Inter-American Coalition for Regulatory Convergence – Medical Technology Sector (IACRC)

Position Paper on Mexican Technical Regulation NOM 241-SSA1-2021
"Good Manufacturing Practices of Medical Devices"

4 May 2022

Summary

The Mexican Medical Device Regulatory Authority, the Federal Commission for Protection against Health Risks (COFEPRIS), recently published an updated technical regulation NOM-241-SSA1-2021 "Good Manufacturing Practices of Medical Devices" (known as the Good Manufacturing Practices (GMP) regulation for Medical Devices). NOM-241-SSA1-2021 extends its scope, and COFEPRIS's related regulatory authority, to medical device manufactures located in the export-only zone of contract manufacturers ("maquiladoras") in conflict with: (A) the USMCA Chapters on Good Regulatory Practices, Technical Barriers to Trade, and the Medical Device Annex, (B) the WTO Agreement on Technical Barriers to Trade (TBT), (C) the process for developing technical regulations under the Mexican Regulatory Improvement Law of 2018, and (D) the terms of the IMMEX (Export Only) Program.[1] . NOM-241-SSA1-2021 was developed in a manner inconsistent under Mexican law and treaty obligations, will unnecessarily and negatively impact the trade of medical devices, will negatively affect patient access to related medical technologies in and outside of Mexico and it will undermine efforts to combat and recover from the COVID-19 pandemic. NOM-241-SSA1-2021 will also negatively impact Mexican government efforts to attract and maintain medtech manufacturing as an essential link in the North American and global medtech supply chain and in considerations of reshoring and partnership in the Americas.

Estimated Economic Impact

The IACRC estimates the economic impact of NOM-241-SSA1-2021 to be in the range of USD 250 to 500 million per year.

Position

The IACRC recommends that NOM-241-SSA1-2021 be retracted in its entirety or otherwise be made consistent with Mexico's domestic law and international treaty obligations through the following specific changes:

- Mexican government full recognition of audits of device manufacturers' quality management systems that are in accordance with the requirements established by the Medical Device Single Audit Program (MDSAP) and conducted by auditing organizations authorized by the regulatory authorities participating in MDSAP to audit under the MDSAP requirements, and / or ISO 13485

[1] More information on these references is provided in Annex I to this document.

certified manufacturers independent whether they sell their products either under marketing authorizations either as imported or locally manufactured.

- Mexican government limitation of the measure's scope to manufacturing sites which register and/or sell products into the Mexican market that are not ISO 13485 certified; and
- Mexican government explicit exemption of the applicability of the measure to the production of Contract Manufacturers ("maquiladoras") under the IMMEX (Export Only) Program.
- The IACRC also recommends that the regulation undergo a complete Regulatory Impact Assessment (RIA) under the observation that the RIA and the process previously conducted to develop NOM-241-SSA1-2021 was not consistent with Mexico's obligations for Good Regulatory Practices as stipulated within the USMCA and Mexican Regulatory Improvement Law.

Annex I below provides the detailed background information regarding NOM 241-SSA1-2021 and the IACRC positioning above.

Annex 1 – Detailed Background Information Regarding NOM 241-SSA1-2021

Contents

Policy Reference Links

The treaty, legal and regulatory requirements referred to in this document are summarized here for easy reference, including the relevant portions available in English and Spanish:

1. "Good Regulatory Practices for the Manufacturing of Medical Devices" NOM 241-SSA1-2021 (English / Spanish)
2. Decree to promote the manufacturing, contract manufacturing "maquiladora" and export services - IMMEX (Export Only) Program (English – relevant items / Spanish)
3. Regulatory Improvement General Law of 2018 (English / Spanish)
4. General Health Law – Articles 194-Bis and 260 (English / Spanish)
5. USMCA – Annex 12-E - Medical Devices (English / Spanish)
6. USMCA – Chapter 11 – Technical Barriers to Trade (English / Spanish)
7. USMCA – Chapter 28 – Good Regulatory Practices (English / Spanish)

IMMEX (Export Only) Program Summary

The IMMEX (Export Only) Program is a Mexican government framework established via DECREE for the promotion of manufacturing, "maquiladora" (contract manufacturing), last reformed published on 24 December 2020, that supports manufacturing production within designated geographies in Mexico as a support to the Mexican, North American, and global supply chains. The legal provisions of the IMMEX (Export Only) Program require that the semi-finished and/or finished goods manufactured within the program be exported out of Mexico and not be sourced directly into the Mexican market. One design feature and benefit to the IMMEX (Export Only) Program is the cost savings achieved by eliminating the Mexico-only market access costs – given that: (a) the final product may not be intended for the Mexican market, and (b) that the final product will separately need to go through the market access requirement of the respective final country, including the cases for which that final country is Mexico.

