Brazil: INMETRO-ANVISA-USFDA-NIST Workstream
Medical Device Conformity Assessment

1. Good Regulatory Practices in Brazil

The current Brazilian federal legislation has incorporated modern concepts of Good Regulatory Practices (GRP) that include regulatory impact assessment (RIA), prior public consultation, monitoring of international standards and compliance with international rules, notably the rules provided for in the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (WTO TBT Agreement), among others.

Law 13,874/2019, also known as the Economic Freedom Law, internalized obligations already enshrined in international principles and rules (such as the WTO TBT Agreement and guidelines of the Organization for Cooperation and Development (OECD)) that aim to carry out a prior (ex ante) regulatory impact analysis, with information and data on the possible effects of the normative act to be published by the competent body to verify the reasonableness of its economic impact. This action on the part of the Brazilian regulatory bodies must observe the principle of subsidiary and exceptional intervention of the State in the exercise of economic activities.

From this guideline, it is understood that the current Brazilian rules should be reviewed for regulatory quality control to maintain an efficient management of the legal framework in force in the country. In addition to the Economic Freedom Act, the update of the Brazilian regulatory framework to include GRP guidelines converges with other Brazilian rules, such as Decree 10.411/2019, and the international agreements recently signed by Brazil, notably the Brazil-United States Protocol on Trade Rules and Transparency (ATEC) Annex II, which brings relevant rules on transparency and GRP, already internalized in Presidential Decree 11.092/2022.

2. Roles of National Regulating Authorities in Brazil and in the U.S. regarding Medical Devices:

2.1. Brazilian National Health Regulatory Agency – ANVISA

In the Brazilian Health System, Law 8,080/1990 provided that the following is the responsibility of the health system:

(i) establish criteria, parameters and methods for the sanitary control of the quality of products, substances and services for human consumption or use;

(ii) formulate, evaluate and elaborate norms and participate in the execution of the national policy and production of inputs and equipment for health in articulation with other governmental agencies;

(iii) control and supervise procedures, products and substances of interest to health.

Subsequently, in 1999, Law 9.782/1999 that created the National Health Surveillance Agency (ANVISA), provided that it is withing the scope of the Brazilian Federal Government (“Union”) to standardize, control and inspect products, substances and services of interest to health and such competence can be executed by the Ministry of Health by ANVISA or by other governmental bodies of the executive branch, within their respective areas of expertise.

Among ANVISA's competencies are the registrations of products, in accordance with its rules of operation, coordination and execution of quality control of goods and products. In the definition of products are included medical-hospital equipment, dental hemotherapy, as well as diagnostic and imaging equipment.

Before the creation of ANVISA, in 1994, the Quality Assurance System of Health Products (Proequipo) of the Ministry of Health had already been established, through Ordinance 2,043/1994, then repealed by Inter-ministerial Ordinance 692/2009.

The Inter-ministerial Ordinance 692/2009 (involving the Ministry of Health and the Ministry of Development, Industry and Commerce) formalized a technical cooperation agreement between the health system (led by ANVISA) and the metrology system (led by INMETRO) to conduct quality control of medical devices. The ordinance provides, among other provisions, the role of INMETRO as a body for establishing compulsory testing and certification requirements of medical products originally regulated by ANVISA. Therefore, under the terms of federal legislation, ANVISA delegated to INMETRO the competence to conduct conformity assessment procedures for products regulated by ANVISA:

> "Art 5. **When required by ANVISA**, **the manufacturer or supplier of the product must carry out the conformity assessment** of the product in the laboratory part of the System, in accordance with section IV of art. 4th.
>
> §1 **The conformity assessment program to be adopted for the products covered by this Ordinance will be defined by ANVISA, in cooperation with INMETRO**, within the scope of SBAC.
>
> § 2 In assessing the conformity of products, specific technical regulations must be used or, if they do not exist, the Technical Standards of the Brazilian Association of Technical Standards (ABNT), or the technical standards of international recognition, primarily in that order."[1]

ANVISA has internally implemented a system of good regulatory practices (GRP), aiming to improve the quality of its regulation, reduce costs for the public and the private sectors related to the circulation and commercialization of products regulated by it. These include: establishing the most appropriate internal processes and procedures; improvement of social participation channels and implementation of tools that provide more transparency and improvement in the management of regulation.

