



A common European approach to the regulatory testing of nanomaterials

Metrology and Standardization as nanotechnology legislation support

FERNANDA SARAIVA
IPQ, Caparica 3 April 2014



Summary

- Metrology
- Nanometrology
- Conformity assessment
- Players in the field
 - Metrology institutes
 - Standardizations body
 - Research centers
 - Regulatory bodies
- Conclusions

Metrology

Science of measurement and its application.

includes all theoretical and practical aspects of measurement, whatever the measurement uncertainty and field of application.

International Vocabulary of Metrology -- Basic and general concepts and associated terms (VIM),
Available from www.bipm.org
ISO/IEC Guide 99:2007

“ If you can’t measure it, you can’t improve it”
Lord Kelvin

Measure for what?

§ **Supervise / Monitor**

(observe and record - Commercial transactions: buying and selling products, water, fuels light)

§ **Check / Control**

(compare and act to keep within specified values)

§ **Investigate, innovate, create**

(understand the small differences, compare results)

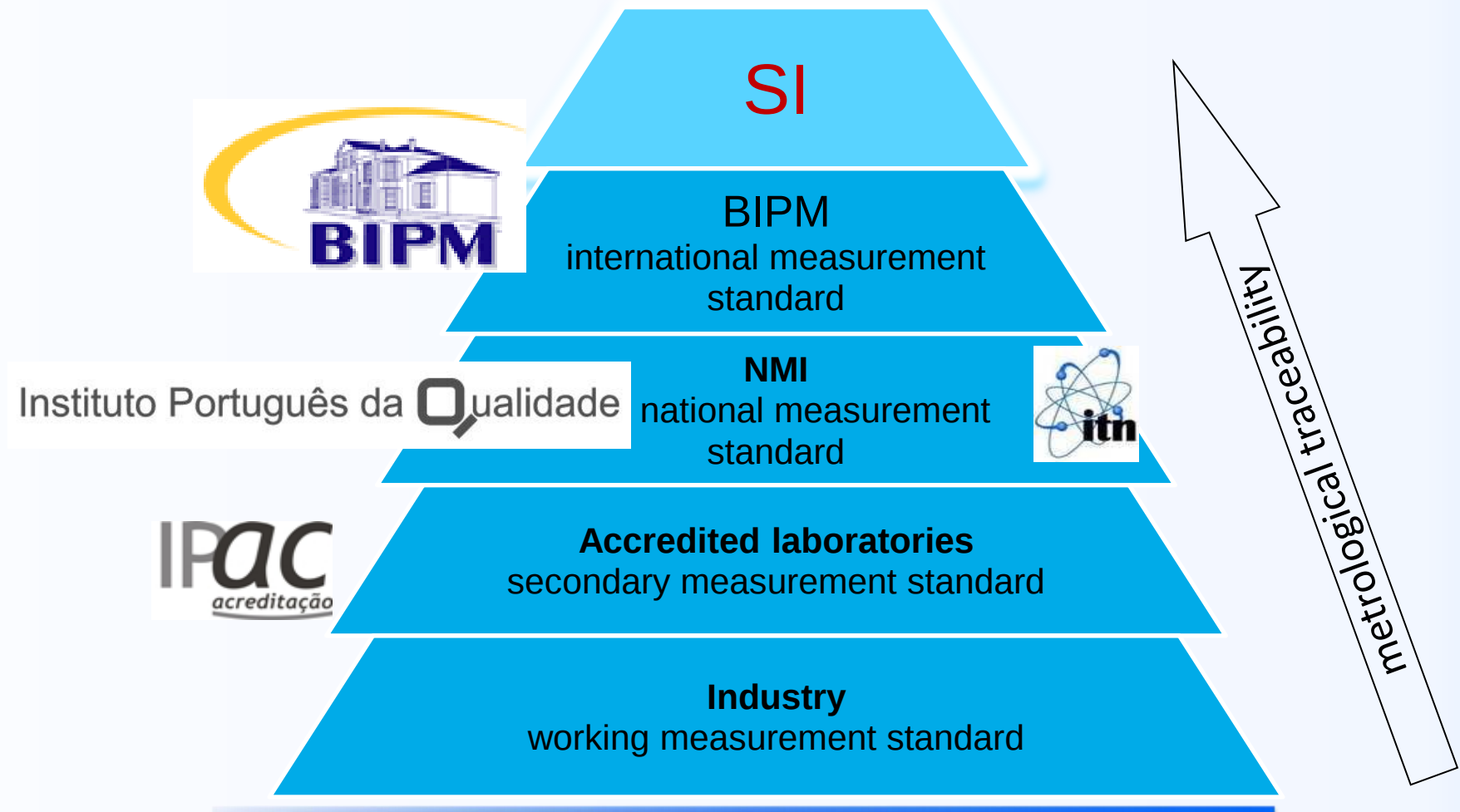
Measurement

Process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity. Measurement implies comparison of quantities or counting of entities (VIM 2.1)

