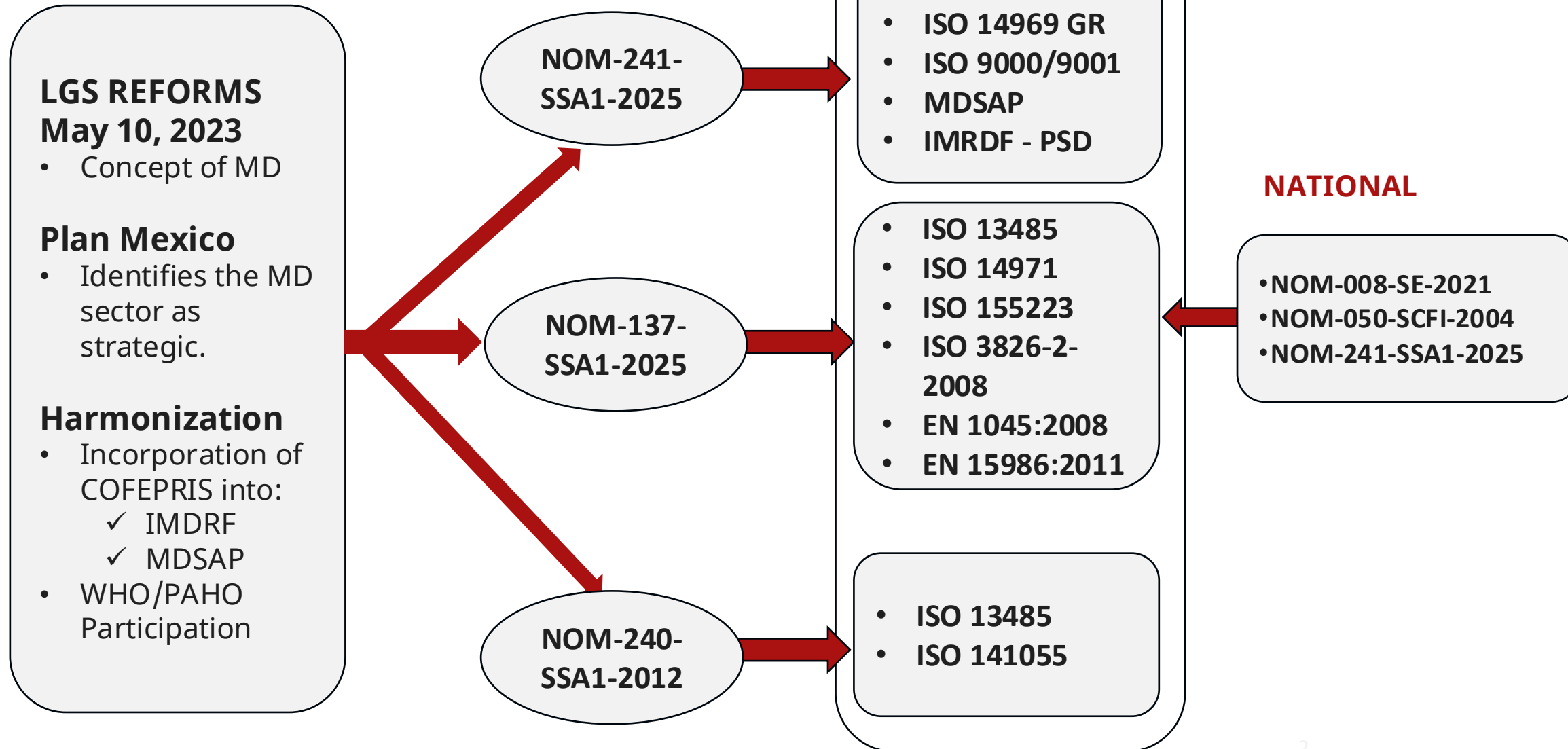


***Advanced Training for Medical Device Regulators on
Critical and Emerging Technologies 2026
(ATCET-2026)***

**Regulatory Framework for Medical Devices in Mexico
What Can We Expect from the Latest Regulatory
Updates?**

June 15, 2026

REGULATORY FRAMEWORK





Supplement for Medical Devices 6.0

December 2026

- Chapters on General Information and Solutions and Reagents
- General Methods of Analysis (38)
- General Methods of Analysis Specific to Medical Devices (37)
- Monographs on Sterilization of Medical Devices (4)
- Product Monographs (244) (196 DM and 48 RF)
- 13 Appendices



Supplement for establishments engaged in the sale and supply of medicines, medical devices, and other health supplies 7.0

