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PUBLIC COMMENT No. 8 DATED MARCH 25, 2021

Proposal for Inmnetro's Regulatory Model.

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 Annex I to Decree no. 6276, dated November 28, 2007, and article 105, item V of 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, decides:

Article 1 The proposal for Inmnetro's Regulatory Model, annexed to this Public Comment, is disclosed.

Article 2 From the date this Public Comment is published in the Official Gazette elapses the term of 60 (sixty) days for the submission of suggestions and opinions related to the proposed text.

Article 3 Opinions and suggestions should be sent according to the template spreadsheet available at the website http://www.inmetro.gov.br/legislacao/, preferentially via electronic media, and to the following addresses:

- Instituto Nacional de Metrologia, Qualidade e Tecnologia – Inmetro

Assessoria da Presidência Av. Nossa Senhora das Graças, 50 - prédio 6 Xerém

CEP [Postal Code] 25250-020 - Duque de Caxias/RJ [State of Rio de Janeiro], or

- E-mail: gtmriconsultapublica@inmetro.gov.br

Paragraph 1st Opinions and suggestions that are not sent according to the model mentioned in the caput will not be considered valid for the public comment and will be returned to the claimant.

Paragraph 2nd If the claimant does not find the spreadsheet in the website mentioned, they may request it via e-mail or physical address, as outlined in the caput. Article 4 By the end of the due date set forth in article 2 of the present Public Comment, Inmetro and the entities standing forth their interest on the subject matter will act together to appoint representatives in subsequent discussions so as to show the results in a public hearing.

Article 5 This Public Comment shall become effective on the date of its publication in the Official Gazette.

MARCOS HELENO GUERSON DE OLIVEIRA JUNIOR

ANNEX

PROPOSAL OF FINAL ORDINANCE TEXT

Inmnetro's Regulatory Model is Approved.

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. 10139, dated 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, dated December 18, 2019, which regulates the provisions of *Lei de Liberdade Econômica* [Economic Freedom Act] so as to provide the criteria and procedures for the determination of economic activity risk classesment, 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 dated February 5, 2020, that regulates the right to develop, implement, operate or market products or services in disagreement with the outdated technical standard subject matter of the Economic Freeedom Act;

Considering the provisions of Decree no. 10.411, dated June 30, 2020, which regulates the *Análise de Impacto Regulatório* [Regulatory Impact Analysis], subject matter of article 5 of Law no. 13.874, dated September 20, 2019, and article 6 of Law no. 13848, dated June 25, 2019;

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

Considering the importance of monitoring and incorporating the innovations and technologies resulting 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 can be adequately adaptable and also flexible, so as to promote a more dynamic regulation that follows the market's progress;

Considering the regulatory activity is crucial for the protection of society, and for the innovation and competitiveness of the national industry, therefore contributing for the country's economic and egalitarian growth;

Considering the society demands the implementation of improvements in Inmetro's regulatory processes, supported by manifestations and participations in meetings, consultations with stakeholders and further media, and interactions provided by Inmetro in the last few years;

Considering the work performed in the multidisciplinary group's scope, which was created to provide support to the modernization of the current regulatory model, namely the *Grupo de Trabalho de Modernização do Modelo Regulatório do Inmetro* (Working Group for the Modernization of Inmetro's Regulatory Model - GTMRI), officially executed by Inmetro's Ordinance no. 212, dated June 10, 2020;

Considering it is imperative to strengthen Inmetro's regulatory activity making use of the proper engagement, information, and participation of the stakeholders, by adopting and implementing the result-oriented monitoring and assessment practices, keeping adequate, efficient, and effective regulatory activities;

Considering the public comment, in which the society provided their contributions to prepare the text approved herein, disclosed by Public Comment no. 6, dated March 23, 2021, published in the Official Gazette dated xx, xxxx, section xx, page xx, decides:

Object and scope of application

Article 1 The Inmnetro's Regulatory Model is hereby approved, being annexed to this Ordinance, and setting forth the principles and guidelines to be observed for the regulatory activity's improvement.

