



Survey on Metrological Control for the Medical Measurement Instruments

The Working Group on Medical Measurements

The 21st Forum Meeting

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 - Introduction
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Introduction



- Drafted: Working Group on Medical Measurements
- Issued : September 2, 2014
- Responded :
 - 6 Member Economies, including Australia, Japan, Mongolia, the Philippines, Viet Nam, and Chinese Taipei (by October 12, 2014)



Member Economies' Replies-1



	Japan		Mongolia		The Philippines		Viet Nam		Chinese Taipei	
	M	H	M	H	M	H	M	H	M	H
Clinical Thermometers, Mercury-in-Glass with Maximum Device (OIML R 7)	X	X	X	X	X*	-	X	X	X	X
Mechanical Non-Invasive Sphygmomanometers (OIML R 16-1)	X	X	X	X	X*	-	X	X	X	X
Non-Invasive Automated Sphygmomanometer (OIML R 16-2)	X	X	X	X	X*	-	-	-	-	X
Medical Syringes (OIML R 26)	-	N/A	-	-	X*	-	-	-	-	-
Standard Graduated Pipettes for Verification Officers (OIML R 40)	-	N/A	X	X	X*	-	-	-	-	-

M: Metrology Authority H: Health Authority

*: DOH



Member Economies' Replies-2



	Japan		Mongolia		The Philippines		Viet Nam		Chinese Taipei	
	M	H	M	H	M	H	M	H	M	H
Westergren Tubes for Measurement of Erythrocyte Sedimentation rate (OIML R 78)	-	N/A	-	-	X*	-	-	-	-	-
Electroencephalographs - Metrological Characteristics (OIML R 89)	-	N/A	-	-	X*	-	X	X	-	-
Electrocardiographs - Metrological Characteristics - Methods and Equipment for Verification (OIML R 90)	-	N/A	-	-	X*	-	X	X	-	-
Measuring Instrumentation for Human Response to Vibration(OIML R103)	-	N/A	-	-	X*	-	-	-	-	-
Pure-Tone Audiometers (OIML R104)	-	N/A	-	-	X*	-	-	-	-	-



Member Economies' Replies-1



	Japan		Mongolia		The Philippines		Viet Nam		Chinese Taipei	
	M	H	M	H	M	H	M	H	M	H
Clinical Electrical Thermometers for Continuous Measurement (OIML R 114)	-	-	X	X	X*	-	-	-	X	X
Clinical Electrical Thermometers with Maximum Device (OIML R 115)	X	X	-	-	X*	-	X	X	X	X
Equipment for Speech Audiometry (OIML R 122)	-	-	-	-	X*	-	-	-	-	-
Ergometers for Foot Crank Work (OIML R128)	-	-	-	-	X*	-	-	-	-	-
Spectrophotometers for Medical Laboratories (OIML R 135)	-	-	X	X	X*	-	-	-	-	-



Member Economies' Replies-4



	Japan		Mongolia		The Philippines		Viet Nam		Chinese Taipei		
	M	H	M	H	M	H	M	H	M	M	
Thermographic Instruments (OIML R 141)	-	N/A	-	-	X*	-	-	-	-	-	-
Automated Refractometers (OIML R 142)	-	N/A	X	X	X*	-	-	-	-	-	-



Clinical Thermometers, Mercury-in-Glass with Maximum Device (OIML R 7) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	METI	MHLW	Measurement Act	Measurement Act (and others)
Mongolia	MASM	MASM	The Mongolian Law of Guarantee on Measurement Uniformity	The Mongolian Law of Guarantee on Measurement Uniformity
The Philippines	DOH	-	-	-
Viet Nam	STAMEQ	STAMEQ	Circular 23/2013/TT-BKHHCN; ĐLVN 21:1998; ĐLVN 232:2010	Circular 23/2013/TT-BKHHCN; ĐLVN 21:1998; ĐLVN 232:2010
Chinese Taipei	BSMI	FDA	Regulations Governing Verification and Inspection of Measuring Instruments Technical Specification for Verification and Inspection of Thermometers	Regulations for Governing The Management of Medical Device