Table 1: Overview of the Current and Proposed Mexican MedTech GMP Regulatory Scenarios

	NOM-241-SSA1-2012	NOM-241-SSA1-2021
Enforcement	Current	21 June 2023
Scope	Applies to manufacturers located in the Mexican territory: - Required for products sold in the Mexican territory under a registration approval issued by COFEPRIS; - Required for finished products to be exported under a Free Sale Certificate (FSC) issued by COFEPRIS; - Does not apply to Contract Manufacturers ("maquiladoras") under the IMMEX (Export Only) Program.	Applies to manufacturers located in the Mexican territory: - Required for products sold in the Mexican territory under a registration approval issued by COFEPRIS; - Required for finished products to be exported under a Free Sale Certificate (FSC) issued by COFEPRIS; - Required by contract Manufacturers ("maquiladoras") under IMMEX (Export Only) Program.
Alignment to ISO 13485	Partial	Partial
Compliance with MDSAP and USMCA	No	No

Among the requirements established by the Mexican government to grant a registration approval for medical devices is a demonstration that the manufacturing facilities operate under Good Manufacturing Practices. For this purpose, COFEPRIS accepts: (1) a COFEPRIS-issued GMP Certificate for locally manufactured and imported products; (2) a certificate of compliance with ISO 13485 by a Certification Body (only for imported products), (3) a GMP certificate via the MDSAP (only for imported products). This differentiation constitutes a Specific Trade Concern (STC) as it applies a differing set of regulatory and market access requirements to local manufacturing facilities (independent of their nationality) as compared with imported products.

When it enters into force, NOM-241-SSA1-2021 will widen the above-mentioned discrepancy as it will impact not only local manufacturing facilities which sell products in Mexico but also the contract manufacturers under the IMMEX (Export Only) Program, which are required to export 100% of their production, constituting a Specific Trade Concern.

A straightforward possibility to eliminate this particular STC aspect is to extend the recognition of ISO 13485 and MDSAP audits as equivalent to the COFEPRIS GMP Certificate (currently only for imported products) to locally manufactured products. This could be achieved by NOM-241, FEUM's Supplement of Medical Devices and any other relevant legal instrument, establishing the equivalence of the three instruments (ISO 13485, MDSAP audits and COFEPRIS GMP) for all situations: imported and local.

Table 2: Overview of Mexican MedTech GMP Certificate Requirements

	Issuance of GMP Certification for device registration approval	Manufacturing facility located in Mexico (independent of nationality)	Manufacturing facility located outside of Mexico (Importer)
1	COFEPRIS	Required	Optional
2	Certification Body for ISO 13485	No	Yes
3	Recognized MDSAP Auditing Organization	No	Yes*

* A legal document that clearly includes this alternative has not been published.

Regulatory History

The regulatory history of NOM-241-SSA1-2021 is provided here as a guide to the regulatory process under which it was developed.

NOM-241-SSA1-2021 is an update of the Mexican Good Manufacturing Practices (GMP) for Medical Devices technical regulation which formally began with the publication of the first draft on 4 September 2018 and which was finalized with the publication of the final version on 20 December 2021. The regulatory process actually began informally prior to 4 September 2018 through meetings of the "Technical Advisory Group" convened by COFEPRIS through the Mexican Pharmacopeia (FEUM) as documented below.

The IACRC lauds the Mexican government for having conducted many of the steps of GRP in the revision of NOM-241, including the conducting of a partial RIA and providing the opportunity for a public consultation on the RIA, and via several rounds of comments. However the IACRC is of the assessment that the elements of GRP as stipulated within Mexico's domestic and international commitments were insufficiently applied due to:

a) the lack of an adequately broad RIA scope to examine the applicability of the NOM-241 to the conditions of the IMMEX (Export Only) Program which underpins a large section of Mexico's medical technology production;

b) the limited application by COFEPRIS of a science-based review of the comments submitted and the limited regulatory rationale and science-based decision making conveyed by COFEPRIS;

c) the limited visibility of the deliberations of the COFEPRIS/FEUM "Technical Advisory Group", as they are only available to its members;

d) partially complying with Mexico's international and domestic obligations for the application of Good Regulatory Practices, the USMCA and the WTO/TBT Agreement.

Table 3: Summary of the regulatory history for NOM-241
(includes links to the documents which are referred to throughout the other sections of this document)