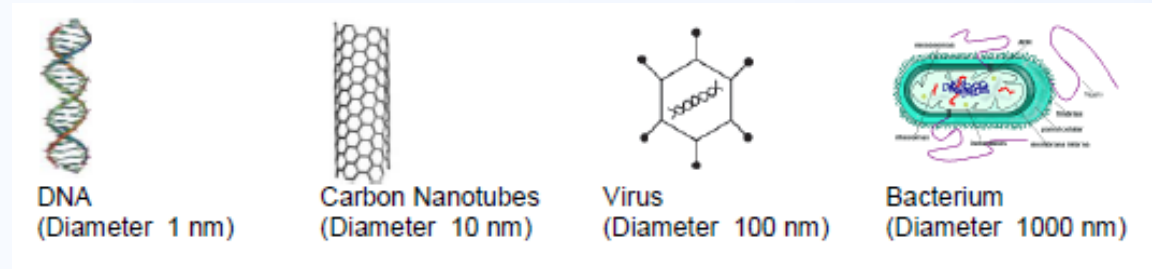


Measurement standards

Hierarchy of measurement standards



Nanometrology



Science of measurements at the nanoscale (1 nano[unit] a 100 nano[unit] ($=10^{-9}$ [unit]))

Is not a special kind of metrology

Concepts such metrological traceability, uncertainty method validation are the same.

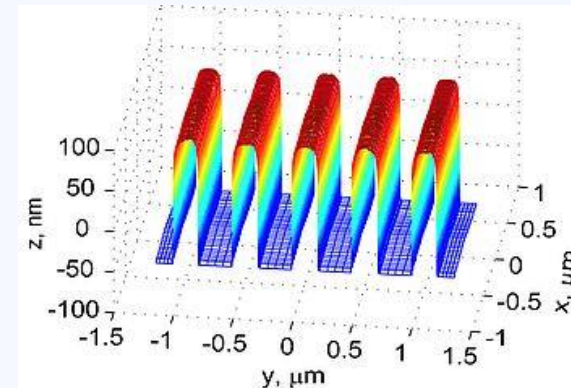
New challenges

(new reference materials, measurement instrumentation, test methods, environments: vacuum or biological media)

National Metrological Institutes

New method for the measurement of structure widths with atomic resolution

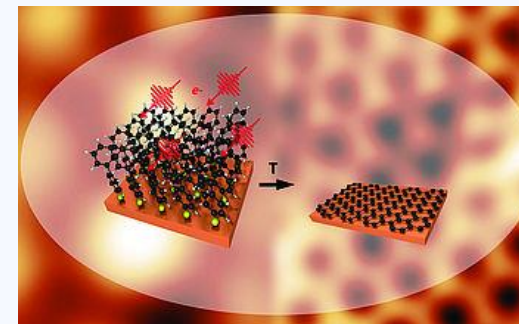
Calibrating accurately and traceably using a combination of a transmission electron microscope and an atomic force microscope



3D representation of a C D AF M image, measured on a group of 5 features

Aromatic graphene

New production method broadens the perspectives for the utilization of the “magical material” – many different forms are possible



The cover picture of the scientific journal “Advanced Materials” gives a schematic representation of the conversion of the monolayer of the complex molecule biphenyl thiol into the two-dimensional graphene crystal by electron irradiation and thermal treatment. (Fig.: Advanced Materials 25 (2013). Copyright Wiley-VCH Verlag GmbH & Co. KGaA. Reproduced with permission.)

