

**THE EURASIAN ECONOMIC COMMISSION**

**THE BOARD**

**RECOMMENDATION**

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| September 13, 2021 | **No. 22** | Moscow |

**On the Guidelines for Assessing and Authorizing Organizations of the Eurasian Economic Union Member States to Inspect Medical Device Manufacturing Facilities**

The Eurasian Economic Commission's Board, in accordance with Article 31 of the Treaty on the Eurasian Economic Union dated May 29, 2014 and Article 3 of the Agreement on Unified Principles and Rules for the Circulation of Medical Devices (Medical Accessories and Medical Equipment) within the Eurasian Economic Union dated December 23, 2014, as well as with a view to ensure uniform approaches to inspecting medical device manufacturing facilities,

**recommends** that the Eurasian Economic Union Member States apply the Guidelines for Assessing and Authorizing Organizations of the Eurasian Economic Union Member States to Inspect Medical Device Manufacturing Facilities according to the Annex from the date this Recommendation is published on the official website of the Eurasian Economic Union.

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| Chairman of the Boardof the Eurasian Economic Commission | M. Myasnikovich |

ANNEX

to Recommendation of the Board

of the Eurasian Economic Commission

No. 22 dated September 13, 2021

**GUIDELINES**

**for Assessing and Authorizing Organizations of the Eurasian Economic Union Member States to Inspect Medical Device Manufacturing Facilities**

I. General Provisions

1. These Guidelines define approaches to assessing and authorizing organizations of the Eurasian Economic Union Member States (hereinafter, the Member States and the Union, respectively) to inspect compliance of medical device manufacturing facilities with the Requirements for Implementing, Maintaining and Assessing the Quality Management System for Medical Devices Depending on the Potential Risk of Their Use approved by Decision No. 106 of the Eurasian Economic Commission's Council dated November 10, 2017 (hereinafter, the Requirements for the Quality Management System).

2. For the purposes of applying these Guidelines, the authorized authority means the public authority of a Member State authorized to carry out and (or) coordinate activities in the field of circulation of medical devices on the territory of this state.

Other concepts used in these Guidelines have the meanings determined by the acts in the field of circulation of medical devices comprising the law of the Union.

II. Activities of the Authorized Authority to Assess and Authorize Inspecting Organizations

3. If the inspecting organization is an authorized authority, the assessment of and authorizing this authority shall be in accordance with the legislation of the respective Member State.

4. The authorized authority shall authorize the organizations applying for conducting manufacturing facilities inspections (hereinafter referred to as applicants), based on their applications for each subgroup of medical devices according to the list stipulated in Annex No. 2 to the Requirements for the Quality Management System, on the results of assessing their compliance with these Requirements, as well as on the requirements for organizations of Member States to authorize them to inspect medical device manufacturing facilities, approved by the Eurasian Economic Commission (hereinafter referred to as the requirements for inspecting organizations).

5. The authorized authority shall perform the following functions:

a) consideration of applications and documents received from applicants;

b) conducting inspections in accordance with the legislation of the respective Member State in order to authorize applicants;

c) authorizing applicants and maintaining a list of inspecting organizations;

d) supervising manufacturing facilities inspections by inspecting organizations;

e) planning and conducting regular and unscheduled inspections of inspecting organizations;

e) withdrawal of authority or reduction of the scope of authority of an inspecting organization.

6. Before making a decision to conduct an inspection in order to authorize the applicant, the authorized authority shall consider the application within 15 working days from the date of its receipt.

The application shall be accompanied by documents containing the following information:

intended scope of authorization (by subgroups of medical device);

location and principal activity of the applicant, its branches (if any) and persons belonging to the same group (indicating the grounds on which such persons are included in this group, in accordance with the requirements for inspecting organizations);

the current quality management system of the applicant and its compliance with the requirements for inspecting organizations.

If the result of considering the application is negative, within 3 working days after the authorized authority makes such decision, a written notification shall be sent to the applicant indicating the reasons for the refusal (non-compliance of the application and the attached documents with the provisions of this paragraph or the grounds stipulated in paragraph 18 of the Requirements for the Quality Management System) in electronic form and by registered mail with advice of delivery or delivered in any other way that allows to confirm the fact of its receipt. In this case, an inspection to authorize the applicant shall not be conducted.

