

On approval of the rules for conducting sanitary-epidemiological audit

Unofficial translation

Order № KR DSM-234/2020 of the Minister of Healthcare of the Republic of Kazakhstan as of December 4, 2020. It is registered with the Ministry of Justice of the Republic of Kazakhstan on December 8, 2020 under № 21736.

Unofficial translation

In accordance with paragraph 4 of Article 50 of the Code of the Republic of Kazakhstan “On Public Health and the Healthcare System” as of July 7, 2020, I hereby **ORDER**:

1. To approve the appended rules for conducting sanitary-epidemiological audit.
2. To invalidate Order № 216 of the Minister of National Economy of the Republic of Kazakhstan “On Approval of the Rules for Conducting Sanitary-Epidemiological Audit” as of March 17, 2015 (registered in the State Registration Register of Regulatory Legal Acts under № 10846, published on June 1, 2015 in the “Adilet” Legal Information System).
3. In accordance with the procedure established by the legislation of the Republic of Kazakhstan, the Committee for Sanitary and Epidemiological Control of the Ministry of Healthcare of the Republic of Kazakhstan shall ensure:
 - 1) the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;
 - 2) the posting of this order on the website of the Ministry of Healthcare of the Republic of Kazakhstan;
 - 3) the submission of information on the implementation of the measures provided for in subparagraphs 1) and 2) of this paragraph to the Legal Department of the Ministry of Healthcare of the Republic of Kazakhstan within ten working days of the state registration of this order with the Ministry of Justice of the Republic of Kazakhstan.
4. Control over the execution of this order shall be entrusted to the supervising deputy minister of healthcare of the Republic of Kazakhstan.
5. This order comes into effect ten calendar days of its first official publication.

*Minister of Healthcare of
the Republic of Kazakhstan*

A.Tsoi

Approved by Order
№ KR DSM-234/2020
of the Minister of Healthcare
of the Republic of Kazakhstan
as of December 4, 2020

Rules for conducting sanitary-epidemiological audit

Chapter 1. General provisions

1. These rules for conducting sanitary-epidemiological audit (hereinafter referred to as the Rules) are developed in accordance with paragraph 4 of Article 50 of the Code of the Republic of Kazakhstan “On Public Health and the Healthcare System” as of July 7, 2020 (hereinafter referred to as the Code) and establish the procedure for conducting sanitary-epidemiological audit by individuals and legal entities..

2. Sanitary-epidemiological audit is carried out at facilities subject to state control and supervision in the field of sanitary and epidemiological welfare of the population.

3. The following terms and definitions are used in these Rules:

1) audit contract – a contract for conducting sanitary-epidemiological audit entered into by an applicant and an auditor, which is concluded in accordance with the Civil Code of the Republic of Kazakhstan;

2) auditor’s report - a written official document, which is the result of the conducted sanitary-epidemiological audit;

3) objects of state sanitary-epidemiological control and supervision - epidemiologically significant facilities, the list of which is determined in accordance with paragraph 3 of Article 36 of the Code;

4) sanitary-epidemiological audit - an alternative form of control of epidemiologically significant facilities subject to state control and supervision in the field of sanitary and epidemiological welfare of the population, which is conducted to identify and assess sanitary and epidemiological risks and develop recommendations for bringing these facilities in line with the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of the population;

5) an auditor in the field of sanitary and epidemiological welfare of the population (hereinafter referred to as the auditor) - an individual carrying out activities on conducting sanitary-epidemiological audit;

6) an audit organization in the field of sanitary and epidemiological welfare of the population (hereinafter - the audit organization) - a legal entity (commercial organization) set up to carry out activities on conducting sanitary-epidemiological audit;

7) an audited entity in the field of sanitary and epidemiological welfare of the population (hereinafter referred to as the audited entity) - a legal entity, branches and (or) representative offices of a legal entity acting on its behalf, an individual entrepreneur in whose respect the sanitary-epidemiological audit is carried out.

Chapter 2. Sanitary-epidemiological audit

4. Sanitary-epidemiological audit is carried out by an auditor (audit organization) in accordance with the provisions of Articles 48, 49 and 50 of the Code and these Rules, at the request of the audited entity with account of specific tasks, timing and scope of the sanitary-epidemiological audit provided for by the audit contract.

