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Production of radionuclides for medical use at WWR-c reactor, radiopharmaceutical production under GMP standards

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At WWR-c reactor of Karpov Institute of Physical Chemistry, Obninsk, the following radionuclides for medical use are produced: 99Mo, 125I, 131I, 135Xe, 153Sm, 59Fe.

Also there is a production of other radionuclides at WWR-c reactor, including radionuclides for scientific research and development or for non-repeat orders. However, there is no great demand for the other medical radionuclides to be produced at the reactor.

At present the most crucial task is to increase the production of one of the most high-demand radionuclides 99Mo for diagnosing of oncological diseases. Due to failure of starting two 99Mo reactor-generators in Canada, the lack of this isotope has appeared [1]. This fact significantly raised the chances of Karpov Institute to stand with Russian 99Mo on the world market. That is why the task to increase the production of the above mentioned radionuclides and generators on their base with simultaneous properties improvement is an important economic goal.

Experience of 99Mo production at WWR-c reactor.

In 1983 Karpov Institute accepted a challenge to set up 99Mo production. One channel at reactor core periphery was selected for that purpose. After the force-cooled channel was designed and target design in 1985 the first batch of 99Mo was produced. The volume of 99Mo production was about 20 Ci per week [2].

In 2002 the target was modified and the number of targets in the channel was raised up to 4 pieces. Also the procedure of target processing was optimized and the coefficient of 99Mo radiochemical release was increased from 60 up to 85 %. Thus, the channel capacity for 99Mo production grew up to 30 Ci per week. This production capacity was enough for the full cover of Russian hospitals in existing 99Mo demand.

At the end of 2008, one additional channel was installed in cell 8-1 of WWR-c reactor core that allowed to double the 99Mo production starting from 2009. Thus, starting from 2009 Karpov Institute could produce both 30 Ci per week (commercial) required for local hospitals and up to 50 Ci per week of 99Mo for export shipments. Since 2012 two more channels have been installed. This allowed to double the existed production of 99Mo. In 2015 the current volume of 99Mo production is 200 Ci per week (commercial). The potentiality of 99Mo production at WWR-c reactor went up to 400 Ci per week, what is to be realized after the advancement of the radiochemical process. In 2016 it is intended to perform the production modernization (irradiation, radiochemical release).

Production line for 99mTc-generators loading.

As of today Karpov Institute weekly produces 100 –130 generators with different nominal activities.

In order to decrease the possibility of human mistakes during the process of generators loading and to increase their quality and also according to the new GMP requirements for drug manufacturing Karpov Institute decided to optimize Karpov generators production by changing manual loading to automatized one. The new production line shall correspond to the following main requirements:

• Automatic operation with minimal operator intervention;
• Production volume should equal to 200 generators per week;
• Production equipment shall be installed in rooms which correspond to GMP requirements.

During 2007 –2009, one of Karpov Institute buildings was refurnished to construct "clean"rooms with production line for automatized loading of molybdenum-technetium generators under GMP (Good Manufacturing Practice) standards.

In 2013, the installation of the major equipment was finished and pre-commissioning activities were performed [3]. At the beginning of 2015 the cold startup of the line was performed. Karpov Institute together with the engineering company trains the Institute's specialists in the field of loading of molybdenum-technetium generators. The estimated period of commercial commissioning of this facility is 2015 year. As of today the specialists undergo training on working in compliance with GMP standards.

At present the development of the project on the conversion of additional buildings of the Institute to manufacture other radiopharmaceuticals under GMP standards is in progress at Karpov Institute.

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Organization

Karpov Institute of Physical Chemistry

Country

Russian Federation

Author: Mr GREMIACHKIN, Vladimir (Karpov Institute of Physical Chemistry)

Co-authors: Mr KOCHNOV, Oleg (Karpov Institute of Physical Chemistry); Mr POZDEEV, Vitalii (Karpov Institute of Physical Chemistry)

Presenter: Mr GREMIACHKIN, Vladimir (Karpov Institute of Physical Chemistry)

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