IMDRF International Medical Device Regulators Forum

# IMDRF Membership Application Form (Cover Page)

**Applications must be submitted at least two (2) months before an IMDRF Management Committee face-to-face Closed Session, which are usually held two (2) times each year (for example, March and September (variable each year)).**

If the application is for a Regional Harmonization Initiative (RHI) the application must be submitted by the Chair of the RHI. Any questions should be directed to the Chair of the IMDRF Management Committee which is listed on the IMDRF website.

## Contact Details for Applicant:

Name of Applicant Organization: Comisión Federal para la Protección Contra Riesgos Sanitarios – COFEPRIS (Federal Commission for Protection from Sanitary Risks)

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## Type of Membership

**Affiliate Member**

IMDRF/MC/N69 FINAL:2023 (Edition 8)

# AFFILIATE MEMBER APPLICATION

***ONLY complete this section if applying to become an IMDRF Affiliate Member***

**1.** Is your organization a Regulatory Authority?

(●) Yes ( ) No

**2.** Describe your organization's current or future policy/strategy or plan regarding the implementation of IMDRF guidelines

Building upon its commitment to modernize the regulatory framework, COFEPRIS continues to develop a far-reaching strategy which not only seeks to revise national regulatory provisions but also insert them into global schemes. This strategy is a step towards securing a position as an affiliate member in the IMDRF. Utilizing resources and policies from the IMDRF, including MDSAP, COFEPRIS aims to fine-tune its regulatory framework, aligning it more closely with the international standards set by IMDRF and participating NRAs.

This comprehensive strategy that brings together actions of training, updating of the national regulatory framework, and participation in international mechanisms and fora for harmonization, aims to meet convergence and enforce improvement opportunities by optimizing our competences through an institutional reconstruction having streamlining, justice and transparency as main pillars.

By considering the IMDRF as a guiding force for regulatory harmonization in the field of medical devices, we aspire to narrow the existing gap with global best practices. This alignment is envisioned to simplify the implementation of reliance mechanisms, thereby expediting authorization processes. We are confident that this proactive strategy will aid in alleviating the current backlog in medical device approvals.

From the above, we recently adopted a policy promoting the recognition and utilization of data, reports, and decisions from various international bodies. This encourages different technical sectors within our organization to pinpoint opportunities to refine our regulatory processes. A significant initiative underway is to simplify and unify existing equivalence provisions into a cohesive synthesis (Document reference: OCF-OCF-P-01-POI-03-PO-01; refer to attached documents for details in Spanish and English courtesy translation).

Recognizing the international cooperation is one of the tools available for countries to find solutions to the problems they share with other nations, COFEPRIS, in collaboration with primary partners such as the United States and other allied countries of the Americas region, has leveraged collaboration activities to revamp medical device regulations in line with best international practices, using IMDRF guidelines as a pivotal reference point, aiming to increase the predictability of the regulatory systems.

As we continue to identify avenues for further refinement in our National Standards, by incorporating guidelines particularly tailored for medical devices from the IMDRF, also in synchronizing with Trade Agreements binding commitments, we foster an even playing field by allowing national manufacturers facilitate their entry into international markets, encouraging competence and improving access to health products for world population.

**Additional information (not mandatory):**

**3.** Please describe any activities or initiatives your organization has undertaken or is currently undertaking in the field of medical devices including any guidances developed in emerging and technical regulatory issues:

Aspiring to strengthen our technical, operational, and regulatory capabilities, COFEPRIS is participating in various global health regulation initiatives, such as forums, collaborations, and training programs. Our primary focus is on enhancing the harmonization of medical devices' processes both internationally and domestically, aligning with global standards, specifically IMDRF guidelines, including ISO 13485 and MDSAP, which ultimately aims to facilitate faster access to healthcare products and elevate public health standards in line with the UN's Sustainable Development Goals and the National Development Plan.

Our alignment with WHO's global directive and regional resolutions like PAHO's CD50.R9 (2010) underscores our dedication towards promoting regulatory optimization and efficiency. Furthermore, affiliations with globally recognized entities empower us to initiate equivalence recognition modalities, fostering regulatory convergence and streamlining processes.

