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OF BURNAZYAN FMBC OF FMBA
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STATE SCIENTIFIC CENTER OF THE RUSSIAN FEDERATION — FEDERAL MEDICAL BIOPHYSICAL
CENTER NAMED AFTER A.I. BURNAZYAN OF FMBA OF RUSSIA: 75 YEARS ON GUARD
OF PEOPLE'S HEALTH

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Abstract. The article presents the history of creation, formation and development of the State Scientific Center of the Russian Federation — Federal Medical Biophysical Center named after A.I. Burnazyan of the Federal Medical and Biological Agency of Russia (A.I. Burnazyan Federal Biophysical Center, the Center). The Institute of Biophysics of USSR Ministry of Health and Clinical Hospital № 6, predecessors of the Center, were engaged in the elimination of medical and sanitary consequences of Chernobyl Radiation Accident (1986). The main directions of activities of the A.I. Burnazyan Federal Medical Biophysical Center — the flagship institution of Russian health care in the field of biophysics, radiation and nuclear medicine are considered. The perspectives of scientific activity of the Center related to solving actual problems of modern radiobiology, radiation safety and biomedical technologies are outlined. It is concluded that it is expedient to create the Disaster Medicine Service of the Federal Medical and Biomedical Agency of Russia.

Keywords: A.I. Burnazyan Federal Medical Biophysical Center, biophysics, Chernobyl accident, Emergency Medicine Service of FMBA of Russia (project), emergency response, emergency situations, Federal Medical and Biological Agency (FMBA of Russia), nuclear medicine, radiation safety, radiation accidents, radiobiology

Conflict of interest. The authors declare no conflict of interest

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ГОСУДАРСТВЕННЫЙ НАУЧНЫЙ ЦЕНТР РОССИЙСКОЙ ФЕДЕРАЦИИ – ФЕДЕРАЛЬНЫЙ
МЕДИЦИНСКИЙ БИОФИЗИЧЕСКИЙ ЦЕНТР ИМЕНИ А.И.БУРНАЗЯНА ФМБА РОССИИ:
75 ЛЕТ НА СТРАЖЕ ЗДОРОВЬЯ ЛЮДЕЙ

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Резюме. Представлена история создания, становления и развития Государственного научного центра Российской Федерации – Федерального медицинского биофизического центра имени А.И.Бурназяна ФМБА России (ФМБЦ им. А.И.Бурназяна, Центр). Отмечено, что особой страницей в деятельности Института биофизики Минздрава СССР и Клинической больницы №6 – предшественников ФМБЦ им. А.И.Бурназяна – является работа по ликвидации медико-санитарных последствий радиационной аварии (РА) на Чернобыльской АЭС (1986). Рассмотрены основные направления деятельности ФМБЦ им. А.И.Бурназяна – флагманского учреждения российского здравоохранения в области биофизики, радиационной и ядерной медицины. Намечены перспективы научной деятельности Центра, связанные с решением актуальных вопросов современной радиобиологии, радиационной безопасности и биомедицинских технологий. Сделан вывод о целесообразности создания Службы медицины катастроф ФМБА России

Ключевые слова: аварийное реагирование, авария на Чернобыльской АЭС, биофизика, радиационная безопасность, радиационные аварии, радиобиология, Служба медицины катастроф ФМБА России (проект), Федеральное медико-биологическое агентство (ФМБА России), Федеральный медицинский биофизический центр им. А.И.Бурназяна, чрезвычайные ситуации, ядерная медицина

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In 2021, the State Scientific Center of the Russian Federation — Federal Medical Biophysical Center named after A.I. Burnazyan of FMBA of Russia (hereinafter - the Center, FMBC named after A.I. Burnazyan) celebrates its 75th anniversary. Over the years, the Center has repeatedly proven its high competence in nuclear medicine, radiation safety, radiobiology, and emergency response.

In May 1946, a radiation laboratory was established on the initiative of A.I. Burnazyan. Its purpose was to study the effect of radiation on the human body and to develop possible means of treatment and protection against the radiation factor. At that time the need for scientific substantiation of radiation safety norms and rules, maximum permissible doses and maximum concentrations of various toxic substances, as well as the study of early specific signs and clinics of new occupational diseases and poisonings caused by radioactive substances was maturing.

To solve these problems, in August 1947, in accordance with the Decree of the Council of the USSR Ministry of Health, the Third Main Directorate (now the Federal Medical and Biological Agency, FMBA) was established under the USSR Ministry of Health. Its system included special research institutes to study the effects of radiation and other physical and chemical factors on the human body. It also included medical-sanitary units for treatment and rehabilitation of victims of radiation and of other physical factors.