Regulatory Process Step	Date	Description
	Prior to 04 Sep 18 and through 11 Jan 22	COFEPRIS, through FEUM, convenes a series of meetings regarding its regulatory intent with the "Technical Advisory Group", a committee comprised of selected stakeholders that are appointed and operates under the rules established in Art. 12, 20, 32 and 33 of the "Internal Operation Rules of the Permanent Commission of the Pharmacopeia of the Mexican National States" (English / Spanish). Although decisions made by this group are to be reached via consensus between the private sector stakeholders and the government representatives on the committee (utilizing a scientific and technological basis, as stated in Art. 28 g), in practice the government can summarily disregard the private sector inputs without scientific-base justification which happened in the development of NOM-241. The proceedings of the Technical Advisory Group are not made public, yet internally available, as also stated in Art. 28 g).
I	04 Sep 18 – 29 Oct 21	CONAMER (formerly COFEMER) – issues the first draft of PROY-NOM-241-SSA1-2018 for public consultation. This draft does not take into consideration several inputs of various participants of the "Technical Advisory Group", as referred to above. (This link includes the reference to the historical documents from initial publication in 2018 through the latest published in October 2021 (Spanish) – excluding anything related to the "Technical Advisory Group")
II	04 Sep18	CONAMER publishes PROY-NOM-241-SSA1-2018 along with its Regulatory Impact Analysis for public consultation (Spanish).
III	14 Jun 19	COFEPRIS publishes via the Official Daily Gazette a second draft of PROY-NOM 241-SSA1-2018 (English / Spanish). This draft also does not address significant comments of the "Technical Advisory Group." Neither COFEPRIS nor FEUM provide written regulatory justification, scientific rationale, or any response to comments submitted through this group.
IV	21 Jun 19	The Mexican government notifies the 2nd version of the measure to the WTO/TBT as G/TBT/N/MEX/454 (English / Spanish), Notification Summary (only available in English).
V	06 Aug 20	CONAMER publishes the (partial) Regulatory Impact Analysis of the 2nd draft for public consultation:

		a. Impact Analysis and Cost/Benefit Evaluation of Draft NOM 241, July 2020 – Version 2 (English Relevant sections / Spanish)
VI	06 Aug 20	CONAMER publishes COFEPRIS' responses to public comments: a. Part I (Relevant Sections in English / Spanish) b. Part II (Relevant Sections in English / Spanish)
VII	21 Aug 20	CONAMER publishes its Final Opinion (English / Spanish)
VIII	03 Sep 20	Industry submits its comments on the 2nd RIA: a. CANIFARMA (English / Spanish) – published at CONAMER's website, with no reply; b. AMID (English / Spanish) and reply from COFEPRIS (English / Spanish) – not published at CONAMER's website.
IX	20 Dec 21	Final version of NOM-241-SSA1-2021 is published in the Official Daily Gazette of the Federation (English / Spanish)
X	11 Jan 22	Government of Mexico submits its Response to Comments received via the domestic public consultation on the measure (item VI above) to the WTO/TBT via G/TBT/N/MEX/454/Add.1 (English)
XI	11 Jan 22	Government of Mexico submits the final measure NOM-241-SSA1-2021 published at the Official Daily Gazette of the Federation on 20 December 2021, WTO/TBT via G/TBT/N/MEX/454/Add.2 (English). * * It is noted that G/TBT/N/MEX/454/Add.2 was notified using the ICS code 11.040 but without noting the affiliated HS codes – adding delay to the identification of the measure by the Coalition within the ePing system.

Observation: Three factors exist within the structure of the current Mexican medical device regulatory framework that led to the insufficient application of GRP in the development of NOM 241-SSA1-2021 and its elements comprising technical barriers to trade and health:

1. The Mexican medical device regulatory framework is bifurcated between COFEPRIS and also the Mexican Pharmacopeia (FEUM) which is a separate government agency constituted independently under the General Health Law and which develops the initial drafts of medical device technical regulations. The administrative rules that apply to COFEPRIS are different to the ones that apply to FEUM, for the latter being defined under "NOM-001-SSA1-2020, which establishes the structure of the Pharmacopeia of the United Mexican States and its supplements and the procedure for its review, update, edition and dissemination" (English / Spanish);
2. As evidenced by its name, FEUM is an historically pharmaceutical-oriented body. In 2006, FEUM began issuing a Supplement for Medical Devices, currently in its 5th edition, whose content is developed under the above-mentioned rules and NOM-001-SSA1-2020. This had the effect of

involving FEUM in the development of technical regulations for medical devices in Mexico together with COFEPRIS, but not fully subject to the administrative procedures of COFEPRIS;

3. Neither COFEPRIS or FEUM today have standard operating procedures, nor NOM-001-SSA1-2020, that codify their compliance with GRP or TBT provisions of international treaties or domestic legislation.

Table 4: Itemization of the IACRC-identified Specific Trade Concerns of NOM-241-SSA1-2021

