

TECHNICAL ASSISTANCE AND MAINTENANCE OF MEDICAL DEVICES

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**ABIMED - Brazilian High Technology
Health Products Industry Association**



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Positioning and Normative Framework for the Topic

INTRODUCTION

ABIMED and its members warn about the importance of hiring duly authorized and trained companies and professionals to perform corrective and preventive maintenance services on medical equipment. This is high-technology equipment and only a qualified team, with specific training and which does refresher courses continuously, can ensure the best service and the correct functioning of the equipment.

The companies that hold the product registration at ANVISA (National Agency of Sanitary Surveillance, the Brazilian sanitary authority) have the direct support of their factories, both in the national territory and abroad, guaranteeing access to the best and most experienced engineers, who support the most complex cases. In this sense, the contracting of service providers—who are not properly trained by the legal manufacturer of the product in the country or who are not authorized by the manufacturer or registration holder at ANVISA—can represent a risk not only for the good performance of the product and the quality of service provided by the health care provider, but above all for the health and physical integrity of patients and users.

Manufacturers and equipment registration holders respectively follow strict manufacturing, import and distribution norms, which establish traceability requirements for the identification of components, manufacturing materials, intermediate and finished equipment throughout the production, storage, distribution, and installation stages of its equipment, parts, and accessories. Repair parts—when not provided by the equipment manufacturer—lose their traceability, which implies in the absence of relevant information to the Quality System, hindering the process of ensuring the correct functioning of the equipment in use, as well as carrying out any recall recommended by the manufacturer.

Furthermore, according to ANVISA'S Resolution RDC 16/2013, the manufacturer must establish and maintain procedures to ensure that the finished products submitted to technical assistance by the manufacturer or its representative, satisfy the original product specifications. Thus, services provided by third parties not approved by the manufacturer or product registration holder do not have protocols that can guarantee the original product specifications.

In addition to the aspect of quality, the use of non-original parts in the equipment can mischaracterize them, being tantamount to their adulteration. Such occurrence is subject to notification at ANVISA, in accordance with ANVISA'S Resolution RDC 67/2009, which "Provides for technovigilance normative applicable to medical devices registration holders in Brazil."

In view of the foregoing, this document aims to warn about the risk of contracting services from a company not authorized by the manufacturer or registration holder and the use of parts of unknown origin. Thus, we emphasize the responsibility on the part of health care providers to define and standardize criteria for each stage of health technology management established by ANVISA'S Resolution RDC 509/2021, aiming at the protection of workers; the preservation of public health and of the environment, and, above all, patient safety.

CONSIDERATIONS BASED ON THE CURRENT NORMATIVE FRAMEWORK

1. OBLIGATIONS OF THE PRODUCT MANUFACTURER/ REGISTRATION HOLDER AT ANVISA

According to Federal Decree No. 8,077, of August 14, 2013, which regulates Federal Law No. 6,360, of September 23, 1976, the companies that are registration holders, manufacturers or importers of medical devices are liable to guarantee and to enforce the maintenance of the quality, safety, and efficacy of the products up to the end consumer, to avoid risks and adverse health effects, as stated in article 15, paragraph 1, of the aforementioned normative.

Additionally, as recommended in ANVISA's Collegiate Board Resolution RDC No. 67, of December 21, 2009, which "Provides for technovigilance normative applicable to medical devices registration holders in Brazil", the liability lies with the manufacturer/registration holder at ANVISA, according to the excerpt of the normative described below:

Art. 3 — For the purposes of this Resolution, the medical device registration holder is the holder of the medical device registration at Anvisa.

Single paragraph. The registration holder is legally liable for the medical device registered in his name in Brazil and, as such, is the one who must answer to the sanitary authorities about any technical complaint, adverse event, situation of serious threat to public health, alert, action in the field, and other occurrences that represent sanitary risk and are related to his products.

In addition, according to ANVISA's Collegiate Board Resolution RDC No. 16, of March 28, 2013, which "Approves the Technical Regulation of Good Manufacturing Practices for Medical Devices and In Vitro Diagnosis Medical Devices and provides other measures", the liability for the installation of medical devices and their technical assistance is also assigned to the manufacturer/registration holder at ANVISA, according to its items 8.1 and 8.2:

8.1. Installation. Each manufacturer must establish and maintain appropriate instructions and procedures for the correct installation of the products. When the manufacturer or its authorized representative installs a product, the manufacturer or its authorized representative must verify that it works according to established criteria. The results of this verification must be recorded. The manufacturer must ensure that installation instructions and procedures are distributed together with the product or that they are otherwise available to the one in charge of the installation of the product.

