FNCA

Forum for Nuclear Cooperation in Asia

Production of Radiopharmaceuticals in Kazakhstan

2024

Key producers of the Radiopharmaceuticals in Kazakhstan

INSTITUTE OF NUCLEAR PHYSICS

Institute of Nuclear Physics (Almaty)
Scientific & Technical Center of Radiochemistry and Isotope Production

MEDICAL CENTER HOSPITAL OF THE PRESIDENT'S AFFAIRS ADMINISTRATION OF THE REPUBLIC OF KAZAKHSTAN

Nuclear Medicine Center, Medical Center Hospital of President's Affairs Administration of the Republic of Kazakhstan (Astana)

UMC UNIVERSITY Medical Center
Наука • Образование • Здравоохранение

Republican Diagnostic Center (Astana)

Коммунальное государственное предприятие на праве хозяйственного ведения "Центр ядерной медицины и онкологии" управления здравоохранения области Абай

Center for Nuclear Medicine and Oncology, Health Department of Abai region (Semey)

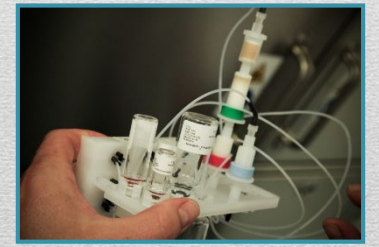
Institute of Nuclear Physics

The Institute of Nuclear Physics (INP) implements full-scale operation of radiopharmaceuticals starting with the development of the production technology and control methods to the realization of all the production stages, including radioactive isotope (radioisotope) production.

In 2016, the Scientific & Technical Center of Radiochemistry and Isotope Production INP initiated production of radiopharmaceuticals which meet the European requirements:

- Sodium pertechnetate ^{99m}Tc, injectable solution from transportable $^{99Mo/99m}$Tc generator for functional diagnostics of human organs and systems using gamma scintigraphy and single-photon emission computed tomography (SPECT)
- ^{18}F-Fluorodeoxyglucose, injectable solution for diagnostics and monitoring of cancer therapeutics (treatment) by positron emission computer tomography (PECT)
- Sodium iodide ^{131}I, oral use solution for study of functional status of thyroid gland by gamma scintigraphy and single-photon emission computed tomography (SPECT)
- Sodium iodide ^{131}I, oral solution (for therapy) in therapy of thyroid gland cancer and hyperthyroidism.



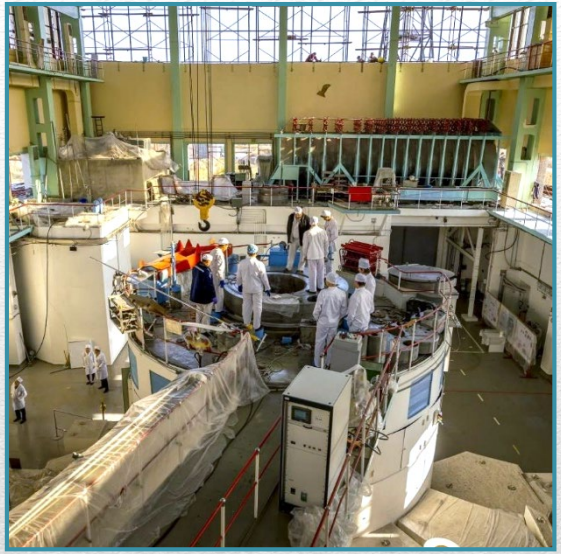



Institute of Nuclear Physics

The radioisotopes Technetium and Iodide are produced in the WWR-K reactor.

The research reactor WWR-K is a multipurpose tank-type research reactor with a thermal neutron energy spectrum.

The reactor was put into operation in 1967 with the fuel of Uranium dioxide with enrichment of 36% on Uranium-235. Since the conversion to low-enriched fuel in 2016 the reactor is operating with U-235 with the enrichment less than 20%.



