

STANDARDIZATION OF ELECTRICAL EQUIPMENT FOR MEDICAL USE

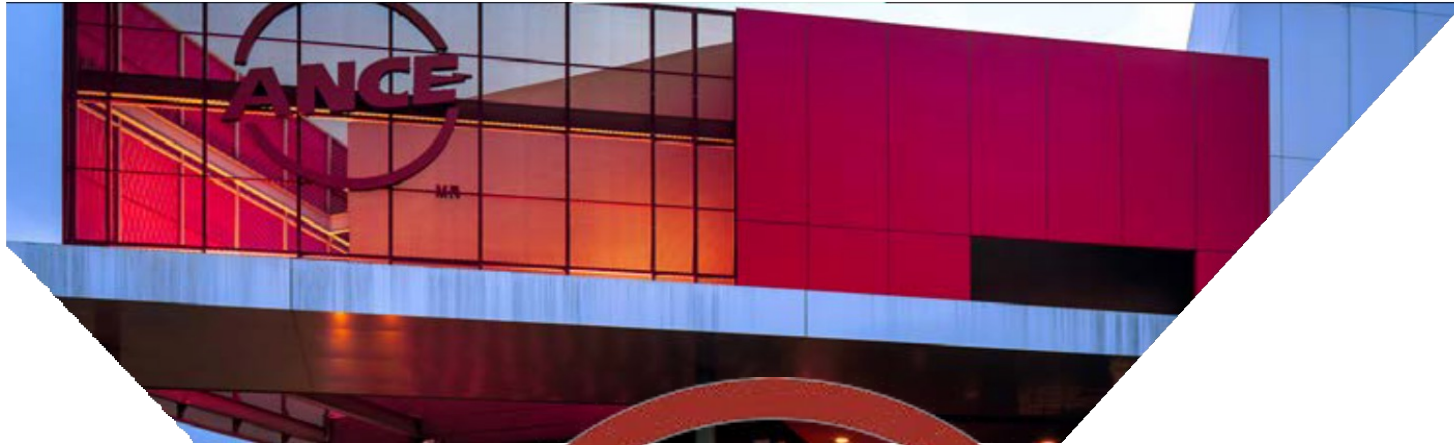
Eng. Luis Iván HERNÁNDEZ
Director of Standardization
ANCE

CONTENT

- **Quality Infrastructure Law**
- **Technical Regulations**
- **Standardization**
- **Standards Development**
- **ANCE Committee (CONANCE)**
- **Participation in International Standardization activities**
- **Regulation Scheme based on Standards**

STANDARDIZATION AND CERTIFICATION ASSOCIATION (ANCE)

Since 1992 leader in the development of standards and regulations for the benefit of competitiveness in the market, through the continuous search for excellence and quality.



SOLUTION PROVIDERS AT:

Technical Regulations, Standardization, Inspection, Test Laboratory, Calibration, Proficiency Testing Provider, Certification, Training, System Management and Third Authorized Party.

STRATEGICALLY LOCATED:

BRANCHES

Mexico City; Zapopan, Jalisco; Apodaca, Nuevo León.

REPRESENTATIVE OFFICES

Tijuana, B. C.; Mérida, Yucatán, Uruapan, Michoacán; CANACO, Mexico City; China y Washington, D.C.

COLLABORATORS AND EXPERTS

Responsible for meeting the needs of our customers with solid experience nationally and internationally.

WE ADD VALUE

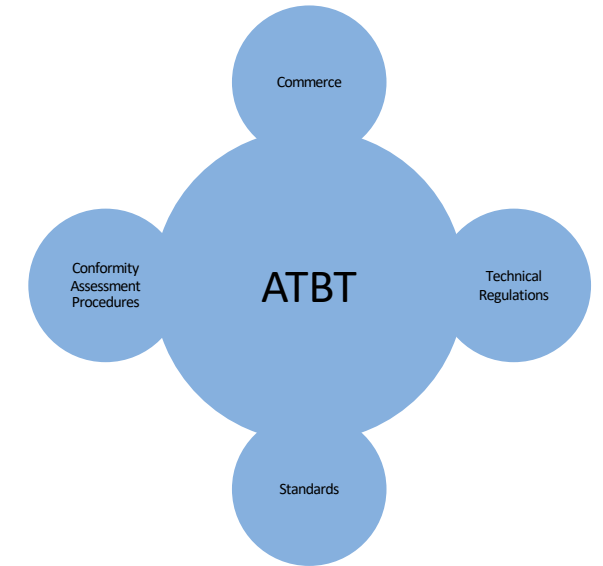
Together we develop business actions for continuous improvement.