Paragraph 1 The principles and guidelines approved herein shall be observed and adopted throughout the regulatory activity steps.

Paragraph 2 The principles and guidelines outlined in the Annex to this Ordinance will be detailed, whenever required, in guides, manuals, or further communication instruments.

Terms and transient provisions

Article 2 The transition period of 5 (five) years is hereby set forth for the implementation of Inmetro's Regulatory Model, as of the date this Ordinance is published.

Sole paragraph. During this transition period, Inmetro's Operational Units shall promote actions for the adoption and implementation of the provisions set forth in the caput in all of their regulatory processes.

Revocation clause

Article 3 It is hereby revoked, as of the date this Ordinance becomes effective, Inmentro's Ordinance no. 252, dated May 27, 2015, published in the Official Gazette, dated May 28, 2015, section 1, pages 55 to 56.

Term

Article 4 This Ordinance becomes effective as of xxxxxxxxxxxxxxxxxxxxxxxxxxx. [specific date to be entered by the President's Office, as set forth in article 4 of Decree no. 10139, 2019].

ATTACHMENT - INMNETRO'S REGULATORY MODEL - PRINCIPLES AND GUIDELINES

1. INTRODUCTION

The current national and global situation has been setting out a strong evolution in recent years through intensified competitiveness, deep changes due to the economy's digitalization (which covers the so-called Industry 4.0), the unsuitable position of Brazilian's competitiveness in the international scenario, the Federal government guidelines to promote a Brazilian regulatory environment with more economic freedom as a development strategy, so as to provide the means to develop a modernization of legislation and, further, the development of Inmetro's Strategic Plan for the period from 2021 to 2023.

Amongst the activities performed by Inmetro,a paramount body of Quality Infrastructure in Brazil, that shall be improved is regulation, since its impacts are crucial for the Country's competitiveness. Therefore, it is imperative to reassess the Institute's regulation activities, so better outcomes can be provided to the society and its mission and policy objectives set forth can be complied with. Accordingly, it is necessary to provide a critical review of what was commonly defined as the regulatory model, in order to modernize it in a way to overcome all new challenges to be faced. Inmetro's regulatory model, that is, the way Inmetro organizes and carries out the operation of its regulatory functions, aiming at meeting the regulatory objectives for which it is responsible, covers the regulation related to legal metrology and product, process, and service regulation as for the security, protection of human, animal, and plant life and health, protection of environment, and prevention of deceptive trade practices, according to the powers vested in the Institute by Law.

The current regulatory model requires improvement since its founding characteristics, resulting from the respective evolution over the last 30 years, ended up worsening the regulatory process complexity and toning down its performance.

The critical analysis of the regulatory model carried out identified several issues affecting the efficacy and efficiency of Inmetro's regulation activity, and also acknowledged the correlation of this poor performance to the way the regulation is established and implemented. Amongst the issues identified, the following should be emphasized:

- Overly prescriptive and detailed regulations, making them difficult to be complied with by the companies, as well as their proper maintenance and update;

- Bureaucratic processes that do not contribute to add clear value;

- Unreasonably long regulation analysis, development, implementation, maintenance, review, and update processes, which are also extremely expensive (process demanding several years from the first move to establish a regulation to its full implementation);

- Regulation established individually, resulting in too many regulations to be met by the companies and generated by Inmetro (121 regulation in Legal Metrology and 176 regulations for products and services - as of 2020);

- Limitation and progressive decrease in resources for Inmetro activities;

- Several stakeholders have the impression that the inspection process is excessively expensive and has poor efficiency and efficacy.

- The use of bureaucratic pre-market mechanisms for an important amount of products and services (e.g., the approval of imports and registration).

It is worth noting that Inmetro's regulation activity started to increase as of the beginning of this century, as a response to society's demands, resulting from the Brazilian economy development and evolution and, due to the fact that Inmetro's role as the regulation body is broadly acknowledged by the society as necessary, relevant, and that it should be kept and improved.