By follow international standards, COFEPRIS foresees enhanced transparency and predictability in the regulation of medical devices, eliminating conflicts and duplications, thereby maximizing productivity and reducing technical and regulatory burdens.

This alignment with international standards guarantees streamlined and faster reviews, cost reduction, and efficient resource allocation, fostering global harmony in regulation and enhancing surveillance.

Our main actions can be summarized as follows:

- Strengthening regulatory capacities through training.
- Regulation harmonization and procedures standardization.
- Encouraging risk-focused audits.
- Assurance of safe and effective medical devices through joint stringent vigilance (i.e. MDSAP).
- Streamlining reviews and optimizing authorization processes.
- Reducing operational costs and fostering COFEPRIS performance improvement.

These actions lead us to develop, update and broaden the scope of reliance criteria, encompassing a more comprehensive range of products, processes, and references, including relationships with not just the NRA but other globally recognized regulatory authorities and mechanisms such as MDSAP. This update aims to prevent redundant efforts, streamline conformity assessments, and strengthen regulatory decisions, enhancing transparency in the regulatory framework. It also plans for the more efficient allocation of resources to priority areas, facilitating market access and ultimately serving the population and manufacturers by expanding healthcare supply availability and reducing costs.

In October (13/10/2023) COFEPRIS published the Regulatory Certainty Strategy for the Medical Devices Sector, a document that makes visible the actions carried out to develop the maturity of the regulatory system at the best international practices level, optimizing the use of available resources and using the technical capacity of the institution as well as the commitment of continuous improvement. It seeks to provide certainty and transparency to all actors involved in the supply chain of medical devices, from the industry to patients, and even to other international authorities, since it uses international cooperation as a strategic axis to strengthen sanitary authorization mechanisms and promotion of the productive development of the sector. So we are pleased to share this strategy by which the regulation of COFEPRIS and its harmonization goals are conducted: https://www.gob.mx/cms/uploads/attachment/file/874923/Regulatory_Certainty_Strategy__1_.pdf

Additionally, in efforts to align regulatory procedures and processes, COFEPRIS is in the process of revising the relevant Official Mexican Standards (NOMs) to incorporate increasingly IMDRF guidances, as detailed under section 4 and 5 below.

**4.** Does your organization have a system for conformity assessment of devices building on GHTF and IMDRF guidance documents?

(●) Yes ( ) No

If yes, please provide a description of your conformity assessment program:

## Good Regulatory Practices Committee

As part of the Regulatory Certainty Strategy for the Medical Device Sector, COFEPRIS is conforming a Good Regulatory Practices Committee with the objective that all changes in the regulatory framework have coherence and viability, with a focus on continuous improvement and in accordance with Good Regulatory Practices. This collegiate body, dependent on the Scientific Committee, will have the following authorities among other:

Develop executive work plans for the appropriate implementation of harmonized, improved and administratively simplified regulatory modifications.

Supervise and accompany the implementation of regulations with change management actions and training, both within the technical teams and in the regulated sectors, to guarantee an effective process of adoption of the new regulatory framework.

Generate impact evaluation mechanisms before and after changes to the regulatory framework.

In this body that supervises and accompanies the implementation of the new regulatory framework, it is contemplated to establish impact evaluation mechanisms, and the verification of GRP to guarantee compliance with international and national obligations; as well as foresees a better use of indicators to adequately measure the performance and progress of regulatory convergence.

This committee also seeks to address the Quality Infrastructure Law published in July 2020, which instructs a systematic review process by which the Official Mexican Standards must be reviewed at least every five years after their publication or last modification.

**Official Mexican Standards on Good Manufacturing Practices / MDSAP**

It is worth mentioning that currently all our specific Official Mexican Standards on medical devices are being updated targeted at achieving harmony with international benchmarks, taking GHTF/IMDRF as main reference, but one of the greatest advances that have been made in recent times is the reform of NOM-241-SSA1-2021. Good Manufacturing Practices for establishments dedicated to the manufacture of medical devices, which came into effect on June 20th 2023.

The Standard outlines the Good Manufacturing Practices required for medical device manufacturing processes. This encompasses everything from facility design, product development, receiving, preparation, mixing, production, assembly, handling, packaging, conditioning, stability, analysis, control, storage, to distribution based on the product type. Its main objective is to ensure that medical devices consistently meet the requisite quality and performance for end consumers or patients.