QUALITY INFRASTRUCTURE LAW



NATIONAL QUALITY INFRASTRUCTURE SYSTEM

- Prosperity
- Health
- Wellbeing



Source: https://www.unido.org/sites/default/files/2017-02/QI_Spanish_final_0.pdf

TECHNICAL REGULATIONS

Official Mexican Technical Regulation: technical regulation of mandatory observance issued by the competent Technical Regulations Authorities whose essential purpose is the promotion of quality for economic development and the protection of the legitimate objectives of public interest provided for in this order, through the establishment of rules, denomination, specifications or characteristics applicable to a good, product, process or service, as well as those relating to terminology, market or labelling and information. The Official Mexican Technical Regulations shall be considered as Technical Regulations or Sanitary or Phytosanitary Measures, as they fall within the corresponding definitions provided for in the international treaties to which the Mexican State is a Party.



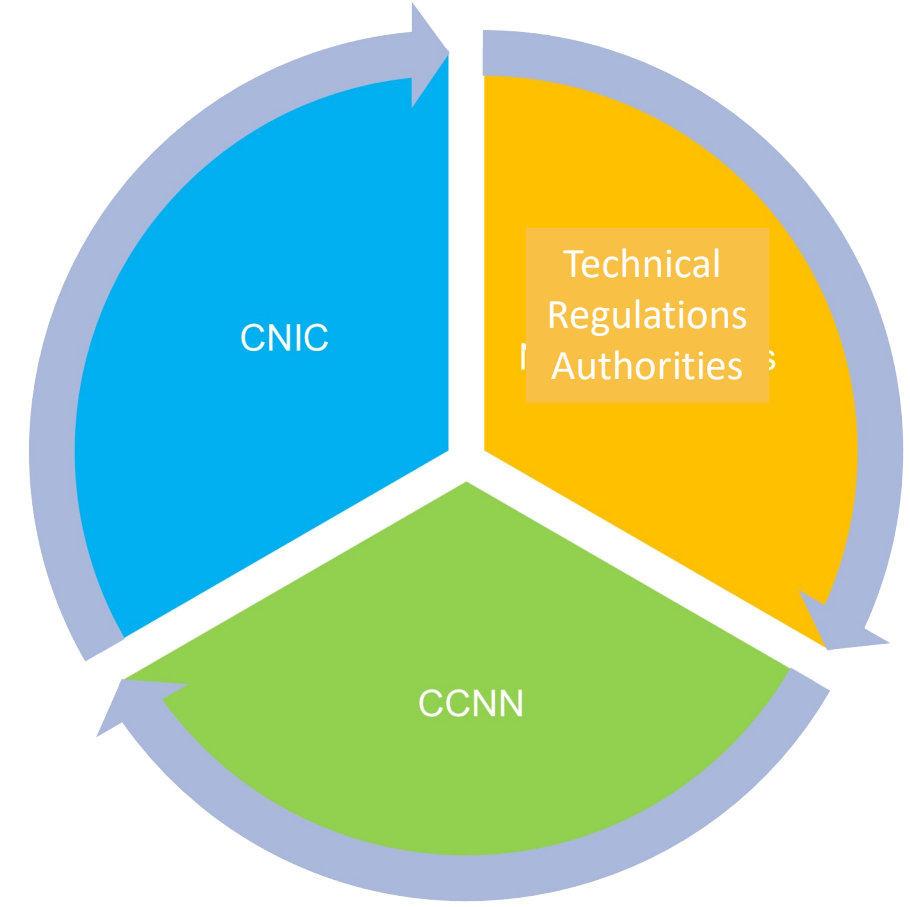
