The Brazilian National Quality Infrastructure: an overview and recent developments

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Metrology, Standardisation and Industrial Quality, as from 1973

- **SINMETRO – the system**
  National System of Metrology, Standardisation and Industrial Quality

- **CONMETRO – ministerial council**
  National Council of Metrology, Standardisation and Industrial Quality

- **INMETRO**
  Secretariat of CONMETRO

- **Technical Advisory Groups (under review)**
  - Metrology
  - Standardisation
  - Conformity Assessment
  - Regulation
  - Technical Barriers to Trade
  - Codex Alimentarius
**Standardisation**

The **Brazilian Association of Technical Standards**, created in 1940, is the sole standardisation body in Brazil.

ABNT adopts the Code of Good Practice for the Preparation, Adoption and Application of Standards (Annex 3, TBT Agreement)

Total of 141 technical committees and study commissions, for 8,131 standards under macro sectors (2018):

- Chemicals, manufacturing technology and materials: 28.3%
- Machinery, mechanical & transport equipment: 20.9%
- Energy, electrical electronics, ICT: 15.8%
- Health, safety & environment: 12.2%
- Building & infrastructure: 10.5%
- Others: 12.3%
Both TBT National Notification Authority and Enquiry Point come under INMETRO.

- National Metrology Institute
- Legal Metrology Regulation Authority
- Product Safety Regulation Authority
- National Accreditation Body

- TBT NNA & EP
The main regulators

Most TBT notifications for regulations are issued by:

• ANVISA – Brazilian Health Regulatory Agency
• MAPA – Ministry of Agriculture, Livestock and Food Supply
• INMETRO – Natl. Inst. of Metrology, Quality and Technology

Around 160 TBT notifications per year:

37% ANVISA
34% MAPA
23% INMETRO
6% other regulators
Metrology: research; calibrations; tests; production of reference materials

Scientific and Industrial Metrology

- Physical metrology
- Chemical metrology
- Biological metrology

Time and frequency metrology

- Time Service
- National Observatory

Ionising radiation metrology

- Institute for Radiation Protection and Dosimetry
- National Nuclear Energy Commission

They all provide traceability to accredited and non-accredited calibration and testing laboratories; research facilities and others
Innovation and Metrology Campus

1.7 million $m^2$; 52,700 $m^2$ built

52 laboratories

55 buildings in the Campus

Inmetro’s system workforce

6,620 professionals, all over the country
Legal Metrology

Measurement instruments and pre-packaged goods

Regulation

Pattern approval

Verifications and market surveillance

legal agreement

Institutes of Weights and Measures, in each state

Member
Brazilian Network for Legal Metrology and Quality – Inmetro

28.6 million measurement instruments verified per year

626,000 preliminary evaluations of pre-packaged goods

635,000 surveillance rounds of product conformity assessment
Accreditation: CGCRE/Inmetro

Calibration laboratories (ISO 17025): ~1,000
Testing laboratories (ISO 17025): ~1,000
Management system certification bodies: ~100
  quality, environmental, social responsibility etc.
Product certification bodies: ~120
Inspection bodies: ~780
  dangerous products, vehicle safety & emissions etc.
Reference material providers: 10
Proficiency test providers: 16
OECD—GLP recognised test facilities: 45

~ 2,700 accredited bodies
970 external assessors
4,000 assessments a year
Accreditation: CGCRE/Inmetro

CGCRE is signatory to several MRA:

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

... and is the Brazilian Authority for Monitoring Compliance to the Principles of Good Laboratory Practices – GLP
Product safety regulation

- 195 regulatory measures
- 612 ordinances (~ 9,000 pages)
- 684 product categories regulated
- 50 supplementary ordinances per year
- $220,000 for each new regulatory measure
- 7 years to implement a new measure from scratch...

- 260,000 import licences issued per year for regulated products
- 57,000 registration applications per year
- ~2,000 import licences issued per year for measurement instruments
- 300 consumer accidents reported to the Inmetro’s Monitoring System

... only 12% regulated scope covered
Product safety regulation

Under the present regulatory model...

• only 1 in 10 products comes under regulation;
• regulation is individually applied for every product;
• rules are dense, detailed and prescriptive, hindering innovation and competitiveness;
• certification + registration + import control indistinctly applied as a general rule (regulatory burden);
• same treatment for good and bad manufacturers and importers;
• market surveillance is inefficient.
Product safety regulation

Present regulatory model is very prescriptive...

1. Low performance
2. Adverse effects to the economy
3. Not aligned with best international practices
4. Not aligned with present governmental policy guidelines
Product safety regulation: the new Inmetro model

What if 100 % of the scope were regulated?

The new regulatory model for products that come under the regulation scope of Inmetro aims at increasing performance and coverage.

It is assumed that:

• suppliers are responsible for the product they offer on the market;
• suppliers must perform risk analysis and take actions to mitigate risks;
• certification bodies will have more freedom but greater responsibility;
• conformity assessment models will be applied according to need and risk;
• presumption of conformity to standards will be in place.
Better regulatory performance

- Less bureaucracy
- Better use of resources
- Simplification

New regulatory model

- Better coverage
  - Rules environment based on General Regulations and Essential Requirements
- Better solutions
  - Focus on solving regulatory problems
- Better compliance
  - Supplier Accountability

Flexibility
Product safety regulation: the new Inmetro model

General Regulation

- Transverse regulations for groups of products (eg. children products)
- Transverse regulations for specific risks (electrical safety, chemical safety)

Toys  Gas water heaters  etc.
Product safety regulation: the new Inmetro model

Focus on problem solving

The basic idea, inspired by what other countries do, is developing a **monitoring strategy** capable of identifying problems related to inputs, products and services within Inmetro's legal competence.
Product safety regulation: the new Inmetro model

Next steps

• Simplification of import licensing procedures: 2019;
• Simplification of registration: 2019;
• Withdrawal of low impact regulation: 2019
• Development of the General Regulation: 2020
• Development of the second level regulations: 2020-2021
# Product safety regulation: the new Inmetro model

Public call for comments was notified. Links directed to a form with questions and to document containing detailed study.

## Notification summary: G/TBT/N/BRA/890

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<th>Notifying Member(s)</th>
<th>Brazil</th>
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<tr>
<td>Symbol, title and description of content</td>
<td>Ordinance 322, 03 July 2019. G/TBT/N/BRA/890 The National Institute of Metrology, Quality and Technology (INMETRO) has initiated the process to elaborate the General Regulation of Products and Services under the regulatory scope of Inmetro. Therefore, it is launching a public enquiry to promote social participation in such process.</td>
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<tr>
<td>Distribution date</td>
<td>12/07/19</td>
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<tr>
<td>Products</td>
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<td>Objectives</td>
<td>Protection of Human health or Safety</td>
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| Link(s) to full text | [http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC002584.pdf](http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC002584.pdf)  
Thank you

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INMETRO’s mission

The right measure to foster trust for society and competitiveness for the productive sector