

OFFICIAL JOURNAL OF THE UNION

Published on: 11/19/2024 | Edition: 223 | Section: 1 | Page:

105 Agency: Ministry of Health/National Health Surveillance Agency/Collegiate Board

RESOLUTION RDC Nº 938, OF NOVEMBER 14, 2024

Provides for Good Storage Practices and Certification of Good Storage Practices for goods and products subject to health surveillance in Customs Warehouses

THE COLLEGIATE BOARD OF DIRECTORS OF THE NATIONAL HEALTH SURVEILLANCE AGENCY, in the exercise of the power conferred upon it by art. 15, III and IV, in conjunction with art. 7, III, and IV, of Law No. 9,782, of January 26, 1999, and art. 53, VI, §§ 1º and 3º of the Internal Regulations approved by the Collegiate Board Resolution - RDC No. 585, of December 10, 2021, resolves to adopt the following Collegiate Board Resolution, as deliberated at a meeting held on November 13, 2024, and I, the Chief Executive Officer, determine its publication.

CHAPTER I

PRELIMINARY PROVISIONS

Section I

Object

Art. 1 This Resolution establishes the requirements for Good Storage Practices and the Granting of Certification of Good Storage Practices for goods and products subject to sanitary control and inspection in customs warehouses.

Section II

Scope

Art. 2 This Resolution applies to companies that carry out the activity of storing goods and products subject to health control and inspection in customs warehouses.

§ 1º The provisions of the caput of this article include express shipping companies and postal shipments.

§ 2º The provisions of the caput of this article do not apply to duty-free shops, special deposits and warehouses that exclusively store bulk cargo of food or vegetable oils.

§ 3º Compliance with the requirements described in this standard will depend on its applicability with in relation to the specific activities carried out by the establishment and stored products.

Section III

Definitions

Art. 3 For the purposes of this Resolution, the following definitions are adopted:

I - senior management of the company: responsible for providing resources and with the authority to establish or change the company's quality policy and system;

II - bonded warehouse: area declared by the competent customs authority, in the primary zone or in the secondary zone, where, under customs control, storage and customs clearance of goods (coming from abroad, or destined for abroad) takes place;

III - storage: safe keeping, movement, handling and conservation of goods and products, whether they are unloaded or not;

IV - health authority: authority directly responsible for implementing the measures appropriate sanitary measures in accordance with relevant legislation and regulations;

V - goods and products subject to health control and inspection: materials, raw materials, inputs, parts, finished products, bulk products, semi-finished products and in natura products, and others subject to health surveillance as set out in Law No. 9,782 of 1999, including, among others, medicines, food, cosmetics, sanitizing products, medical devices, cells, tissues, organs;

VI - thermolabile good or product: good or product, whose maximum temperature specification is equal to or lower than 8°C, which undergoes a change in its effectiveness or safety when not stored or transported under the conditions predefined to maintain its quality;

VII - Good Storage Practices (GSP): set of actions that ensure the maintenance of the quality of a good or product, through adequate control during the storage, clearance and inspection process by the approving bodies;

VIII - calibration: set of operations that establishes, under specified conditions, the relationship between the values indicated by a measuring instrument or system, or values represented by a materialized measurement, and the corresponding known values of a reference standard;

IX - bulk cargo: liquid or dry cargo shipped and transported without packaging, without identification marks and without counting units;

X - bill of lading: document issued, on the date of shipment of the good or product, by the carrier or consolidator, constituting the international transport contract and proof of the disposition of the good or product to the importer;

XI - contamination: unwanted introduction of impurities of a chemical or microbiological nature, or foreign matter, into raw material, intermediate product, bulk product or finished product or into their shipping boxes during the storage or transportation stages;

XII - outsourcing contract: document mutually agreed and controlled between the parties, establishing the duties and responsibilities of the contracting and contracted companies;

XIII - deviation: failure to comply with requirements determined by the Management System Quality or necessary for maintaining the quality, safety and efficacy of products;

XIV - shipping: set of procedures related to shipping for the purpose of transporting goods and products;

XV - risk management: systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risks associated with a given product or process;

XVI - importer: natural or legal person responsible for the entry of goods or products from abroad into national territory;

XVII - human biological material: tissue or fluid constituting the human organism, such as excrement, bodily fluids, cells, tissues, organs or other fluids of human origin or isolated from them;