TECHNICAL REGULATION

TECHNICAL REGULATIONS

Bodies responsible for Technical Regulations

Examples

- | | |
|---|---|
|  SEMARNAT
SECRETARÍA DEL MEDIO AMBIENTE Y RECURSOS NATURALES |  STPS
SECRETARÍA DE TRABAJO Y PREVISIÓN SOCIAL |
|  SENER
SECRETARÍA DE ENERGÍA |  SECTUR
SECRETARÍA DE TURISMO |
|  SE
SECRETARÍA DE ECONOMÍA |  SEGOB
SECRETARÍA DE GOBERNACIÓN |
|  SADER
SECRETARÍA DE AGRICULTURA Y DESARROLLO RURAL |  SEDATU
SECRETARÍA DE DESARROLLO AGRARIO, TERRITORIAL Y URBANO |
|  COMUNICACIONES
SECRETARÍA DE COMUNICACIONES Y TRANSPORTES |  ARTF
AGENCIA REGULADORA DEL TRANSPORTE FERROVIARIO |
|  SALUD
SECRETARÍA DE SALUD |  CRE
COMISIÓN REGULADORA DE ENERGÍA |



STANDARDIZATION

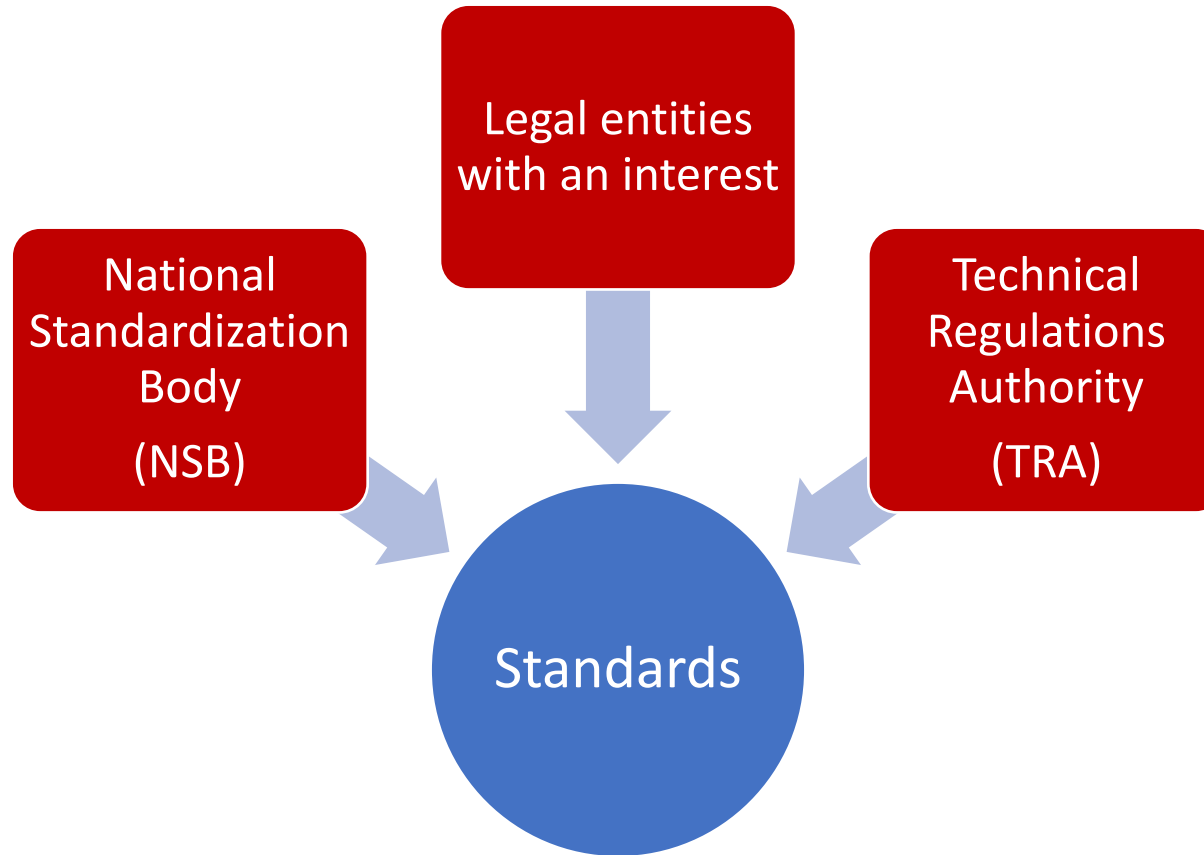
Standard: Technical document that provides for a common and repeated use of rules, specifications, attributes or test methods applicable to a good, product, process or service, as well as those relating to terminology, symbology, packaging, market, labelling or alignment.



