**Notification of the National Medical Products Administration on Solicitation of Public Opinions on *Measures for the Supervision and Administration of Medical Device Operations (Revised Draft for Comment)***

|  |  |
| --- | --- |
| 下载 打印 | [分享到新浪微博](http://v.t.sina.com.cn/share/share.php?title=&url=https%3A%2F%2Fwww.nmpa.gov.cn%2Fxxgk%2Fggtg%2Fqtggtg%2F20210326101246169.html" \t "_blank) [分享到QQ空间](http://sns.qzone.qq.com/cgi-bin/qzshare/cgi_qzshare_onekey?url=https%3A%2F%2Fwww.nmpa.gov.cn%2Fxxgk%2Fggtg%2Fqtggtg%2F20210326101246169.html&title=&api_key=" \t "_blank) 分享到微信 |

Issued on: March 26, 2021

To implement the *Regulation on Supervision and Administration of Medical Devices* and further standardize the supervision and administration of medical devices operations, we have drafted the *Measures for Supervision and Administration of Medical Device Operations (Revised Draft for Comment)* and are now solicit public opinions. The public can make feedback through the following ways and means:

1. Log in the website of the Ministry of Justice of the People's Republic of China (www.moj.gov.cn, www.chinalaw.gov.cn) to enter the Column “Soliciting Legislative Opinions” in the main menu of the home page to give opinions.

2. Postal address: Department of Medical Device Supervision and Administration, National Medical Products Administration (No. 1 Beiluyuan, Zhanlan Road, Xicheng District, Beijing); postal code: 100037, and state “Solicitation of Public Opinions on the Measures for Supervision and Administration of Medical Device Operations” on the envelop.

3. E-mail: qxjgec@nmpa.gov.cn.

The deadline for feedback of opinions and suggestions is April 25, 2021.

National Medical Products Administration

March 26, 2021

**Measures for the Supervision and Administration of Medical Device Operations (Revised Draft for Comment)**

**Chapter I General Provisions**

Article 1 [Purpose] The Measures are established in accordance with the *Regulation on Supervision and Administration of Medical Devices* for the purpose of strengthening supervision and administration of medical device operations, normalizing medical device operation activities, and safeguarding the safety and effectiveness of medical devices.

Article 2 [Applicable Scope] Those engaged in the medical device operations and the supervision and administration of medical device operations within the territory of the People’s Republic of China shall follow and abide by the Measures.

The medical device operation as called in the Measures refers to purchasing, storage, sales (including wholesales, retailing and on-line sales), transportation, distribution, after-sales service, and other activities of medical devices for the purpose of making profits.

Article 3 [Operation requirements] Enterprises engaged in medical device operations shall follow laws, regulations, rules, standards, and norms to make sure the information of medical device operation process is authentic, accurate, complete and traceable.

Medical device registrants and filers can sell their registered or filed medical devices by themselves and can entrust medical device operation enterprises for sales.

Operation conditions as specified in the Measures shall be conformed to where medical device registrants and filers sell their registered or filed medical devices by themselves.

Article 4 [Classification management] Depending on the risk level of medical devices, the medical device operations shall be administered in classified manners.

Operation of Class I medical devices shall not require licensing or filing; operation of Class II medical devices shall be administered through filing management; operation of Class III medical devices shall be administered through licensing management. Provisions on business license and filing, otherwise stipulated, shall be followed.

Article 5 [Authorization clarification] The National Medical Products Administration shall supervise and guide the supervision and administration of nationwide medical device operations.

Provincial medical products administrations shall supervise and guide supervision and administration of medical device operations in their respective administrative region.

Medical products administrations of municipal and county governments with districts are responsible for supervision and administration of medical device operations in local administrative regions.

Article 6 [Separation of duties] Professional technical institutions set or assigned by medical products administrations to conduct inspection, testing, monitoring and evaluation etc. of medical devices shall undertake relevant technical work and issue technical conclusions according to their duties, providing technical support for supervision and administration of medical device operations.

Article 7 [Information construction] The Information Center, NMPA is responsible for information construction of supervision and administration of medical device operations to realize the full life-cycle information sharing and collaborative application of medical devices through national medical device data sharing platform and medical device operation monitoring online platform.

Local medical products administrations shall make full use of national medical device data sharing platform and medical device operation monitoring online platform to ensure effective interchange of information, collect, summarize, analyze, and process regulatory data of medical devices, and realize precise supervision.

Article 8 [Information disclosure] Medical products administrations shall timely disclose medical device business license, filing, supervision and inspection, administrative penalty, and other information in accordance with laws, so as to facilitate public inquiry and accept social supervision.

Article 9 [Industry self-regulation] Medical device industry organizations shall strengthen industry self-regulation, push forward the construction of credit system and industry standards, urge enterprises to perform operation activities in accordance with laws; organize and carry out publicity, training and experience sharing of regulations and laws of medical devices, encourage management innovation of enterprises, and promote the overall improvement of operation quality management level of the medical device industry.

Article 10 [Complaints and report] Individuals or organizations that discover illegal business activities of medical devices shall have the right to report to the medical products administrations. The medical products administrations shall publicize their contact information for receipt of consultation, complaints or report. The medical products administrations shall timely verify and handle the report and make replies upon receipt of the report. The informant shall be rewarded in accordance with relevant provisions if the report is verified to be authentic after investigation.

