



Overview of Brazil's Quality Infrastructure System



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Global Project Quality Infrastructure
SCN Quadra 1 Bloco C,
Ed. Brasília Trade Center
70711-092, Brasília, DF, Brasil
E info@gpqi.org | www.gpqi.org

Design

Oliver Hick-Schulz

Photo credits

Davi Costa – Unsplash, Maarten van den Heuvel – Unsplash, Maick Maciel –
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Text

Global Project Quality Infrastructure

The German Federal Ministry for Economic Affairs and Climate Action (BMWK) has
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Implemented by

Table of Contents

| | |
|---|----|
| 1 Introduction | 4 |
| 2 National Systems | 6 |
| The National System of Metrology, Standardisation and Industrial Quality (SINMETRO) | 8 |
| The National Health Surveillance System (SNVS) | 10 |
| The Unified Agricultural Health Care System (SUASA) | 10 |
| The National Environment System (SISNAMA) | 11 |
| 3 Standardisation | 12 |
| Standards development process of ABNT | 14 |
| Acceptance of International Standards in Brazil | 16 |
| 4 Accreditation | 17 |
| Accreditation Board for Certification Bodies (DICOR) | 20 |
| Accreditation Board for Testing and Calibration Laboratories (DICLA) | 20 |
| 5 Conformity assessment | 22 |
| INMETRO's conformity marking | 23 |
| 6 Market surveillance | 25 |
| INMETRO | 26 |
| 7 Metrology | 27 |
| Scientific and industrial metrology | 28 |
| Legal metrology | 29 |
| 8 Footnotes | 31 |
| 9 Other references | 32 |

1. Introduction

As South America’s largest economy, with a domestic market larger than that of Western Europe, Brazil plays an important role in regional and global trade. However, the country’s trade performance and participation in global value chains remains below its potential: in 2019, Brazil ranked as the 26th largest global exporter and 25th largest importer, despite being the world’s 9th largest economy.

The challenges of doing business in Brazil, often referred to as the ‘Brazil cost’, help explain this scenario, as the country ranked 141st in ‘burden of government regulation’ in 2019 (out of 141 economies), according to the World Economic Forum.¹ In this context, an internationally coherent quality infrastructure (QI) system can significantly improve trade facilitation and integration in global markets. As defined by leading international QI institutions,² the concept of quality infrastructure refers to a ‘system of organisations (public and private), together with the policies, relevant legal

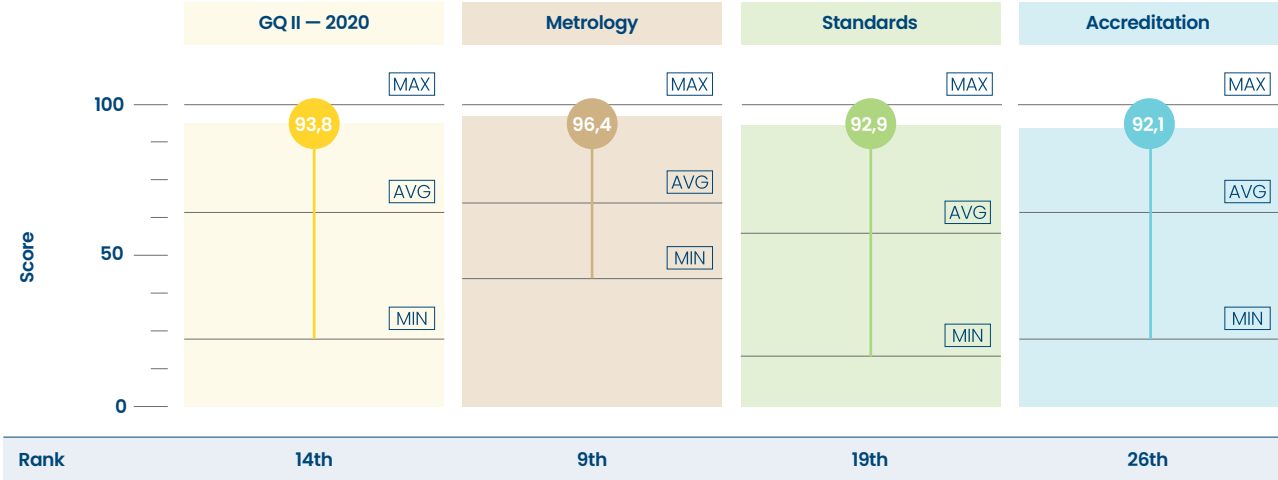
and regulatory framework and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes’.

Beyond facilitating trade, QI can underpin economic development and support policy objectives in areas ranging from consumer protection and food safety to environmental protection and climate change mitigation or adaptation.

In fact, QI systems are expected to play an important role in implementing and measuring progress towards achieving the UN’s Sustainable Development Goals, including SDG 8 on Industry, Innovation and Infrastructure.³

In Brazil, quality infrastructure is promoted by a network of interconnected institutions, systems and regulations, covering the areas of standardisation, accreditation, conformity assessment, market surveillance and metrology, as outlined throughout this study. Historically, the development of

Figure 1 – Brazil’s country profile



Source: Global Quality Infrastructure Index Report 2020

Brazil's QI system can be traced to the creation of the National Institute of Technology (INT) in 1921, which gave birth to institutions such as the Brazilian Association of Technical Standards (ABNT) in 1940 and the National Institute of Metrology, Quality and Technology (INMETRO) in 1973.

Today, after decades of consolidation, Brazil's quality infrastructure system ranks 14th out of 184 economies worldwide, according to the Global Quality Infrastructure Index – representing the most developed QI system in Latin America. As seen in figure 1, Brazil's QI system ranks 9th for metrology, 16th for standards and 26th for accreditation.

Despite significant improvements in recent decades, many challenges remain for Brazil's quality infrastructure system and overall regulatory environment. To further facilitate trade, unburden businesses and promote innovation, many sectors require institutional reform and regulatory simplification. This study provides an overview of some of the main components of the intricate web of systems and institutions responsible for quality infrastructure in Brazil, which oversee the safety, quality and environmental soundness of goods, services and processes.