<http://www.ptb.de/cms/en/publikationen/zeitschriften/ptb-news.html>,
acedido em 2014-03-28

Metrology at the nanoscale for:



Characterization



(measurement of physical and chemical properties: size, force, shape, composition)



Mechanics



(measurement of mechanical properties: hardness, elasticity, nanotribology, volume materials)



Photonics, Electronics, Magnetics



(reproducible measurements of: resistance, refractive index)



Fabrication – manufacturing

metrology to support the manipulation of matter on an atom scale,
measurement methods to control and predict the nanoscale structure

Nanometrological challenges

- § New reference materials
- § Long chains of metrology traceability
- § New measurement instrumentation
- § Measurement of new characteristics unique to the nanoscale
- § Rapid and accurate calibration methods against a know standard
- § Measurement in exigent environments

Importance of Metrology

- § Improvement of the scientific understanding
- § Quality control and conformity assessment
- § Elimination of trade barriers
- § Confidence for the consumer

Conformity assessment

Initial specifications of the product requirements of the customer



Match measurement specifications to product specifications



Selection of measurement method and equipment with metrological performance appropriate



Measurement and report



Use of the measurement results by customer for product conformity



conform

Not conform

Players in the field

§ Metrology Institutes (NMI)

§ Standardization bodies

§ Research centres

■ University, Laboratory

§ Industry

§ Citizens

Metrology Institutes (NMI)

- Development and realisation of measurements at the highest level of accuracy and with the smallest uncertainty
- Demonstration of compatibility results by international comparisons make sure that measurement results agree within their uncertainties.
- Production of certified reference materials
- Comparability of SI-traceable measurement results performed with high accuracy measurement instrumentation



Instituto Português da Qualidade



Standartization Bodies

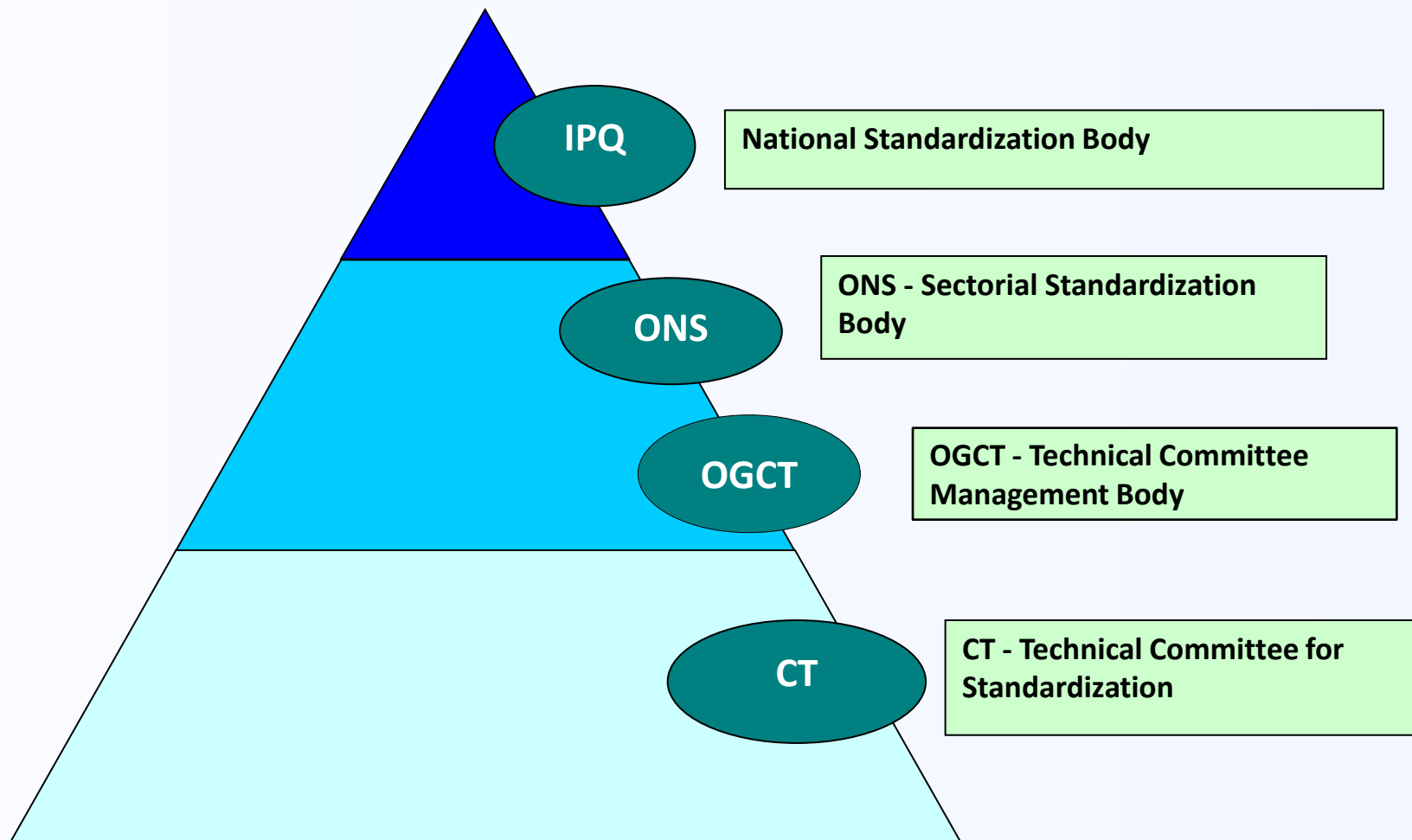
- CEN – European Committee for Standardization
- ISO – International Organization for Standardization
- CENELEC – European Committee for Electrotechnical Standardization
- ETSI – European Telecommunications Standards Institute
- IEC – International Electrotechnical Commission