NOM-241-SSA1-2021 details the GMP requirements for medical devices. A primary stipulation is the foundation on a Quality Management System (QMS). This standard aligns with the provisions of ISO 13485, which is recognized by the GHTF/IMDRF, and also takes into account other international benchmarks:

- 21.8 ISO 11135-1:2014. Sterilization of health care products-Ethylene oxide-Part 1: Requirements for development, validation and routine control of sterilization process for medical devices.
- 21.9 ISO/TS 11135-2:2014 Sterilization of health care products-Ethylene oxide-Part 2: Guidance on the application of ISO 11135-1.
- 21.10 ISO 11137-1:2013. Sterilization of health care products--Radiation-Part 1: Requirements for validation and routine control of a sterilization process for medical.
- 21.11 ISO 11137-2:2006 Sterilization of health care products Radiation-Part 2: Establishing the sterilization dose.
- 21.12 ISO 11137-3:2006 Sterilization of health care products Radiation-Part 3: Guidance on dosimetric aspects.
- 21.13 ISO 19011:2011. Guidelines for quality and /or environmental management systems auditing.
- 21.14 ISO 14644-1:2015. Cleanrooms and associated controlled environments--Part 1: Classification of air cleanliness.
- 21.15 ISO 14644-2:2015. Cleanrooms and associated controlled environments--Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1.
- 21.16 ISO 14644-3:2005. Cleanrooms and associated controlled environments--Part 3: Test methods
- 21.17 ISO 14644-4:2001. Cleanrooms and associated controlled environments--Part 4: Design, construction and start-up.

- 21.18 ISO 14644-5:2004. Cleanrooms and associated controlled environments--Part 5: Operations.
- 21.19 ISO 14971:2009. Medical devices--Application of risk management to medical devices.
- 21.20 ANSI/ASQC 01-1988. Generic guidelines for auditing of quality systems.
- 21.21 Code of Federal Regulations Title 21; Part 820, Medical Device Good Manufacturing Practices Manual.- Washington, Food and Drug Administration, 2001.
- 21.22 Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing--Current Good Manufacturing Practice. - Washington, Food and Drug Administration, September 2004.
- 21.23 Final Version of Annex 15 to the EU Guide to Good Manufacturing Practice; European Commission, Brussels, 2015.
- 21.24 European Commission, Guide to Good Manufacturing Practice Annex I.
- 21.25 European Commission, Guide to Good Manufacturing Practice Annex 1, Manufacture of Sterile Medicinal Products, June 2008.
- 21.26 European Commission, Guide to Good Manufacturing Practice Annex 15, Qualification and validation, July 2001.
- 21.27 Manufacture of Sterile Medicinal Products, January 1997.
- 21.28 Points to Consider for Aseptic Processing, PDA Journal of Pharmaceutical Science and Technology, 2003, Volume 57, Number 2, Supplement.
- 21.29 U.S. Foods and Drug Administration. Guidance for Industry Process Validation: General Principles and Practices. Washington, January 2011.
- 21.30 European Medicines Agency, Guideline on process validation for finished products-information and data to be provided in regulatory submissions, United Kingdom, 27 February 2014.
- 21.31 ISPE. GAMP 5, A Risk-Based Approach to Compliant GxP Computerized Systems. 2008.
- 21.32 IMDRF/SaMD WG/N10FINAL:2013. Software as a Medical Device (SaMD): Key Definitions. December 2013.
- 21.33 IMDRF/SaMD WG/N12FINAL:2014. Software as a Medical Device (SaMD): Possible Framework for Risk Categorization and Corresponding Considerations. September 2014.
- 21.34 IMDRF/SaMD WG/N41FINAL:2017. Software as a Medical Device (SaMD): Clinical Evaluation. June 2017.
- 21.35 Guidance for Industry and Food and Drug Administration Staff. Mobile Medical Applications: Guidance for Food and Drug Administration Staff. February 2015.