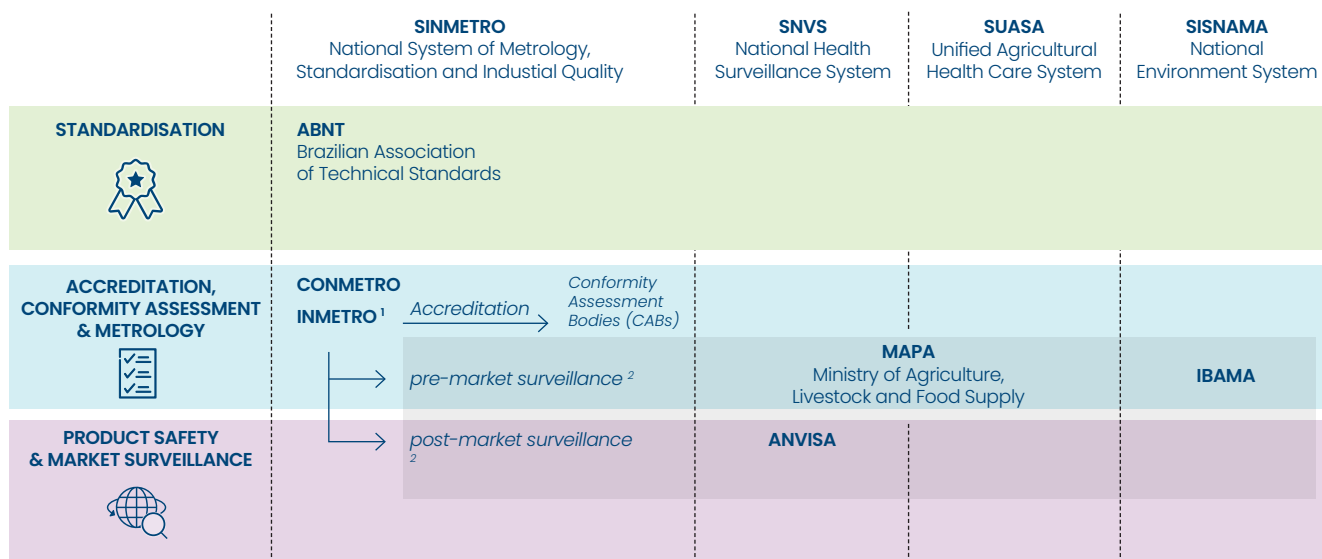


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The National System

Quality infrastructure, in Brazil, can be seen as a collection of interconnected national sub-systems in which interlinked institutions, systems and regulations address areas such as standardisation, accreditation, conformity assessment, market surveillance and metrology.

Figure 2 – Overview of the national quality infrastructure systems



¹ Inmetro has the status of federal autarchy linked to the Ministry of Economy (ME)

² Pre-market surveillance via product registration and import licensing requirements

Brazil's quality infrastructure (QI) system is composed of a collection of interlinked national 'sub-systems', which comprise sectoral ministries and their corresponding implementing bodies.

National technical regulations are prepared either by ministries or their implementing technical bodies (e.g. ANVISA, INMETRO, IBAMA). Although formally a part of SINMETRO, ABNT is the national standardisation body and produces standards that fall under the scope of other national sectoral systems – in fields such as environmental governance, food safety and health.

With regard to metrology, conformity assessment and accreditation, INMETRO performs the overarching roles of both national metrology institute and official accreditation body, developing product regulations and conformity assessment schemes. Although first-party conformity assessment is accepted by INMETRO under certain circumstances through a supplier's declaration, third-party conformity assessment is most often the required modality, to be carried out by independent conformity assessment bodies (CABs).

This feature has strong implications for market surveillance in Brazil's QI system, which largely centres on pre-market mechanisms – such as product registration and import consents before a product

is placed into the market. INMETRO and other regulatory bodies also implement post-market surveillance activities to a limited degree.

Within both conformity assessment and market surveillance, INMETRO shares attributions with regulatory bodies such as ANVISA, responsible for regulating and monitoring health goods, or IBAMA, which provides certification for certain environmental products.

In addition, there are technical regulations that do not fall under the above-mentioned sectoral 'sub-systems', but are part of Brazil's QI system. They include the so-called Regulating Norms (NRs – Normas Regulamentadoras), which aim to regulate workplace safety, and therefore impact industrial activity (e.g. through machinery safety regulation). NRs have traditionally been issued by the Ministry of Labour.

Finally, there are additional agencies and ministries responsible for regulating products and services in specific sectors, such as the National Telecommunications Agency (ANATEL), or the National Traffic Council and Department (CONTRAN/DENATRAN) for transport and vehicles.

The following paragraphs describe the different 'sub-systems' of the Brazilian QI system in more detail.

The National System of Metrology, Standardisation and Industrial Quality (SINMETRO)



ABNT

The Brazilian Association of Technical Standards (ABNT) is a non-governmental institution founded in 1940 as SINMETRO's **standardisation body**. It is a founding member of ISO and a member of IEC, COPANT and AMN. ABNT is recognised by other international organisations and associations, such as IEC, IAF and ILAC. ABNT is also accredited by INMETRO, which configures ABNT as a certification body internationally recognised, since CGCRE, from INMETRO, is a member of IAF and ILAC.

ABNT's core competence is to produce Brazilian standards (ABNT-NBR), drawn up by standardising committees (ABNT/CB), sectoral standardisation bodies (ABNT/ONS) and special study commissions (ABNT/EEC). During the process of developing voluntary national standards, proposals are submitted to national public consultations before their final issuance. In addition to national standards developed entirely by committees, ABNT also adopts supporting standards based on international standards, mainly ISOs and IECs.

CONMETRO

The National Council of Metrology, Standardisation and Industrial Quality (CONMETRO) is the **normative body** of SINMETRO, responsible for formulating, coordinating and supervising the national policy for metrology, industrial standardisation and quality certification. It is an inter-ministerial council integrated by representatives of different ministries, as well as of ABNT, the National Industry Confederation (CNI) and the Institute of Consumer Protection (IDEC), among others.

INMETRO

The National Institute of Metrology, Quality and Technology (INMETRO) is the **executive body of SINMETRO, responsible for preparing, implementing and monitoring compliance with technical regulations pertaining to product quality and measurement standards**. It is a federal autarchy connected to the Ministry of the Economy's Special Secretariat for Productivity, Employment and Competitiveness (SEPEC/ME). INMETRO performs the role of national accreditation body, developing conformity assessment schemes to be implemented by independent conformity assessment bodies (CABs).

INMETRO is also responsible for monitoring and supervising the observance of technical regulations and conformity assessment schemes across the productive sector, resorting to both pre-market and post-market surveillance mechanisms (see page 26).

The scope of INMETRO's legal competence is defined by Law No. 12545/2011, which describes the Institute's responsibility for:

'Exercising power of administrative police, issuing technical regulations in the areas of conformity assessment of products, inputs and services, as long as they do not constitute the object of competence of other agencies or entities of the federal public administration, covering the following aspects:

- **safety**
- **protection of human, animal,**
- **plant life and health,**
- **protection of the environment,**
- **prevention of deceptive trade practices.**

As such, it is noteworthy that INMETRO's regulatory competence is residual – i.e. it is defined in terms of products that are not already regulated by other entities. In some cases, other regulatory bodies may also delegate to INMETRO the development of conformity assessment schemes for products regulated under their competence, usually through formal agreements.

Moreover, INMETRO's current regulatory model is based on the development of individual technical regulations per each single product and sub-product, rather than by product families or risk categories. As a result, INMETRO features limited regulatory coverage: it is estimated that only 12% of products falling under INMETRO's legal competence are effectively regulated and monitored.

Aiming to enhance regulatory effectiveness and better align its Regulatory Model with international best practices, INMETRO is currently undergoing a wide-ranging modernisation process. In June 2020, the **Working Group on INMETRO's Regulatory Model Modernisation (GTMRI)** was created to advise INMETRO's presidency on the process. In dialogue with private sector stakeholders, a **modernisation proposal** was developed and submitted for public consultation on 23 March, 2021.

The regulatory model outlined in the proposal reflects elements of the EU's New Approach and New Legislative Framework, e.g. its emphasis on general regulations with essential requirements. This contrasts sharply with INMETRO's current approach of regulating individual products with highly prescriptive requirements. The proposal also outlines the use of risk assessment to optimise conformity assessment and market surveillance.

