ТЕХНІКА ТА МЕТОДИ ЕКСПЕРИМЕНТУ
ENGINEERING AND METHODS OF EXPERIMENT

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EXPERIMENTAL STUDY OF THE METHOD FOR OBTAINING THE RADIOPHARMACEUTICALS "SODIUM PERTECHNETATE (^{99m}Tc)" USING AN EXTRACTION INSTALLATION IN "HOT" CELLS OF THE NSC "KHARKIV INSTITUTE OF PHYSICS AND TECHNOLOGY"

This paper presents the results of the first testing of technological equipment to produce radiopharmaceuticals "Sodium pertechnetate (^{99m}Tc), extraction, solution for injection" with technological equipment located in the laboratory of radioisotope production at NSC "Kharkiv Institute of Physics and Technology" (KIPT). The "hot" cells and technological equipment mounted inside the cells meet the requirements of the European standard and guarantee the safety of operators during the production process. The technology for producing radiopharmaceuticals is based on the extraction of ^{99m}Tc with methyl ethyl ketone from alkaline solutions of ^{99}Mo. ^{99m}Tc is obtained as a daughter product of ^{99}Mo radioactive decay, which is formed as a result of the ^{98}Mo(n, γ)^{99}Mo radiation capture reaction during irradiation of natural molybdenum oxide powder MoO_3 (^{98}Mo 24.13 %) with neutrons inside the core of a nuclear facility. Since the NSC KIPT Subcritical Assembly "Neutron Source" is at the stage of physical start-up, the ampoules with MoO_3 powder were irradiated in the core of the WWR-M research nuclear reactor of the Institute for Nuclear Research of the National Academy of Sciences of Ukraine. The results of gamma spectrometric studies of the initial solution containing radioisotopes ^{99}Mo + ^{99m}Tc and the finished solution with radioisotope ^{99m}Tc showed the absence of radionuclide impurities.

Keywords: radiopharmaceutical, radioisotope, ^{99m}Tc, solvent extraction, radionuclidic purity.

1. Introduction

Radionuclide research methods, which use radiopharmaceutical drugs (RPhD), take one of the leading places in the diagnosis of various diseases. In nuclear medicine, ^{99m}Tc is the most widely used RPhD in the world. According to the International Atomic Energy Agency and other profile organizations, about 80 - 85 % of all diagnostic procedures in nuclear medicine are performed using ^{99m}Tc. This is due to several key factors:

- optimal physical properties: short half-life (6.01 h) and gamma-quanta radiation with 140 keV energy, which is optimally suited for registration with *SPECT* systems and minimizes radiation danger to the patient [1 - 4];
- the smallest ^{99m}Tc radiotoxicity [5], so that this radioisotope is allowed for diagnostic studies of pregnant and newborns [6].
- the variety of ^{99m}Tc dosage forms (more than 30) provides the possibility of diagnosis of various organs (bones, kidneys, lungs, myocardium, brain, etc.).

Currently, the production of RPhD based on ^{99m}Tc radioisotope in Ukraine is absent, and the pharmaceutical market is represented only by drugs of foreign production. Therefore, the primary task for the development of domestic nuclear medicine is the organization of its production in Ukraine.

The production of RPhD is one of the very important and complex areas in modern medicine, which must meet the requirements of Good Manufacturing Practice (GMP). The medicinal product manufacturer is obliged to ensure the control of their quality in the production process and at the stage of the final product.

In the process of manufacturing, radioisotope productions, radiochemical synthesis, and permanent monitoring of the quality of input materials, production conditions, and finished products are carried out. High-tech equipment and clean materials are used for the production of RPhD [7, 8].

In recent years, the NSC KIPT has been conducting work on the organization of the production of sodium pertechnetate (^{99m}Tc) in the form of a solution for injection.

The purpose of this work was to carry out technical testing of technological equipment, mounted in the modules of hot cells, as well as the technological process of producing an injection solution of ^{99m}Tc sodium pertechnetate, followed by determining its pertechnetate purity.

2. Production technology

The literature describes various methods of obtaining RPhD based on ^{99m}Tc radioisotope: eluting of ^{99}Mo/^{99m}Tc generators of chromatographic type 0.9 % with sodium chloride solution [9, 10]; technology of extraction removal of ^{99m}Tc methyl ethyl ketone from alkaline solutions ^{99}Mo, followed by evaporation of extract to dry residue and dissolving it in isotonic sodium chloride solution [11].

The method of extraction by the solvent of methyl ethyl ketone is one of the most effective methods. In a solution of NaTc(^{99m}Tc)O_4 extraction, the content of radiochemical and radionuclide impurities is an order of magnitude lower than in chromatographic generators [11].