XVIII - standard operating procedure (SOP): written and authorized procedure that provides instructions for carrying out specific operations in the development of product storage operations and other activities of a general nature (for example, operation, maintenance and cleaning of equipment, qualification, cleaning of facilities and environmental control, sampling and inspection);

XIX - qualification: set of actions carried out to certify and document that any facilities, systems and equipment are properly installed and/or function correctly and lead to the expected results;

XX - thermal qualification: documented verification that the equipment or area of controlled temperature ensures thermal homogeneity inside;

XXI - quarantine: temporary retention of products, isolated physically or by other means that prevent their use, while awaiting a decision on their destination;

XXII - reception: set of activities related to arrival, checking and internalization in stock of goods and products;

XXIII - Quality Management System (QMS): is a system composed of an organizational structure, procedures, processes, resources and appropriate systematic actions, with the purpose of ensuring that a product or service meets certain quality requirements;

XXIV - validation: confirmation by analysis and objective evidence that the requirements defined for a given purpose consistently leads to the expected result; and

XXV - verification: confirmation by analysis and presentation of objective evidence that the specified requirements have been met, including the process of examining the results of an activity to determine conformity with established specifications.

CHAPTER II

QUALITY MANAGEMENT SYSTEM

Section I

General requirements

Art. 4 Bonded warehouses that store goods and products subject to health surveillance must establish and maintain a Quality Management System (QMS) to ensure that the requirements of this Resolution are met and that the storage of goods and products occurs in a way that does not compromise their quality.

Sole paragraph. As part of its activities in the QMS mentioned in the caput of this article, each storage company must establish and maintain effective QMS instructions and procedures, written in an instructive manner, in clear and unambiguous language, in accordance with the requirements of this Resolution and other current normative acts.

Art. 5 The size and complexity of the company's activities must be taken into account when developing a QMS or modifying an existing one.

§ 1º The QMS must incorporate risk management principles, including the use of appropriate tools.

§ 2 Even though some aspects of the QMS are corporate, the effectiveness of the system must be demonstrated at the specific establishment level.

Art. 6º A QMS suitable for the storage of goods and products subject to health surveillance must ensure that:

I - goods and products are stored in such a way that quality is maintained;

II - all stages related to the storage process are clearly defined, systematically reviewed, demonstrating that they are capable of keeping goods and products in the required conditions;

III - operations are clearly specified, procedures are followed correctly, operators are trained for this;

IV - management responsibilities are clearly specified;

V - measures are taken for the selection and monitoring of material suppliers and services, as well as to verify the compliance of each approved supplier;

VI - there are processes to ensure the management of outsourced activities;

VII - a state of control and monitoring is established and maintained through systems effective;

VIII - there are records demonstrating that all steps required by the defined procedures and instructions were carried out as planned;

IX - the results of process monitoring are taken into account in the investigation of deviations and with the aim of taking preventive actions to avoid potential deviations that may occur in the future;

X - the instruments and equipment are appropriate and are calibrated and qualified, where applicable;

XI - continuous quality improvements are implemented;

XII - procedures are implemented for the prospective assessment of planned changes and their approval prior to implementation, taking into account regulatory requirements;

XIII - after the implementation of any change, an evaluation is carried out to confirm that the quality objectives have been achieved and that there has been no detrimental impact on the quality of the service;

XIV - the non-conformities identified are fully recorded and investigated with the objective of determining the root cause and implementing appropriate corrective and preventive actions;

XV - there is a self-inspection and/or quality audit process that regularly assesses the effectiveness and applicability of the QMS;

XVI - there are systems available with information on the storage stages that allow the complete history of a good or product to be tracked;

XVII - complaints about the service provided are recorded, examined, the causes of quality deviations investigated and appropriate measures adopted in relation to the deviations and in relation to the prevention of recurrence;

XVIII - there is adequate management of the solid waste generated; and

XIX - a program to control vectors and harmful synanthropic animals should be implemented using safe agents, regularized with the competent bodies and which do not pose a risk of contamination to stored products.

Art. 7º The QMS must be defined and documented.

Sole paragraph. A Quality Manual or equivalent documentation must be established and contain a description of the QMS, including management responsibilities.