8.2. Technical assistance. Each manufacturer must establish and maintain procedures to ensure that finished products, submitted to technical assistance by the manufacturer or its representative, meet specifications.

For the performance of the technical assistance activity referred to in RDC 16/13, the registration holder at ANVISA must establish and maintain procedures that ensure the traceability of the services performed, as well as promote the analysis of these records, to carry out occasional corrective and preventive actions, if necessary, according to the excerpt from the normative described below:

8.2.1. Technical assistance records. Each manufacturer must establish and maintain procedures to ensure that technical assistance records are kept and that they identify:

- 8.2.1.1. Product subject to the service;*
- 8.2.1.2. Control number used;*
- 8.2.1.3. Date of performance of the service;*
- 8.2.1.4. Service provider identification;*
- 8.2.1.5. Description of the service performed; and*
- 8.2.1.6. Results of inspections and tests for approval of the service.*

8.2.2. Each manufacturer must periodically analyze the technical assistance records. In cases where the analysis identifies failure trends that represent danger or records involving death or serious injury, corrective/preventive action should be initiated according to the requirements of this Technical Regulation.

Besides ensuring the necessary records on technical assistance and their respective analysis, the manufacturer/registration holder must ensure the qualification of the team involved in the whole process, as described in RDC 16/13:

2.3 – Personnel

2.3.3. *Consultants. Each manufacturer must ensure that any consultant who advises on methods employed or on the controls used for design, purchasing, manufacturing, packaging, labeling, storage, installation, or technical assistance of products has sufficient qualifications (instruction, training, and experience) to advise on matters for which he was hired. The hiring of consultants must be conducted in accordance with the purchase control requirements provided for in this Technical Regulation.*

2. TECHNICAL ASSISTANCE AND PRODUCT SPECIFICATIONS

Once the liability of the manufacturer/registration holder on the product has been identified, it is necessary to assess the definition of technical assistance assigned by the competent body. RDC 16/13 defines technical assistance in its Annex—Technical Regulation of Good Manufacturing Practices for Medical Devices and In Vitro Diagnosis Medical Devices, as follows:

1.1.2. *Definitions*

1.2.1. *Technical assistance: Maintenance or repair of a finished product in order to return it to its specifications.*

Item 1.2.7 of the same normative provides the definition for the term specifications, as follows:

1.2.7. *Specifications: requirements to which products, components, production activities, technical assistance, services, quality system, or any other activity must comply.*

As described in item 4.2.1 of the same normative, the product specifications are part of the Product Master Record (or RMP, according to its abbreviation in Portuguese):

4.2.1. *Each manufacturer must keep product master records. The RMP for each type of product must include or refer to the following information:*

4.2.1.1. *Product specifications, including the respective drawings, composition, formulation, component specifications, software design specifications, and their source codes;*

[...]

4.2.1.5. Installation, maintenance and technical assistance methods, and procedures.

Considering the definitions presented above, it is possible to understand that only the manufacturer/registration holder or their representatives have the necessary information to perform the technical assistance, since only these have knowledge about the technical specifications of the products.

Thus, according to the definitions contained in RDC 16/13, it is understood that any other type of maintenance performed on medical devices that is not in accordance with (i) the methods and procedures defined in the RMP and that (ii) does not have the purpose of returning the equipment to its specifications cannot be considered technical assistance.

Still, item 4.1 of RDC 16/13, which deals with Project Control, reinforces the concept that the manufacturer/registration holder has the necessary knowledge about the products to perform technical assistance, as described:

4.1. *Project Control*

4.1.1. *General Instructions — Each manufacturer must establish and maintain product design control procedures to ensure that the requirements specified for the project are followed.*

Another normative that reinforces the point addressed above is INMETRO'S (The National Institute of Metrology, Quality and Technology) Ordinance No. 384, OF DECEMBER 18, 2020, which "Approves the Conformity Assessment Requirements for Equipment under Health Surveillance Regime—Consolidated" and emphasizes that the definitions regarding the procedures for technical assistance and product specifications are compiled in the RMP. The previously mentioned ordinance reads as follows:

[...]

4.2 *Original characteristics — They comprise the technical specifications, indication and purpose of use, physical characteristics (including the list of critical components and accessories), chemical characteristics (when applicable), the content of accompanying documents, and the markings on the equipment, which constitute the characteristics of equipment*

design at the time of granting the product certification, which must also correspond to the characteristics of the equipment regularized at ANVISA, or to be regularized at ANVISA.