The regulatory model is expected to be implemented over a total period of five years. During the transition period, pilot sectors will be selected to test the model's guidelines

Box 1: Modernisation of INMETRO's Regulatory Model

Aiming to facilitate business and reduce companies' regulatory burden in Brazil, the Economic Freedom Act (Law No. 13874) was passed in 2019, followed by a series of presidential decrees with requirements for federal regulators, including:

Decree 10139/2019 on the revision and consolidation of normative acts;

Decree 10178/2019 on the risk classification of economic activities;

Decree 10411/2020 on the parameters for regulatory impact analysis.

In order to implement the Economic Freedom Act's Decrees, INMETRO has enacted a series of Ordinances with direct impact on technical regulation processes, conformity assessment and market surveillance, namely:

INMETRO Ordinance No. 244/2020: Establishes parameters and deadlines for the revision and consolidation of all INMETRO's product regulations, aiming to reduce duplications and ambiguities. Through this process, INMETRO expects to reduce its regulatory stock from 778 normative acts to 306 by December 2021.

INMETRO Ordinance No. 282/2020: Determines the risk classification of products regulated by INMETRO under compulsory conformity assessment. Out of 98 products analysed, 11 were classified as low risk – thus exempt from product registration and import consent requirements (see page 26). In addition, 25 products were classified as medium risk – thus subject to simplified procedures – and the remaining 62 products as high risk.

INMETRO Ordinance No. 265/2020: Determines the risk classification of measuring equipment regulated by INMETRO under legal metrology. Out of 38 products analysed, 9 were classified as low risk – thus exempt from model approval and import consent requirements.

Box 2: INMETRO and the Economic Freedom Act

The National Health Surveillance System (SNVS)



SNVS comprises a set of actions aimed at eliminating, reducing or preventing health-related risks, by controlling and monitoring products and services with sanitary implications. Coordinated and supervised by the Ministry of Health, SNVS deals with regulations pertaining to medical devices and hospital equipment, establishing the regulatory framework that underlies key aspects of the healthcare industry.

ANVISA

The Brazilian Health Regulatory Agency (ANVISA) is an autarchy linked to the Ministry of Health. As the coordinating body of SNVS, it plays a key role in regulating and monitoring the production, marketing and use of health-related products and services. Although other state and municipal authorities have similar competences, regulation from ANVISA prevails in most cases. ANVISA's Sanitary Surveillance and its public agents are holders of so-called 'police power', allowing them to carry out administrative and surveillance acts, such as irregularity inspection, assessment and prohibition of establishment, in order to guarantee product safety and quality.

The Unified Agricultural Health Care System (SUASA)



SUASA comprises different actions focused on protecting animal and plant health, monitoring the use of agricultural inputs and ensuring product quality and safety for agricultural goods.

MAPA

The Ministry of Agriculture, Livestock and Food Supply (MAPA) is SUASA's central authority, responsible for coordinating state-level institutions in plant and animal health surveillance. MAPA is responsible for classifying and inspecting products of plant and animal origin, as well as monitoring the use of agricultural inputs: it plays a key role in pest control and the dissemination of good animal health practices, especially regarding the use of vaccines and antibiotics. The major role of MAPA in regulating sanitary and phytosanitary measures and techniques is evidenced by the various notifications made by the body to the WTO's TBT and SPS committees.



3

Standardisation

The draft and publishing of Brazilian standards is an exclusive attribution of ABNT - Brazilian Association of Technical Standards, which is the national standardisation body.

Standardisation in Brazil is largely government-driven, led by the ABNT – Brazilian Association of Technical Standards – which, as the national standards body, is exclusively authorised to draft Brazilian standards (ABNT NBR), prepared by its Brazilian Committees (ABNT/CB), Sectoral Standardisation Bodies (ABNT/ONS) and Special Study Commissions (ABNT/EEC). With regard to publicising technical standards, according to a resolution by the Brazilian Superior Court, those who acquire legal access to ABNT standards may also publicise and commercialise them ([see case Target](#)).⁴

ABNT has played a major role in the economic development of Brazil over the years by providing basic standards, product standards, test methods and codes of practices that have supported industrial development. Some of the key activities initially undertaken by ABNT in promoting standardisation included assistance to industry in developing company standards and running campaigns in engineering institutes to promote the educational use of standards.

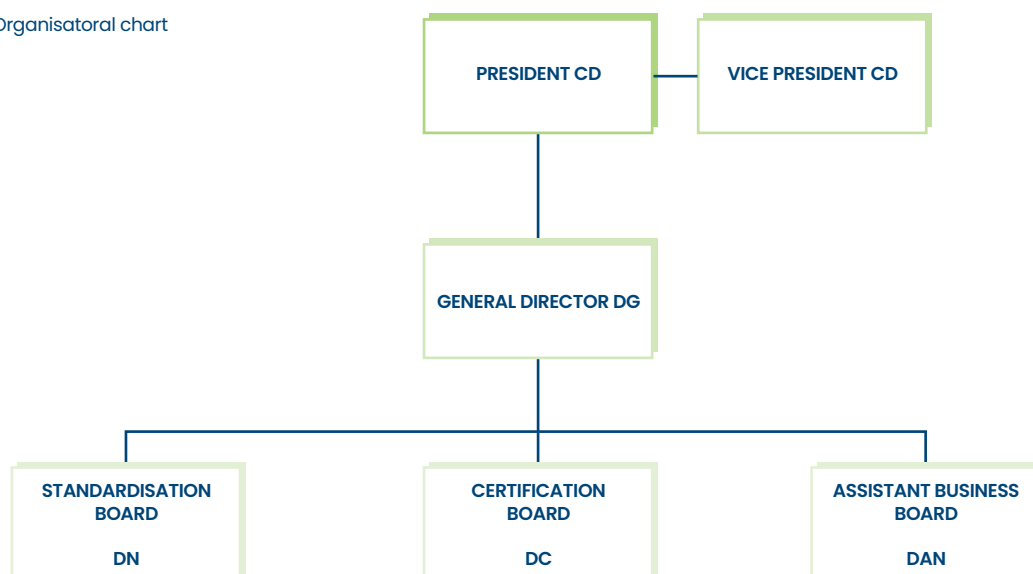
ABNT was one of the founding members of the International Organization for Standardization (ISO), where it has presided over technical committees, served as a secretariat for eight technical

committees and participated in 250 technical committees of the Pan-American Technical Norms Commission (COPNAT) and of the Association for Standardization of Mercosur (AMN). Since its founding, ABNT has also been a member of the International Electrotechnical Commission (IEC) and has presided over one IEC technical committee and participated in 120 technical committees.

ABNT participates actively in various technical committees, such as ISO TC 176 (quality), ISO TC 207 (environmental) and ISO/CASCO, in addition to the ISO/TMB (Technical Management Board). ABNT signed the WTO/TBT Code of Good Practice in 1995 and follows its Annex 3. Activities related to the accreditation and conformity assessment in SINMETRO are based on the ABNT/ISO/IEC standards and guidelines.

Established in 1940, ABNT has also been active in conformity assessment since 1950 and has programmes for the certification of products, systems and environmental labelling. This activity is based on internationally accepted technical guides and principles and based on a multidisciplinary technical and auditing structure, guaranteeing credibility, ethics and recognition of services provided.