Article 11 [Honors and awards] Units and individuals making remarkable contributions to the quality management activities and the supervision and administration of medical device operation shall be honored and awarded according to relevant national provisions.

**Chapter II Business Licensing and Filing**

Article 12 [operation conditions] Those who engaged in medical device operations shall meet the following conditions:

(I) Having a quality management body or quality management personnel appropriate to its business scope and scale, and the quality management personnel shall have relevant professional qualifications or professional titles;

(II) Having business operation and storage premises appropriate to its business scope and scale; excluding those entirely relying on storage facilities of third-party logistics enterprises and therefore not in need of storage warehouse of their own;

(III) Having storage conditions appropriate to its business scope and scale;

(IV) Having a quality management system appropriate to their traded medical devices;

(V) Having competent capacities for providing specialized guidance, technical training, and after-sale service of their traded medical devices, or outsourcing third-party technical support;

(VI) Having an information management system conforming to the quality management requirements for medical device operations, so as to ensure the traceability of traded products.

Article 13 [Application material] The operation enterprises who engaged in the operations of Class III medical devices shall file applications to the medical products administrations of local municipal government with districts, together with the following documents:

(I) Copies of Business License;

(II) Copies of ID card, academic certificate or professional title certificate of the legal representative, chief executive, and quality manager;

(III) Description of organizational structure and functional departments;

(IV) Description of business scope and operation mode;

(V) Photocopies of location map and plane plan of the business premise and warehouse, property ownership title certificate or lease agreement (with property ownership title certificate attached);

(VI) A list of the equipment and facilities for operations;

(VII) A list of operation quality management system, working procedure and other documentations;

(VIII) Introduction to the information management system, and description of its functions;

(IX) Proof of authorization to the person who is taking care of application affairs.

Medical device business license applicants shall make sure the documents submitted is lawful, authentic, accurate and complete.

Applicants are not required to provide the related information that can be reviewed online.

Article 14 [Acceptance] The medical products administrations of local municipal governments with districts shall handle such applications in accordance with the following different cases upon receipt of applications:

(I) Applications within the department's scope of authority and obligation, with complete documents and data, in the form required by laws and regulation, shall be accepted and handled accordingly;

(II) For incomplete application data or applications not meeting the legal form requirements, a notice shall be given immediately or sent out to the applicant within 5 working days to notify the applicant of all the documents needed to be supplemented. In absence of such a notice after the deadline date, the application shall be deemed as accepted from the date it was first received;

(III) If there is error in the applications that can be corrected on site, the applicant shall be allowed to correct it on the site;

(IV) The department shall promptly make decision of denying the applications with subject matters beyond its scope of authority and obligation, and notify the applicant to apply to the appropriate department.

The medical products administrations of local municipal government with districts shall give a notice about acceptance or denial of an application based on its decision on whether or not accept the application for medical device business license.

Article 15 [Licensing hearing] In case that vital interest relationship between the applicant and others is directly involved in the medical device business licensing, the medical products administrations of local municipal government with districts shall inform the applicant and interest parties to apply for the right of hearing in accordance with laws, regulations, and relevant stipulations. During the review of medical device business licensing application, the medical product administrations shall announce to the society and hold public hearing in case that major licensing items of public interest is involved.

Article 16 [Review and approval of licenses] Medical products administrations of local municipal government with districts shall review application documents after acceptance of the business license application, conduct on-site inspections in accordance with Medical Devices Operation Quality Management Norms if necessary, and make a decision within 20 working days from the date of acceptance. The time of rectification shall be not included in the time-frame of review.

A written approval decision shall be made to grant a Medical Device Business License to the application meeting all the set requirements and a Medical Device Business License shall be issued to the applicant within 10 working days; a written denial decision shall be made to the application not meeting the requirements, together with specific justifications.

Article 17 [Operation filing] The enterprises engaged in the operations of Class II medical devices shall handle filing at the medical products administrations of local municipal government with districts, fill in the Class II medical device operation filing form, and provide the documents stipulated in Article 13 of the Measures.

The medical device operation filer shall ensure that the materials submitted are legal, true, accurate and complete.

Article 18 [Filing document verification and on-site inspection] The medical products administrations of local municipal government with districts shall immediately check the soundness and integrity of the submitted application documents submitted by the enterprise for the operation of Class II medical devices and handle filing to those meeting all the set requirements. The medical products administrations of local municipal government with districts shall carry out on-site inspections of Class II medical device operation enterprises within three months since commencement dates of filing management for such enterprises.

Article 19 [Simplified procedures] Enterprises applying for Class III medical device business license and dealing with Class II medical device operation files at the same time may submit a set of documents to the competent medical products administration of local municipal government with districts in accordance with provisions, and complete on-site inspections.

Enterprises obtaining Class III medical device business license and dealing with Class II medical device operation files shall handle Class II medical device operation filing to the competent medical products administration of local municipal government with districts in accordance with provisions. If there is no change in the materials submitted in accordance with Article 13 of the Measures, the relevant materials may be exempted from submission.

New independent operation site shall apply for separate medical device business license or filing certificate.

Article 20 [Licensing certificate] Medical Device Business License shall be valid for 5 years; it shall contain license number, enterprise's name, legal representative, chief executive, registered address, operation address, operation mode, business scope, warehouse address, issuing authority, issue date, validity period, etc.

Medical Device Business License shall be in the uniform form unified by the NMPA and printed by the competent medical products administration of local municipal government with districts.

Electronic medical device business license made by the competent medical products administration has the equal legal effect with paper license.