Section II

Managerial responsibility

Subsection I

Quality policy

Art. 8 The company's senior management must establish its policy and objectives of commitment to quality, which must be measurable and consistent with the established policy.

Art. 9 The company's senior management must maintain the quality policy at all levels of the organization.

Art. 10. The company's senior management must ensure that the quality policy is described in the Quality Manual and that it is understood by all employees who may affect or influence the quality of a product.

Subsection II

Organization and responsibilities

Art. 11. Each bonded warehouse must:

I - establish and maintain an adequate organizational structure, represented by means of an organizational chart, with sufficient personnel to ensure that goods and products are stored in accordance with the requirements of this Resolution; and

II - establish the responsibility, authority and interrelationship of all personnel who manage, perform and verify quality-related work, with the necessary independence to carry out their responsibilities and provide adequate resources and designate trained personnel to perform the activities.

Art. 12. The company must designate an individual from senior management who, regardless of from other functions, have authority and responsibility to:

I - ensure that the QMS requirements are established and maintained in accordance with this Resolution; and

II - report the performance of the QMS to the company's senior management for review and provide information on improving the QMS.

Sole paragraph. The designation referred to in the caput of this article must be documented.

CHAPTER III

GUYS

Art. 13. The company must have an appropriate number of employees with adequate qualifications, ensuring that the responsibilities assigned individually are not so extensive as to present risks to the quality of goods and products.

Art. 14. Individual duties and responsibilities must be formally described and fully understood by those involved, who must have sufficient authority to perform them.

Art. 15. Requirements related to health, hygiene and personnel clothing, according to the activities to be carried out.

Art. 16. The system for training employees whose duties have an impact on the QMS must be described.

§ 1º The employees referred to in the caput of this article must receive initial and periodic training, in accordance with the complexity of the activity and compatible with the training action carried out.

§ 2 Records must be kept that allow the identification of the trainee, the date of execution and the workload, as well as the strategy used, the subjects covered and the evaluation of the effectiveness of the training.

§ 3º The training requirements relevant to each job position, expressed by the policies, programs, procedures and forms must be defined and formalized.

Art. 17. It is forbidden to smoke, eat, drink (with the exception of drinking water, which must be available in a specific sector), chew, keep plants, food, personal medicines, personal objects or any object foreign to the sector, in the storage, receiving and shipping areas.

CHAPTER IV

FACILITIES AND EQUIPMENT

Section I

General requirements

Art. 18. The exercise of the activity of storage of goods and products subject to surveillance Sanitary care in a bonded warehouse requires, at a minimum:

I - separate receiving and shipping areas;

II - area dedicated to the storage of goods and products subject to health surveillance;

III - area or location for storage of prohibited goods and products;

IV - area or location for storage of products subject to the special control regime, when applicable;

V - area or location for storage of goods and products in quarantine;

VI - storage area for products containing radionuclides, when applicable;

VII - area or location suitable for carrying out physical and remote inspection of cargo, including in refrigerated locations (when applicable);

VIII - cleaning materials storage area;

IX - administration area;

X - canteen, dining room or outpatient clinic area, where applicable, and changing rooms, toilets and washrooms, without direct communication with storage areas; and

XI - systems available with information on the stages of receiving, storage (including movement and handling), shipping and status of the good or product (such as available, blocked, interdicted, lost, released, shipped).

§ 1 Warehouses that receive medicines and pharmaceutical supplies that do not require special storage conditions must have, at a minimum, facilities that keep the products at a maximum temperature of 30°C at all stages of storage.

§ 2º When the separation required in item I of the caput of this article is not possible, the use of means that prevent the crossing of flows, exchanges and mixtures must be ensured.

§ 3 Any storage areas must have restricted access, and the areas or locations indicated by items IV and VI of the caput of this article must be separated from the others and must have differentiated access control.

§ 4º The separation required in § 3º regarding the area or location indicated in item IV of the caput of this article may be made by means of walls or bars, provided that they completely prevent access to the products.

§ 5 The access door to the area or location indicated in item IV of the caput of this article must remain locked, being accessible only to persons authorized by the responsible pharmacist, in accordance with the specific legislation in force.

§ 6º The replacement of the physical area described in items III and V of the caput of this article by a system qualified computerized is possible.