Figure 3 – Organisational chart



Source: Adopted from ABNT

ABNT is governed by a governing council of 26 members, including representatives from the Ministry of Economy, Ministry of Science, Technology and Innovation and Ministry of Defence, as well as other state governments and union territories, consumer organisations, industry associations, scientific and research organisations and the national accreditation body.

It is important to clarify that the area of standardisation in SINMETRO is under the responsibility of ABNT, which has authority over sectoral standardisation bodies (ONS) for the performance of these tasks. Similarly, ABNT represents Brazil in ISO/IEC and in regional standardisation forums and is supported by government and private entities.

ABNT's current organigram is composed of a presidency, a vice-presidency and a general directory, under which stand three offices: the standardisation office, certification office and administration and business office (see page 13):

Standards development process of ABNT

The process of preparing an ABNT technical document is initiated based on a request, which can be presented by any person, company, entity or regulatory body involved with the subject to be standardised.

In the technical sense, the standard is a document established by consensus and approved by a recognised body. It provides for the common and repetitive use, rules, guidelines or necessary characteristics of products or related processes and production methods. Compliance with the provisions of a standard is not mandatory.

There are different kinds of supporting standards issued by ABNT, ranging from a fully original standard developed under its Standardising Committees (CBs) to those based on international standards, mainly ISO and IEC. The key is to observe the number of the standard:

1. if it is a standard identical to an international standard, it will appear, for example, as ABNT NBR ISO No. XXX;
2. if it is based on an international standard, a reference to this international standard will be in the preamble of the standard;
3. if it is an original standard, it will appear as ABNT NBR No. XXX.

Production of original standards follows a specific process: (i) the company expresses interest; (ii) a study commission draws up a standard project after analysis of the industry technical committee and inclusion in the Sectoral Standardisation Plan (PNS) by consensual decision;⁵ (iii) the project is submitted to national consultation; (iv) the standard is approved, assigned an ABNT NBR and becomes available to the public.

Participation in the standardisation process is open to any interested party and can be done in several ways:

- Requesting the preparation of an ABNT technical document: anyone can request the preparation of an ABNT technical document, for existing or potential problems that are recurrent in several companies. For this, you must send a request to the Planning and Projects Management, filling out the [request form](#).
- Participating in the preparation of a Brazilian standard: representatives of parties interested in the subject in question can participate in meetings of the study commissions (ECs) responsible for the preparation or revision of the standard. Simply [request your participation in the Study Commission](#).
- The work of the Study Commissions can be monitored by [ABNT Livelink](#)
- It is possible to get in direct contact with the relevant technical committees by using the e-mails and phone numbers on [the available list](#).

- Making recommendations to draft standards: when the EC approves the basic text, it is conformed and edited as a draft standard and is available for national consultation. At this stage, anyone can recommend the approval or rejection of the text or suggest modifications. The national consultation can be accessed through [ABNT's website](#).
- Revisiting the content of Brazilian standards: every year, Brazilian standards that have completed five years since publication have their content analysed in a process called 'systematic analysis'. At this point, a specific national consultation to society is made through the website www.abnt.org.br/consultanacional, to assess the need for such standards to be revised, maintained or cancelled.

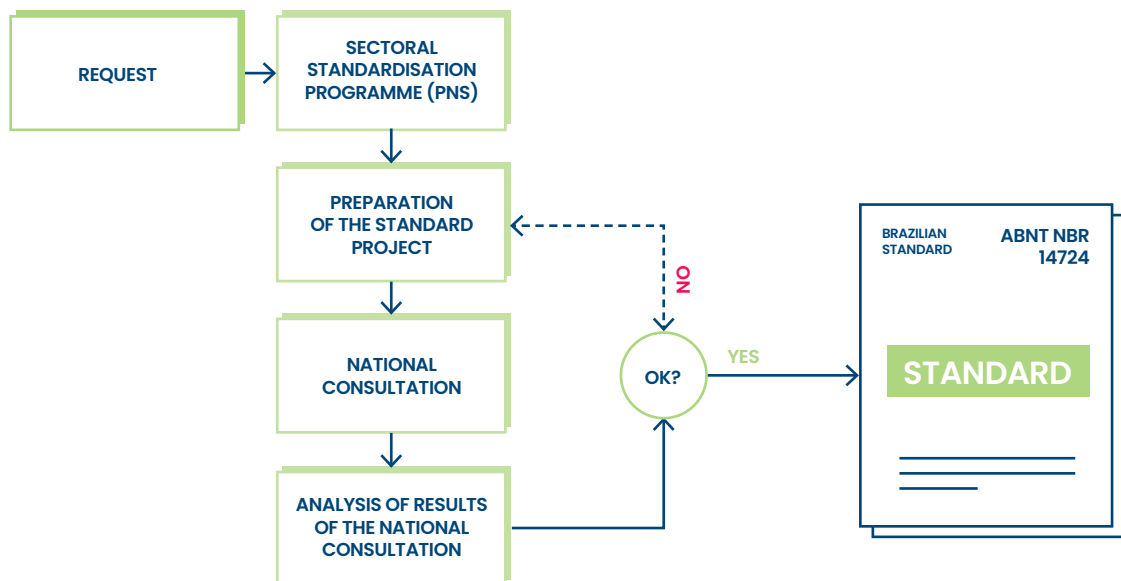
The pertinence of the request is analysed by ABNT and, if feasible, the matter is taken to the corresponding technical committee for inclusion in its Sectoral Standardisation Programme (PNS). If there is no technical committee related to the subject, ABNT proposes the creation of a new technical committee, which can be a Brazilian committee (ABNT/CB), a sectoral standardisation body (ABNT/ONS) or a special study commission (ABNT/EEC).

The subject is widely discussed by the Study Groups, with participation open to any interested party, regardless of their association with ABNT, until reaching consensus, thus generating a 'standard proposal'.

Before the standard proposal is submitted for national consultation by ABNT, it is edited and receives the acronym ABNT NBR and its respective number. After editing, the standard proposal is submitted for national consultation, with broad dissemination, thereby providing an opportunity for all interested parties to study it and offer their considerations. The national consultation is carried out via the internet and can be accessed through ABNT's website. The list of standard projects under national consultation is also published in the Federal Official Gazette.

During the national consultation, any person or entity can submit comments and suggestions. All comments are analysed and answered by the Study Commission responsible, which holds a meeting to analyse the considerations received. Any interested party that expressed itself during the national consultation process is invited to participate in this meeting, to decide, by consensus, whether this standard proposal should be approved as an ABNT technical document.

Figure 4 – Standards development process of ABNT



Source: Adopted from ABNT

Finally, accepted suggestions are consolidated in the standard proposal, which is approved and published by ABNT as an ABNT technical document.

It is important to note that the standardisation process is executed by bodies that rely on the participation of diverse stakeholders (producers, consumers, universities, laboratories, research centres and government), it must be governed by transparency principles.

Standardisation bodies are responsible for the preparation, adoption and dissemination of publicly available standards. ABNT is the main Brazilian standardisation body recognised to perform the standardisation process at national level. As such, it is a member of the corresponding regional and international organisations for standardisation.