The maternal isotope to produce the ^{99m}Tc is the ^{99}Mo, which can be obtained by irradiation by neutrons of natural molybdenum or molybdenum enriched by the ^{98}Mo isotope, and can also be released from a mixture of uranium fission products [12 - 14]. Obtaining ^{99}Mo from irradiated uranium is an expensive, complex process that requires a deep cleaning of the final product from radionuclide impurities. During ^{235}U fission, in addition to ^{99}Mo (6.1 %), more than 20 long-lived radionuclides are formed with lifetimes from 0.1 to 60 days. In addition to gamma-radiating radionuclides, in the process of uranium activation, neutrons also produce long-lived alpha-radiation nuclides, including isotopes of plutonium, neptunium, americium, and curium [15]. Therefore, a simpler and more accessible activation method of irradiation of natural molybdenum powder (^{98}Mo 24 %) in a nuclear reactor is selected to obtain a ^{99m}Tc isotope.

In view of the benefits of this method of obtaining the ^{99m}Tc isotope, the NSC KIPT implemented the technology of its extraction discharge using methyl ethyl ketone from alkaline solutions of ^{99}Mo using a stationary extraction generator.

3. Equipment and research methods

The objects of the study were four sealed “hot” cells installed in the building of the Laboratory of Radioisotopes of NSC KIPT, installed technological equipment for radiopharmaceutical production, an injection solution based on the radioisotope ^{99m}Tc, and the technological process of its production.

The location of the “hot” cells in the building of the Radioisotope Laboratory of NSC KIPT is shown in Fig. 1. In addition to the extraction process, the “hot” cells also perform dosing, sterilization, and packaging of the final injection solution containing ^{99m}Tc.

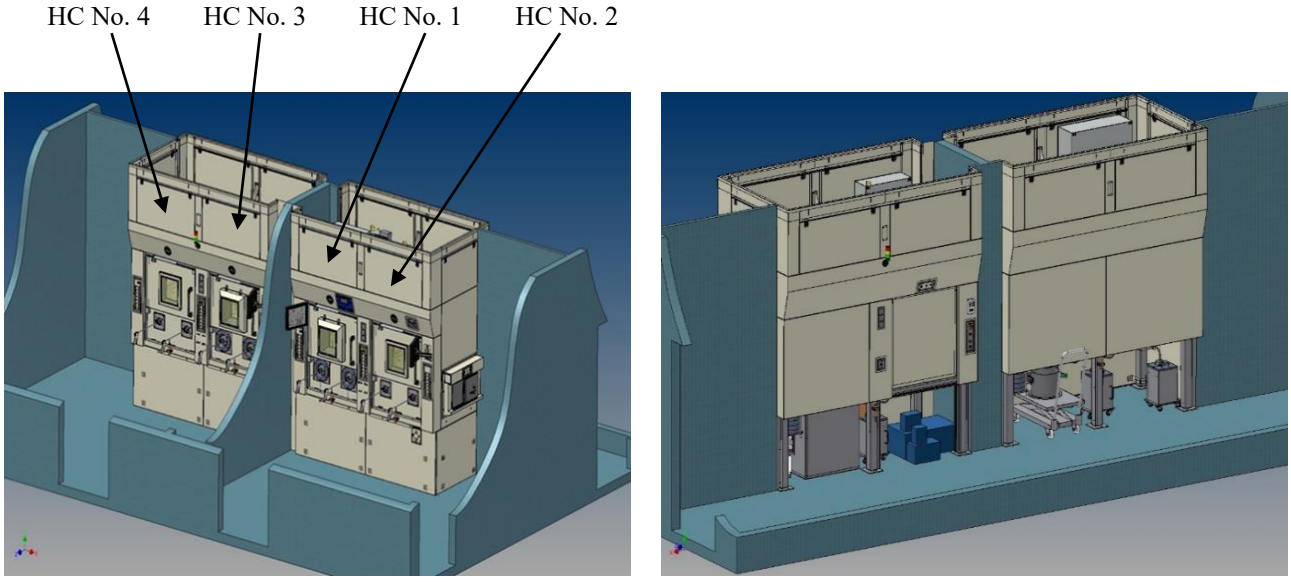

Fig. 1. The location of the “hot” cells in the building of the Radioisotope Laboratory of NSC KIPT. (See color Figure on the journal website.)

The cells are interconnected by a protected channel for transferring containers with different solutions and are installed in such a way that their rear walls are open to a separate service room. This room is intended for routine maintenance and repair of “hot” cells, as well as for transportation of irradiated material and radioactive waste.

The “hot” cells are equipped with a built-in six-channel ALMO 6 radiation monitoring system. This system uses GM-detector 188550C to measure gamma radiation dose rates from 10μSv/h to 20 mSv/h at photon energies of 40 keV – 1.3 MeV.

Information about the radiation situation from each detector is displayed on the display located on the front panel of the “hot” cell of HC No. 1. Using

this display, the warning and emergency dose rate levels for all six detectors can be changed via the touch keyboard.

All rooms inside, where the "hot" cells are located, belong to the controlled area for work with radioactive materials.

All "hot" cells have biological lead shielding, which provides a sufficient level of radiation protection. The inner case of each cell is an insulated stainless-steel structure. "Hot" cells are equipped with observation windows, manipulators, maintenance doors, pipelines, electrical connections, lighting, etc.

