



On approval of the rules for the collection, storage and use of blood and tissues of persons exposed to ionizing radiation

Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan dated October 20, 2020 No. ҚР DSM - 141/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on October 22, 2020 No. 21474

Unofficial translation

In compliance with subparagraph 75) of article 7 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On people's health and the health care system" **ORDER:**

1. To approve the rules for the collection, storage, use of blood and tissues of persons exposed to ionizing radiation in accordance with the appendix to this order.

2. To recognize as invalid the order of the Minister of Health and Social Development of the Republic of Kazakhstan dated January 30, 2015 No. 43 "On approval of the Rules for the collection, storage, use of blood and tissues of persons exposed to ionizing radiation" (registered in the Register of state registration of regulatory legal acts under No. 10374, published on March 18, 2015 in the information and legal system "Adilet").

3. The Department for Organization of Medical Aid of the Ministry of Health of the Republic of Kazakhstan, in the manner prescribed by law, shall ensure:

1) state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

2) posting this order on the Internet resource of the Ministry of Health of the Republic of Kazakhstan after its official publication;

3) within ten working days after the state registration of this order, submission to the Legal Department of the Ministry of Health of the Republic of Kazakhstan information on the implementation of the measures provided for in subparagraphs 1), 2) of this paragraph.

4. Control over the execution of this order shall be entrusted to the supervising vice minister of health of the Republic of Kazakhstan.

5. This order shall be enforced upon the expiration of ten calendar days after the day of its first official publication.

*The Minister of Healthcare
of the Republic of Kazakhstan*

A. Tsoy

Appendix
to the order of the Ministry of
Healthcare of the Republic of Kazakhstan
October 20, 2020
№ RK MH - 141/2020

Regulations for the collection, storage and use of blood and tissues of persons exposed to ionizing radiation

Chapter 1. General provisions

1. These rules for the collection, storage and use of blood and tissues of persons exposed to ionizing radiation (hereinafter referred to as the Rules) have been developed in accordance with paragraph 75) of Article 7 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On the health of the people and the health care system" (hereinafter - Code) and determine the procedure for the collection, storage and use of blood and tissues (hereinafter referred to as biological material) from persons exposed to ionizing radiation.

2. The collection, storage and use of biological material from persons exposed to ionizing radiation shall be carried out by a scientific organization in the field of public health.

3. The collection of biological material is carried out from the following persons exposed to ionizing radiation:

those who received radiation doses higher than the permissible ones during the elimination of a radiation accident established by regulatory legal acts in the field of sanitary and epidemiological welfare of the population;

who received an effective dose of radiation from sources of ionizing radiation, exceeding the dose limit established by regulatory legal acts in the field of sanitary and epidemiological welfare of the population for personnel and persons with diseases causally related to this exposure;

who lived, worked or served (including urgent service) in the territories contaminated with radioactive substances during the period of air and ground nuclear explosions from 1949 to 1965;

who lived, worked or served (including urgent service) in the territories contaminated with radioactive substances during the period of underground nuclear explosions from 1966 to 1990;

children and all subsequent generations of persons exposed to ionizing radiation.

Chapter 2. Procedure for collection of biological material from persons exposed to ionizing radiation

4. The collection of biological material from persons exposed to ionizing radiation is carried out in the presence of their voluntary informed consent and the absence of transfusions of blood products and X-ray examinations during the previous three months.

5. The sampling of biological material is carried out by specialists of health care organizations during medical and diagnostic manipulations (taking biopsy material, surgical interventions for oncological diseases).

6. Blood sampling is carried out from a vein in accordance with the rules of procurement, processing, quality control, storage, sale of blood and its components, approved in accordance

with subparagraph 84) of Article 7 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On the health of the people and the health care system ".

7. When taking biological material, it is marked.

8. When sampling biological material, accompanying documents are filled out containing the following information: passport data, place of residence of the investigated person, date of taking biological material, information about the state of health (about past diseases, the presence of chronic and malignant diseases, data on the passage of X-ray studies, the use of medicinal drugs, alcohol abuse), information about the health status of close relatives (anamnesis of previous diseases, the presence of malignant neoplasms, chronic diseases).

9. Transportation of samples of biological material to the storage site is carried out in compliance with the temperature regime from + 4 to + 6 degrees Celsius.

Chapter 3. Procedure for storage and use of biological material of persons exposed to ionizing radiation

10. Storage of biological material is carried out in a healthcare organization.

11. Storage of blood samples and paraffin blocks containing tissue samples is carried out in separate rooms, observing the temperature regime in the room from + 5 to + 22 degrees Celsius.

12. Blood samples are stored in an automated system for freezing and storing cellular material in liquid nitrogen or in deep-freeze refrigeration units, observing the temperature regime in the chamber from - 135 to - 196 degrees Celsius.

13. Each of the blood samples is stored in special containers - cryovials or cryovials.

14. Storage tanks should be fitted with an automatic alarm system to monitor nitrogen levels and replenishment times.

15. Maintenance of special equipment for storing samples of biological material is carried out by personnel authorized to work on this equipment.

16. During storage of biological material, constant temperature control is carried out.

17. Electrical equipment is kept in good condition, located in a separate room and provided with uninterrupted, backup power.

18. Information about biological material shall be entered into an electronic database created on the basis of a healthcare organization that stores biological material. The biological material received for storage is assigned an identification code, indicating the following information: passport data, place of permanent residence of the investigated person, type of biological material, date of taking the biological material.

19. The electronic database of biological material is drawn up in the form of a register of biological material of persons exposed to ionizing radiation.

20. To obtain biological material, the following documents shall be submitted to a scientific organization in the field of health care that stores biological material:

a statement indicating the size of the sample of biological material and the timing of the study;

applications are considered within 7 working days from the date of their receipt.

The head of a scientific organization in the field of health, carrying out the storage of biological material, makes a decision to issue a biological sample within five working days from the date of receipt of the application.

The issuance of biomaterials is carried out within 7 working days from the moment the decision is made by the head of the scientific organization in the field of health, which stores the biological material.

21. The use of biological material of persons exposed to ionizing radiation is allowed only for scientific purposes by subjects of scientific and (or) scientific and technical activities that have an official recognition of the compliance of their activities with the requirements and standards established by the legislation of the Republic of Kazakhstan.

22. After completion of the research, the scientific organization or researcher who conducted the research shall provide the head of the scientific organization in the field of health care that issued the biological material:

- samples of biological material unused in the research process;
- report on the study of each sample of biological material.