An overview of the standards catalogue adopted by the different ABNT committees makes it possible to verify the degree of internationalisation of Brazilian standards. However, ABNT does not provide a list of all international standards adopted in full or modified by any of its committees. The search tool available requires a keyword search that goes from product to product at ABNT's website: [ABNTCatálogo](#).

| Division councils – macro | Number of technical committees |
|---|---------------------------------------|
| Electronics and information technology | 12 |
| Chemicals | 50 |
| Civil engineering | 40 |
| Food and agriculture | 24 |
| Management systems | 31 |
| Mechanical engineering and machinery | 17 |
| Household & commercial products, entertainment & sports | 32 |
| Health, safety and environment | 51 |
| Services | 11 |
| Transport engineering | 6 |
| Total | 274 |

Regarding voluntary compliance with the requirements established by a technical standard, it is worth noting that Brazil has a particularity in relation to the other countries that are signatories to international agreements. Law No. 8078, of September 1990, the Consumer Protection Code, in its article 39, paragraph VIII, states that in the absence of technical regulations, products must be placed on the market in compliance with technical standards.

Acceptance of International Standards in Brazil

On 5 February 2020, the Brazilian government signed Decree No. 10229 and in so doing took another step towards facilitating economic activity in Brazil. The decree sets out new possibilities for developing, implementing, operationalising and commercialising a product or service which does not comply with outdated national technical standards. Specifically, where Brazilian national standards are outdated, and applicable international standards (ISO, IEC, CAC, ITU, OIML) exist, economic activities in Brazil, including the marketing of products, will now be possible if they are aligned with these applicable international standards.

Decree 10229 continues the transition towards the implementation of market liberalisation initiated by Decree 10178 on risk-based procedures for product licensing, which was approved in December 2019. Decree 10178 establishes the categorisation of economic activities in three risk classes.

Both decrees were created within the framework of implementing the reforms ruled by the Economic Freedom Act (Law No. 13874), approved by Brazilian President Jair Bolsonaro on 20 September 2019. The Act aims to reduce bureaucracy in economic activities and to facilitate the opening and operation of companies in terms of investments and trade, thereby improving the overall regulatory environment in Brazil for doing business. The Government expects the law to facilitate and give greater legal certainty to businesses, with an increase of approximately 7% of national GDP in ten years.



4

Accreditation

As the national official body for accreditation, INMETRO coordinates the Brazilian Accreditation System under the administrative control of the Brazilian Ministry of Economy.

The Brazilian Accreditation System is coordinated by INMETRO – the executive body of the Brazilian National System for Metrology, Standardisation and Industrial Quality (SINMETRO) under the administrative control of the Special Secretariat for Productivity, Employment and Competitiveness (SEPEC) of the Ministry of Economy (ME). It is coordinated by INMETRO’s General Accreditation Coordination (CGCRE) – the only national official body for accreditation in Brazil.

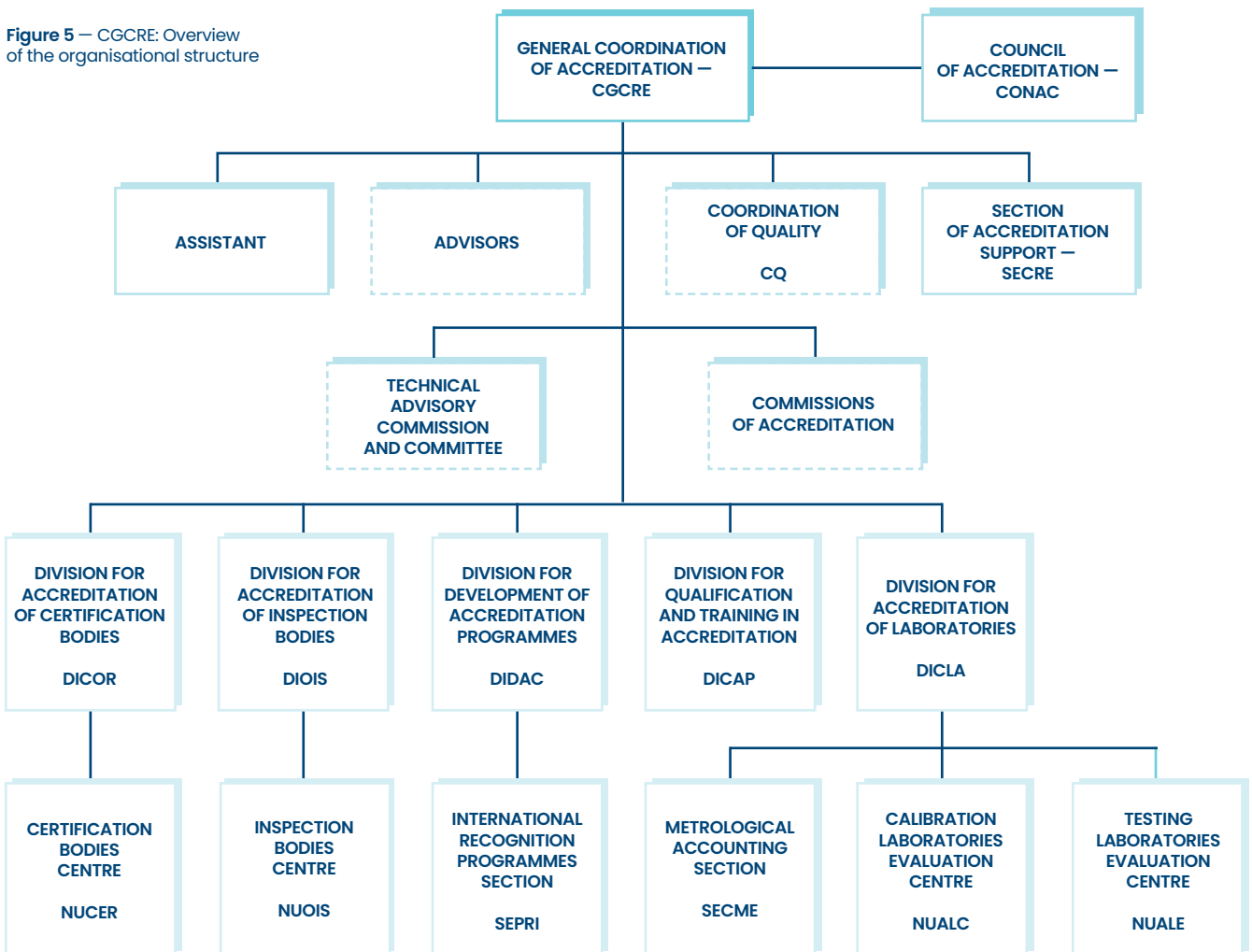
In order to safeguard the impartiality and maintenance of the main principles and policies for operating the accreditation system, CGCRE provides in its structure for the opportunity for effective participation of interested parties in the

accreditation of conformity assessment bodies (CABs) through the Council of Accreditation (CONAC).

CGCRE is responsible for the management and implementation of five accreditation ‘boards’ under the scope of the Brazilian accreditation system:

- Division for Accreditation of Laboratories (DICLA)
- Division for Accreditation of Certification Bodies (DICOR)
- Division for Development of Accreditation Programmes (DIDAC)
- Division for Qualification and Training in Accreditation (DICAP)

Figure 5 – CGCRE: Overview of the organisational structure



Source: INMETRO – Prepared by GPQI Brazil

DICLA operates under the framework of ISO/IEC 17025, the international standard for calibration laboratories and testing, and ISO15189, the international standard for the quality and competencies of medical laboratories. The other boards operate under self-regulating norms.