These specific IMDRF provisions were considered to implement the general requirements established in the following numerals:

- 12.10.13.1 The analytical/technical validation of the software as medical device must include at least:
- 12.10.13.1.1 Technical documentation of the design and development of software, that means, the way it was built (at least, input data, operating systems, programming language, databases used, etc.).
- 12.10.13.1.2 Documentary evidence that the software processes the input data correctly and reliably and generates accurate, complete and precise output data.
- 12.10.13.1.3 Execution of tests that demonstrate that the software meets the specifications established for the intended medical purpose.

The Standard, released in December 2021 and effective from June 2023, is a revision of the former Mexican Official Standard NOM-241-SSA1-2012 Good Manufacturing Practices for establishments producing medical devices. The primary aim of this revision was to modernize the regulatory framework for medical device manufacturing. It provides more specific guidelines than its 2012 version, introducing distinct sections for the design, development, storage, and distribution of medical devices, as well as warehouse handling. Additionally, it aligns its definitions and concepts of good manufacturing practices with international standards.

This revision brings enhanced clarity and assurance to users through these significant modifications:

- Refined Language: The wording has been modified for clearer understanding and to eliminate ambiguities.
- Detailed Requirements for Manufacturing Lines: While some were broadly covered before, they're

now thoroughly described. This includes specifics for various categories of medical devices, like sterile formulated and formulated medical devices, polymeric and elastomeric plastic medical devices, diagnostic agents (in vivo/in vitro), metal-mechanical medical devices, textile medical devices, assembled medical devices, medical devices with biological processes, ceramic/glass medical devices, medicated medical devices, radiopharmaceuticals. Notably, the radiopharmaceuticals section references Annex 3 from the PIC/S Guide, following COFEPRIS's membership in the organization.

- Focused Topics: The new edition breaks down topics like Quality Risk Management, Design and Development, Good Storage and Distribution Practices, Subcontracted Activities, Quality Control Laboratory, syncing with ISO 13485. Some areas have even more comprehensive requirements for implementing the Quality Management System.
- Restructured Sections: Some parts, related to the Quality Management System such as Documentation and Returns and complaints, have been reorganized to better align with ISO 13485.
- Conceptual Harmony: The updated standard aligns its principles with other Mexican Official Standards on Good Manufacturing Practices (NOM-059-SSA1-2015 Good Manufacturing Practices for Medicines and NOM-164-SSA1-2015 Good Manufacturing Practices for Drugs), and various international guidelines.
- Flexibility in Compliance: Options are available for users to meet requirements, like in the context of reduced analysis mentioned under the Manufacturing Systems chapter.

All the aforementioned adjustments are found in the following chapters or sections of the standard: Quality Management System, 7. Quality Risk Management, 8. Design and Development, 10. Facilities and Equipment, 11. Qualification and Validation, 12. Manufacturing Systems, 13. Quality Control Laboratory, 17. Subcontracted Activities, 19. Good Storage and Distribution Practices.

[Please find the complete versions of NOM-241-SSA1-2021 in Spanish at: https://dof.gob.mx/nota_detalle.php?codigo=5638793&fecha=20/12/2021#gsc.tab=0 and also attached a courtesy translation to English]

While the Standard was recently published, we have already pinpointed new areas for enhancement. A primary focus is the explicit recognition of MDSAP audits, which aligns with binding commitments under the Free Trade Agreement with the United States and Canada (USMCA). To ensure this recognition in a timely manner, Mexico is working on a mechanism that allows reliance on MDSAP certificates as a proof of QMS conformity for marketing authorization.

**This regulatory update which incorporated all the provisions on quality management systems for manufacturers of the ISO 13485, as well as the operation that it entails, allowed us to adapt to the MDSAP basis and achieve the Affiliation into the Program in November 2023.** [Please find attached COFEPRIS - MDSAP Affiliated member notice letter or listed participants at https://www.fda.gov/medical-devices/cdrh-international-affairs/medical-device-single-audit-program-mdsap]

**Equivalence Agreements**

COFEPRIS has garnered beneficial experiences from recognizing conformity assessments conducted by reference authorities like the FDA, Health Canada, and PMDA/MHLW (mechanisms dating from 2010-2012: https://dof.gob.mx/nota_detalle.php?codigo=5164641&fecha=26/10/2010#gsc.tab=0 and https://dof.gob.mx/nota_detalle.php?codigo=5231033&fecha=25/01/2012#gsc.tab=0), demonstrating the tangible benefits of reliance for public health by providing with a more agile registration path in Mexico; likewise, we issued temporary provisions to address the health care needs of the COVID-19 pandemic, allowing the emergency use of certain products, based on the information that was becoming available daily and on the decisions that other agencies of reference they took in this regard, to face the disease (https://www.dof.gob.mx/nota_detalle.php?codigo=5585043&fecha=28/01/2020 and http://www.dof.gob.mx/nota_detalle.php?codigo=5621987&fecha=22/06/2021&print=true).