7. If the result of considering the application is positive, within a period not exceeding 30 working days from the date of receiving the application, the authorized authority shall conduct an inspection in order to authorize the applicant.

The objectives of an inspection to authorize the applicant shall be:

assessment of the conformity of the processes and procedures of the applicant's quality management system with the requirements for inspecting organizations;

analysis of evidence of compliance by the applicant with the procedures and objectives established by its quality management system, taking into account the planned authorization;

analysis of the operational management of the applicant's quality management system processes;

confirmation of the applicant's competence to fulfill the obligations in the scope of authorization and the availability of the necessary resources.

Checking the branches of the applicant (if any) at their location shall additionally include:

analysis of the relationship between the applicant and its branches, as well as methods for monitoring the activities of branches related to the scope of authorization;

assessment of quality management systems of branches and their compliance with the requirements of the applicant;

assessment of the conformity of the branches' activities related to the scope of authorization with the requirements of the quality management system of the inspecting organization, as well as these Guidelines.

8. Based on the results of the inspection of the applicant by the authorized authority, a decision shall be made on authorization (expansion of the scope of authorization) of the applicant or on refusal of authorization (expansion of the scope of authorization), which shall be formalized by an order (disposition) of the authorized authority (indicating the reasons for refusal).

Within 3 working days from the date of adopting the relevant decision, the authorized authority should notify the applicant of that decision in any way allowing to confirm the fact of its receipt.

If, based on the results of the inspection of the applicant by the authorized authority, a decision is made to refuse authorization, the applicant shall be entitled to re-submit an application in accordance with these Guidelines no earlier than after 90 calendar days.

Within 3 working days from the date of the decision to authorize the applicant (expand the scope of authorization), the authorized authority shall post information about that on its official website on the Internet information and telecommunication network and enter information about the applicant in the list of inspecting organizations.

9. As part of a regular or unscheduled inspection of an inspecting organization, the authorized authority shall be entitled, at its own expense, to send its representatives to supervise an inspection of manufacturing facilities by the inspecting organization.

Supervision over the manufacturing facilities inspection by the inspecting organization shall be carried out by the authorized authority in order to assess the performance of the inspecting organization in terms of:

compliance of the manufacturing facilities inspection with the Requirements for the Quality Management System;

capabilities of the inspecting organization:

to determine whether the manufacturer of medical devices complies with the legislation of the Member States in the field of circulation of medical devices;

to make a reliable report on the results of the manufacturing facilities inspection, including the identified violations;

to establish teams of inspectors involving employees having the necessary competences.

10. The inspecting organization should notify the authorized authority about the date of the upcoming inspection no later than 30 working days prior to the inspection day.

11. The authorized authority shall notify the inspecting organization and the inspected medical device manufacturer about the forthcoming supervision of the manufacturing facilities inspection by the inspecting organization no later than 5 working days prior to the inspection day.

12. When choosing a manufacturing facilities inspection for supervision by an authorized authority, the following factors shall be taken into account:

a) the class of potential risk of using manufactured medical devices;

b) the format of the manufacturing facilities inspection (primary, regular (scheduled) or unscheduled);

c) the location of the manufacturing facilities to be inspected;

d) personal data of the members of the inspection team;

e) production processes and technologies employed;

f) problems identified as a result of monitoring the safety, quality and effectiveness of medical devices associated with the inspected manufacturer or its products.

13. Prior to the manufacturing facilities inspection with the participation of representatives of the authorized authorities, the inspecting organization should submit the following documents and information to the authorized authority at its request:

a) contact information of the manufacturer of medical devices;

b) quality guidelines of the manufacturer of medical devices;

c) the planned scope of the manufacturing facilities inspection;

d) reports on previous manufacturing facilities inspections (if any);

e) information on violations identified during previous manufacturing facilities inspections (if any);

f) the composition of the inspection team, as well as the rationale for the selection of team members;

g) copies of documents submitted by the inspecting organization to the inspection team for planning the manufacturing facilities inspection;

h) manufacturing facilities inspection program;

i) other requested information.

14. During the manufacturing facilities inspection, the representative of the authorized authority shall not be entitled to interfere with and influence the course and result of the manufacturing facilities inspection. The representative of the authorized authority and the inspection team shall interact only after the completion of the manufacturing facilities inspection.