CGCRE has developed its own visual identity: all internal and external documents under its responsibility must display the accreditation mark; all Conformity Assessment Bodies (CABs) accredited by CGCRE must display the accreditation mark to prove their regular status.

CGCRE is a member of several international multilateral arrangements, including:

- International Accreditation Forum (IAF)
- International Laboratory Accreditation Cooperation (ILAC)
- Interamerican Accreditation Cooperation (IAAC)
- American Aerospace Quality Group (AAQG)
- Global Partnership for Good Agricultural Practice (Globalgap)
- Environmental Protection Agency (EPA)
- Programme for the Endorsement of Forest Certification Schemes (PEFC).

Share of Accredited Bodies by Cgcre/Inmetro (April 2021)



- TEST LABORATORIES
- CALIBRATION LABORATORIES
- INSPECTION AND CERTIFICATION BODIES
- REFERENCE MATERIAL PROVIDERS
- PROFICIENCY TESTING PROVIDERS

Source: INMETRO — Prepared by GPQI Brazil



Accreditation mark from CGCRE to be used by CABs.⁶

Parties involved in these mutual or multilateral recognition arrangements (MRA) agree to recognise the results of each other's conformity assessments and accreditations. In practice however, some technical regulations in Brazil overrule these international arrangements and lead to duplicate testing and certification of products when imported to Brazil.

Accreditation Board for Certification Bodies (DICOR)

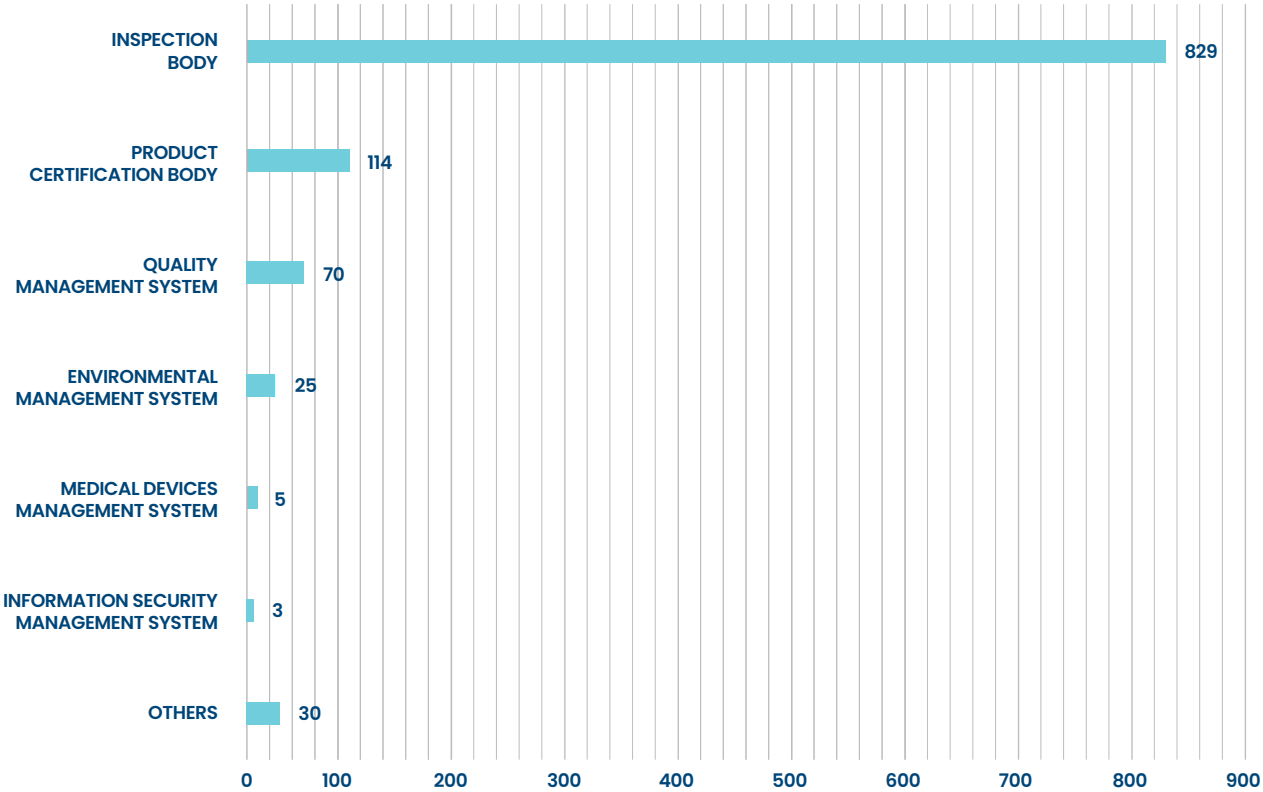
DICOR is responsible for providing the national accreditation system for conformity assessment bodies, including for bodies engaged in metrology activities. Given the strong presence of INMETRO in product certification, most of the accreditation schemes operated by the CGCRE are for inspection bodies and quality management systems (see figure below).

Accreditation Board for Testing and Calibration Laboratories (DICLA)

Calibration accreditation services in Brazil commenced in 1980 under the umbrella of the Brazilian Network for Calibration (RBC) initiative, which brings together calibration bodies accredited by INMETRO from industry, universities and technology institutes. RBC operates in compliance with ISO Guide 25, coordinating the Brazilian metrology systems and providing general metrology services which establishes safeguards for consumer protection.

In the realm of laboratories which perform tests, there is the Brazilian Network for Testing Laboratories (RBLE), which brings together bodies accredited by INMETRO, national or international, to perform testing in Brazil.

Number of bodies currently accredited by DICOR*



*Currently suspended accreditation licences were excluded from the graphic numbers

Source: INMETRO – Prepared by GPQI Brazil

DICLA grants accreditations for all laboratories performing tests or calibration for their schemes. DICOR has prescribed the use of DICLA accredited laboratories for all accredited third-party inspection and product certification schemes.

There are currently **1,696** laboratories accredited by DICLA, of which testing laboratories account for **71%**, calibration laboratories for **26%** and medical laboratories, proficiency testing providers and reference material providers for **3%**. The laboratories belong to diverse sectors and interests such as those providing commercial services, owned by government and regulators, captive laboratories of industries, as well as laboratories doing research and academic work.

5

Conformity Assessment

Within SINMETRO, the Brazilian Conformity Assessment System (SBAC), coordinated by INMETRO, is responsible to define the objectives and mechanisms of conformity assessment in Brazil.

INMETRO

ENERGIA
Televisor

Fornecedor **ENVISION**
Marca
Modelo

100
240
volts

Mais eficiente

A B C D E

Menos eficiente

6,61
kWh/mês

80 cm 32" pol.