5. The relationship between the auditor (audit organization) and the audited entity arises on the basis of a contract for conducting sanitary-epidemiological audit in accordance with the civil legislation of the Republic of Kazakhstan.

6. To conduct sanitary-epidemiological audit, auditors and audit organizations comply with the qualification requirements specified in the provisions of Article 49 of the Code.

Chapter 3. The conducting of sanitary-epidemiological audit

7. The sanitary-epidemiological audit is carried out in accordance with the plan for the sanitary-epidemiological audit, which is drawn up by the auditor (audit organization) with account of the requirements of Article 50 of the Code and approved by the audited entity.

8. An application for sanitary-epidemiological audit is registered in the application log in accordance with the form in Appendix 1 to these Rules.

9. To develop a plan for conducting sanitary-epidemiological audit, it is necessary to preliminarily get acquainted with the specifics of the audited entity.

10. The timing and scope of the sanitary-epidemiological audit are established by the plan for conducting the sanitary-epidemiological audit, which is drawn up by the auditor (audit organization) and approved by the audited entity. The audit plan is an integral part of the contract.

11. The plan for the sanitary-epidemiological audit is drawn up in any form with account of the specifics of a particular production and includes:

1) the checking of the conditions of production, transportation, storage, use and sale of raw materials, products subject to state sanitary and epidemiological supervision, conditions and regime of work, living, rest, food, water supply, as well as the performance of works and the provision of services;

2) the checking of accounting and reporting related to the implementation of production control and final acts of medical examination of employees;

3) the checking of the organization of medical examinations, hygienic training of employees and control of the availability of personal medical records;

4) the determination of the volume and list of samples from environmental objects for toxicological, radiological, sanitary and hygienic, bacteriological, virological, physicochemical examinations;;

5) laboratory and instrumental measurements;

6) preparation of recommendations for improving the sanitary-epidemiological situation at the facility;

7) opinions on the epidemic significance of the object, with an assessment of sanitary-epidemiological risks and determination of the degree of risk, information on the violations identified, the reliability of documentation and reporting.

12. The purpose of the sanitary-epidemiological audit is to establish compliance of the facility with the requirements of sanitary rules, hygienic standards, approved in accordance

with subparagraph 113) of paragraph 15 of the Regulations on the Ministry of Health of the Republic of Kazakhstan, approved by Resolution of the Government of the Republic of Kazakhstan dated February 17, 2017 № 71, ensuring control of safety and (or) harmlessness of production for humans and the environment, identification of possible violations of technological processes, non-compliance of raw materials and products with current regulatory documents, exceeding the maximum permissible concentrations of harmful substances and maximum permissible levels of physical factors in the workplaces and development of necessary measures to reduce the risks of the influence of harmful factors on the health of workers and the population.

Footnote. Paragraph 12 - as amended by the order of the Minister of Health of the Republic of Kazakhstan dated 05.04.2023 № 60 (effective ten calendar days after the date of its first official publication).

13. The nomenclature, volume and frequency of laboratory studies and tests are determined with account of the sanitary and epidemiological characteristics of production, the presence of harmful production factors, the risk of their impact on human health and environment.

14. Laboratory research and measurements are carried out on the basis of production laboratories, testing laboratories (centers) with the appropriate scope of accreditation, which are accredited in accordance with the legislation in the field of technical regulation and metrology.

15. The selection and delivery of samples for laboratory research and measurements is carried out in accordance with regulatory documents on standardization for each type of sample to be taken.

16. The number of samples, the procedure for their selection, the rules for identification and storage, drawing up of the act of sampling products shall comply with the requirements of regulatory documents on standardization for the declared products.

17. The necessary information shall be collected and systematized at the audited entity and at other organizations. The information shall include:

- 1) requirements of regulatory legal acts on issues of sanitary and epidemiological well-being of the population, concerning the activities of the audited entity;
- 2) reporting on production control, acts and protocols on certification of workplaces;
- 3) copies of laboratory and instrumental research protocols for the last three years (if available);
- 4) information about applications from citizens and public associations regarding the audited entity's activity.

