the obligation to meet any requirements of any country to which or across which the packaging container containing radioactive materials is to be transported.

This decision expires on 31 January 2033.

Rationale:

In accordance with Section 44(1) of the Administrative Procedure Code, the SÚJB initiated administrative proceedings with the Party to the Proceedings in the matter of type approval of the product on the basis of an application filed by the Party to the Proceedings, which was received on 21 December 2022, and appointed as the official person responsible for conducting the proceedings Mgr. Zdeněk Venclík.

This decision is issued upon review of the submitted documentation, which was submitted to the State Office of Nuclear Safety in accordance with the provisions of Section 138 of the Atomic Act and subsequently with the provisions of Section 12(1) and 2(a) of Decree No. 379/2016 Coll., on type approval and transport, and the relevant points of Annex No. 4 to this Decree.

In accordance with the above laws the application the Party to the Proceedings was substantiated by the following information and documentation:

- a) identification of applicant and manufacturer: UJP PRAHA a.s., Nad Kamínkou 1345, 156 10 Praha – Zbraslav (Section 138(1) and (2)(a) of Act No. 263/2016 Coll.);
- b) identification of the approved product: construction type UK 12 S, type B(U) (Section 138(2) and (2)(b) of Act No. 263/2016 Coll.);
- c) description of use: the UK 12 S package container will be used for road and air transport of radioactive irradiators type approved as special form radioactive materials in closed cases (Section 138(2)(c) of Act No. 263/2016 Coll.);
- d) a list of the legal regulations and technical standards according to which the product was designed and manufactured: this is contained in the documents UK 12 S Package container – Description, Components, Specifications of Materials and Manufacturing Methods, package container number code023Cv01m01, UJP PRAHA a.s., 01/22 and UK 12 S Package container – Standards Used for Development, package container number code024Cv01m01, UJP PRAHA a.s., 09/22 (Section 138(2)(d) of Act No. 263/2016);

- e) dates and method of performing operational inspections: contained in the document “UK 12 S Package container – Instructions for use and maintenance”, package container number code020Cv03m01, UJP PRAHA a.s., 09/2022, as amended (Section 138(2)(e) of Act No. 263/2016 Coll.);
- f) operating instructions of the package container in the Czech language, including rules for the safe handling of the product and maintenance of the product: this is the subject of the document “UK 12 S Package container – Instructions for use and maintenance”, package container number code020Cv03m01, UJP PRAHA a.s., 09/2022, as amended (Section 138(2)(f) of Act No. 263/2016 Coll.);
- g) required validity period of product type approval: 10 years (Section 138 paragraph (2) g) of Act No. 263/2016 Coll.);

The following documents required in Annex 2 of Act No. 263/2016 Coll., the Atomic Act, were attached to the application of the party to the proceedings:

- The material specification of the radioactive or fissile substances for which the package container is designed, in particular the description of their physical and chemical state (Annex No. 2 para. (a)(1) of Act No. 263/2016 Coll.) is contained in the document "UK 12 S Package Container – Operating and Maintenance Instructions", package container number code020Cv03m01, UJP PRAHA a.s., 06/2022, as amended;
- a detailed technical specification of the package including a detailed description of the structural type of package including structural documentation, complete technical drawings, and list of materials and technical methods used in its manufacturing including technical drawings (Annex No. 2 para. a) point 2 of Act No. 263/2016 Coll.) is provided in the following documents:
 - UK 12 S Packaging Container – description, components, and specification of materials and manufacturing methods, package container number code023Cv01m01, UJP PRAHA a.s., 01/22;
 - Drawing documentation – set of technical drawings numbers: 847-00 00 000;
- manufacturer management program system (Annex No. 2) para. (a)(3) of Act No. 263/2016 Coll.) has been certified by the following documents:
 - ISO 9001:2015 Management System Certificate for UJP PRAHA a.s., certificate number: 289260-2019-AQ-CZS-RvA, DNV-Business Assurance, Mária Lichnerová, date of issue 5 June 2022, date of original issue 4 July 2007 (copy),
 - ISO 14001:2015 Management System Certificate for UJP PRAHA a.s., certificate number: 289260-2019-AE-CZS-RvA, DNV-Business Assurance, Mária Lichnerová, date of issue 5 June 2022, date of original issue 4 July 2007 (copy),
 - Management System Certificate ISO 13485:2016/ NS-EN ISO 13485:2016 for UJP PRAHA a.s., certificate number: 10000209856-MSC-NA-CZE Rev. 0.0, DNV GL PRESAFE AS, Eugenie Winger Husebye, date of issue 20 June 2022, date of original issue 03-Oct-2019 (copy);
- technological and manufacturing documentation with a detailed description of the material and technological methods used in manufacturing the containment system (Annex No. 2 para. (a)(4) of Act No. 263/2016 Coll.) is contained in the following documents:
 - UK 12 S Packaging Container – description, components, and specification of materials and manufacturing methods, package container number code023Cv01m01, UJP PRAHA a.s., 01/22;
 - Drawing documentation – set of technical drawings numbers: 847-00 00 000;