Clinical Hospital of the Moscow Health Department No. 6. On the initiative of A.I. Burnazyan, in accordance with the Order of the Ministry of Health of the USSR from September 25, 1948 № 14 on the basis of the Moscow Neurosurgical Hospital for the disabled of World War II a closed type clinical hospital was created. The patients of the hospital were the employees of institutions and enterprises of nuclear power industry. Later the hospital was transferred to the jurisdiction of the Third Main Directorate of the USSR Ministry of Health.

Medical-Sanitary Unit No. 12. In May 1948 on the basis of order of A.I. Burnazyan a medical-sanitary unit ¹12 was organized on the territory of I.V. Kurchatov Institute on the basis of a small outpatient clinic of 7 doctors' offices. Doctors and medical personnel of the medical unit served the personnel of the Russian Research Center "Kurchatov Institute", Institute of High-Technology Scientific Research of Inorganic Materials named after A.A. Bochvar, the Research Institute of Instrument Engineering, the Institute of Biophysics of USSR Ministry of Health, as well as the residents of nearby areas. In 2004, the medical unit №12 was transformed into Clinical Hospital №86 of the Federal Medical and Biological Agency of Russia.

Institute of Biophysics of the USSR Ministry of Health. In 1948 the Institute of Biophysics of the Ministry of Health of the USSR was established on the basis of a radiation laboratory. The work of a large team of hygienists resulted in several editions of state radiation safety standards and basic sanitary rules to ensure radiation safety. The team edited more than a hundred monographs, thousands of articles, a

set of sanitary norms and rules, hygienic standards, regulatory and methodological documents on all areas of radiation safety of personnel and population and on all facilities of the nuclear fuel cycle.

The Chernobyl accident is a special page in the history of the Institute of Biophysics and Clinical Hospital No. 6.

Since April 1986 dozens of specialists in radiation hygiene and personnel safety have directly participated in Chernobyl accident consequences elimination. On December 19, 1994 the Institute of Biophysics was granted the status of the State Scientific Center of the Russian Federation.

In the first hours after the catastrophe, scientists, doctors, and specialists from emergency teams arrived at Chernobyl and organized medical triage and medical evacuation of the most severely injured to Clinical Hospital No. 6. There they were provided with medical care. Also, necessary complex studies on exposure assessment using methods developed by the staff of the Institute were performed. The Institute specialists provided scientific and methodological guidance to radiation safety services. Their contribution concerned the issues of individual dosimetry, decontamination, organization of individual personnel protection, psychophysiological support, etc. As a result valuable scientific data were obtained. Their analysis and generalization allowed to develop practical recommendations on prevention of radiation accidents and on improvement of preparedness of emergency rescue teams to eliminate consequences of probable radiation accidents.

Today, the Burnazyan Federal Biomedical Center is the flagship institution of Russian health care in the field of biophysics, radiation and nuclear medicine. The Center's scientific activities are focused on the development of biomedical and additive technologies, radiopharmaceuticals, radiation monitoring and dosimetry. The Center performs scientific research work under the state defense order, federal target programs, cooperation with SC "Rosatom" and international organizations in its field of activity. In 2020 the Center was included in the National Project "Science" with a project to create a center for additive technologies. These developments, implemented in clinical practice, will be a big step forward in the development of Russian health care.

The Center has a multidisciplinary clinic with an annual capacity of 20,000 patients. The clinic provides specialized, including high-tech, medical care to the assigned contingent, as well as to all those in need of quality medical care. The assigned contingent includes employees of nuclear industry enterprises and athletes of the Russian Federation national teams.

The Center's educational activities are determined by the state's tasks to ensure safe living conditions for the Russian population. At the forefront of this work is the Medical-Biological University of Innovation and Continuing Education of FMBA of Russia. As in all leading institutions of higher education, during the COVID-19 pandemic, the University did not cease its educational activities, and its thesis defense took place online.

Together with Rosatom and FMBA specialists, scientists from the Center regularly take part in educational and training events. They practice actions to eliminate consequences of radiation emergencies.

The Center conducts research in the field of molecular, biochemical and genetic mechanisms of radiation lesion formation and postradiation recovery. One of them is treatment of local radiation lesions with mesenchymal stem cells combined with microsurgical technique. This method showed good results in the experiment.

During the peak of the pandemic of the new coronavirus infection COVID-19, the Center continued to provide routine medical care. In 2020, for the first time in Russia, the Center used a unique technology of Salvage liver transplantation — staged liver transplantation for primarily unresectable tumors. The Center has the largest experience of liver transplantation for oncological and parasitic pathologies in the country. Since 2010 the Center has performed more than 400 transplants.

