

SEGUNDA SECCION
PODER EJECUTIVO
SECRETARIA DE ECONOMIA

DECLARATORIA de vigencia de la Norma Mexicana NMX-EC-15189-IMNC-2015.

Al margen un sello con el Escudo Nacional, que dice: Estados Unidos Mexicanos.- Secretaría de Economía.- Subsecretaría de Competitividad y Normatividad.- Dirección General de Normas.

DECLARATORIA DE VIGENCIA DE LA NORMA MEXICANA NMX-EC-15189-IMNC-2015, LABORATORIOS CLÍNICOS-REQUISITOS DE LA CALIDAD Y COMPETENCIA (CANCELA A LA NMX-EC-15189-IMNC-2008).

La Secretaría de Economía, por conducto de la Dirección General de Normas, con fundamento en los artículos 34 fracciones II, XIII, y XXXIII de la Ley Orgánica de la Administración Pública Federal; 3 fracción X, 51-A, 54 y 66 fracción V de la Ley Federal sobre Metrología y Normalización; 45 y 46 del Reglamento de la Ley Federal sobre Metrología y Normalización, y 21 fracción I, IX y XXI del Reglamento Interior de esta Secretaría y habiéndose satisfecho el procedimiento previsto por la Ley de la materia para estos efectos, expide la declaratoria de vigencia de la norma mexicana que se enlista a continuación, misma que han sido elaborada, aprobada y publicada como Proyecto de Norma Mexicana bajo la responsabilidad del Organismo Nacional de Normalización denominado Instituto Mexicano de Normalización y Certificación, A.C. (IMNC), lo que se hace del conocimiento de los productores, distribuidores, consumidores y del público en general. El texto completo de la norma que se indica puede ser adquirido en la sede de dicho organismo ubicado en Manuel Ma. Contreras 133, 6o. piso, Colonia Cuauhtémoc, Delegación Cuauhtémoc, Código Postal 06500, México, D.F., teléfono 5546-4546 y/o al correo electrónico: normalizacion@imnc.org.mx, o consultado gratuitamente en la biblioteca de la Dirección General de Normas de esta Secretaría, ubicada en Puente de Tecamachalco número 6, Colonia Lomas de Tecamachalco, Sección Fuentes, Naucalpan de Juárez, Código Postal 53950, Estado de México.

La norma mexicana NMX-EC-15189-IMNC-2015, entrará en vigor 60 días naturales después de la publicación de esta Declaratoria de Vigencia en el Diario Oficial de la Federación.

CLAVE O CÓDIGO	TÍTULO DE LA NORMA
NMX-EC-15189-IMNC-2015	LABORATORIOS CLÍNICOS – REQUISITOS DE LA CALIDAD Y COMPETENCIA (CANCELA A LA NMX-EC-15189-IMNC-2008).
Objetivo y campo de aplicación	
Esta norma mexicana especifica los requisitos de la calidad y competencia en los laboratorios clínicos, para el desarrollo de sus sistemas de gestión de la calidad y la evaluación de su propia competencia, también puede ser utilizada para confirmar o reconocer la competencia de los laboratorios clínicos por los clientes del laboratorio, autoridades regulatorias y organismos de acreditación.	
Concordancia con normas internacionales	
Esta norma coincide totalmente con la norma internacional ISO 15189:2012, "Medical laboratories – Requirements for quality and competence"	
Bibliografía	
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[3]	ISO 3534-1, Statistics-Vocabulary and symbols-Part 1: General statistical terms and terms used in probability
[4]	ISO 5725-1, Accuracy (trueness and precision) of measurement methods and results-Part 1: General principles and definitions

[5]	ISO 9000:2005, Quality management systems-Fundamentals and vocabulary
[6]	ISO 9001:2008, Quality management systems-Requirements
[7]	ISO 15190, Medical laboratories-Requirements for safety
[8]	ISO 15194, In vitro diagnostic medical devices-Measurement of quantities in samples of biological origin-Requirements for certified reference materials and the content of supporting documentation
[9]	ISO/IEC 17011, Conformity assessment-General requirements for accreditation bodies accrediting conformity assessment bodies
[10]	ISO/IEC 17043:2010, Conformity assessment-General requirements for proficiency testing
[11]	ISO 19011, Guidelines for auditing management systems
[12]	ISO/IEC 27001, Information technology-Security techniques-Information security management systems-Requirements
[13]	ISO 27799, Health informatics-Information security management in health using ISO/IEC 27002
[14]	ISO/TS 22367, Medical laboratories-Reduction of error through risk management and continuous improvement
[15]	ISO 22870:2006, Point-of-care testing (POCT)-Requirements for quality and competence
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[28]	CLSI GP17-A2: Clinical Laboratory Safety-Second Edition; Approved Guideline. CLSI: Wayne, PA., 2004
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[30]	CLSI GP21-A3; Training and Competence Assessment-Third Edition; Approved Guideline. CLSI: Wayne, PA, 2009
[31]	CLSI GP22-A3; Continual Improvement-Third Edition; Approved Guideline. CLSI: Wayne, PA, 2011

- [32] CLSI GP26-A4; A Quality Management System Model for Laboratory Services-Fourth Edition-Approved Guideline. CLSI: Wayne, PA, 2011
- [33] CLSI GP27-A2; Using Proficiency Testing to Improve the Clinical Laboratory-Second Edition; Approved Guideline. CLSI: Wayne, PA, 2007
- [34] CLSI GP29-A2; Assessment of Laboratory Tests When Proficiency Testing is Not Available-Second Edition; Approved Guideline. CLSI: Wayne, PA, 2007
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México, D.F., a 13 de mayo de 2015.- El Director General de Normas y Secretariado Técnico de la Comisión Nacional de Normalización, **Alberto Ulises Esteban Marina**.- Rúbrica.