LEGAL REGULATION OF NUCLEAR MEDICINE CENTERS: CURRENT STATUS AND DEVELOPMENT OBJECTIVES

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In 2015, Resolution of the Government of the Russian Federation No. 2144-p dated October 23, 2015, approved the "road map": Development of Nuclear Medicine Centers. The nuclear medicine centers are currently designed and built in many cities of the Russian Federation. At the same time, experts draw attention to the gaps in the legal regulation of relations concerning construction of nuclear medicine facilities, application to nuclear medicine centers of regulations on design, construction, and commissioning of nuclear power plants, the low level of competence of contractors that win tenders on the basis of formal evidence of compliance with the requirements of procurement laws, and insufficient classification of radiopharmaceuticals.

There are few legal researches on the problems of legal regulation of nuclear medicine. Therefore, it seems to be relevant to perform legal research on the current state of legal support for nuclear medicine, design, construction, and operation of the nuclear medicine centers providing diagnostic services and treating individuals. It is necessary to decide what is legal meant by the nuclear medicine center, what social relations arise in the process of creation and functioning of the nuclear medicine centers, to study sources of legal support of the nuclear medicine centers, and to determine the objects of their further development. The article proposes classifications of the nuclear medicine centers, inter alia, on the following grounds: (1) by the organizational and legal form of incorporation: the business subdivision of a medical institution and the independent medical institution; (2) by functional purpose — diagnostic centers; diagnostic and treatment centers; centers where diagnostics is performed, radiopharmaceuticals are made, and patients are treated; (3) as the object of design and construction: the department in an existing medical institution and the separate object of design and capital construction.

Proper legal support is necessary for all parties to the social relations: for enterprises producing isotope products, manufacturing diagnostic equipment, and producing medical preparations, for design and contracting organizations involved in the design and construction of the nuclear medicine centers, for health care professionals; for individuals who need to undergo diagnostics and treatment, for government agencies and organizations that regulate and control activities. The article presents proposals for possible unification of regulations governing creation and functioning of the nuclear medicine centers.

Keywords: *energy law, nuclear law, legal use of radioactive isotopes in medicine, legal framework of the nuclear medicine centers.*

8.8 million people die of cancer every year. 70 percent of these deaths occur in developing countries. In some African countries, less than 15 percent of oncological patients survive for five years after cervical and breast cancer is diagnosed. In many industrially advanced countries of the world, these diseases are often cured.

Experts note that to reduce cancer mortality, it is necessary to detect such diseases at the early stages and to more actively implement modern methods of treatment. [1]

Applications of nuclear medicine include not only oncology, but also cardiology, hepatology, urology and nephrology, pulmonology, endocrinology, hematology, allergology, pediatrics, immunology, traumatology, neurology, and neurosurgery. [2]

In 1954, the Society of Nuclear Medicine was established in the state of Washington. In 2012, the society changed its name to the Society of Nuclear Medicine and Molecular Imaging. In 1971, the US Chamber of Nuclear Medicine, which sets educational standards and assesses the competence of physicians in the field of nuclear medicine, was created. The Chamber has the right to officially certify specialists in the field of nuclear medicine. In 1985, the European Association of Nuclear Medicine was founded. In 1996, the Interregional Public Organization of Nuclear Medicine Society of Nuclear Medicine was established in Russia. [3]

There are few legal research studies on the problems of legal regulation of nuclear medicine.

Various aspects of the legal regulation of nuclear medicine were studied in the works of A.I. Ioyrysh, G.B. Romanovsky, and V.V. Romanova. The work of A.I. Ioyrysh examines the definition of the concept of radioactive isotopes for medical use, civil and criminal liability for violation of the requirements for the use of these substances for diagnostic and therapeutic purposes. [4]

The work of G.B. Romanovsky studies the concept of nuclear medicine, the legal basis, on which relations are regulated in diagnostics and the use of radiopharmaceuticals. The expanded concept of nuclear medicine is understood by G.B. Romanovsky to include five components: radioisotope diagnostic methods, radionuclide and radiation therapy, technologies for production of radiopharmaceuticals, use of charged particle accelerators for production of isotopes and radiation therapy, computer technologies for obtaining and storing images in tomography, for planning radiation therapy and other calculations. [5] The paper by V.V. Romanova discusses peculiarities of the legal framework of radioactive isotopes and radioisotope products used for nuclear medicine. [6]

Medical and technological aspects relating to creation of PET centers were studied in the work of Medradi+Preparat Group. [7]