An important area of activity of the A.I. Burnazyan Federal Medical and Biological Center of the Federal Medical and Biological Agency of Russia is active participation in the implementation of medical and social policy to improve and to develop the system of protection, life saving and health preservation of victims of emergency situations. This applies both to workers in certain areas of the economy with particularly hazardous working conditions, and to the population of certain territories of the Russian Federation served by FMBA of Russia.

Specialists at the Russian Federal Medical and Biological Agency, including the A.I. Burnazyan Federal Medical and Biological Center, solve specific tasks of medical-sanitary and medical-biological support of employees of special facilities and territories of importance to the country's economy and security. One of the peculiarities of these facilities is that they are widely dispersed throughout the country, including border regions.

In addition, the Center and other medical organizations of FMBA of Russia are tasked with the medical support of work to localize and to eliminate medical and sanitary consequences of terrorist acts. Terrorist acts may involve radioactive substances, highly toxic chemical compounds, and biological agents. Thus the given socially dangerous phenomena can arise in various territories. Including the territories of closed administrative-territorial formations and the settlements located in them. Such conditions require the use of special technologies for organization and implementation of medical care, as well as their continuous improvement, taking into account the development of medical science and health care practice.

In conditions of hybrid warfare, facilities and territories serviced by FMBA of Russia may become priority targets for terrorist attacks or high-precision weapons strikes. It is very likely that several emergency zones will arise — simultaneously or within a short period of time — foci of human destruction, disruption of life support systems, complete or partial failure of some medical and other medical organizations that provide medical and biomedical support to facility employees and the population living in these territories.

Sufficient medical forces and means are available to eliminate medical and sanitary consequences of probable emergencies at the facilities and territories currently serviced by the Center and — in general — by the Agency. Their dislocation is justified taking into account the specifics of tasks of

medico-sanitary and medico-biological support of special facilities and territories.

The organization and provision of medical assistance to victims in emergency situations is carried out in medical treatment organizations (medical-sanitary units, clinical hospitals, centers). They are usually located in the immediate vicinity of organizations and enterprises with particularly hazardous working conditions. The system of providing emergency medical aid and of organizing measures for timely liquidation of medical and sanitary consequences of accidents is built taking into account the specifics of the main production, in close interaction with the relevant services of industrial ministries, organizations and enterprises, regional health care, institutions and formations of the All-Russian Disaster Medicine Service.

In order to maintain the readiness of management bodies and medical organizations of FMBA of Russia to respond and to act in emergency situations, a system of operational duty officers has been created and is functioning. There is round-the-clock duty and interaction. This includes participation in operational meetings led by the National Center for Crisis Management of EMERCOM of Russia and the National Defense Management Center of the Russian Federation held via videoconferencing.

In addition, a system for monitoring possible radiation, chemical and biological threats that could lead to medical and sanitary consequences has been created and is being developed. The system also monitors the condition of victims, their need for consultations, including telemedicine, and monitors medical evacuations. The technologies of collecting, summarizing and analyzing the relevant information are perfected. The results of monitoring allow us to quickly obtain the necessary information to make more informed decisions.

To improve the readiness of the Center, as well as of other management bodies and medical organizations of FMBA of Russia to respond and to take adequate actions in case of the most probable emergencies of radiation, of chemical and biological nature at the facilities and territories serviced by the Agency — a comprehensive work on creating multiple scenarios of response to such emergencies and training on their implementation is carried out. Relevant leading specialists are involved in this work.

In order to improve the system of organization and provision of medical care and medical evacuation, specialists of the Center and of other FMBA organizations are working to optimize the routing of medical evacuation of patients and casualties in emergency situations. For example, in September 2021, specialists from medical organizations will take part in an interdepartmental scientific and practical exercise conducted by the Ministry of Emergency Situations of Russia in the Arctic zone of the Russian Federation. They will also participate in the development of the Universal Integrated Rescue Center project to support the activities of rescuers in the Arctic.

Every year, the work of the automated information and telecommunication system, which functions around the clock in the interests of disaster medicine, is improved. Currently, 209 medical organizations of the Agency are connected to the federal segment of the Telemedicine System, and their number will grow.

In 2020, specialists of medical institutions of the Federal Medical and Biomedical Agency of Russia conducted 924 telemedicine consultations at the federal level, and in five

months of 2021 over 1.6 thousand telemedicine consultations were performed, including by medical specialists of the Center. These data show that the FMBA of Russia has created, actively operates and develops a system for organizing and conducting telemedicine consultations.