Impact on Contract Manufacturers under "IMMEX (Export Only) Program"	
The scope of NOM-241-SSA1-2021 leaves room for misinterpretation regarding its potential applicability to Contract Manufacturers which, under the "IMMEX (Export Only) Program" (2), which manufacture components, semi-finished or finished products, under the license of the Legal Manufacturers located in the USA, items that are required to be re-exported to: - Comply with the re-export obligation under the program, - Get the components or semi-finished products, turned into actual finished products or finished products to comply with the conditions under which a commercialization approval is granted to the USA based Legal Manufacturer, by the US FDA.	
Original Text	**IACRC Observation**
1.2 Scope: This technical regulation is mandatory in the national territory, for all facilities dedicated to the manufacture of medical devices, conditioning warehouses, storage, and distribution of medical devices. **Impact Analysis and Cost/Benefit Evaluation (V.a)** **<u>RIA</u>** **<u>9. Provide the calculation on the costs and benefits that the regulation implies for each interested private party or group of interested private parties:</u>** This NOM Project has the main purpose of updating the regulatory frameworks for the legal entities that hold a sanitary registration who choose and request from COFEPRIS a Certificate of Good Manufacturing Practices (BPM). It is	Even though both facilities and processes for which the NOM 241 would be enforced are clearly stated at NOM-241 project, RIA 9, Cost 1, within the "Impact Analysis and Cost/Benefit Evaluation", as can be read in the left column, contradictions and / or imprecisions are identified on the way it is addressed at: - "Purpose and Scope of Application", - Last paragraph on ITEM 7 within the reply provided by COFEPRIS to AMID dated September 11, 2020. Ask: A clear disclosure should be made that the NOM-241 is not enforced to the Contract Manufacturers (Maquiladoras), under the "Decree to promote the manufacturing, contract manufacturing "maquiladora" and export services – IMMEX (Export Only) Program" (2),

important to highlight that, in order to commercialize medical devices, it is only necessary to obtain the Sanitary Registration issued by COFEPRIS. The BPM is applicable to the manufacturer of medical devices that are commercialized in the country and who wish to demonstrate the compliance with the necessary requirements implemented in the manufacturing process in accordance with the applicable Technical regulations, and therefore ensure safe and efficient medical devices; … **Cost 1** … However, it is necessary to remind that the provisions in this technical regulation amendment project apply for those legal entities that manufacture medical devices that require a Sanitary Registration for marketing and choose to undergo this proceeding before COFEPRIS in order to obtain a Certificate of Good Manufacturing Practices for medical devices (BPM, by its Spanish acronym), … **Purpose and Scope of Application:** **Purpose.** This technical regulation has the purpose of establishing the minimum requirements for the design, development, manufacture, storage, and distribution processes for medical devices based on their risk level, with the intent of ensuring that they consistently comply with the quality, safety, and functionality requirements in order to be used by the final consumer or patient. **Scope of Application.** Compliance with this technical regulation is mandatory in the national territory for all facilities dedicated to the manufacture of medical devices and warehouses dedicated to	which by the nature of the program, production is: - Required to be re-exported, under the requirements established under Art. 4; - Required to complete the manufacturing and approval process by the related health authority abroad, where the legal manufacturer is established, to actually become a medical device as defined by the General Health Law Arts. 194-Bis and 262 (4). Products and components under the program, which are to be re-exported to finish manufacturing and sanitary registration abroad, are not required to be supported by a GMP (BPM) issued by COFEPRIS.

conditioning, storing, and distributing medical devices. **Reply letter from COFEPRIS to AMID, dated September 11, 2020 (VIII.b)** **ITEM 7** … Regarding the contract manufacturers, I would like to point out that this industry is currently also complying with the requirements of Good Manufacturing Practices, including having Quality Assurance personnel, since they carry out manufacturing activities. With regard to their concern about having documentation in Spanish, it is important to point out that article 16 of the Health Supplies Regulation establishes this requirement and also specifies the type of documentation that must be translated. … _bookmark0	

Negative impact on Local Manufacturers and Contract Manufacturers under "IMMEX (Export Only) Program" holding certifications issued via ISO 13485 or MDSAP	
Marketing authorizations for imported medical devices are granted by COFEPRIS upon the recognition of ISO 13485 certifications as evidence of compliance with GMP. Locally manufactured products are required for a GMP issued by COFEPRIS despite the fact that the manufacturer might already hold an ISO 13485 certification. NOM 241-SSA1-2021 is not in compliance with the USMCA and WTO/TBT legal obligations as it poses differentiated, inequitable requirements to local and contract manufacturers under the IMMEX (Export Only) Program by only recognizing an ISO 13485 or MDSAP Certification to demonstrate partial compliance with NOM 241-SSA-1-2021 and does not recognize them for full compliance.	
Original Text	**IACRC Observation**
6.7 Facilities that have certification under the current ISO13485 standard issued by bodies authorized by national accreditation bodies or internationally recognized ones, for the conformity assessment it will be recognized as equivalent to the requirements established in section 6 of this Standard.	At Section 6.7, under Quality Management System, as can be read in the left, it is only recognized in part the ISO 13485 as to fulfill the requirements to obtain a BPM issued by COFEPRIS.