The actions for Regulatory Quality Improvement at ANVISA involve:

(i) Regulatory Planning (Regulatory Agenda);

(ii) Improvement of the regulation process;

(iii) Regulatory Impact Analysis (RIA), regulatory stock management and administrative simplification;

(iv) Monitoring and

(v) Regulatory Outcome Assessment (ARR).

The objective of these actions is to reduce the risks of producing ineffective or confusing regulatory instruments that unnecessarily increase the burden of regulation and without the due process of

[1] https://bvsms.saude.gov.br/bvs/saudelegis/gm/2009/pri0692_08_04_2009.html (in Portuguese only).

consultation with the sectors affected. ANVISA was one of the precursor agencies in Brazil to implement GRP, something that was later consolidated and legislated at the federal level.

2.2. National Institute of Metrology, Standardization, and Industrial Quality – INMETRO

General Context. The Brazilian legislation (Laws 5.966/1973 and 9.933/1999) established the Brazilian conformity assessment system for products, inputs and services created the National Institute of Metrology (INMETRO), linked to the Ministry of Development Industry and Commerce (MDIC).

It was established its performance as a central body with the competence, among others, to certify the quality of industrial products in general. INMETRO's competence includes, among others:

(i) the publication of technical regulations in the areas of conformity assessment of products, provided that such products are not covered by the competence of other organs of the federal public administration, including aspects related to the protection of health and life;

(ii) execute, coordinate and supervise the activities of legal metrology and compulsory conformity assessment regulated by it or delegated to it;

(iii) the registration of objects subject to compulsory conformity assessment, within the scope of its competence.

INMETRO's Internal Regulations, published through MDIC Ordinance 2/2017, constitute the main document that governs the internal activities of the entity. This document does not currently include rules for good regulatory practices. In addition to the Internal Regulations, INMETRO published in 2022 Ordinance 30/2022, which approves INMETRO's Regulatory Model, presenting the guidelines that INMETRO's regulatory processes must follow, as well as the activities arising from them, from development to implementation of rules, including market surveillance actions and identification of legal improvements, providing for the amendment of legal instruments, if necessary, such as laws, resolutions and ordinances.

Ordinance 30/2022 was designed taking into account the Brazilian legislation on GRP currently in force and establishes, among others, that:

(i) The principles and guidelines defined therein must be observed and adopted **at all stages of the regulatory activities carried out by INMETRO.**

(ii) The principles and guidelines may be detailed in guides, manuals or other communication tools.

(iii) **The edition of new normative acts must meet the guidelines of the Ordinance.**

INMETRO has a period of five (5) years from the date of publication of the Ordinance to fully implement the Regulatory Model that follows the guidelines set forth therein.

Medical device sector. INMETRO published Ordinance 384/2020, approving the Conformity Assessment Requirements (CAR) and the Specifications for the Conformity Identification Seal for Equipment under the Sanitary Surveillance Regime. These requirements are included, respectively, in Annexes I and II of the Ordinance, which also repealed the previous Ordinances 350/2010; 54/2016 and 544/2016. Specifically, Articles 1 and 2 state:

> "Art. 1 The Conformity Assessment Requirements and the Specifications for the Conformity Identification Seal for Equipment under the Sanitary Surveillance Regime - Consolidated are approved, as set out, respectively, in Annexes I and II available in http://www.inmetro.gov.br/legislacao.
>
> Art. 2 It is not the sphere of legal competence of INMETRO the technical regulation of equipment under sanitary surveillance regime, as well as the exercise of administrative police power, being INMETRO's role the supervision as to the use of the mark, focusing on compliance with the rules of Conformity Assessment."