§ 7 The areas mentioned must protect goods and products from inclement weather, such as rain, wind, extremes of heat, cold and solar radiation, dust and harmful synanthropic animals, and keep them in conditions that meet the product conservation specifications.

Art. 19. Goods and products that present a risk of fire or explosion and other dangerous products must be stored in safe and protected areas, properly segregated and identified, in accordance with specific legislation in force.

Art. 20. All storage areas for goods and products subject to health surveillance must be equipped with the necessary instruments to monitor temperature and humidity.

§ 1º Monitoring must be carried out by instruments positioned in accordance with the thermal qualification study of areas with temperature control or in accordance with thermal mapping in other areas that store products under health surveillance and must be representative of temperature variations throughout the day.

§ 2º Monitoring must be recorded, and records must be kept for at least 2 (two) years after its generation.

§ 3 In the case of thermolabile products, monitoring must be continuous.

§ 4º Instruments must be calibrated in the temperature range they will measure, before their first use and at intervals defined and justified by the instrument's performance and measurement sensitivity.

§ 5º Monitoring of areas cannot be interrupted during calibration of the instruments, and there must be spare instruments for maintaining the measurement.

Art. 21. Storage areas for goods and products subject to health surveillance that require controlled temperature must be equipped with the equipment and instruments necessary to control the required temperature.

Art. 22. The facilities must have dimensions compatible with the volume of operations carried out.

Art. 23. The facilities must have smooth surfaces, without cracks and without dust release, to facilitate cleaning and avoid contaminants, and must be kept in good condition.

Art. 24. The facilities must be in satisfactory hygienic and sanitary conditions and be clean. with the aid of equipment and sanitizing agents approved for this purpose.

Sole paragraph. The cleaning operations referred to in the caput of this article must be recorded.

Art. 25. The facilities must be equipped with adequate lighting to allow all operations are carried out accurately and safely.

Art. 26. Areas intended for maintenance, when existing, must be separated from areas storage.

Sole paragraph. Repairs, maintenance and calibrations carried out must not compromise the quality of stored products.

Section II

Qualifications and Validations

Art. 27. Computerized equipment and systems that impact product quality must be qualified or validated before use and periodically, or after any change considered significant.

§ 1º All areas with temperature control must be qualified, usually in three stages: installation, operation and performance.

§ 2º The conditions of routine warehouse operations must be represented in the thermal qualifications of temperature-controlled areas.

§ 3º The protocols used for qualifications and validations must be based on standards Brazilian or internationally recognized references.

§ 4º Risk analysis can be used as a tool to waive the need for qualification of equipment that does not have an impact on quality.

Art. 28. There must be a preventive maintenance program for equipment that has an impact on quality.

CHAPTER V

STORAGE

Section I

General requirements

Art. 29. The storage conditions of goods and products must follow the specifications of the manufacturer of the good or product or, in the case of human biological material, as required by the importer.

Sole paragraph. If information on storage conditions of goods and products are not available in the cargo manifest, the warehouse must request them from the importer.

Art. 30. The conditions of receipt, storage (including movement and handling) and dispatch must be recorded to allow the complete history of a good or product to be tracked.

Art. 31. There must be contingency plans to protect goods and products stored in temperature-controlled areas in the event of a power failure or failure of refrigeration equipment.

Art. 32. Products must not be placed directly on the floor or against walls, must be kept at a minimum distance from the ceiling and must not be in places where direct sunlight hits them.

Art. 33. Pallets must be made of a material that allows cleaning and does not constitute a source of contamination, such as treated wood, aluminum or plastic materials.

Art. 34. Storage must follow a logical addressing that avoids exchanges and provides the unequivocal location of the stored products.

Art. 35. Storage must comply with the load configuration (such as stacking) established for the good or product.

Art. 36. Any good or product that poses a risk to other goods and products subject to health surveillance must be stored separately.

Section II

Receipt

Art. 37. Each operation involving the receipt of goods or products subject to health surveillance is I need to check and record:

I - if the good or product has a special control regime according to Ordinance No. 344, of May 12, 1998, or any other that may replace it;

II - transportation and storage conditions, including special temperature and humidity requirements, if applicable;

III - the quantities received against the bills of lading, cargo manifest and invoice; and

IV - the integrity of the cargo.