Clinical Thermometers, Mercury-in-Glass with Maximum Device (OIML R 7) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	NMIJ	X	-	-	Local Government	-	-	-
Mongolia	-	-	-	-	-	Central/ National	Central/ National Every Year	Central/ National Every Year
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	Central/ National, State/ Regional, Local/ Municipal	Central/ National, State/ Regional, Local/ Municipal	-	Central/ National, State/ Regional, Local/ Municipal
Chinese Taipei	-	X	-	-	Central/ National	-	-	-



Clinical Thermometers, Mercury-in-Glass with Maximum Device (OIML R 7) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	-	-	-	-	-
Mongolia	-	-	MASM/ Professional Inspection Agency (PIA)	The Mongolian Law on Guarantee on Measurement Uniformity and Law on Inspection	Sampling Check
The Philippines	-	-	-	-	-
Viet Nam	ĐLVN 232:2010	STAMEQ, Sub-directorates for Standards, Metrology and Quality	STAMEQ, Sub-directorates for Standards, Metrology and Quality	Circular 23/2013/TT-BKHCN; Circular 28/2013/TT-BKHCN; ĐLVN 09:2011	-
Chinese Taipei	Registration	FDA	-	-	- 10



- METI: Ministry of Economy, Trade and Industry
- MHLW: Ministry of Health, Labour and Welfare
- NMIJ: National Metrology Institute of Japan
- DOH: Department of Health, Philippines
- MASM: Mongolian Agency for Standardization and Metrology
- Directorate for Standards, Metrology and Quality
- BSMI: Bureau of Standards, Metrology and Inspection, Chinese Taipei
- FDA: Food and Drug Administration, Chinese Taipei



Mechanical Non-Invasive Sphygmomanometers (OIML R 16-1) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	METI	MHLW	Measurement Act	Measurement Act (and others)
Mongolia	MASM	MASM	The Mongolian Law of Guarantee on Measurement Uniformity	The Mongolian Law of Guarantee on Measurement Uniformity
The Philippines	DOH	-	-	-
Viet Nam	STAMEQ	STAMEQ	Circular 23/2013/TT-BKHHCN; ĐLVN 21:1998; ĐLVN 232:2010	Circular 23/2013/TT-BKHHCN; ĐLVN 21:1998; ĐLVN 232:2010
Chinese Taipei	BSMI	FDA	Regulations Governing Verification and Inspection of Measuring Instruments, Technical Specification for Verification and Inspection of Thermometers	Regulations for Governing the Management of Medical Device



Mechanical Non-Invasive Sphygmomanometers (OIML R 16-1) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	NMIJ	X	-	-	Local Government	-	-	-
Mongolia	-	-	-	-	-	Central/ National, State/ Regional, Local/ Municipal	Central/ National, State/ Regional, Every Year	Central/ National, State/ Regional, Local/ Municipal, Every Year
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	Central/ National, State/ Regional, Local/ Municipal	Central/ National, State/ Regional, Local/ Municipal	Central/ National, State/ Regional, Local/ Municipal	Central/ National, State/ Regional, Local/ Municipal
Chinese Taipei	-	X	-	-	Central/ National	-	-	- 13



Mechanical Non-Invasive Sphygmomanometers (OIML R 16-1) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	-	-	-	-	-
Mongolia	-	-	MASM, Professional Inspection Agency (PIA)	The Mongolian Law on Guarantee on Measurement Uniformity and Law on Inspection	100% Periodically Check
The Philippines	-	-	-	-	-
Viet Nam	ĐLVN 232:2010	STAMEQ, Sub-directorates for Standards, Metrology and Quality	STAMEQ, Sub-directorates for Standards, Metrology and Quality	Circular 23/2013/TT-BKHCN; Circular 28/2013/TT-BKHCN; ĐLVN 09:2011	100% Periodically Check
Chinese Taipei	Registration	FDA	-	-	-



Non-Invasive Automated Sphygmomanometer (OIML R 16-2) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	METI	MHLW	Measurement Act	Measurement Act (and others)
Mongolia	MASM	MASM	The Mongolian Law of Guarantee on Measurement Uniformity	The Mongolian Law of Guarantee on Measurement Uniformity
The Philippines	DOH	-	-	
Viet Nam	-	-	-	-
Chinese Taipei	-	FDA	-	Regulations for Governing the Management of Medical Device