MAIN TECHNICAL PARAMETERS

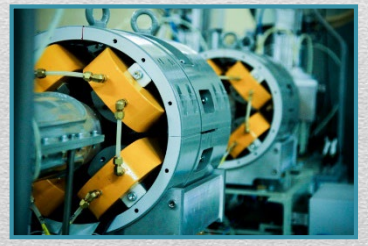
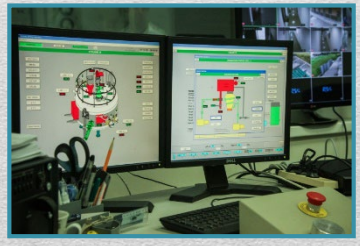
Design power – 6 MW
Core height/core diameter – 600 mm/720 mm
Coolant – Desalinated water
Moderator, reflector– Desalinated water and beryllium
Maximum thermal neutron flux density – $2 \cdot 10^{14}$ n/(cm^2·s)
Duration of the normal irradiation cycle of the reactor is 21 days.

Institute of Nuclear Physics

The main equipment of the Scientific & Technical Center of Radiochemistry and Isotope Production:

- The cyclotron Cyclon® 30 XP has 4 beam transportation channels, including three stations for irradiation of solid targets with a pneumatic transportation system and one station for irradiation of a liquid target with a transportation system
- 18 “hot” cells with basic equipment
- air treatment systems for “clean” industrial premises, exhaust and filtration, water cooling.

Cyclotron Cyclone® 30 XP with current beam 400 μA put into operation in 2016.
The energy range of 15 to 30 MeM makes it possible to produce radioisotopes for nuclear medicine: ^{11}C, ^{13}N, ^{15}O, ^{18}F, ^{64}Cu, ^{67}Ga, ^{111}In, ^{123}I, ^{201}Tl ...
The output of double beam makes it possible to simultaneously irradiate two targets and simultaneously obtain two different isotopes, or two identical ones used more often.

Nuclear Medicine Center

In October 2022, the Nuclear Medicine Center was opened on the basis of the Medical Center Hospital on the President's Affairs Administration of the Republic of Kazakhstan, providing radioisotope diagnostic services. On May 25, 2023, a GMP certificate was received for the operation of a cyclotron production complex based on the cyclotron Cyclone® KIUBE.

Евразийский экономический союз

СЕРТИФИКАТ

Currently, the production of 4 radiopharmaceuticals has been established:

- ^{18}F-FDG (fluorodeoxyglucose)
- ^{18}F-NaF (sodium fluoride) for the diagnosis of bone metastases and bone malignancies
- ^{11}C–Met (methionine carbon) for diagnosing brain tumors
- ^{18}F-DOPA (dehydroxyphenylalanine) for the diagnosis of neuroendocrine oncological pathology.

Two third-party gallium-based products are used: ^{68}Ga-PSMA for the diagnosis of prostate cancer and ^{68}Ga-DOTA for the diagnosis of neuroendocrine tumors.

