The Process of Development of Technical Regulations Applicable to Medical Devices and In Vitro Diagnostic Reagents and the guarantee of compliance with international obligations – Part I

OFFICIAL MEXICAN STANDARDS

ECONOMÍA
SECRETARÍA DE ECONOMÍA

DGN
DIRECCIÓN GENERAL DE NORMAS

México 2021
Año de la Independencia

Official Mexican Standards

Article 10 of the LIC: The NOMs are intended to address the causes of the problems identified by the Standardization Authorities that affect or jeopardize the **legitimate objectives of public interest.**

Standardization Authorities (SAs) identify or detect a problem

Therefore, the SAs propose a solution to the problem through a NOM

Therefore, the causes of the problem are addressed in such a way that it is eradicated or mitigated.

This problem affects or puts at risk any Legitimate Objective of Public Interest

This NOM seeks to be the solution to the detected problem

Regulatory Policy Cycle

NOM Proposal

Standardization Process

Entry into force

Implementation

Market Surveillance

Systematic Review

NOM

NOM Proposal

Minimum requirements:

- ✓ Title.
- ✓ Objective, field of application and OLIP pursued.
- ✓ Identification, specifications, characteristics, technical provisions, data and information of the good, product, process, service, terminology, marking or labelling and information to which it will be applicable.
- ✓ PEC, and the infrastructure for Conformity Assessment.
- ✓ Authorities that will carry out the Verification or Surveillance for compliance.
- ✓ Reference to Standards for implementation.
- ✓ Use as a basis the International Standards applicable in the matter and establish the degree of agreement with them.
- ✓ Bibliography.
- ✓ Classification considering the OLIP.
- ✓ Proposal for regulatory impact analysis.

Standardization Process

How does it work?

- ✓ Progressive and successive stages.
- ✓ Dialectical scheme.
- ✓ NOMs evolve over time along with the regulatory improvement process
- ✓ The IASB determines the coordination mechanism between the different Standardization Authorities when their competences affect.

1 Preparation of the **Proposal** by the Standardization Authority

CCONNSE

2 Constitution of the Working Group (WG) for the study and discussion of the **Draft** of Official Mexican Standards.

CCONNSE

3 The Standardization Authority publishes the project in the DOF for **Public Consultation** for 60 calendar days.

CCONNSE

4 Presentation to the **Response** Committee **to the comments** received during the public consultation and the adjustments to the draft Official Mexican Standard, for its final resolution.

CCONNSE

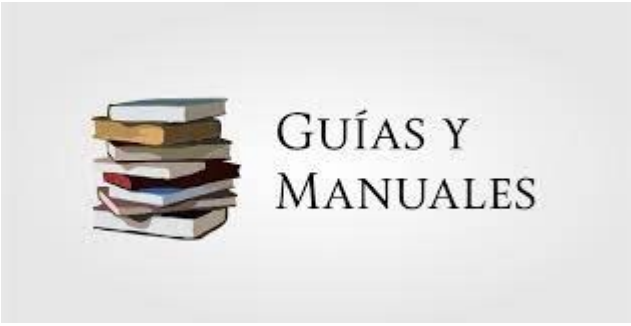
5 Publication in the Official Journal of the Federation as a **Definitive Standard**.