In order to organize telemedicine consultations for victims of emergencies, the collection and processing of operational reports on emergencies using the information system "Operational reports on the progress of medical and sanitary consequences of emergencies in the FMBA of Russia" was organized.

At present, the Center and other medical organizations of the Federal Medical and Biological Agency of Russia are implementing a set of measures to develop the system of medical care for victims of emergencies. These measures cover not only the clinical base, medical-sanitary units, hospitals and centers, but also mobile medical formations, and also include the training of medical personnel in disaster medicine. In particular, a modern mobile field hospital is being formed on the basis of the Center. The necessary conditions and facilities will be created in it for performing the most informative diagnostic examinations and obtaining in a short time the relevant data on the condition of the victims. This will make it possible to provide them with adequate medical aid, first of all, in emergency and urgent forms, and to prepare them for further medical evacuation to designated medical treatment facilities.

The creation of mobile medical formations with dual purpose is carried out taking into account their purpose, and also taking into account the requirements for specialists trained to provide emergency, including specialized emergency, medical care and disaster medicine; the requirements for modern treatment and diagnostic complexes, devices and appliances, medical and other types of necessary equipment. One of the important requirements is the ability to deliver these formations to the area of application not only by road, but also by air transport.

In addition, together with scientists from Lomonosov Moscow State University, work was done to improve medical evacuation vehicles — portable transportable isolated robotic medical evacuation complexes.

The practice of involvement of medical formations and organizations of FMBA of Russia in the elimination of medical and sanitary consequences of emergencies such as the catastrophic flooding in Krasnodar Region (2012), flooding in the Far East (2013), the Georgian-South Ossetian armed conflict (2008), pandemic of the new coronavirus infection and others, shows: the management and coordination of forces and means when working in modes of daily activity and emergency — needs to be improved.

The results of the analysis of the multidisciplinary work to eliminate medical and sanitary consequences of various emergencies, including terrorist acts and local armed conflicts, convince us that it is advisable to create a Disaster Medicine Service (hereinafter, the Service) within the FMBA of Russia.

This conclusion fully agrees with the decision of the meeting of the Government Commission for the Prevention and Elimination of Emergency Situations and Ensuring Fire Safety. According to this decision it was recommended to FMBA of Russia to study the issue of establishment of the Disaster Medicine Service of FMBA of Russia and — in case of positive decision — to amend regulatory legal acts of the Russian Federation governing the establishment and functioning

of the All-Russian Disaster Medicine Service — a subsystem of the Unified State System for Prevention and Liquidation of Emergency Situations — Minutes of March 19, 2021, p.1, IV.

The practical work of the All-Russian Disaster Medicine Service in organizing and providing medical aid to victims and their medical evacuation in emergency situations confirms the correctness of the basic conceptual provisions adopted at its creation, as well as the feasibility of the organizational structure created. In the state reports on the state of protection of population and territories of the Russian Federation from emergencies of natural and man-made character, this subsystem was repeatedly noted as the most effective in the framework of the RSChS.

The creation of the Service will make it possible to functionally unite the medical forces and means of the Federal Medical and Biological Agency of Russia into a single system. First of all, the forces and means of constant readiness of the federal level, designed to eliminate medical and sanitary consequences of emergencies. Due to the implementation of such an organizational decision, there will be an increase in the efficiency of response to emergencies, the level of guaranteed life-saving and health preservation of victims in emergencies at the facilities and territories served by the Center and the entire FMBA of Russia, not only in peacetime, but also in wartime.

In addition, the establishment of the Service will improve the quality of management activities in the field of disaster medicine, the quality of work of the medical treatment organizations subordinated to the Agency on issues of interaction with health authorities and relevant medical treatment organizations of the subjects of the Russian Federation, as well as with medical services and organizations of other federal executive bodies deployed in the territories of regions — in the interests of eliminating medical and sanitary consequences of emergencies

With the presence of the Service there will be created conditions: for systematic generalization of experience of preparation of medical forces and means for response and actions in emergency situations; for organization and performance of the most significant scientific works; for more targeted professional training of medical personnel involved in liquidation of medical and sanitary consequences of emergencies, on disaster medicine; for monitoring of their competences and professional growth, as well as of condition and development of regulatory, educational, methodical and material base.

Prospects for the scientific development of the Center are related to the solution of the following topical issues of modern radiobiology, radiation safety and biomedical technologies.