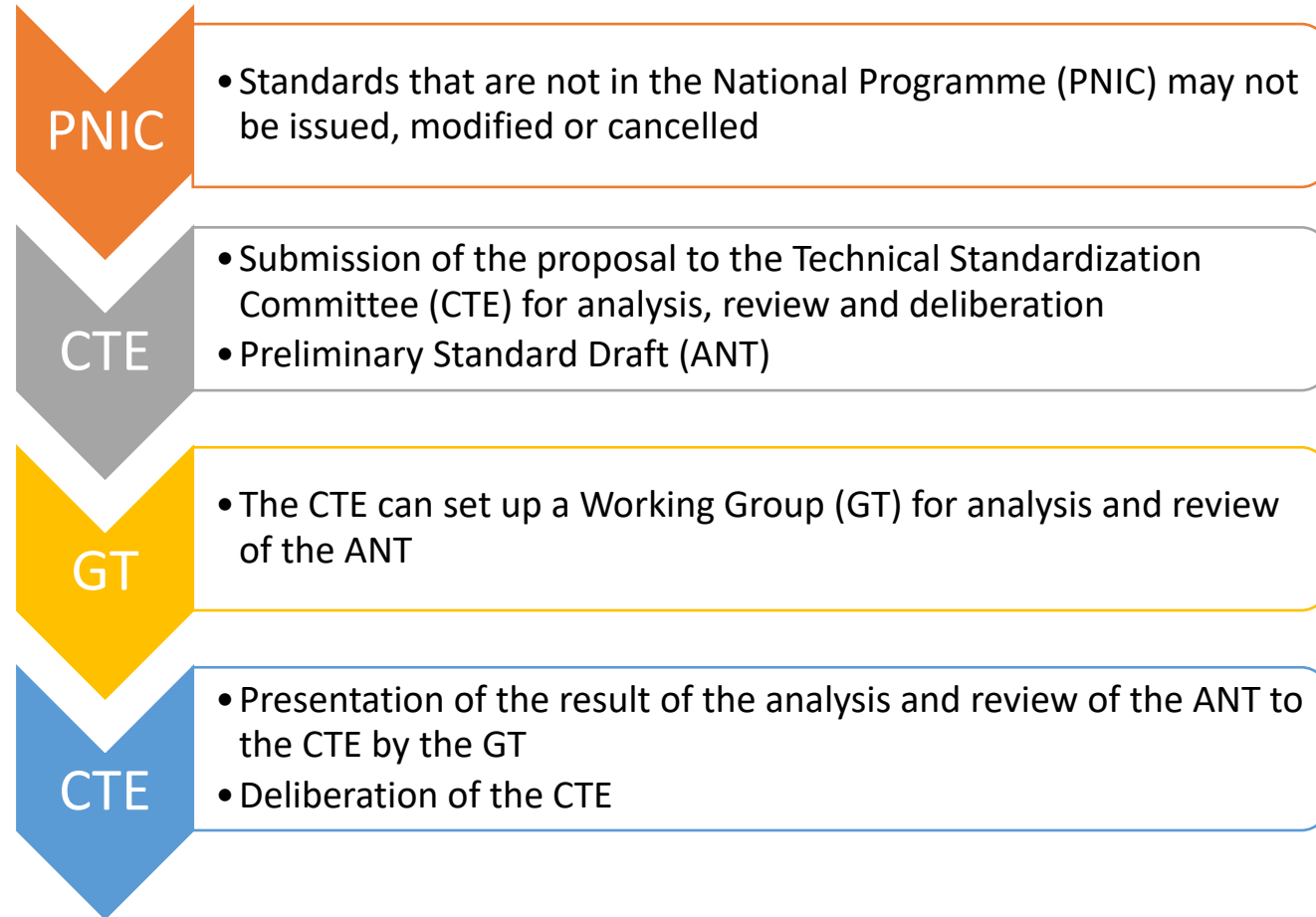
STANDARD



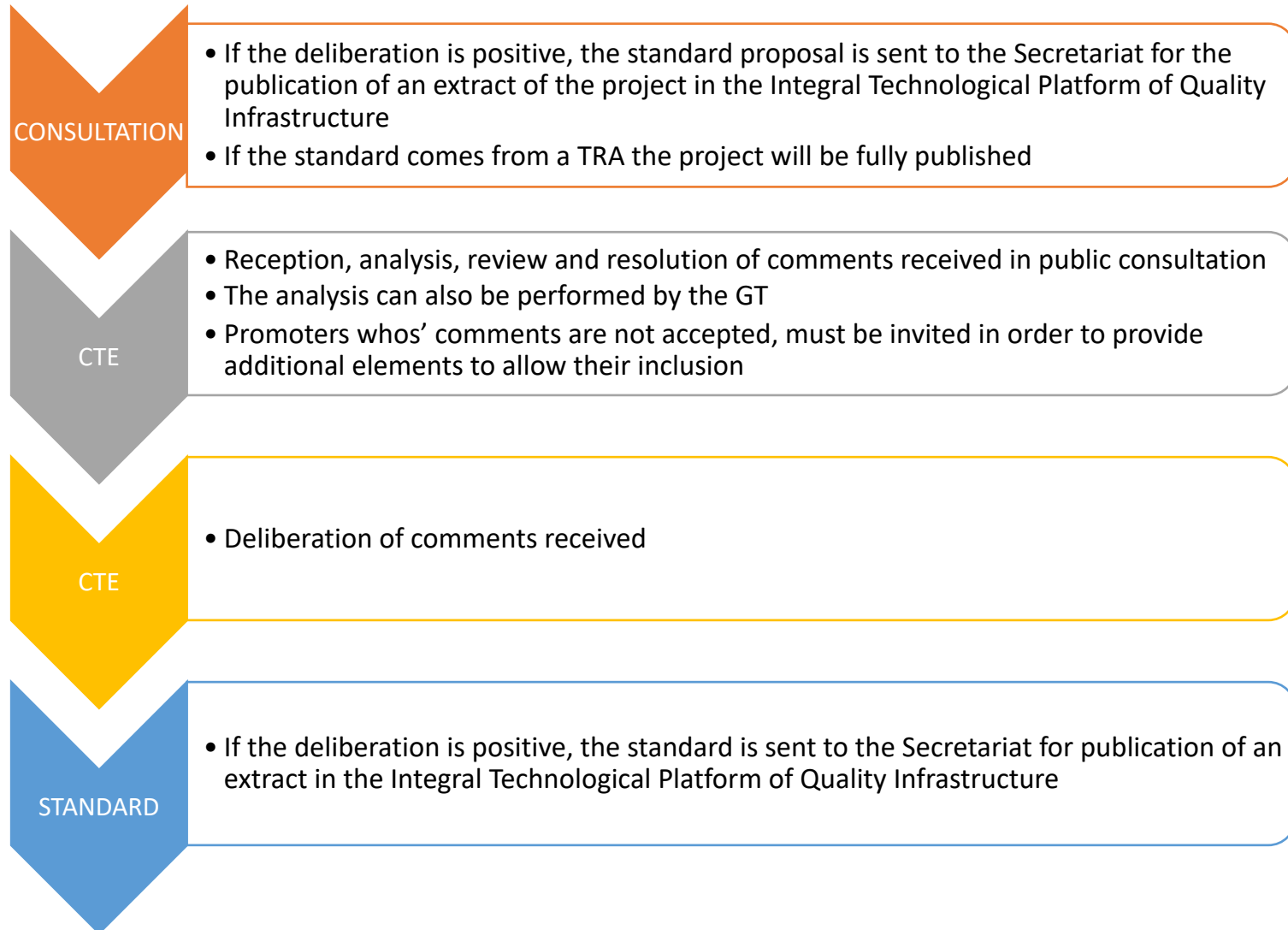