Article 21 [Licensing changes] For changes to licensed items, the applicant shall apply for changes of Medical Device Business License to the original issuing authority, and provide the documents related to the change contents as stipulated in Article 13 of the Measures.

For changes to business address, business mode, business scope and warehouse address, the original issuing authority shall make a decision on change approval or change denial within 20 working days upon receipt of the change application. If a change is denied, a written justification shall be given to the applicant. For changes to other items, the original issuing authority shall immediately approve the changes. The Medical Device Business License after change shall keep its number and validity period unchanged.

Article 22 [Changes and filing of remote warehouses] A storehouse to be set up across administrative regions shall meet the conditions as specified in Article 12 of the Measures. And the concerned enterprise shall apply for the changes to the original issuing authority or filing department and handle filing at the medical products administration of local municipal government with districts.

Article 23 [Division/merger cases] In case the medical device operation enterprise is newly established due to division or merger, it shall apply for medical device business license or handle filing of Class II medical device operation; in case the medical device operation enterprise renews due to division or merger, it shall apply for changes of licensing or handle filing in accordance with the provisions of the Measures; in case the medical device operation enterprise is dissolved due to division or merger, it shall apply for revoking of Medical Device Business License or cancel the filing of Class II medical device operation.

Article 24 [Licensing renewal] For renewal of Medical Devices Business License upon expiry, the medical device operation enterprise shall apply to the original issuing department for renewal of the license 6 months prior to its expiry date.

The original issuing department shall review such renewal application and carry out necessary field examination in accordance with provisions of Article 16 of the Measures, and make approval or disapproval decision on the renewal application before expiry date of the Medical Devices Business License. Application satisfying set requirements shall be approved and renewed, and the number of corresponding Medical Device Business License shall remain unchanged as before. The starting date of renewal is the next day after the expiry date of the original license. Those not meeting the requirements shall be ordered to correct; if still not meeting the requirements after corrections, their renewal applications shall be not approved, and the justification of denial shall be given in writing. If no decision is available after the due time, the renewal application shall be deemed having been approved.

Article 25 [Change filing] In case there are changes to the business address, business mode, business scope, warehouse address, or other items of Class II medical device operation enterprise, filing of these changes shall be made at the original filing department in time.

The medical products administration of local municipal government with districts shall conduct an on-site inspection within 3 months after the medical device operation enterprise changes corresponding filing information.

Article 26 [Licensing suspension] For medical device operation enterprises currently under pending cases of investigations by the medical product administrations for illegal operation activities, or having not paid off/served out administrative penalties imposed on them, the medical product administrations shall suspend the licensing till such cases have been resolved.

Article 27 [Reissuance of lost licenses] In case the Medical Device Business License is lost, the medical device operation enterprises shall apply to the original issuing authority for the reissuance. The original issuing authority shall timely reissue the Medical Device Business License. The reissued Medical Device Business License shall have number and validity period same as the original license.

Article 28 [Licensing revoking and filing cancellation] In the case where the medical device operation enterprise is under the situations in which its license shall be revoked or its filing shall be cancelled as specified in the applicable laws and regulations, or the enterprise voluntarily asks for revoking its license during its validity period, the medial products administrations of local municipal government with districts shall revoke its Medical Devices Business License or cancel its filing in accordance with the provisions of laws and regulations, and shall make it public.

Article 29 [Circumstances for exemption of operation filing] Class II medical devices with safety and effectiveness will not being affected by distribution process may be exempted from operation filing. The specific list of these products shall be formulated, adjusted and publicized by the NMPA.

Article 30 [Circumstance 1 for exemption of business license or filing] Organizations engaged in the storage, allocation and supply of non-profit contraceptive medical devices shall comply with relevant provisions and be exempted from medical device business license and filing.

Article 31 [Circumstance 2 for exemption of business license or filing] Medical device registrants and filers sell their registered or filed medical devices at their domicile or manufacturing address shall be exempted from medical device business license or filing, but shall comply with required operation conditions; medical device operation enterprises storing medical devices at other sites and selling on the spot shall follow provisions to handle medical device business license or filing.

Article 32 [Online sales] Medical device registrants, filers or operation enterprises engaged in online sales shall follow provisions of the Measures to handle licensing or filing, and inform the website name, domain name, IP address and other relevant information to the medical products administrations of local municipal government with districts. Operation of Class I medical devices and Class II medical devices exempted from operation filing shall be excluded.

Article 33 [Prohibited actions] No organizations or individuals shall be allowed to forge, alter, trade, lease or lend the Medical Device Business License.

**Chapter III Operation Quality Management**

Article 34 [Quality management system] Enterprises engaged in medical device operation shall establish a operation management system and quality control measures in accordance with laws, regulations and requirements of Medical Devices Operation Quality Management Norms to cover the entire quality management process, including purchasing, acceptance, storage, sales, transportation, after-sales service and etc., and shall make appropriate records, so as to assure constant compliances of operations and operation conditions.

Article 35 [Traceability requirements] Medical device operation enterprises shall establish and implement a product traceability system to make sure the product concerned is traceable. Medical device operation enterprises are encouraged to establish an information traceability system with UDI.

Article 36 [Purchasing channel management] Medical device operation enterprises purchase medical devices from medical device registrants, filing person and operation enterprises with legal qualifications.