An extraction unit is installed inside the extraction "hot" cell (HC No. 1), which is designed to separate the radioisotope ^{99m}Tc from irradiated MoO_3 targets by the extraction method. The thickness of the side walls of the cell is 100 mm, the thickness of the upper and lower walls is 70 mm, which meets international requirements and ensures a dose rate on the outer surface of the cells of less than 5 μSv·h^{-1}. The viewing window of the cell is made of lead glass with a thickness of 230 mm and a density of at least 5.2 g·cm^{-3}.

In the dispensing "hot" cell (HC No. 2), the final product is prepared for shipment for storage in the finished product warehouse. The thickness of the side walls is 50 mm, and the thickness of the upper and lower walls is 50 mm, which meets international requirements. The viewing window of the cell is made of lead glass with a thickness of 115 mm and a density of at least 5.2 g·cm^{-3}.

The preparation "hot" cell (HC No. 3) is designed to receive the irradiated target, dissolve the target material, measure activity, and store used solutions. The thickness of the side walls is 100 mm, and the thickness of the upper and lower walls is 70 mm, which meets international requirements. The viewing window of the cell is made of 230 mm thick lead glass with a density of at least 5.2 g·cm^{-3}.

The recirculation "hot" cell (HC No. 4) is designed for intermediate storage (holding) of spent solutions. The thickness of the side walls is 50 mm, and the thickness of the upper and lower walls is 50 mm, which meets international requirements. The inspection window of the cell is made of 115 mm thick lead glass with a density of at least 5.2 g·cm^{-3}.

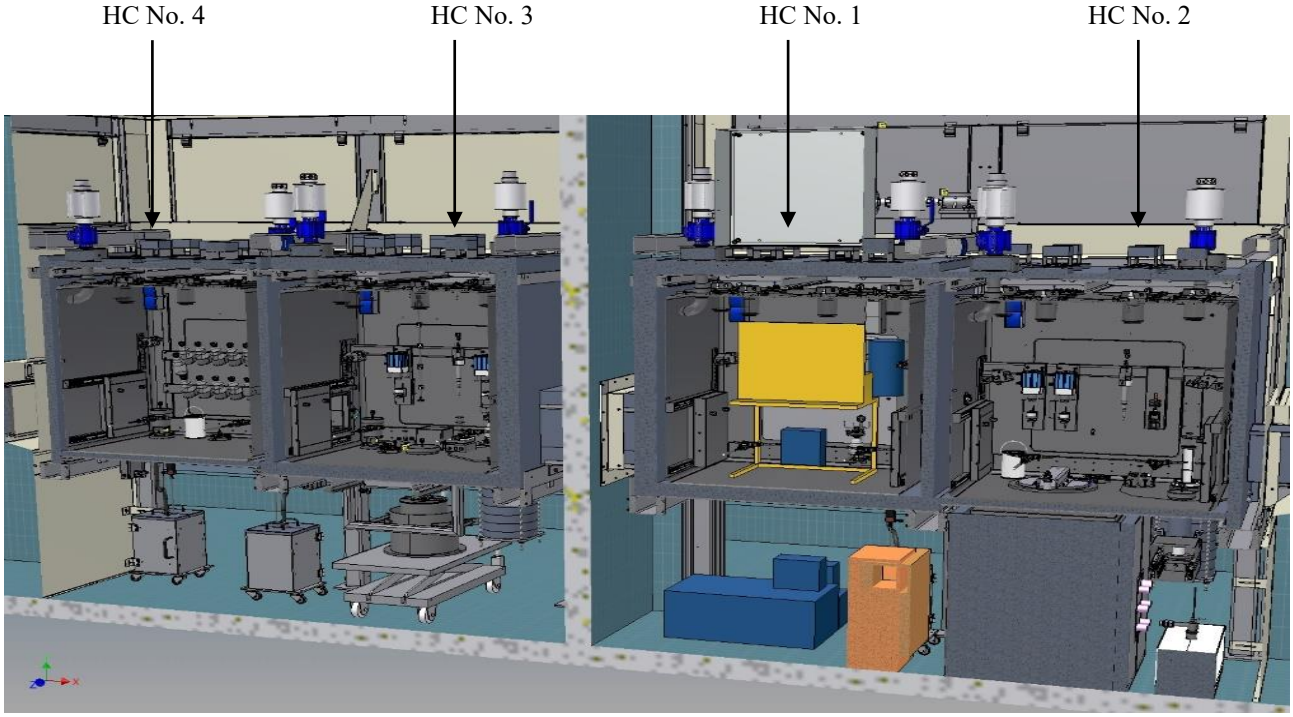

Fig. 2. The location of the process equipment inside the "hot" cells.
(See color Figure on the journal website.)

Fig. 2 shows the location of the process equipment inside the "hot" cells.

The appearance of the extraction unit for the production of "Sodium pertechnetate (^{99m}Tc), extraction" is shown in Fig. 3. This unit is located inside the "hot" cell of HC No. 1. The main technological characteristics of the extraction unit are given in Table 1.