STANDARDIZATION



STANDARDS DEVELOPMENT



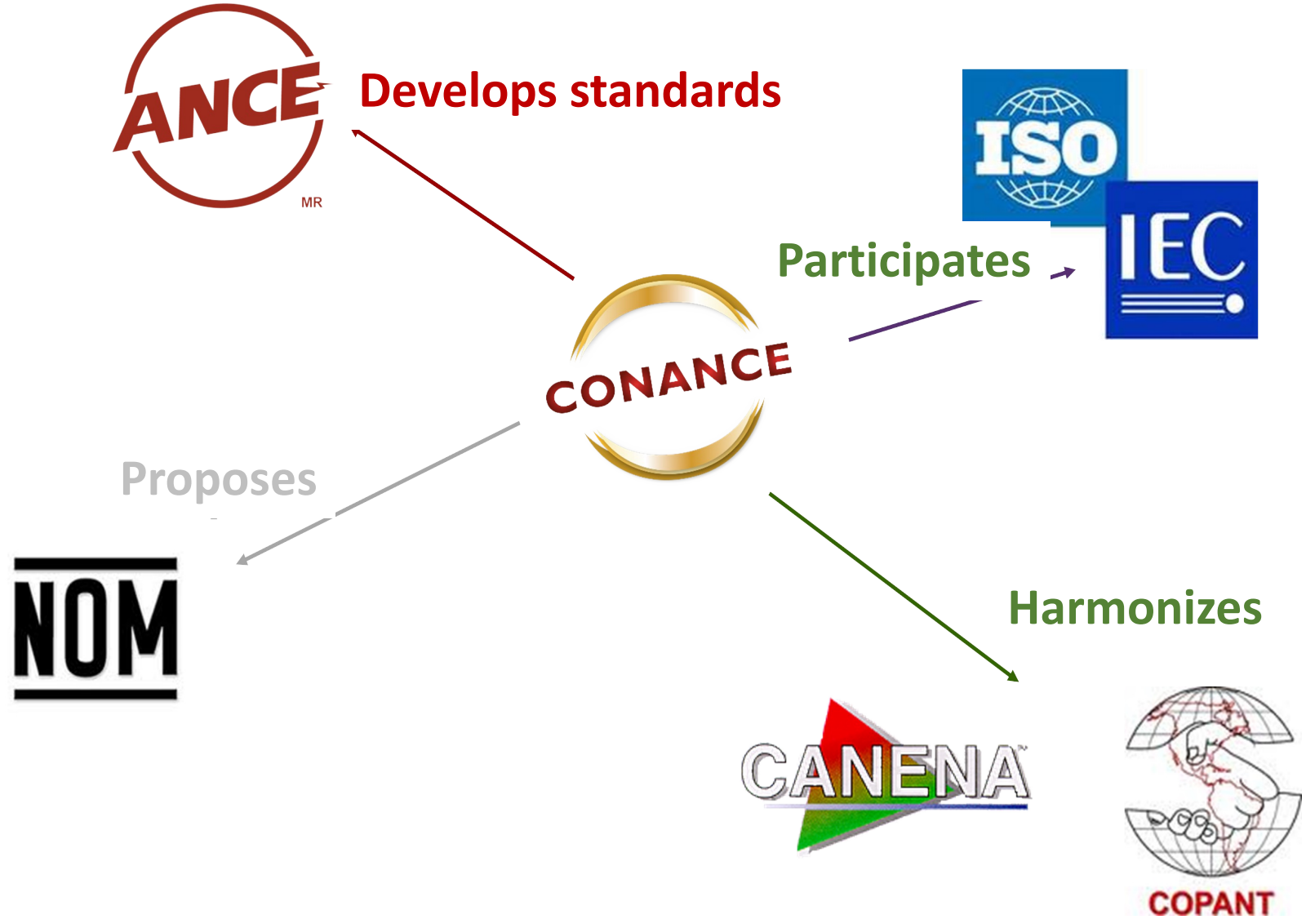
STANDARDS DEVELOPMENT



CONANCE (ANCE's Committee)