Art. 38. Stored cargo must have identification that allows traceability with the bill of lading or equivalent document.

Art. 39. Cargo that does not comply with the receipt requirements must be placed in quarantine while awaiting their disposal by the quality area.

§ 1º In the event of non-compliance with the requirements upon receipt or discrepancies in the information, the importer must be notified.

§ 2 While the cargo remains in quarantine, the storage conditions specified by the manufacturer of the good or product or, in the case of human biological material, by the importer must be maintained.

Section III

Thermolabile Goods and Products

Art. 40. Exposure to ambient temperature must be minimized during the receipt, movement, inspection and dispatch of thermolabile goods and products, including the adoption of refrigerated areas next to the receiving and dispatch spaces, when necessary.

Sole paragraph. The total time of exposure of thermolabile goods and products to temperature environment, during the operations referred to in the caput of this article, must be recorded.

Art. 41. Equipment used in the storage of thermolabile goods and products must have, in addition to the primary source of electrical energy, an alternative source capable of providing immediate energy supply in the event of failure of the primary source.

Sole paragraph. The time for activating the alternative source and the duration of the energy supply from the alternative source must be known.

Art. 42. In each temperature-controlled area there must be an alarm system to minimum and maximum temperatures, so that contingency measures can be adopted, if necessary.

Art. 43. Emergency cooling alternatives, such as liquid nitrogen or dry ice, may be acceptable, provided that the conservation conditions established by the manufacturer of the good or product or, in the case of human biological material, by the importer are maintained.

Sole paragraph. When adopting the alternatives referred to in the caput of this article, precautions must be taken to prevent temperature excursions below the specified minimum.

Art. 44. The movement of stock of thermolabile goods and products must be planned. in advance to minimize temperature variations.

CHAPTER VI

QUALITY DOCUMENTATION AND RECORDS

Art. 45. Documentation constitutes an essential part of the QMS, being fundamental to operating in accordance with the requirements of Good Storage Practices.

§ 1 The various types of documents and media used must be fully defined in the QMS of the company.

§ 2 Documentation may exist in a variety of forms, including printed media, electronic or photographic.

§ 3 The documentation system used must establish, control, monitor and record all activities that, directly or indirectly, affect all aspects of the quality of the stored products.

§ 4 The documentation constituting the QMS must include sufficient instructional details to facilitate common understanding of the requirements, in addition to allowing satisfactory recording of the various processes and evaluation of any observations, so that the continued application of the requirements can be demonstrated.

Art. 46. Each company must establish and maintain document control procedures to ensure that all quality documents are correct and suitable for their intended use.

Art. 47. Each company must designate people from the Quality area to evaluate and approve all quality documents prior to their issuance.

§ 1º The approval referred to in the caput of this article, including the date and manual or electronic signature of the person responsible for approving the documents, must be documented.

§ 2º Documents must have unique identification and the effective date must be defined.

§ 3 The documents must include the names, positions and sectors of the developers, technical reviewers, quality reviewers and approvers.

§ 4 The preparation, review and approval stages must be carried out by different people.

Art. 48. Each company must ensure that all documents are up to date and available at the places of application and that all unnecessary or obsolete documents are removed from use, or protected from unintended use.

Art. 49. Each company must keep records of changes in documents that must include:

I - the description of the change;

II - identification of altered documents;

III - identification of the affected documents;

IV - identification of the person responsible for the change;

V - the date of approval of the change; and

VI - the date on which the change comes into effect.

Art. 50. A list of current documents must be maintained in order to identify the situation of documents and ensure that only current and approved documents are in use.

Art. 51. All quality documents and records must be legible, readily retrievable, and stored using security measures against any unauthorized modification, damage, deterioration or loss.

Sole paragraph. The correction of registered data must be carried out by means of justification, need for change, preserving the possibility of reading the originally recorded data.

Art. 52. All documents and records archived digitally must have a copy of security.

Art. 53. Procedures and instructions must be maintained for at least 5 (five) years after its obsolescence.

§ 1º Manual or electronic records made must be kept for the same period provided for in the caput of this article, with the exception of temperature and humidity records.

§ 2º Access to the documents and records mentioned in the caput and §1º of this article must be restricted to people delegated by the SGQ.

