

DISCLAIMER

THIS TRANSLATION IS PRODUCED BY GLOBAL PROJECT QUALITY INFRASTRUCTURE (GPQI) AND MAY BE USED ONLY FOR REFERENCE PURPOSES. THIS ENGLISH VERSION IS NOT AN OFFICIAL TRANSLATION OF THE ORIGINAL BRAZILIAN DOCUMENT. IN CASES WHERE ANY DIFFERENCES OCCUR BETWEEN THE ENGLISH VERSION AND THE ORIGINAL BRAZILIAN VERSION, THE BRAZILIAN VERSION SHALL PREVAIL WHICH CAN BE FOUND [HERE](#). THE GIZ SHALL ACCEPT NO RESPONSIBILITY OR LIABILITY FOR DAMAGE OR LOSS CAUSED BY ANY ERROR, INACCURACY, OR MISUNDERSTANDING WITH REGARD TO THIS TRANSLATION.

OFFICIAL GAZETTE

Published: 02/03/2022 | Edition: 41 | Section: 1 | Page: 93

Agency: Brazilian Ministry of Economy/National Institute of Metrology, Quality and Technology

ORDINANCE NO. 30, OF FEBRUARY 25, 2022

Approves the Regulatory Model of Inmetro - Vision, Objectives, Principles and Guidelines.

THE PRESIDENT OF INSTITUTO NACIONAL DE METROLOGIA, QUALIDADE E TECNOLOGIA [NATIONAL INSTITUTE FOR METROLOGY, QUALITY, AND TECHNOLOGY] - INMETRO, by the powers vested in him by article 4, paragraph 2nd of Law no. 5966, dated December 11, 1973, and article 3, items I and IV of Law no. 9933, dated December 20, 1999, combined with the provisions of article 18, item VI of the Annex I to Decree no. 6276, dated November 28, 2007, and article 105, item V of the Annex to Ordinance no. 2, dated January 4, 2017, of the former Brazilian Ministry of Industry, Foreign Trade, and Services, considering what is outlined in SEI Process no. 0052600.006768/2020-83;

Considering the provisions of Law no. 13.874, dated September 20, 2019, which establishes the Declaração de Direitos de Liberdade Econômica [Declaration of the Economic Freedom Rights] and other provisions;

Considering Decree No. 10,139 of November 28, 2019, which establishes the review and consolidation of normative acts subject to decrees and further legal corresponding provisions;

Considering Decree No. 10,178 of December 18, 2019 which regulates the provisions of the Declaração de Direitos de Liberdade Econômica [Declaration of the Economic Freedom Rights] so as to provide the criteria and procedures for the determination of economic activity risk assessment, set forth the deadline for tacit approval, and include elements to the Carta de Serviços ao Usuário [Letter of User Services];

Considering Decree No. 10,229 of February 5, 2020 which regulates the right to develop, execute, operate or market product or service in disagreement with the outdated technical standard subject matter of the Economic Freedom Act;

Considering the provisions of Decree No. 10,411 of June 30, 2020, which regulates the Regulatory Impact Analysis, which deals with Article 5 of Law No. 13,874 of September 20, 2019, and Article 6 of Law No. 13,848 of June 25, 2019;

Considering the regulation of Inmetro, as part of quality infrastructure, is an activity that contributes to the economic prosperity and well-being of society;

Considering the importance of monitoring and incorporating innovations and technologies arising from the society's digital transformation (particularly in the so-called Industry 4.0), in Inmetro's regulatory activities;

Considering the need to develop and implement regulatory actions that are sufficiently adaptable and flexible, in order to promote more dynamic regulation, which follows market advances;

Whereas regulatory activity is an instrument of great importance to the protection of society, innovation and the competitiveness of national industry, contributing to the economic and isonomic growth of the country;

Considering the demand of society for the implementation of improvements in the regulatory process of Inmetro, which was proven through demonstrations and participation in meetings, consultations with stakeholders and other means of communication and interaction carried out in recent years by Inmetro;

Considering the work carried out within the multidisciplinary group, established to assist in the modernization of the current regulatory model, the Working Group on Modernization of the Regulatory Model of Inmetro (GTMRI), formalized through Inmetro Ordinance No. 212, of June 10, 2020;

Considering it is essential to strengthen Inmetro's regulatory activity, with due engagement, information and participation of stakeholders, through the adoption and implementation of monitoring and evaluation practices of results, maintaining adequate, efficient and effective regulatory performance;

Whereas Brazil has been implementing good regulatory practices aligned with international criteria and agreements;

Considering the Strategic Plan 2021-2023, launched in March 2021, with the main objective of adapting Inmetro to society (in particular in the so-called Industry 4.0) transforming the two major areas in which it operates - technological support to organizations and support for the functioning of markets; and

Considering the public consultation that collected contributions from society in general for the preparation of the text now approved, published by Inmetro Ordinance No. 8 of March 25, 2021, published in the Official Gazette of March 29, 2021, section 1, page 75, resolves:

Object and scope of application

Article 1 The Regulatory Model of Inmetro, set out in the Annex to this Ordinance, which establishes the principles and guidelines to be observed for the improvement of its regulatory performance, is approved.

