2013 Working Group Report-1

The Working Group on Medical Measurements
The Twentieth Forum Meeting of APLMF
YOGYAKARTA, Indonesia
Nov 6, 2013
Jin-Hai. Yang

附件五

Overview

- Application for APEC TILF Special Account fund for ***Workshop on duplicate control on medical devices with measuring function***
- 2014 Working Plan

Workshop
on duplicate control on medical devices
with measuring function

The real scene of legal measures on medical measurement control among APLMF region

- Responsible Authorities for Metrology control

	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	*None*	None	None
R 114 –Clinical electrical thermometers for continuous measurement	None	No Metrological Control	DGN	*FDA*	None	None
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

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

Workshop
on duplicate control on medical devices with measuring function

METI: Ministry of Economy, Trade and Industry, Japan

NMIJ: National Metrology Institute of Japan

AIST: National Institute of Advanced Industrial Science and Technology, Japan

MHLW: Ministry of Health, Labour and Welfare

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

FDA: U.S. Food and Drug Administration

STAMEQ: Directorate for Standards and Quality, Viet Nam

BSMI: Bureau of Standards, Metrology, and Inspection, Chinese Taipei

What concerns focused by health agency ?

- Safety
- Effectiveness

What measures taken by health agency ?

- Registration
- Quality Management System, Good Manufacturing Practices
- Adverse Events Report

What measures metrology authorities can do on medical devices?

- Type approval
- Verification
  - initial verification
  - re-verification
  - subsequent verification

Why APEC should undertake the project ?

- bridge the dialogue between health authorities and metrology authorities to reduce duplicate controls
- improve the accuracy of medical devices

Workshop
on duplicate control on medical devices with measuring function

How the workshop will meet forum's work-plan or medium-term plan ?

- The project will develop a shared understanding of control schemes to increase transparency and promote better controlling procedure.

- This workshop supports capacity-building activities including exchanging views and experience on best practices from health and metrology authorities

Implementing plan

- Design and disseminate the questionnaire to seek comments on contents/topics of the programs mentioned above, and identify appropriate trainers/experts/speakers to attend the activities;
- This workshop supports capacity-building activities including exchanging views and experience on best practices from health and metrology authorities

2014 Work plan

- Hold a workshop regarding on ***Workshop on duplicate control on medical devices with measuring function***
- Update the Survey on the Metrological Control for the Medical measurement Instruments

Comments ?

Guild to the Complementary Controls of Medical Devices on Metrological and Medical Supervision (draft)

2013 Working Group Report

The Working Group on Medical Measurements
The Twenty Forum Meeting
Nov. 6, 2013
Pei-Lin Hou

Overview

- Medical Regulatory Controls
- Comparison with Metrology Regulatory Controls
- Suggestions

Main Purposes of Regulatory Control

Medical Regulatory System[1]

- Ensure a high level of protection of public health and safety
- Public Trust and confidence in Medical Devices based on safety and performance of such devices

Legal Metrology[2]

- Protect the interests of individuals and enterprises; national interests; public health and safety, including in relation to the environment and medical services; meet the requirements of international trade
- Providing confidence on Measurement Results of medical device

1 Principles of Conformity Assessment for Medical Devices, SGI Final Document GHTF/SG1/N40：2006, Global Harmonization Task Force
2 Elements for a Law on Metrology,OIML D1,2004 edition

The definition of Medical Device※

Any **instrument, apparatus, implement, machine, appliance**, implant, *in vitro* reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of such as

- **diagnosis, prevention, monitoring**, treatment or alleviation of disease,
- diagnosis, **monitoring**, treatment, alleviation of or compensation for an injury, and so on .....

※Medical Devices – Quality management systems – requirements for regulatory purposes (ISO 13485：2003)

Conformity Assessment Elements for Medical Device※

- Quality Management System
- Technical Documentation

  (Ensure device safety and performance)
- Registration

※ Principles of Conformity Assessment for Medical Devices, SGI Final Document GHTF/SG1/N40：2006,

Quality Management System

- ISO 13485:2003
- Ensure that medical devices will be safe and perform as intended by the manufacturer
- Type examination is acceptable in some cases
- System for post-market surveillance which includes complaint handling, post-market vigilance and corrective & preventive actions is required to ensure the continued conformity

Elements of Quality Management System

- Management
- Design and Development
- Product Documentation
- Production and Process Controls
- Corrective and Preventive Actions (CAPA)
- Purchasing Controls
- Documentation and Records
- Customer Related Processes Subsystem

Medical Regulatory Controls by Risk

- Medical regulatory controls are proportional to the level of risk associated with a medical device.
- The level of regulatory control increases with increasing degree of risk
- The risk depends substantially on

✓ intended purpose of medical device

✓ the effectiveness of the risk management techniques applied during design, manufacture and use

✓ Intended user(s).mode of operation, and/or technologies

What's the differences between medical and metrology regulatory controls ?