For irradiation, molybdenum oxide (MoO_3) powder weighing 10 g was placed in quartz ampoules, which were placed in aluminum containers. The irradiation was carried out inside the core of the WWR-M research nuclear reactor of the Institute for Nuclear Research of the National Academy of Sciences of Ukraine (INR NASU) at a neutron flux density of $1 \cdot 10^{14}$ n·cm^{-2}·s^{-1}.

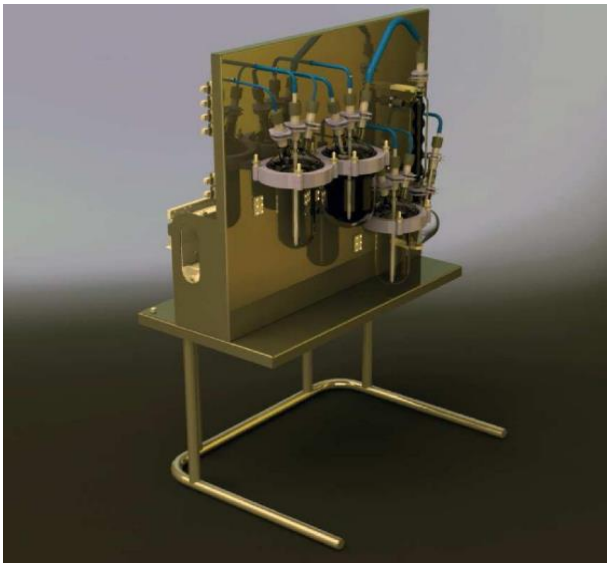

Fig. 3. The appearance of the extraction unit. (See color Figure on the journal website.)

Table 1. **Technological characteristics of the extraction facility**

Parameter	Value
Irradiated material (activating)	Up to $7.4 \cdot 10^{11}$ Bq ^{99}Mo
Chemical formula (1st stage of extractor)	K_2Mo_4 in 5M KOH + 5M K_2CO_3
Washing (2nd stage of extractor)	2.5M K_2CO_3
Volumetric characteristics 1st and 2nd extractor stages	
Extracting substance	Methyl ethyl ketone / 2-butanone ($CH_3COC_2H_5$)
Extractant flow rate	50 ml per cycle
Eluent	0.9 % NaCl
Process duration	40 - 45 min

After irradiation in the reactor, an ultrapure germanium detector with an efficiency of 11 % was used to perform control measurements of the samples' activity, which was located at a distance of 5520 mm from the aluminum ampoule container. An 82.4 mm thick iron (Fe) absorber filter was installed between the aluminum ampoule container and the detector to ensure acceptable loading of the gamma spectrometry system.

The irradiated ampoules were delivered to NSC KIPT by special vehicles of State Enterprise "Isotope" (Kyiv).

The analytical method of gamma spectrometry (SPhU, 2.2.66) [16] used a BEGe 3830 HPGe detector (Canberra, USA) with an area of 38 cm^2, 3 cm thick with an energy resolution of 0.468 keV for energy of 5 - 9 keV, 0.572 keV for energy of 122 keV and 1.7 keV for energy of 1332 keV.

To process the experimental spectrometric data, NSC KIPT used the software for calculating the detector registration efficiency under irradiation with complex-shaped radioactive sources ISOCS (In Situ Object Counting System), which is included in the spectrometer package. The identiFINDER®2 portable radionuclide identification detector was used as auxiliary equipment.

During the work, individual dosimetric monitoring of personnel was carried out using thermosluminescent dosimeters of the RADOS individual thermoluminescent dosimetry complex. Contamination of the hands and feet of the personnel was monitored using a radiometer type LB-147 (manufactured by Canberra Packard, USA).

Radiation monitoring in the premises where the work was performed was carried out by the MKS-AT1117M radiometer-dosimeter with the BDKG-01 detection unit.

4. Study results and discussion

The production of sterile RPhDs requires strict compliance with the requirements of GMP [17, 18], which guarantees the quality and safety of drugs administered to patients intravenously.

In accordance with the requirements of the Guideline ST-N of the Ministry of Health of Ukraine 42-4.0:2020 [18], the equipment used in the preparation, production, and quality control must be fit for purpose and prevent contamination of the final product.

Any equipment can potentially affect the quality and purity of radiopharmaceuticals or lead to erroneous test results if misused or improperly maintained.

All stages of production are carried out using isolated equipment intended exclusively for work with radiopharmaceuticals. Whenever possible, closed equipment or equipment storing products are used to prevent contamination.

The manufacturer of the equipment (Isotope-Technologies Dresden GmbH, Dresden, Germany) tested the cells in accordance with the European standard DIN 25 412-2 [19] and confirmed their tightness and determined the leakage rate. The test results are shown in Table 2.

Table 2. **The results of leakage control of "hot" cells**

"Hot" cells number	L, %	Permissible limits according to DIN 25 412-2
1	0.00	The tightness of the box should correspond to the leakage rate (L ≤ 0.25 % volume per h)
2	0.17	
3	0.21	
4	0.21	

The data in Table 2 show that the tightness characteristics comply with the established standards, i.e., guarantee the safety of operators when handling radioactive materials.