Paragraph 1 - The principles and guidelines approved by this Ordinance must be observed and adopted at all stages of regulatory activities carried out by Inmetro.

Paragraph 2 - The principles and guidelines, set out in the Annex to this Ordinance, may be detailed, in guides, manuals or other communication instruments.

Terms and transient provisions

Article 2 The transition period of 05 (five) years, from the date of publication of this Ordinance, is established for the implementation of the Regulatory Model of Inmetro.

Paragraph 1 - In the transition period, Inmetro's Operating Units shall promote actions for the adoption and implementation of the caput established in all its regulatory processes.

Paragraph 2 - The edition of new normative acts during the transition period must comply with the guidelines of this Regulatory Model.

Revocation clause

Article 3 It is hereby revoked, The Inmetro Ordinance No. 252, of May 27, 2015, published in the Official Gazette of May 28, 2015, section 1, pages 55 to 56, after the transition period established in the caput of art. 2 of this ordinance.

Term

Art. 4 This Ordinance enters into force on April 1, 2022, as determined by Article 4 of Decree No. 10,139, 2019.

MARCOS HELENO GUERSON DE OLIVEIRA JUNIOR

ATTACHMENT

INMETRO REGULATORY MODEL - VISION, OBJECTIVES, PRINCIPLES AND GUIDELINES.

1. INTRODUCTION

The national and global context has had a strong evolution in recent times, with the intensification of competition, profound changes resulting from the digitization of the economy (which covers the so-called Industry 4.0), the unsatisfactory position of Brazilian competitiveness in the international scenario, the federal government's guidelines to promote a regulatory environment in Brazil of greater economic freedom as a development strategy, giving rise to a modernization of legislation and also a paradigm shift initiated by the development of Inmetro's Strategic Plan for the period 2021 to 2023.

Among the activities of Inmetro, the central body of The Quality Infrastructure of Brazil, which should be improved is the regulation, which has very important impacts on the country's competitiveness. It is therefore necessary to reassess the institute's regulatory activities so that it can better respond to society and fulfil its mission and established policy objectives. Thus, it is

necessary to critically review what has been called a regulatory model to modernize it so that it can respond to the new challenges that arise.

Inmetro's regulatory model, that is, the way Inmetro organizes and operationalizes its regulatory function in order to achieve its regulatory objectives, covers the regulations related to legal metrology and the regulation of products, processes and services in relation to safety, protection of life and human health, protection of the environment and the prevention of deceptive trade practices, in accordance with the powers conferred to the Institute by legislation.

The current regulatory model needs to be improved as the characteristics that compose it, the result of its evolution in the last 30 years, have increased complexity and decreased the performance of the regulatory process.

The critical analysis of the regulatory model carried out by Inmetro within the Framework of the Inmetro Regulatory Model Modernization Working Group (GTMRI) identified several problems that affect the effectiveness and efficiency of Inmetro's regulatory activity, as well as recognized the relationship of this performance with the way in which regulation is established and implemented. Among the problems identified are the following:

- Very prescriptive and detailed regulations, making it difficult for companies to serve, as well as maintain and update them;
- Bureaucratic processes, time-consuming and with steps that do not generate value for the desired result;
- Very time-consuming process of analysis, development, implementation, maintenance, review and updating of regulations, in addition to being very costly (process that requires several years, from the initiative to establish a regulation to its full implementation);
- Established regulations object to object, resulting in a large number of regulations to be met by companies and managed by Inmetro;
- Increasing limitation of the availability of resources to the public administration to develop its activities;
- Statement by several stakeholders that the surveillance process should focus on the post-market.; and
- The use of excessively bureaucratic pre-market mechanisms for an important number of products and services (such as consent to imports and registration).

It should be noted that inmetro's regulatory activity accelerated greatly from the beginning of the century, in response to the demands of society. These demands were the result of the maturation and development of the Brazilian economy and the broad recognition by society of the importance and the need to maintain and improve Inmetro's role as a regulator.