Controlled medical device

- Medical regulatory control

  By definition, cover extensively

- *Legal metrology control*

  Designated by legal metrology authority (few)

Medical Device subject to legal metrology control

- R7 Clinical thermometers, mercury-in-glass with maximum device
- R16-1 Non-invasive mechanical sphygmomanometers
- R16-2 Non-invasive automated sphygmomanometers
- R26 Medical syringes
- R78 Westergren tubes for measurement of erythrocyte sedimentation rate
- R89 Electroencephalographs - Metrological characteristics - Methods and equipment for verification
- R90 Electrocardiographs - Metrological characteristics - Methods and equipment for verification
- R114 Clinical electrical thermometers for continuous measurement
- R115 Clinical electrical thermometers with maximum device
- R133 Liquid-in-glass thermometers
- R135 Spectrophotometers for medical laboratories
- Ophthalmic instruments – Impression and Applanation Tonometers Version 4 – November 2009

Conformity assessment elements

- Medical regulatory control

  By Risk

- *Legal metrology control*
  - ✓ *Uniformity*
  - ✓ *Risk assessment for metrological supervision*

Technical Requirements

- Medical regulatory control

  Extensively, cover safety and performance issues

- *Legal metrology control*
  - ✓ *Accuracy*
  - ✓ *Safety, software identification, EMC, Clinical evaluation*

The responsibilities of Stakeholders

- **Medical regulatory control**

  Regulatory Authority： Review document and audit manufacturer

  Manufacturer ：Demonstrate safety and performance of medical device by establish and maintain QMS, prepare Technical Document, registration

- ***Legal metrology control***

  Regulatory Authority ：Verify medical device usually by testing and evaluation

  Manufacturer ： have the device type approved, verified before placing on the market, registration

  User ：Maintain the accuracy of device

Difference Between Metrological And Medical Regulatory Controls

Lifecycle / Supervision	Pre-manufacturing	Manufacturing	In-service
Medical supervision	✓Registration, including manufacturer and medical devices, relevant documents needed.	✓Quality management system (ISO 13485:2003) ✓Technical documentation	✓Adversary event report and market surveillance. ✓Accreditation for laboratories that using medical devices(in some member economies)
Metrological supervision	✓Type approval if required ✓Licensing for manufacturer if required,	✓Initial verification	✓Inspection ✓Market surveillance ✓Field surveillance ✓Re-verification

What kind of medical regulatory control already done in your economic?

Which devices need to be under legal metrology control?

What type of controls can we provide ?