For the extraction separation of ^{99}Mo and ^{99m}Tc, it is possible to use various extractants, such as methyl ethyl ketone, methylisobutylketone, and organophosphorus compounds [20, 21]. Paper [20] presents the results of the extraction of ^{99m}Tc with methyl ethyl ketone from various systems: 5M solution of sodium hydroxide (NaOH) in methyl ethyl ketone, 2M solution of potassium carbonate (K_2CO_3) in methyl ethyl ketone. It is shown that it is rational to use a mixture of alkali and carbonate, which plays the role of a salting agent. It should be noted that if enriched molybdenum targets are used for irradiation with the need for further regeneration for re-irradiation, only potassium should be used as an alkali metal. This is necessary to exclude the possibility of traces of sodium in the target and, accordingly, radionuclide impurities in the final product. We considered this possibility of impurities in the radiopharmaceutical and chose a mixture of 5M KOH + 5M K_2CO_3 (see Table 1).

With this extraction unit, the extraction process can be repeated daily for about one week. The extraction unit is operated automatically. A thermostat and a cryostat for the evaporation process are built into the system.

A brief description of the technological process for obtaining radiopharmaceuticals "Sodium pertechnetate [^{99m}Tc], extraction" is as follows: an irradiated quartz ampoule with MoO_3 powder was opened using a special device located in HC No. 3, after which the powder was dissolved in a mixture of 5M solutions of potassium hydroxide (KOH) and potassium carbonate (K_2CO_3). The ^{99}Mo activity was monitored in the resulting solution sample. The solution was pumped into an extraction unit to perform the ^{99m}Tc extraction process. At the end of the process, the extract is fed into an evaporator and evaporated to a dry residue.

The dry residue is dissolved in a 0.9 % NaCl solution to the required specific activity. All technological operations, including washing and preparation of the drug, are performed automatically. The process equipment is controlled via a touch screen using specialized software. Ready-made solutions of the starting reagents are fed into the cell immediately before the start of production. The process is completed by filtration, bottling, and packaging of the RPhD in bottles, followed by steam sterilization (autoclaving) in accordance with the requirements of the State Pharmacopoeia of Ukraine [16] to produce parenteral medicines. This technological equipment is located in the HC No 2. The duration of the process is 40 - 45 min (see Table 1).

Irradiation of three quartz ampoules with MoO_3 powder (mass of MoO_3 powder in each ampoule was 10 g) was carried out in the core of the WWR-M research nuclear reactor of the INR NASU at a neutron flux density of $1{\cdot}10^{14}$ n·cm^{-2}·s^{-1}. The average irradiation time of the ampoules was 5 h.

Table 3 shows the ^{99}Mo activity in irradiated samples at the time and date of shipment to NSC KIPT.

Table 3. **^{99}Mo activity in irradiated samples**

Sample No.	Activity, GBq	Time and date of measurements
1	54	8^{00}, 09.03.2017
2	50	8^{00}, 12.03.2017
3	46	8^{00}, 15.03.2017

The activity of ^{99}Mo in the samples, depending on the waiting time to ^{99m}Tc extraction, is shown in Fig. 4.

Selected samples of the output solution containing ^{99}Mo + ^{99m}Tc radioisotopes and samples of filtered and sterilized generated (produced) solution with ^{99m}Tc radioisotope in a volume of 1 ml in glass bottles were transported to the control laboratory for gamma spectrometric analysis. The measured gamma spectra are shown in Figs. 5 - 8.

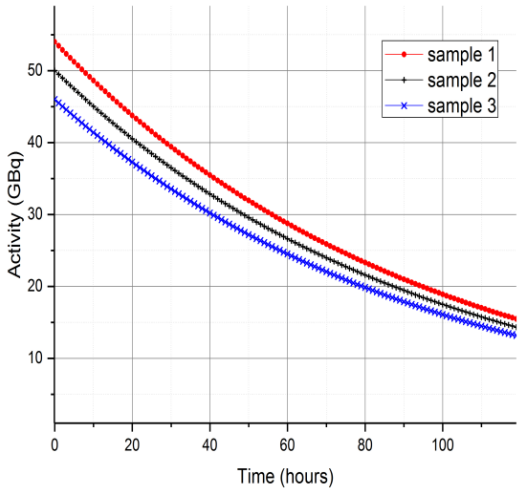

Fig. 4. Activity of ^{99}Mo radioisotope in irradiated samples depending on the waiting time before ^{99m}Tc extraction. (See color Figure on the journal website.)

The following issues are denoted by numbers in the Figures:

1 – ^{99}Mo gamma lines with energies of 181.1, 366.4, 739.5, and 777.9 keV;

2 – 281.0 keV peak (the result of random summing of two gamma quanta with energy of 140.5 keV);

3 – ^{187}W gamma lines with energies of 479.5, 685.8, and 772.9 keV.

The results of the analysis of the obtained ^{99m}Tc samples are shown in Table 4.