CONANCE



CONANCE



173 countries

MEMBERSHIPS

TC: 32

SC: 30

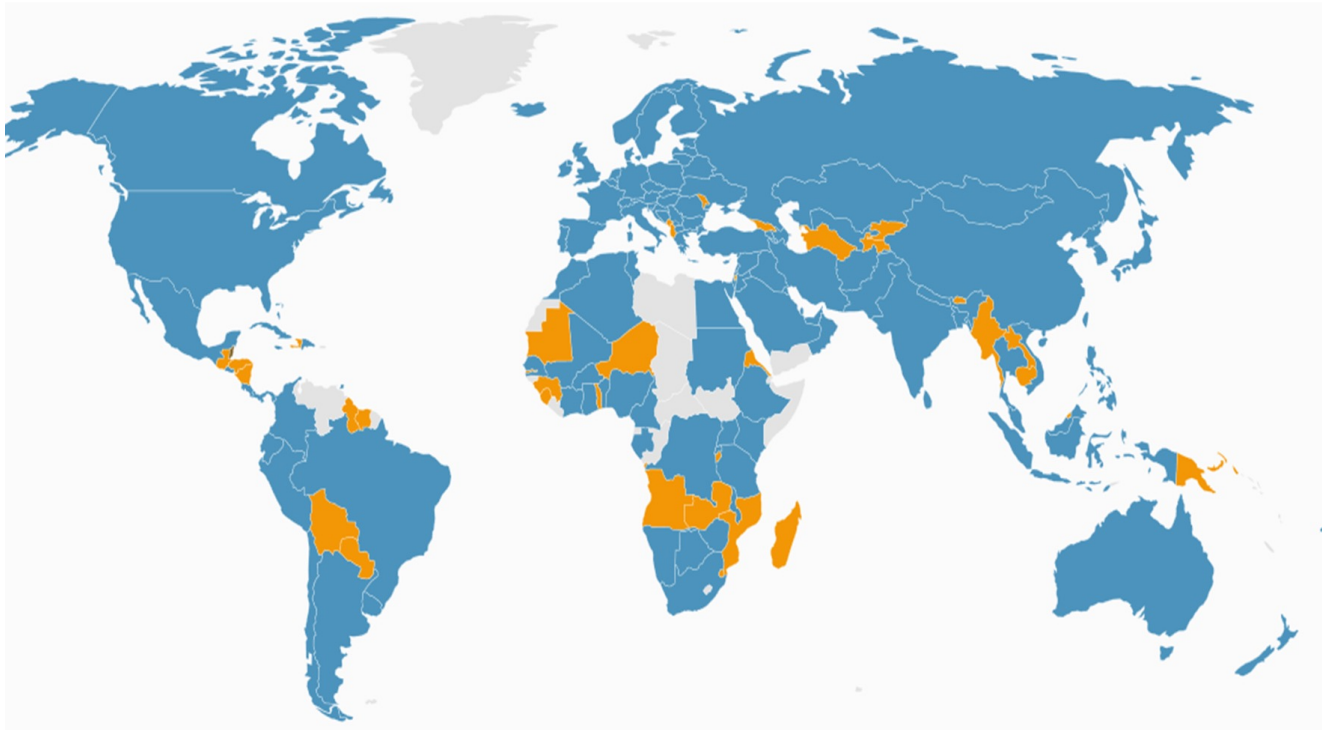
SyC: 1



450 STANDARDS

CONANCE

100 STANDARDS



■ Whole members ■ Observer members ■ Subscribed members



167 countries

MEMBERSHIPS	
TC:	6
SC:	2

INTERNATIONAL STANDARDS

Mexican Committees: to the committees created by the Commission at the request of the Secretariat or the Technical Regulation Authorities for the attention of international standards organizations. The Mexican Committees must be composed of the various interested sectors in accordance with the provisions of the Regulations of this Law.

INTERNATIONAL STANDARDS



INTERNATIONAL STANDARDS



International
Organization for
Standardization



Ministry of Economy /
Directorate-General for
Technical Regulation
(member body)



STANDARDS-BASED REGULATION

Regulation

Essential purpose:
Safety, health,
protection of the
environment and
infrastructure

Internationally
accepted principles

What?



