



Inter-American
**Coalition for
Regulatory Convergence**
MEDICAL TECHNOLOGY SECTOR

National Standards Bodies



National Standards Bodies (NSBs) ISO Member Bodies from the Americas (Members of the Pan-American Standards Commission)

Antigua and Barbuda	ABBS	Cuba	NC	Nicaragua	DNM
Argentina	IRAM	Dominica	DBOS	Panama	COPANIT
Bahamas	BBSQ	Dominican Republic	INDOCAL	Paraguay	INTN
Barbados	BNSI	Ecuador	INEN	Peru	INACAL
Belize	BZBS	El Salvador	OSN	Saint Kitts and Nevis	SKNBS
Bolivia	IBNORCA	Guatemala	COGUANOR	Saint Lucia	SLBS
Brazil	ABNT	Guyana	GNBS	Saint Vincent and the Grenadines	SVGBS
Canada	SCC	Haiti	BHN	Sao Tome and Principe	SENAPIQ STP
Chile	INN	Honduras	OHN	Suriname	SSB
Colombia	ICONTEC	Jamaica	BSJ	Trinidad and Tobago	TTBS
Costa Rica	INTECO	Mexico	DGN	United States	ANSI
				Uruguay	UNIT



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Current Coalition participation in International Organization for Standardization (ISO) Medical Device Committees

	Argentina	Brazil	Canada	Chile	Colombia	Costa Rica	Ecuador	Dominican R.	Mexico	Panama	Peru	USA
ISO/TC 76, Transfusion, infusion, injection and blood processing equipment	O											P
ISO/TC 84, Devices for admin of medicines & catheters	O		P		O							P
ISO/TC 106, Dentistry	O	P	P									P
ISO/TC 121, Anesthesia and respiratory equipment*	P	P	P									P
ISO/TC 150, Implants for surgery	P	P				O						P
ISO/TC 157, (non-systemic) Contraceptives and STI prophylactics	O	P							P			P
ISO/TC 194, Biological and clinical evaluation of medical devices	P	P	P									P
ISO/TC 198, Sterilization of health care products	P	P	P		P	O					O	P
ISO/TC 209, Cleanrooms and associated environs.	O	P	P									P
ISO/TC 210, Quality Mgt and associated aspects for medical devices	P	P	P	O	P		O		P	P		P
ISO/TC 212, Clinical lab testing and IVD test systems	P	O	P	P	P					P	O	P
ISO/TC 215, Health informatics	O	P	P		O		O		P		O	P

P = Participating member

O = Observer member



IEC National Committees from the Americas (* Members of the Forum of the IEC National Committees of the Americas – FINCA)

<u>Argentina</u> *	aea.org.ar
<u>Brazil</u> *	cobei.org.br
<u>Canada</u> *	scc.ca
<u>Chile</u> *	cornelec.cl
<u>Colombia</u> *	icontec.org
<u>Cuba</u>	nc.cubaindustria.cu
<u>Mexico</u> *	economia.gob.mx
<u>Peru</u>	inacal.gob.pe
<u>United States of America</u> *	ansi.org



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Current Coalition participation in International Electrotechnical Commission (IEC) Medical Device Committees (abbrev. titles) IEC/IEC	Argentina	Brazil	Canada	Chile	Colombia	Costa Rica	Ecuador	Dominican R.	Mexico	Panama	Peru	USA
IEC/TC 62, Electrical equipment in medical practice		P	P						O			P
IEC/SC 62A, Common aspects of electrical equipment used in medical practice		P	P						O			P
IEC/SC 62B, Diagnostic imaging equipment		P	P									P
EC/SC 62C, Equipment for radiotherapy, nuclear medicine and radiation dosimetry		P	P									P
IEC/SC 62D, Electromedical equipment		P	P									
IEC/TC 66, Safety of measuring, control and laboratory equipment		P	P									
IEC/TC 76, Optical radiation safety and laser equipment		P	P									P
TC 87, Ultrasonics		P										P

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Every Coalition association, member company and MD RA should have:

- An Organization-wide Standards Strategy / Policy
- A Designated Standards Lead (Standards Executive)
- A Designated liaison to the local National Standards Body
 - and medical device technical / policy committees
- A Mapping of organization participation in international standardization (technical and policy) – worldwide
- Identification of who tracks WTO/TBT notifications and submits comments on them
- Identification and coordination between QARA and GR/Trade teams