Segurança Desempenho

nsal estimado baseia-se num funcionamento diário de 4 horas ligado e 20 horas em

The objectives and mechanisms of conformity assessment in Brazil are defined by the Brazilian Conformity Assessment System (SBAC), a sub-system of SINMETRO. As SBAC's managing body, INMETRO plays a central role in conformity assessment in Brazil, combining the roles of (i) technical regulator, and (ii) provider of conformity assessment schemes – including for other regulators.⁷

The conformity assessment mechanisms defined by SBAC are:

- supplier's declaration⁸
- certification
- inspection
- testing

Selection of a particular mechanism for inclusion in a conformity assessment scheme is based on factors such as product/service characteristics, consumer accident risks, production volume and level of difficulty for surveillance. These and other factors also determine if the

product/service will be subject to compulsory or voluntary conformity assessment, as well as the economic agent responsible for the evaluation – whether first, second or third-party conformity.⁹

See below for an overview of SBAC's conformity assessment mechanisms and their application characteristics.

As of February 2021, INMETRO had 152 compulsory technical regulations and/or conformity assessment schemes in force, along with 24 voluntary conformity assessment schemes.

The development of technical regulations and conformity assessment schemes is carried by INMETRO's Directorate of Conformity Assessment (DCONF). At this stage, technical conformity assessment requirements are defined for each regulated object. It is noteworthy that INMETRO's technical regulations often refer to existing technical standards, effectively turning originally voluntary criteria into mandatory requirements.

Figure 6 – Mechanisms of the Brazilian Conformity Assessment System (SBAC)

| MECHANISM | SCOPE | | | ECONOMIC AGENT | | | APPLICATION | |
|------------------------|--------------------|----------------------|-----------|----------------|-----------|-----------|-------------|------------|
| | Products/ Services | Management/ Services | Personnel | 1st Party | 2nd Party | 3rd Party | Voluntary | Compulsary |
| Supplier's declaration | ✓ | | | ✓ | | | | ✓ |
| Certification | ✓ | ✓ | ✓ | | | ✓ | ✓ | ✓ |
| Inspection | ✓ | | | | | ✓ | ✓ | ✓ |
| Testing | ✓ | | | ✓ | ✓ | ✓ | ✓ | ✓ |

Source: INMETRO, 2015

After a new technical regulation and/or conformity assessment scheme is finalised, DCONF is also responsible for supporting its implementation process, by organising outreach activities to promote behavioural change among companies and CABs affected.

INMETRO's conformity marking

Within the Brazilian Conformity Assessment System (SBAC), the rules for applying INMETRO's conformity marking were established most recently by Regulation No. 274 of 2014.

The regulation establishes that DCONF is the body responsible for authorising accredited CABs to apply INMETRO's marking on products that were subject to conformity assessment based on a scheme developed by INMETRO. The different types of markings inform consumers about the scope of the assessment (e.g. health, safety, performance, sustainability), distinguish between voluntary and compulsory assessment, and identify the type of economic agent responsible (whether first or third party).



From left to right, top to bottom: Safety, Environment, Conformity, Performance, Health, Sustainability. Source: INMETRO, 2015



6

Market surveillance

A key component of quality infrastructure, market surveillance in Brazil is performed by various regulators and institutions. Unlike the EU, Brazil does not have a centrally coordinated market surveillance system.

Acknowledged as a key component of quality infrastructure, market surveillance in Brazil is performed by a series of regulators and institutions. Unlike the EU, Brazil does not have a centrally coordinated market surveillance system, or a dedicated ministerial division. The applicable market surveillance procedures and responsibilities depend on the regulated products and corresponding authorities.

INMETRO

As the official body responsible for ‘executing, coordinating and supervising’ conformity assessment, INMETRO plays a key role in performing market surveillance for products under its legal competence – but also for products that fall under the competence of other regulators, who have delegated to INMETRO the development of a conformity assessment scheme.

As illustrated by Figure 2 (page 7), INMETRO’s market surveillance activities are mostly focused on pre-market,¹⁰ but also include post-market activities. In both cases, the aim is to induce producers to comply with applicable regulations and conformity assessment schemes.

INMETRO enforces **pre-market surveillance** primarily through two mechanisms, namely:

- **Product registration:** required for all products subject to INMETRO’s compulsory conformity assessment schemes, according to Law No. 12545/2011. It is the official act through which CABs are authorised to apply INMETRO’s conformity marking (see page 24), given that the applicable conformity assessment requirements are fulfilled.
- **Import consent:** required for all imported products subject to INMETRO’s compulsory conformity assessment schemes. It is required for the issuance of import licenses and subsequent customs clearance for imported goods. When specified in the relevant technical regulation, an import consent requires prior product registration.

In addition, INMETRO’s **post-market activities** fall under two main modalities:

- **‘Formal’ surveillance:** refers to visits carried out by INMETRO’s surveillance officers in commercial establishments, aiming to verify the presence of INMETRO’s conformity marking and other mandatory markings on product labels.
- **Conformity verification:** refers to the collection and testing of product samples to verify their compliance with applicable conformity assessment schemes. If non-compliant products are identified, suppliers are subject to punitive measures, as defined in Law No. 9933/1999 and INMETRO Resolution No. 333/2012. These activities are carried out within INMETRO’s Conformity Verification Programme (PVC) and tested by accredited laboratories of the Brazilian Network of Testing Laboratories (RBLE).

INMETRO’s post-market surveillance activities are generally carried out by state-level and municipal-level authorities that make up the **Brazilian Legal Metrology and Quality Network (RBMLQ-I)**.

RBMLQ-I represents INMETRO’s executive arm throughout the national territory, being responsible for post-market surveillance of all products under the institute’s legal competence, including measuring equipment. RBMLQ-I is composed of 26 delegated bodies, of which 23 are part of state governments, one is part of a municipal government and two are regional superintendencies within INMETRO.

Although INMETRO’s market surveillance activities focus on regulated products with compulsory conformity assessment schemes, there are also initiatives for monitoring regulated products under voluntary conformity assessment schemes, or those without a conformity assessment scheme.



7

Metrology

In Brazil, the activities of Legal Metrology are an attribution of INMETRO. It collaborates internationally and engages in international fora to promote the uniformity of its application in the world - for example, through an active participation in Mercosul and the International Organization of Legal Metrology (OIML).

Scientific and industrial metrology

INMETRO's Scientific and Industrial Metrology unit is one of the main units of the National Institute for Metrology, Quality and Technology (INMETRO), created by Law No. 5966 of 12/11/1973, which established the National System of Metrology, Standardisation and Industrial Quality (SINMETRO) and defined as the highest body the National Council for Metrology, Standardisation and Industrial Quality (CONMETRO). It is coordinated by the Directorate of Scientific Metrology and Technology (DIMCI).

In order to maintain the credibility of INMETRO's metrology laboratories, several actions were taken, notably interlaboratory comparisons with national and international institutions, in areas such as: temperature, humidity, high resistance and inductance resistance, including key comparisons made under the coordination of the International Bureau of Weights and Measures (BIPM), in addition to comparisons made at national level.

INMETRO has continuously pursued the recognition of its accreditations in several international forums. **Currently, some very important recognitions have already been obtained from the International Accreditation Forum (IAF), the International Laboratory Accreditation Cooperation (ILAC) and the International Bureau of Weights and Measures (BIPM).**

A particular highlight is the cooperation between INMETRO and the National Metrology Institute of Germany (PTB) and the German Federal Institute for Materials Research and Testing (BAM). The cooperation includes subjects such as the research and development of programmes conducted in these institutions with the participation of DIMCI specialists; conversely, DIMCI receives visits from specialists from these institutions, who come to collaborate with INMETRO.