15. The report by the representative of the authorized authority on the assessment of the performance of the inspecting organization based on the results of supervising the manufacturing facilities inspection by the inspecting organization shall be made in writing and submitted to the authorized authority and the inspecting organization.

16. At least once in 2 years, the authorized authority shall ensure that a regular audit of the inspecting organization is conducted to assess compliance by the inspecting organization with the Requirements for the Quality Management System and requirements for inspecting organizations. A regular inspection shall be carried out at the location of the inspecting organization.

The objectives of regular inspections shall be:

effectiveness assessment of the quality management system adopted by the inspecting organization;

confirmation that the inspecting organization complies with the Requirements for the Quality Management System and the requirements for inspecting organizations;

assessment of the inspecting organization's activities related to the initial determination of competencies and subsequent continuous improvement of the professional knowledge and skills of employees involved in manufacturing facilities inspections;

performance assessment in considering appeals and handling requests;

assessment of reports on the results of a manufacturing facilities inspection;

confirmation that the inspecting organization conducts internal audits and analysis of its quality management system;

assessment of all changes that have occurred in the inspecting organization since the date of the last inspection by the authorized authority.

17. The grounds for conducting an unscheduled inspection of an inspecting organization shall be:

a) an application of the inspecting organization to change the scope of authorization;

b) a notification of the inspecting organization about the changes affecting its authority, in accordance with the requirements for inspecting organizations. The need for an unscheduled inspection of the inspecting organization on the specified basis shall be determined by the authorized authority taking into account the degree of influence of the changes that have occurred on the result of the previous inspection independently in each specific case;

c) the decision of the authorized authority, taken on the basis of information about possible violations in the activities of the inspecting organization, including on the basis of the report by a representative of the authorized authority on the assessment of the inspecting organization's performance based on the results of supervising a manufacturing facilities inspection by the inspecting organization;

d) effectiveness assessment of measures taken to eliminate violations identified during the previous audit.

18. If, as a result of a regular or unscheduled inspection of an inspecting organization, violations of the Requirements for the Quality Management System and requirements for inspecting organizations are identified, the authorized authority should notify the inspecting organization of the need to eliminate the identified violations and set a deadline for their elimination, which should allow the inspecting organization to eliminate all identified violations and which should not exceed 90 calendar days.

Until the violations are eliminated, the inspecting organization may conduct manufacturing facilities inspections, except for cases where the expertise of the employees responsible for conducting manufacturing facilities inspections and the persons involved by the inspecting organization in conducting manufacturing facilities inspections does not correspond to the scope of authorization of the inspecting organization.

III. Procedure for Inspecting Organization Assessment

19. As part of the inspections for the purpose of authorizing applicants, as well as regular and unscheduled inspections of inspecting organizations, an assessment of the conformity of the inspecting organization to the Requirements for the Quality Management System and requirements for inspecting organizations should be carried out, which shall include the analysis and assessment of the following processes:

Management;

Involvement of External Experts;

Measurements, Analysis and Improvements;

Employee Competence Management;

Manufacturing Facilities Inspection and Decision-Making Based on Its Results;

Information and Documentation Management.

These processes shall be assessed regardless of how the inspecting organization organizes its activities and quality management system.

An inspection in order to authorize applicants shall contain an assessment of all 6 processes. Regular inspection shall contain an assessment of 5 processes, with the Management process excluded.

20. The purpose of assessing the Management process shall be to confirm that the top management of the inspecting organization has ensured that an effective quality management system is implemented and operated to ensure control of activities related to manufacturing facilities inspections and to make decisions based on the results of manufacturing facilities inspections.

The assessment result of the Management process should confirm that the inspecting organization has succeeded in:

implementing the processes necessary for its quality management system, their application at each level, as well as ensuring their consistency and interconnection;

creating a quality management system that contributes to effective manufacturing facilities inspections and the adoption of informed decisions based on the results of manufacturing facilities inspections, compliance with the requirements in the field of circulation of medical devices established within the Union and the contractual commitments;

establishing the quality targets that are consistent with the quality policy of the inspecting organization and are regularly updated to ensure that the inspecting organization complies with the requirements established within the Union in the field of circulation of medical devices;

ensuring that the necessary resources and competent staff are available;

authorizing its employees and allocating their responsibilities, as well as establishing the organizational structure;

developing, documenting and implementing procedures for managing impartiality, confidential information security, transparency of manufacturing facilities inspections and decision-making;

ensuring the effectiveness of the quality management system and its processes.