In view of these challenges and upon the identification and analysis of issues, Inmetro established the modernization of its regulatory model as one of its top priorities, and consulted and involved the stakeholders in the consultation processes, including the private sector, technological entities, and consumer representatives. To conduct the regulatory model's modernization process, it has created a multidisciplinary group to support the modernization of Inmetro's Regulatory Model - GTMRI, through Inmetro's Ordinance no. 212, dated June 10, 2020.

To comply with the provisions of Inmetro's Ordinance no. 212, several actions and studies were performed to define a more efficient and flexible new regulatory model to respond to the current regulatory needs and technological innovations.

The main emphasized actions are the compilation and analysis of visions and propositions from the stakeholders for Inmetro's Regulatory Model modernization, as well as studies carried out to identify and present the main characteristics and recent evolutions of the National and regional systems dedicated to Quality Infrastructure activities, namely for regulation, standardization, accreditation, and assessment of compliance, metrology, and inspection in the United States of America, South Korea, Europe, and those influenced by the Industry 4.0 paradigm, aiming at opening the way for a critical appraisal and improved understanding of the trends for these activities.

In this regard, this document is based on the compilation and consolidation of the outcomes of these diversified actions performed and conducted by Inmetro for the modernization of its Regulatory Model.

This document outlines the guidelines to be followed by Inmetro's regulatory processes and the activities deriving from them, from development to implementation, including market surveillance and legal improvement identification actions, provided the change of legal instruments, if required, such as laws, resolutions, and ordinances.

The model proposed herein is centered on strengthening the regulatory activity by ensuring the industry and market will follow all technological innovations with more engagement, information, and participation of the stakeholders, therefore encouraging and promoting the monitoring of outcomes and assessment practices, so as to properly maintain the regulatory practice focused on the intended purpose and relevance, remaining effective and proportional to the problems faced.

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

- Vision

- Objectives

- Principles

- Guidelines

2. GLOSSARY

For the purposes of this document, the following definitions are applied, using as a reference the International Vocabulary of Metrology Terms - VIM, the International Vocabulary of Legal Metrology Terms - VIML, ABNT ISO/IEC Guide 2: 2006 Standardization and related activities -

General vocabulary, and standard ABNT NBR ISO/IEC 17000 (Conformity assessment: Vocabulary and general principles).

It is worth noting that a new review of the standard ISO/IEC 17000 was published in 2020, and the referred standard is under process of adoption in Brazil.

2.1 Accreditation - it is a third-party attestation related to a conformity assessment body formally demonstrating its competence to conduct specific conformity assessment activities. [ABNT NBR ISO/IEC 17000].

2.2. Regulatory Impact Analysis - RIA - systematic analysis process based on evidence with the purpose of assessing the potential impacts of action alternatives available, on the basis of a definition of a regulatory issue, to reach the intended objectives, to guide and provide a subsidy to the decision-making process [adapted from *Diretrizes Gerais e Guia Orientativo para Elaboração de Análise de Impacto Regulatório - AIR* - Brazilian Government Affairs Office of the Presidency of the Republic].

2.3 Regulatory Result Assessment - RRA - performance assessment instrument for adopted or amended normative acts, considering whether the originally intended objectives and results were reached, as well as the further impacts observed on the market and society due to its implementation [adapted from *Diretrizes Gerais e Guia Orientativo para Elaboração de Análise de Impacto Regulatório - AIR* - Brazilian Government Affairs Office of the Presidency of the Republic].

