



Medical Device Regulatory Requirements for Mexico

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Introduction to the Mexican Regulatory System

The Secretariat of Commerce and Industrial Promotion (SECOFI) is the organization that manages and coordinates standardization activities in Mexico. The Mexican regulatory system consists of mandatory standards known as NOMs and voluntary standards known as NMXs. NOMs address the protection of consumer health and safety, commercial information, and the protection of ecology and the environment. NOMs are issued by Mexican Government Secretariats according to the jurisdiction of each one. Any person, either national or foreign, may propose the creation, revision, amendment or cancellation of a Mexican Official Standard. The General Directorate of Standards (DGN) is the administrative unit of SECOFI in charge of receiving these requests and initiating the process. The Mexican Secretariat of Commerce publishes the Program of Standardization listing the mandatory and voluntary Mexican standards that are to be created or revised each year. Nine private sector organizations are accredited to develop standards and/or certify products and/or services in specific fields. Some of these organizations have their own laboratories and perform the entire certification process, or they may work in conjunction with other entities and subcontract third-party laboratories. Other government agencies have their own laboratories in which products are tested to certify compliance with the appropriate NOMs.

Test laboratories are commercial companies responsible for certifying that products meet standards. Laboratory accreditation is currently being turned over to the private sector,

but remains under the supervision of the Government. The Government will authorize one private sector body to grant laboratory accreditation to both calibration and test laboratories; however, if a laboratory accreditation is for the certification of products to a mandatory standard, then the Secretariat responsible for the implementation of the mandatory standard must approve the accreditation. Authorizations as Test Laboratories are valid for two years and can be renewed upon written request. As of January 1998, conformity assessment bodies located in the United States and Canada may apply for accreditation to test products to Mexican standards.

Medical Device NOM Certification Requirements

Mexico currently has few standards for medical devices, but agencies are preparing more standards to be issued in the near future. As of November 1997, Official Standards for medical equipment are:

- NOM-001-SCFI-1993 for ultraviolet & infrared ray apparatus

published in the Official Gazette, October 13, 1993.

- NOM-003-SCFI-1993 for electric massage apparatus, published in

the Official Gazette, October 13, 1993.

- NOM-157-SSA1-1996, for protection and security measures for the

use of diagnostic X-ray equipment, published in the Official

Gazette, September 29, 1997.

- NOM-158-SSA1-1996, for technical specifications for X-ray

medical equipment, published in the Official Gazette, October 20,

1997.

Registration with the Secretariat of Health

To be imported into Mexico, all medical or health care products that touch the human body must be registered with the Mexican Secretariat of Health. This registration is required for wound care materials, surgical devices or material, hygienic products, dentistry products, family planning products, implantable prosthesis, diagnostic agents, reagents, medical equipment and instruments, external prosthesis, orthosis and functional aids.

To start the registration process, it is necessary to fill out an application (original and one copy) and present the following documents pertaining to the product, to the manufacturer, and to the manufacturer's representative/distributor in Mexico:

1. Representative/distributor's name, address, and telephone number.
2. Name and address of the institution/company that will prepare or store the product.
3. Name, address (in the country of origin), telephone and fax number of the product manufacturer.
4. Name and signature of the responsible person in Mexico.
5. Copy of one of the following documents pertaining to the Mexican distributor or representative: Operating authorization or certification document or current sanitary authorization or certification of a visit by the Secretariat of Health for verification and

authorization.

6. Copy of the authorization of the responsible person from the Mexican distributor/representative's office. (By law, all stores or establishments related to chemical and medical products must have a chemical engineer or physician responsible for their activities).

7. Technical information pertaining the product to demonstrate that it complies with the characteristics and efficiency as authorized in the country of origin. This information must be in Spanish and include:

7.1. Use or purpose.

7.2. Quantitative or percentage formula.

7.3. Technical specifications of the finished product, procedures to evaluate it, and evaluation's results report.

7.4. Sterilization technique used for the product and analytical certificate including the results of the test.

7.5. Clinical information pertaining to the product's safety and effectiveness (if applicable).

7.6. Different product's presentations and/or description of the different packaging systems used (all of them) with test results showing the product keeps sterility in its package (if applicable).

8. Original and copy of the proposed label, **in Spanish**, according to the correspondent standard, and containing the following data:

8.1. Commercial name of the product

8.2. Product's use and warning legends (if applicable).

8.3. Catalog, lot or serial number (if applicable).

8.4. Sanitary registration number from the Mexican Secretariat of Health.

8.5. Name or business name and address of the manufacturer.

8.6. Name or business name and address of the distributor.

9. Original and copy of the product's manual **in Spanish**, and the original from the country of origin. Attach catalogs or manuals with the original product presentation.