As part of the Management process assessment, it shall be necessary to:

check and confirm that the quality guidelines and the necessary documentation related to the quality management system are properly developed and drawn up;

check and confirm that the organization has a quality policy and quality targets, that the quality targets are measurable and consistent with the quality policy, and that measures have been taken to achieve them;

check the organizational structure of the inspecting organization and related documents, confirm that they contain provisions on official duties and authority, including the responsibility associated with the activity to inspect manufacturing facilities and timely exchange of information with authorized authorities, as well as ensuring compliance with the quality management system requirements of the inspecting organization;

confirm that the competence of the inspectors of the inspecting organization corresponds to its field of activity and the number of inspectors is sufficient to perform the scope of inspection work, including the number of external experts involved;

confirm that the inspecting organization has developed and implemented impartiality management procedures;

confirm that the quality management system is analyzed at scheduled intervals.

21. The purpose of assessing the Involvement of External Experts process shall be to confirm that the actions performed at the instruction of the inspecting organization by external experts are controlled by the inspecting organization.

The assessment result of the Involvement of External Experts process should confirm that the inspecting organization has succeeded in:

developing, documenting and implementing procedures necessary to control the activities of external experts, including control of their professionalism, confidentiality and impartiality management;

formalizing agreements with external experts in writing, including their obligations to comply with the requirements of the inspecting organization in terms of confidentiality and impartiality;

confirming that it has the competence to analyze the results of the activities by external experts.

As part of the Involvement of External Experts process assessment, it shall be necessary to:

establish that in using the services of external experts, the inspecting organization monitors their compliance with the requirements established within the Union in the field of circulation of medical devices, including in terms of their professionalism, impartiality, confidentiality and conflict of interests;

confirm that the relationship of the inspecting organization with external experts is formalized in a contract in such a way as to ensure the possibility for the authorized authority to conduct inspections and supervise the actions of external experts. These agreements should include obligations by external experts to comply with the requirements of the inspecting organization that ensure control of impartiality and confidentiality;

confirm that the inspecting organization has the competence to assess the activities of external experts, as well as confirm the applicability of the objective evidence they provide to decision-making.

22. The purpose of assessing the Measurements, Analysis and Improvements process shall be to confirm that:

information related to manufacturing facilities inspections, professionalism of inspectors, decisions on compliance with the requirements established within the Union in the field of circulation of medical devices and the quality management system of the inspecting organization was collected and analyzed to identify actual and potential violations;

actual and potential violations are examined;

if necessary, effective measures are taken to correct, eliminate and prevent violations.

The assessment result of the Measurements, Analysis and Improvements process should confirm that the inspecting organization has succeeded in:

developing, documenting and implementing procedures for measurements, analysis and improvements that meet the requirements for inspecting organizations;

identify and analyze sources of data on quality, including internal audits, external assessment and appeals, in order to detect actual and potential violations;

examine actual and potential violations;

take effective measures to correct, eliminate and prevent violations (if necessary);

check the effectiveness of such measures (if any).

As part of the Measurements, Analysis and Improvements process assessment, it shall be necessary to:

confirm that the inspecting organization has developed and implemented a procedure for measuring, controlling, analyzing and improving the effectiveness of its quality management system, as well as its compliance with the requirements for inspecting organizations;

determine how the inspecting organization can track sources of data on quality and processes that could allow to identify actual and potential violations. These sources of data on quality include, but are not limited to, the results of internal and external audits, involvement of external experts, and appeals. confirm that measurement and control activities cover the professionalism of inspectors, the effectiveness of manufacturing facilities inspections, making compliance decisions based on manufacturing facilities inspections, and adhering to the code of business conduct in the field of medical devices in the processes Employee Competence Management and Manufacturing Facilities Inspection and Decision-Making Based on Its Results;

determine how investigations are conducted to establish the causes of identified violations; confirm that, if necessary, measures were taken to correct, eliminate or prevent violations; that these measures were effective and did not adversely affect the manufacturing facilities inspection and the decisions taken, and also establish that the measures to correct and prevent violations are relevant to the risks posed by the identified actual or potential violations;

determine whether it was required to notify the authorized authority about any corrective actions of the inspecting organization that may affect the authority of the inspecting organization;

confirm that control measures have been developed to identify cases of manufacturing facilities inspections that do not meet the requirements for inspecting organizations, and that decisions based on the results of such inspections on compliance with the requirements established within the Union in the field of circulation of medical devices reflect this information. confirm that relevant decisions have been made, justified and documented;

confirm that in case of detecting violations of the requirements during a manufacturing facilities inspection, the measures taken were relevant to the risks of violations, and that a relevant notification was sent to the authorized authority;

confirm that internal audits are conducted in accordance with documented procedures and ensure that the quality management system meets the requirements for inspecting organizations.