From the above, an equivalence agreement project is being developed, taking some reliance practices from the pandemic transitioning them into permanent regulatory measures, and aiming to reformulate, streamline and clarify the criteria and recognition schemes, standardizing and providing greater clarity to their application, even revitalize previous agreements such as the one regarding Health Canada that

became obsolete after its full migration to MDSAP, expanding the scope as well to other international authorities. This is a highly sought item still under development.

**Reclassification of Medical Devices**

Also, closely linked to the conformity assessment, we can highlight the intentions to restructure the risk classification of medical devices in Mexico.

Mexico has a classification of medical devices divided into three categories:

- ✓ Class I: Devices with minimal risk to the human body. Their safety and effectiveness are fully evaluated, and they are generally devices that are not introduced into the human body.
- ✓ Class II: Products that may have variations in their composition or concentration. They are introduced into the human body for a period of less than 30 days.
- ✓ Class III: New or recently accepted products in medical practice, or products introduced into the human body and remaining for more than thirty days.

Although this classification has allowed for a proper risk-based evaluation of these health products, it is currently outdated compared to some international provisions, which complicates regulatory harmonization or the understanding of regulatory provisions for newly established companies in the country, so the Pharmacopeia of the United Mexican States (FEUM), a tool that due to its legal characteristics allows us to lead the direction of the technical standards and the rest of our regulatory framework, already proposes decision trees as recommended by the IMDRF regarding risk classification.

Therefore, COFEPRIS, through the FEUM, will issue the necessary provisions to achieve a harmonized classification with international recommendations, migrating to a classification into four categories:

I. Low risk
II. Low to moderate risk
III. Moderate to high risk
IV. High risk.

This classification will allow: Adequate evaluation times for each type of product; risk-based criteria and requirements; and the lowest-risk category to function as a notification to the health agency, as these products do not require evaluation due to the low probability of causing harm to health.

COFEPRIS projects that the new classification will be effective in the near future, desirably in the course of 2024.

**5.** Please indicate which IMDRF documents were implemented and provide relevant documentation to support evidence of implementation:

**Pharmacopoeia of the United Mexican States**

As already mentioned, the Pharmacopoeia of the United Mexican States (FEUM) serves as a dynamic representation of the legislative trajectory in Mexico due to its procedural flexibility allows swift adaptations, compared to General Health Laws or even Official National Standards, which is the most advanced national technical document in the field.

The FEUM launched its Medical Devices Supplement Fifth (5th) Edition, on April 2023 (https://www.farmacopea.org.mx/publicaciones-detalle.php?m=3&pid=13). This key document outlines a series of monographs detailing requirements for medical devices. The enhancements incorporated in this new edition are manifold, and include several references from GHTF/IMDRF: refined classification criteria, revised guidelines for market authorization, along with modifications and extensions, reorganized grouping or categorization principles, stability study inclusions, and provisions for software as a medical device.

The improvements include: the definition of "Medical Device" in line with IMDRF's international definition, better criteria for classification based on risks levels according to IMDRF suggestions, amendments in

Guidelines for market authorization, modifications and extensions. Grouping or sorting criteria, Stability studies and Software as medical device. As previously quoted, its contents are the forefront of medical device regulation and some other areas, and is an effective tool to accelerate the application of some regulatory criteria referred in this document.

The Pharmacopoeia definitions, guidelines and standards carries out, at least in the technical stronghold, the fastest future of our regulation, and it is also an instrument standing on international references and collaboration that even is recognized by other countries.

NOM-241-SSA1-2021. Good Manufacturing Practices for establishments dedicated to the manufacture of medical devices

Also widely referred to in the answer to question 4, this National Standard on Good Manufacturing Practices for Medical Devices, updated in December 2021 and valid from June 2023, comprehensively adopted provisions from the ISO 13485 quality management system, as recommended by IMDRF and the basis of MDSAP, allowing the consideration of COFEPRIS to become an Affiliate Member and to recognize its Audit Reports and Certificates.