Article 37 [Purchase inspection system] Medical device operation enterprises shall establish an incoming acceptance inspection record-keeping system to inspect supplier enterprise qualifications, authorization of sales personnel, registration certificate or filing certificate of medical devices, production and business license or filing certificate of medical devices and quality certificate upon purchase of medical devices. Information contained in such incoming acceptance inspection records shall be true, accurate, complete and traceable.

Incoming acceptance inspection records include:

(I) The name, specifications, models, and quantity of the medical device;

(II) Medical device registration certificate number or filing certificate number;

(III) Name of medical device manufacturer, production license number or filing certificate number;

(IV) The production batch number or serial number, service period or expiration date and purchase date of the medical devices;

(V) Name, address and contact information of suppliers.

Procurement acceptance inspection records shall be kept for two more years after expiration of validity periods of the medical devices, and at least for five years for those without a validity period. Procurement acceptance inspection records for implantable medical devices shall be kept permanently.

Article 38 [Management of transportation and storage] Medical device operation enterprises shall take effective measures to ensure that the transportation and storage of medical devices comply with the requirements specified in the instructions for use (IFU) or labels of the medical devices, and keep good records of them so as to guarantee safe quality of the medical devices.

If there are special requirements for temperature, humidity and other environmental conditions, corresponding measures shall be taken to ensure the safety and effectiveness of medical devices.

Article 39 [Management of entrusted storage and transportation] Medical device operation enterprises commissioning other transport carriers for transportation of its medical devices shall verify and evaluate medical devices transportation quality assurance capability of such carriers, and sign a contract service agreement to specify quality responsibilities during transportation process to ensure product quality and safety en-route.

Article 40 [Entrusted storage and transportation management] Medical device operation enterprises providing storage and distribution services for other medical device registrants, filers or operation enterprises shall sign written agreement with principal party, specifying each party's rights and obligations, have competent storage and distribution facilities and conditions appropriate for the concerned products, and have computerized information management platform and technical means for real time digital data exchange with clients and tracing of whole product operation and quality management process.

Article 41 [Entrusted operation] If the medical device registrant and filers entrust sales, they shall entrust a qualified medical device operation enterprise and sign an entrustment agreement to clarify the rights and obligations of both parties.

Article 42 [Stipulations of purchasing and sales activities] Medical device registrants, filers or operation enterprises operation enterprises shall be liable for medical device purchasing and sales activities undertaken by their representative offices or their salespersons in the names of the enterprises.

During selling the medical devices, salespersons of the medical device operation enterprises shall provide an authorization letter sealed with the enterprise's business stamp. The authorization letter shall contain information such as types of medical devices under this authorization, regions of sales, validity period and ID card number of the salesperson.

Article 43 [Management of sales records] Medical device operation enterprises engaged in wholesale business of Class II and Class III medical devices and retailing of Class III medical devices shall establish a sales record-keeping system. Information contained in sales records shall be true, accurate, complete, and traceable.

The sales records should include:

(I) Name, specification, model, registration certificate number or filing certificate number and quantity of concerned medical devices;

(II) The production batch number or serial number, service life or expiration date and sales date of the medical device;

(III) Name of medical device manufacturer, production license number or filing certificate number.

For enterprises engaged in wholesale business, the sales records shall also include the name, address, and contact information and number of relevant license documents of the buyer.

Sales records shall be kept for two more years after expiration of validity periods of the medical devices, and at least for five years for those without a validity period. Sales records of implanted medical devices shall be kept permanently.

Other medical device operation enterprises are encouraged to establish sales record systems.

Article 44 [Contractual after-sales obligations] Medical device operation enterprises shall agree on quality and after-sale obligations with suppliers to guarantee safe use of medical devices after selling. Medical device operation enterprises commissioning suppliers or appropriate organizations for product installation, repair, maintenance, and technical training service may be exempted from setting up its own technical training and after-sale service department/team, but shall have responsible personnel for this end.

Article 45 [Personnel responsible for after-sales management] Medical device operation enterprises shall be staffed with full-time or part-time personnel responsible for after-sale service management, investigating causes for quality issues raised in customer complaints, taking effective actions for handling and feed-back and maintaining proper records, and informing the registrant, filer, manufacturer and operation enterprises of the concerned medical devices, if necessary.

Article 46 [Monitoring of adverse events] Medical device operation enterprises shall assist medical device registrants and filers to monitor adverse events of the medical devices traded, and report to the technical organization monitoring adverse events of medical devices in accordance with provisions of medical products administrations.

Article 47 [Recall management] Medical device operation enterprises shall immediately stop trading once they found their traded medical devices have non-conformance to mandatory standards and other defects, inform medical device registrants, filers and other relevant units, record operation suspension and notification and assist in product recall.

Article 48 [Resuming business reports] Medical device wholesale enterprises and Class III medical device retailing enterprise ceasing operation for more than a year, if wishing to resume operation, shall submit written application to the competent medical products administration and shall be allowed to resume operation only after satisfying all set requirements.

Article 49 [Self-examination reports] Medical device wholesale enterprises and Class III medical device retailing enterprises shall establish a quality management self-examination system and conduct full-range self-examination in accordance with Medical Device Operation Management Norms, and submit an annual self-examination report to the competent medical products administration at the end of each year.

Article 50 [Prohibited actions] Units engaged in medical device operations shall not sell medical devices produced by enterprises that have not been registered or filed according to laws, have not obtained production license or filing in accordance with laws or have no qualification documents, and shall not sell outdated, invalid or obsolete medical devices.