Non-Invasive Automated Sphygmomanometer (OIML R 16-2) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	X	X	-	-	-	-	-	-
Mongolia	-	-	-	-	-	Central/ National	Central/ National, Every Year	Central/ National, Every Year
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	-	-	-	-
Chinese Taipei	-	X	-	-	Central/ National	-	-	-



Non-Invasive Automated Sphygmomanometer (OIML R 16-2) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	-	-	-	-	-
Mongolia	-	-	MASM, Professional Inspection Agency (PIA)	The Mongolian Law on Guarantee on Measurement Uniformity and Law on Inspection	Sampling Check
The Philippines	-	-	-	-	-
Viet Nam	-	-	-	-	-
Chinese Taipei	Registration	FDA	-	-	-



Medical Syringes (OIML R 26) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	-	N/A	-	N/A
Mongolia	-	-	-	-
The Philippines	DOH	-	-	
Viet Nam	-	-	-	-
Chinese Taipei	-	FDA	-	Regulations for Governing The Management of Medical Device



Medical Syringes (OIML R 26) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	-	N/A	-	N/A	-	N/A	-	N/A
Mongolia	-	-	-	-	-	-	-	-
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	-	-	-	-
Chinese Taipei	-	X	-	-	X	-	-	-



Medical Syringes (OIML R 26) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	N/A	N/A	N/A	N/A	N/A
Mongolia	-	Recognized Third Parties- MASM (Mongolian national accreditation system, MNAS)	Professional Inspection Agency	Mongolian Law on Inspection	Sampling Check
The Philippines	-	-	-	-	-
Viet Nam	-	-	-	-	-
Chinese Taipei	Registration	FDA	-	-	-



Standard Graduated Pipettes for Verification Officers(OIML R 40) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	-	N/A	-	N/A
Mongolia	MASM	MASM	The Mongolian Law of Guarantee on Measurement Uniformity	The Mongolian Law of Guarantee on Measurement Uniformity
The Philippines	DOH	-	-	
Viet Nam	-	-	-	-
Chinese Taipei	-	FDA	-	Regulations for Governing the Management of Medical Device



Standard Graduated Pipettes for Verification Officers(OIML R 40) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	-	N/A	-	N/A	-	N/A	-	N/A
Mongolia	-	-	-	-	-	Central/ National	Every Two Year	Central/ National, Every Two Year
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	-	-	-	-
Chinese Taipei	-	-	-	-	-	-	-	-



Standard Graduated Pipettes for Verification Officers (OIML R 40) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	N/A	N/A	N/A	N/A	N/A
Mongolia	-	MASM (Mongolian national accreditation system, MNAS)	MASM and PIA	The Mongolian Law on Guarantee on Measurement Uniformity and The Law on Inspection	Sampling Check
The Philippines	-	-	-	-	-
Viet Nam	-	-	-	-	-
Chinese Taipei	-	-	-	-	-



Westergren Tubes for Measurement of Erythrocyte Sedimentation Rate (OIML R 78) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	-	N/A	-	N/A
Mongolia	-	-	-	-
The Philippines	DOH	-	-	
Viet Nam	-	-	-	-
Chinese Taipei	-	-	-	-



Westergren Tubes for Measurement of Erythrocyte Sedimentation Rate (OIML R 78) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	-	N/A	-	N/A	-	N/A	-	N/A
Mongolia	-	-	-	-	-	-	-	-
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	-	-	-	-
Chinese Taipei	-	-	-	-	-	-	-	-



Westergren Tubes for Measurement of Erythrocyte Sedimentation Rate (OIML R 78) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	N/A	N/A	N/A	N/A	N/A
Mongolia	-	-	-	-	-
The Philippines	-	-	-	-	-
Viet Nam	-	-	-	-	-
Chinese Taipei	-	-	-	-	-



Electroencephalographs - Metrological Characteristics (OIML R 89) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	-	N/A	-	N/A
Mongolia	-	-	-	-
The Philippines	DOH	-	-	-
Viet Nam	STAMEQ	STAMEQ	Circular 23/2013/TT-BKHHCN; ĐLVN 44:2009; ĐLVN 219:2010-	Circular 23/2013/TT-BKHHCN; ĐLVN 21:1998; ĐLVN 232:2010 -
Chinese Taipei	-	-	-	-