Comparison of the measured gamma spectra of the samples of the initial solutions containing ^{99}Mo + ^{99m}Tc radioisotopes and solutions with the ^{99m}Tc radioisotope confirms the absence of any radionuclide impurities in the developed preparation.

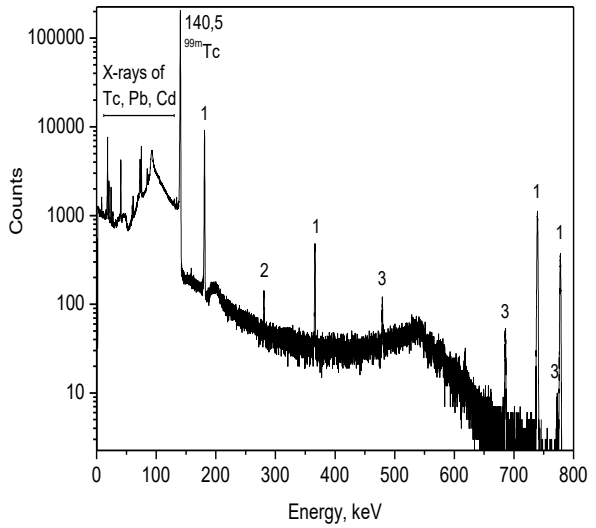

Fig. 5. Gamma spectrum of ^{99}Mo + ^{99m}Tc (sample No. 1). Date of measurement - 10.03.2017.

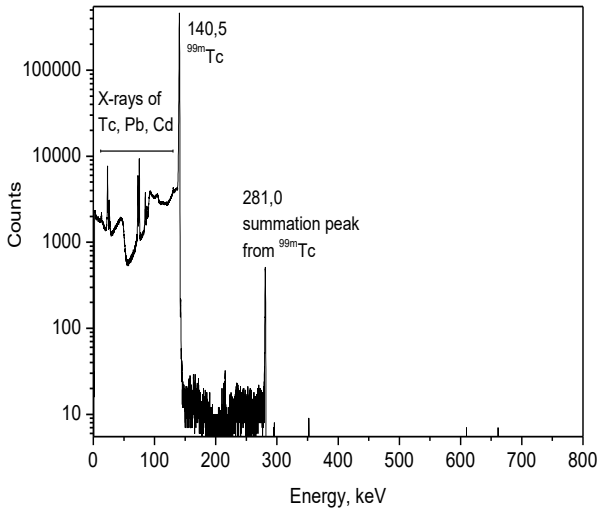

Fig. 6. Gamma spectrum of ^{99}Tc sample (the first extraction).

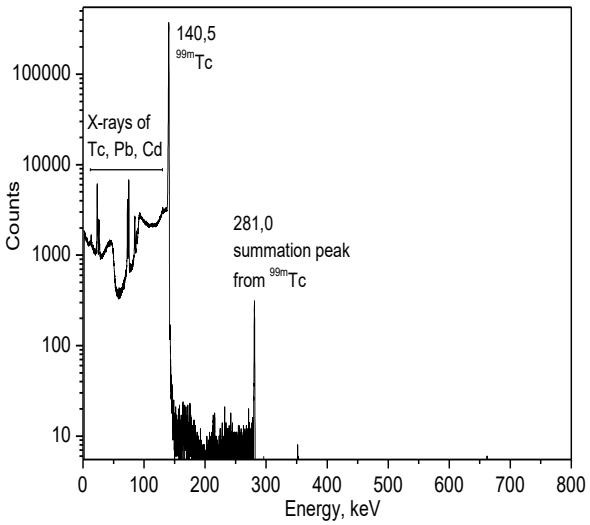

Fig. 7. Gamma spectrum of ^{99}Tc sample (the second extraction).

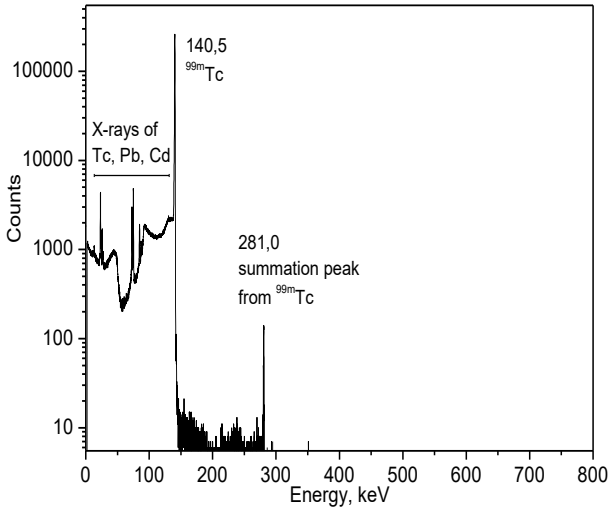

Fig. 8. Gamma spectrum of ^{99}Tc sample (the third extraction).

