AdvaMed, [AMID](https://nam12.safelinks.protection.outlook.com/?url=http%3A%2F%2Famid.org.mx%2F&data=02%7C01%7CSBipes%40AdvaMed.org%7Cb1b71c544e8a44148f5408d7e6f1cf6e%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637231798582517466&sdata=0sr71uXFTdg3Ltx5WugUnSGDB10ln6xZF%2BpGM71TtKk%3D&reserved=0), [CANIFARMA](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.canifarma.org.mx%2F&data=02%7C01%7CSBipes%40AdvaMed.org%7Cb1b71c544e8a44148f5408d7e6f1cf6e%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637231798582527459&sdata=SA%2BgwYRT%2FlXpnnbuq2acah6dLnCmVrmcehHXybwNEOg%3D&reserved=0), [Baja Medical Device Cluster](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.industriamedica.org%2FLobby%2FBajaMedical.aspx&data=02%7C01%7CSBipes%40AdvaMed.org%7Cb1b71c544e8a44148f5408d7e6f1cf6e%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637231798582537455&sdata=dbGq7IvWVrCWGFJUJLgjpUMZcGdgxYuvhvlR%2BwZ5Cfc%3D&reserved=0) (Tijuana, BC), [MCA Foundation](https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmcamericas.org%2F&data=02%7C01%7CSBipes%40AdvaMed.org%7Cb1b71c544e8a44148f5408d7e6f1cf6e%7C97eb9e6f7f7349c9a55d57aba9d88792%7C0%7C0%7C637231798582537455&sdata=lziJv876xkCskfFnbTi9ktCjk%2BCCTD%2BuBzahf3lkT%2Fk%3D&reserved=0) (El Paso-Juárez, Chih.)

**Guidance for Medical Technology Companies**

**(Updated May 22, 2020)**

**Legal Context**

Per the [31 March Directive](https://www.dof.gob.mx/nota_detalle.php?codigo=5590914&fecha=31/03/2020&print=true) - [(unofficial English translation)](http://documents.nam.org/IEA/Decree%20extraordinary%20actions%20COVID19.pdf?_zs=wBNqd1&_zl=9Uke6):

1. MedTech is an essential sector (the directive does not say for COVID-19 only);
2. COVID-19 safety protocols must be implemented:
	1. no detailed specifications have been published
	2. MedTech facilities without these protocols will be ordered to be closed despite (1)
3. Official federal positions to be published via the Federal Official Daily Gazette
4. Federal positions have primacy over state-level requirements.

Per the [21 April Directive](https://www.dof.gob.mx/nota_detalle.php?codigo=5592067&fecha=21/04/2020):

1. States may implement their own “Federal+” provisions
2. Official positions to be published via the respective state DOs.

**Inspections**

Criteria for inspections has been made available by the Labor and Social Prevision Secretariat in a pdf format to various private entities but has not been published in their website:

[Criterios Aplicables para el Desarrollo de Inspecciones Extraordinarias Derivadas de la Declaratoria de Emergencia Sanitaria por Causa de Fuerza Mayor, a la Epidemia de Enfermedad Generada por el Virus SARS-CoV2 (COVID-19)](https://www.ccmexico.com.mx/public_html/documentos/juridico/STPS_Criterios_Inspecciones_Extraordinarias.pdf), (Applicable Criteria for the implementation of Extraordinay Inspections under “Force Majeur” required by the Declaration of Sanitary Emergency produced by the Illness caused by the SARS-CoV2 (COVID-19)) - Courtesy of BIO El Paso – Juárez (Attached document, which is also available at the Mexico City Chamber of Commerce, Services and Tourism website – hereby linked) – Unofficial English translation, attached Document No. 1.

Notes:

1. Missing to include Med Tech Sector, after being classified as essential activities at [31 March Directive](https://www.dof.gob.mx/nota_detalle.php?codigo=5590914&fecha=31/03/2020&print=true) - [(unofficial English translation)](http://documents.nam.org/IEA/Decree%20extraordinary%20actions%20COVID19.pdf?_zs=wBNqd1&_zl=9Uke6) in Article 1, bullet II, a)

*II. They will only continue functioning the following activities, considered as essential:*

1. *The ones that are directly necessary to assist the sanitary emergency, such as the labor activities of the medical, para-medical, administrative and support of the National Health System. Also, the ones that take part on the supply, service and providing, among which pharmaceutical, both for production and distribution (pharmacies); manufacturing of supplies, medical equipment and technologies for health care are to be highlighted;*
2. Inspections would be performed at facilities suspect or accused to be operating in violation of applicable work regulations that may put workers at risk for COVID-19.
3. Workers are not to be interviewed.