For a more effective and complete assessment of the facility, the audited entity shall submit the documents referred to in subparagraphs 2), 3) and 4) of paragraph 2 of Article 50 of the Code.

Footnote. Paragraph 17 - as amended by the order of the Minister of Health of the Republic of Kazakhstan dated 05.04.2023 № 60 (effective ten calendar days after the date of its first official publication).

18. The audited entity is inspected and employees are interviewed in order to assess the compliance of the documentation with the actual situation at the audited entity, to determine the qualifications of the audited entity’s specialists, to develop proposals to improve the performance of the audited entity.

19. Based on the results of the inspection of the facility for its compliance with the requirements of the legislation in the field of sanitary and epidemiological welfare of the population, a comparative analysis and assessment of the degree of sanitary and epidemiological danger of the planned or ongoing activity, the sufficiency and reliability of production control, the auditor (audit organization) makes recommendations (proposals) to stabilize the situation (state) of the facility.

20. The grounds for recognizing the results of the sanitary-epidemiological audit as invalid are provided for in paragraph 5 of Article 50 of the Code.

21. Disputes arising as a result of conducting the sanitary-epidemiological audit are resolved in court.

Chapter 4. Auditor’s report and procedure for its issuance

22. Based on the results of the sanitary-epidemiological audit, an auditor’s report is drawn up, which contains conclusions on the compliance of the facility with regulatory legal acts in the field of sanitary and epidemiological welfare of the population in accordance with the form in Appendix 2 to these Rules.

23. An auditor’s report with conclusions on the compliance of the facility with the requirements of regulatory legal acts in the field of sanitary and epidemiological welfare of the population is submitted by the auditor (audit organization) to the territorial subdivision of the state body for the sanitary and epidemiological welfare of the population within five working days of the audit’s completion.

24. Annually, by the tenth of January after the reporting year, auditors (audit organizations) submit information on the conducted audit in the form approved by the state body for the sanitary and epidemiological welfare of the population in accordance with paragraph 3 of Article 48 of the Code to the department of the state body for the sanitary and epidemiological welfare of the population.

Appendix 1
to the rules for conducting
sanitary-epidemiological audit
Form

Application log

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№	Date, month, year of registration of the application	The applicant's surname, name, patronymic (if any)	Name of the facility	Field of activity of the facility	Audit period, the auditor's surname, name, patronymic (if any)	Conclusions of the auditor's report, report №, date of issue	Received by, signature

Appendix 2
to the rules for conducting
sanitary-epidemiological audit
Form
To the head of

Surname, name, patronymic (if any)
or full name of the audited entity
(individual or legal entity),
(IIN, BIN)
Address

Auditor's report as of “_____” _____ 20__ № _____

In accordance with Article 50 of the Code of the Republic of Kazakhstan
“On Public Health and the Healthcare System” as of July 7, 2020,

(surname, name, patronymic (if any) of the
auditor and (or) full name of the audit organization, the record number of the Registry of
permits
and notifications) conducted the sanitary-epidemiological audit of

(full name of the audited entity)
at the address: _____
(location of the audited entity)

Grounds for conducting the sanitary-epidemiological audit:

(the application's date and №, a copy of the plan for conducting the sanitary-epidemiological audit approved by the applicant)

Having considered the presented materials: _____

I have established that: _____
(description of the results of the facility's inspection, checking of conditions)

Based on the results of laboratory studies and (or) measurements):

(№ and date of the protocol, issued by ..., data on the accreditation of the laboratory (center), protocols' copies are attached)

The nature and assessment of possible risks associated with the economic and other activities of the audited entity: _____

Conclusions: the facility _____
(full name of the audited entity)

complies with the requirements of regulatory legal acts in the field of the sanitary-epidemiological welfare of the population _____

(full name and date of approval of the regulatory legal act, for the compliance with which the audit was conducted)

Recommendations _____

Head of the audit organization (auditor) _____
(surname, name, patronymic (if any), position)

Stamp (if any) here

Date

Acknowledgement of receipt of the report _____
(surname, name, patronymic (if any) and signature of the recipient, date)

