The Brazilian National Quality Infrastructure: an overview and recent developments

Léa Contier de Freitas
Deputy Head for International Affairs
TBT National Notification Authority and Enquiry Point
National Institute of Metrology, Quality and Technology

13/11/2019

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 & infrastrucuture	10.5%
others	12.3%

TBT National Notification Authority and Enquiry Point

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

INMETRO

Scientific and Industrial Metrology

- Physical metrology
- Chemical metrology
- Biological metrology

designation

Time and frequency metrology
Time Service
National Observatory

Ionising radiation metrology
Institute for Radiation Protection and Dosimetry
National Nuclear Energy Commission

Bureau International des Poids et Mesures

MRA Signatory

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

INMETRO

Innovation and Metrology Campus

1.7 million m²; 52,700 m² built

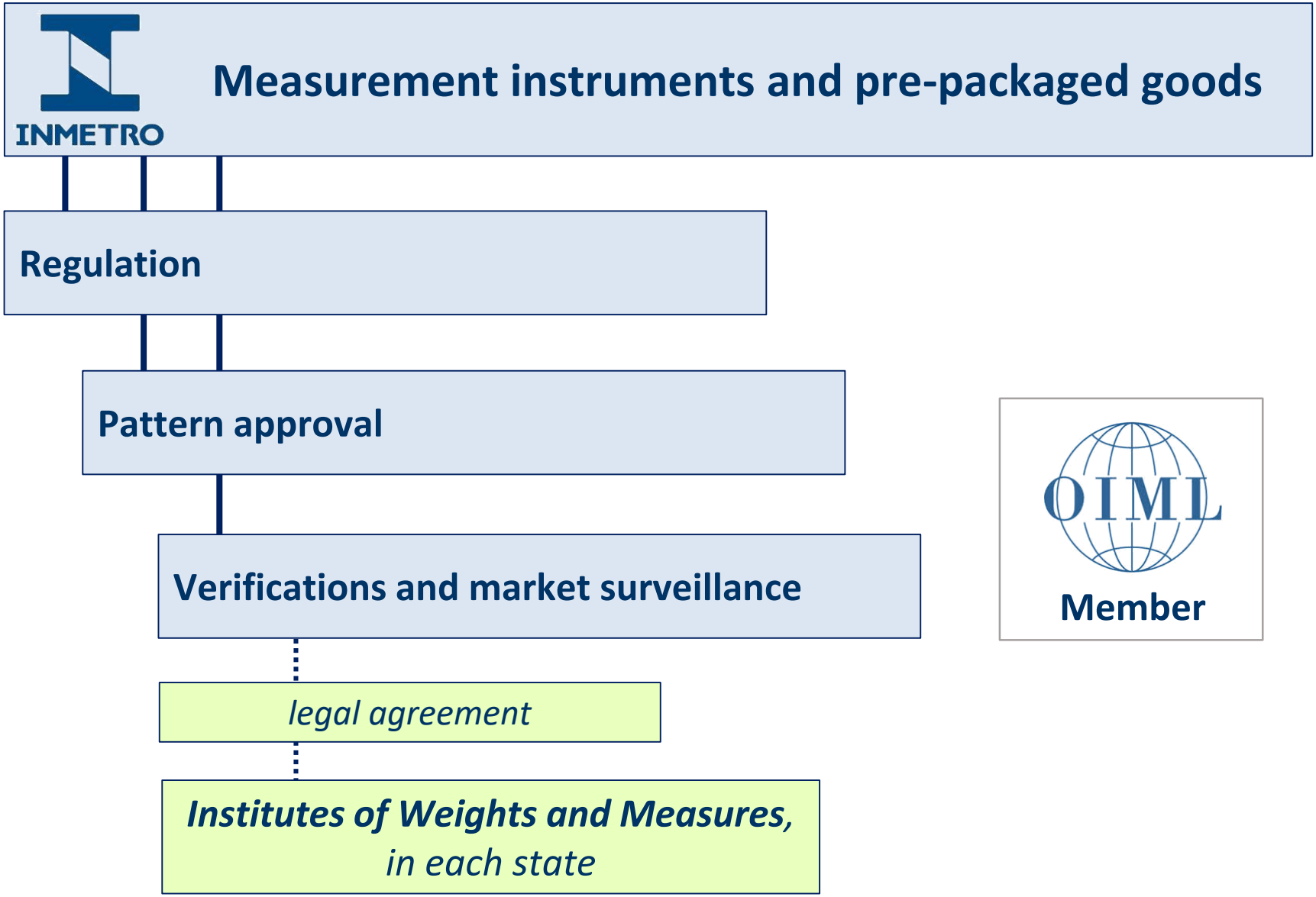
52 laboratories

55 buildings in the Campus

Inmetro's system workforce

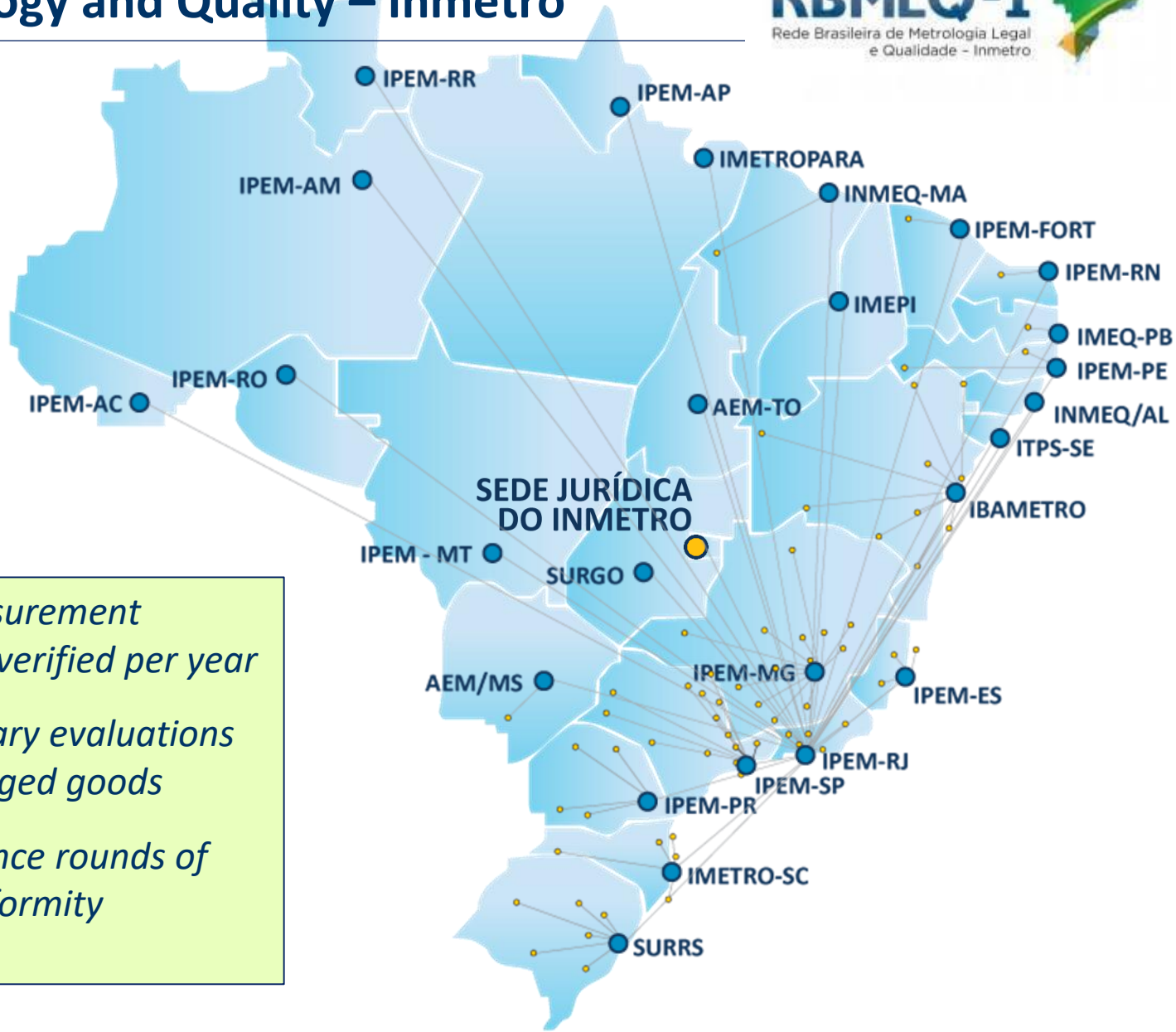
6,620 profissionals, all over the country

