



Survey on the Metrological Control for the Medical measurement Instruments

The Working Group on Medical Measurements
Singapore
November 15-17, 2006



- Issued : August 29, 2006
- Responded :
 - Six Member Economies, including Cambodia, Japan, Mexico, U.S.A, Vietnam, and Chinese Taipei (by October 12, 2006.)



Medical Measurement Instruments with OIML Recommendation



• Q3-A-Responsible Authorities for Metrology control-1

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
R 7 – Clinical thermometers, mercury-in-glass with maximum device	None	METI & NMIJ/AIST	None	FDA	STAMEQ	BSMI
R 16-1 –Mechanical non-invasive sphygmomanometers	None	METI & NMIJ/AIST	DGN	FDA	STAMEQ	BSMI
R 16-2 – Non-invasive automated sphygmomanometer	None	METI & NMIJ/AIST	DGN	FDA	None	BSMI
R 26 –Medical syringes	None	No Metrological Control	DGN	FDA	None	None
R 78 –Westergren tubes for measurement of erythrocyte sedimentation rate	None	No Metrological Control	DGN	FDA	None	None
R 90 – Electrocardiographs - Metrological characteristics - Methods and equipment for verification	None	No Metrological Control	DGN	FDA	STAMEQ	None
R 104 -Pure-tone Audiometers	None	No Metrological Control	DGN	FDA	None	None
R 114 –Clinical electrical thermometers for continuous measurement	None	No Metrological Control	DGN	FDA	None	BSMI
R 115 –Clinical electrical thermometers with maximum device	None	METI & NMIJ/AIST	DGN	FDA	STAMEQ	BSMI
R 128 –Ergometers for foot crank work	None	No Metrological Control	DGN	FDA	None	None
R 135 –Spectrophotometers for medical laboratories	None	No Metrological Control	DGN	FDA	None	None



Medical Measurement Instruments with OIML Recommendation



• Q3-A-Responsible Authorities for Metrology control-2

METI: Ministry of Economy, Trade and Industry

NMIJ: National Metrology Institute of Japan

AIST: National Institute of Advanced Industrial Science and Technology

DGN: DIRECCIÓN GENERAL DE NORMAS, DGN, (General Bureau of Standards, Economy)

FDA: U.S. Food and Drug Administration

STAMEQ: Directorate for Standards and Quality

BSMI: Bureau of Standards, Metrology, and Inspection



Medical Measurement Instruments with OIML Recommendation



- Q3-B-Relative Regulations for Metrology control-1

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
R 7 – Clinical thermometers, mercury-in-glass with maximum device	None	Measurement Law	None	2	STAMEQ	The Weights and Measures, 9, and 10
R 16-1 –Mechanical non-invasive sphygmomanometers	None	Measurement Law	1	3	STAMEQ	The Weights and Measures, 9, and 11
R 16-2 – Non-invasive automated sphygmomanometer	None	Measurement Law	None	3	None	The Weights and Measures, 1, and 12
R 26 –Medical syringes	None	No Metrological Control	None	4	None	None
R 78 –Westergren tubes for measurement of erythrocyte sedimentation rate	None	No Metrological Control	None	5	None	None
R 90 – Electrocardiographs - Metrological characteristics - Methods and equipment for verification	None	No Metrological Control	None	6	STAMEQ	None
R 104 -Pure-tone Audiometers	None	No Metrological Control	Federal Law for Metrology and Normalization	None	None	None
R 114 –Clinical electrical thermometers for continuous measurement	None	No Metrological Control	None	7	None	None
R 115 –Clinical electrical thermometers with maximum device	None	Measurement Law	None	7	STAMEQ	The Weights and Measures, 1, and 13
R 128 –Ergometers for foot crank work	None	No Metrological Control	None	None	None	None
R 135 –Spectrophotometers for medical laboratories	None	No Metrological Control	None	8	None	None



Medical Measurement Instruments with OIML Recommendation



- Q3-B-Relative Regulations for Metrology control-2

1: NOM-009-SCFI-1993 INSTRUMENTOS DE MEDICIÓN-ESFIGMOMANÓMETROS DE COLUMNA DE MERCURIO, DE ELEMENTO SENSOR ELÁSTICO PARA MEDIR LA PRESIÓN SANGUÍNEA DEL CUERPO HUMANO

2: Section 21 CFR 880.2920 Clinical mercury thermometer

3: Section 21 CFR 870.1130 Noninvasive Blood Pressure Measurement System

4: Section 21 CFR 880.5860 Piston syringe - Recognized standards include many ISO standards