Entry into force

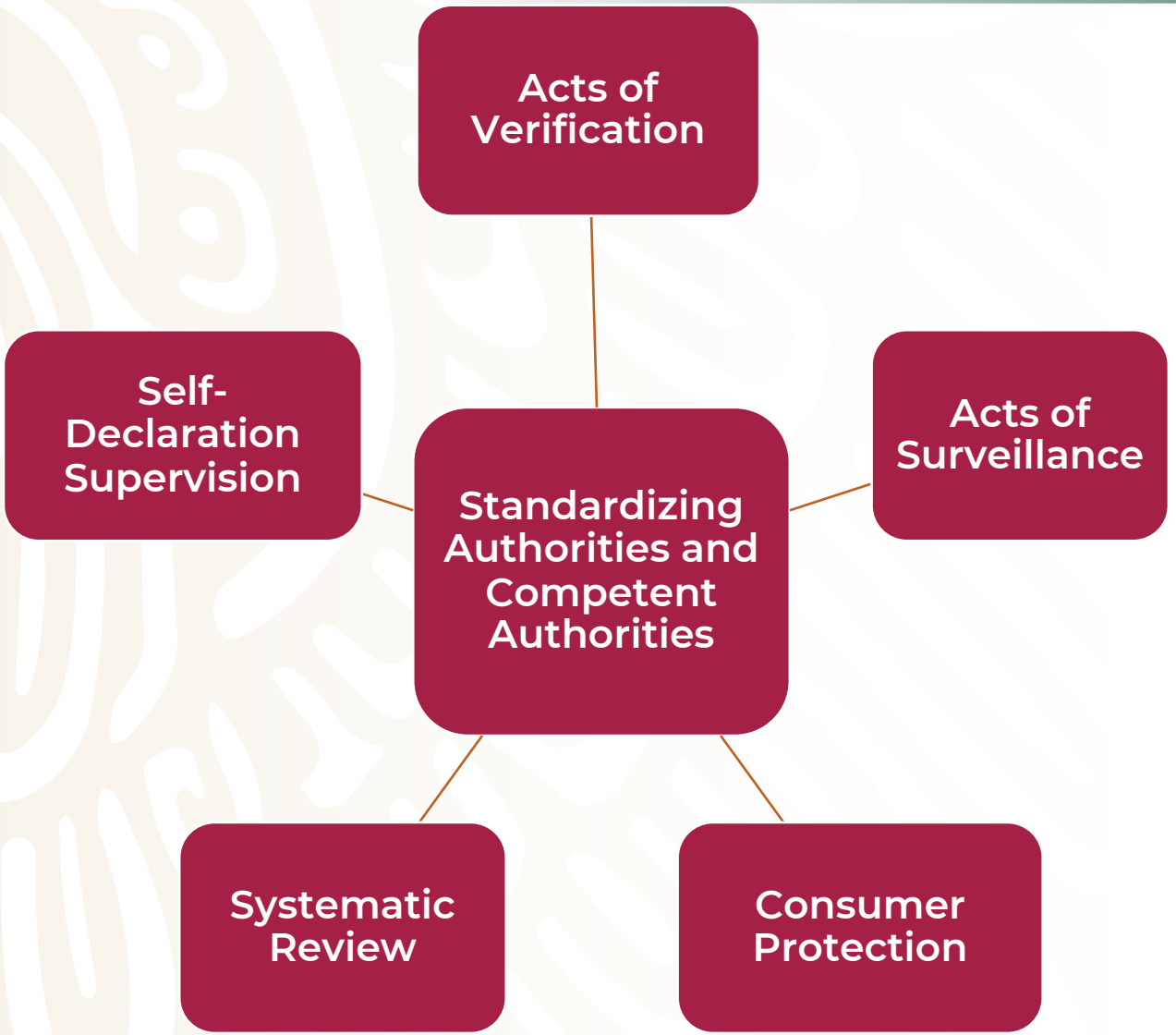
The **Standardization Authorities** have the exclusive attribution of issuing Official Mexican Standards in matters related to their attributions, determining their **date of entry into force** and verifying their compliance.

NOM Implementation

- ✓ Dissemination
- ✓ Training
- ✓ Promotion
- ✓ Generation of criteria
- ✓ Issuance of guides and manuals
- ✓ Dialogue with obligated subjects
- ✓ Among others



Market Surveillance



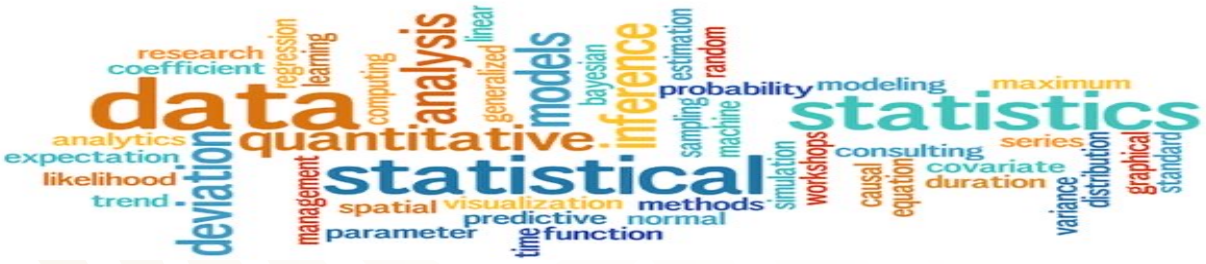
Article 139 of the Quality Infrastructure Law

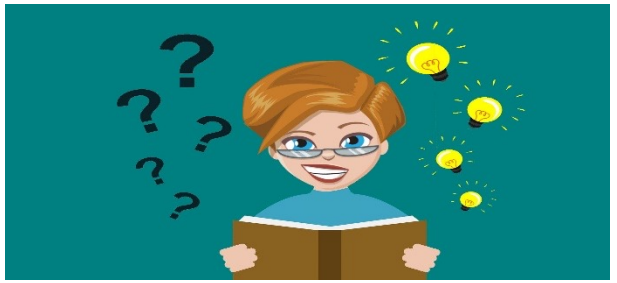
Systematic Review

The NOMs must be reviewed at least every **5 years** after their publication in the DOF or that of their last modification and must notify the report to the Executive Secretariat of the Commission with the results of the review, within **60 days** after the end of the corresponding five-year period.

The report containing the systematic review must be prepared by the corresponding SAs, which may be assisted by the respective CCNN, and must contain at least the following elements:

- ✓ Diagnosis that may include an analysis and evaluation of alternative measures;
- ✓ Impact or benefits of the Official Mexican Standard;
- ✓ Qualitative and quantitative data, and
- ✓ Confirmation or, where appropriate, the proposal for modification or cancellation.





THANK YOU!

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