Legal Metrology



Brazilian Network for Legal Metrology and Quality – Inmetro

RBMLQ-I
Rede Brasileira de Metrologia Legal e Qualidade - 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

INMETRO

Product safety regulation

195	regulatory measures
612	ordinances (~ 9,000 pages)
684	product categories regulated
50	supplementary ordinances per year
US$ 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

INMETRO

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

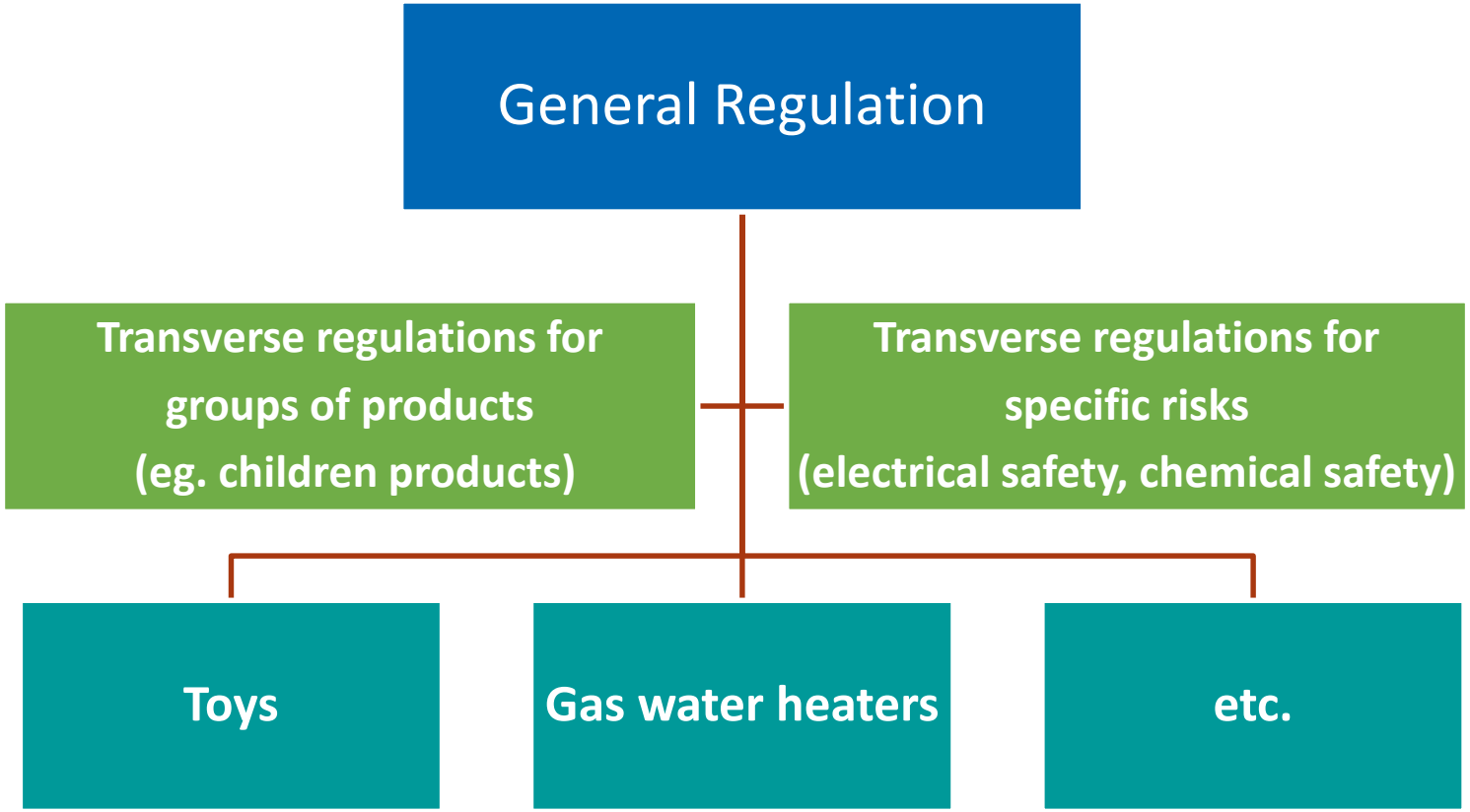
Focus on solving regulatory problems

Better compliance

Supplier Accountability

Flexibility

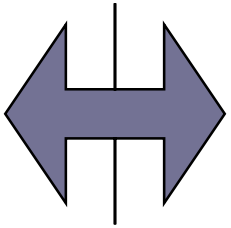
Product safety regulation: the new Inmetro model



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.

Passive Monitoring



Active Monitoring

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

Notifying Member(s)	Brazil