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

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

2.6 Consumer - individual or legal entity that purchases or uses products or services as the end consumer [adapted from Law 8078/1990 - *Código de Defesa do Consumidor* [Consumer Code]]

2.7 Conformity statement (supplier statement) - procedure through which a supplier provides a written guarantee that a product is in conformity with the specified requirements [ABNT NBR ISO/IEC GUIDE 2: 2006]

2.8 Supplier - individual or legal entity, whether public or private, national or foreign, as well as entities without legal personality, that develop production, assembling, creation, construction, transformation, import, export, distribution, or sale of products or service provision [adapted from Law 8078/1990 - *Código de Defesa do Consumidor*]

2.9 Inspection - activity aimed at observing if the obligations provided for in [legal] standards are being or not complied with by the agents [adapted from *Diretrizes Gerais e Guia Orientativo para Elaboração de Análise de Impacto Regulatório - AIR* - Brazilian Government Affairs Office of the Presidency of the Republic].

2.10 Metrology - science of measurement and its application [Inmetro Ordinance no. 150, 29/Mar/2016];

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

2.11 - Legal Metrology - Practice and process of applying metrology to a legal regulating structure and of implementing its execution.

Note 1: The legal metrology scope may vary according to the country.

Note 2: Legal metrology includes:

- establishment of legal requirements;

- conformity control/assessment of regulated products and activities;

- supervision of regulated products and activities; and

- provision of the infrastructure required for the traceability of measurements and measurement instruments regulated with IS or national standards.

Note 3: Regulations out of the legal metrology scope may exist, and they are related to measurement accuracy and adjustment of measurement methods

[Inmetro Ordinance no. 150, 29/Mar/2016].

2.12 Technical standard - A non-mandatory document established by a consensus and issued by a recognized body, which provides, for common and repeated use, guidelines or characteristics for services, products, goods, people, processes, or production methods. It can also outline the terminology, symbols, packaging requirements, marking, or labeling applicable to a product [Conmetro - *Guia de Boas Práticas de Regulamentação* [Guide of Good Regulatory Practices] - GBPR].

2.13 Conformity Assessment Body - the body that performs conformity assessment activities, except accreditation [ABNT ISO/IEC 17000].

2.14 Accreditation body - the body that is authorized to execute accreditation [ABNT NBR ISO/IEC 17000].

2.15 Regulation - a contemporary action by the Government, which generally refers to a set of legal-normative instruments (laws, decrees, regulations, and other standards) that the Government uses to establish obligations to be complied with by the private sector, citizens, and the Government [adapted from *Diretrizes Gerais e Guia Orientativo para Elaboração de Análise de Impacto Regulatório - AIR* - Brazilian Government Affairs Office of the Presidency of the Republic].

2.16 Technical regulation - a regulation that establishes technical requirements, either directly or by reference or incorporation of contents of a [technical] standard, a technical specification or a practice code [adapted from ABNT NBR ISO/IEC GUIDE 2: 2006].

2.7 Essential requirements - a result to be reached or a risk to be treated, when there are no technical solutions specified about the procedures to do it, with the purpose of providing and ensuring the protection of security, health, and environment [adapted from Blue Guide on the implementation of EU product rules, 2016].

2.18 Conformity Assessment System - rules, procedures, and management for conformity assessment [ABNT NBR ISO/IEC 17000].

2.19 Market Surveillance - activities with the purpose of assessing the performance of products or services in the market versus the requirements established by the Law or identifying potential security risks or regulatory problems.

Note: market surveillance includes inspection activities.

2.20 Regulatory Objective - the intended objective with the regulatory intervention.

3. ACRONYMS USED

ABNT - Brazilian Association of Technical Standards

RIA - Regulatory Impact Analysis

RRA - Regulatory Result Assessment

Conmentro - *Conselho Nacional de Metrologia, Normalização e Qualidade Industrial* [National Council of Metrology, Standardization, and Industrial Quality]

ISO - International Organization for Standardization

OECD - Organization for Economic Co-operation and Development

OIML - International Organization of Legal Metrology

SBAC - *Sistema Brasileiro de Avaliação da Conformidade* [Brazilian System on Conformity Assessment]

Sinmetro - *Sistema Nacional de Metrologia, Normalização e Qualidade Industrial* [National System of Metrology, Standardization, and Industrial Quality]

EU - European Union

UNECE - United Nations Economic Commission for Europe

UNCTAD - United Nations Conference on Trade and Development

4. VISION

It is considered that this model should meet the following future vision for the regulatory model: Regulatory model, as a part of Quality Infrastructure, that meets the society expectations, ensures a safe and dynamic market, is flexible and embraces innovations, promotes competitiveness, and boosts digitalization (Industry 4.0).