5: Waived from regulation in accordance with P.L. 100-578 The Clinical Laboratory Improvements Amendments

6: Section 21 CFR 870.2340 Electrocardiograph - Recognized standards include many ISO standards



Medical Measurement Instruments with OIML Recommendation



- Q3-B-Relative Regulations for Metrology control-3

7:Section 21 CFR 880.2910 Clinical electronic thermometer - Recognized standards include ASTM standards

8:P.L. 100-578 The Clinical Laboratory Improvements Amendments provides the FDA with responsibility to categorize the complexity and level of regulatory oversight to be applied. Spectrophotometers used for certain analytes has a high complexity

9:Regulations Governing Verification and Inspection of Measuring Instrument

10:Technical Specification for Verification and Inspection of Thermometers

11:Technical Specification for Verification and Inspection of Non Invasive Automated Sphygmomanometers

12:Verification will be implemented from 2009

13:Technical Specification for Verification and Inspection of Thermometers(Verification will be implemented from 2008)



Medical Measurement Instruments with OIML Recommendation



- Q4.1-A-Metrology control Procedure-Type Approval or Evaluation/Time Interval-1

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
R 7 – Clinical thermometers, mercury-in-glass with maximum device	No required	X/Not Specified (initial only)	No required	No required ^a	X	No required
R 16-1 –Mechanical non-invasive sphygmomanometers	No required	X/Not Specified (initial only)	No required	X ^b	X	No required
R 16-2 – Non-invasive automated sphygmomanometer	No required	X/Not Specified (initial only)	No required	X ^b	X	No required
R 26 –Medical syringes	No required	No required	No required	X ^c	X	No required
R 78 –Westergren tubes for measurement of erythrocyte sedimentation rate	No required	No required	No required	No required	X	No required
R 90 – Electrocardiographs - Metrological characteristics - Methods and equipment for verification	No required	No required	No required	X ^c	X	No required
R 104 -Pure-tone Audiometers	No required	No required	No required	No required	X	No required
R 114 –Clinical electrical thermometers for continuous measurement	No required	No required	No required	X ^c	X	No required
R 115 –Clinical electrical thermometers with maximum device	No required	X/Not Specified (initial only)	No required	X ^c	X	No required
R 128 –Ergometers for foot crank work	No required	No required	No required	No required	X	No required
R 135 –Spectrophotometers for medical laboratories	No required	No required	No required	Check with website ^d	X	No required



Medical Measurement Instruments with OIML Recommendation



Q4.2--The level of implementing Pattern Approval or Evaluation

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
R 7 – Clinical thermometers, mercury-in-glass with maximum device	None	Central/National	None	None	Central/National	None
R 16-1 –Mechanical non-invasive sphygmomanometers	None	Central/National	None	None	Central/National	None
R 16-2 – Non-invasive automated sphygmomanometer	None	Central/National	None	None	None	None
R 26 –Medical syringes	None	None	None	None	None	None
R 78 –Westergren tubes for measurement of erythrocyte sedimentation rate	None	None	None	None	None	None
R 90 – Electrocardiographs - Metrological characteristics - Methods and equipment for verification	None	None	None	None	Central/National	None
R 104 -Pure-tone Audiometers	None	None	Central/National	None	None	None
R 114 –Clinical electrical thermometers for continuous measurement	None	None	None	None	None	None
R 115 –Clinical electrical thermometers with maximum device	None	Central/National	None	None	Central/National	None
R 128 –Ergometers for foot crank work	None	None	None	None	None	None
R 135 –Spectrophotometers for medical laboratories	None	None	None	*	None	None

*: The CLIA provides "Guidelines for Laboratories" and laboratories may be subject to accreditation requirements and proficiency testing.



Medical Measurement Instruments with OIML Recommendation



Q4.3--The level of implementing Verification

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
R 7 – Clinical thermometers, mercury-in-glass with maximum device	None	1	None	2	1,2,3	1
R 16-1 –Mechanical non-invasive sphygmomanometers	None	1*	None	2	1,2,3	1
R 16-2 – Non-invasive automated sphygmomanometer	None	1 *	None	2	None	1
R 26 –Medical syringes	None	None	None	None	None	None
R 78 –Westergren tubes for measurement of erythrocyte sedimentation rate	None	None	None	None	None	None
R 90 – Electrocardiographs - Metrological characteristics - Methods and equipment for verification	None	None	None	2	1,2,3	None
R 104 -Pure-tone Audiometers	None	None	1	None	None	None
R 114 –Clinical electrical thermometers for continuous measurement	None	None	None	None	None	None
R 115 –Clinical electrical thermometers with maximum device	None	1 *	None	None	1,2,3	1
R 128 –Ergometers for foot crank work	None	None	None	None	None	None
R 135 –Spectrophotometers for medical laboratories	None	None	None	None	None	None