In view of these challenges and the finding and analysis of problems, Inmetro established the modernization of its regulatory model as one of its priorities, consulting and involving stakeholders in consultation processes, including the private sector, technology entities and consumer representatives. To conduct the process of modernization of the regulatory model, a

multidisciplinary group was established to assist in the modernization of the Regulatory Model of Inmetro - GTMRI, through Inmetro Ordinance No. 212, of June 10, 2020.

In compliance with the provisions of Inmetro Ordinance No. 212, several actions and studies were carried out in order to define a proposal for a new regulatory model that is more effective, more efficient and more flexible capable of responding to current regulatory needs and technological innovations.

The main actions are the compilation and analysis of the views and propositions of stakeholders for the modernization of the Regulatory Model of Inmetro, in addition to studies carried out with the objective of identifying and presenting the main characteristics and recent developments of national and regional systems dedicated to quality infrastructure activities, namely for regulation, standardization, accreditation and conformity assessment, metrology and surveillance in the United States of America, South Korea, Europe and those arising from the influence of Industry 4.0, with a focus on enabling a critical assessment and a better understanding of trends for these activities.

In this sense, this document is based on the compilation and consolidation of the results of these various actions carried out and conducted by Inmetro for the modernization of its Regulatory Model.

This document provides the guidelines that Inmetro's regulatory processes must follow, as well as their activities arising from development to implementation, including market surveillance actions and identification of legal improvements, providing for the change of legal instruments, if necessary, such as laws, resolutions and ordinances.

The model proposed in this document is focused on strengthening regulatory activity, ensuring industry and market monitoring in the face of technological innovations, with greater engagement, information and participation of stakeholders, encouraging and promoting the practices of monitoring and evaluating results, aiming that regulatory action remains adequate to the intended purpose and relevance, as well as, remain effective and proportionate to the problems faced.

The proposal for the modernization of Inmetro's Regulatory Model consist of the following elements:

- Vision;
- Objectives;
- Principles; and
- Guidelines.

2. GLOSSARY

For the purposes of this document apply the following definitions, having as reference the International Vocabulary of Terms of Metrology - VIM, the International Vocabulary of Terms of Legal Metrology - VIML, the ABNT ISO/IEC Guide 2: 2006 Standardization and related activities - General Vocabulary and the STANDARD ABNT NBR ISO/IEC 17000 (Conformity Assessment: Vocabulary and general principles).

It should be mentioned that a new revision of ISO/IEC 17000 was published in 2020, and this standard is in the process of being adopted in Brazil

2.1 Accreditation - third party attest for a conformity assessment body formally demonstrating its competence to carry out specific conformity assessment activities. [ABNT NBR ISO/IEC 17000, adapted].

2.2 Regulatory Impact Analysis - AIR - procedure, based on the definition of regulatory problem, evaluation prior to the issue of normative acts, which will contain information and data on their probable effects, to verify the reasonableness of the impact and support decision-making. [Decree No. 10,411 of June 30, 2020, adapted].

2.3 Regulatory Results Assessment - ARR - verification of the effects arising from the edition of a normative act, considering the achievement of the originally intended objectives and the other impacts observed on the market and society, as a result of its implementation. [Decree No. 10,411 of June 30, 2020].

2.4 Conformity Assessment - demonstration that the specified requirements are met [ABNT NBR ISO/IEC 17000].

2.5 Certification - third-party attestation related to a conformity assessment object, except accreditation. [ABNT NBR ISO/IEC 17000, adapted].

2.6 Consumer - natural or legal person who acquires or uses product or service as final recipient. [Law 8078/1990 - Consumer Protection Code, adapted].

2.7 Declaration of Conformity (supplier's declaration) - procedure by which a supplier gives written assurance that a product complies with the specified requirements. [ABNT NBR ISO/IEC 17050-1:2005, adapted].

2.8 Inspection - Activity that seeks to observe the practices of economic agents in relation to the obligations to do or not to do, provided for in legal norms, in order to verify if they are being met. [General Guidelines and Guidance for The Elaboration of Regulatory Impact Analysis - AIR - Civil House of the Presidency of the Republic, adapted].

2.9 Supplier (Distributor, Importer or Assembler) - Legal, public or private entity, legally established in the country, which develops production, assembly, creation, construction, processing, import, export, recovery, repair, fractionation, packaging, packaging, distribution or marketing of the product or provision of the service regulated by Inmetro." (Source: Inmetro Vocabulary of Conformity Assessment, annexed to Inmetro Ordinance No. 248/2015).

2.10 Quality Infrastructure - System that covers all organizations (public and private), added to the relevant policies, legal and regulatory structures and practices necessary to support and improve the quality, safety and environmental safety of products, services and processes. (Source: International Network on Quality Infrastructure (INetQI)).

