On approval of the Rules for accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines and medical devices

Unofficial translation

Order of the Acting Minister of Healthcare of the Republic of Kazakhstan dated October 27, 2020 No. ҚР ДСМ-157/2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on October 29, 2020 No. 21540

Unofficial translation

In accordance with paragraph 6 of Article 25 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and the health care system" **I HEREBY ORDER:**

1. To approve the attached Rules for accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines and medical devices.

2. To declare as terminated:

1) Order of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated May 29, 2015 No. 412 "On approval of the Rules for the accreditation of testing laboratories carrying out monopoly activities for the examination and assessment of the safety and quality of medicines and medical devices" (registered in the State Register of Normative Legal Acts under No. 11487, published on July 14, 2015 in the Legal Information System “Adilet”);

2) paragraph 5 of the List of some amended orders of the Ministry of Healthcare of the Republic of Kazakhstan and the Ministry of Healthcare and Social Development of the Republic of Kazakhstan, approved by Order of the Minister of Healthcare of the Republic of Kazakhstan dated April 22, 2019 No. ҚР ДСМ-44 "On amendments to some orders of the Ministry of Healthcare Of the Republic of Kazakhstan and the Ministry of Healthcare and Social Development of the Republic of Kazakhstan" (registered in the State Register of Normative Legal Acts under No. 18582, published on May 2, 2019 in the Reference Control Bank of normative legal acts of the Republic).

3. The Committee for Medical and Pharmaceutical Control of the Ministry of Healthcare of the Republic of Kazakhstan, in accordance with the procedure established by the legislation of the Republic of Kazakhstan, 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 Healthcare of the Republic of Kazakhstan after its official publication;

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

4. Control over the execution of this order shall be entrusted to the supervising Vice-Minister of Healthcare of the Republic of Kazakhstan.

5. This Order shall come into effect upon the expiration of ten calendar days after the day of its first official publication.

Acting Minister of Healthcare
of the Republic of Kazakhstan *M. Shoranov*

Approved
by Order of the Acting
Minister of Healthcare of the
Republic of Kazakhstan
dated October 27, 2020
No. ҚР ДСМ-157/2020

The Rules for accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines and medical devices

Chapter 1. General Provisions

1. These Rules for accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines and medical devices (hereinafter referred to as the Rules) have been developed in accordance with paragraph 6 of Article 25 of the Code of the Republic of Kazakhstan dated July 7, 2020 "On public health and health care system" (hereinafter referred to as the Code) and shall determine the procedure for accreditation of testing laboratories carrying out monopoly activities for the examination and assessment of the safety and quality of drugs and medical devices.

2. In accordance with paragraph 6 of Article 25 of the Code, accreditation of testing laboratories carrying out monopoly activities in the examination and assessment of the safety and quality of medicines, medical devices (hereinafter referred to as Accreditation) shall be carried out by a state body in the field of circulation of medicines and medical devices (hereinafter referred to as the State body).

3. The following basic concepts shall be used in these Rules:

1) accreditation - the procedure for the official recognition by the state body of the applicant's competence to carry out work on the examination and assessment of the safety and quality of medicines and medical devices;

2) an accreditation certificate - an official document issued by a state body, confirming the competence of the entities of accreditation to carry out work on the examination and assessment of the safety and quality of medicines and medical devices;

3) re-accreditation - the next procedure for the official recognition by the state body of the applicant's competence to carry out work on the examination and assessment of the safety and quality of medicines and medical devices;

4) applicant - a testing laboratory carrying out monopoly activities for the examination and assessment of the safety and quality of medicines and medical devices, having applied for accreditation.

Chapter 2. Procedure for accreditation

4. Accreditation shall be carried out within a period not exceeding forty working days from the date of receipt of the application, and include the following main stages:

1) acceptance, consideration of the application and the submitted documents;

2) examination of the applicant's facility at the location;

3) deciding on accreditation or refusal of accreditation;

4) issuance of an accreditation certificate.

5. For accreditation, the applicant shall submit the following documents to the state body:

1) an application for accreditation in the form in accordance with Annex 1 to these Rules, signed by the head of the applicant or a person authorized by him/her and certified by the seal of the organization;

2) passport of the testing laboratory in the form in accordance with Annex 2 to these Rules, approved by the head of the applicant;

3) quality manual in accordance with subparagraph 3-1) of paragraph 1 of Article 15 of the Law of the Republic of Kazakhstan dated July 5, 2008 "On Accreditation in the Field of Conformity Assessment" (hereinafter referred to as the Law).

