

Life Sciences Practice Group Newsletter



Quality Infrastructure Law

On July 1, 2020, the "Quality Infrastructure Law" was published in the Federal Official Gazette, replacing the Federal Law of Metrology and Standardization.

The purpose of this Law is to update the regulatory framework that corresponded to the Federal Law of Metrology and Standardization. Within its content, the following stands out:

National Quality Infrastructure System, consisting of:

- a. National Quality Infrastructure Commission- in charge of directing and coordinating activities related to standardization, conformity assessment and metrology;
- b. Standardization Authorities- in charge of the creation and issuance of Mexican Official Standards (NOMs);
- c. National Consultative Committees on Standardization- in charge of promoting and publicizing of the NOMs, and their compliance.

Mexican Official Standards

- a. National Standardization Program - work program focused on planning, conducting, coordinating

and information on standardization and metrology activities at the national level. This will be reviewed, approved and updated annually and published in the Federal Official Gazette during the first two months of each year. Likewise, standardizing authorities are forbidden to issue, modify or cancel NOMs on subjects not included in the Program, except for emergency NOMS.

NOMs must be drafted and structured in accordance with the provisions of this Law and its Regulations and must be reviewed at least every 5 years after its publication in the Federal Official Gazette or after its last amendment.

- b. The Procedure for the elaboration, issuance, modification and cancellation of the Mexican Official Standards is established.
- c. An Integral Technological Platform for Quality Infrastructure is established to serve as the main means of publicity and consultation of NOMs and Standards.

System for Conformity Assessment

- a. Integrated by Accreditation Entities and Conformity Assessment Bodies, whose list

will be published in the Integral Technological Platform of Quality Infrastructure.

- b. The requirements and procedures to act as an Accreditation Entity are established.
- c. The Conformity Assessment Procedure corresponding to each preliminary project, project and NOM must comply with the corresponding procedure.

Quality and Innovation System

As part of the National Infrastructure System, it is in charge of the development and application of the Standards (which replaces the Mexican Standards).

- a. The procedures for the development of the Standards are established, as well as the procedures for clarifications, modifications and cancellations of the same.
- b. These Standards will be reviewed every five years after their publication in the Integral Quality Infrastructure Technology Platform.
- c. The requirements and procedure to be followed by legal entities wishing to be considered as subjects entitled to standardize and those wishing to register as National Standardization Organizations are established.

International Regime for Standardization and Conformity Assessment

Standardizing Authorities should promote harmonization with international standards and best practices and international conformity assessment systems are established.

Metrology and Scientific Metrology System

It is established as the responsible entity for ensuring the uniformity and reliability of the measurements made in the country, and ensure the comparability of these with other countries.

New provisions on metrology add new figures, such as legal metrology, industrial or applied metrology, designated metrology institutes, among others.

The Mexican Official Standards and the Standards should attempt to conform to international parameters.

Sanctions

Compared to the Federal Law on Metrology and Standardization, there is a significant increase in the concepts and amounts to be paid as fines arising from acts of verification and monitoring of that law.

Legal Remedies

In addition to administrative appeals and revocation, a Complaint Appeal is established. The Federal Law on Administrative Procedure and the Federal Law on Litigious Administrative Proceedings are applicable for this purpose.

This Law will enter into force on August 30, 2020, and will void the Federal Law of Metrology and Standardization, and other provisions that contradicts those provided in this Law.

The corresponding Regulations must be issued within a period not exceeding 12 months as of the entry into force of this Law, and the National Commission on Quality Infrastructure must issue the guidelines on regulatory improvement within 180 calendar days as of the entry into force of the Regulations.

The Proposals, Preliminary Drafts and Draft Mexican Official Standards and Standards that are pending at the date of entry into force of this Decree that have not been published must comply with the provisions of the Federal Law of Metrology and Standardization, its Regulations and other secondary provisions in force at the time of their preparation and until their conclusion.

Our team of experts can assist you in the analysis of this Law, opinion or any other question derived from it.

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