6.7.1 Inspections will be carried out under a reduced approach, except for subsection 6 and its subsections of this Standard. **Impact Analysis and Cost/Benefit Evaluation (V.a)** **Summary of Benefits.** In the last years, the medical devices industry has grown steadily, driven by worldwide technological advances, the digitization and inclusion of new technologies, the growing demand by the population, which place the industry in a steady growth and development scenario. The USMCA has included new provisions to strengthen the industrial platform in North America with the purpose of guaranteeing that the trade between the three countries is easier, **preventing the redundancy of requirements**, increase the collaboration between authorities during the inspections and **promoting the homologation of processes for the authorization of sanitary registrations for commercializing pharmaceutical products and medical devices**	Under **IMPACT ANALYSIS AND COST/BENEFIT EVALUATION, Summary of Benefits**, obligations under USMCA are clearly recognized, therefore, enforcement for Contract Manufacturers (Maquiladoras) under the IMMEX (Export Only) Program and local manufacturers holding an ISO 13485 certification and/or a MDSAP based certification would be in violation of the USMCA's Annex 12-E on Medical Devices (5) Article 12.E.4: Enhancing Regulatory Compatibility, paragraph 3 states: "The Parties shall seek to improve their cooperation on inspections of medical device manufacturers' quality management systems. To this end, each Party shall recognize audits of device manufacturers' quality management systems that are in accordance with the requirements established by the Medical Device Single Audit Program (MDSAP) and conducted by auditing organizations authorized by the regulatory authorities participating in MDSAP to audit under the MDSAP requirements." for which making mandatory the compliance with the NOM-241 would be contrary to the obligation for recognition, thereby stated. Furthermore, the current text of the project does not outline the obligation to recognize MDSAP as an equivalent process to the issuance of a GMP Certificate by COFEPRIS.
Impact Analysis and Cost/Benefit Evaluation (V.a) **RIA** **8. Does the regulation proposal include schemes that differentiated impact over sectors or economics agents?**	Furthermore, under **IMPACT ANALYSIS AND COST/BENEFIT EVALUATION, RIA, 8**, reinforced at **Conclusions,** as can be read on the left column, nonetheless the aforementioned inconsistencies and contradictions, it is stated that there is no differentiated impact to the diverse incumbents. Requiring a BPM issued by COFEPRIS to already certified facilities either under ISO 13485 or MDSAP Program, either for contract

No, since its provisions and application are intended equally for all establishments dedicated to the manufacturing of medical devices, conditioning warehouses, storage and distribution of medical devices; verification and monitoring of compliance with this Technical regulation, under the responsibility of the Secretariat of Health through the Federal Commission for the Protection of Health Risks and the governments of federal entities. Similarly, a consideration is made that the Project being commented, does not affect competition and free concurrence in the markets, nor does it affect the movement and transit of both domestic and imported goods. Likewise, it is considered that there is no impact, alteration or non-compliance to Mexico's commitments acquired at international trade treaties and general rules for international trading, nor is economic activity unduly restricted by establishing minimum requirements for design processes, development, manufacturing, storage and distribution of medical devices, based on their level of risk, according to the quality standards implemented internationally, as well as good manufacturing practices and recent scientific evidence inquired at the moment; in order to ensure that they consistently meet the requirements of quality, safety and functionality to be used by the end consumer or patient, as protection and safeguarding the health of the population. **<u>Conclusions</u>** It does not consider plans that have a differentiated impact to the economic sectors or agents for which this technical regulation is applicable, since its provisions and application is intended equally for all the facilities dedicated to the manufacture of medical devices, conditioning, storage, and distribution warehouses for medical devices that require a Sanitary Registration. The inspection and the	manufacturers under the IMMEX (Export Only) Program or facilities supplying medical devices to the local market which require a sanitary registration issued by COFEPRIS, shows a clear unbalance and negative impact on competitiveness both for the exports and the local market, the latter as local manufacturers already holders of the aforementioned certifications, would be unfairly treated as compared to importers which are only required to be certified on ISO13485 or the MDSAP Program as a requirement for a sanitary registration.

surveillance of the compliance of this technical regulation corresponds to the Secretariat of Health through the Federal Commission for Protection against Health Risks and the government of the Federal States. At the same time, it is deemed that the Project does not affect the free competition of the markets, nor the circulation and the transit of merchandise both national and imported. Furthermore, it is deemed that there is not damage, alteration, or non-compliance with Mexico's commitments included at international trade agreements and general international trade standards, and that the economic activity is not unduly restricted, by establishing the minimum requirements for the design, development, manufacture, storage, and distribution processes for medical devices based on their risk level, in accordance with the quality standards implemented internationally, along with the Good Manufacturing Practices and the recent scientific evidence currently available, with the purpose of ensuring they consistently comply with the quality, safety, and functionality requirements in order to be used by the final consumer or patient. In general, it is established that under the assumptions made during the impact analysis and cost-benefit evaluation of the Mexican Official Technical Regulation Draft PROY-NOM-241-SSA1-2018, Good Manufacturing Practices for Medical Devices, it is economically and socially effective, and does not have an impact on the free competition in the markets, nor on the circulation and transit of merchandise both national and imported. Furthermore, it is deemed that there is not damage, alteration, or non-compliance with Mexico's commitments included at international trade agreements and general international trade standards, and that the economic activity is not unduly restricted, by establishing the minimum requirements for the	