Electroencephalographs - Metrological Characteristics (OIML R 89) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	-	N/A	-	N/A	-	N/A	-	N/A
Mongolia	-	-	-	-	-	-	-	-
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	Central/ National, State/ Regional, Local/ Municipal	Central/ National, State/ Regional, Local/ Municipal	Central/ National, State/ Regional, Local/ Municipal	Central/ National, State/ Regional, Local/ Municipal
Chinese Taipei	-	-	-	-	-	-	-	-



Electroencephalographs - Metrological Characteristics (OIML R 89) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	N/A	N/A	N/A	N/A	N/A
Mongolia	-	-	-	-	-
The Philippines	-	-	-	-	-
Viet Nam	ĐLVN 232:2010	STAMEQ, Sub-directorates for Standards, Metrology and Quality	STAMEQ, Sub-directorates for Standards, Metrology and Quality	Circular 23/2013/TT-BKHCN; Circular 28/2013/TT-BKHCN; ĐLVN 09:2011	100% Periodically Check
Chinese Taipei	-	-	-	-	-



Electrocardiographs - Metrological Characteristics - Methods and Equipment for Verification (OIML R 90) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	-	N/A	-	N/A
Mongolia	-	-	-	-
The Philippines	DOH	-	-	
Viet Nam	STAMEQ	STAMEQ	Circular 23/2013/TT-BKHHCN; ĐLVN 21:1998; ĐLVN 232:2010	Circular 23/2013/TT-BKHHCN; ĐLVN 21:1998; ĐLVN 232:2010
Chinese Taipei	-	-	-	-



Electrocardiographs - Metrological Characteristics - Methods and Equipment for Verification (OIML R 90) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	-	N/A	-	N/A	-	N/A	-	N/A
Mongolia	-	-	-	-	-	-	-	-
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	Central/ National, State/ Regional, Local/ Municipal	Central/ National, State/ Regional, Local/ Municipal	Central/ National, State/ Regional, Local/ Municipal	Central/ National, State/ Regional, Local/ Municipal
Chinese Taipei	-	-	-	-	-	-	-	-



Electrocardiographs - Metrological Characteristics - Methods and Equipment for Verification (OIML R 90) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	N/A	N/A	N/A	N/A	N/A
Mongolia	-	-	-	-	-
The Philippines	-	-	-	-	-
Viet Nam	ĐLVN 232:2010	STAMEQ, Sub-directorates for Standards, Metrology and Quality	STAMEQ, Sub-directorates for Standards, Metrology and Quality	Circular 23/2013/TT-BKHCN; Circular 28/2013/TT-BKHCN; ĐLVN 09:2011	100% Periodically Check
Chinese Taipei	-	-	-	-	-



Measuring Instrumentation for Human Response to Vibration (OIML R 103) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	-	N/A	-	N/A
Mongolia	-	-	-	-
The Philippines	DOH	-	-	-
Viet Nam	-	-	-	-
Chinese Taipei	-	-	-	-



Measuring Instrumentation for Human Response to Vibration (OIML R 103) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	-	N/A	-	N/A	-	N/A	-	N/A
Mongolia	-	-	-	-	-	-	-	-
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	-	-	-	-
Chinese Taipei	-	-	-	-	-	-	-	-



Measuring Instrumentation for Human Response to Vibration (OIML R 103) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	N/A	N/A	N/A	N/A	N/A
Mongolia	-	-	-	-	-
The Philippines	-	-	-	-	-
Viet Nam	-	-	-	-	-
Chinese Taipei	-	-	-	-	-



Pure-Tone Audiometers (OIML R 104) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	-	N/A	-	N/A
Mongolia	-	-	-	-
The Philippines	DOH	-	-	-
Viet Nam	-	-	-	-
Chinese Taipei	-	-	-	-



Pure-Tone Audiometers (OIML R 104) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	-	N/A	-	N/A	-	N/A	-	N/A
Mongolia	-	-	-	-	-	-	-	-
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	-	-	-	-
Chinese Taipei	-	-	-	-	-	-	-	-