The IPQ is the National Standardization Body

Assignments to NSB/IPQ:

- Overall coordination of national standardization;
- Voting process;
- Approval and edition of Standards;
- Adoption of European Standards;
- Representation of the NSB/IPQ at the highest levels of the
- CEN/CENELEC and ISO/IEC.

The national structure of Standardization



Standardization

§ Technical standards

- Written voluntary document laid down by a specialized body on the basis of a consensus between experts appointed by the stakeholders.
- It may set out specifications for a specific physical object, terminology, process and organizations, good laboratory practice, social responsibility ...

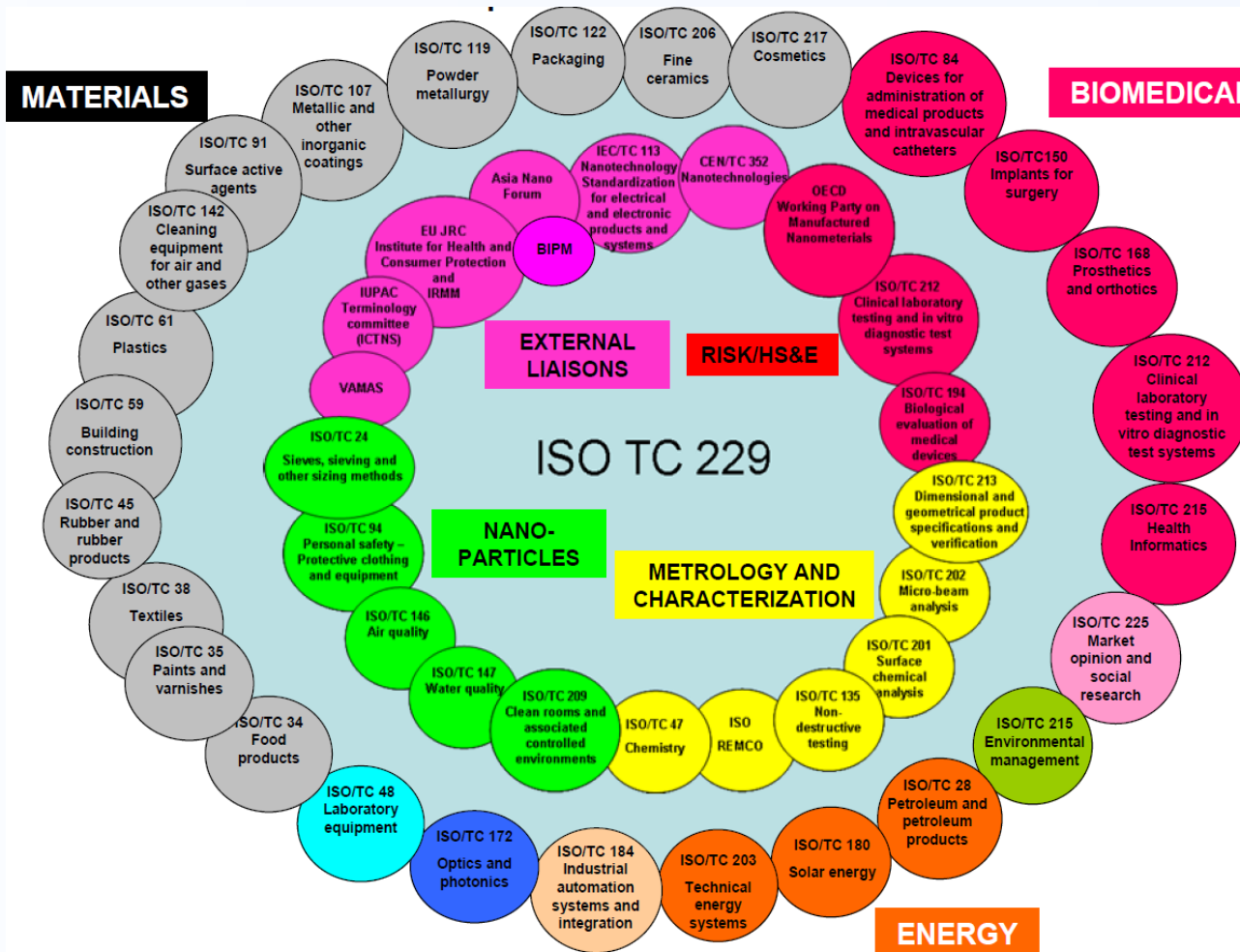
Standardization

CEN/TC 352 - Nanotechnologies

- § understanding and control of matter and processes at the nanoscale, typically, but not exclusively below 100 nanometres in one or more dimensions, where the onset of size dependent phenomena usually enables novel applications,
- § utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules or bulk matter, to create improved materials, devices and systems that exploit these new properties

Specific tasks include developing standards for: classification, terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulation; science-based health, safety and environmental practices; and nanotechnology products and processes. Standards in each of these areas could be specific to a product, process or industry.

ISO/TC 229 - Nanotechnologies



P. Hatto; *Needs and Expectations from the ISO TC 229 Nanotechnologies*; BIPM Workshop on Metrology at Nanoscale, Paris, 18-19 February 2010

CEN/TC 352 - Nanotechnologies

Subcommittees and Working Groups	Title
CEN/TC 352/WG 1	Measurement, characterization and performance evaluation
CEN/TC 352/WG 2	Commercial and other stakeholder aspects
CEN/TC 352/WG 3	Health, safety and environmental aspects

http://www.iso.org/iso/home/standards_development/list_of_iso_technical_committees/iso_technical_committee.htm?commid=381983