CHAPTER VII

OUTSOURCING

Art. 54. Outsourcing of activities that impact the quality of stored products must be preceded by approval of the contract by the QMS.

§ 1 The approval referred to in the caput of this article results from the qualification of the provider of the contracted service.

§ 2º The qualification of the provider must be guided by the verification of specific requirements and must be registered.

§ 3 The maintenance of the provider's status as qualified must be periodically reassessed using indicators established for this purpose.

Art. 55. The contract between the contractor and the contractor must establish the responsibilities of each party.

Sole paragraph. The contract referred to in the caput of this article must provide that the subcontracting depends on prior evaluation and approval by the original contractor.

Art. 56. The contractor must provide the contractor with all the information necessary to carry out the contracted operations correctly, in accordance with the quality requirements and any other legal requirements.

Art. 57. The contractor and the contractor must be able to meet the legal and regulatory requirements applicable to them.

Art. 58. The contractor must have adequate facilities and qualified personnel to satisfactorily perform the service requested by the contractor.

CHAPTER VIII

CORRECTIVE AND PREVENTIVE ACTIONS

Section I

General requirements

Art. 59. Each enterprise shall establish and maintain procedures for:

I - analyze work processes and operations, quality audit reports, quality records, maintenance and qualification records, complaints and other sources of quality data, in order to identify existing and potential causes of nonconformities related to the process or QMS;

II - investigate the cause of non-conformities related to the process or the QMS;

III - identify and execute the necessary actions to prevent the occurrence, correct what happened and prevent the recurrence of non-conformities;

IV - verify the effectiveness of the corrective action;

V - record activities related to corrective and preventive actions;

VI - ensure that information about quality problems is properly disseminated to those directly involved in maintaining quality or preventing the occurrence of such problems;

VII - submit relevant information about identified quality problems and preventive and corrective actions to the company's senior management for knowledge and monitoring, as well as to the competent health authority, when applicable.

§ 1º With regard to item II of the caput of this article, in cases where the true root cause(s) of the problem cannot be determined, consideration should be given to identifying the most likely root cause(s) and addressing them.

§ 2º With regard to item II of the caput of this article, when human error is suspected or identified as the cause, this must be justified, taking care to ensure that errors or problems in the process, procedure or system have not been overlooked, if applicable.

§ 3º In order to comply with the provisions of item IV of this article, any change made, where applicable, must observe change control procedures.

Section II

Complaints Management

Art. 60. A customer service must be established and disclosed to customers for the receipt of complaints.

Art. 61. Complaints relating to the quality or integrity of goods and products subject to health surveillance must be registered and investigated.

§ 1º The investigation must classify the complaints as valid or unsubstantiated, confirming or discarding related nonconformities.

§ 2º The investigation is responsible for defining the root cause of the problem, assessing the impacts on assets and products and communicate to the importer and, if necessary, to the health authority.

§ 3 The investigation must consider the possibility that other products may have been affected by the same root cause.

§ 4 Corrective actions must be defined, implemented and monitored for situations in which the recurrence of non-compliance poses a risk to the products.

Section III

Self-inspections

Art. 62. Processes with an impact on Quality must be self-inspected in accordance with frequency established and justified by the company.

Art. 63. Self-inspections must be conducted by non-affiliated professional(s) hierarchically to the process or department inspected.

Sole paragraph. The professionals referred to in the caput must be specifically trained for the self-inspection activity to assess Good Storage Practices, as established in this

Resolution.

Art. 64. Self-inspections must be compiled into reports with the following information: minimum:

I - identification of the inspection team;

II - period;

III - non-conformities identified;

IV - corrective and preventive actions listed and their respective completion and implementation deadlines;

V - actions to monitor the adoption and effectiveness of corrective and preventive actions; and

VI - assessment and agreement of the heads of each affected department and the senior management company administration.

CHAPTER IX

CERTIFICATION OF GOOD STORAGE PRACTICES IN BONDED WAREHOUSES

Art. 65. Certification of Good Storage Practices in Customs Warehouses is optional and is subject to the existence of a technical opinion from the competent area of Anvisa attesting that the establishment meets the technical requirements for Good Storage Practices set out in this Resolution.

