



STATE OFFICE FOR NUCLEAR SAFETY

Date: **12th December 2024**
Ref. No.: **SÚJB/OEHO/31472/2024**
File No.: **SÚJB/POD/30949/2024/1**
Unit: **Registers and Exposure Assessment Division**
Senovážné náměstí 1585/9, 110 00 Prague
Handled by: **Ing. Miluše Budayová**
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DECISION

The State Office for Nuclear Safety (hereinafter referred to as "SÚJB") as the administrative authority competent pursuant to Section 208(a) of Act No. 263/2016 Coll., the Atomic Act (hereinafter referred to as "Atomic Act"), in the administrative proceedings pursuant to Section 22(1)(a) of the Atomic Act in the matter of a new decision on the issuance of a permit to carry out activities within the framework of exposure situations, which is the handling of an ionizing radiation source, namely the import, export and distribution of an ionizing radiation source pursuant to Section 9(2)(f)(2) to (4) of the Atomic Act, initiated pursuant to Section 44(1) of Act No. 500/2004 Coll., the Rules of Administrative Procedure (hereinafter referred to as "Rules of Administrative Procedure"), on the basis of an application dated 9th December 2024, received by the SÚJB on 9th December 2024, under reference No. SÚJB/POD/30949/2024, submitted by the party to the proceedings

Party: **LACOMED, spol. s r.o.**
Address: **Vodárenská 699, 278 01 KRALUPY NAD VLTAVOU**
Company ID No.: **46348875**
SÚJB's registration No.: **109461,**

(hereinafter referred to as "Party to the Proceedings"), pursuant to Section 27(1)(a) of the Rules of Administrative Procedure, has decided as follows:

The SÚJB, pursuant to Section 67(1) of the Rules of Administrative Procedure, pursuant to Section 9(2)(f)(2) to (4) and Section 22(1)(a) of the Atomic Act,

authorizes the Party to the Proceedings to handle an ionizing radiation source

namely:

1. to **import** an ionizing radiation source,
2. to **export** an ionizing radiation source,
3. to **distribute** an ionizing radiation source,

namely unsealed radionuclide sources as specified in Table 1 and sealed radionuclide sources as specified in Table 2.

Table 1 Specification of unsealed radionuclide sources (URS).