Pure-Tone Audiometers (OIML R 104) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	N/A	N/A	N/A	N/A	N/A
Mongolia	-	-	-	-	-
The Philippines	-	-	-	-	-
Viet Nam	-	-	-	-	-
Chinese Taipei	-	-	-	-	-



Clinical Electrical Thermometers for Continuous Measurement (OIML R 114) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	METI	MHLW	Measurement Act	Measurement Act (and others)
Mongolia	MASM	MASM	The Mongolian Law of Guarantee on Measurement Uniformity	The Mongolian Law of Guarantee on Measurement Uniformity
The Philippines	DOH	-	-	-
Viet Nam	-	-	-	-
Chinese Taipei	BSMI	FDA	Regulations Governing Verification and Inspection of Measuring Instruments, Technical Specification for Verification and Inspection of Thermometers	Regulations for Governing The Management of Medical Device



Clinical Electrical Thermometers for Continuous Measurement (OIML R 114) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	NMIJ	X	-	-	Local Government	-	-	-
Mongolia	-	-	-	-	-	Central/ National	Central/ National, Every Year	Central/ National, Every Year
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	-	-	-	-
Chinese Taipei	-	X	-	-	-	Central/ National	-	-



Clinical Electrical Thermometers for Continuous Measurement (OIML R 114) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	-	-	-	-	-
Mongolia	-	-	MASM, Professional Inspection Agency (PIA)	The Mongolian Law on Guarantee on Measurement Uniformity and Law on Inspection	Sampling Check
The Philippines	-	-	-	-	-
Viet Nam	-	-	-	-	-
Chinese Taipei	Registration	FDA	-	-	-



Clinical Electrical Thermometers with Maximum Device (OIML R 115) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	METI	MHLW	Measurement Act	Measurement Act (and others)
Mongolia	-	-	The Mongolian Law of Guarantee on Measurement Uniformity	-
The Philippines	DOH	-	-	-
Viet Nam	STAMEQ	STAMEQ	Circular 23/2013/TT-BKHHCN; ĐLVN 21:1998; ĐLVN 232:2010	Circular 23/2013/TT-BKHHCN; ĐLVN 21:1998; ĐLVN 232:2010
Chinese Taipei	BSMI	FDA	Regulations Governing Verification and Inspection of Measuring Instruments, Technical Specification for Verification and Inspection of Thermometers	Regulations for Governing The Management of Medical Device



Clinical Electrical Thermometers with Maximum Device (OIML R 115) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	NMIJ	X	-	-	Local Government	-	-	-
Mongolia	-	-	-	-	*	-	*	-
Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	Central/ National, State/ Regional, Local/ Municipal	Central/ National, State/ Regional, Local/ Municipal	Central/ National, State/ Regional, Local/ Municipal	Central/ National, State/ Regional, Local/ Municipal
Chinese Taipei	-	X	-	-	-	Central/ National	-	-

*No verification indicated during pre or post-market. Verification implemented by central level authority.



Clinical Electrical Thermometers with Maximum Device (OIML R 115) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	-	-	-	-	-
Mongolia	-	-	-	-	-
The Philippines	-	-	-	-	-
Viet Nam	ĐLVN 232:2010	STAMEQ, Sub-directorates for Standards, Metrology and Quality	STAMEQ, Sub-directorates for Standards, Metrology and Quality	Circular 23/2013/TT-BKHCN; Circular 28/2013/TT-BKHCN; ĐLVN 09:2011	100% Periodically Check
Chinese Taipei	Registration	FDA	-	-	-



Equipment for Speech Audiometry (OIML R 122) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	-	N/A	-	N/A
Mongolia	-	-	-	-
The Philippines	DOH	-	-	-
Viet Nam	-	-	-	-
Chinese Taipei	-	-	-	-



Equipment for Speech Audiometry (OIML R 122) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	-	N/A	-	N/A	-	N/A	-	N/A
Mongolia	-	-	-	-	-	-	-	-
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	-	-	-	-
Chinese Taipei	-	-	-	-	-	-	-	-