It is prohibited to sell imported medical devices that are outdated, invalid, obsolete, or used.

**Chapter IV Supervision and Administration**

Article 51 [Inspection responsibility] Medical products administrations of provinces, autonomous regions, and municipalities directly under the Central Government are responsible for supervising and guiding the supervision and administration of the operation of medical devices in their respective administrative region, and examine the supervision and administration work of the operation of medical devices in the administrative region.

The medical products administrations of municipal and county governments with districts are responsible for supervision and inspection of medical device operation activities in the administrative region.

Article 52 [Establishment of supervision directory] The medical products administrations of municipal government with districts shall establish a directory of medical device operation enterprises to be supervised in the administrative region, specify supervision objects of municipal and county-level medical products administrations, and make it public.

Article 53 [Classified management] The medical products administrations of municipal government with districts implement classified dynamic management according to the quality management of medical device operation enterprises and risks of medical device products traded. The medical products administrations of municipal government with districts determine the supervision level of medical device operation enterprises according to the actual situation, clarify key points of supervision and inspection, and organize the implementation.

Article 54 [Double random and one public] The medical products administrations of municipal and county governments with districts shall accelerate the improvement of “Double random and one public” supervision system. The medical products administrations of municipal government and counties with districts shall establish and complete lists of market entities and inspectors, and arrange batch-to-batch spot inspection objects according to annual spot inspection work plan. Differentiation supervision measures shall be taken for spot inspection objects with different risks and credits in accordance with provisions of laws and regulations and the actual situation of the supervision field and the law enforcement team to reasonably determine and dynamically adjust the spot-check proportion and the probability to be checked, not only ensuring the necessary coverage of spot inspection and supervision effect, but also preventing excessive inspection and enforcement.

Article 55 [Inspection plan] The medical products administrations of municipal and county governments with districts shall formulate an annual inspection plan, specifying key targets for medical device supervision and administration, inspection frequency and coverage and supervise their implementation.

Article 56 [Risk discussion system] Medical products administrations shall, on a regular basis, strengthen risk consultation and judgment based on supervision and inspection, product sampling inspection, adverse event monitoring, complaint and report, administrative punishment, public opinion information, etc., and do a good job in the investigation, prevention, control, and disposal of hidden risks of quality and safety of medical devices.

Article 57 [Supervision responsibilities for remote warehouses] The warehouses set up across administrative regions by medical device operation enterprises shall be supervised by the medical products administrations in the place where the warehouses are located.

Medical products administrations where medical device operation enterprises and warehouses locate shall strengthen supervision information sharing and conduct a joint inspection if necessary.

Article 58 [Inspection requirements] Medical products administrations shall, in principle, organize supervision and inspection by means of intruder supervision and inspection, with no fewer than two people during on-site inspection, present law enforcement certificates, truthfully record the on-site inspection, and inform the inspected enterprises in writing of the inspection results. In case of corrective actions are needed, it shall define the specific corrective actions to be made and time frames for such corrective actions, and carry out follow-up inspections.

Article 59 [Inspection functions and power] Medical products administrations have the following functions and power in supervision and inspection:

(I) Enter the site for inspection and sampling;

(II) Review, copy, seal up, and detain relevant contracts, bills, account books and other relevant materials;

(III) Sealing up and detaining medical devices that do not meet mandatory requirements, and parts and accessories illegally used, etc.;

(IV) Relevant functions and power required by national laws and regulations.

Medical device operation enterprises, relevant organizations and individuals shall coordinate with the supervision and inspection, provide relevant documents and materials, and shall not conceal, refuse or obstruct.

Article 60 [Inspection of quality management system] The medical products administrations of municipal and county governments with districts shall conduct supervision and inspection on medical devices operation enterprises' compliance with operation quality management norms, supervise over enterprise’s legitimate operations.

Article 61 [Inspection of annual self-inspection reports] The medical products administrations of municipal and county governments with districts shall review the annual self-examination reports submitted by medical device wholesale enterprises and Class III medical device retailing enterprises, and carry out field examination if necessary.

Article 62 [Key inspection objects] Medical products administrations shall strengthen on-site inspections under one of the following circumstances:

(I) Having serious problems in last annual supervision and inspection;

(II) Having administrative penalty due to violation to relevant laws and regulations;

(III) Newly founded medical device wholesale enterprises and Class III medical device retailing enterprises;

(IV) Providing storage and distribution service for other medical device manufacturing and operation enterprises;

(V) Key inspection enterprises determined by the risk discussion;

(VI) Other circumstances requiring enhanced on-site inspections.

Article 63 [Extension inspection] Medical products administrations may conduct an extension inspection of other relevant units providing products or services for medical device operation activities and warehouses set across administrative areas according to inspections, if necessary.

Article 64 [Supervision and spot inspection] Medical products administrations shall strengthen spot inspections of operating process of medical devices, and shall timely handle with unqualified products.

Medical products administrations above the provincial level shall timely publish medical device quality announcement in accordance with the conclusions of spot inspections.

Article 65 [Emergency measures] If there are hidden risks of quality and safety in the operation of medical devices and no timely measures are taken to eliminate them, the medical products administrations may take such measures as warning, questioning, and ordering rectification within a time limit.

Medical products administrations may instruct the suspension of sales, and mandatory recall and take other emergency control measures for medical devices that cause injuries to human bodies, or that is evidenced to have potential health risk and that seriously violate the Medical Devices Quality Management Norms and might have a direct impact on the quality of the products.