Table 4. **Activity of the output solution containing radioisotopes ^{99}Mo + ^{99m}Tc and ^{99}Tc solution obtained in the extraction**

Sample	Analysis date	Time of spectrum storing	Activity ^{99}Mo, GBq	Specific activity ^{99m}Tc, MBq/ml
Sample No. 1 from 09.03.2017				
Sample ^{99}Mo + ^{99m}Tc	10.03.2017	13:30	38 ± 1.9	–
The first extraction Sample ^{99m}Tc	10.03.2017	15:45	–	160 ± 8
The second extraction Sample ^{99m}Tc	11.03.2017	13:45	–	136 ± 7
The third extraction Sample ^{99m}Tc	13.03.2017	16:20	–	95 ± 5
Sample No. 2 from 12.03.2017				
Sample ^{99}Mo + ^{99m}Tc	14.03.2017	13:30	29 ± 1.5	–
The first extraction Sample ^{99m}Tc	15.03.2017	16:15	–	98 ± 5
Sample No. 3 from 15.03.2017				
Sample ^{99}Mo + ^{99m}Tc	16.03.2017	13:30	34 ± 1.7	–
The first extraction Sample ^{99m}Tc	16.03.2017	16:40	–	182 ± 9

Table 5. **Results of gamma spectrum analysis from an aluminum container with a quartz ampoule and MoO_3 powder**

Isotope	λ, s^{-1}	E, keV	A, GBq
^{99}Mo	$2.920 \cdot 10^{-6}$	739.5	59
		777.9	59
^{56}Mn	$7.467 \cdot 10^{-5}$	846.8	3000
		1810.7	2900
		2113.1	2900
^{24}Na	$1.287 \cdot 10^{-5}$	1368.6	5.2
		2754.0	5.1
^{72}Ga	$1.366 \cdot 10^{-5}$	834.1	4.4

Next, radionuclide impurities from an aluminum container with a quartz ampoule and MoO_3 powder were monitored at the end of irradiation. The results of the analysis are shown in Table 5.

Table 5 shows that, in addition to the required ^{99}Mo, side radioisotopes were produced as a result of neutron activation of chemical elements that make up the aluminum container.

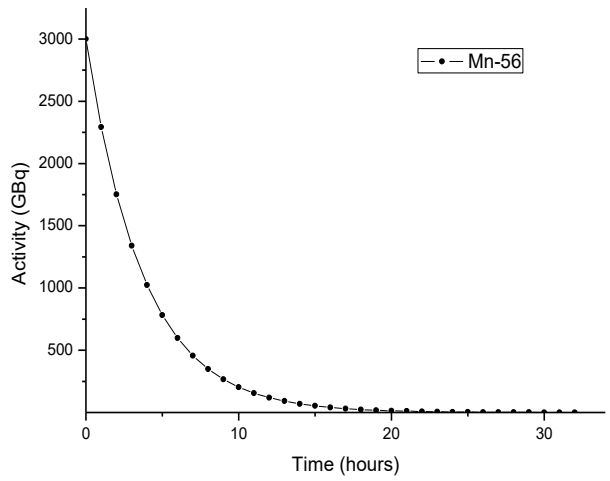

Fig. 9. Activity decay of the produced radioisotope ^{56}Mn.

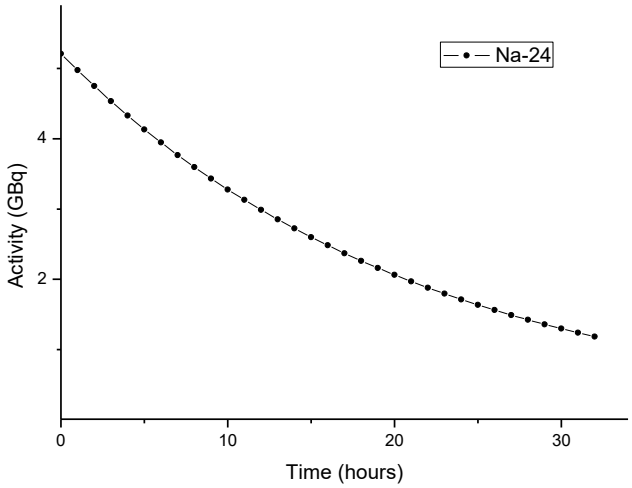

Fig. 10. Activity decay of the produced radioisotope ^{24}Na.

Taking into account the decay constants λ, the decrease in the accumulated radioisotope activities in the samples occurred according to Figs. 9 - 11.

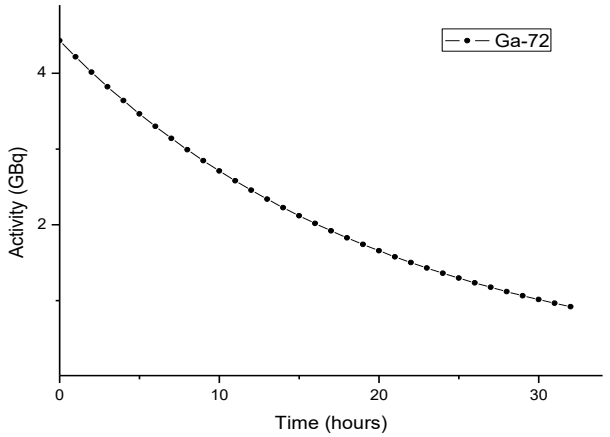

Fig. 11. Activity decay of the produced radioisotope ^{72}Ga.