5. OBJECTIVES

Based on the established vision, the general objectives for the regulatory model are:

- To be steady and perennial, covering and following the increasing expectations of society and market

- To overcome all current model problems identified

- To be a market protection and streamlining instrument, and to facilitate businesses

6. PRINCIPLES

The principles guiding the regulatory model are as follows:

6.1. Scope

The regulatory process scope shall include the competence and scope of work of INMETRO, so as to meet the expectations and needs of society - in conformity with its institutional mission.

6.2 Focus on objectives and results

The regulatory model shall focus on the regulatory objectives and respective intended results, aiming at continuously delivering efficacy and efficiency.

6.3 Flexibility

The regulatory model shall be flexible to the extent of allowing to meet the current and future society needs and expectations by adopting the appropriate solutions to solve the regulatory problems and challenges faced, and for the compliance with the regulatory objectives identified, incorporating innovation attributes.

6.4 Compatibility

The regulatory model shall be consistent with the economy’s digitalization process, in a way that provides the capacity to respond to current and future regulatory problems and challenges identified.

6.5 Equality

The regulatory model shall open the way for equality in the treatment of the affected economic actors, regardless of nationality or origin, keeping the balance of the competitiveness conditions.

6.6 Harmonization

The regulatory model shall ensure that the preparation and execution of its processes are aligned with national and international good regulatory practices.

6.7 Supplier and risk-based liabilities

The regulatory model shall be based on suppliers undertaking to comply with their liabilities before the Brazilian legal structure, adopting a risk management vision.

6.8 Evolution of Market Surveillance Inspection

One of the core elements of a regulatory model is the market surveillance process, including inspection, follow up, and monitoring activities, to the extent of ensuring the compliance with the regulatory objectives.

6.9 Agility

The regulatory model shall ensure fast and efficient responses.

6.10 Feasibility

The regulatory model shall employ excellence in the compliance with its objectives, using less resources, including the optimization of its processes and investment in new technologies.

7. GUIDELINES

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

7.1 Regulatory process

The regulatory process must:

- Cover the areas Inmetro has regulatory liabilities to comply with, respecting their specificities (such as legal metrology, regulation of products and services, among others), and respective their legal competencies;

- Be planned and guided considering risks and the regulatory objectives to be reached; and

- Be focused on regulatory objectives and results as soon as the regulatory problems are identified. The regulatory objectives should:

. Set forth the regulation objectives with the regulatory agenda, under its responsibility altogether

. Identify the problems to be solved and the objectives to be reached for each regulatory initiative

. Include the regulatory stock management with the support of the stakeholders

. Be covered by the regulatory scope attributed to Inmetro

. Design how to identify regulatory problems and execute the respective problem-solving activities with other regulatory authorities. To this end, Inmetro may cooperate to provide technical support to the regulatory process of other authorities, such as the support to establish conformity assessment procedures included in the regulatory process of these other authorities.

- Be based on clear rules and sound technical basis

- Be predictive, with an anticipatory behavior, defining different methods to adopt a more prospective and coordinated approach to respond to the emerging opportunities and risks in an agile and innovation-receptive manner

- Promote the balance of interests, equality treatment, transparency, and impartiality

- Ensure the participation of the stakeholders (including users, entities, entities with legal personality, and consumers, as well as other regulatory bodies), establishing ongoing communication

- Establish broader regulations with improved response to innovation and greater flexibility

- Establish regulations to cover, whenever possible, risk category or product categories instead of specific products

- Anticipate the market surveillance mechanisms, including inspection and conformity assessment procedures considered, whenever applicable and appropriate

- Anticipate the market surveillance mechanisms related to its regulatory scope to identify trends, risks, and problems that may result in regulatory problems.