23. The purpose of assessing the Employee Competence Measurement process shall be to confirm that inspectors, final assessors and external experts have professionalism that meets the requirements for inspecting organizations.

The assessment result of the Employee Competence Management process should confirm that the inspecting organization has succeeded in:

determining the necessary competencies of employees for effective performance in the field of manufacturing facilities inspection;

developing, documenting and implementing procedures necessary for assessing and monitoring professionalism of inspectors, final assessors and external experts;

identifying training needs and providing access to training to inspectors and final assessors;

maintaining up-to-date records confirming the effective implementation of the Employee Competency Management process;

confirming the effectiveness of employee competence management methods.

As part of the Employee Competence Management process assessment, it shall be necessary to:

confirm that the inspecting organization has determined the necessary competences of employees for effective performance in the field of manufacturing facilities inspection and that the inspecting organization has access to the technical knowledge necessary to make decisions about the manufacturer's compliance with the legislation of the Member States in the field of circulation of medical devices;

confirm that the inspecting organization has developed, documented and implemented procedures for the initial assessment of professionalism of inspectors, final assessors and external experts;

confirm that the inspecting organization records information on the area of professional competence of inspectors, final assessors and external experts who, according to their professional assessment, can perform duties related to manufacturing facilities inspection. confirm that professional competence records are kept up to date;

confirm that the inspecting organization has identified training needs, provided access to relevant training, and has ensured that inspectors and final assessors receive such training in accordance with the requirements for inspecting organizations;

confirm that the inspecting organization has developed, documented and implemented procedures for monitoring the professionalism and performance of employees involved in the activity to inspect manufacturing facilities. confirm that if professionalism of any employee ceases to meet the requirements for inspecting organizations, his/her status is reviewed;

confirm that the process for professional assessment, training, fulfilling confidentiality and impartiality obligations and ensuring compliance with the code of business conduct by inspectors, final assessors and external experts is implemented and documented.

24. The purpose of assessing the process Manufacturing Facilities Inspection and Decision-Making Based on Its Results shall be to confirm that the inspecting organization ensures control over processing of applications for a manufacturing facilities inspection. This process includes considering an application for manufacturing facilities inspection, defining a manufacturing facilities inspection program, planning and conducting a manufacturing facilities inspection and issuing a report on its results.

The assessment result of the process Manufacturing Facilities Inspection and Decision-Making Based on Its Results should confirm that the inspecting organization has succeeded in:

developing, documenting and implementing the procedures necessary to control the process Manufacturing Facilities Inspection and Decision-Making Based on Its Results;

developing and implementing an inspection program for each specific case of manufacturing facilities inspection;

planning and conducting manufacturing facilities inspections in accordance with the manufacturing facilities inspection program, including the appointment of a competent team of inspectors;

considering measures to eliminate violations taken by the manufacturer based on the results of the manufacturing facilities inspection;

making informed decisions based on the results of manufacturing facilities inspections and the analysis of manufacturers' appeals;

controlling the corrective actions of manufacturers in accordance with the decisions based on the results of the manufacturing facilities inspection;

handling appeals effectively;

maintaining up-to-date records confirming the effectiveness of implementing the process Manufacturing Facilities Inspection and Decision-Making Based on Its Results.