2.11 Metrology - measurement science and its applications. [Ordinance Inmetro no. 150, 29/03/2016].

Note: Metrology encompasses all theoretical and practical aspects of measurement, whatever the measurement uncertainty and the field of application. [VIM, Ordinance Inmetro no. 232/2012, 2.2].

2.12 Legal Metrology - Practice and process of applying to metrology a legal and regulatory structure and implement its execution.

Note 1: The scope of legal metrology may differ from one country to another.

Note 2: Legal metrology includes:

- establishment of legal requirements;
- control / evaluation of compliance of products and regulated activities;
- supervision of regulated products and activities; and
- provision of the necessary infrastructure for the traceability of measurements and measuring instruments regulated to the SI or national standards.

Note 3: There may be regulations outside the scope of legal metrology, pertaining to measurement accuracy and the adequacy of measurement methods. [Ordinance Inmetro no. 150, 29/03/2016].

2.13 Technical standard - Document established by consensus and issued by a recognized body, which provides, for common and repeated use, rules, guidelines or characteristics for products, services, goods, people, processes or production methods, the fulfillment of which is not mandatory. It may also deal with terminology, symbols, packaging requirements, marking or labelling applicable to a product. [Conmetro - Good Regulatory Practice Guide - GBPR, adapted].

2.14 Conformity Assessment Body - body carrying out conformity assessment activities, except accreditation. [ABNT NBR ISO/IEC 17000].

2.15 Accreditation Body - body authorised to carry out accreditation. [ABNT NBR ISO/IEC 17000].

2.16 Stakeholders - correspond to all elements (persons, institutions, groups, government agencies, etc.) that in some way affect or are affected by your organization. [ABNT ISO 9001:2015].

2.17 Regulation - a contemporary form of state action and refers, in general, to the set of legal-normative instruments (laws, decrees, regulations and other norms) available to the government to establish obligations that must be fulfilled by the private sector, citizens and the government itself. [General Guidelines and Guidance for The Elaboration of Regulatory Impact Analysis - AIR - Civil House of the Presidency of the Republic].

2.18 Technical regulation - Document stating the characteristics of a product or the production processes and methods related to it, including the applicable administrative provisions, the compliance of which is mandatory. It may deal in part or exclusively with terminology, symbols and packaging, marking

or labelling requirements applicable to a product, service, goods, persons, process or method of production.

Note: A technical regulation may be supplemented by technical guidelines, establishing some means of obtaining compliance with the requirements of the Regulation, i.e. some prescription deemed satisfactory to obtain compliance. [Conmetro - Good Regulatory Practice Guide - GBPR].

2.19 Essential requirement - result to be achieved or the risk to be treated, without specifying the technical solutions of how to do, with the aim of providing and ensuring protection of safety, health and environment. [EU, Blue Guide on applications of EU Product Rules, 2016, adapted].

2.20 Risk - effect on uncertainty on objectives.

Input Note 1: An effect is a deviation from what is expected. It can be positive, negative, or both, and can address, create, or result in opportunities and threats.

Entry Note 2: Objectives can have different aspects and categories, and can be applied at different levels.

Input Note 3: Risk is usually expressed in terms of sources of risk, potential events, their consequences and their probabilities.

[ABNT NBR ISO 31.000:2018] .

2.21 Conformity Assessment System - rules, procedures and management to carry out the conformity assessment. [ABNT NBR ISO/IEC 17000].

2.22 Market surveillance - activities with the objective of evaluating the performance of products or services in the market in relation to the requirements established in the legislation or identifying potential safety risks or regulatory problems.

Note: Market surveillance includes surveillance activities.

2.23 Regulatory objective - objective that is intended to be achieved with regulatory intervention.

3. ACRONYMS USED

ABNT - Brazilian Association of Technical Standards.

AIR - Regulatory Impact Analysis.

ARR - Conmetro Regulatory Outcome Assessment - National Council of Metrology, Standardization and Industrial Quality.

IEC - International Electrotechnical Commission.

ISO - International Organization for Standardization.

OECD - Organization for Economic Cooperation and Development.

OIML - International Organization of Legal Metrology.

EU - European Union.

UNECE - United Nations Economic Commission for Europe.

UNCTAD - United Nations Conference on Trade and Development.

4. VISION

It is understood that this model should meet the following vision of the future for the regulatory model: Regulatory model, as part of the Quality Infrastructure, which meets the expectations of society, ensures a safe, isonomic and dynamic market, is flexible and welcomes innovation, promotes competitiveness and enhances digitization (Industry 4.0).