6. To consider the application and the submitted documents, as well as to conduct a survey of the applicant's facility at the location (hereinafter referred to as the Survey), the state body shall form an accreditation group of at least two people. The composition of the group shall be determined by the state body and include a head, a specialized specialist of the state body.

The examination shall be carried out in the presence of representatives of the testing laboratory and the legal entity, which includes the testing laboratory.

The examination period shall not exceed ten working days, calculated from the moment the accreditation team arrives at the applicant's location.

7. Based on the results of the survey, the head of the group, taking into account all the comments of its members, shall draw up a report of the examination of the testing laboratory (hereinafter referred to as the Report) in the form in accordance with Annex 3 to these Rules in duplicate and signed by the members of the group.

One copy of the report shall be provided to the applicant, the second copy shall be provided to the state body.

8. The applicant, within twenty working days from the date of receipt of a notification (in any form) on the elimination of the revealed inconsistencies, shall eliminate the inconsistencies identified during the survey and notify the state body and the group of their elimination in writing with the submission of supporting documents.

The accreditation team shall review the submitted documents within five working days.

9. The state body, within five working days from the date of receipt of the group's report, shall decide to issue an accreditation certificate in the form in accordance with Annex 4 to these Rules or send a reasoned refusal to the applicant in writing (in any form).

10. The accreditation certificate shall be issued for five years in accordance with paragraph 1 of Article 21 of the Law. After the expiration of the accreditation period, the testing laboratory is subject to re-accreditation.

11. Re-accreditation shall be carried out in compliance with all the stages provided for in paragraph 5 of these Rules. The application for re-accreditation shall be submitted by the applicant no later than six months before the expiration of the accreditation certificate.

12. During the validity of the accreditation certificate, the testing laboratory shall notify the state body of any changes affecting changes in the accreditation certificate, structural and qualitative changes associated with the activity.

13. In case of changing the name of the subject of accreditation, changing the name of the location address without physically moving the object, within a month, the subject of accreditation notifies the state body in writing, with the attachment of the relevant documents confirming the specified information. The state body, within ten working days from the date of receipt of the application, shall re-issue the certificate.

Annex 1
to the Rules for accreditation of
testing laboratories carrying out
monopoly activities in the
examination and assessment of the
safety and quality of medicines
and medical devices
The form

Application for accreditation

1. Name of the legal entity, organizational and legal form

_____

hereby requests for accreditation of the testing laboratory for the implementation of monopoly activities for the examination and assessment of the safety and quality of medicines and medical devices.

2. Legal address of the organization (location, telephone, e-mail):

_____

—

3. Surname, name, patronymic (if any) of the head of the legal entity

_____
__

4. Last name, first name, patronymic (if any), telephone number of the employee responsible for communication with state accreditation body

_____
__

5. The applicant is informed of the Rules for the accreditation of testing laboratories carrying out monopoly activities for the examination and assessment of the safety and quality of medicines and medical devices (hereinafter referred to as the Rules).

Head _____ _____
(signature) (surname, initials)
"___" _____ 20__.

Annex 2
to the Rules for accreditation of
testing laboratories carrying out
monopoly activities in the
examination and assessment of the
safety and quality of medicines
and medical devices
The form
Approved by

_____
(Head of the organization,
surname, initials, signature)
"___" _____ 20___

Test laboratory passport

_____
__

(name of the legal entity)

_____
__

(last name, first name, patronymic (if any), telephone number of the head of the testing laboratory)

_____
__

(post address of the laboratory)

_____
__

(name, postal address of the legal entity that includes the testing laboratory)

_____
__

(phone, fax, email, test laboratory website)

Table 1. Equipping the testing laboratory with test equipment (hereinafter referred to as TE)

Determined parameters of the tested products	Name of TE, type, brand, manufacturer, serial and inventory numbers	Main technical characteristics of the TE	Commissioning year	Date and number of the TE certification document, frequency	Note
1	2	3	4	5	6

Table 2. Equipment with measuring instruments (hereinafter referred to as MI) for testing products in a testing laboratory

Name of the determined characteristics (parameters) of the product	MI name, type (brand), manufacturer, serial and inventory numbers	Commissioning year, inventory number	Metrological characteristics of MI		Date, number of the certificate (certificate) of verification or attestation, frequency	Additional information
			Measuring range	Accuracy class, measurement errors		
1	2	3	4	5	6	7

Note. A measuring instrument is a technical means intended for measurements, having normalized metrological characteristics, reproducing and (or) storing a unit of the physical quantity, the size of which is assumed to be unchanged (within the specified error) for a known time interval.