Equipment for Speech Audiometry (OIML R 122) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	N/A	N/A	N/A	N/A	N/A
Mongolia	-	-	-	-	-
The Philippines	-	-	-	-	-
Viet Nam	-	-	-	-	-
Chinese Taipei	-	-	-	-	-



Ergometers for Foot Crank Work (OIML R 128) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	-	N/A	-	N/A
Mongolia	-	-	-	-
The Philippines	DOH	-	-	-
Viet Nam	-	-	-	-
Chinese Taipei	-	-	-	-



Ergometers for Foot Crank Work (OIML R 128) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	-	N/A	-	N/A	-	N/A	-	N/A
Mongolia	-	-	-	-	-	-	-	-
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	-	-	-	-
Chinese Taipei	-	-	-	-	-	-	-	-



Ergometers for Foot Crank Work (OIML R 128) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	N/A	N/A	N/A	N/A	N/A
Mongolia	-	-	-	-	-
The Philippines	-	-	-	-	-
Viet Nam	-	-	-	-	-
Chinese Taipei	-	-	-	-	-



Spectrophotometers for Medical Laboratories (OIML R 135) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	-	-	-	
Mongolia	MASM	MASM	The Mongolian Law of Guarantee on Measurement Uniformity	The Mongolian Law of Guarantee on Measurement Uniformity
The Philippines	DOH	-	-	-
Viet Nam	-	-	-	-
Chinese Taipei	-	-	-	-



Spectrophotometers for Medical Laboratories (OIML R 135) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	-	-	-	-	-	-	-	-
Mongolia	-	-	-	-	-	Calibration	Central/ National, Every Year	Central/ National, Every Year
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	-	-	-	-
Chinese Taipei	-	-	-	-	-	-	-	-



Spectrophotometers for Medical Laboratories (OIML R 135) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	-	-	-	-	-
Mongolia	-	-	MASM and PIA	The Mongolian Law on Guarantee on Measurement Uniformity and The Law on Inspection	Sampling Check
The Philippines	-	-	-	-	-
Viet Nam	-	-	-	-	-
Chinese Taipei	-	-	-	-	-



Thermographic Instruments (OIML R 141) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	-	-	-	-
Mongolia	-	-	-	-
The Philippines	DOH	-	-	-
Viet Nam	-	-	-	-
Chinese Taipei	-	-	-	-



Thermographic Instruments (OIML R 141) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	-	-	-	-	-	-	-	-
Mongolia	-	-	-	-	-	-	-	-
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	-	-	-	-
Chinese Taipei	-	-	-	-	-	-	-	-



Thermographic Instruments (OIML R 141) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	-	-	-	-	-
Mongolia	-	-	-	-	-
The Philippines	-	-	-	-	-
Viet Nam	-	-	-	-	-
Chinese Taipei	-	-	-	-	-



Automated Refractometers (OIML R 142) -1



	Responsible Authority		Relative Regulations	
	M	H	M	H
Japan	-	-	-	-
Mongolia	MASM	MASM	The Mongolian Law of Guarantee on Measurement Uniformity	The Mongolian Law of Guarantee on Measurement Uniformity
The Philippines	DOH	-	-	-
Viet Nam	-	-	-	-
Chinese Taipei	-	-	-	-



Automated Refractometers (OIML R 142) -2



	Type Approval or Evaluation Pre-market		Type Approval or Evaluation Post-market		Verification Pre-market		Verification Post-market	
	M	H	M	H	M	H	M	H
Japan	-	-	-	-	-	-	-	-
Mongolia	-	-	-	-	-	Calibration	Central/ National, Every Year	Central/ National, Every Year
The Philippines	-	-	-	-	-	-	-	-
Viet Nam	-	-	-	-	-	-	-	-
Chinese Taipei	-	-	-	-	-	-	-	-



Automated Refractometers (OIML R 142) -3



	Conformity Assessment Procedure Review of Technical Documentation	Conformity Assessment Bodies	Post-market Control		The Level of Implementation for Post-market Control
			Responsible Authorities	Relative Regulations	
Japan	-	-	-	-	-
Mongolia	-	-	-	-	-
The Philippines	-	-	-	-	-
Viet Nam	-	-	-	-	-
Chinese Taipei	-	-	-	-	-