10. Description of the product's manufacturing process.

11. Description of product's structure, raw materials, parts and function.

12. Document proving application of good manufacturing practices.

13. Laboratory test verifying product's specifications with the signature of the sanitary responsible person in a domestic or foreign institution, including:

13.1. Analytical certificate of the physical-chemical, micro-biological, and biological tests used for the finished product.

13.2. Stability proof (if applicable).

14. Bibliographic references.

15. Domestic or international standard to which the product complies with.

16. Country of origin free sale sanitary documents of the product (FDA authorization in the U.S.)

17. A copy of the Agent/Distributor Agreement, notarized by a Mexican Consular official (if in English, translated into Spanish by an authorized translator). If the importer is a subsidiary of a foreign company, an agent/distributor agreement is only required when the product is not manufactured by the parent company laboratory or manufacturing plant.

18. Certificate for Good Manufacturing Practices issued by the country of origin authority (FDA for the U.S.).

19. Original analysis certificate from the manufacturer, in company's stationary, and signed by the chemical or sanitary responsible.

20. Original and 2 copies of the registration fee payment receipt.

Requestors must get a response to the registration application under the following terms:

- 15 working days, when presenting a positive technical report issued by a third party institution authorized by the Secretariat of Health specifying that the product complies with all the required effectiveness, technical and security conditions.

- 30 working days, for "Class I" products: those that are very well known in the medical practice, with proved effectiveness and safety, and that are not introduced to the human body.

- 35 working days, for "Class II" products: those that are well known in the medical practice, but have a variation in the raw materials of which they are made, or different component concentration, and that are introduced and kept in the human body for less than 30 days.

- 60 working days, for "Class III" products: those new products, products made with new raw materials, or products recently approved in the medical practice, or products that are introduced and kept in the human body for more than 30 days.

If no response is obtained in the specified terms, requestors must understand that the registration is denied, excepting for "Class I" products, where requestors not receiving an answer must understand that the registration is approved.

Registration fees for imported health care and medical products vary from US \$300 to US \$400 per each product. Current exchange rate is 9.30 pesos per US dollar.

IN ALL CASES THE REGISTRATION, WHEN APPROVED, BELONGS TO THE MANUFACTURER, WHO ALWAYS HAS THE OPTION OF CHANGING DISTRIBUTOR/REPRESENTATIVE IN MEXICO. MANUFACTURERS ARE OBLIGATED TO INFORM THE SECRETARIAT OF HEALTH ON ANY NEW APPOINTMENT FOR DISTRIBUTOR(S) IN MEXICO FOR IMPORTED REGISTERED PRODUCTS.

Labeling for Imports

On November 18, 1998, the Mexican Secretariat of Health published the official standard for labeling of medical devices: NOM-137-SSA1-1995. This standard specifies the information that must be contained in labels of domestic and foreign manufactured medical devices offered to

Mexican consumers.

This standard applies to health care materials, diagnostic agents, contrast mediums, dental materials, prosthesis, orthoses, products for hygiene, laboratory kits, laboratory tests, medical instruments, apparatus, equipment, devices and accessories.

According to this standard, labels must include the following information in Spanish:

1. Product name (commercial name of the product). This is the only information that can be in a different language, when necessary.
2. Trademark or logo, name or business name and address of the manufacturer and distributor registered with the Mexican Secretariat of Health.
3. Name and address of the importer.
4. The Country of Origin.
5. The Sanitary Registration number.
6. Expiration date, if the product has a shelf life (sterile quality) of less than five years.
7. Lot or Serial number.
8. Contents, specifying the number of units, volume or weight.
9. Warnings and precautions in the case of toxic products.
10. Use, handling, and care instructions for the products, when they are not obvious. If required, instructions must be attached. In these cases the label must specify: "See attached instructions".
11. For sterile products, state that "sterility is not guaranteed if the original package is broken".
12. Legend specifying that the product is free of toxins or pyrogenes, when applicable.
13. Specification if the product is disposable, if applicable.
14. Manufacturing date. This information may be included where the lot is specified.
15. Nominal dimensions, if applicable.
16. Storage temperature requirements specified such as: ---K(c) to ---K(C), or similar legends.
17. Specific instructions for the disposal of the container, if necessary.
18. Side effects caused by product, if applicable.
19. Ingredients and active elements, if applicable.
20. When a label can not be adhered because of specific reasons or size, the Secretariat of Health will decide what to do.