Despite this standard has been recently updated, like any technical-legal provision, it can be continually improved and adapted, therefore we requested its inclusion in the National Standardization Program to effect its modification in 2024 to amend areas of opportunity, such as clarification about the scope, especially to avoid ambiguity and prevent misinterpretations, and mainly to explicitly recognize MDSAP. On the other hand, there are sections of this Standard that do not allow us to move forward freely in the harmonization of inspection procedures: hence we plan to remove the sections on stabilities or storage to another independent/specific provisions such as the pharmacopoeia.

**NOM-240-SSA1-2012. Post Marketing surveillance of Medical Devices (Technovigilance).**

This standard delineates the essential guidelines governing the conduct of technovigilance activities, a critical initiative aimed at safeguarding patient health and ensuring product safety. This standard mandates adherence across the Mexican territory, encompassing public, social, and private health institutions within the National Health System. It extends to encompass health professionals, technicians, assistants, registration holders of medical devices, their legal representatives in Mexico, as well as distributors, retailers, establishments offering health supplies, and research units conducting studies with these devices. Furthermore, it is applicable to users of medical devices. [Please refer to the full documentation in Spanish at https://dof.gob.mx/nota_detalle.php?codigo=5275834&fecha=30/10/2012#gsc.tab=0, along with a courtesy translation to English attached for a comprehensive understanding]. For the development of this standard the following main documents were taken as reference:

- 4.1.1 Global Harmonization Task Force. GHTF/SC(PD3)/N4:2007.
- 4.1.13 (Global Harmonization Task Force. GHTF/SG2/N54R8:2006.
- 4.1.13 Global Harmonization Task Force. GHTF/SC(PD3)/N4:2007
- 4.1.18 Global Harmonization Task Force. GHTF/SC(PD3)/N4:2007.
- 4.1.2 Global Harmonization Task Force. GHTF/SC(PD3)/N4:2007.
- 4.1.20 Global Harmonization Task Force. GHTF/SC(PD3)/N4:2007
- 4.1.23 Global Harmonization Task Force. GHTF/SC(PD3)/N4:2007
- 4.1.27 (Global Harmonization Task Force. GHTF/SG2/N54R8:2006.
- 4.1.27 (Global Harmonization Task Force. GHTF/SG2/N54R8:2006.
- 4.1.27 Global Harmonization Task Force. GHTF/SC(PD3)/N4:2007.
- 4.1.28 (Global Harmonization Task Force. GHTF/SG2/N54R8:2006.
- 4.1.28 Global Harmonization Task Force. GHTF/SC(PD3)/N4:2007
- 4.1.3 Global Harmonization Task Force. GHTF/SC(PD3)/N4:2007.
- 4.1.4 (Global Harmonization Task Force. GHTF/SG2/N54R8:2006
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- 7.2.14 (Global Harmonization Task Force. GHTF/SG2/N54R8:2006.

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- 8.1.2.1 (Global Harmonization Task Force. GHTF/SG2/N54R8:2006.
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- 9.1 (Global Harmonization Task Force. GHTF/SG2/N54R8:2006.
- 9.2 (Global Harmonization Task Force. GHTF/SG2/N54R8:2006.
- 9.3 (Global Harmonization Task Force. GHTF/SG2/N54R8:2006.
- 12.3.2(Global Harmonization Task Force. GHTF/SG2/N54R8:2006.
- 12.3.3 (Global Harmonization Task Force. GHTF/SG2/N54R8:2006.
- A.4.1.1 (Global Harmonization Task Force. GHTF/SG2/N54R8:2006.
- A.4.3. (Global Harmonization Task Force. GHTF/SG2/N54R8:2006.
- A.4.4. (Global Harmonization Task Force. GHTF/SG2/N54R8:2006.

However, this standard, since 2012 version, has considered the GHTF post-market surveillance guidelines, but it required a new review because it will also consider other national aspects: based on what the technical area has advanced, more specific activities will be included for State Technovigilance Centers as well as Institutional Coordinating Centers for Technovigilance, with the aim of promoting the importance of Technovigilance among healthcare professionals and capturing the majority of adverse incident reports by healthcare professionals.