In practice, inspections will be conducted in the states at all manufacturing sites to determine if:

(a) they are essential per (1) above;

(b) they have implemented (2) above.

Inspections will be conducted by: (a) state-level authorities, (b) local representatives of the federal secretariat of labor and social prevention, (c) local representatives of the federal health sanitary agency (COFEPRIS).

The legal basis for these inspections is:

1. For the state-level inspectors, if available, are consolidated and continuously updated by: National Commission for Regulatory Improvement (CONAMER) at [Respuestas Regulatorias a la epidemia COVID-19](https://conamer.gob.mx/respuestas-regulatorias-covid-19/) (Regulatory Response to COVID-19 Epidemic)
2. For Secretariat of Labor and Social Foresight:

[Ley Federal del Trabajo](http://www.diputados.gob.mx/LeyesBiblio/pdf/125_020719.pdf) (Federal Labor Law) – Articles 527, 540 (paragraphs I, III and V, 541, 542 y 543;

[Reglamento General de Inspección del Trabajo y Aplicación de Sanciones](http://www.diputados.gob.mx/LeyesBiblio/regla/n395.pdf) (Regulation for General Inspection and Sanctions Application (RGIAS)) - Articles 18 and 19;

[Reglamento Interior de la Secretaría del Trabajo y Previsión Social](https://dof.gob.mx/nota_detalle.php?codigo=5570275&fecha=23/08/2019) (Secretariat of Labor and Social Foresight Internal Regulation) – Article 18, paragraphs I and XXXV.

1. For COFEPRIS:

[Ley General de Salud](http://www.salud.gob.mx/unidades/cdi/legis/lgs/LEY_GENERAL_DE_SALUD.pdf) (General Health Law), Article 17 bis, paragraph XI, XII and XIII

[Reglamento de la COFEPRIS](http://www.salud.gob.mx/unidades/cdi/nom/compi/r130404.html) (COFEPRIS Regulation) Article 12, paragraph VI and XIII, Article 13, paragraph XV, Article 15, paragraphs VII and VIII

Note:

Scope of inspection should be limited to:

* Confirmation that activities performed at the facility are in line with the company declaration before the Secretary of Finance and are listed in the [21 April Directive](https://www.dof.gob.mx/nota_detalle.php?codigo=5592067&fecha=21/04/2020);
* Confirmation that activities are performed in line with the Health and Safety Protocols established to minimize the COVID-19 infection risk;
* Inspections are not to be video recorded, nor published by any non-official media.

Facilities can only have MedTech production operating. Authorities have authorization to order non-MedTech production to close down. Authorities do not have clear authorization to order MedTech production to close down if non-MedTech production is identified in the same facilities. That said, operations that house both MedTech and non-MedTech production in the same facility run the risk of having the whole facility ordered shut down (legally errant or not).

If a company deems that it is in compliance with the federal requirements, the legal basis for these inspections is legally questionable.

As the specific criteria for the inspections have not been published at official websites, guidelines have been issued by the Secretariat of Labor and Social Foresight, nevertheless, the inspections are highly subjective (and raise serious industry concern regarding margin for unethical conduct).

It generally takes 3-5 business days for the inspectors to re-inspect a facility.

The process to request a reinspection following identification of non-conformities or shut down orders has not been published yet not at the federal, nor state levels.

Contact details for officials in Baja California are as follows:

Ministry or Labor at Baja California´s State:

Sergio Moctezuma Martínez López

Minister of Labor

Email: smmartinez@baja.gob.mx

Phone number: (686)9045506, ext. 5506

Health Risk Protection office:

David Gutierrez Inzunza

Head of office

Email: not available

Phone number: (686)5570158

Health Risk Protection office:

Rocio Reyna

Executive assistant

Email: rreyna@isesaludbc.com

Phone number: (686)5570158

It is important to ask the inspector´s full contact information to keep it in the facility records.