5. OBJECTIVES

From the established view, the general objectives desired for the regulatory model are:

- Be stable and perennial, comprehensive and to follow the evolution of the expectations of society and the market, preserving its safety, protection of life and human, animal and plant health and the protection of the environment;
- Overcome the problems identified in the current model; and
- Be an instrument of protection and market growth and facilitator of business, ensuring the prevention of deceptive trade practices.

6. PRINCIPLES

The principles that guide the regulatory model are:

6.1 Coverage

The scope of the regulatory process includes Inmetro's competence and scope of action, provided in the legislation so that it can meet the needs and expectations of society.

6.2 Focus on goals and results

The regulatory model should focus on regulatory objectives and intended results continuously seeking effectiveness and efficiency.

6.3 Flexibility

The regulatory model should be flexible enough to meet the needs and expectations of society, adopting the appropriate solutions to solve the problems and regulatory challenges posed and the fulfillment of the regulatory objectives identified and at the same time incorporating innovation.

6.4 Compatibility

The regulatory model must be compatible with the process of digitization of the economy and technological and market trends, so that it has the ability to respond to the identified, current and future regulatory problems and challenges.

6.5 Isonomy

The regulatory model should ensure an isonomic treatment of impacted economic actors, regardless of their nationality, origin or size, keeping the conditions of competitiveness balanced.

6.6 Regulatory harmonisation and convergence

The regulatory model and its implementation should seek alignment with good national and international regulatory practices, in compliance with national legislation.

6.7 Based on risks and supplier accountability

The regulatory model should be based on a vision of risk management and the accountability of suppliers in fulfilling their responsibilities to the Brazilian legal structure.

6.8 Market surveillance

The regulatory model should have as one of its central elements market surveillance activities, including surveillance, using the appropriate monitoring and monitoring tools, in order to ensure compliance with regulatory objectives. It should also have an education and prevention approach.

6.9 Agility

The regulatory model should ensure rapid and effective responses to the needs of society.

6.10 Viability

The regulatory model should have a decision-making process supported by an analysis of the feasibility of implementing its devices, covering the cost-benefit vision for the institute and society, as well as applicable technical feasibility criteria.

6.11 Transparency

The regulatory model should operate transparently, including through the provision of data and information to the general public.

6.12 Predictability

The regulatory model should be predictable as a way to promote legal certainty of established economic and commercial relations.

7. GUIDELINES

Based on the principles defined, the main guidelines for the design, development and implementation of the regulatory model are:

7.1 Regulatory process

The regulatory process should:

- Cover the legal competence and scope for which Inmetro has regulatory responsibilities, respecting its specificities (such as legal metrology, conformity assessment, regulation of products and services, among others);

- Be planned, considering a regulatory agenda and oriented to the consideration of risks and regulatory objectives to be achieved; and

- Focus on regulatory objectives and results, from the identification of regulatory problems.

- Regulatory objectives should:

- . Identify the problem to be solved and the objectives to be achieved for each regulatory initiative with the participation of stakeholders;

- . Establish the objectives of the regulation, together with the regulatory agenda, under its responsibility as a whole;

- . Contemplate the management of the regulatory stock under its responsibility, with the participation of stakeholders; and

- . Be covered by the regulatory scope assigned to Inmetro.

- . Include cooperation with other regulatory authorities and stakeholders in identifying and acting to solve regulatory problems. In this sense, Inmetro can act with technical support within its competencies, to the regulatory process of other authorities, such as, for example, in supporting the establishment of conformity assessment procedures that are part of the regulatory process of these other authorities, establishing procedures to ensure that the decision-making process is adequately reflected in the Regulatory Impact Analysis, as appropriate;

- Establish the objectives of the regulation, together with the regulatory agenda, under the responsibility of Inmetro;

- Be based on technically based clear rules;

- Be predictive and with an anticipatory posture, enabling the adoption of different methods and coordinated approaches to respond to emerging opportunities and risks, in an agile and receptive way to innovation, enabling regulatory experimentation (e.g., Regulatory Sandbox);

- Ensure the balance of interests, equal treatment, transparency and impartiality;

- Ensure the participation of stakeholders (including users, entities, regulated entities and consumers and other regulatory bodies), since the beginning of the regulatory process, establishing a permanent dialogue and communication;

- Establish more comprehensive, innovation-responsive and more flexible regulations;

- Establish regulations to cover, where possible, risk categories or categories of products, except where justified;

- Ensuring the application of market surveillance mechanisms, including inspection, and the conformity assessment procedures considered, when applicable and appropriate;

- Ensure the application of market surveillance mechanisms in relation to its regulatory scope, to identify trends, risks and situations that may result in regulatory problems;

- Explain the supplier's responsibility with regard to the obligations to ensure that the products and services are safe and comply with the applicable regulations;

- Use the conformity assessment in a compatible, proportionate and appropriate way to the identified risks and the solution of the regulatory problem;

- Adopt the assumption that compliance with the technical standards and other applicable normative documents identified confer presumption of conformity to the regulations; and

- Implement a process of systematic and periodic critical analysis of inmetro's regulatory stock, with the participation of stakeholders.