[...]

4.19 Product Master Record (RMP) — *Compilation of documents containing specifications, instructions, and procedures for obtaining a finished product, as well as its installation, technical assistance, and maintenance.*

3. OBLIGATIONS OF HEALTH CARE PROVIDERS

In spite of the responsibility for the performance of technical assistance and its inherent activities, whether of the manufacturer/registration holder of the product at ANVISA or its representatives, it is assigned to health care establishments to promote the management of health technologies, defined by ANVISA’s Collegiate Board Resolution RDC No. 02, of January 25, 2010, which “Provides for the management of health technologies in health care providers”, as follows:

XI — health technology management: set of management procedures, planned, and implemented based on scientific and technical, normative and legal basis, with the objective of ensuring traceability, quality, efficacy, effectiveness, safety and, in some cases, the performance of health technologies used in the provision of health care services, from its entry into the healthcare facility to its disposal, aiming at the protection of workers, the preservation of public health and the environment, and patient safety.

Article 4 of RDC 509/2021 emphasizes the liability of health care providers in managing the technologies defined above, as shown below:

“Art. 5 — The health care providers must define and standardize criteria for each stage of the management of health technologies covered by this Resolution used in the provision of healthcare services.”

Considering the excerpts mentioned in RDC 509/2021, it is possible to assume that it is the responsibility of health care providers to ensure

that the technical assistance on medical devices under their custody is carried out by a company duly trained for this purpose, to ensure that the equipment returns to its initial specifications following the procedures provided by the registration holder/manufacturer in their RMP.

Furthermore, health care providers must guarantee the formalization of the records regarding technical assistance, as presented in the excerpt below, which is an integral part of ANVISA's Collegiate Board Resolution RDC No. 63, of November 25, 2011, which "Provides for Requirements of Good Practices for the Operation of Health Care Services":

*Art. 23 — The health care service must keep available, according to its type of activity, documentation, and record referring to:
[...]*

IX — Corrective and preventive maintenance of equipment and instruments.

Still regarding the responsibilities for health care providers, the activities involving equipment that emit radiation (X-RAYS) have some specificities, as presented in ANVISA'S COLLEGIATE BOARD RESOLUTION RDC No. 330, OF DECEMBER 20, 2019, which "Establishes sanitary requirements for the organization and functioning of diagnostic or interventional radiology services; and regulates the control of medical, occupational, and public exposures resulting from the use of such technologies":

Art. 22 — The one legally liable for the diagnostic or interventional radiology service must:

I — ensure the safety; the quality of the processes; and the protection of the patients, the team, and the public in general, ensuring both the material and human resources, besides the implementation of the necessary measures to guarantee the fulfillment of the requirements of this Resolution and of the other applicable regulations;

(...)

Art. 28 — The diagnostic or interventional radiology service must establish and implement image quality normative guarantee its maintenance, and ensure that the equipment is operated only within the conditions of use established in this Resolution, in the other applicable regulations, and in the

manufacturers' specifications.

(...)

Section III

Regarding outsourced suppliers, maintenance services, technical assistance for equipment, quality control, and radiological protection

Art. 77 — The health care service must adopt mechanisms to ensure that manufacturers; importers; distributors; companies providing maintenance services, technical assistance for equipment, quality control or radiological protection:

I — meet the requirements established in this Resolution and in the other applicable regulations;

II — ensure that their technical teams are legally licensed, qualified, and aware of the performance and safety requirements of the equipment used;

III — ensure that the equipment and devices used in the tests and assessments satisfy the requirements established in this Resolution, in the manufacturers' instructions for use, and in the other applicable regulations;

IV — record all services or interventions performed in the diagnostic or interventional radiology systems, containing, at least, the identification of the health care service and the equipment involved, the details of the service, the identification of the person responsible for the performance of the service or intervention, and signature of the health care service representative;

V — when applicable, deliver the equipment to the one legally liable for the diagnostic or interventional radiology service together with the acceptance test report, the results of all tests described in the applicable regulations, in addition to the tests recommended by the manufacturer to prove the performance related to specific requirements that are not provided for in this Resolution;

VI — carry out verification after any intervention or repair in diagnostic or interventional radiology equipment, and formally certify the return to the operating conditions before the complaint; and

VII — file, for a minimum period of 5 (five) years, copies of certificates issued, equipment acceptance tests, records of technical assistance services, as well as the respective equipment destruction certificates, if any.