design, development, manufacture, storage, and distribution processes for medical devices based on their risk level, in accordance with the quality standards implemented internationally, along with the Good Manufacturing Practices and the recent scientific evidence currently available, with the purpose of ensuring they consistently comply with the quality, safety, and functionality requirements in order to be used by the final consumer or patient, as protection and safeguarding of the population's health. **Benefits** … Mexico is the eighth exporter of medical devices worldwide. The more relevant legal entities are located in Baja California, Chihuahua, Jalisco, Guanajuato, Veracruz, Chihuahua, Puebla, Mexico City, and the State of Mexico. Mexico holds the third place worldwide for tubular suture needles, the fourth as an exporter of instruments and devices for medicine, surgery, odontology, or veterinary medicine; the country is also the fourth worldwide exporter of medical furniture and as a global exporter of syringes, catheters, cannulas, and similar instruments. A yearly sustained growth rate for the industry of 6.2% is foreseen. Nowadays, Mexico got consolidated as the main exporter of medical equipment for the most important market: The United States, with 91% of the exports directed to that country and creating an attractive, strong, and sustained market. **BENEFIT 2. Savings resulting from the removing two days for the inspection visit for obtaining the Certificate of Good Manufacturing Practices.** **…** The reduction of the duration of the sanitary inspection visits is considered with the implementation of the provisions included in this Technical regulation amendment project PROY-NOM-241-SSA1-2018, particularly for the inspection visits performed at legal entities that	NOM-241 as published will produce a significant negative impact to the global supply chain, given the relevance of the role of the Contract Manufacturing (Industria Maquiladora) as documented at **Benefits,** and also under the **IMPACT ANALYSIS AND COST/BENEFIT EVALUATION**, as can be read in the left column, as well as the aforementioned lack of compliance with obligations under USMCA, would also be in explicit violation of the obligations that Mexico holds before the WTO/TBT and the OECD. Despite being considered under **Benefit 2**, under **IMPACT ANALYSIS AND COST/BENEFIT EVALUATION,** as can be read in the left column, the reduction on three days for the length of an inspection for local manufacturers holding a certification issued by ISO 13485 or the MDSAP Program, cannot be considered as such, since the whole inspection process is a duplicative and burdensome requirement, as broadly described above.

hold an ISO 13485 Certification, since during those visits there will be savings on supervision times for the sanitary inspectors intended for these purpose as they will simply validate the previously certified processes, focusing the time mainly in the supervision of the production systems with the purpose of ensuring the safety, the stability, and the certainty of the manufacture of the specified medical devices. As a result of these adjustments, it is anticipated that a sanitary inspection visit that currently takes 5 business days on average will be carried out in 3 days. …	Ask: In order for Mexico to comply with the obligations stated in the above mentioned paragraph 3, Article 12.E.4 of the Annex 12-E on Medical Devices (5) it is necessary that NOM-241 clearly state the recognition of MDSAP certificates and refer to the related program documents, available at the FDA site under MDSAP Documents. In addition, to comply with WTO/TBT obligations, Mexico should fully recognize ISO13485 Certified local manufacturers as does for importers.

Implementation Costs – Impact on financial viability and potential investments

Implementation Costs as calculated in the RIA(V), which is based on a much smaller blueprint estimation as compared to the figures provided by the National Statistics Directory of Economic Entities, misrepresent the real implementation costs, which will create a burden on the financial viability of many and will disincentivize foreign investment, negatively impacting the country's position as exporter, on its attractiveness for reshoring, as well as on employment.

Original Text	IACRC Observation
Impact Analysis and Cost/Benefit Evaluation (V.a)) … Table 9. Summary of costs associated with the implementation of the Project Official Mexican Technical Regulation Draft PROY-NOM-241-SSA1-2018.	The **IMPACT ANALYSIS AND COST/BENEFIT EVALUATION** significantly underestimates the actual implementation costs when compared to the analysis performed by CANIFARMA, published by CONAMER (VIII.a), which did not get a reply from the authorities, as estimations performed by COFEPRIS, only consider the number of current holders of BPM issued by COFEPRIS, not the figures, proposed by CANIFARMA, which are actually also published on page 34 of the aforementioned document (National Statistics Directory of Economic Entities) which report 2,346 entities specialized on medical devices. - Implementation Cost as per Table 9, page 31: $9.2 Million Dollars*

Type of Cost	Estimated Cost
Cost 1. Implementation of the Quality Management System.	$ 104'750,000 (Aprox. 5M USD)
Cost 2. Administrative burden for documenting the various stages in design and development of devices.	$ 24'570,000 (Aprox. 1.2M USD)
Cost 3. Implementation	$ 47'923,125

of Good Warehousing and Distribution Practices.	(Aprox. 2.4M USD)
Cost 4. Implementation of alternate power supplies for the manufacturing of sterile medical devices produced under aseptic processing.	$ 5'984,000 (Aprox. 300K USD)
Total	**$ 183'227,12 (Aprox. $9.2 M USD)**

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…

In this regard, our country in 2019, and according to the National Statistic Directory of Economic Entities (DENUE), there are 2,346 identifiable specialized medical devices economic units.