As part of assessing the process Manufacturing Facilities Inspection and Decision-Making Based on Its Results, it shall be necessary to:

confirm that the inspecting organization has documented the procedures for conducting manufacturing facilities inspections;

confirm that the inspecting organization can inspect manufacturing facilities in accordance with the manufacturing facilities inspection program, which includes the selection of critical suppliers taking into account the features of a particular manufacturer of medical devices and determining the duration of a manufacturing facilities inspection in accordance with the Requirements for the Quality Management System;

confirm that the inspecting organization includes employees with the necessary competencies in the inspection teams. Confirm that the inspecting organization has allocated responsibilities within the inspection team and informed the medical device manufacturer of the composition of the inspection team and the manufacturing facilities inspection program;

confirm that the inspecting organization conducted the manufacturing facilities inspection in accordance with the manufacturing facilities inspection program and the Requirements for the Quality Management System and that the requirements for reporting on the inspection results, including the assessment of violations (if any), were met;

confirm that the inspecting organization controls the decision-making process based on the results of manufacturing facilities inspections, including monitoring of the corrective actions by manufacturers, and, if necessary, conducts unscheduled manufacturing facilities inspections;

confirm that the inspecting organization makes informed decisions based on the results of manufacturing facilities inspections;

confirm that the inspection organization assesses and makes informed decisions on appeals and that appeals are taken into account in the Measurements, Analysis and Improvements process;

confirm that the inspecting organization maintains up-to-date records of activities related to manufacturing facilities inspections and decision-making based on their results.

25. The purpose of assessing the Information and Documentation Management process shall be to confirm efficient document flow and exchange of information between the inspecting organization, manufacturers of medical devices and authorized authorities.

The assessment result of the Information and Documentation Management process should confirm that the inspecting organization has succeeded in:

implementing an effective process for document flow control;

making information about its activities available to authorized authorities and manufacturers of medical devices;

properly organizing its work to conclude contracts with manufacturers of medical devices on manufacturing facilities inspections;

taking the necessary measures to ensure confidentiality.

As part of the Information and Documentation Management process assessment, it shall be necessary to:

confirm that the document flow control procedures stipulated by the quality management system of the inspecting organization and the requirements for inspecting organizations have been developed, documented and implemented;

confirm that the inspecting organization has provided manufacturers of medical devices with access to information on its activity to inspect manufacturing facilities, including information on the inspection processes and decision-making based on their results, on the procedure for considering appeals, the cost and procedure for paying for a manufacturing facilities inspection;

confirm that the inspecting organization properly formalizes its contractual relations with manufacturers of medical devices, defining the responsibilities of each party. Check that, under the terms of the contracts, the authorized authority is entitled to supervise manufacturing facilities inspections carried out by the inspecting organization and assess them;

confirm that the inspecting organization has implemented a system to monitor reporting on manufacturing facilities inspections and provide other requested information to the authorized authority;

confirm that the inspecting organization has developed, documented and implemented procedures to ensure protection of confidential information.

IV. Withdrawal of Authority or Reduction of the Scope of Authority of an Inspecting Organization

26. The authorized authority shall make a decision to withdraw the authority of an inspecting organization to conduct manufacturing facilities inspections or to exclude subgroups of medical devices from the scope of its authorization (to reduce the scope of authorization) in the following cases:

failure to eliminate the identified violations in due time and (or) failure to provide documents and (or) information upon request;

provision of false information to the authorized authority.

A decision to withdraw the authority of an inspecting organization or to reduce the scope of authorization should be formalized by an order (disposition) of the authorized authority.

27. Within 3 working days from the date of the decision to withdraw the authority or to reduce the scope of authorization, the authorized authority should notify the inspecting organization of the decision taken in any way that allows to confirm the fact of its receipt. If the inspecting organization does not agree with the decision of the authorized authority, it shall be entitled to appeal it to the court at the location of the authorized authority.

28. From the date of receiving the notice on withdrawal of authority, the inspecting organization should not:

a) accept new applications for manufacturing facilities inspections;

b) conduct manufacturing facilities inspections for manufacturers whose applications have already been accepted.

29. From the date of receiving the notice on reducing the scope of authorization, the inspecting organization should not:

a) accept new applications for inspecting manufacturing facilities of subgroups of medical devices excluded from the scope of its authorization;

b) conduct inspections of manufacturing facilities of subgroups of medical devices excluded from the scope of its authorization for manufacturers whose applications have already been accepted.

30. The authorized authority may exclude information from the list of inspecting organizations in the following cases:

a) an application for exclusion from the list of inspecting organizations signed by the manager of the inspecting organization is filed;

b) the authorized authority adopts a decision to withdraw the authority of the inspecting organization.

31. The authorized authority shall make appropriate changes to the list of inspecting organizations and post inspection schedule on its official website on the Internet information and telecommunication network in the manner and within the time limits established by the Requirements for the Quality Management System.

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