Ordinance 384/2020 provides that it is the competence of the regulatory body, in this case ANVISA, to draw up the technical regulations applicable to products under the Sanitary Surveillance Regime. On the other hand, it is up to INMETRO to develop and approve the conformity assessment requirements that must be met by medical devices manufacturers under the sanitary surveillance regime. Therefore, there is a need to apply GRP in two different scenarios:

(i) in the process of creation and implementation of the technical regulations (RDC) by ANVISA and also;

(ii) in the process of creation and approval of the conformity assessment requirements by INMETRO.

When Ordinance 384/2020 was drafted, there was extensive discussion between the medical device sector, ANVISA and INMETRO in order to enable the application of GRP. However, INMETRO does not currently have or maintain a mandatory internal regulation requiring INMETRO rulemaking to follow GRP, as currently provided for in Brazilian legislation. This Ordinance was partially revised by INMETRO Ordinance number 254 of 06/09/2021, which changed some of its provisions. In this case, GRP procedures established in Brazilian law and already observed by ANVISA were also not observed by INMETRO.

2.3. U.S. Food and Drug Administration – USFDA

According to the FDA, manufacturers are encouraged to use FDA-recognized consensus standards in their premarket submissions. Conformance is voluntary unless a standard is 'incorporated by reference' into regulation. Demonstrating conformity with FDA-recognized standards facilitates the premarket review process. If a manufacturer elects to conform to one or more FDA-recognized consensus standards to satisfy part of a premarket review requirement, the manufacturer may submit a "declaration of conformity" to the standard. The FDA Center for Devices and Radiological Health (CDRH) has expanded its standards program to include a conformity assessment initiative working with qualified accreditation bodies and testing laboratories, the Standards and Conformity Assessment Program (S-CAP).

The S-CAP seeks to promote patient safety, advance regulatory science, and support a least burdensome regulatory framework. S-CAP fosters a collaborative approach to standards development and application by drawing upon expertise from across the product development, conformity assessment and standards communities.

S-CAP supports the FDA's mission by driving the development, recognition, and appropriate use of voluntary consensus standards for medical devices, radiation-emitting products and emerging technologies.

FDA links:
Here are some helpful links:

STANDARDS AND CONFORMITY ASSESSMENT PROGRAM (S-CAP)

Email S-CAP at: CDRHStandardsStaff@fda.hhs.gov

Standards & Conformity Assessment Program
www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#intro

FDA Recognized Consensus Standards Database
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Non-recognized Standards Database
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/nr_results.cfm

STANDARDS GUIDANCES

Recognition and Withdrawal of Voluntary Consensus Standards guidance
www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices guidance
www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff
https://www.fda.gov/media/113230/download

Accreditation Scheme for Conformity Assessment – ASCA

Email: ASCA@FDA.HHS.GOV

ASCA web page
www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca

ASCA program guidance
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program

ASCA Standards-specific guidance
Basic Safety and Essential Performance standards-specific guidance:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and

Biocompatibility standards-specific guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme

INDUSTRY EDUCATION

CDRH New Sign up at: https://public.govdelivery.com/accounts/USFDA/subscribers/qualify

CDRH Learn: Multi-Media Industry Education

- Videos, audio recordings, power point presentations, software-based "how to" modules
- www.fda.gov/CDRHLearn

Device Advice: Text-Based Education

- Comprehensive regulatory information on premarket and postmarket topics
- www.fda.gov/DeviceAdvice

Division of Industry and Consumer Education (DICE)

- Email: DICE@fda.hhs.gov
- Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
- Web: www.fda.gov/DICE

2.4. National Institute of Standards and Technology – NIST

The NIST Standards Coordination Office (SCO) is responsible for implementing the documentary standards and conformity assessment coordination provisions of the National Technology Transfer and Advancement Act (NTTAA). Under the NTTAA, NIST is assigned responsibility to coordinate federal, state, and local documentary standards and conformity assessment activities, with the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures. SCO provides guidance, training, information, and assistance to government so that industry, government agencies, conformity assessment bodies, standards bodies, and other stakeholders can successfully work together on essential standardization and conformity assessment activities.