1. Central/National, 2. State/Regional 3. Local/Municipal *Accredit Designated Manufactures



Medical Measurement Instruments with OIML Recommendation



Q5.1-A–Other Control (e.g. health concerned) Responsible Authorities

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
R 7 – Clinical thermometers, mercury-in-glass with maximum device	None	MHLW	None	Hospital and accredited health facility Requirements	None	Dep. Of Health
R 16-1 –Mechanical non-invasive sphygmomanometers	None	MHLW	Health Dep.*	Hospital and accredited health facility Requirements	None	Dep. Of Health
R 16-2 – Non-invasive automated sphygmomanometer	None	MHLW	None	Hospital and accredited health facility Requirements	None	Dep. Of Health
R 26 –Medical syringes	None	MHLW	None	None	None	Dep. Of Health
R 78 –Westergren tubes for measurement of erythrocyte sedimentation rate	None	MHLW	None	None	None	Dep. Of Health
R 90 – Electrocardiographs - Metrological characteristics - Methods and equipment for verification	None	MHLW	None	Hospital and accredited health facility Requirements	None	Dep. Of Health
R 104 -Pure-tone Audiometers	None	MHLW	Health Dep. & Labor Dep.	None	None	Dep. Of Health
R 114 –Clinical electrical thermometers for continuous measurement	None	MHLW	None	None	None	Dep. Of Health
R 115 –Clinical electrical thermometers with maximum device	None	MHLW	None	None	None	Dep. Of Health
R 128 –Ergometers for foot crank work	None	MHLW	None	None	None	Dep. Of Health
R 135 –Spectrophotometers for medical laboratories	None	MHLW	None	None	None	Dep. Of Health

*: SECRETARÍA DE SALUD, SS, (Health Department, Federal Government)



Medical Measurement Instruments with OIML Recommendation



Q5.1-B–Other Control (e.g. health concerned) Relatives Regulations

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
R 7 – Clinical thermometers, mercury-in-glass with maximum device	None	Medicines Act	None	None	None	Pharmaceutic Law
R 16-1 –Mechanical non-invasive sphygmomanometers	None	Medicines Act	None	None	None	Pharmaceutic Law
R 16-2 – Non-invasive automated sphygmomanometer	None	Medicines Act	None	None	None	Pharmaceutic Law
R 26 –Medical syringes	None	Medicines Act	None	None	None	Pharmaceutic Law
R 78 –Westergren tubes for measurement of erythrocyte sedimentation rate	None	Medicines Act	None	None	None	Pharmaceutic Law
R 90 – Electrocardiographs - Metrological characteristics - Methods and equipment for verification	None	Medicines Act	None	None	None	Pharmaceutic Law
R 104 -Pure-tone Audiometers	None	Medicines Act	None	None	None	None
R 114 –Clinical electrical thermometers for continuous measurement	None	Medicines Act	None	None	None	Pharmaceutic Law
R 115 –Clinical electrical thermometers with maximum device	None	Medicines Act	None	None	None	Pharmaceutic Law
R 128 –Ergometers for foot crank work	None	Medicines Act	None	None	None	Pharmaceutic Law
R 135 –Spectrophotometers for medical laboratories	None	Medicines Act	None	None	None	Pharmaceutic Law



Medical Measurement Instruments with OIML Recommendation



Q5.2–Other Control Procedure

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
R 7 – Clinical thermometers, mercury-in-glass with maximum device	None	None	None	Quality Control Procedures	None	*
R 16-1 –Mechanical non-invasive sphygmomanometers	None	None	None	Quality Control Procedures	None	*
R 16-2 – Non-invasive automated sphygmomanometer	None	None	None	Quality Control Procedures	None	*
R 26 –Medical syringes	None	None	None	None	None	*
R 78 –Westergren tubes for measurement of erythrocyte sedimentation rate	None	None	None	None	None	*
R 90 – Electrocardiographs - Metrological characteristics - Methods and equipment for verification	None	None	None	Quality Control Procedures	None	*
R 104 -Pure-tone Audiometers	None	None	None	None	None	None
R 114 –Clinical electrical thermometers for continuous measurement	None	None	None	None	None	*
R 115 –Clinical electrical thermometers with maximum device	None	None	None	None	None	*
R 128 –Ergometers for foot crank work	None	None	None	None	None	*
R 135 –Spectrophotometers for medical laboratories	None	None	None	None	None	*