7.2 Risk assessment and management approach

- Use risk assessment to support the decision:

- . in the identification of regulatory problems;

- . in the decision to regulate or not;

- . regulatory approach;

- . in the decision to include conformity assessment procedures;

- . the decision on the conformity assessment procedures to be used;

and

- . in the planning and exercise of market surveillance, including

inspection.

- Establish methods for applying the risk approach in decision-making

that are:

- . with solid technical basis;

- . appropriate to the intended application;

- . objective, flexible, clear and transparent;

- . accessible and public; and

- . reviewable.

- Consider that compliance with technical standards is an effective means of identifying and addressing risks.

7.3 Supplier accountability

Suppliers are responsible for the products and services that are the object of their activity. Regulations shall ensure that suppliers:

- Offer on the market, products or services, in accordance with the legislation, including applicable regulations;

- Carry out the monitoring, identification and treatment of the risks of their products or services subject to regulation; and

- Take necessary measures when a product or service does not meet the requirements or may cause harm to the consumer, informing the authorities of the actions implemented.

7.4 Use of Conformity Assessment

In the context of the use of the Conformity Assessment in the Regulatory Model of Inmetro, the regulation must:

- Adopt the appropriate conformity assessment procedures for the regulation of products, services and legal metrology, according to the identified risks, the objectives intended to be achieved and the categories of products and services;

- Identify risks, costs, effectiveness and efficiency when selecting conformity assessment procedures to ensure maximising compliance and competition conditions, avoiding the adoption of a more costly option than necessary and in proportion to the risks involved;

- Provide for the scalability and specific conditions of Micro and Small Enterprises, ensuring the treatment of risks and regulatory effectiveness;

- Be flexible in establishing the means of demonstration of compliance with the regulations requested in the conformity assessment procedures. For this you must:

- . Establish an articulated set of conformity assessment procedures that can be used in regulation either for products and services or for Legal Metrology; and

- . Provide for the use of conformity assessment procedures, taking into account risks and establishing an articulated set of conformity assessment procedures that can be used in regulation.

- Establish clear mechanisms for identifying the conformity of objects with regulations, including metrological control;

- Promote the participation of accredited Conformity Assessment Bodies, within the scope of legal metrology as support to market surveillance, including inspection, developed by the organisms of the Brazilian Network of Metrology and Quality of Inmetro - RBMLQ-I; and

- Use of voluntary compliance assessment programs, including by sectoral entities, where appropriate.

7.5 Essential requirements and use of technical standards

The activity of establishing technical regulations shall:

- Define essential requirements to address identified risks and meet regulatory objectives;

- Consider essential requirements that establish what should be achieved and not how it should be achieved;

- Draft the regulations in a non-prescriptive manner;
- Identify and publish the list of technical standards and other normative documents that confer presumption of conformity to technical regulations;
- Recognise that technical standards are voluntary and must be followed for the presumption of conformity to be implemented;
- Establish a mechanism through which the supplier who does not follow the identified technical standards can demonstrate that the product or service meets the essential requirements. In this case, the burden of demonstrating compliance with the essential requirements rests with the supplier; and
- Establish mechanisms through which the technical standards, necessary for the implementation of technical regulations, are developed, published and maintained by ABNT, recounting the engagement of the regulatory authority in its elaboration.

7.6 Market Surveillance

Market surveillance is an integral part of the regulatory process and should:

- Be exercised in relation to the regulatory scope of Inmetro, either to ensure that the regulations in force is complied with, or to monitor the market and identify regulatory problems that require technical regulation or for its revision;
- Be exercised with a focus on the regulatory results targeted and consider the risks identified in relation to the products and services made available to society;
- Be proactive and act to ensure compliance with regulations;
- Include information collection activities in databases, the constitution and management of databases of accidents, complaints or other problems, the performance of tests and other technical activities and punctual or systematic interventions to evaluate the products and services offered in the Brazilian market, both through physical and virtual stores;
- Consider market monitoring initiatives carried out by civil society, including sector or specialized entities, other government agencies and regulatory authorities and partnerships;
- Consider the activities or initiatives of private entities that contribute to the achievement of regulatory objectives, including voluntary compliance assessment initiatives and the participation of private entities, in accordance with legal limits and responsibilities;
- Have your inspection and monitoring costs justified by risk analysis and review them whenever appropriate;
- Seek financing mechanisms to fund market surveillance activities, including surveillance, aiming at their financial support;