Future Works-1



	Medical measurement the WG should work	Activities needed	Number of people to participate	expert(s) contribute as trainers	Other comments
Japan	Clinical Thermometers, Sphygmomanometers-	Seminar, Survey	1	1	-
Mongolia	a	a	a	a	Need professional training and seminar/presentation on all kind of measurements medical device
The Philippines	-	-	-	-	b
Viet Nam	Non-Invasive Automated Sphygmomanometers, Infrared Thermometers, Radiation Meters (Nuclear radiation, X-Ray Radiation, UV Radiation), SpO2 Meter, Erythrocyte Sedimentation Rate Meter	Training, Seminar, presentation, Workshop with hands-on experience	10 for training and 10 for seminar	-	-
Chinese Taipei	Blood-Glucose Meter	Seminar	2	-	-



Future Works-2



Note: a

Medical measurement the WG should work	Activities needed			Number of people to participate	expert(s) contribute as trainers
Non-Invasive Automated Sphygmomanometer (R 16-2)	Training/ Workshop	Seminar	-	6	-
Medical Syringes (R 26)	Training/ Workshop	Seminar	Concultans	2	-
Electroencephalographs - Metrological Characteristics (R 89)	Training/ Workshop		Concultans	5	1
Electrocardiographs - Metrological Characteristics - Methods and Equipment for Verification (R 90)	Training/ Workshop		Concultans	5	1
Measuring instrumentation for Human Response to Vibration (R 103)	Training/ Workshop	Seminar	Concultans	5	1
Pure-tone Audiometers (R 104)	Training/ Workshop		Concultans	1	1
Equipment for Speech Audiometry (R 122)	Training/ Workshop		Concultans	5	2
Ergometers for Foot Crank Work (R 128)	Training/ Workshop		Concultans	5	1



Future Works-3



Note: a

Medical measurement the WG should work	Activities needed			Number of people to participate	expert(s) contribute as trainers
Spectrophotometers for Medical Laboratories (R 135)	Training/ Workshop	-	Conculturans	5	1
Thermographic Instruments (R 141)	Training/ Workshop	Seminar	Conculturans	2	1
Eye Tonometer	Training/ Workshop	Seminar	Conculturans	5	1
Medical Software	Training/ Workshop	-	Presentation	-	-



Future Works-4



Note:b

- ❖ Our existing National Metrology Act (Law) requires Pattern Approval of all Test and Measuring Instruments (TMIs). However, there is no capability yet for performing Pattern Approval Testing on medical devices/instruments. Although, verification tests, which maybe part of Pattern Approval, is performed by the NML, ITDI on medical devices/instruments submitted by customers.
- ❖ These devices are:
 1. clinical thermometers, mercury-in-glass (R 7)
 2. non-invasive mechanical and automated sphygmomanometers (R 16-1, 16-2)
 3. standard graduated pippettes (R 40)
 4. refractometers (R 142)
 5. thermographic instruments (R 141)
 6. clinical electrical thermometers (R 114, 115)
- ❖ The Metrology Law recognizes Pattern Approval Certificates issued by Foreign Testing Laboratories/Authorities/Accredited/Recognized by International Bodies based on ISO 17025, OIML and other applicable International Standards. The survey form has been referred to Department of Health (DOH) which has authority on medical devices and related matters. In addition, the DOH is a member of the National Metrology Board (NMB). The NML, ITDI is interested in participating in trainings, seminars presentation covering legal metrology medical devices/instruments.



Conclusion



1. Few member economies show their concern on medical measurement instruments;
2. It seems that metrology authority needs the cooperation from health authority;
3. Training activities are needed in various field and this working group would like to organize training courses in the future under APLMF/APEC full support.



2015 Working Plan



❖ Adverse report of medical instruments in Asia Pacific region

1. Methodology

- 1) Collect the data of adverse report of medical instruments in Asia Pacific region in past 5 years;
- 2) Analysis the data of adverse report of medical instruments in Asia Pacific region.

2. Objects

- 1) Address the threaten of malfunction/inaccuracy of medical measurement instruments;
- 2) Seek the opportunity to organize a workshop to build-up the cooperation between metrology authority and health authority in the future;
- 3) Bridge the dialogue between metrology authority and health authority.



Comments?
Question?



Thank you