Suggestions

Accuracy

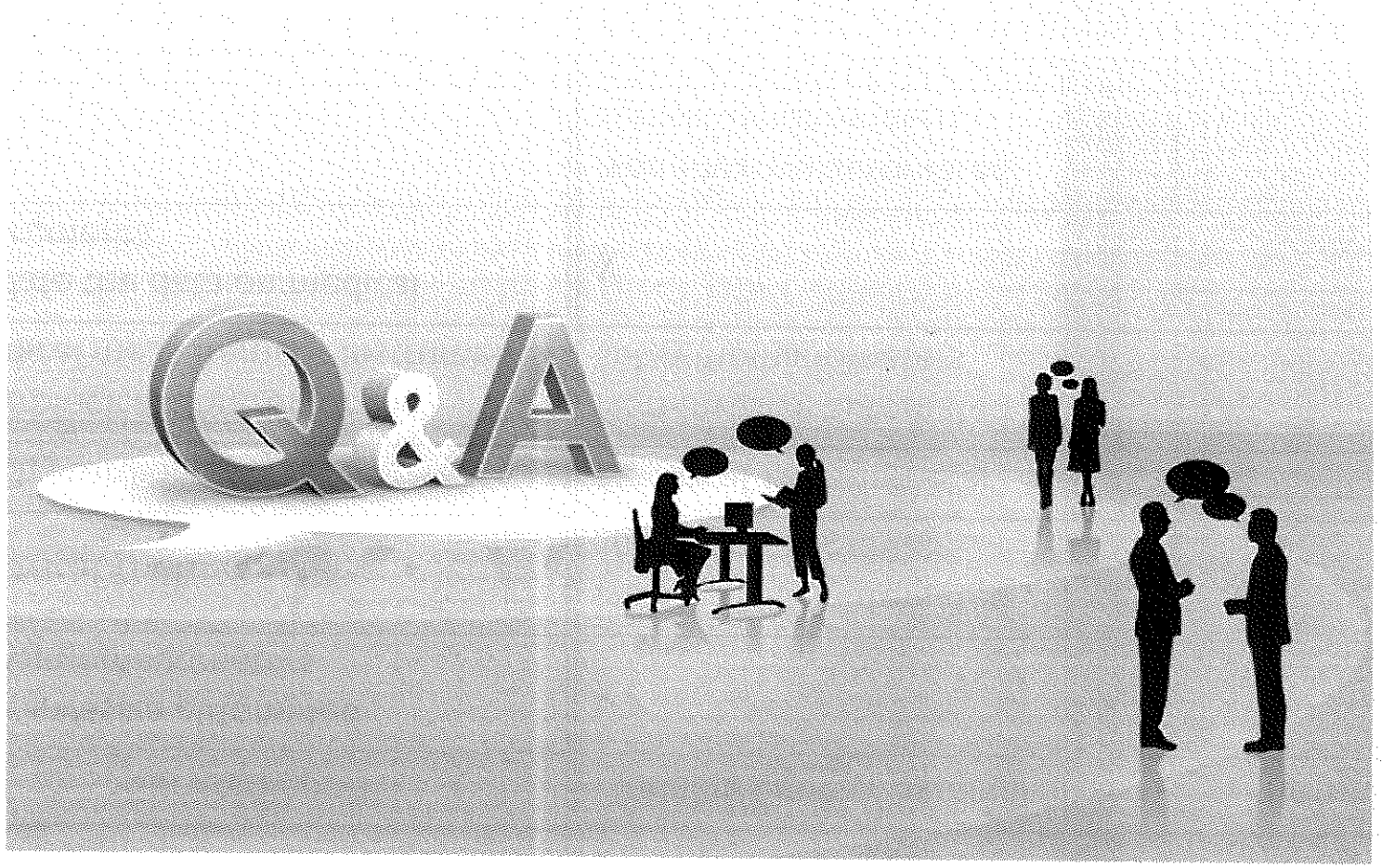
- Initial Verification
- Type Approved
- Calibration of the Standards

Post market surveillance

- Re-verification
- Inspections

Regulation and Legislations

- Legislations
- One-stop window for manufacturer and importer


Q&A

Activities of WG

on Medical Measurements

Year	Survey/Report	Training Course/ Seminar	Remark
2003	Non-invasive automated sphygmomanometers	X	
2004	Electrical Thermometer	Non-invasive automated sphygmomanometers	
2005	Electrocardiograph	Electrical Thermometer	
2006	Metrological Control for the Medical measurement Instruments	Non-invasive automated sphygmomanometers	
2007	Update the data on medical instruments	X	
2008	X	Non-invasive automated sphygmomanometers	
2009	Infrared Ear Thermometer		
2010	Blood Glucose Meter		
2011			Study on complementary control of medical device
2012			Guide to the Application of ionizing radiation metrology in medicine

Device safety and performance※

- Chemical, physical and biological properties.
- Infection and microbial contamination.
- Manufacturing and environmental properties.
- Devices with a diagnostic or measuring function.
- Protection against radiation.
- Requirements for medical devices connected to or equipped with an energy source.
- Protection against mechanical risks.
- Protection against the risks posed to the patient by supplied energy or substances.
- Protection against the risks posed to the patient for devices for self-testing or selfadministration.
- Information supplied by the manufacturer.
- Performance evaluation including, where appropriate, clinical evaluation.

※Essential Principles of Safety and Performance of Medical Devices Study Group 1 Final Document GHTF/SG1/N41R9：2009