Sole paragraph. The request for Certification referred to in this Resolution will be rejected when there is a technical report that attests:

I- failure by the establishment to comply with the technical requirements of Good Practices Storage;

II- the unilateral cancellation by the establishment of inspections agreed between the parts;

III- the imposition of an obstacle by the establishment to receiving health inspections from Anvisa, including requests to change the inspection date motivated unilaterally by the establishment and not accepted by Anvisa; or

IV- the absence of documentation capable of proving that the establishment provides services to technical requirements of Good Storage Practices.

Art. 66. The analysis of Certification petitions is carried out in chronological order of the date of filing.

Art. 67. Once the process of analyzing the Certification petition has begun, which constitutes the exercise of police power by Anvisa, requests to reuse the fee for other purposes will not be accepted.

Art. 68. Validity of the Certification of Good Storage Practices in Warehouses Customs is 4 (four) years, counted from the date of its publication in the Official Gazette of the Union.

Art. 69. The Certification of Good Storage Practices in Customs Warehouses will be cancelled at any time, whenever there is a technical opinion that certifies that the establishment does not meet the technical requirements of Good Storage Practices.

Art. 70. Certification of Good Storage Practices in Customs Warehouses will be granted for each establishment and class of stored product.

Art. 71. The following Certifications of Good Storage Practices in Customs Warehouses are subject to petition:

I - Certification of Good Storage Practices for Medicines and Pharmaceutical Supplies in Bonded Warehouses; and

II - Certification of Good Storage Practices for Medical Devices in Bonded Warehouses.

Art. 72. In order for Certification to occur without interruption of continuity with the Certification in force, the petition for Certification of Good Practices must be filed within the time period between 270 (two hundred and seventy) and 180 (one hundred and eighty) days before the expiration of the current Certificate.

Art. 73. In the case of article 72 of this Resolution, having assessed the technical and protocol requirements set out in this Resolution, Anvisa must express its opinion on granting or denying the new certification by the Certificate's expiration date.

Art. 74. The absence of a statement, as set out in article 73 of this Resolution, gives rise to the publication by the technical area, up until the expiration date of the current Certificate, of the automatic renewal of the Certificate, unless the time resulting from compliance with requirements by the company impacts the fulfillment of this deadline.

§ 1º The automatic renewal of the Certificate does not exclude the possibility of its analysis and eventual cancellation, at any time, if it is proven that the establishment does not comply with the Good Storage Practices requirements.

§ 2 For the purposes of the provisions of the caput and except for the cases provided for in §1 of this article, any situation in the petition for Certification of Good Practices that does not determine the publication of the approval or rejection in the Official Gazette of the Union by the expiration date of the current Certificate shall be considered as the absence of a statement by the health authority.

Art. 75. The request to change the corporate name in the Good Practices Certificates Current storage is possible, without changing the validity date of the current Certificate.

Art. 76. Petitions for Certification of Good Storage Practices in Customs Warehouses filed between the date of publication of this Resolution and its entry into force will be analyzed as provided for in this Resolution.

CHAPTER X

FINAL PROVISIONS

Art. 77. When requested by the competent health surveillance bodies, companies must provide information or deliver documents, within the established deadlines, as well as comply with the Health Notification, so as not to impede the surveillance action and the measures that may be necessary.

Art. 78. Anvisa may, at any time, preventively suspend the storage of goods and products subject to health surveillance in customs warehouses when the activity poses a risk to the quality or integrity of the products.

Art. 79. The deadline is set until September 1, 2025 for the completion of the thermal mapping of storage areas, mentioned in § 1 of article 20 of this Resolution.

Art. 80. The deadline is set until March 2, 2026 for the completion of the performance qualifications of all equipment and validation of computerized systems that impact product quality, mentioned in article 27 of this Resolution.

Sole paragraph. Installation and operation qualifications must be completed on the date this Resolution comes into effect.

Art. 81. Failure to comply with the provisions contained in this Resolution constitutes a health infraction, in accordance with Law No. 6,437 of August 20, 1977, without prejudice to other applicable civil, administrative and criminal liabilities.

Art. 82. Annex III of the Collegiate Board Resolution - RDC No. 346, of 16 December, is hereby revoked. December 2002, published in the Official Gazette of the Union No. 245, of December 19, 2002.

Art. 83. This Resolution shall come into force on March 3, 2025.

ANTONIO BARRA TORRES
CEO

This content does not replace that published in the certified version.