Symbol, title and description of content	**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.
Distribution date	12/07/19
Products	**Product name(s):** Public Call for Comments ;
Objectives	Protection of Human health or Safety

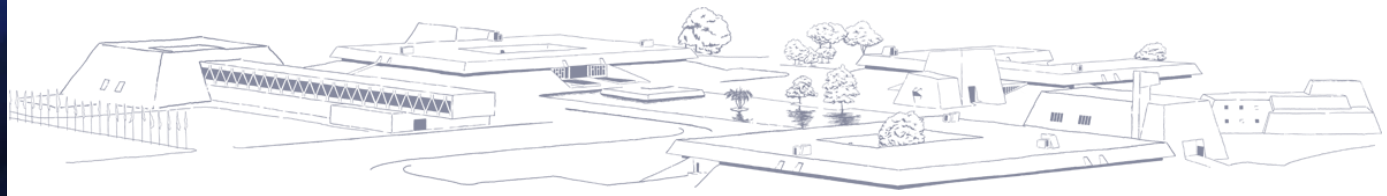
Link(s) to full text	http://www.inmetro.gov.br/legislacao/rtac/pdf/RTAC002584.pdf http://www4.inmetro.gov.br/tomadadesubsidios/regulamento-geral-do-inmetro

INMETRO

Thank you

lcontier@inmetro.gov.br

barreirastecnicas@inmetro.gov.br



INMETRO

INMETRO's mission

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

INMETRO

MINISTÉRIO DA ECONOMIA

PÁTRIA AMADA BRASIL GOVERNO FEDERAL

Ouvidoria: 0800 285 1818

inmetro.gov.br

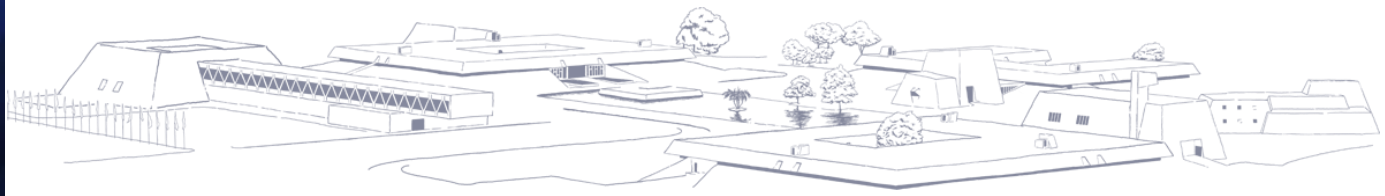
linkedin.com/company/inmetro

instagram.com/inmetro_oficial

facebook.com/Inmetro

youtube.com/tvinmetro

twitter.com/Inmetro

slideshare.net/inmetro

flickr.com/inmetro