In 2015, Resolution of the Government of the Russian Federation No. 2144-p dated October 23, 2015, approved the "road map": Development of Nuclear Medicine Centers. [8] The "roadmap" provides for implementation of the following activities: organization and monitoring of existing nuclear medicine centers as well as those under construction and nuclear medicine facilities planned to be built in the Russian Federation taking into account the needs of the population, making a list of infrastructure facilities; preparation of proposals concerning measures to support the nuclear medicine projects; development and approval of standards of medical care for oncological diseases, introduction of changes in the range of medical services as related to inclusion of medical services related to the use of technologies proton beam therapy; development of guidelines for modern good practice for production of radiopharmaceuticals in medical institutions"; development and approval of the federal state educational standard of higher education "Radiopharmaceuticals".

Nuclear medicine is one of the activities of the State Atomic Energy Corporation Rosatom. [9] Leading equipment manufacturers, producers of radionuclides, manufacturers of low-capacity reactors for production of radionuclides, and producers of radiopharmaceuticals are involved in implementation of this line of activity. The official website of Rosatom State Corporation also provides information on creation of a pilot project for an integrated medical facility — PET Center of Rosatom State Corporation for provision of services to the public as well as on

establishment of a nuclear medicine center at the Far Eastern Federal University.

According to publicly available data, the nuclear medicine centers are currently designed and built throughout the Russian Federation, including Novosibirsk, Grozny, Khabarovsk, Cheboksary, etc. [10]

Modern research of the experts draws attention not only to insufficiency of nuclear medicine centers and high cost of radionuclide studies, but also to insufficiency of the regulatory framework, inconsistency of the existing one, gaps in the legal regulation of relations concerning construction of the nuclear medicine facilities, application to the nuclear medicine centers of regulations on design, construction, and commissioning of the nuclear power plants, low level of competence of contractors that win tenders on the basis of formal evidence of compliance with the requirements of procurement laws, and inadequate classification of radiopharmaceuticals. [11]

Peculiarities of the legal framework of the nuclear medicine centers have not yet been subjects of a separate legal research. Current legislation does not contain a definition of the concept of the nuclear medicine center.

Therefore, legal research on the current state of legal support for nuclear medicine, design, construction, and operation of the nuclear medicine centers providing diagnostic services and treating individuals seems to be relevant.

Legal analysis of relations arising upon use of nuclear technologies allows us to conclude that these relations include relations in connection with design and construction of the nuclear medicine facilities, production of isotope products, manufacture of diagnostic equipment, diagnostic assessment of individuals, creation of therapeutic drugs, and treatment of individuals. It covers both private and public relations.

The nuclear medicine centers can be conditionally classified, including classification on the following grounds:

— by the organization and legal form of incorporation: the business subdivision of a medical institution and the independent medical institution;

— by functional purpose: diagnostic centers; diagnostic and treatment centers; centers where diagnostics is performed, radiopharmaceuticals are made, and patients are treated;

— as an object of design and construction: the department in an existing medical institution and the separate object of design and capital development.

Proper legal support is necessary for all parties to public relations: for enterprises producing isotope products, manufacturing diagnostic equipment, and producing medical preparations, for design and contracting organizations involved in the design and construction of the nuclear medicine centers, for health care professionals; for individuals who need to undergo diagnostics and treatment, for government agencies and organizations that regulate and control activities.

There are currently no separate legislative acts regulating the activities of the nuclear medicine centers.

Certain requirements for the parties to public relations in the field of nuclear medicine are specified in various sources of energy law.

The following should be primarily mentioned among special branch laws: Federal Law No. 170-ФЗ dated November 21, 1995, *On the Use of Nuclear Energy*, and Federal Law No. 3-ФЗ dated January 9, 1996, *On the Radiation Safety of the Population*.

Article 19 of Federal Law No. 170-ФЗ dated November 21, 1995, *On the Use of Nuclear Energy* provides for the following rights of the individual upon performance of medical procedures while using ionizing radiation: (1) upon request, the individual shall be provided with full information about the size of the planned and actually received upon examination or treatment dose; (2) an individual or its legal representative shall be entitled to make a decision on use of ionizing radiation during medical procedures.

At the same time, it appears that these standards are clearly insufficient to regulate relations concerning design, construction, and operation of the nuclear medicine centers and interaction of various parties of emerging public relations. Federal Law No. 170-ФЗ dated November 21, 1995 *On the Use of Nuclear Energy* is a basic federal law regulating relations in the field of use of nuclear energy.