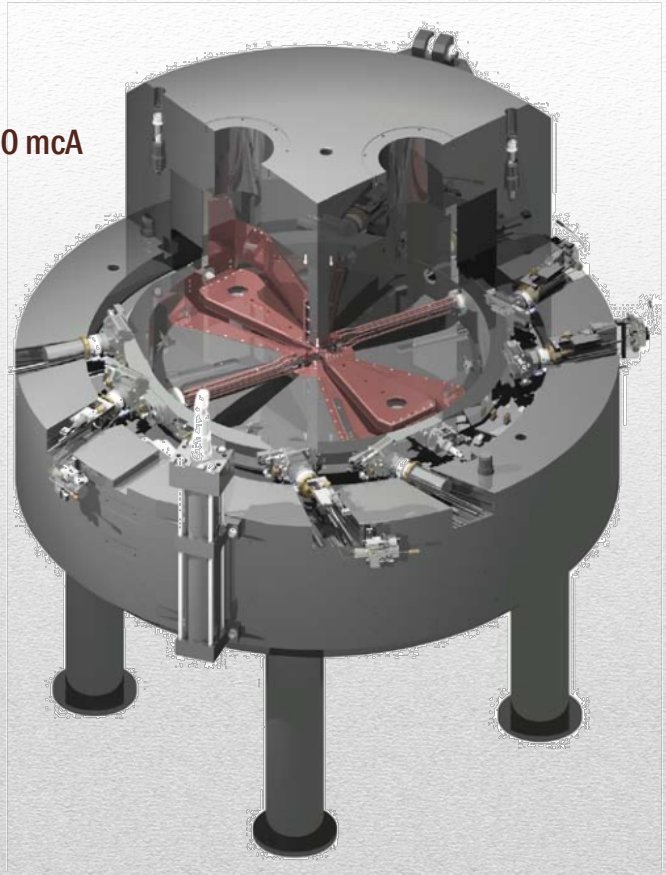
Republican Diagnostic Center

The radiopharmaceutical production department of the Center for Nuclear Medicine and Radiation Diagnostics of the RDC is equipped with high-tech equipment:

- cyclotron Cyclon® 18/9 with proton energy up to 18 meV and beam current up to 170 mcA
- Synthesis modules
- Equipment of quality control laboratory.

Provides production of two radiopharmaceuticals for PET and CT:

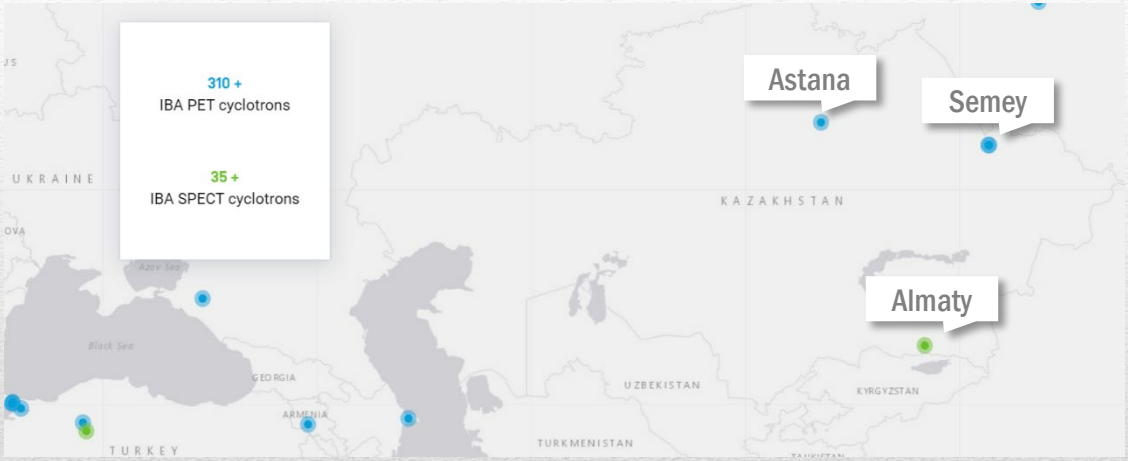
- ^{18}F-FDG (Fluorodeoxyglucose)
- ^{18}F-NaF (soda-water).

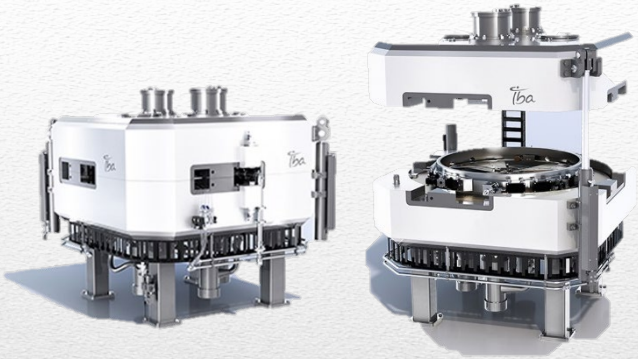


Center for Nuclear Medicine and Oncology

Коммунальное государственное предприятие на праве хозяйственного ведения "Центр ядерной медицины и онкологии" управления здравоохранения области Абай

Cyclotron Cyclone® KIUBE was installed and put into operation in 2021;
started production of ^{18}F-FDG (2021) and ^{18}F-NaF (2023).