- description of the sampling and types of tests to be carried out if the packaging assembly is designed for a maximum normal operating pressure greater than 100 kPa (Annex 2(a)(5) of Act No. 263/2016 Coll.) – not relevant if the OS is not intended to be used as a pressure vessel;
- documentation demonstrating the provision of radiation protection, if the package has been designed for fissile materials, documentation demonstrating the assurance of retaining a subcritical state (Annex No. 2 para. (a)(6) of Act No. 263/2016 Coll.) – package not designed for fissile material – this part of the requirement is not relevant, the provision of radiation protection is the subject of the document "Protocol from the calculation of effective dose rate when using the UK 12 S container", prepared by Ing. Soňa Konopásková, CSc., in the program MicroShield 7.01, dated 26 September 2012
- a list and justification of the assumptions concerning the properties of the irradiated nuclear fuel used in the safety analyses for subcriticality calculations, if the containment is designed for irradiated nuclear fuel (Annex 2(a)(7) of Act No. 263/2016 Coll.) – not relevant if the package container is not designed for irradiated nuclear fuel;
- list of the special requirements necessary for heat dissipation in relation to the specific type and mode of transport, if the package container is designed for radioactive or fissile heat-producing material (Annex 2 para. (a)(8) of Act No 263/2016 Coll.) – not relevant, the package container is not designed for a radioactive or fissile heat-producing substance. . A calculation of the heat trend and surface temperature of the package for permitted activities and nuclides of the radioactive contents of the package is provided in the document "UK 12 S Package container Determination of Surface Temperature of Package container", package container number code022Cv02m01, UJP PRAHA a.s., 12/04;
- a reproducible representation of the appearance of the package container with maximum dimensions of 21 cm × 29.7 cm (Annex 2 para. (a)(9) of Act No 263/2016 Coll.) is contained in the document "UK 12 S Package container – Operating and Maintenance Instructions", package container number code020Cv03m01, UJP PRAHA a.s., 09/2022, as amended;
- documentation of testing or calculations and analyses with their independent verification by an authorized person (Annex No. 2 para. (a)(9) of Act No. 263/2016 Coll.) is provided in the following documents:
 - Test Performance REPORT No. 305/96, EKOLOGIE divize a.s. NYCOM, zkušebna TOS, Litoměřice,
 - Immersion Test Protocol No. 04/21 in the sense of Decree No. 379/2016 Coll., Annex No. 1, part II 5., para. 29 performed according to the UJP PRAHA a.s. methodology number: M_10-1-1 rev. 0, UJP PRAHA a.s., 14 June 2021
 - Strength check of the container for transport of radioactive contents, ZAK-22185, SVS FEM s.r.o., Trnkova 3104/117c, 628 00 Brno.
- □ The documentation submitted by the Party to the Proceedings included the document "Extract from the Commercial Register maintained by the Municipal Court of Prague, Section B, Entry 2366 for UJP PRAHA a.s.", verified by JUDr. Alena Procházková, 31 October 2022, Prague and the document "SHEET OF AGREEMENT TO FULFILLMENT OF REQUIREMENTS FOR AIR TRANSPORT, package container UK 12 S", Prepared by: P. Krupička on 11 Oct 2022.