*: Type Approval/Evaluation and Verification



Medical Measurement Instruments with OIML Recommendation



Q5.3–The level of Implementation for other Control

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
R 7 – Clinical thermometers, mercury-in-glass with maximum device	None	None	None	None	None	Central/National
R 16-1 –Mechanical non-invasive sphygmomanometers	None	None	None	None	None	Central/National
R 16-2 – Non-invasive automated sphygmomanometer	None	None	None	None	None	Central/National
R 26 –Medical syringes	None	None	None	None	None	Central/National
R 78 –Westergren tubes for measurement of erythrocyte sedimentation rate	None	None	None	None	None	Central/National
R 90 – Electrocardiographs - Metrological characteristics - Methods and equipment for verification	None	None	None	None	None	Central/National
R 104 -Pure-tone Audiometers	None	None	Central/National	None	None	None
R 114 –Clinical electrical thermometers for continuous measurement	None	None	None	None	None	Central/National
R 115 –Clinical electrical thermometers with maximum device	None	None	None	None	None	Central/National
R 128 –Ergometers for foot crank work	None	None	None	None	None	Central/National
R 135 –Spectrophotometers for medical laboratories	None	None	None	None	None	Central/National



Medical Measurement Instruments without OIML Recommendation



- Q3-A-Responsible Authorities for Metrology control

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
Tonometer	None	No Metrological Control	None	None	None	None
Ultrasound equipment – ultrasonography units	None	None	DNG	None	None	None
Electroencephalography	None	None	None	None	STAMEQ	None
Electrotherapy	None	None	None	None	STAMEQ	None
Computed Tomography	None	None	None	None	STAMEQ	None
Cobal-60 Teletherapy	None	None	None	None	STAMEQ	None



Medical Measurement Instruments without OIML Recommendation



- Q3-B-Relative Regulations for Metrology control

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
Tonometer	None	None	None	None	None	None
Ultrasound equipment – ultrasonography units	None	None	Federal Law for Metrology and Normalization	None	None	None
Electroencephalography	None	None	None	None	STAMEQ	None
Electrotherapy	None	None	None	None	STAMEQ	None
Computed Tomography	None	None	None	None	STAMEQ	None
Cobal-60 Teletherapy	None	None	None	None	STAMEQ	None



Medical Measurement Instruments without OIML Recommendation



- Q4.1-A-Metrology control Procedure-Type Approval or Evaluation/Time Interval

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
Tonometer	None	No Metrological Control	None	None	None	None
Ultrasound equipment – ultrasonography units	None	No Metrological Control	Not Required	None	None	None
Electroencephalography	None	No Metrological Control	None	None	X	None
Electrotherapy	None	No Metrological Control	None	None	X	None
Computed Tomography	None	No Metrological Control	None	None	X	None
Cobal-60 Teletherapy	None	No Metrological Control	None	None	X	None



Medical Measurement Instruments without OIML Recommendation



- Q4.1-B-Metrology control Procedure-Verification Approval or Evaluation/Time Interval

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
Tonometer	None	No Metrological Control	None	None	None	None
Ultrasound equipment – ultrasonography units	None	No Metrological Control	X/ 2 Years	None	None	None
Electroencephalography	None	No Metrological Control	None	None	X/ 2 Years	None
Electrotherapy	None	No Metrological Control	None	None	X/ 2 Years	None
Computed Tomography	None	No Metrological Control	None	None	X/ 2 Years	None
Cobal-60 Teletherapy	None	No Metrological Control	None	None	X/ 2 Years	None



Medical Measurement Instruments without OIML Recommendation



Q4.2--The level of implementing Pattern Approval or Evaluation

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
Tonometer	None	None	None	None	None	None
Ultrasound equipment – ultrasonography units	None	None	Central/National	None	None	None
Electroencephalography	None	None	None	None	Central/National	None
Electrotherapy	None	None	None	None	Central/National	None
Computed Tomography	None	None	None	None	Central/National	None
Cobal-60 Teletherapy	None	None	None	None	Central/National	None



Medical Measurement Instruments without OIML Recommendation



Q4.3--The level of implementing Verification

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
Tonometer	None	None	None	None	None	None
Ultrasound equipment – ultrasonography units	None	None	1	None	None	None
Electroencephalography	None	None	None	None	1,2	None
Electrotherapy	None	None	None	None	1,2	None
Computed Tomography	None	None	None	None	1,2	None
Cobal-60 Teletherapy	None	None	None	None	1,2	None