- Make explicit the supplier’s liability for the object, which includes the obligation of ensuring that the products and services are safe and comply with the application regulation

- Use the conformity assessment in a consistent, proportional, and proper manner regarding the identified risks and the solution of the regulatory problem

- Have an approach determining that the compliance with the technical standards confers the assumption that the regulation is also being complied with

7.2 Supplier’s liability

The suppliers (manufacturers, importers, distributors, service providers, and remaining actors responsible for the product or service being sold - pursuant to article 3 of *Código de Defesa do Consumidor*) are

responsible for products and services that are the subject matter of their activities. The regulation should ensure that the suppliers:

- Supply the market with products and services in conformity with the current legislation and/or regulations;

- Perform the monitoring, identification, and treatment of risks related to their products or services under the regulation and

- Adopt the required measures when a product or service does not comply with the requirements or may result in damages to the consumer, by informing the authorities about the implemented actions.

7.3 Use of Conformity Assessment

As for the use of the Conformity Assessment in Inmetro's Regulatory Model, the regulation must:

- Adopt adequate conformity assessment procedures for the regulation of products, services and legal metrology, according to the risks identified, the intended objectives, and product and services categories

- Identify the risks, costs, efficacy, and efficiency when selecting conformity assessment procedures, in order to ensure the highest conformity and competitiveness conditions

- Anticipate the scalability and specific conditions of Micro- and Small-Sized Companies, ensuring that the risks will be managed and the regulation's efficacy

- Be flexible when stablishing means to demonstrate that the regulation is being complied with, as requested in the conformity assessment procedures. To do this, the following is required:

. Establish a joint set of conformity assessment procedures, which can be used in the regulation of products and services or for Legal Metrology

. Foresee the use of the supplier's statement as one of the conformity assessment procedures, according to the risks

. Foresee the use of mandatory certification, when appropriate, due to the risks

. Foresee the use of other conformity assessment procedures, always considering the risks

- Establish clear marking mechanisms to identify the conformity with the regulations, including those related to metrology control

- Promote the participation of accredited Conformity Assessment Bodies, in the scope of legal metrology, as supporting agents to the ancillary activities developed by bodies composing the *Rede Brasileira de Metrologia e Qualidade do Inmetro* [Brazilian Network of Metrology and Quality - Inmetro] - RBMLQ-I

- Encourage the creation of voluntary conformity assessment programs, including by sectoral entities, when appropriate

7.4 Essential requirements and use of technical standards

The activity of establishing technical regulations must:

- Define the essential requirements that allow the risk identification and the compliance with the regulatory objectives

- Consider the essential requirements that establish what should be reached and not how it should be reached

- Be described in a non-prescriptive manner.

- Identify and publish a list of selected technical standards that confer the assumption that the technical regulation is being complied with.

- Recognize that the technical standards are voluntary, establishing a mechanism through which a supplier may demonstrate that it meets the essential requirements, while not necessarily complying with the technical standards identified as conferring the assumption of conformity. In this case, the burden of such demonstration is borne by the supplier since it is related to its role as the regulation provider.

- Establish mechanisms through which the technical standards, that are required for the implementation of the technical regulation, are developed, published, and kept by ABNT, considering as well the engagement of the regulatory authority in its preparation.