Article 66 [Cause inspection] For any medical device operation enterprises being lodged with complaint, or with potential product safety issues as discovered by other information or by routine supervision and examination, or with a record of misconduct, the medical products administration may conduct on-the-fly examination.

Article 67 [Responsibility appointment]. Where a medical device operation enterprise is in any of the following circumstances, the competent medical products administration may conduct questioning to its legal representative or its principal:

(I) Having serious safety hazards in its operation;

(II) Products traded by the enterprise are repeatedly complained and reported or exposed by the media due to safety issues;

(III) Having a poor credit level as determined in credit level evaluation;

(IV) Issues found have been inadequately corrected or not corrected;

(V) Other situations necessary to have questioning.

Medical products administrations shall include the medical device operation enterprises appointed into the annual key inspection plan to increase the supervision and inspection frequency.

Article 68 [Revoking and cancellation of business qualifications] For medical device operation enterprises no longer meeting the business license or filing prerequisites, no longer conforming to license or filing information or having lost contact, the original issuing/filing department shall, after publication, legitimately revoke their Medical Devices Business License or cancel the Class II medical device operation filing information, and then announce to the public.

Article 69 [Supervision archives] Medical products administrations shall establish medical device operation enterprises supervision and administration archives to record license and filing information, routine supervision inspection results, poor credit record, investigation of illegal operations and penalties and other information in the enterprise’s supervision and administration archives.

Article 70 [Requirement for confidentiality] State secrets, trade secrets, technical secrets or individual privacy known in investigations or inspections shall be kept confidential in accordance with laws.

Article 71 [Credit management] Medical products administration may include the medical device operation enterprises and their legal representative or principal in the list of persons with poor credit and make the list public under one of the following circumstances:

(I) Medical device operation enterprises refusing implementing the suspension of sales, mandatory recall and other decisions instructed by medical products administrations;

(II) Medical device operation enterprises refusing corrections after questioning.

Article 72 [Combination of administrative and criminal penalty] In the course of supervision and inspection, the medical products administrations shall collect and fix evidence in a timely manner when discovering suspected violations of medical device laws and regulations, and file a case for investigation in accordance with law; if a crime is suspected, it shall be promptly transferred to the public security organ for handling.

Article 73 [Joint punishment] Medical products administrations shall increase the supervision and inspection frequency, and implement a joint punishment according to national provisions for medical device operation enterprises with poor credit record.

Article 74 [Honest law enforcement] Medical products administrations and their staff shall standardize law enforcement, strictly follow the discipline of clean and honest administration, and shall not ask for or accept properties, seek other benefits, or interfere with the normal operation activities of enterprises during supervision and inspection.

**Chapter V Legal Responsibilities**

Article 75 [Punishment for no licensing] Under any of the following circumstances, penalties shall be imposed in accordance with Article 81 of *the Regulation on Supervision and Administration of Medical Devices*:

(I) Enterprise conducting operations of Class III Medical Devices without license;

(II) Enterprise trading Classes II and III medical devices not legally registered;

(III) Class III medical device operation enterprises change business site, business mode, business scope or warehouse address without license;

(IV) Enterprises conducting medical device operations failing to renew Medical Device Business License upon expiry and continuing to engage in medical device operation activities.

Article 76 [Punishment for false licensing materials] If a Medical Device Business License is obtained through provisions of false or fake documents or through other deceitful means, the offender shall be punished in accordance with Article 83 of the *Regulation on Supervision and Administration of Medical Devices*.

Article 77 [Punishment for no filing] Under any of the following circumstances, penalties shall be imposed in accordance with Article 84 of the *Regulation on Supervision and Administration of Medical Devices*:

(I) Enterprises selling class-I medical devices without filing;

(III) Enterprises selling class-II medical devices which shall be filed but fail to do so;

(III) The information that has been filed for operations do not meet the requirements;

(IV) Changes to filed items are not reported to the original filing authority for filing changes.

Article 78 [Punishment for false filing documents] If false documents are provided during filing, the offender shall be punished in accordance with Article 85 of the *Regulation on Supervision and Administration of Medical Devices*.

Article 79 [Management of violation of license and filing certificate] If a Medical Device Business License is obtained through provisions of false or fake documents or through other deceitful means, the offender shall be punished in accordance with Article 83 of the *Regulation on Supervision and Administration of Medical Devices*.

If the Medical Device Operation Filing Certificate is forged, altered, traded, leased or lent, the offender shall be ordered by the medical products administration to correct, and punished with a penalty of more than 10,000 Yuan and less than 30,000 Yuan.

Article 80 [Punishment 1 for non-compliance] Under any of the following circumstances, penalties shall be imposed in accordance with Article 86 of the *Regulation on Supervision and Administration of Medical Devices*:

(I) Enterprise engaged in operation of medical devices not meeting mandatory standards or product technical requirements that have been registered or filed;

(II) Enterprise engaged in operation of unqualified, outdated, expired, or obsolete medical devices;

(III) Enterprises that refuse recalls instructed by the medical products administration;

(IV) Enterprises that refuse the suspension of importing or trading medical devices instructed by the medical products administration;

(V) Enterprise engaged in operation of imported outdated, expired, or obsolete and other used medical devices.