Search for markers of radiation injury, radiotolerance of cells, tissues and organism, risk of distant effects of radiation; development of diagnostic methods and prognostic criteria for the tasks of radiation medicine. Development of means and methods for prevention and treatment of radiation injuries. Preclinical studies of counterradiation synthetic and natural substances for different scenarios of radiation exposure — radiation accidents, accidents at atomic productions, radiation diagnostics and therapy, space flights. Study of mechanisms of formation of molecular and cellular effects of ultra-short pulse and dense-ionizing radiation. Development of approaches to decrease the radioresistance of human tumor stem cells.

Further research on the diagnosis and treatment of human radiation injuries with combined lesions (trauma, gamma-neutron damage with RW contamination) using a unique information resource — acute radiation disease database to analyze dose-time-effect relationships for various conditions of uniform and non-uniform accidental exposure.

Development and implementation of technologies to extend the working life of highly qualified employees of the nuclear industry, including search and application of effective health improvement programs that increase the level of psychophysiological adaptation of the personnel of particularly hazardous industries.

Maintaining the readiness of the emergency response and medical and sanitary support system of FMBA of Russia during radiation accidents and at the stages of radioactive waste and spent nuclear fuel management. Improving the system of emergency response and medical and sanitary support, including in the Arctic zone of the Russian Federation.

To conduct comprehensive radiation and hygienic monitoring of the environment and the state of health of the population living in the regions where nuclear power plants and other radiation hazardous facilities are located and in the areas of nuclear and uranium legacy.

Medico-hygienic assessment of the impact of work on the handling of new advanced fuels on the environment and on the health of the population living in the areas of the enterprises involved in the industrial production of such fuel.

Medical and hygienic safety of work with rocket fuel components at Baikonur and Vostochny cosmodromes.

Expertise in medical nuclear forensics.

Ensuring qualitative performance of comprehensive radiation and hygienic studies at the enterprises of the nuclear weapons complex of the State Company "Rosatom". Development of scientific research to ensure radiation safety of personnel during the manufacture and handling of new types of nuclear fuel for NPPs in the "Breakthrough" project area. Active participation in working groups to harmonize Russian legal and regulatory and methodological documents with international recommendations of the International Commission on Radiological Protection and the International Atomic Energy Agency — IAEA (2021-2022). Use of

voxel-phantom technology to solve problems of emergency dosimetry and optimization of radiation protection.

Establishment at the Burnazyan Federal Medical and Biological Center of Medical and Biological Research of special traumatic agents and of non-ionizing radiation factors.

In the field of nuclear medicine — commissioning of TR-24 cyclotron will allow a breakthrough expansion of the range of radionuclides and radiopharmaceuticals based on them. Development of polyvalent radiopharmaceuticals with ^{44}Sc , ^{64}Cu , ^{68}Ga for diagnosing both oncological (folate, FAPI, sialic acid) and non-oncological pathologies, including pathologies of cardiovascular system (stenosis, thrombosis), chronic obstructive pulmonary disease, rheumatoid arthritis etc. Development of the concept of theranostic radiopharmaceuticals on the basis of $^{68}\text{Ga}/^{177}\text{Lu}$, and later — $^{44}\text{Sc}/^{47}\text{Sc}$ and $^{64}\text{Cu}/^{67}\text{Cu}$. Development of the concept of application of radiopharmaceuticals on the basis of labeled monoclonal antibodies for diagnostics (^{64}Cu , ^{89}Zr) and therapy (^{90}Y , ^{177}Lu). Development of radiopharmaceuticals for radionuclide therapy on the basis of alpha-emitting radionuclides (^{212}Pb , ^{225}Ac , ^{227}Th ...). Development and testing of new generators ($^{68}\text{Ge}/^{68}\text{Ga}$, $^{44}\text{Ti}/^{44}\text{Sc}$), which meet the world standards, with the potential registration as medical devices. Optimization of the finished dosage form of ^{177}Lu based therapeutic radiopharmaceuticals for therapy of prostate cancer (ligands for PSMA) and other malignant neoplasms. Development of research in the field of three-dimensional dosimetry systems, proton-capture neutron-capture therapy using ^{11}B , ^{10}B and ^{10}B .

As part of the regenerative medicine development program at FMBA of Russia — to carry out scientific justification, development and production of a biomedical cellular product based on a clean room complex according to GMP-standards ISO-5. Creation of volumetric cell-based models using 3D-printing (bioprinting). Development of technology for obtaining pancreatic islet cells for further transplantation to patients with severe decompensated diabetes. Development of new methods of autoimmune diseases treatment (scleroderma, psoriasis, alopecia, etc.) using regenerative medicine principles.

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