7.5 Market Surveillance

The market surveillance is an integral part of the regulatory process and must:

- Be enforced considering Inmetro's regulatory scope, whether to ensure that the current regulation is being complied with, or to follow up the market and identify regulatory problems requiring technical regulation or the respective review

- Be enforced focusing on the regulatory results and considering the risks

- Be proactive and executed to ensure the regulation is being complied with

- Include database information collection activities, the creation and management of accident-related database, or a database related to other problems, the conduction of tests and other technical activities in products or services offered in the Brazilian market, specific or systematic interventions in the assessment of products, services, measurement instruments offered in the market (including online services), among other measures

- Consider market follow up initiatives by the civil society, including sectoral entities or specialized entities, other Government bodies, regulatory authorities, and partnerships

- Consider private entity activities or initiatives that contribute for reaching the regulatory objectives proposed, including voluntary conformity assessment initiative and the participation of private entities, according to the legal limits and responsibilities

- Support their inspection and monitoring costs through risk analysis

- Establish financing mechanisms to pay for the market surveillance activities, with the purpose of ensuring its financial support

- Promote and encourage market surveillance actions with the participation of other public bodies, such as those of *Sistema Nacional de Defesa do Consumidor* [National Consumer Defense System]

- Include an educational approach, particularly when a new regulation or review is released and, in this case, with no sanctions being imposed

- Specific items related to inspection:

. Establish intensity and focus in the inspection, considering the risks and efficacy versus the resources employed

. Include sanction application, which must be equivalent to the violations and focused on the regulation efficacy

. Be exercised by public authorities with delegation mechanisms established with Inmetro. That includes considering the participation of other bodies or entities in material and ancillary inspection activities, including private entities

. Consider the voluntary procedures of the conformity assessment

. Be planned and based on risks, regulatory objectives to be reached, and its operational capacity. It means that planning inspection actions may include several activities, such as visual inspections, collection of samples for tests, among others. While planning and implementing inspection actions, civil society initiatives should be considered, including the specific sector, market follow up, and use of voluntary conformity assessment procedures

. Consider the background of the suppliers regarding the aspects related to compliance with regulation, when appropriate, , always observing the involved risks

. Establish mechanisms to pay for the inspection activities, with the purpose of ensuring its financial support

. Establish mechanisms to share inspection costs with the non-conformity product or service suppliers

. Involve consumers and other stakeholders, such as class entities, associations, and specific sectors. To this end, agile and efficient mechanisms must be established, including whistleblowing, with the support of Information and Communication Technologies - ICT, whenever appropriate

. Reinforce the cooperation with the Brazilian Federal Revenue Service, to optimize the market control actions, including customs, to prevent non-conformity products to be sold to consumers, as well as those from electronic cross-border trades

. Ensure the right of defense and resource mechanisms, based on agile and efficient procedures according to the respective responsibilities, avoiding delays to pay penalties

. Consider a vertical approach to establish educational measures and sanctions

. Apply sanctions in an agile and efficient manner, so as to encourage the compliance with the regulation

7.6 Risk management and assessment approach

- The risk assessment should be used to support decisions relating to:

.the identification of regulatory problems

.the decision to regulate or not regulate

. the regulation approach

.the decision to include or not conformity assessment procedures

. decision regarding to which conformity assessment procedures will be used

. planning and application of market surveillance, including inspection

- Establish risk approach application methods in the decision-making process that:

. have a sound technical basis

. are adequate to the intended application

. are objective, clear, and transparent

. are accessible and public

. can be reviewed

- Considering that the compliance with the technical standard is an efficient way to identify and manage risks

7.7 Regulatory impact and results

Inmetro’s Regulatory Model should:

- Systematically perform the Regulatory Impact Analysis, whenever pertinent or relevant, going beyond the minimum required by the Law; it should include the following:

. Assess the necessity and impacts of the inclusion of trial clauses and extinction and review clauses, as well as transition and implementation policies, and a way to ensure that the regulation is adjusted to change required in the Fourth Industrial Revolution scenario

. analyze the risks and check if there are other methods, such as self-regulation and co-regulation, that can be tested before the regulation

- Promote the coordination, with other national regulators and inspectors, to identify common challenges due to innovations and jointly cooperate to develop and implement response strategies

- Systematically and periodically perform the Regulatory Result Assessment - RRA - to ensure the focus on regulation results

- Improve the methods of performing the RIA and RRA studies and promoting engagement of stakeholders, including consultations

7.8 International harmonization and alignment

Inmetro's Regulatory Process should:

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

- Seek regulatory convergence and international harmonization, according to the country's needs and scenario

- Promote the active engagement and participation in quality regulation fora (for example: OECD, UNECE, OIML, UNCTAD)

- Consider and promote the acceptance of foreign conformity assessment results, with the adoption of appropriate acceptance and validation mechanisms, when relevant and whenever possible, aiming at obtaining reciprocity and respecting the national legislation

- Design, plan and actively engage in initiatives related to the modernization of regulation practices, so as to foster the development of the industry 4.0 and a digital society

- Establish partnerships and joint efforts with foreign regulatory authorities, aiming at a regulatory convergence, good regulatory practices, and acceptance or acknowledgment of the Brazilian regulation or its respective results

7.9 Governance

The regulatory process governance should:

- Consider the participation of stakeholder representatives

- Reinforce Conmetro as an instance of stakeholders' participation

- Be efficient and ensure agile decision-making processes

- Be balanced so as to ensure the best possible decisions

- Be focused on the defined regulatory objectives and results

- Have regulatory impact and result monitoring mechanisms

- Have periodic review mechanisms for the regulatory process, including agenda and regulatory stock management

- Manage the implementation process, including by following and supervising the transition phase and its full adoption

7.10 Implementation

Implementation of Inmetro's Regulatory Model is a critical phase for its success. It should cover a series of elements and activities that, as whole, will path the way for the effective and full implementation of these guidelines.

The implementation should include the following:

7.10.1 Implementation planning

The planning shall include:

- A target date for the Model's full implementation, based on which all published regulation should follow its guidelines

- A structure dedicated to planning and supervision of its implementation, an integral part of the model's governance

- The establishment of a transition phase for the model adoption in a gradual, safe, and efficient manner, resulting in the full model adoption on the target date established

- The disclosure of the implementation plan to the public and its follow up should be monitored and included as one of the activities

- The development and adoption of supporting instruments, tools, and methods required

- The execution of pilot tests to validate the Model, understand the obstacles, and identify solutions for an efficient implementation.

7.10.2 Instruments and tools required

For the Model's implementation, a set of rules and instruments, tools, and support methods should be developed and established. These include, but are not limited to:

- Standardization of assessment methods and risk management required for the Model's application in several anticipated situations (see 7.6)

- Standardization of conformity assessment modalities to be considered and guidance for their use

- Identification of adjustment needs regarding the legal framework for the Model's implementation

- Methods to identify and establish the essential requirements

- Processes to articulate the Model's implementation with national standardization, including identification of technical standards; identification and management of standardization demands; guidance of regulatory authority participation in the standardization process; and assessment of the respective adjustment to the regulatory objectives

- Methods for market surveillance

- Methods for inspection

- Rules for the engagement of the civil society in market surveillance activities, including inspection

7.10.3 Legal framework - adjustment to current instruments

For the full Model's efficacy, it is convenient to improve some of the legal instruments, particularly those related to market surveillance. They must be identified and a strategy and process for their review should be established

7.10.4 Diffusion

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

7.10.5 Training

Training sessions should be established for those involved in the Model's implementation, as well as the most directly affected, including other Government bodies, private sector, and other relevant actors in the civil society.

7.10.6 Transition phase

A transition phase must be established for the implementation of the model, which should be made by product or risk class categories, according to a schedule prepared together with stakeholders and made available to the public.

- The criteria to decide upon the prioritization of product or risk categories should include the following considerations:

. Product or service risks, or relevance of risk class to the society

. Availability of the proper quality infrastructure

. Feasibility, including the mobilization capacity of the corporate sector

- The transition phase should also ensure that the methods, tools, and instruments required are available, that the quality infrastructure needed is available as well, and that the actors involved received proper training.

- The transition phase should be dimensioned in a pragmatic and realistic manner, set in years.

7.10.7 Pilot tests

Planned, pilot tests for the model application must be conducted to validate and test the efficacy of its implementation.