Article 81 [Punishment 2 for non-compliance] Under any of the following circumstances, penalties shall be imposed in accordance with Article 88 of the *Regulation on Supervision and Administration of Medical Devices*:

(I) Traded medical devices with instructions for use and/or labels not in compliance with applicable provisions;

(II) Enterprise failing to transport and/or store medical devices in accordance with requirements specified in the medial device’s instructions for use and labels.

Article 82 [Punishment 3 for non-compliance] Under any of the following circumstances, penalties shall be imposed in accordance with Article 89 of the *Regulation on Supervision and Administration of Medical Devices*:

(I) Medical device wholesale enterprises and Class III medical device retailing enterprises do not submit annual self-examination reports as required;

(II) Enterprise purchases medical devices from suppliers without legal qualification;

(III) Medical device operation enterprises failing to establish and implement medical devices procurement acceptance inspection record system as required by provisions of the Measures;

(IV) Medical device operation enterprises engaged in Class II and Class III medical devices wholesale operations and Class III medical devices retailing operations having failed to establish and implement sales record system as required by provisions of the Measures;

(V) Medical device operation enterprises fail to monitor adverse events of medical devices in accordance with the provisions of the *Regulation on Supervision and Administration of Medical Devices*, fail to report adverse events as required, or fail to cooperate with the investigation of adverse events conducted by technical organizations for adverse events monitoring of medical devices and medical products administration departments;

(VI) Enterprises fail to cooperate with supervision and inspections conducted by the medical products administration, fail to truthfully provide relevant documents and materials, or conceal, refuse, evade or obstruct the supervision and inspections.

Article 83 [Punishment 4 for non-compliance] For any one of the following circumstances, the enterprise shall be ordered by the medical products administration for correction and imposed with a penalty of between 10,000 to 30,000 Yuan:

(I) Medical device operation enterprises could no longer conform to Medical Devices Quality Management Norms due to changes in operation conditions and had not carried out required correction;

(II) Medical device operation enterprises violate the Measures to provide storage and distribution service for other medical device manufacturing and operation enterprises.

Article 84 [Punishment 5 for non-compliance] Medical products administrations shall decide to suspend sales of the medical device if the medical device registrant, filer and operation enterprises falsely advertise their products, and make public; if the medical device is still being sold, the medical device illegally sold by the enterprise shall be confiscated by the medical products administration above the county level with a penalty of more than 10,000 Yuan and less than 30,000 Yuan.

Article 85 [Punishment 6 for non-compliance] For any one of the following circumstances, the enterprise shall be ordered and warned by the medical products administration for correction within specific deadline; if issues persist, the enterprise shall be imposed with a penalty of between 5,000 to 20,000 Yuan:

(I) Class III medical device operation enterprises do not handle changes to name, legal representative, principal responsible person and domicile in accordance with provisions of the Measures;

(II) Medical device operation enterprises delegate medical device salespersons without authorization documents as stipulated in the Measures;

(III) Medical device wholesale enterprises and Class III medical device operation enterprises ceasing operations for more than a year do not submit a written report to the competent medical products administration for business resumption in advance and resume operation without authorization;

(IV) Medical device operation enterprises do not agree on quality and after-sale responsibilities with suppliers;

(V) Medical device operation enterprises commissioning other transport carriers for transportation of its medical devices do not evaluate medical devices transportation quality assurance capability of such carriers, and sign a contract service agreement;

(VI) Medical device registrants commissioning medical device operation enterprises not conforming to conditions to sell medical devices or fail to sign an entrustment agreement with the entrusted medical device operation enterprises to specify the rights and obligations of both parties to entrust the sale of medical devices.

Article 86 [Exception clauses] A medical device operation enterprises can be exempted from administrative punishment if it fulfills incoming acceptance inspection obligations, has sufficient evidences proving that it does not know the traded medical devices are Class I medical devices not filed, Class II and Class III medical devices without registration certificate, or medical devices not conforming to mandatory standards or products technical requirements registered or filed, medical devices without qualification certifications, or outdated, invalid or obsolete medical devices, and gives a true explanations of the source of their purchase, and medical devices that do not meet statutory requirements shall be confiscated.

Article 87 [Special provisions for punishment to specific personnel] In the administrative punishment, if the relevant responsible person is prohibited from practicing, it shall be clearly stated in the punishment decision and disclosed to the public in accordance with the law.

Article 88 [Prohibited personnel regulations] If the medical device operation enterprises violate the provisions of the *Regulation on Supervision and Administration of Medical Devices* to employ prohibited practitioners, the medical products administration shall order corrections and give warnings; if they refuse to make corrections, they shall be ordered to suspend business until the license is revoked or the filing certificate is cancelled.

**Chapter VI Supplementary Provisions**

Article 89 [Implementation date] The Measures shall be implemented as of X, X, 202X. The *Measures for the Supervision and Administration of Medical Device Operations* (Decree No. 8 of NMPA) issued on July 30, 2014 shall be abolished simultaneously.

**Instruction to the Drafting of the *Measures for the Supervision and Administration of Medical Device Operations (Revised Draft for Comment)***

**I. Background of revision**

Medical devices are directly related to people's lives and health. The Party Central Committee and the State Council pay high attention to the quality and safety of medical devices. The *Regulation on Supervision and Administration of Medical Devices* (hereafter referred to as the *Regulations*) was deliberated and adopted in the executive meeting of the State Council on December 21, 2020. To carry out the newly revised *Regulation*, to adapt to needs for supervision and administration work of medical devices under the new situation, implement the entity responsibility of enterprises, strengthen supervision measures, regularize medical device operation activities, ensure the product quality and safety of medical devices, the NMPA started the revision of *the Measures for Supervision and Administration of Medical Device Operations* (hereafter referred to as the *Measures*) in March 2019. The NMPA conducted in-depth basic research, extensively solicited the opinions of local medical products administrations, medical device manufacturing and operation enterprises and medical device industry associations, and entrusted relevant units to carry out subject research. On the basis of repeated studies and revisions, the *Measures* (Revised draft for comment) have been formed.

