Investigating the Regulatory System and Recognized Standards for the

"Non-invasive Automated Sphygmomanometer"

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Outline

- Introduce the Regulatory Systems
  - Health authority
  - Legal metrology authority
- Introduce Recognized Standards
  - OIML R16-2
  - IEC 80601-2-30

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Main Purposes of Regulatory Systems

Medical Regulatory Control[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

*1 " Principles of Conformity Assessment for Medical Devices", Final Document **GHTF/SG1/N40** : 2006, Global Harmonization Task Force*

Legal Metrological Control[2]

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

2 "Elements for a Law on Metrology", OIML D1,2012 edition

Regulatory Control of Health authority

- Quality Management System
  - as ISO 13485
- Technical Documentation
  - ensure device safety and performance
  - follow harmonized guidelines like GHTF* SG1-N11(:2008), SG1-N41R9(:2005) and relevant recognized standards
- Registration
  - Necessary documents depend on the risk classification which refers to related directives or regulations

**GHTF: Global Harmonization Task Force*

Regulatory Control of Legal Metrological Authority

- Related Metrology Laws and regulations
  - as OIML D1,D9, D16…
  - contents of these documents:
    - ✓ providing elements which justify the need for setting up legal provisions
    - ✓ providing comments and explanations which clarify the meaning and the consequences of some proposed legal provisions.
    - ✓ Providing **suggestions of Articles**
    - ✓ Setting up Structure of metrological supervision
    - ✓ Providing Principles of assurance of metrological control
- Verification & Inspection According to Relevant Technical Specifications
  - as OIML R16-2 “Non-invasive automated sphygmomanometers”

Regulatory Control of Legal Metrological Authority

- R7 Clinical thermometers, mercury-in-glass with maximum device
- R16-1 Non-invasive mechanical 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

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- **Introduce Recognized Standards**
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Recognized Standards from Health Authority (For example)

Economy	Competent Authority	Recognized Standard
U.S.	Food and Drug Administration	ISO 81060-2 (Second edition 2013-05-01), IEC 80601-2-30 (Edition 1.1 2013-07)
		IEC 80601-2-30:2009 & A1:2013, Medical electrical equipment - Part 2-30, IEEE ISO 11073-10407 (First edition 2010-05-01)
Germany	Federal Institute for Drugs and Medical Devices	EN 1060-1, 1996; EN 1060-3, 1997; EN 1060-4, 2004; IEC 80601-2-30, 2013; ISO 81060-2, 2013
China	China Food and Drug Administration; General Administration of Quality Supervision, Inspection and Quarantine of PRC	YY 0670, non-invasive automated sphygmomanometers, 2008; JJG 692, Verification Regulation of Non-invasive Automated Sphygmomanometers, 2010
Japan	Ministry of Health, Labour and Welfare	JIS T 1115, 2005; IEC 80601-2-30, 2013; ISO 81060-2, 2013
R.O.C.	Taiwan Food and Drug Administration	CNS 13075, CNS 15041-1, CNS 15051-3, EN 1060-4: 2004. OIML R16-2: 2002, ,EN 1060-3: 1997+A2: 2009, IEC 80601-2-30: 2013, ISO 81060-2: 2013, IEC 11073-10407: 2010

OIML R16-2

"Non-invasive automated sphygmomanometers"

Scope

- general, performance, efficiency, mechanical and electrical safety requirements,
- including non-invasive electronic or automated sphygmomanometers and their accessories which are used for the non-invasive measurement of arterial blood pressure.

Metrological requirements

(under required conditions of temperature and related humidity)

- Maximum permissible errors of the cuff pressure indication:

  ± 0.4 kPa (± 3 mmHg) at any measuring point

- Maximum permissible errors of the overall system as measured by clinical tests (carried out by the manufacturer)

  maximum mean error of measurement: ± 0.7 kPa (± 5 mmHg);

OIML R16-2

Technical requirements

- Pneumatic system:

  --Blood pressure measuring systems shall be capable of automatic zero setting.

  --Air leakage shall not exceed a pressure drop of 0.8 kPa/min (6 mmHg/min).

  -- pass the rapid exhaust test

- Electromagnetic compatibility

  electromagnetic interferences shall not lead to degradations in the cuff pressure indication or in the result of the blood pressure measurement (Testing should be carried out in accordance with the relevant OIML provisions.)

- Stability of the cuff pressure indication

Metrological controls

- Test samples for type approval : At least three samples shall be tested.
- Sealing
- Marking of the device: name or trademark of manufacturer, serial number and year of fabrication, measuring range and measuring unit…
- The reveal of Manufacturer's information

IEC 80601-2-30

Medical electrical equipment –Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

- Automated sphygmomanometers ME (medical electrical) equivalents used for the non-invasive estimation of the blood pressure by utilizing an inflatable cuff, a pressure transducer, a valve for deflation, and displays used in conjunction with automatic methods for determining blood pressure.

- This standard specifies requirements for the basic safety and essential performance for this ME equivalents and its accessories including the requirements for the accuracy of a determination.

- This standard covers electrically-powered intermittent, indirect measurement of the blood pressure without arterial puncture, ME equivalents with automatic methods for estimating blood pressure, including blood pressure monitors for the home healthcare environment.

IEC 80601-2-30

- The contents include
  - ✓ Protection against electrical hazards, mechanical hazards, unwanted and excessive radiation hazards, excessive temperature hazard
  - ✓ Leakage Currents and dielectric strength tests
  - ✓ Electromagnetic compatibility of ME equivalents and ME systems

- Some important determinations:
  - ➢ Maximum pressure in normal condition

    The maximum pressure obtainable in normal condition shall not exceed 150 mmHg (20 kPa) for an automated sphygmomanometers in neonatal mode and not exceed 300 mmHg (40 kPa) otherwise.
  - ➢ Nominal blood pressure indication range

    a) Automated sphygmomanometers shall be capable of indicating diastolic blood pressure over at least the range of 20 to 60 mmHg in neonatal mode and 40 to 130 mmHg otherwise.

    b) Automated sphygmomanometers shall be capable of indicating systolic blood pressure over at least the range of 40 to 110 mmHg in in neonatal mode and 60 to 230 mmHg otherwise.

ISO 81060-5 _reference

Non-invasive sphygmomanometers — Part 5: Requirement for the repeatability and reproducibility of NIBP simulators for testing

- addresses requirements on the **repeatability** and **reproducibility** of an NIBP(Non-Invasive Blood Pressure) simulator to test an automated sphygmomanometer.

- requirement for technical parameters:
  - Accuracy of the static pressure
  - Accuracy of the pulse rate
  - Repeatability of oscillations
  - Reproducibility of oscillations
  - Repeatability and reproducibility of the envelope of the oscillations
  - Repeatability of the shape of oscillations
  - Reproducibility of the shape of oscillation

Summary

- **The main purposes between medical regulatory control and legal metrological control have consistency.**
- **The technical requirements for medical regulatory control including performance and safety are covered extensively, especially chemical, physical and biological infection and microbial contamination.**
- **For Legal metrological control, we focused on the structure of supervision, measuring accuracy and stability.**
- **The non-invasive Automated Sphygmomanometer is regulated following the above principles.**

The end

Thanks for your attention!

Subject Matter Expert

Jin-Hai Yang
Technical Specialist , 2th section, 4th Division
Bureau of Standards, Metrology and Inspection(BSMI)
(www.bsmi.gov.tw)
TEL: 886-2-2396-3360 ext.723
FAX: 886-2-2397-0715
E-mil: jh.yang @bsmi.gov.tw

Blood pressure recording BPR
Blood pressure simulation BPS