The documentation thus submitted to SÚJB meets all the requirements under the aforementioned provisions of the Atomic Act.

The State Office for Nuclear Safety has reviewed the request from the perspective of its formalities according to the cited provisions of the Atomic Act and has deemed it satisfactory.

The SÚJB therefore states that the reviewed safety documentation meets the relevant provisions of the Atomic Act and the relevant provisions of Decree No. 379/2016 Coll., on type approval and transport and demonstrates suitability of the UK 12 S package container for its use in transport of the radioactive substances stated in condition 1 and in accordance with the other conditions of this decision.

Along with the application ref. 1020/05/22/Ko dated 19 Dec 2022, the applicant waived the right to participate in the evidence in the proceedings initiated by his application pursuant to Article 51(2) of the Procedural Regulation. From the presentation of evidence outside of the oral hearing, on 16 Jan 2023 a report was drawn up identified with ref. SÚJB/ONRV/XXXX/2023.

The administrative fee of CZK 1,000 was paid as specified by Act No. 634/2004 Coll. on administrative fees, according to line item 107 letter 1 f) of the Annex to this Act.

Rationale for the conditions of the decision:

General rationale of the conditions

The conditions of the decision are set out on the basis of the requirements of the Atomic Act and its implementing legislation in order to make them specific to the circumstances of the applicant and the type of package approved. All requirements of the Atomic Act and its implementing regulations are and must be applied when using the type approved package container, without exceptions. During the course of the administrative proceedings, the requirements of atomic legislation were considered met and further clarified by the conditions of the decision. It can therefore be stated that the SÚJB specifies the conditions for the decision on a legal basis as stipulated by the Atomic Act.

Detailed rationale for the conditions

Rationale for condition 1:

Condition 1, in accordance with the general rationale for the decision, stipulates the permitted radioactive content of the PC (package container). This condition specifies the provisions of the legal regulations pertaining to the requirements for possible package container content according to Section 9(4)(b) of the Atomic Act and subsequently Section 4(1) and the relevant points 31 through 33 of Annex No. 3 to Decree No. 379/2016 Coll., on type approval and transport.

Rationale for condition 2:

Condition 2, in accordance with the general rationale for the conditions of the Decision, sets out details of the manipulation, maintenance, and inspection of the package container, which must be carried out in accordance with Section 141(1)(k) and (3)(b) of the Atomic Act and subsequently Section 7(1)(a) and (b) and the relevant paragraphs of Annex 4 to Decree No 379/2016 on type approval and transport.

Rationale for condition 3:

Condition 3, in accordance with the general rationale for the conditions of the decision, specifies the details of quality assurance for the manufacture and use of the package container in accordance with Section 29(1)(a)(4) and other relevant parts of Section 29 of the Atomic Act and subsequently according to Decree No. 408/2016 Coll., on management system requirements.

Rationale for condition 4:

Condition 4 in accordance with the general rationale for the conditions of the decision specifies detailed requirements for reporting accidents pursuant to Section 25(1)(a-c) of the Atomic Act.

Rationale for condition 5:

Condition 5 in accordance with the general rationale for the conditions of the decision specifies the validity period of the requested decision for a period of 10 years in accordance with Section 139(1)(a)(2) of the Atomic Act.

For these reasons SÚJB has decided as specified in the statement of this decision.

Advice

An appeal may be filed against this decision through SÚJB, Sekce jaderné bezpečnosti (Nuclear Safety Section), Senovážné náměstí 9, 110 00 Praha 1, with the SÚJB chairwoman, within 15 days of the delivery of this decision.

On behalf of State Office for Nuclear
Safety

electronically signed

RNDr. Peter Lietava
Department for RAW & SNF Handling

Distribution list: party to the proceedings

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file