**II. Overall thinking of revision**

Firstly, comprehensively carry out the requirements of the new *Regulation*. Comprehensively carry out the requirements of the new *Regulation* and newest requirements for strengthening supervision and administration of medical devices of the Party Central Committee and the State Council, revise the contents inconsistent with the new *Regulation*, and supplement and improve relevant provisions. Secondly, resolutely implement the “Four Most Strictly” Requirements. Combine with the actual supervision and administration of medical devices, clarify the authority, and strengthen the responsibility with problem orientation, make targeted supplementation to prominent problems restricting supervision and administration, solve urgent needs of supervision and administration, and improve the efficiency of supervision and administration. Intensify the punishment for violations of laws and regulations, further clarify the identification and responsibility investigation of illegal acts, increase penalties and punish the specific person to increase the cost of violations. Thirdly, deepen and push the reforms of “streamline the government, delegate power, and improve government services”. Strive to reflect and meet the needs of the reform of administrative review and approval system, simplify the procedures for licensing and filing, consolidate the achievements of the reforms of “streamline the government, delegate power, and improve government services”, and release the innovative vitality of the market. Fourthly, strictly carry out the entity responsibility of enterprises. Laid the entity responsibility of enterprises through refining the basic regulatory system and strengthening the concept of risk control.

**III. Main contents revised**

(I) Carry out the medical device registrant and filer system and strengthen their quality and safety responsibilities throughout the whole life-cycle

Comprehensively implement the medical device registrant and filer system to provide convenience for registrants and filers to sell their registered and filed medical devices on the one hand, and to strengthen the entity responsibility of registrants and filers to sell their registered and filed products on the other hand. The Measures specify that medical device registrants and filer can sell their registered or filed medical devices by themselves and can entrust medical device operation enterprises for sales. Operation conditions as specified in the Measures shall be conformed to where medical device registrants and filers sell their registered or filed medical devices by themselves. Medical device registrants or filers shall entrust a medical device operation enterprises meeting conditions and sign a contract service agreement to specify rights and obligations of both parties.

(II) Strictly implement requirements for “streamline the government, delegate power, and improve government services” to simplify documents and procedures for licensing handling.

The *Measures* cancel the provisions on submitting “other certification materials” in handling business license and filing in the original *Measures*, and specify that the relevant materials that can be checked online are not required to be provided by the applicant. Adjust “reviewing the application materials within 30 working days” into “making a decision within 20 working days from the date of acceptance”. Enterprises applying for Class III medical device business license and handling with Class II medical device operation filing at the same time may submit a set of documents and complete on-site inspections. Class II medical devices whose product safety and effectiveness are not affected by the circulation process may be exempted from operation filing.

(III) Clarify the authority of supervision and inspection and strengthen regulatory measures

The *Measures* specify that the medical products administrations of provinces, autonomous regions, and municipalities directly under the Central Government are responsible for supervising and guiding the supervision and administration of the operation of medical devices in their respective administrative region, and examine the supervision and administration work of the operation of medical devices in the administrative region. The medical products administrations of municipal and county governments with districts are responsible for supervision and inspection of medical device operation activities in the administrative region. The medical products administrations of municipal government with districts shall establish a list of medical devices operation enterprises to be supervised in the administrative region, specify supervision objects of municipal and county-level medical products administrations, and make them public. The medical products administrations of municipal government and counties with districts shall accelerate the improvement of “Double random and one public” supervision system. The medical products administrations of municipal government and counties with districts shall establish and complete lists of market entities and law enforcement inspectors, and select inspection objects in accordance with the arrangements of the annual spot inspection work plan. Differentiation supervision measures shall be taken for spot inspection objects with different risks and credits in accordance with provisions of laws and regulations and the actual situation of the supervision field and the law enforcement team to reasonably determine and dynamically adjust the spot-check proportion and the probability to be checked, not only ensuring the necessary coverage of spot inspection and supervision effect, but also preventing excessive inspection and enforcement.

(IV) Increase regulatory measures to address the lack of regulatory measures

The Measures stipulate that if there are hidden dangers of product quality and safety exist in the manufacturing and trading of medical devices while measures are not taken to eliminate them in time, the medical products administrations can take such measures as warning, questioning, and ordering rectification within a time limit. Medical products administrations may instruct the suspension of sales, and mandatory recall and take other emergency control measures for medical devices that cause injuries to human bodies, or that is evidenced to have potential health risk and that seriously violate the Medical Devices Quality Management Norms and might have a direct impact on the quality of the products. For medical device operation enterprises refusing implementing the suspension of sales, mandatory recall and other decisions instructed by medical products administrations and medical device operation enterprises refusing corrections after questioning, medical products administration may include the medical device operation enterprises and their legal representative or principal in the list of persons with poor credit and make the list public.

*No part of this publication can be reproduced or transmitted in any form without the prior written permission of the publisher. Standard Translation (Beijing) reserves all the right for the final interpretation.*