For the sake of clarity of the definition of legal regulation, it is necessary to define the concept of the nuclear medicine centers and the concept of radioisotope products for nuclear medicine among the objects of use of nuclear energy.

Issues relating to the legal framework of these centers as the objects of design, construction, and operation of the nuclear medicine centers, and the legal status of the parties to public relations can be specified in a separate chapter by analogy with Chapters VI, VII, VIII, IX, and XI of this law.

Development and documentation of relevant regulations in a separate special law may be an alternative option.

Further considering the current conditions of legal support of nuclear medicine, the provisions of Federal Law No. 3-ФЗ dated January 9, 1996, *On the Radiation Safety of the Population* should be noted. Pursuant to Article 9 of Federal Law No. 3-ФЗ dated January 9, 1996, *On the Radiation Safety of the Population*, state regulation is envisaged in the field of ensuring radiation safety, and it shall be performed through establishment of sanitary rules, norms, hygienic standards, radiation safety rules, sets of rules, labor safety rules, and other regulatory documents on radiation safety.

The main hygienic standards (permissible dose limits) for the population and the health care professionals are set out in clause 2 of this article. At the same time, a reservation is made that the regulated values of the main limits of radiation doses shall not include the doses received by the individuals (patients) during medical X-ray procedures and treatment. The values of dose limits established in the law shall be initial ones when establishing the levels of exposure of the human body and its individual organs.

The following shall be mentioned among the subordinate regulatory legal acts: Resolution of the Government of the Russian Federation No. 718 dated June 16, 1997 On the Procedure for Creation of the Unified State System of Control and Accounting for Individual Radiation Doses for Citizens, Order of the Ministry of Health of the Russian Federation No. 211н dated April 27, 2015, *On Approval of the Procedure for Production of Radiopharmaceutical Medicinal Products Directly in Medical Institutions*, and Resolutions of the Chief State Sanitary Physician of the Russian Federation.

Thus, for example, Resolution of the Chief State Sanitary Physician of the Russian Federation No. 27 dated July 14, 2015, approved the Sanitary and Epidemiological Requirements to Handling of Radioisotope Devices and Their Design, Resolution of the Chief State Sanitary Physician of the Russian Federation No. 31 dated July 20, 2015, approved the Hygienic Requirements for Ensuring Radiation Safety upon Preparation and Performance of Positron Emission Tomography, and Resolution of the Chief State Sanitary Physician of the Russian Federation No. 26 dated June 16, 2008, approved the Hygienic Requirements for Ensuring Radiation Safety upon Radiation Treatment Using Open Radionuclide Sources.

However, for implementation of active design, construction, and operation of the nuclear medicine centers, it is practical to develop a special legal regulation for design, construction, commissioning, and operation of these centers taking into account the peculiarities related to the form of incorporation and functional purpose (diagnostic centers, diagnostic and treatment centers, and integrated nuclear medicine centers). The legal provision for a balance of interests of the parties to public relations in this field is also an important task. Profit earning is important for the companies engaged in production and supply of isotope products, construction and maintenance of the nuclear medicine centers, production and supply of radiopharmaceuticals; therefore, these parties to public relations need an efficient legal regulation providing not only for requirements and responsibilities, but also for measures of state support and possible preferential taxation. Not only territorial availability of the nuclear medicine centers, but also affordability of diagnostics and treatment is important for individuals.

In Article 4 of Federal Law No. 3-ФЗ dated January 9, 1996, *On the Radiation Safety of the Population*, the legislator puts legal measures to the first place among the priority measures to ensure radiation safety. Further development of legal regulation of nuclear medicine, including

establishment and operation of the nuclear medicine centers, requires thorough systematization of existing regulatory legal acts in the field of nuclear medicine and determining their compliance with the current development objectives of nuclear medicine.

It seems actual to raise the issue of carrying out work on unification of regulations on various aspects of legal regulation of social relations arising in the field of nuclear medicine, including design, construction, commissioning, and operation of the nuclear medicine centers. This concerns development of unified concepts, wording of requirements concerning the legal framework of isotope products, the legal framework of the nuclear medicine centers as the objects of design, construction, and operation, legal status of the entities involved in design, construction, and operation of the nuclear medicine centers, the rights and obligations of medical personnel, the rights and obligations of individual patients of the nuclear medicine centers, contractual regulation, government regulation and control. ■

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