- Promote and encourage market surveillance actions with the participation of other public agencies, including those that make up the National Consumer Protection System;

- Include an educational approach, in particular when a new regulation or revision is launched, without necessarily giving rise to sanctions;

- Specifically with regard to supervision, it shall:

- . Establish intensity and focus of the inspection taking into account the risks and their effectiveness in relation to the resources employed;

- . Include the application of sanctions, proportionate to infringements and focused on the effectiveness of regulation;

- . Be exercised by Inmetro and other public authorities with which Inmetro establishes delegation mechanisms. This includes considering the participation of other support bodies or entities in supervisory activities, including private entities;

- . Take into account voluntary conformity assessment procedures;

- . Be planned and oriented according to the risks, regulatory objectives to be achieved and their operational capacity. This means that planning inspection actions can consider various activities such as visual inspections, sample collection for tests, etc. In the planning and implementation of surveillance actions should be considered government and civil society initiatives, including the specific sector, market monitoring and the use of voluntary conformity assessment procedures establishing specific criteria;

- . Consider the history of suppliers in relation to aspects related to compliance with regulations, when appropriate, and according to the risks involved;

- . Establish mechanisms by which suppliers of non-compliant products or services share the costs of supervision;

- . Involve consumers and other stakeholders, such as class entities, associations and specific sectors. To this end, establish agile and effective mechanisms, including complaints, using Information and Communication Technologies - ICT where appropriate;

- . Establish cooperation mechanisms with national, foreign and international or regional organizations with activities in market regulation or surveillance (such as similar regulatory bodies of other Mercosur members and foreign authorities among others) and private entities, for the exchange of information in order to optimize market control actions and, thus, avoid the commercialization of non-compliant products and services;

- . Strengthen cooperation with the Receita Federal, the taxation authority, to optimize market control actions, including customs, to prevent non-compliant products from reaching consumers, including those from cross-border e-commerce;

- . Ensure the right of defence with agile and effective procedures, facilitating redress mechanisms arising from surveillance activities;

- . Consider an escalating approach to the establishment of educational measures and sanctions; and

- . Apply sanctions in an agile and effective manner, in order to discourage non-compliance with regulations.

7.7 Regulatory impact and results

The Regulatory Model of Inmetro must:

Systematically carry out the Regulatory Impact Analysis, whenever applicable or relevant, taking into account the requirements of the legislation; this should include:

- . Assess the need and impacts of including trial clauses and extinction and review clauses, as well as transition and implementation policies, in order to ensure that regulation adapts to the changes required by the market and society; and

- . Analyze risks and check for other methods such as self-regulation and co-regulation that can be tested before regulating.

- Promote coordination with other national and international regulators and supervisors to identify common challenges arising from innovations and act together to develop and implement response strategies, including avoiding the development of regulations inconsistent, incompatible or duplicated with other regulations or other regulators;

- Perform periodically and systematically the Evaluation of Regulatory Results - ARR in order to ensure the focus on the results of the regulation and monitor the effectiveness of the regulations and their review, and may be considered even their elimination, in case of non-achievement of the objectives initially established;

- Improve the methods to carry out the studies of Regulatory Impact Analysis - AIR and Evaluation of Regulatory Results - ARR and promote the engagement, including consultation, of stakeholders; and

- Recognize that the Regulatory Impact Analysis - AIR and Regulatory Outcome Assessment - ARR process are instruments to support decision-making, regarding the adoption of new regulations, or the need for review or revocation of an existing one.

7.8 International alignment and harmonisation

The Regulatory Process of Inmetro must:

- Be aligned with good international practices and guidelines and meet the commitments made by Brazil in international agreements;

- Seek regulatory convergence and international harmonization, according to the context and needs of the country;

- Promote engagement and active participation in the fora of good regulatory practices (e.g.: OECD, UNECE, OIML, UNTACD);

- Consider and promote the acceptance of foreign compliance assessment results, with the adoption of appropriate acceptance and validation

mechanisms, when relevant to the regulation and whenever possible seeking reciprocity and respecting national legislation;

- Contemplate engagement and active participation in initiatives related to the modernization of regulatory practices for the implementation of Industry 4.0 and the digital society; and

- Establish partnerships and cooperation with foreign regulatory authorities, aiming at regulatory convergence, good regulatory practices and acceptance or recognition of Brazilian regulation or its results.