- Implementation Cost as per CANIFARMA's calculation**, using the same base cost per unit as COFEPRIS: $215.2 Million Dollars*

Reconciling the differences in the base numbers for calculation of the actual implementation cost is essential to produce a reliable result, i.e. Contract manufacturers (Maquiladoras) which manufacturing output is 100% under the IMMEX (Export Only) Program, are not current holders of a BPM issued by COFEPRIS, condition that should remain as such, as per the rationale provided earlier in this document.

*Estimated exchange rate: 1 USD:20 MXP.
** Implementation cost accounts for 93% of the average annual sector investment.

Ask:
Update the calculation of the Implementation Costs reconciling and accessing actual figures, plus computing associated compliance costs such as those related to the inspection itself, as well as for document translations, among many others, for facilities which are already holders of certifications issued via ISO13485 or MDSAP.

Alignment with International Standards and References & Compliance with International Obligations

NOM 241-SSA2-2021 explicitly acknowledges to be only partially aligned with ISO13485. Both within the RIA (V) and within the COFEPRIS responses to industry comments during the public consultations. Solid scientific support is not provided to justify the misalignments.

Original Text	IACRC Observation
6.7 Facilities that have certification under the current ISO13485 standard issued by bodies authorized by national accreditation bodies or internationally recognized ones, for the conformity assessment it will be recognized as equivalent to the requirements established in section 6 of this technical regulation.	As stated in the published NOM-241, under the subsections referred to in the left column, there is no full compliance with ISO 13485, furthermore, there is no evidence throughout the **Impact Analysis and Cost/Benefit Evaluation (V.a)** that solid science evidence exists, nor is provided, to support it.

6.7.1 Inspections will be carried out under a reduced approach, except for subsection 6 and its subsections of this technical regulation. **20.** Compliance with international standards, and Mexican technical regulations. This technical regulation partially complies with the following standards: **20.1** ISO13485:2016 Medical Devices-Quality management systems-Requirements for regulatory purposes. **20.2** ISO 14969:2004 Medical Devices-Quality Management Systems-Guidance on the application of 13485:2003 **Comments Provided and replies to the Project - Part I (VI.a)** **Page 1** Number: B000183418 Date: 26/09/2018 Petitioner: AMID Comments 3.8 Risk Analysis. Systematic instrument integrated by a set of techniques used in the identification, collection, register, analysis and systematic evaluation of the probability of occurrence of damage during its development, manufacturing, including the life cycle of the medical device, which may affect the systems' functionality, equipment, processes or quality of inputs and finished product, aimed at establishing preventive positions or actions, in order to control and/or minimize the consequences to users, health personnel, environment, production and/or facilities. ISO 14971 is the internationally accepted standard for risk analysis where the definition is stated in numeral 2.17. **Comment not accepted.**	Even further the replies to comments hereby reproduced, are only a few examples of replies to comments which are vague as to refer the applicable International Standard. They do not reflect compliance with the aforementioned obligations before WTO/TBT, OECD and USMCA to pursue full alignment with applicable international standards, unless justified by solid science. Furthermore, beyond the proposed amendments and additions included in the project, provisions already included in the current NOM-241 which are not aligned with International Standards, despite not being raised as a trade concern yet still imply lack of compliance with WTO/TBT, OECD and USMCA obligations. Ask: The described elements reconfirm the need of a whole new review process to ensure compliance with the aforementioned obligations, including proper adherence to GRPs and Transparency principles.

This numeral is brought in line with the rest of the GMP standards, non-existent confusion or inconvenience with the given definition.	
Page 11 Number: B000184335 Date: 14/11/2018 Petitioner: CANIFARMA 12.2.1.5.2 Inputs ~~must~~ may be ~~analyzed~~ inspected or evaluated by the Quality function of the medical device manufacturing site, if their analysis has not already been performed prior to its receipt at the manufacturing site. This change is proposed due to the diversity of inputs based on risk management, supplier control processes, and within the framework of the technical agreement with suppliers. **Comment not accepted.** This numeral is brought in line with the rest of the GMP standards, as well as with international standards, the numeral already takes into consideration that analysis does not apply in all cases, as it states "or evaluated", they are currently complying that evaluation.	
Page 20 Number: B000184335 Date: 14/11/2018 Petitioner: CANIFARMA 15.3 A~~n annual~~ Stabilities program should be implemented based on statistical criteria that considers the Number of Batches manufactured to guarantee the shelf life of the Medical Device, which should be endorsed or authorized by the sanitary responsible. The elimination is proposed as the determination of the frequency can be based on risk management terms.	