All information must conform to the product specifications previously approved (registration process) by the Secretariat of Health for each case.

The label may be attached after the product is imported but before sold to consumers. The

attached label should not cover the original label.

For bulk products, the information is only required on the bulk container.

The labeling requirements *do not* apply to:

1. Highly specialized medical equipment.
2. Medical equipment used in commercial, industrial or by service providers and not sold to consumers.
3. Medical equipment imported by persons or institutions for their own use.
4. Medical equipment imported by educational or scientific institutions.
5. Samples of health care products or diagnostic agents imported to be used exclusively for the certification process to comply with Mexican standards.
6. Other medical equipment, when a label can not be adhered because of specific reasons or size. In this situation, the Secretariat of Health will decide the course of action.
7. Other medical equipment, health care products or diagnostic agents determined by the Secretariat of Health.

This information must be on products for retail sale. Listing this information on the container in which a product is packed for shipment will not satisfy the labeling requirement. The above-mentioned requirements also comply with the labeling standard NOM-050-SCFI.

Packaging

According to the emergency Mexican standard NOM-EM-004-REGNAT-1996 issued on July 5, 1996, because of fitosanitary reasons, all products that are imported inside of a wood box or container or having wood packaging, may be inspected at the point of entry to Mexico.

NOM Certification Requirements

The Secretariat of Health is very active in preparing and issuing standards for medical products.

Updated information on NOMs and other sanitary processes can be found in the web page of the Mexican Secretariat of Health: www.ssa.gob.mx

Import Documentation

The basic Mexican import document is the "pedimiento de importacion". This document must be accompanied by a commercial invoice (in Spanish), a bill of lading, and documents

demonstrating guarantee of payment of additional duties for undervalued goods if applicable, and documents demonstrating compliance with Mexican product safety and performance regulations if applicable. Although it is no longer required that a Mexican customs broker prepare and submit the import documentation, use of one is recommended if an importer has not had significant experience in preparing Mexico's import documentation.

NAFTA Certificate of Origin

Under the North American Free Trade Agreement certain products, including most medical devices, that "originate" in Canada, Mexico, or the United States enjoy low or zero tariff rates when traded between these three countries. In order to receive this preferential treatment products that qualify must have a NAFTA certificate of origin. For information on Rules of Origin and the Certificate of Origin see the Trade Information Center website at <http://tradeinfo.doc.gov>. Click on "country/regional information" followed by "NAFTA (Canada/Mexico); Overview of NAFTA Certificate of Origin/Rules of Origin."

Contacts

Embassy of the United States of America

Commercial Service

Paseo de la Reforma No. 305

Col. Cuauhtemoc

06500 Mexico, D.F.

Tel: (011-52-5) 211-0042

Fax: (011-52-5) 207-8938

Contact: Ivan Rios, Standards Attache (ext. 4718)

The Commercial Service helps American companies and business people export their products to Mexico.

American Chamber of Commerce of Mexico,A.C.

Lucerna No. 78

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Fax: (011-525) 703-2911, 703-3908

Contact: Victor Manuel Moncada, International Trade Director

Non-profit organization which helps American companies

do business in Mexico.

Secretariat of Health

General Coordination for Construction,

Conservation and Equipment

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Tel: (011-52-5) 709-0356

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Contact: Lic. Simon Ruiz Rodriguez, Equipment Director

This unit is charge of selecting equipment for the high speciality health care units of the Secretariat of Health and also advises state authorities on the equipment they should buy for the state health care units.

Secretariat of Health

General Directorate for Health Products Control

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Col. Chapultepec Morales

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Contact: Lic. Jorge Estrada Poumian, Imports Deputy Director

This agency is in charge of controlling and registering the importation of all products related to health care.

Secretariat of Health

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This unit is in charge of preparing standards to regulate the manufacturing, trading and use of health care products.

Secretariat of Health

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Contact: Dra. Marisela Verdejo, Director

This agency is in charge of controlling and registering X-ray equipment, domestic and imported.

General Directorate of Standards (DGN)

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Contact: Lic. Carmen Quintanilla Madero, Director General

Lic. Ricardo Gonzalez Aguilar, Standards Officer

Ing. Carlos Martinez Nava, Certification Director

This agency authorizes the operation of certification and calibration laboratories and verification units.

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Contact: Dr. Rodolfo A. De Mucha Macias, Chief of the Unit

This area is in charge of testing and verifying the technical specifications of all health care products purchased by the IMSS.

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