Directorate of Scientific Metrology and Technology (DIMCI)

Among the competences attributed to INMETRO, the Directorate of Scientific Metrology and Technology (DIMCI) is responsible for:

- maintaining and preserving the standards of measurement units, as well as implementing and maintaining the chain of traceability of the standards of measurement units in Brazil;
- implementing national metrology policies;
- strengthening the country's participation in international activities related to metrology, in addition to promoting exchanges with foreign and international entities and bodies;
- providing technical support to the National Metrology, Standardisation and Industrial Quality Council – CONMETRO – as well as to its advisory committees, acting as its Executive Secretariat.
- Additionally, DIMCI also provides training for staff at the technical levels of metrology, as well as Master's degrees, for which professionals serve as teachers on the technical course in Metrology at INMETRO and Master's degree course in Metrology and Quality.
- INMETRO's scientific and industrial metrology laboratories carry out a range of activities which correlate to their specific function: Standardisation of SI units.
- Maintaining its credibility as a national metrological reference laboratory in Brazil, by ensuring traceability of national standards to BIPM standards.
- By coordinating key comparisons with the national standards of other countries, either by other National Metrology Institutes (INM) or by BIPM itself, whilst supporting the International System of Units (SI).

- Through national standards, these laboratories give traceability to the reference standards of laboratories accredited by INMETRO and the laboratories of units, research centres and the industry in general.
- Cooperation agreements with similar organisations.
- Research and development activities, including partnerships with other institutions in the country and abroad.
- Provision of standard calibration services and measuring instruments, as well as tests.

Brazilian Calibration Network (RBC) and Brazilian Network of Testing Laboratories (RBLE)

Made up of laboratories accredited by INMETRO, the Brazilian Calibration Network (RBC) brings together technical skills and training linked to industries, universities and technological institutes qualified to carry out calibration services. Accreditation implies proof of a laboratory's technical competence, credibility and operational capacity. The accreditation granted by INMETRO through the Division of Calibration Laboratories Accreditation (DICLA) and linked to the General Coordination for Accreditation (CGCRE) is carried out in accordance with international 'accreditation' procedures.

Currently, standards for pressure laboratories (accredited by RBC), depending on their accuracy, are directly or indirectly traceable to the Pressure Laboratory (LAPRE). These laboratories carry out numerous calibrations of pressure gauges, for which the number of calibrations is difficult to predict. Usually, the demand for services from a laboratory increases from the moment it becomes accredited in the Brazilian Calibration Network. LAPRE technicians regularly participate in the technical evaluation of pressure laboratories in the Brazilian Calibration Network. Additionally, they provide technical advice on new services requested by CGCRE.

Legal metrology

Coordination and implementation of legal metrology activities in Brazil is incumbent upon INMETRO, through its **Directorate of Legal Metrology (DIMEL)**, in compliance with the competence attributed to it by Law No. 5966/73, Law No. 9933/99, Law No. 10829/03 and Resolution No. 11/88 of CONMETRO. INMETRO also plays an active role in cooperating with MERCOSUR and the International Organization of Legal Metrology (OIML).

In Brazil, measuring instruments, pre-measured products and materialised measures used in economic activities and concerning people's safety and health are subject to metrological regulation and control. In this respect, new measurement instruments must have their model approved by INMETRO, which examines, tests and verifies if they are fit for purpose. After manufacturing, each instrument must be submitted for initial verification to ensure its accuracy before use. When a product is in use, its holder is responsible for maintaining its accuracy and correct use, verified by periodic checks – in most cases, through yearly inspections.

Accordingly, INMETRO's metrological control mechanisms comprise:

- The **control of measuring instruments or materialised measures**, carried out by actions relating to:
 - technical approval of a model
 - verification
 - inspection.
- **Metrological supervision**, which consists of the procedures carried out during the manufacture, use, maintenance and repair of a measuring instrument or materialised measure, to ensure that the regulatory requirements are being met. It also comprises checks on the accuracy of pre-measured goods.
- **Metrological examination**, which consists of a set of operations with the purpose of examining and certifying the condition in which

a measuring instrument or materialised measure is found and determining its metrological qualities in line with specific regulatory requirements.

When non-compliant products are identified, INMETRO resorts to applying penalties such as fines, the seizure or interdiction of instruments, or revocation of model approval and/or suspension of a model's initial verification, should its use facilitate fraud against consumers.

To exercise the metrological control under its competence, INMETRO issues regulations pertaining to authorised measurement units, technical and metrological requirements and marking requirements, with which manufacturers, importers and holders of measuring instruments must comply.

The preparation of regulations is usually based on the recommendations of the International Organization of Legal Metrology (OIML), to which Brazil is affiliated as a member country. They are also a result of INMETRO's collaboration with manufacturers, represented by their class entities, and consumer representative entities, through their participation in **Metrological Regulation Working Groups/Technical Commissions**.

Moreover, the metrological supervision of measuring instruments and materialised measures is effectively carried out by the **Brazilian Legal Metrology and Quality Network (RBMLQ-I)**. RBMLQ-I represents INMETRO's executive arm throughout the national territory, being responsible for post-market surveillance of all products under the institute's legal competence, including measuring equipment. RBMLQ-I is composed of 26 delegated bodies, of which 23 are part of state governments, one is part of a municipal government and two are regional superintendencies within INMETRO.

8. Footnotes

- [1] Schwab, K. 2019. [The Global Competitiveness Report 2019](#). World Economic Forum.
- [2] BIPM, OIML, ISO, IEC, ITU, IAF, ILAC, ITC, UNIDO, etc. See Harmes-Liedtke, U; Di Matteo, J. 2021. Global Quality Infrastructure Index Report 2020. GQII Data & Analytics Paper N^o1.
- [3] UNIDO. 2020. [Rebooting Quality Infrastructure for a Sustainable Future](#). United Nations Industrial Development Organization.
- [4] The Target case exemplifies the possibility for an agent (other than ABNT) to publish and publicly share technical standards acquired legally and directly from ABNT.
- [5] It is important to note that the criteria of representativeness must be met, resulting in parity in voting. In other words, the productive sector has only one vote, regardless of the number of representatives from that sector; the consumer representative also has only one vote, and so on.
- [6] In 2017, 39% of INMETRO's technical regulations and/or conformity assessment schemes in force fell within the legal competence of other national regulators, such as ANVISA, ANTT, ANP and Contran.
- [7] It is noteworthy that, as practised by INMETRO, conformity assessment through a supplier's declaration is not completely exempt from third-party control mechanisms: although certification by accredited CABs is not required, initial and periodic third-party laboratory testing may be required, depending on the specific scheme.
- [8] First-party conformity assessment refers to evaluations carried out by producers/suppliers, while second-party conformity assessment is carried out by final users (e.g. consumers) and third-party assessment by independent bodies without a producer or user interest in the product/service/system.
- [9] Controls that aim to ensure that products comply with applicable regulations and conformity assessment schemes before they are placed into the market.
- [10] Controls that aim to ensure that products comply with applicable regulations and conformity assessment schemes before they are placed into the market.

9. Other references

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UNIDO. 2020. Rebooting Quality Infrastructure for a Sustainable Future. United Nations Industrial Development Organization. [↗](#)