Accepted
globally as
good
governance
practice

STANDARD

Effective means of
demonstrating compliance
with the essential
purposes of regulation

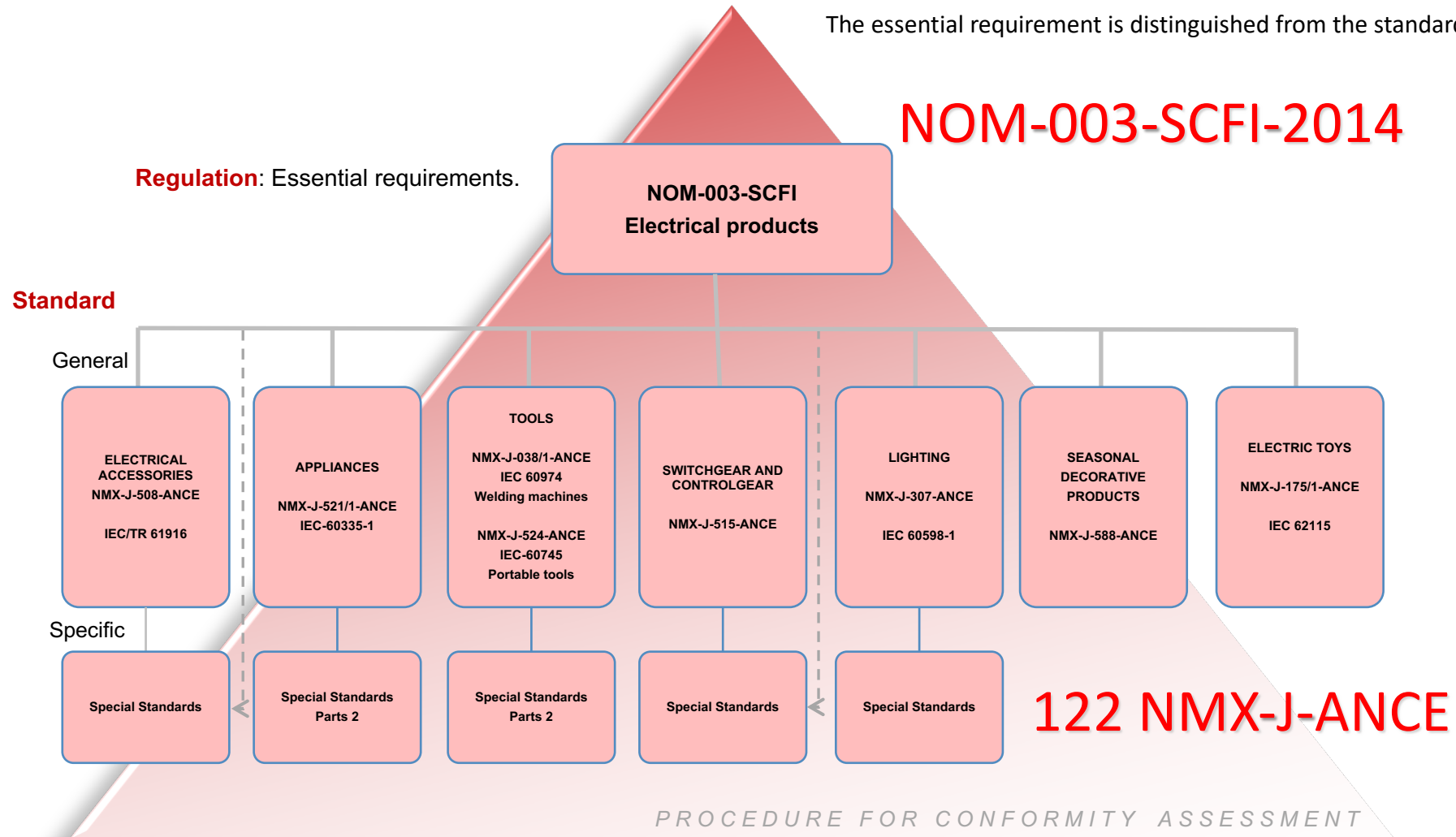
Based on international and
regional standards

How?



STANDARDS-BASED REGULATION

The essential requirement is distinguished from the standard.



THANK YOU!

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