**Recommendations for Safety Measures (Update)**

[Guía de Acción para los Centros de Trabajo de Sectores Económicos Esenciales ante COVID-19 24Apr20](https://www.gob.mx/stps/documentos/guia-de-accion-para-los-centros-de-trabajo-ante-el-covid-19)

(Guidelines for actions at the Work Centers under the Essential Activities Economic Sectors to cope COVID-19)

Protocolo de Protección Personal del Sector IMMEX – Consejo Nacional de la Industria Maquiladora y Manufacturera de Exportación (Protocol for Personal Protection of the IMMEX Sector- National Council of the Exports Maquila and Manufacturing Industry ) – Courtesy of INDEX (Attached Document No. 2)

**Recommendations for Inspection Documentation**

Essential Activities and Inspections Preparedness – Mejía Guizar y Kargl (Attached document)

**Recommendations for Company Conduct During Inspections**

* Inspection Orders should comply with the criteria established at the [Reglamento General de Inspección del Trabajo y Aplicación de Sanciones](http://www.diputados.gob.mx/LeyesBiblio/regla/n395.pdf) (General Inspection and Sanctions Application Regulation (RGIAS)), Article 28, paragraph I;
* Inspection should be conducted according to the [NOM-030-STPS-2009, Servicios preventivos de seguridad y salud en el trabajo - Funciones y actividades](http://asinom.stps.gob.mx:8145/upload/nom/32.pdf) (Preventive services for safety and health at work);
* Essential Activities and Inspections Preparedness – Mejía Guizar y Kargl (Attached Document No. 3 - English version, Document No. 4 - Spanish version).

**Other Resources**

* Caso de Auditoría por Secretaría del Trabajo y Previsión Social en una planta de Dispositivos Médicos en la Ciudad de Chihuahua, Chihuahua (Case Study of an Audit conducted by Labor and Social Oversight to a Medical Devices Manufacturing Facility in Chihuahua, Chihuahua)– Courtesy of BIO El Paso-Juárez (Attached Document No. 5 – Spanish version)
* Bio Mejía Guizar y Kargl, Abogados (Attached Document No. 6 – English versión, Document No. 7 – Spanish version)
* Webinars Q&A Summary (Attached Document No. 8 – Spanish version)

Recent Publications related to:

 Process to restart activities, published at the Official Daily Gazette:

May 14, 2020:

[ACUERDO por el que se establece una estrategia para la reapertura de las actividades sociales, educativas y económicas, así como un sistema de semáforo por regiones para evaluar semanalmente el riesgo epidemiológico relacionado con la reapertura de actividades en cada entidad federativa, así como se establecen acciones extraordinarias.](https://conamer.gob.mx/respuestas-regulatorias-covid-19/GobiernoFederal/Index)

Agreement that establishes a strategy to re-open social, educational and economic activities, as well as a regional “traffic-light” system for a weekly evaluation of the epidemiological risk related to the re-opening of activities at every federal entity, as well as to establish extraordinary measures.

May 15, 2020:

[ACUERDO por el que se modifica el diverso por el que se establece una estrategia para la reapertura de las actividades sociales, educativas y económicas, así como un sistema de semáforo por regiones para evaluar semanalmente el riesgo epidemiológico relacionado con la reapertura de actividades en cada entidad federativa, así como se establecen acciones extraordinarias, publicado el 14 de mayo de 2020.](https://conamer.gob.mx/respuestas-regulatorias-covid-19/GobiernoFederal/Index)

May 17,2020

Guidelines for Sanitary Safety in the workplace, published by the Economy Secretariat:

[LINEAMIENTOS TÉCNICOS DE SEGURIDAD SANITARIA EN EL ENTORNO LABORAL](https://www.gob.mx/cms/uploads/attachment/file/552549/Lineamientos_de_Seguridad_Sanitaria._Versio_n_17_mayo_final.pdf)

Among the description of the system, this document establishes in Chapter 4 the safety measures that are to be established at the work place. i.e.:

B.1 “… a distance of a minimum of 1.5m between persons that are not using personal protection equipment (PPE) and the reduction in frequency and face to face interactions among workers, including the areas adequacy to reduce human density intramural and extramural when at the maximum,, high and medium levels, for which the following should be established (at a minimum but not limited to): …”