The initial modification project was submitted in August 2023 for consideration by the Technical Standardization Committee, which is a broad group composed by Government, Academia, and Industry, which began sessions in September and it will subsequently be published for public consultation tentatively in the first quarter of 2024.

**NOM-137-SSA1-2008, Medical Devices Labeling**

The Medical Devices Labeling Standard (NOM-137-SSA1-2008), is currently under review for a comprehensive update to streamline and enhance product distribution both nationally and internationally. This overhaul is primarily aimed at aligning the standard with the "Principles of Labeling for Medical Devices and IVD Medical Devices" as outlined in the document IMDRF/GRRP WG/N52 FINAL:2019. Additionally, this revision is being formulated with consideration of other pertinent contributions from the IMDRF, as well as key international standards and documents from ISO and European entities. [Please refer to the current full version (2008) in Spanish at https://www.dof.gob.mx/normasOficiales/3570/SALUD13_C/SALUD13_C.htm, along with a courtesy translation to English attached for detailed information].

Current NOM-137-SSA1-2008 international references:

- EN 980:2007 Graphical symbols for use in the labelling of medical devices.
- Guidance for industry and FDA staff. Use of symbols on labels and in labeling of in vitro diagnostic devices intended for professional use.- Washington, Food and Drug Administration, noviembre 2004.
- 6.9 Code of Federal Register Part 91-4179 Medical Device Good Manufacturing Practices Manual.- Washington, Food and Drug Administration, abril 2004.
- 6.10 Global Harmonization Task Force. GHTF/SG1/N43:2005 Rotulación de equipos y dispositivos médicos.- 2005.
- 6.11 Latex labeling required for medical devices. Talk Paper Food and Drug Administration US Department of Health and Human Services. Septiembre 1997.

Coming NOM-137-SSA1-XX (2024) international references:

- 8.7 Guidance for industry and FDA staff. Use of symbols on labels and in labeling of in vitro diagnostic devices intended for professional use.- Washington, Food and Drug Administration,

noviembre 2004.
- 8.8 Code of Federal Register Part 91-4179 Medical Device Good Manufacturing Practices Manual.- Washington, Food and Drug Administration, abril 2004.
- 8.9 Global Harmonization Task Force. GHTF/SG1/N43:2005 Rotulación de equipos y dispositivos médicos.- 2005.
- 8.10 Global Harmonization Task Force GHTF/SG1/N77:2012 Principles of Medical Devices Classification.- 2 de noviembre de 2012.
- 8.11 Reglamento (UE) 2017/745 DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 5 de abril de 2017 sobre los productos sanitarios, 24.04.2020.
- 8.12 Reglamento (UE) 2017/746 DEL PARLAMENTO EUROPEO Y DEL CONSEJO de 5 de abril de 2017 sobre los productos sanitarios, 28.01.2022.
- 8.13 ISO 15223-1:2021 Medical devices- Symbols to be used with information to be supplied by the manufacturer- Part 1: General requirements.
- 8.14 ISO 15223-2:2010 Medical devices-Symbols to be used with medical device labels, labelling, and information to be supplied-Part2: Symbols development, selection and validation.
- 8.15 ISO 20417:2021 Medical Devices-Information to be supplied by the manufacturer.
- 8.16 ISO 7010:2019 Graphical symbols-Safety colours and safety signs-Registered safety signs.
- 8.17 ISO 3864-1:2011 Graphical symbols - safety colours and safety signs -Part 1: Design principles for safety signs and safety marking.
- 8.18 OMS/EB/152/11 (GMRF) WHO Global model regulatory framework for medical devices including in vitro diagnostic medical devices (GMRF), WHO/BS/2022.24.25.
- 8.19 OPS/HSS/MT/22-0007 Principios de etiquetado de los dispositivos médicos y los dispositivos médicos de diagnóstico in vitro, 2022.
- 8.20 IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of safety and Performance of Medical Devices and IVD Medical Devices.
- 8.21 IMDRF/GRRPWG/N52 FINAL:2019 Principles of Labelling for Medical Devicess and IVD Medical Devices, 21 March 2019.
- 8.22 IMDRF/AIMD WG/N67 Machine Learning-enabled Medical Devices: Key Terms and Definitions, 6 May 2022.
- 8.23 MD-MDCG 2021-26 Question and answers on repackaking & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746, october 2021
- 8.24 ISO IEC GUIDE 63, Guide to the development and inclusion of safety aspects in International Standars for medical devices, 2019.
- 8.25 ISO IEC GUIDE 51, Safety aspects -Guidelines for their inclusion in standars, 2014.
- 8.26 21 CFR PART 801. (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=801)
- 8.27 WHO/BS/2022.2425, WHO Global model regulatory framework for medical devices including in vitro diagnostic medical devices (GMRF).

