

Provisions for self-Testing in Medical Device Registration

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In order to strengthen the registration and management of medical devices (including in vitro diagnostic reagents), standardize the registration and self-inspection of registration applicants, and ensure the orderly development of medical device registration and review work, in accordance with the "Regulations on the Supervision and Administration of Medical Devices" and the "Administrative Measures for the Registration and Filing of Medical Devices". The Regulations on the Registration and Filing of In Vitro Diagnostic Reagents are formulated.

1. Self-inspection capability requirements

(1) Overall requirements

If self-inspection is carried out during registration, the registration applicant shall have the self-inspection ability, incorporate the self-inspection work into the medical device quality management system, be equipped with inspection equipment and facilities that meet the product inspection requirements, and have corresponding quality inspection departments or full-time inspectors. Strictly control the inspection process to ensure that the inspection results are true, accurate, complete and traceable, and take the main responsibility for the self-inspection report.

(2) Inspection ability requirements

1. Personnel requirements. The registration applicant shall have inspectors and management personnel (including reviewers and approval personnel) suitable for the inspection activities carried out. The applicant for registration shall be equipped with full-time inspectors, and the inspectors shall be officially hired personnel and can only work in the enterprise.

The educational background, technical ability and quantity of the inspectors should match the product inspection work. Inspectors should be familiar with relevant laws and regulations, standards and product technical requirements for medical devices, master the principles of inspection methods, test operation skills, work instructions, quality control requirements, laboratory safety and protection knowledge, measurement and data processing knowledge, etc., and should pass Training and assessment of medical device-related laws and regulations, quality management and related professional technology.

Inspectors, reviewers, approval personnel, etc. shall be authorized by the registration applicant in accordance with regulations.

2. Requirements for equipment and environmental facilities. The registration applicant shall be equipped with equipment and environmental facilities that meet the requirements of the inspection method, establish and save the files, operating procedures,

measurement/calibration certificates, use and maintenance records of the equipment and environmental facilities, and conduct value traceability in accordance with relevant regulations.

For laboratories that carry out special professional inspections, such as biological evaluation, electromagnetic compatibility, biological safety, in vitro diagnostic reagent laboratories, etc., their environmental facilities should meet their specific professional requirements.

3. Sample management requirements. The registration applicant shall establish and implement inspection sample management procedures to ensure that the samples are controlled and maintained in a corresponding state.

4. Inspection quality control requirements. Registration applicants should use appropriate methods and procedures to carry out all inspection activities. When applicable, it includes the evaluation of measurement uncertainty and the use of statistical techniques for data analysis.

Encourage registered applicants to participate in related proficiency testing/interlaboratory comparison projects organized by proficiency testing institutions to improve testing capabilities and levels.

5. Recorded control requirements. All quality records, original inspection records and relevant certificates/certificate copies and

other technical records should be archived and kept for an appropriate period. Records include, but are not limited to, equipment usage records, original inspection records, purchase and acceptance records of raw and auxiliary materials for inspection, etc. The retention period of records shall meet the requirements of relevant laws and regulations.

(3) Management system requirements

Where a registration applicant conducts self-inspection, it shall establish and implement a management system suitable for self-inspection in accordance with the requirements of relevant inspection work and self-inspection of declared products.

The self-inspection work shall be incorporated into the medical device quality management system. Registration applicants should formulate quality management system documents related to self-inspection (including quality manuals, procedures, work instructions, etc.), risk management of inspections carried out, and documents related to medical device regulations, etc., and ensure their effective implementation And controlled.

(4) Basis for self-inspection

The registration applicant shall conduct inspections in accordance with the product technical requirements of the products to be declared for registration.

The formulation of inspection methods should be compatible with the corresponding performance indicators, and priority should be

given to the use of promulgated standard inspection methods or recognized inspection methods.

The inspection method shall be verified or confirmed to ensure the repeatability and operability of the inspection.

For in-vitro diagnostic reagent products, the test method should also clearly indicate the reference product/standard product used, the sample preparation method, the batch and quantity of the reagent used, the number of tests, the calculation method, etc.

(5) Other matters

1. The applicant for registration of entrusted production may entrust the entrusted production enterprise to carry out self-inspection, and the registration applicant shall issue the corresponding self-inspection report. The self-inspection capability of the entrusted production enterprise shall meet the requirements of these regulations.

2. The domestic group company or its subsidiary where the domestic registration applicant is located has a laboratory accredited by the China National Accreditation Service for Conformity Assessment, or the overseas group company or its subsidiary where the overseas registration applicant is located has a laboratory accredited by the foreign government or government. For laboratories accredited by the corresponding laboratory qualification certification body, with the authorization of the group company, the corresponding laboratory may carry out self-inspection for the registered applicant, and the

registered applicant shall issue the corresponding self-inspection report.

2. Self-inspection report requirements

(1) The self-inspection report submitted when applying for product registration shall be a full-project inspection report that meets the technical requirements of the product. Submit the corresponding self-inspection report in accordance with relevant regulations for change of registration and renewal of registration. The report format should meet the requirements of the inspection report template (Annex 1).