radionuclide	A _{max} * [GBq]
<i>radiochemical generator</i>	
⁹⁹ Mo/ ^{99m} Tc	30
⁸¹ Rb/ ^{81m} Kr	0.74
⁸² Sr/ ⁸² Rb	5.8
⁸⁵ Sr/ ⁸² Sr (ratio: 0.55)	5.8
<i>radiopharmaceuticals</i>	
¹⁸ F	10
¹⁷⁷ Lu	10
¹²³ I	3,8
¹³¹ I	7.4
⁹⁰ Y	20
<i>RIA kit</i>	
¹²⁵ I	0.002
<i>standard</i>	
⁴⁰ K, ⁵⁶ Co, ⁹⁵ Zr, ⁹⁹ Mo, ^{99m} Tc, ¹¹³ Sn, ¹³³ Xe, ¹³⁷ Cs, ¹³⁹ Ce, ¹⁴¹ Ce, ¹⁴⁴ Ce, ²⁰³ Hg, ²¹⁰ Po, ²¹⁰ Pb, ²²² Rn, ²²⁸ Ra, ²³² Th, U _{nat}	0.0005
⁹³ Zr, ²³¹ Pa, ²³² U, ²³³ U, ²³⁶ U, ²³⁶ Pu,	0.00037
<i>standard, radiochemicals</i>	
³ H, ⁷ Be, ¹⁴ C, ²² Na, ²⁴ Na, ²⁶ Al, ²⁸ Mg, ³² Si, ³² P, ³³ P, ³⁵ S, ³⁶ Cl, ⁴¹ Ca, ⁴⁴ Ti, ⁴⁵ Ca, ⁴⁶ Sc, ⁴⁷ Sc, ⁴⁸ V, ⁴⁹ V, ⁵¹ Cr, ⁵² Fe, ⁵² Mn, ⁵⁴ Mn, ⁵⁵ Fe, ⁵⁵ Co, ⁵⁷ Co, ⁵⁸ Co, ⁵⁹ Fe, ⁵⁹ Ni, ⁶⁰ Co, ⁶³ Ni, ⁶⁴ Cu, ⁶⁵ Zn, ⁶⁷ Cu, ⁶⁷ Ga, ⁶⁸ Ge, ⁷² Se, ⁷³ As, ⁷⁵ Se, ⁷⁶ As, ⁷⁷ Br, ⁷⁹ Se, ⁸² Br, ⁸² Sr, ⁸³ Rb, ⁸⁵ Kr, ⁸⁵ Sr, ⁸⁶ Rb, ⁸⁶ Y, ⁸⁸ Y, ⁸⁸ Zr, ⁸⁹ Sr, ⁸⁸ Zr, ⁹⁰ Y, ⁹⁰ Sr, ⁹³ Mo, ⁹⁴ Nb, ⁹⁵ Nb, ⁹⁹ Tc, ¹⁰⁶ Ru, ¹⁰⁷ Pd, ¹⁰⁹ Cd, ^{110m} Ag, ¹¹¹ In, ^{113m} Cd, ^{114m} In, ¹¹⁵ Cd, ^{115m} Cd, ^{117m} Sn, ¹¹⁹ Sb, ¹²⁴ Sb, ¹²³ I, ¹²⁴ I, ¹²⁵ I, ¹²⁶ Sn, ¹²⁷ Xe, ¹²⁹ I, ¹³¹ I, ¹³³ Ba, ¹³⁴ Cs, ¹³⁴ Ce, ¹³⁷ Cs, ¹³⁹ Ce, ¹⁴⁷ Nd, ¹⁴⁷ Pm, ¹⁴⁸ Gd, ¹⁵¹ Sm, ¹⁵² Eu, ¹⁵³ Sm, ¹⁶⁰ Tb, ¹⁶¹ Tb, ¹⁶³ Ho, ¹⁶⁶ Ho, ^{166m} Ho, ¹⁶⁹ Er, ¹⁶⁹ Yb, ¹⁷⁰ Tm, ¹⁷⁷ Lu, ¹⁸⁶ Re, ¹⁸⁸ W, ¹⁹² Ir, ¹⁹⁴ Ag, ¹⁹⁴ Hg, ¹⁹⁸ Au, ¹⁹⁹ Au, ²⁰¹ Tl, ²⁰³ Pb, ²⁰⁴ Tl, ²⁰⁷ Bi, ²⁰⁹ Po, ²¹¹ At, ²¹² Pb, ²²³ Ra, ²²⁴ Ra, ²²⁵ Ac, ²²⁵ Ra, ²²⁶ Ra, ²²⁷ Ac, ²²⁷ Th, ²²⁸ Th, ²²⁹ Th, ²³⁴ U, ²³⁵ U, ²³⁶ Np, ²³⁷ Np, ²³⁸ U, ²³⁸ Pu, ²³⁹ Pu, ²⁴⁰ Pu, ²⁴¹ Pu, ²⁴² Pu, ²⁴¹ Am, ²⁴³ Am, ²⁴⁴ Cm, ²⁴⁸ Cm, ²⁴⁹ Bk, ²⁴⁹ Cf, ²⁵² Cf, ²⁵⁴ Es, ²⁵⁷ Fm	0.37

* maximum activity of one piece of URS

Table 2 Specification of sealed radionuclide sources (SRS)).

radionuclide	A _{max} * [MBq]
¹³⁷ Cs	5
¹⁴ C, ²² Na, ³⁶ Cl, ⁵⁴ Mn, ⁵⁷ Co, ⁶⁰ Co, ⁶⁵ Zn, ⁸⁸ Y, ⁹⁰ Sr, ¹²⁹ I, ¹³³ Ba, ¹⁴⁷ Pm, ¹⁵² Eu, ²⁰⁴ Tl, ²³⁴ U, ²³⁵ U, ²³⁹ Pu, ²³⁸ U, ²⁴¹ Am	0.8

* maximum activity of one piece of SRS

Reasoning

The SÚJB initiated administrative proceedings with the Party to the Proceedings in the matter of a new decision on the issuance of a permit to carry out activities within the framework of exposure situations, which is the import, export and distribution of an ionizing radiation source (hereinafter referred to as "IRS"), unsealed and sealed radionuclide sources, on the basis of an application submitted by the Party to the Proceedings on 9th December 2024.

The Party to the Proceedings has applied for the issuance of a new decision due to a change in the performance of the activities already carried out within the framework of exposure situations that were authorized by the decision of the SÚJB ref. No. SÚJB/OEHO/22813/2024.

The application, already according to the initial assessment, fulfilled the requirements for submission set out in Section 37(2) of the Rules of Administrative Procedure and it was clear from it what the Party to the Proceedings was applying for and what it was seeking.