(...)

There are also specific obligations for health care that provide radiotherapy services, which can be verified in ANVISA'S Collegiate Board Resolution RDC No. 20, of February 2, 2006, which "Establishes the Technical Regulation for the operation of radiotherapy services, aiming at defense of the health of patients, professionals involved, and the general public", as excerpts below:

5.5.3 The institution must establish a preventive maintenance program for the radiotherapy equipment, defining the procedures and the frequency of the actions to be carried out.

5.5.4 The holder of the radiotherapy service must formally appoint a Responsible Technician for the maintenance of the radiotherapy equipment, legally licensed by the CONFEA/CREA system for such activities.

5.5.4.1 In the event the equipment maintenance service is outsourced, the radiotherapy service must enter into a formal contract with the service provider, legally licensed by the CONFEA/CREA system for such activities.

5.5.5 The holder of the radiotherapy service must ensure the safety and performance of all equipment and sources used in the radiotherapy service, regardless of whether or not he is the owner.

4. SHARED RESPONSIBILITY

In view of the obligations mentioned above for medical devices registration holders at ANVISA and for health care providers, the responsibility for ensuring their safety and quality is understood to be shared among those involved, in accordance with ANVISA'S Collegiate Board Resolution RDC No. 23, of April 4, 2012, which "Provides for the mandatory execution and notification of field actions by medical devices registration holders in Brazil", in the following excerpt:

Art. 2 — The holder of a medical device registration is the holder of the medical device registration/enrollment at Anvisa.

Single paragraph. The registration holder, as well as the other agents involved from production to use of the product, or disposal of it when applicable, are jointly and severally responsible for maintaining the quality, safety, and efficacy of the products for health care to the end consumer.

In view of the obligations reported here, it is understood that it is an obligation of health care providers to ensure that technical assistance for medical device is carried out by companies/professionals that have the necessary knowledge about the technical specifications of the products in question.

If the establishment promotes maintenance without using the technical assistance provided by the registration holder/manufacturer or their representatives, there will be no guarantee that the repair performed has complied with the procedures established by the manufacturer and, consequently, that the product will return to the technical specifications defined in the RMP, which can lead to health risks during its use.

At the same time, it is the responsibility of the manufacturers/registration holders to ensure that technical assistance is carried out in accordance with the referenced normative, either through their own staff or through third parties, duly trained, qualified and that have the necessary knowledge on the product's specifications, so that the product may return to its technical specifications provided for in the RMP.

5. REGULATION OF TECHNICAL ASSISTANCE ACTIVITY

Considering the normative referenced here, it appears that activities involving medical device are regulated and subject to inspection and/or licensing. Although there is currently no specific regulation for the licensing of companies that exclusively provide technical assistance services, the activity is duly regulated and its compliance with the current sanitary normative must be verified by the manufacturer/registration holder, since this is legally answerable for the medical device in the country, having the obligation to guarantee their safety and quality.

In cases in which technical assistance is outsourced, the manufacturer must verify compliance with the current sanitary normative, considering that the referred activity, in some cases, is similar to the production process, since its objective is to return the equipment to its initial technical specifications and, for that purpose, assistance may involve the replacement of defective parts.

Additionally, it is emphasized that technical assistance may also involve, in some cases, the storage and transportation of a medical device, when assistance is provided in a different place from where it is located. Thus, the activities involved in this transport operation must occur in accordance with the requirements of Good Practices for the Distribution and Storage of Medical Devices, presented in RDC 16/13.

6. CONCLUSION

The liability for safety and quality of products, still unused and distributed in the country, belongs to their respective manufacturers or importers, who hold the registration of the product at the National Agency of Sanitary Surveillance Agency (ANVISA).

As for the Medical Devices already in use in the national territory, the liability is jointly and severally shared between the companies that hold the registration at ANVISA and the health care providers that have the custody of the medical devices.

Thus, the responsibility for ensuring the proper use of the equipment and the maintenance of the specified technical conditions rests with the health care establishment, which should only hire companies duly qualified and trained by the manufacturer/registration holder to carry out the technical assistance, when necessary.

It is the responsibility of health care providers to define and standardize criteria for each stage of health technology management defined by ANVISA's Collegiate Board Resolution RDC No. 509, of May 27th, 2021, aiming at the protection of workers, the preservation of public health and of the environment, as well as patient safety.