(2) The self-inspection report should have accurate conclusions, be easy to understand, use standard words, concise language, clean and tidy, and no alteration is allowed. The signature and seal shall comply with the relevant requirements of "Medical Device Registration Application Material Requirements and Approval Certificate Document Format", "In Vitro Diagnostic Reagent Registration Application Material Requirements and Approval Certificate Document Format".

(3) The products inspected in the same registration unit should be able to represent the safety and effectiveness of other products in this registration unit.

3. Commissioned inspection requirements

(1) Fiduciary conditions

If a registration applicant submits a self-inspection report, if he does not have the inspection capabilities for some items in the product technical requirements, he can entrust the relevant items to

be inspected by a qualified medical device inspection agency. Qualified medical device inspection institutions shall comply with the relevant provisions of Article 75 of the Regulations on the Supervision and Administration of Medical Devices.

(2) Evaluation of the trustee

The registration applicant shall evaluate the qualifications and inspection capabilities of the trustee in the medical device production quality management system documents, establish a directory of qualified trustees, and keep the evaluation records and evaluation reports.

(3) Sample consistency

The registration applicant shall ensure the consistency between the self-inspected samples and the entrusted inspection samples, communicate with the entrusted party in a timely manner, report problems, and assist in the inspection work.

(4) Form a self-inspection report

The registration applicant shall summarize the reports issued by the trustee and combine the inspection items completed by the registration applicant to form a complete self-inspection report. For items involving entrusted inspection, in addition to indicating the entrusted inspection agency in the remarks column, the original entrusted inspection report shall also be attached.

4. Application materials requirements

If the registration applicant submits a product inspection report through self-inspection, it shall submit the following application materials:

(1) Self-inspection report. If the commissioned inspection project is involved, the qualification certification documents of the relevant inspection agency shall also be provided.

(2) A statement of having the corresponding self-inspection capability. The registration applicant shall promise to have the ability to self-inspect the corresponding specific items in the product technical requirements, including the corresponding personnel, equipment, facilities and environment, and carry out the inspection in accordance with the requirements of the quality management system.

(3) Relevant materials of the quality management system. Including the configuration table of inspection equipment (including standard products) (see appendix 2); the software used for medical device inspection should specify its name, release version number, release date, supplier or agent and other information (for format refer to appendix 2) ; Medical device registration self-inspection inspection personnel information form (see Annex 3); Inspection-related quality management system document list, such as quality manuals, procedure documents, work instructions, etc. The document name should include document number information, etc.

(4) Explanation about model coverage. Provide relevant information on model coverage, including typical

descriptions, analysis of differences between covered models/configurations and main inspection models/configurations, etc.

(5) Statement of self-guarantee for the authenticity of the report. If the registration applicant entrusts relevant items for inspection, the self-assurance statement should include a declaration of the consistency of the self-inspected samples and the entrusted inspection samples.

The self-inspection laboratory of the domestic registration applicant has been accredited by the China National Accreditation Service for Conformity Assessment (CNAS), or the self-inspection laboratory of the overseas registration applicant has been accredited by the foreign government or the corresponding laboratory qualification certification agency accredited by the government, It is not necessary to submit the content of items (2) and (3) of this article, but the corresponding recognized supporting documents and supporting materials for the corresponding inspection scope shall be submitted. If the group company or its subsidiary is authorized by the group company to carry out self-inspection by the corresponding laboratory, a letter of authorization shall be submitted.

V. On-site inspection requirements

For those submitting self-inspection reports, when conducting on-site inspections of the medical device registration quality management system, the drug regulatory authority shall not only

follow the requirements of the relevant medical device registration quality management system verification guidelines, but also in accordance with the "Self-inspection Capability Requirements" in the first part of this article. Perform verification and explain it in the on-site verification report. During the inspection, personnel familiar with the inspection shall be selected to participate in the inspection.

On-site inspections can be referred to, but not limited to the following methods:

(1) Qualification requirements of inspectors : check the on-the-job certificate of inspectors, the training records of inspectors and approved personnel in the relevant personnel information table, personal files and other documents, and conduct face-to-face communication with the corresponding personnel to verify whether the qualifications and abilities meet the relevant quality management System requirements.

(2) Operational skills of inspectors: Randomly check the items claimed to be self-inspected, and require the corresponding inspectors in the medical device registration self-inspection inspector information form to check the reserved samples or self-inspection samples in accordance with the operation instructions (or operating procedures) During the on-site operation, the entire inspection process should be repeated, the inspection methods meet the requirements, and the inspection results are consistent with the conclusions in the company's registration documents.

(3) Facilities and environment: laboratories that carry out special professional inspections, such as biological laboratories, electromagnetic compatibility laboratories, in vitro diagnostic reagent laboratories, etc., check whether the laboratory's facilities, environment, and monitoring records meet the requirements of product inspection .

(4) Inspection equipment: Check whether the information in the equipment configuration table for self-inspection submitted in the application materials is consistent with the relevant equipment on site. Check whether the verification/calibration records and measurement confirmation data of the inspection equipment meet the inspection requirements. Check the list of inspection equipment. The list should indicate the source of the equipment (self-purchased/leased), and check the corresponding contract documents.