It is important to note that although this review has previously looked at the guidelines "Unique Device Identification system (UDI system) Application Guide (IMDRF/UDI WG/N48). Technical document, 21 March 2019" and "Common Data Elements for Medical Device Identification (IMDRF/RPS WG/N19). Technical document, 24 March 2016", they are not intended to be implemented in this version but they will be taken again into consideration for future reviews according to the technical and regulatory conditions in the country.

As in the case of NOM-240 on Technovigilance, the Labelling Standard modification project was submitted for consideration by the Technical Standardization Committee on August 2023, and finished its revision at the end of November that year (2023) expected to be published for public consultation tentatively in the first quarter of 2024 and published during the same year.

**6.** Does your organization have laws and regulations in place for medical devices that build on GHTF and IMDRF foundations and principles?

(●) Yes ( ) No

If yes, please provide the relevant law or regulation a comprehensive description of its contents and a description of related enforcement activities:

In May 2023, at the level of the General Health Law (which is the overarching Law that gives authority to COFEPRIS to oversee the safety of products under its jurisdiction), modifications were made to include the term "Medical Device" as such, since previously they were only referred to as "other supplies" (https://www.dof.gob.mx/nota_detalle.php?codigo=5688291&fecha=10/05/2023#gsc.tab=0). It may seem like a simple change, but it actually holds great significance as it is a key element from which all other regulations derive and depend on.

In the same vein, work is already underway on a reform project for the Health Supplies Regulation, in which, among other products, the provisions related to medical devices are being revised, and we can now work under the shelter of this term, following the modification of the Law, allowing us to take another step in defining harmonization matters, of course, in line with what IMDRF suggests. This regulation also establishes general provisions on authorization requirements, among others.

Likewise, in international treaties, which are binding provisions for the country along with ordinances of a Federal law, are referred to commitments regarding the reduction of technical barriers to trade, which in the specific field of medical devices, calls to harmonization with the principles of the IMDRF. In this regard, in order to facilitate international trade on health products, there is active work for regulatory convergence in the framework of trade agreements: The USMCA with United States, Canada and México and the Pacific Alliance integrated by Chile, Colombia, Peru and Mexico, where were developed sectorial annexes and there is one specific for Medical Devices to reduce Technical Barriers to Trade. The first one focused mainly in Good Regulatory Practices, convergence and MDSAP recognition (ANNEX 12-E MEDICAL DEVICES: https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/12_Sectoral_Annexes.pdf); the second one establishes the basis for standardization of minimum technical requirements of authorization and a recognition scheme for low-risk medical devices that is in negotiation (FREE TRADE COMMISSION OF THE ADDITIONAL PROTOCOL TO THE FRAMEWORK AGREEMENT OF THE PACIFIC ALLIANCE. DECISION No. 12. Annex 7.11 Quinquies. MEDICAL DEVICES. REMOVAL OF TECHNICAL OBSTACLES TO TRADE IN MEDICAL DEVICES: https://alianzapacifico.net/instrumentos-decisiones-de-la-comision-de-libre-comercio-del-protocolo-adicional-al-acuerdo-marco-de-la-alianza-del-pacifico/#).

But regardless of international commitments, there is a strong conviction of COFEPRIS as a National Regulatory Authority to adopt more international guidelines, in this context our intention is to progressively implement the IMDRF guidelines and recommendations in our national regulations.

## SIGNATURE PAGE

**Amina Hayat Achaibou Taright**
**Director of International Affairs**
**COFEPRIS**

Signature

**10/01/2023**
Date