For comparison, NSC KIPT analyzed and determined the element composition of the material of the unirradiated aluminum capsule. The results are shown in Table 6.

Table 6. **Element content in the aluminum capsule material**

Element	Z	Content, %
Al	13	97.20
Si	14	1.25
Mg	12	0.75
Mn	25	0.45
Fe	26	0.21
Cu	29	0.05
Cl	17	0.04
V	23	0.03
S	16	0.03
Ti	22	0.03
Cr	24	0.01

In addition to the activity of short-lived radioisotopes, irradiation of the aluminum capsule is likely to lead to the formation of radioisotopes ^{59}Fe ($T_{1/2}$ = 44.5 days) and ^{51}Cr ($T_{1/2}$ = 27.7 days), which contribute to the radiation situation during work in the Radioisotope Laboratory building.

5. Conclusion

As a result of the research, the technology for producing radiopharmaceuticals "Sodium pertechnetate [^{99m}Tc], extraction" was tested, based on the method of extraction of ^{99m}Tc with methyleneketone from a solution of ^{99}Mo + ^{99m}Tc and placed in the "hot" cells of the Laboratory of Radioisotopes of NSC KIPT. The efficiency and reliability of the technological equipment were tested. Five samples of the radiopharmaceutical "Sodium pertechnetate (^{99m}Tc)" were obtained, for which activity and radionuclide purity were determined. It was found that the specific activity of all samples met the acceptance criteria (from 74 to 1480 MBq/ml) at the date and time of receipt.

The results of the studies confirm the practical possibility of organizing domestic Ukraine production of radiopharmaceuticals "Sodium pertechnetate [^{99m}Tc], extraction, solution for injection" based on "hot" cells of the Laboratory of Radioisotopes of NSC KIPT using the NSC KIPT SCA "Neutron Source" for irradiation of the starting material - molybdenum oxide (MoO_3).

The radionuclides formed as a result of irradiation of an aluminum container in which a quartz ampoule with MoO_3 powder was placed were identified, and their activity was determined. It has been established that in order to reduce the total activity loaded into HC No. 3, containers made of high-purity aluminum for irradiation should be used. This will increase the permissible activity of ^{99}Mo and reduce the radiation load on personnel.

The studies conducted and the results obtained constitute the necessary scientific and technical basis for the development of regulatory technological documentation required for the organization of the production of RPhDs. In addition, they are an important component in the formation of the relevant section of the registration dossier in the Common Technical Document format – a set of documents confirming the efficacy, safety, and quality of the medicinal product.

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ЕКСПЕРИМЕНТАЛЬНЕ ДОСЛІДЖЕННЯ МЕТОДУ ОТРИМАННЯ РАДІОФАРМАЦЕВТИЧНОГО ПРЕПАРАТУ «НАТРІЮ ПЕРТЕХНЕТАТ (^{99m}Tc)» ІЗ ЗАСТОСУВАННЯМ ЕКСТРАКЦІЙНОЇ УСТАНОВКИ В «ГАРЯЧИХ» КАМЕРАХ ННЦ «ХАРКІВСЬКИЙ ФІЗИКО-ТЕХНІЧНИЙ ІНСТИТУТ»

У роботі представлено результати першого тестування технологічного обладнання для виробництва радіофармацевтичного препарату (РФП) «Натрію пертехнетат (^{99m}Tc), екстракційний, розчин для ін'єкцій» на технологічному обладнанні, розташованому в лабораторії виробництва радіоізотопів ННЦ «Харківський фізико-технічний інститут» (ХФТІ). «Гарячі» камери і змонтоване всередині камер технологічне обладнання відповідають вимогам європейського стандарту та гарантують безпеку операторів у процесі виробництва. Технологію отримання РФП засновано на екстракційному виділенні ^{99m}Tc метилетилкетоном з лужних розчинів ^{99}Mo. ^{99m}Tc отримують як дочірній продукт розпаду ^{99}Mo, що утворюється в результаті реакції радіаційного захоплення ^{98}Mo(n, γ)^{99}Mo під час опромінення порошку оксиду природного молібдену MoO_3 (^{98}Mo 24,13 %) нейтронами всередині активної зони ядерної установки. Оскільки підкритична установка «Джерело нейтронів» ННЦ ХФТІ знаходиться на стадії фізичного запуску, опромінення ампул з порошком MoO_3 проводилося в активній зоні дослідницького ядерного реактора типу ВВР-М Інституту ядерних досліджень НАН України. Результати проведених гамма-спектрометричних досліджень вихідного розчину, що містить радіоізотопи ^{99}Mo + ^{99m}Tc, та готового розчину з радіоізотопом ^{99m}Tc показали відсутність радіонуклідних домішок.

Ключові слова: радіофармацевтичний препарат, радіоізотоп, ^{99m}Tc, екстракційне вилучення, радіонуклідна чистота.

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