The Standards Coordination Office at NIST serves as the focal point for federal government standards and conformity assessment coordination, operates the United States Inquiry Point for the World Trade Organization's Technical Barriers to Trade Agreement, and is a key information source for United States industry on standards-related market access issues. The Standards Coordination Office periodically publishes information related to standards and conformity assessment as a service to producers and users of such systems – both in the public and private sector.

Conformity assessment is used in Federal programs to provide confidence that requirements in legislation, regulation, policy, and procurement are met. There are a number of factors that affect a Federal agency conformity assessment program, including the agency's mission; regulations underpinning the need for the conformity assessment program; the dynamics of specific markets

and sectors in the U.S. and internationally; and the current state of conformity assessment programs within the area of interest.

The Office of Management and Budget (OMB) Revised Circular A-119 (2016) *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities* (the Circular) which establishes policies on Federal use and development of voluntary consensus standards and conformity assessment in regulatory, procurement, and program activities. The Circular provides factors for agencies to consider when assessing the effectiveness of conformity assessment options and determining the type(s) of conformity assessment activities to employ. The Circular advises agencies to work closely with OMB and NIST to identify their conformity assessment needs in such areas as regulatory compliance and enforcement, procurement, and other programmatic contexts and to assess whether the use of private sector conformity assessment mechanisms in whole or in part would be beneficial and should be considered.

The Circular refers to NIST guidance in 15 CFR § 287, which provides recommendations to agencies in evaluating the efficacy and efficiency of their conformity assessment activities. To reduce unnecessary burden and make more productive use of Federal resources, the NIST guidance suggests that each agency coordinate its conformity assessment activities with those of other appropriate government agencies and with those of the private sector. The NIST guidance does not preempt the agency authority and responsibility to make regulatory or procurement decisions authorized by statute or required to meet programmatic objectives and requirements. Federal agencies have statutory and international obligations concerning conformity assessment.

Useful link: https://www.nist.gov/standardsgov/conformity-assessment-resources-federal-agencies

3. Statement and Analysis of the GRP/TBT Challenges in Brazil

The inter-ministerial ordinance 692/2009 that established the technical cooperation between ANVISA and INMETRO does not clearly establish which of the two government entities should address issues related to conformity assessment procedures for medical products. There is an opportunity for improvement in the current regulatory production process clarifying this current framework.

ANVISA has already made reference that INMETRO is competent to define and publish conformity assessment requirements. INMETRO, in turn, has already pointed out that within the Brazilian System of Conformity Assessment, ANVISA would be a "client", from whom it receives the technical specifications from the technical regulations applicable to medical devices and from which it must follow the guidance of ANVISA. This regulatory sophistication leads to duplicate efforts and meetings to address the same issues, leaving gaps for all involved parties.

ANVISA is a regulatory agency in Brazil, responsible for issuing technical regulations for products subject to Sanitary Surveillance, and INMETRO, although not a regulatory agency, issues the mandatory compliance requirements for products subject to Sanitary Surveillance control, also becoming a regulator of these products in Brazil.

In addition to the international obligations provided for under the WTO TBT Agreement, the obligations currently provided for in Brazilian legislation and inserted in the form of guidelines in INMETRO Ordinance 30/2022 require INMETRO to perform regulatory impact analysis, public consultation and evaluation of regulatory results, among others. Thus, it is expected that the

conformity assessment requirements (CAR) will be subjected to the same rigor in the regulatory process through which the technical regulations (notably, ANVISA's RDC) that underpin them pass. Only in this way, predictability, transparency, agility, isonomy and the other principles established in INMETRO's regulatory model and in Brazilian legislation will be guaranteed.

In the current context, the implementation of GRP by INMETRO to the requirements of conformity assessment and accreditation to the certifying bodies of medical products regulated by the ANVISA is not verified. This situation generates friction and potential internal conflict between government agencies regarding different criteria and regulatory standards for medical devices that follow the guidelines of both bodies simultaneously.

The sector involved also face difficulties and may be burdened with additional costs related to the establishment of conformity assessment procedures (CAP) that have not always had their regulatory impacts properly measured by observing international GRP rules, including the use of internationally recognized conformity assessment documents, standards and practices and end up creating barriers to trade (notably in non-compliance with the WTO TBT Agreement).