Table 3. Condition of industrial premises of the laboratory (center)

Purpose of the premises (including types of tests performed)	Area, m2	Temperature, C and humidity,%	Illumination at workplaces, lx	Gas level, mg/m3	Noise level dB	Availability of special equipment (ventilation, anti-interference, etc.)	Note
1	2	3	4	5	6	7	8

Note. The table is filled in based on the protocols for measuring the levels of production factors, carried out by specialists from the organizations of the sanitary and epidemiological service. The form is accompanied by a conclusion on the compliance of production facilities with sanitary and hygienic requirements, signed by the head of the organization of the sanitary and epidemiological service.

Table 4. List of normative documents (hereinafter referred to as ND) used in testing

ND designation	ND name	When and by whom it was approved, the number of the resolution (order) of the organization that approved the document, the date of introduction
1	2	3

Table 5. Information about the personnel performing tests for the examination and assessment of the safety of medicines and medical devices

Surname, name, patronymic (if any)	Position	Education, diploma specialty, work experience in the specialty	Types of tests carried out	Date and number of the attestation protocol, frequency	Note
1	2	3	4	5	6

Note: In the table, besides the employees of the testing laboratory, employees of other departments involved in the tests should be indicated (this is indicated in column 6).

Head of the testing laboratory _____ _____

(signature) (surname, initials)

"____" _____ 20___

Annex 3
to the Rules for accreditation of
testing laboratories carrying out
monopoly activities in the
examination and assessment of the
safety and quality of medicines
and medical devices
The form

Testing laboratory survey report

1.Full name of the organization:

_____
__

_____
__

2. Legal address, phone, fax, e-mail:

_____
__

_____
__

3. Terms of the test: "____" _____ 20___ to "____" _____ 20____.

4. Reason: _____
__

_____
__

5. The group consisting of the chairman

_____
_

(last name, first name, patronymic (if any), position, place of work) and a member of the group

_____
__

(last name, first name, patronymic (if any), position, place of work) held verification of

_____
__

(name of organization) applying for accreditation for the right to carry out monopoly activities for the examination and assessment of the safety of drugs and medical devices.

6. The test results:

No.	Criteria for evaluation	Description	Remarks
1	Information on the availability of constituent and legal documents		
2	Independence and confidentiality requirements		
3	Organization and management requirements		
4	Quality system requirements		
5	Personnel requirements		
6	Requirements for environmental conditions and premises		
7	Technical competence		
8	Documentation requirements		
9	Testing		
10	Requirements for handling test specimens		
11	Internal checks		
12	Working with contractors		
13	Handling complaints and appeals		
14	Information support requirements		

7. List of discrepancies:

No.	List of inconsistencies concerning the paragraphs of these Rules	Nonconformity category			Conclusions and solutions
		Critical	Substantial	Minor	

8. Conclusions:

The testing laboratory complies (not complies) with these Rules.

Chairman of the Group _____ _____

__

(signature) (initials, surname) Group member: _____ _____

_

(signature) (initials, surname) Representatives of the testing laboratory: _____ __

__

(signature) (initials, surname) Acquainted with the report:

Head of the organization _____ _____

__

(signature) (initials, surname) "____" _____ 20__

Annex 4
to the Rules for accreditation of
testing laboratories carrying out
monopoly activities in the
examination and assessment of the
safety and quality of medicines
and medical devices

The form

Accreditation certificate of a testing laboratory carrying out monopoly activities in the examination and assessment of the safety and quality of medicines and medical devices

Date of issue "____" _____ 20_____, Series, No. _____

This accreditation certificate was issued by the testing laboratory

_____

__

(name of organization, organizational and legal form, legal address)

_____

__

that, by the decision of the state body, order No. _____ dated "___" _____ 20__ was accredited to carry out monopoly activities for the examination and assessment of safety and quality medicines and medical devices.

The certificate is valid until "____" _____ 20_____

Head of state body _____ _____

(surname, initials) (signature)

Place of stamp