Medical Measurement Instruments without OIML Recommendation



Q5.1-A–Other Control (e.g. health concerned) Responsible Authorities

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
Tonometer	None	MHLW	None	None	None	None
Ultrasound equipment – ultrasonography units	None	MHLW	*	None	None	None
Electroencephalography	None	MHLW	None	None	None	None
Electrotherapy	None	MHLW	None	None	None	None
Computed Tomography	None	MHLW	None	None	None	None
Cobal-60 Teletherapy	None	MHLW	None	None	None	None

MHLW: Ministry of Health, Labour and Welfare

*: Health Department (Subsecretary of Innovation and Quality, CENTEC, COFEPRIS, Programs of Technology Assessment for Health)



Medical Measurement Instruments without OIML Recommendation



Q5.1-B–Other Control (e.g. health concerned) Relatives Regulations

	Cambodia	Japan	Mexico	U.S.A	Viet Nam	Chinese Taipei
Tonometer	None	Medicines Act	None	None	None	None
Ultrasound equipment – ultrasonography units	None	Medicines Act	Mandatory Std. NOM-208-SSA1-2003	None	None	None
Electroencephalography	None	Medicines Act	None	None	None	None
Electrotherapy	None	Medicines Act	None	None	None	None
Computed Tomography	None	Medicines Act	None	None	None	None
Cobal-60 Teletherapy	None	Medicines Act	None	None	None	None



Q6.1–Kind of medical measurement instruments the WG on Medical Measurements should work

	medical measurement instruments	Comments
Cambodia	Clinical thermometers, mercury-in-glass with maximum device, Mechanical non-invasive sphygmomanometers, Non-invasive automated sphygmomanometer, Clinical electrical thermometers for continuous measurement	
Japan	Clinical electrical contact thermometers, Clinical electrical infrared ear-thermometers, Non-invasive automated sphygmomanometer	We expect that such automated portable measuring devices will be widely used in the future.
Mexico		Locally, the metrological control of measuring devices has been focused on industrial applications, neglecting the metrological control of medical devices. Either because of the lack of regulations or limited measuring capabilities to evaluate the conformance of such devices. Traceability of ultrasound measurements to the International System of Units. Are current medical ultrasound measurements traceable to national standards? Do we care? National regulations regarding waster water measurements: NOM 002-SEMARNAT-1996, NOM 052-SEMARNAT-2005
U.S.A		This is a low priority subject for the US.
Viet Nam		
Chinese Taipei	Automated sphygmomanometers, Clinical electrical thermometers	



Q6.2–Activities on medical measurement instruments APLMF should provide

	Training	Seminar	Presentation	Others	Comments
Cambodia	X				Medical devices are described above mostly used in Cambodia. The other devices are used in the modern hospitals
Japan		X	X		We expect the WG will continue to organize seminars and present survey results on medical measurements.
Mexico	X	X	X	X (Creation of an electronic web site to promote the exchange of technical experiences and scientific developments on metrological issues associated to medical devices)	
U.S.A					This is a low priority subject to the U.S.A.
Viet Nam	X	X	X		Especially, for automated sphygmomanometer with digital indicator: -How to verify -How to calibrate/ adjust
Chinese Taipei	X	X	X	X	



Q6.3–Number of people who would participate in the activities

	Training	Seminar	Presentation	Others	Comments
Cambodia	2				We have no method to verify medical devices. Therefore, we need training our officers both management and inspections.
Japan		3	2		We hope to support the activities of WG by preparing speakers for seminars..
Mexico		4	4		
U.S.A	0	0	0		
Viet Nam	5	5	1		
Chinese Taipei	1	1	1	1	



Q6.4–Number of expert(s) contribute as a trainer.

	Training	Seminar	Presentation	Others	Comments
Cambodia					
Japan	2				We hope to support the activities of WG by preparing speakers for seminars..
Mexico					
U.S.A					Depending on the subject the US will make inquires as to the availability of the trainers.
Viet Nam					
Chinese Taipei	3				



Q6.5–Other comments

	Comments
Cambodia	
Japan	We wish the WG will continue present activities such as organizing seminars and survey on medical measurements..
Mexico	
U.S.A	
Viet Nam	
Chinese Taipei	



Survey on the Metrological Control for the Medical measurement Instruments



Conclusion:

1. According to the responses, basically, only the health authority and metrological authority pay their attention to the medical measurements instruments affairs, though the labour authority may involve in this issue.
2. According to the surveys conducted by this WG during past years, the relative regulations in member economies still quite differ from member economy to economy. Therefore, we encourage member economies make their efforts to harmonize their regulation with OIML and to reduce the technical barrier to trade which is one of the main objects of APLMF.
3. This WG would like to organize training courses in the near future if we could get the support from APLMF and member economies.