Brazil's medical device regulatory framework as led by ANVISA is internationally recognized as a global and regional reference with the medical device conformity assessment aspects as managed by INMETRO in a position to benefit from deeper implementation of new GRP requirements. In particular, INMETRO currently lacks mandatory internal structuring that enables the implementation of good regulatory practices, along the lines already carried out by ANVISA. There is sometimes a fragility of the regulatory system due precisely to the joint role of the two bodies, due to lack of clarity about the limitations of each one and how the GRP are applied by the delegated body (in this case, INMETRO).

Considering that INMETRO is Brazil's focal point in the WTO before the TBT committee, it is even more opportune for this regulatory body to implement mandatory GRP and serve as a positive showcase for the country in the international field.

4. Recommendations on GRP implementation in Brazil:

1. **Overall**:
    - Application of mandatory GRP in two distinct regulatory processes: (i) in the process of creation and implementation of the RDC by ANVISA (already ongoing) and also (ii) in the process of creation and approval of the conformity assessment requirements by INMETRO.
2. **How**:
    - Define, by legal or regulatory means, that INMETRO, - as the producer of conformity assessment requirements, which must be complied with by medical devices manufacturers under the Sanitary Surveillance Regime, - is obliged to apply the GRP rules contained in Brazilian legislation and in its own internal structure. The CAR and other rules applicable to the conformity assessment procedures produced by INMETRO must undergo regulatory impact analysis, public consultation and evaluation of regulatory results, among other rules applicable to the regulatory process.

- Option 1 – In case INMETRO wishes to establish a specific self-regulatory procedure for GRP compliance, in an internal mandatory regulation, thus, extending the voluntary guidelines published in INMETRO Ordinance 30/2022, INMETRO may use a compliance checklist for the creation of CAR and regulations. The checklist, of a general nature, applicable by any regulatory authority, regardless of the country or sector regulated, could give rise to INMETRO's own internal regulations for compliance and application of GRP by the body in its technical regulations and in the CAR applicable to the medical device sector.
- Option 2 - Amendment of article 3 of Inter-ministerial Ordinance 692/2009 to include the mandatory use of GRP standards already applied by ANVISA in the specific regulations applicable to the products defined in the Ordinance, even if elaborated, edited or published by INMETRO. Considering that the competence of INMETRO in this case is delegated by ANVISA, the regulatory standards of the Agency of original competence could dictate the performance of the delegated body, in favor of regulatory coherence and economy.
- Option 3 - The government may also consider requiring – as an inter-ministerial obligation – that regulatory agencies that delegate regulation to other regulatory bodies, stipulate the GRP process by which the latter must follow in the delegated regulation (e.g., ANVISA RDCs that delegate conformity assessment to INMETRO), and that such policies be consistent with those of the originating agency – in addition to complying with the broader policy of the Brazilian government in relation to TBT and GRP.

3. **Stakeholders' interaction.** Maintain a single point of contact within the government responsible for technical regulation and CAR of medical devices, even for those rules whose competences have been delegated from one regulatory agency (such as ANVISA) to another regulatory agency (such as INMETRO). This responsibility should cover the entire life cycle of the technical regulation including all GRP steps and also serve as the single point of contact with the public about the regulation.

4. **Participation in international fora.** From a GRP, regulatory, standards and conformity assessment perspective, it would be coherent for INMETRO to participate in the meetings of the *International Medical Device Regulators Forum (IMDRF*) and other international standardizing committees, including but not limited to those of ISO and IEC, to have frequent interaction and alignment with Brazil's global counterpart bodies and practices.

The reasons stated above reinforce the value of the opportunity to review INMETRO's Regulatory Model with a view to mandatorily internalize GRP rules applied to CAR as they apply to the medical device sector. The medical device sector has a long-term partnership with Brazil, ANVISA and INMETRO and continues to dialogue to try to continually increase the alignment of Brazil's rules on conformity assessment procedures with international rules and GRP.