Radioisotopes Application in Therapy

The first industrial batch of Sodium Iodide I131 was produced in 2021 and used by patients of the Center for Nuclear Medicine and Oncology in Semey for the treatment of thyroid diseases, including thyroid cancer. The drug is included in the Kazakhstan National Formulary and is available under health insurance.

The weekly supply of radioactive iodine in Semey allows the treatment of up to 780 patients per year.

Radioisotope Application in Diagnostics

Kazakhstan has several Centers and Divisions of radionuclide diagnostics (first three centers have their own RPhs' production):

1. Hospital of Medicine Center in Astana
2. University Medical Center in Astana
3. Center for Nuclear Medicine and Oncology in Semey
4. Sunkar Oncology Center in Almaty
5. Research Institute of Cardiology and Internal Diseases in Almaty
6. Kazakh Research Institute of Oncology and Radiology in Almaty
7. Orhun Medical in Almaty
8. MedInvestGroup Kazakhstan in Almaty

Two technologies of radionuclide diagnostics are widely used today:

- positron emission tomography (PET) – using ^{18}F –based tracers
- single-photon emission computed tomography (SPECT) –using ^{99m}Tc-based tracers, the reason of their application is in optimal nuclear physical properties, low cost and availability of this isotope. Technetium compounds provide 75–80% of diagnostic needs.

Prospects for Growing Radiopharmaceuticals Production

INSTITUTE OF NUCLEAR PHYSICS, Almaty

At stage of registration:

- ^{99m}Tc-DTPA – set of reagents for Technetium for diagnostics of kidney disease
- sodium o-iodohippurate ^{131}I, injectable solution – for diagnostics of kidney disease
- ^{99m}Tc-phytate – set of reagents for Technetium for diagnostics of liver disease
- ^{99m}Tc-MDF – set of reagents for Technetium for diagnostics of skeletal system.

At stage of clinical testing:

- Sodium iodide ^{131}I, solution for therapy – for therapy of thyroid gland cancer and hyperthyroidism
- Thallium chloride ^{201}Tl, injectable solution – for therapy of cardiovascular diseases
- ^{153}Sm-EDTMF – for palliative treatment of bone metastases at various tumor locations
- ^{18}F-FLT – to determine the rate of proliferation of cancer cells using PET
- ^{18}F-DOPA – for diagnosing Alzheimer's disease, Parkinson's disease, etc.

At stage of development:

- Technology of production of bulk solution of Germanium chloride ^{68}Ge
- Technology of production RPh in therapy of triple negative breast cancer based on “Elagolix -^{177}Lu”.

MEDICAL CENTER HOSPITAL ON THE PRESIDENT'S AFFAIRS ADMINISTRATION OF RK, Astana

Production of additional 6 RPhs is planned to run by 2026.

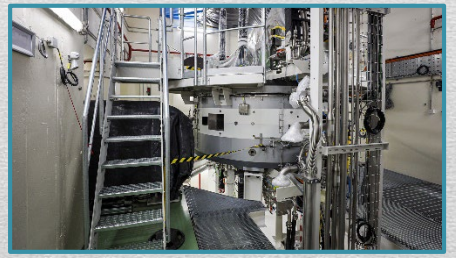
National Scientific Oncology Center in Astana

In 2024, the National Scientific Oncology Center starts its work in Astana.

The Center will be equipped with modern high-tech equipment, presented for the first time in Kazakhstan. Leading international companies from Switzerland and the USA participated in the implementation of the project.

To date, construction work has been completed by 90% – a treatment and diagnostic building for 210 patients with radiation and nuclear medicine centers, a proton therapy center, administrative and technical blocks have been erected.

The medical equipment is currently under commissioning and testing. The facility will operate a proton therapy center designed for 800–1000 patients per year, equipped with a linear accelerator.



Thank you for attention!