7.9 Governance

Governance of the regulatory process must:

- Consider the participation of stakeholders representation;
- Strengthen the Conmetro as an instance of stakeholder participation;

- Be effective and ensure agility in decision-making;

- Have mechanisms to monitor regulatory impacts and results;

- Have mechanisms for periodic review of the regulatory process, including the creation of channels for criticism or suggestions for regulatory review, as well as the establishment of rules for periodic review and updating of regulatory stock;

- Manage the implementation process, including monitoring and supervising the transition phase and its full adoption;

- Establish mechanisms of engagement and dialogue with stakeholders in the review of rules, risks and processes that make up the regulatory model;

- Ensure transparency to the actions adopted and processes carried out within the framework of the regulatory model;

- Establish mechanisms of appeal and appeal relating to technical regulation; and

- Consider the participation of stakeholders representation as a consultative body in order to support the decision-making process.

7.10 Implementation

The implementation of the modernization of the Inmetro Regulatory Model is a critical phase for its success. It should cover a number of elements and activities that, as a whole, will enable the effective full implementation of these guidelines.

Implementation should include:

7.10.1 Implementation planning

Planning should include:

- A target date for the full implementation of the Model, from which all published regulations must follow its guidelines;
- A structure dedicated to the planning and supervision of its implementation, an integral part of the governance of the model;
- Establishment of a transition phase for the adoption of the model in a gradual, safe and effective manner, culminating in the full adoption of the model on the established target date;
- A Plan, available to the public, that includes an implementation schedule, covering the development of steps 7.10.2 to 7.10.7, monitored and monitored;
- The development and adoption of the necessary complementary instruments as well as the necessary tools and methods; and
- The realization of pilots to validate the model, know the difficulties and identify solutions to enable an effective and efficient implementation.

7.10.2 Necessary instruments and tools

For the implementation of the model, it is necessary to develop and establish a set of rules, and instruments, tools and support methods, involving the relevant entities. These include, but are not limited to:

- Standardization of risk assessment and management methods necessary for the application of the model in the various situations envisaged (see 7.2);
- Standardization of conformity assessment modalities to be considered and guidance for their use;
- Identification of the needs of adequacy or adaptation of the legal framework for the implementation of the model;
- Methods to identify and establish the essential requirements;
- Process to articulate the implementation of the model with standardization, including identifying demands for technical standards and other normative documents, establishing and managing the demands of standardization, guiding the participation of regulatory authorities in the standardization process and evaluating their adequacy to regulatory objectives, involving stakeholders;
- Methods for market surveillance;
- Methods for inspection; and
- Rules for the involvement of civil society in market surveillance activities, including surveillance, with participation throughout the stakeholder process.

7.10.3 Legal framework – adjustments to current instruments

For the full effectiveness of the model, some of the legal instruments, in particular those related to market surveillance, should be improved. It will be necessary to identify them and establish a strategy and process for their review.

7.10.4 Diffusion

The diffusion of the Model is a critical success factor. A communication plan should be established and implemented for this purpose.

7.10.5 Training

It will be necessary to establish training actions for those involved in the implementation of the model, as well as those most directly affected, including other government agencies, the private sector and other relevant civil society actors.

7.10.6 Transition phase

It will be necessary to establish a transition phase to implement the model by product categories or risk classes, according to an established schedule, with the involvement of stakeholders and public knowledge.

- The criteria for deciding the prioritization of product categories or risks should include the following considerations:

- . Risks of product or service categories, or relevance of the risk class to society;

- . Availability of the appropriate quality infrastructure;

- . Viability, including the capacity to mobilize the business sector;

- The transition phase should also ensure that methods, tools, instruments, and quality infrastructure are available, and the actors involved are trained;; and

- The transition phase must be scaled in a pragmatic and realistic way.

7.10.7 Pilots

Pilots should be implemented in a planned manner, with the involvement of stakeholders and public knowledge, to validate it, test and improve the effectiveness of its implementation.

DISCLAIMER

THIS TRANSLATION IS PRODUCED BY GLOBAL PROJECT QUALITY INFRASTRUCTURE (GPQI) AND MAY BE USED ONLY FOR REFERENCE PURPOSES. THIS ENGLISH VERSION IS NOT AN OFFICIAL TRANSLATION OF THE ORIGINAL BRAZILIAN DOCUMENT. IN CASES WHERE ANY DIFFERENCES OCCUR BETWEEN THE ENGLISH VERSION AND THE ORIGINAL BRAZILIAN VERSION, THE BRAZILIAN VERSION SHALL PREVAIL WHICH CAN BE FOUND [HERE](#). THE GIZ SHALL ACCEPT NO RESPONSIBILITY OR LIABILITY FOR DAMAGE OR LOSS CAUSED BY ANY ERROR, INACCURACY, OR MISUNDERSTANDING WITH REGARD TO THIS TRANSLATION.