Medical Devices Control

2011 Working Group Report

The Working Group on Medical Measurements

The Eighteenth Forum Meeting

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Brian C.S. Shu

Overview

- Medical Regulatory Control
- Comparison with legal metrology control
- Complementary control

Why we still need legal metrology control ?

What are their differences ?

How to achieve complementary control ?

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

Medical Regulatory Controls by Risk

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

- Ø Classification of Medical Device by Low risk, Low-moderate Risk, Moderate-high Risk risk, high risk

Conformity Assessment Elements for Medical Device※

- Quality Management System
- Technical Documentation

  Device safety and performance
- Registration

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

Quality Management System

- ISO 13485, 21 CFR Part 820 ……
- 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

Subsystems 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

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.**

Devices with a diagnostic or measuring function

- Devices with a measuring function, where inaccuracy could have a significant adverse effect on the patient, should provide **sufficient accuracy, precision and stability** for their intended purpose of the device. The limits of accuracy should be indicated by the manufacturer.
- Diagnostic devices should provide **sufficient accuracy, precision and stability for their intended use**, based on appropriate scientific and technical methods. In particular the design should address sensitivity, specificity, trueness, repeatability, reproducibility, control of known relevant interference and limits of detection, as appropriate.

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 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

Controlled medical device

- Medical regulatory control

  By definition, cover extensively

- *Legal metrology control*

  Designated by legal metrology authority (few)

Conformity assessment

- 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 every medical device usually by testing and evaluation

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

  User ：Maintain the accuracy of device

Comparison
Conformity Assessment Elements

	Registration	Design	Manufacturing	In Service
	PRE-MARKERT			**POST-MARKET**
Medical Regulatory Control	•Manufacturer •Medical device	•QMS (ISO 13485) (Type Approval) •Technical Documentation	•QMS •Technical documentation	•QMS
Legal Metrology Control	*•Manufacturer* *•Installer* *•Repairer*	*•Type Approval*	*•Initial verification* *•(QMS,ISO 9000)*	*•Subsequent verification* *•Inspection* *•Market surveillance* *•Field surveillance*

Complementary Control

- Understand what medical regulatory system could really cover in your economy.

- Identify the needs to undertake complementary control
  - What is the type of medical device needed to be subject to legal metrology control ?
  - What medical regulatory control can't do ?
  - Does management quality system ensure the continued accuracy of device in use ?

- Avoid duplicate control

Questions ?

2012 Plan

The Working Group on Medical Measurements

The Eighteenth Forum Meeting

Sep 5-8, 2011

Activities of Working Group on Medical Measurements

	Survey	Training Course/ Seminar	Report
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	X		Blood Glucose Meter

Action plan

- Update surveys
- Based on surveys, further study on complementary control of medical device
- Discuss with Working Group on Metrological Control System to explore any possibility to draft a guideline of complementary control on Medical Device
- Explore any possibility to hold a training course in 2012 for Infrared Ear Thermometer based on previous survey