The SÚJB further considered whether the statutory conditions for the issuance of a new decision pursuant to Section 22(1)(a) of the Atomic Act were met. According to this provision, the SÚJB will initiate new proceedings and issue a new decision on the issuance of a permit on the basis of an application submitted by the permit holder. As the SÚJB is aware from its official activities (and as correctly stated in the application), the Party to the Proceedings currently holds a permit for the import, export and distribution of unsealed radionuclides sources issued by the decision of the SÚJB No. SÚJB/OEHO/22813/2024. Therefore, in the spirit of the Atomic Act, it is entitled to apply for the issuance of a new decision in this matter and, in such a case, the SÚJB has the power, subject to the fulfilment of other legal prerequisites for the performance of the activity being permitted, to conduct new proceedings and to issue a new decision. Although the Atomic Act does not explicitly state what the application for the issuance of a new decision should be based on in this case, the SÚJB considers, within the meaning of general legal principles and pursuant to Section 45(1) of the Rules of Administrative Procedure, that it should be facts of such a nature or extent as to justify a serious interference with a matter that has been finally decided and with the rights and obligations of the permit holder, such as the conduct of new proceedings and the issuance of a new decision.

The change consists in expanding the list of radionuclides that are handled. This change has been noted in the statement of the decision in table no. 1, where the URS specification is given. Due to the said change, the participant proceedings, he requested the issuance of a new decision in the matter of permitting the import, export and distribution of IRSs. The mentioned the circumstance is a substantial change in the performance of the activity already carried out on the basis of the original permit. SÚJB therefore, he considers that the request for a new decision is based on a relevant reason and justified.

Pursuant to Section 22(2) of the Atomic Act, the new decision revokes the original permit issued on the basis of the SÚJB's decision ref. No. SÚJB/OEHO/22813/2024 dated 11th September 2024.

The Party to the Proceedings fulfils the requirements for the granting of a permit within the meaning of Sections 13 to 15 of the Atomic Act, i.e. the integrity and professional competence of the Party to the Proceedings, or the members of its statutory body, and has submitted documentation for the activity to be permitted, which is required as a prerequisite for the permitting of the activity under Section 16(2) of the Atomic Act.

The actual fulfilment of the material requirements of the atomic legislation to ensure nuclear safety, radiation protection, technical safety, radiation situation monitoring, radiation emergency management and security is documented by the permit holder in the form of documentation for the activity to be permitted in accordance with Section 24(1) and Annex 1 of the Atomic Act. This documentation must be kept up-to-date during the term of the permit and in accordance with the requirements of the implementing legal regulations to the Atomic Act, which set out the details of its content (Section 24(4) of the Atomic Act). In the case of a permit to import, export and distribute IRSs on the basis of an application, the requirements for the scope of the documentation for the activity to be permitted are set out in Annex 1(2)(f) to the Atomic Act. The legal and factual up-to-dateness of this documentation, demonstrating that safety is ensured in its entirety, is a prerequisite for the duration of the permit.

Together with the application, the documentation required for the authorized activity according to § 24 was submitted, respectively Annex No. 1 of the Atomic Law. The participant in the procedure performs the authorized activity based on the documentation:

- "*Programme for Ensuring Radiation Protection*" version 3 of 9th December 2024,
- "*Monitoring programme*", version 3 of 9th December 2024,
- "*Definition of the Monitored Zone*", version 2 of 9th December 2024,
- "*Radiation Emergency Analysis and Assessment*", version 1 of 9th December 2024,
- "*Radiation Protection Optimization Procedures*", version 2 of 9th December 2024,
- "*Radiation Emergency Procedures*", version 1 of 9th December 2024,
- "*Documentation for the Permission to Handle IRSs*", version 3 of 9th December 2024, including justification for the activity, specification of ionizing radiation sources and the expected number, the method of ensuring the return of used IRS to the country of origin or its further use, and evidence of the capability to verify compliance of the product characteristics.

The SÚJB assessed the application including the submitted documentation and found that the Party to the Proceedings fulfilled all the conditions set out by law for the proper and qualified performance of the activity to be permitted.

The permit is issued, in accordance with Section 21(2) of the Atomic Act, for an indefinite period of time, as it does not concern any of the activities listed under points (a) to (h) of the provision in question, for which permits are issued for a fixed period of time. This fact is not mentioned in the Decision in accordance with Section 21(1)(d) of the Atomic Act.

For these reasons, the SÚJB decided as stated in the operative part of the Decision.

Advice

An appeal against this Decision may be lodged with the Chairperson of the SÚJB within 15 days of the date of delivery of this Decision through the SÚJB – Registers and Exposure Assessment Division, Senovážné náměstí 1585/9, 110 00 Prague.

On behalf of the State Office for Nuclear Safety

Mgr. Jana Povolná
Head of the Section for the exposition management
department

Distribution list:

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