Acedido em 2014-03-28

Ambitions for Nanotechnologies Standardization

- § Definition of agreed terminology for nanotechnologies
- § Definition of protocols for toxicity testing of nanoparticles
- § Definition of protocols for evaluating environmental impact of nanoparticles
- § Definition of protocols for whole life cycle assessment of nanoscale materials and products
- § Developing occupational health protocols in particular for industries dealing with nanoparticles and nanoscale devices
- § Developing test methods to detect, characterize and identify nanoparticles

CEN/TC 352 - Nanotechnologies

- § EN ISO 29701:2010 Nanotechnologies - Endotoxin test on nanomaterial samples for in vitro systems - Limulus amoebocyte lysate (LAL) test (ISO 29701:2010)
- § EN ISO 10808:2010 Nanotechnologies - Characterization of nanoparticles in inhalation exposure chambers for inhalation toxicity testing (ISO 10808:2010)
- § EN ISO 10801:2010 Nanotechnologies - Generation of metal nanoparticles for inhalation toxicity testing using the evaporation/condensation method (ISO 10801:2010)

<http://standards.cen.eu>

Metrology and Standardization

- Support regulation in the area of nanotechnologies
- Support of safety testing
- Support of worker, public and environmental safety

Legal metrological control

ISO 6142:2001 - Gas analysis -
Preparation of calibration gas
mixtures - Gravimetric method



OIML R 99-1: Instruments for measuring
vehicle exhaust emissions.



Portaria 20/2007 de 5 de janeiro

ISO 1155:1978 - Information
processing - Use of longitudinal
parity to detect errors in information
messages



OIML R 91: Radar equipment for the
measurement of the speed of vehicles



Portaria 1542/2007 de 6 de dezembro

Conclusion

Metrology + University + Industry +
Investigations centres + Trade Union +
Industrial Associations + Regulators

- ONS – LNEG: Laboratório Nacional de Energia e Geologia



- Standardization Portuguese: technical committee for Nanotechnologies

Thank you

fsaraiva@ipq.pt