



Series AB

# LICENSE

No. 391368

## STATE COMMITTEE OF NUCLEAR REGULATION OF UKRAINE

Identification code 21721088

Series OB

000715

Re-issued to **Ukrainian State Industrial Enterprise "ISOTOPE"**  
(hereafter referred to as "the ionization radiation sources")

**152, Horkyi (Antonovych) Street, 03680, Kyiv**

Legal entity identification code	<b>14308322</b>
To the right of conducting business	<b>using the ionization radiation sources</b>
Place of conducting business	<b>11, Promyslova St., Prolisky village, Boryspil district, Kyiv region (base of the USIE "Isotope"); Customers objects in the territory of Ukraine</b>
Special conditions for conducting business	<b>by virtue of Chapter 2</b>
License is re-issued on the base of	<b>the documents specified in Chapter 2</b>

Name of subdivision or a body which shall control the holding to terms and rules of conducting the licensed business

**Northern State Inspection of Nuclear and Radiation Safety  
of the State Committee of Nuclear Regulation of Ukraine**

Date of the License re-issue **February 06, 2008**

Term of the License **February 06, 2013**

**Vice President** *Signature* **O.A.Makarovska**

**Seal**

Entering alterations to the License  
**Altered on February 06, 2013**

**Head of the Northern  
State Inspection** *Signature* **L.S.Kuraksa**  
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The business concerning the ionization radiation sources (hereafter referred to as "IRS") use shall be conducted by the Licensee according to Requirements and Conditions of Business Conducting Safety (License conditions) Concerning the Ionization Radiation Sources approved by the Order of the State Committee of Nuclear Regulation of Ukraine dated 02.12.2002 No. 125, registered with the Ministry of Justice of Ukraine on 17.12.2002 under the No. 978/7266.

#### Chapter 1. List of Documents Served the Ground for the License Re-Issue

- 1.1. Application (Letter dated 15.01.2008 No. 318) of USIE "ISOTOPE" of the re-issue of License Series OB No.000091 for making business using IRS.
- 1.2. Copies of the USIE "ISOTOPE" constitutive documents: Articles of Association registered by Hosiivskiyi Municipal District Public Administration of Kyiv city dated 24.12.2001 No. 01814; Certificate of the Legal Entity State Registration dated 12.08.1993; Certificate with EDRPOU dated 20.09.2007 under the No. 6829.
- 1.3. Report of analysis of the safety of making business with the IRS use.
- 1.4. Certificate of the Applicant's personnel qualification in the sphere of the nuclear power use.
- 1.5. Guidelines for provision of quality using the IRS.
- 1.6. List of IRS used by the USIE "ISOTOPE".
- 1.7. Emergency response plan of the USIE "ISOTOPE" dated 25.12.2007.
- 1.8. Copy of Contract signed between "Energopolis" and USIE "ISOTOPE" dated 02.03.2006 under the No. 308-06/001 of the insurance of public liability of the Owner of nuclear plant and IRS for the loss indemnity against eventual radiation accident.
- 1.9. Copy of Certificate of hygiene for performing works with IRS dated 25.07.2006 under the No. 13-06 issued by Kyiv regional SES of MH of Ukraine.
- 1.10. Document of the payment of services provided for execution of permitting procedures in the area of the nuclear power use (payment order dated 15.01.2008 under the No. 5).
- 1.11. Decision of the Licensing Commission of Derzhatomrehulivannia (Minutes of the session of 06.02.2008 No. 2008).

#### Chapter 2. Special Conditions for Conducting Business

2.1. With this License it is permitted to conduct business using IRS in frames of parameters specified below:

##### 2.1.1. For Open IRS:

Medical and biological radioactive preparations, kits – maximum annual supply: in number of 50 000 of kits, by activity – about  $5.6 \times 10^{10}$  Bq.

Radiopharmaceutical preparations and labeled compounds - maximum annual supply: in number of 30 000 of kits, by activity – about  $5.6 \times 10^{12}$  Bq.

