Participation of the Americas in the Development of International Standards for Medical Technology – Recommendations for Regulatory Authorities, Coalition Members and Other Stakeholders

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General Directorate of Technical Regulations

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Legal Framework

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- Due to the **increase in international trade** of products, harmonized customs systems are needed to facilitate international trade. **Mexico through the customs system identifies, fiscalizes, verifies and controls the entry and exit of these products.**

- Countries in turn have the **right** to implement **measures to achieve legitimate public interest objectives**, such as the protection of health, the safety of persons or the protection of the environment in trade goods.

- Mexico, through the **Official Mexican Technical Regulations (NOMs)** also known as Technical Regulations, establish the minimum safety and quality requirements so that **both domestic** and **imported products** meet such objectives.

Legal Framework

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Quality Infrastructure Law

- Article 64 establishes that, when a product or service must comply with an official Mexican technical regulation, **its counterparts to be imported must also comply** with the specifications established in said technical regulation.

Foreign Trade Law

- Article 26 establishes that, goods subject to Official Mexican Technical Regulations shall be identified in terms of their **tariff fractions** and the nomenclature that corresponds to them according to the respective tariff.
- The Secretariat will determine, depending on the risk level, the official Mexican Technical Regulations that the customs authorities must enforce at the point of entry of the merchandise into the country.

International harmonization

- The Secretariat leads public policy actions to **strengthen the National Quality Infrastructure System (SNIC)** with the following attributions:
  - **Conclude equivalence** agreements, **mutual recognition** agreements or **approve** the conclusion of such agreements or arrangements by other Standardizing Authorities, Accreditation Entities or **Conformity Assessment Bodies**, as appropriate.
  - **Participate** in the scope of its competence, as well as **give its opinion on the elaboration of International Standards.**

- The Standardizing Authorities are obliged to **pursue public policies** that contribute to the **modernization of the SNIC** and have the following attributions:
  - **Participate**, within the scope of its competence, **in the elaboration of International Standards.**
  - At the request of the Secretariat, **to comment on International Standards**; and
  - Observe and **implement the Code of Good Practice** for the elaboration, adoption and application of Standards, of the **Agreement on Technical Barriers** to Trade of the World Trade Organization.

Technical Regulations Authorities

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SECRETARÍA DE SALUD

CONUEE
COMISIÓN NACIONAL PARA EL USO EFICIENTE DE LA ENERGÍA

COFEPRIS

TURISMO
SECRETARÍA DE TURISMO

AGRICULTURA
SECRETARÍA DE AGRICULTURA Y DESARROLLO RURAL

SECRETARIADO EJECUTIVO
DEL SISTEMA NACIONAL DE SEGURIDAD PÚBLICA

TRABAJO
SECRETARÍA DEL TRABAJO Y PREVISIÓN SOCIAL

MEDIO AMBIENTE
SECRETARÍA DE MEDIO AMBIENTE Y RECURSOS NATURALES

CONAGUA
COMISIÓN NACIONAL DEL AGUA

ASEA
AGENCIA DE SEGURIDAD, ENERGÍA Y AMBIENTE

CNH
Comisión Nacional de Hidrocarburos

COMUNICACIONES
SECRETARÍA DE COMUNICACIONES Y TRANSPORTES

AFAC
AGENCIA FEDERAL DE AVIACIÓN CIVIL

ARTF
AGENCIA REGULADORA DEL TRANSPORTE FERROVIARIO

SEGURIDAD
SECRETARÍA DE SEGURIDAD Y PROTECCIÓN CIUDADANA

MARINA
SECRETARÍA DE MARINA

SENER
SECRETARÍA DE ENERGÍA

CNSNS
Comisión Nacional de Seguridad Nuclear y Salvaguardias

CRE
COMISION REGULADORA DE ENERGIA

DESARROLLO TERRITORIAL
SECRETARÍA DE DESARROLLO AGRARIO, TERRITORIAL Y URBANO

Medical Devices NOMs

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#	Official Mexican Technical Regulations	International alignment
1	**NOM-137-SSA1-2008**, Medical Devices Labeling	This Official Mexican Technical Regulation partially agrees with the following standard: • EN 980:2007 Graphical symbols for use in the labelling of medical devices.
2	**NOM-241-SSA1-2021**, Good Medical Devices Manufacturing Practices	It partially agrees with the following standards: • ISO13485:2016 Medical devices-Quality management systems-Requirements for regulatory purposes. • ISO 14969:2004 Medical devices-Quality Management systems-Guidance on the application of 13485:2003. • ISO 9000:2015 Quality management systems-Fundamentals and vocabulary. • ISO 9001:2015 Quality management systems-Requirements. • NMX-CC-9000-IMNC-2000 Quality Management Systems – Fundamentals and Vocabulary. • NMX-CC-9001-IMNC-2000 Quality Management Systems – Requirements. • Guide to good manufacturing practice for medicinal produc Manufacture of radiopharmaceuticals, PIC/S.

National Advisory Committee of Standardization of Regulation and Health Development.

Technical Regulation Authority: **COFEPRIS**.

In review, NOM proposal for Electromedical Equipment

#	Official Mexican Technical Regulations Proposal	International alignment
2	Proposal of an Official Mexican Technical Regulation for **Electromedical Equipment**.	Electrical safety specifications of Electromedical Equipment (EEM) References with national standards: - NMX-I-J-60601-1-NYCE-ANCE-2017, Electromedical Equipment – Part 1: General Requirements for Basic Safety and Essential Operation. **MOD IEC 60601-1.** - NMX-J-I-60601-1-2-ANCE-NYCE-2020, Electromedical Equipment – Part 2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests. **MOD IEC 60601-1-2.** - NMX-I-60601-2-31-NYCE-2011 Electronics-electromedical equipment – Part 2-31: Specific Requirements for the Basic Safety and Essential Operation of Cardiac External Pacemakers with Internal Power Supply – **IDT IEC 60601-2-31:2011.** - NMX-J-I-60601-2-19-ANCE-NYCE-2021 Electromedical Equipment – Part 2-19: Specific Requirements for Basic Safety and Essential Operation of Infant Incubators – **MOD IEC 60601-2-19.**

Standardizing Authority: **GDS** / **COFEPRIS**.

Conclusions

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- Currently, **there is no NOM of the Ministry of Economy that regulates the electrical-electronic security of medical devices** and that makes any reference to Mexican Standards or international standards in accordance with the new Quality Infrastructure Law.
- **Commonly** at the point of entry into the country, **the demonstration of compliance with NOM-001-SCFI-2018 is requested** when regulating electronic devices.
- The **Ministry of Economy has shown its interest in collaborating** jointly with **COFEPRIS** to identify the needs and opportunities in this sector, in order to **issue a NOM** to guarantee the safety of these electromedical devices in favor of the worker in the health sector, but also with a view to the patient.
- **Mexico-Germany Cooperation – Electromedical Devices** whose objective is to promote opportunities from harmonization of technical regulations and standards with the aim of preventing Technical Barriers to Trade, addressing safety issues of new technologies and improving industry innovation.
- The proposal of the **NOM of Electromedical Equipment** is being **evaluated**.

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Thank you

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