If you use enterprise-made calibrators, quality control products, sample processing reagents, etc., you should check the relevant operating procedures, quality standards, preparation and inspection records, and pay attention to the preparation of calibrators, measurement value transfer procedures, uncertainty requirements, stability studies, etc. , Pay attention to the preparation of quality control products, assignment operating procedures, target value range determination, stability research, etc.

(5) Inspection records: check the original records, inspection equipment use, calibration, maintenance and repair records, inspection environmental conditions records, materials related to

the effectiveness of the inspection samples, audit evaluation records and reports (if any) of the entrusted party, commissioned inspections Report (if any), commissioned inspection agreement (if any), etc.

(6) Inspection quality control ability: check inspection-related quality manuals, procedure documents, standards, work instructions (if applicable), operating procedures, inspection method verification/confirmation records, internal quality control records and other documents.

If the domestic registration applicant's self-inspection laboratory is accredited by the China National Accreditation Service for Conformity Assessment, or the overseas registration applicant's self-inspection laboratory is accredited by a foreign government or a government-recognized laboratory certification body, it can be approved as a medical device. The registration quality management system verification guidelines require processing.

6. Responsibility requirements

The registration applicant shall strengthen the quality management of the whole life cycle of medical devices in accordance with the requirements of the Regulations on the Supervision and Administration of Medical Devices, and be responsible for the safety, effectiveness and authenticity of inspection reports in the entire process of development, production, and inspection of medical devices. .

If the self-inspection report provided by the registration applicant is false, it shall be punished in accordance with Article

83 of the Regulations on the Supervision and Administration of Medical Devices. If the entrusted party issues a false inspection report, it shall be punished in accordance with Article 96 of the Regulations on the Supervision and Administration of Medical Devices.

Attachment: 1. Medical device registration self-inspection report template

2. Configuration table of equipment for medical device registration and self-inspection (including standard/reference products)

3. Information form of medical device registration self-inspection inspector

attachment1

Medical device registration self- inspection report (template)

Report number: XXXX

Registration

applicant:

sample name:

Model

specifications/packaging

specifications:

Production address:

Sound out

1. The registration applicant promises the authenticity, accuracy, completeness and traceability of the inspection results in the report.
2. The signature of the report complies with relevant regulations.
3. The signature of the report without approval is invalid.
4. The alteration of the report is invalid.
5. The registration applicant is responsible for the authenticity of the samples and information entrusted for inspection.

(Name of applicant for registration)

Inspection report home page

Report Number: Total pages of the page

sample name		Sample number / sample lot number	
Model specification / packing specification		identify category	
Entrusted production enterprise		Production Date	On May Day
Number of samples			
Date of receipt	On May Day	Inspection location	
Trustee		Inspection date	
Trustee address		Trustee's contact number	
Entrusted party's postal code		Entrusted sample batch number / number	
Test items			
Test based on			
test results	(signature) Date of issue year, month, day		
Remark	1. The "—" in the report indicates that this item is not applicable, and the "/" in the report indicates that this item is blank. 2. Explain the entrusted inspection items, the qualifications of the entrusted party and the copy of the inspection scope (if applicable). Those that cannot be filled in can be provided in the form of attachments.		

Inspector: Date: Auditor: Date

Approved Person: Position: Date:

(Name of applicant for registration)

Inspection Report

Report Number: Total pages of the page

Test layout drawing (if applicable):

(Name of applicant for registration)

Inspection report photo page

Newspaper reported
the page

Number: Total pages of

Sample photos and description
The sample photo should include the product packaging, label, sample physical image and internal structure diagram (if applicable), etc.
sample description
Sample structure/main components, working principle/inspection principle, scope of application, sample status. The relevant information should be consistent with other application materials.
Remark
Such as model specifications or other specifications.

Where entrustment is involved, the inspection report shall also be accompanied by the entrusted inspection report. The format of the entrusted inspection report shall comply with the relevant regulations of the State Drug Administration.

Annex 2

Configuration table of medical equipment self-inspection equipment (including standard/reference products)

Serial number	Inspection Clause	Item/parameter		Inspection start date	Use equipment (standard product)						Confirmation (Y/N)	Remark
		Item number	name		name	Number /Batch Number	Model specification	Measuring range	Expanded uncertainty/maximum tolerance/accuracy level	Traceability		

Instructions for filling in the form: Whether to confirm (Y/N): Indicates the confirmation of the accuracy of all the information in the row.

Annex 3

Medical device self-inspection inspector information form

Serial number	Name	gender	job title	Education	Major	graduation time	Department	Position and scope of authorization	Years in this position	Remark

Instructions for filling in the form:

1. In the "Post" column, please fill in the laboratory director (if any), office director (if any), inspector, approved personnel, etc.

2. "Period of working in this position" refers to the working years of the person in this position in the laboratory, not the length of service of the person. If the person has worked in this position in other institutions, he can indicate in the "Remarks" column the number of years he has held the position in other institutions.