Comment not accepted
The requirement, per GMP, is at least on an annual basis, which is in line with other GMP standards.

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Number: B000184335
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Petitioner: CANIFARMA

15.6 When a batch of products is reprocessed or reworked, it must be subjected to Stability Studies according to risk management.

The risk management assessment determines whether stability studies are required.

Comment not accepted
This requirement is approved with other GMP standards and only applies to MDs that have a stability study.

Comments Provided and replies to the Project - Part II (VI.b)

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Petitioner	Reply
AMID Subsequent to item **11.11**, the petitioner requests the addition of the wording: "This step can be carried out with a prospective or	**Comment not accepted.** This numeral is brought in line with the rest of the GMP standards as well as with international standards.

concurrent release approach." Proposes "~~This step can be carried out with a prospective or concurrent reléase approach~~." Globally, processes are validated and equipment and systems are qualified and are part of the validation of the process. Furthermore, the validation is referred to, beginning at numeral 11.11		

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CANIFARMA, PiSA. Vizcarra, 3M, Church & Dwight In item **12.2.1.5.2,** which states: "**12.2.1.5.2** Inputs must be analyzed or evaluated by the Quality Function of the Medical Device Manufacturing site." Proposes "Inputs ~~must~~ may be analyzed or evaluated by the Quality Function of the Medical Device Manufacturing site,	**Comment not accepted.** This numeral is brought in line with the rest of the GMP standards as well as with international standards. The numeral already takes into consideration that there is no analysis required for all cases, since it indicates "or evaluated", they are currently complying with that evaluation.	

if their analysis had not already been performed prior to the receipt at the manufacturing site.” The analysis of manufacturing inputs used in facilities located at the border implies their previous analysis by the issuer, which is why it is not necessary to perform a new analysis in our country.	

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CANIFARMA, PiSA. Vizcarra, BD, 3M, Church & Dwight In item **12.3.17.2**, which states: “**12.3.17.2** For sterile Medical Devices shall be kept for at least one year after the expiration date indicated on the final packaging, stored under the conditions indicated on the Label and in sufficient quantity for two complete analysis." Proposes “For sterile Medical Devices shall be kept for at least	**Comment not accepted.** This numeral is brought in line with the rest of the GMP standards as well as with international standards.

one year after the expiration date indicated on the final packaging, stored under the conditions indicated on the Label and in sufficient quantity for two complete analysis. Only for Medical Devices which do not pose an associated risk to its handling and storage, for example, pollution, after the expiration date indicated on the label. Storage time must be defined based on risk level." Storage time should be defined based on the associated risk since in cases where the medical device by its nature may represent a risk after the expiration date it is not possible to keep it for more than one year. Such is the case of culture media.		

Reply letter from COFEPRIS to AMID, dated September 11, 2020 (VIII.b))

Page 1, 2nd. Paragraph

…

it should be noted that this update to **NOM-241-SSA1 -2012**, which establishes more than 90% of the regulatory requirements, which continue to be included in the **Official Mexican Technical Regulation NOM-241-SSA1-2021**, Good Manufacturing Practices for Medical Devices; and it is not a completely new TECHNICAL REGULATION that still requires the implementation of new requirements.	
Utilization of terms aligned with International Standards and References is required as per Mexico obligations on GRP under various treaties as WTO/TBT and USMCA.	
Terminology	
Original Text	**IACRC Observation**
General comment: throughout NOM 241-SSA1-2021 the term “efficacy” (“eficacia” in Spanish) is indistinctly used as an attribute for all medical devices.	It is necessary to revise the correct utilization of the term “efficacy” as it applies only to substances and combined medical devices (combination products) and incorporate the term “performance” to all other medical devices by which NOM-241 would be in compliance with the terminology included in the related international standards and references: IMDRF and ISO. International References and Standards, apply the term “performance” to Medical Devices (i.e. IMDRF’s Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices and ISO 13485). The translation to Spanish of the term “performance” applied for medical devices as per official translation of ISO 13485, as well as in various GHTF’s documents performed by PAHO, is “desempeño”: GHTF/SG1/N40:2006: Spanish - Principios de Evaluación de la Conformidad de Dispositivos Médicos English - Principles of Conformity Assessment for Medical Devices

	GHTF/SG1/N15:2006: Spanish - Principios para la Clasificación de los Dispositivos Médicos English - Principles of Medical Devices Classification SG5/N2R8-2007: Spanish - Evaluación Clínica English - Clinical Evaluation Translations of relevant IMDRF documents to Spanish by PAHO, displaying the word "desempeño" are going to be published in the near future. Based on the above-mentioned references and to comply with international obligations, it is necessary to replace the term "eficacia" by the term "desempeño", except for when used to refer to the substances contained in combined medical devices (combination products).