Products containing Tritium with maximum total activity as  $7.4 \times 10^{15}$  Bq per year.

Generators of radionuclides (including Strontium-87m, Technetium-99m, Indium-113m, Iodine-132, Rhenium-188, Radon-222) with maximum total activity as  $3.7 \times 10^{14}$  Bq, number – 2 000 pieces per year.

Standard (reference) ionization radiation sources:

Aggregative state – solid, bulk, liquid – maximum annual consumption: by number – 12 000 pieces, maximum total activity as  $1.2 \times 10^{10}$  Bq;

Aggregative state – gases – maximum annual consumption: by number – 12 000 pieces, maximum total activity as  $3.6 \times 10^{10}$  Bq.



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**2.1.2. For Sealed IRS:**

Maximum allowed one-off number of packages: with alpha sources – 1 000 pieces; with beta sources – 1 000 pieces; with gamma sources – 2 000 pieces; with X-ray sources – 200 pieces; with neutron sources – 200 pieces.

Maximum activity at the work place –  $2.96 \times 10^{16}$  Bq (as radionuclide Cobalt-60).

Maximum annual IRS delivery by total activity –  $1.036 \times 10^{17}$  Bq.

Sealed SIR maximum activity: alpha-radiation about  $3.7 \times 10^{10}$  Bq; beta-radiation about  $2.22 \times 10^{11}$  Bq; gamma-radiation about  $1.11 \times 10^{13}$  Bq; gamma-radiation Cobalt-60 radionuclide about  $4.44 \times 10^{14}$  Bq; X-ray radiation about  $7.4 \times 10^{10}$  Bq.

Maximum annual supply of the devices, appliances and equipment with SIR including equipment, which structural components are made from depleted Uranium, with alpha sources about 101 000 pieces, with beta sources about 2 500 pieces, with gamma sources about 5 350 pieces, with neutron sources about 500 pieces; SIR maximum total activity about  $2.1 \times 10^{14}$  Bq; maximum total activity of the products containing Tritium about  $2.44 \times 10^{16}$  Bq per year.

Gamma-ray flaw detectors like “Gammarid”, “DVS” etc.; gamma-radiation sources units like: BGV, E; packing ship sets like UKTD-11, UKT1A; gamma-therapy units like: AGAT, ROKUS, LUCH, TERAGAM, TERABALT, TERATRON, COBALT 60F and others; endocavitary gamma-therapy units like: AGAT-V, GAMMAMED and others; and other devices, appliances and equipment with SIR.

Units of the worked-out devices, appliances and equipment with SIR and SIR with operative life terminated, structural components made from depleted Uranium – maximum annual consumption by number – 3 000 pieces, by activity: alpha-radiation sources about  $1.85 \times 10^{12}$  Bq; beta-radiation sources about  $1.85 \times 10^{13}$  Bq; X-ray radiation about  $7.4 \times 10^{11}$  Bq; gamma-radiation (Cobalt-60 radionuclide) about  $4.44 \times 10^{14}$  Bq; for neutron sources about  $5.0 \times 10^{11}$  n/s.

**At that the following types of works are allowed:** receipt (acquisition) and transfer (sale), including the purpose of delivery, charging-recharging, recalibration, repair, adjustment, putting into operation, removal from service, mounting and dismantling, storage of SIR.

**2.2. The Licensee in term till 01.06.2008 shall deliver to Derzhatomgeruliuvannia a copy of the duly issued Act of determination of physical protection level of the radioactive SIR according to requirements of “Procedure of Determination of the Level of Physical Protection of Nuclear Plants, Nuclear Materials, Radioactive Waste, Other Sources of Ionization Radiation According to Their Category” approved by Decree of the Cabinet of Ministers of Ukraine dated 26.04.2003 No. 625.**

**2.3. The Licensee shall take measures for recording and control of nuclear materials according to requirements of the “Rules of Recording and Control of Nuclear Materials” (NP 306.7.122-2006) registered with the Ministry of Justice of Ukraine dated 17.07.2006 under the No. 849/12723.**

**2.4. The Licensee shall use the following codes for recording and control of nuclear materials:**

Code of the material balance area (MBA): RKQ0;

Code of the key measurement point (KMP): A.