Management of Warehouses and Distribution Centers

HARMONIZATION

- ISO
- ASTM
- IMDRF
- FDA Guidelines
- European Directives

NOM-241-SSA1-2025

- Stability
- Risk Management
- Quality Management
- ScDM

NOM-240-SSA1-2012

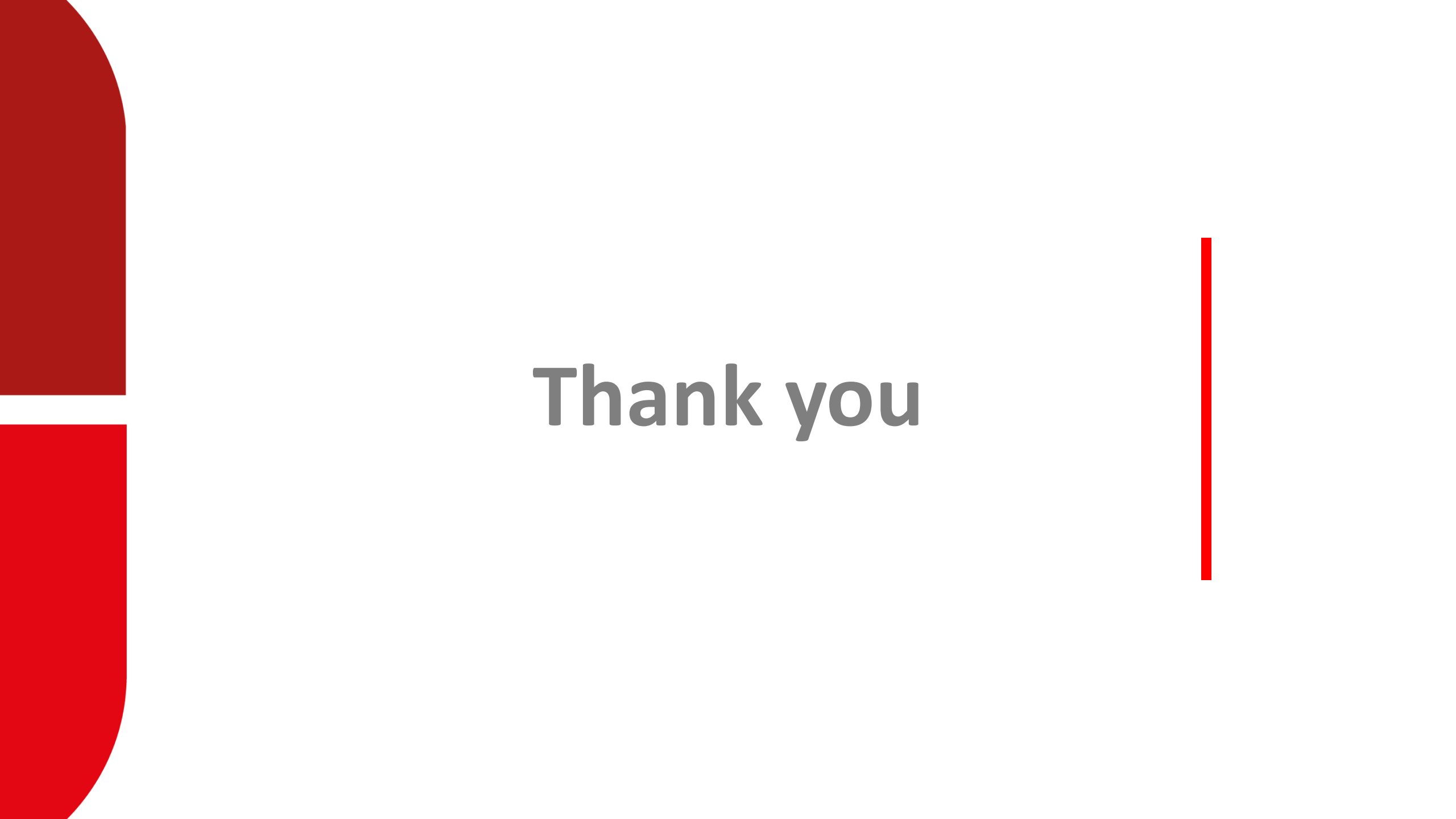
- Appendix VIII. Regulatory. Technovigilance Activities

Amendment to NOM-001-SSA1-2020

The issue has been included in the PNIC 2026, published in the Official Gazette of the Federation on February 24.

Considerations for the draft:

- Expansion of principles
 - GRP for Medical Devices, WHO
 - Quality Infrastructure Act
- Extension of the *vacatio legis* for publications.
- Prioritize alignment with the National Compendium of Health Supplies.
- Greater clarity in the official publication mechanism
- Incorporate dissemination activities
- Create supplementary texts that provide users with a better understanding of the scope of the publications
- The definition of the Pharmacopoeia of the United Mexican States expressly includes "medical devices."
- Strengthen the technical basis of proposals and observations by presenting current regulations, standards, and references as evidence.
- Incorporation of an Addendum to the Annual Work Plan, with defined deadlines for its integration, approval, and publication.
- Expanding the scope of application to expressly include the social sector, in recognition of the participation of civil associations.

The slide features a white background with decorative red elements. On the left side, there is a large red shape composed of two parts: a dark red upper section with a rounded top and a bright red lower section with a rounded bottom. On the right side, there is a single, thin, bright red vertical line.

Thank you