**2.5. The Licensee shall make inspection of actually available number of nuclear material (inventory) on October 15, annually.**

**2.6. In case of emergence of any situation or circumstances which caused or shall cause infringement of the norms and rules of radiation safety, the Licensee shall inform in term of 24 hours the operations desk of Derzhatomreguliuvannia by phone (044) 254-43-34, and Northern State Inspection of Nuclear and Radiation Safety of Derzhatomreguliuvannia by phone (044) 292 01 95.**

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Head of Northern State Inspection Signed

## Alteration No. 1 to the License Series OB No. 000715

### Grounds for alterations:

- 1.1. Application of USIE "ISOTOPE" dated 04.01.2013 No.01 of alteration to the License for making business using IRS.
- 1.2. Copies of the USIE "ISOTOPE" constitutive documents: Articles of Association approved by Order of the State Agency of Ukraine of Administration of the state corporative rights and assets dated 06.07.2012 No.171 and registered by Holosiivskyi Municipal District Public Administration of Kyiv city dated 30.08.2012 under the No. 1 068 105 0004 007051; Certificate of the Legal Entity State Registration Series A00 No. 057063 dated 12.08.1993; Certificate AB No. 521619 issued by the Unique State Register of Enterprises and Organizations of Ukraine (EDRPOU) dated 12.09.2012.
- 1.3. Report of analysis of the safety of making business with the IRS use at the USPE "ISOTOPE", with annexes.
- 1.4. List of IRS to be used at the USPE "ISOTOPE".
- 1.5. Document of the payment of services provided for execution of permitting procedures in the area of the nuclear power use (payment order dated 24.01.2013 under the No. 21).
- 1.6. Certificate of financial possibilities for the loss indemnity by the USPE "ISOTOPE" against eventual radiation accident which can rise in the course of making business with IRS utilization dated 04.01.2013 No. 12-01/1.
- 1.7. Decision of the Licensing Commission of Derzhatomrehuliyuvannia (Minutes of the session of 06.02.2013 No. 5/2013).

### Alterations entered to the License:

1. Text of p. 2.1 of Chapter 2 of the License shall be altered as follows:

#### 2.1.4. Generating appliances:

\* portable X-ray apparatuses like: ERESKO (32MFC3.1; 42MF3.1; 42MF-W3.1; 52MFC3L; 65MF3); ICM SITE-X (SITE-XS); Aolong XXQ (XXG; XXH); RPD (250; 200; 200mini; 15); RAP; RUP; MART-200 (250), maximum accelerating voltage 360kV;

\* X-ray pulse apparatuses like: ARINA (1; 3; 5; 7; 9; 11); PAMIR-300; Sirena-5 (6); Sarma-300 (300U), maximum accelerating voltage 360kV;

\* one-piece portable X-ray apparatuses like: SMART (160WS; 160E/0.4; 160E/1.5; 200; 200PC; 225; 300PC; 300HP), maximum accelerating voltage 360kV;

\* permanent X-ray apparatuses Series ISOVOLT TITAN, maximum accelerating voltage 450kV;

\* cable-type X-ray apparatuses Series "Bastion", maximum accelerating voltage 450kV.

**At that the following types of operations with IRS are allowed:** storage; acquisition (purchase) and transfer (sale) of IRS, with purpose of delivery included.

2. Chapter 2 of the License shall be added with the paragraph 2.7 as follows:

2.7. The Licensee, in term till 06.04.2013, shall develop and submit to the Northern State Inspection and agreed with Derzhatomreguliyuvannia of Ukraine the Plan of Measures for Handling the IRS with Depleted Operating Life, and to provide its fully execution in due term.

3. To prolong the term of the License till February 06, 2020.

### Alterations entered on 06.02.2013.

Head of Northern State Inspection

Signature  
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L.S.Kuraksa

Deputy Head of Northern State Inspection –  
Department Head

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T.O.Zolkover

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