The APLMF Guide to

The complementary controls of medical devices on metrological and medical supervision

1 Foreword

This document was produced by the Asia-Pacific Metrology Forum (APLMF), a grouping of legal metrology authorities in the Asia-Pacific Economic Cooperation (APEC) member economies and other observer economies, whose goals are the development of legal metrology and the promotion of free and open trade in the regions through harmonizing and coordinating the legal metrology activities.

The APLMF draft guideline is developed by working groups, which are formed by representatives from member economies. Certain international and regional institutes also participate in on the basis of consultation.

The general concepts and principles set in this document was in accordance with OIML, ISO, APLMF, IMDRF and other related publications concerning on metrological and medical supervision. It intended to provide guidance for complementary controls of medical devices subject to metrological and medical supervision.

The APLMF publications may be downloaded from the APLMF website in the form of PDF files. Additional information on APLMF Publications may be obtained from the organization's headquarters.

2 Introduction

APLMF conducted series surveys on metrological control for medical devices since 2006. According to the surveys, health and metrological supervision overlap when taking legal controls of medical devices. Neither health nor metrological supervision had taken procedures properly to make sure the intended functions and features of medical devices (including the accuracy being consistently produced and maintained

both in the manufacturing stage and in-use stage).

Medical device industries that produce a range of products designed to diagnose and treat patients are highly diversified. Under medical supervision controls, the safety and performance of medical devices are strictly supervised by regulatory controls and certification established in accordance with the criticality of potential risks to human health. The main purposes of regulatory controls and certification of medical devices are focusing on ensuring high level of protection for public health and safety. Various clinical tests and certifications have been performed depending on the criticality of potential risks to human health as well. The risk levels associated with medical devices are classified by intended purpose. The effective risk management techniques are applied during design, manufacture and use, intended user(s) mode of operation and/or technologies.

Medical devices with measuring functions, where inaccuracy could have significant adverse effects on the patient, should provide sufficient accuracy and stability for their intended purpose of the devices. The manufacturer of medical devices should have appropriate scientific and technical conformity assessment including quality management system (QMS), technical documentation (device safety and performance), and registration which be supervised by medical and metrological supervisions to ensure safety and performance.

Although medical regulation controls and certifications on medical devices under health supervision are depended on the criticality of potential risks to human health, medical supervision and metrological supervision have some similarities and overlaps on medical device controls. The dual supervisions might create technical barriers to trade (TBT) for manufacturers or importers. In order to promote the free and open trade and avoid duplicate control, this document is composed as a guideline for complementary controls of medical device on metrological and medical supervision. As a general guideline, this document only includes the basic information. For further information, please refer to OIML, ISO, APLMF, IMDRF, and other related publications.

This guideline including some recommendations on each sections are listed below：

- Accuracy
- Post-Market surveillance
- Avoid duplicate control

3 Terminology

3.1 Definitions

- 3.1.1 medical devices

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

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body

And which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

NOTE: this definition has been developed by the Global Harmonization Task Force(GHTF)

- 3.1.2 metrological supervision

Metrological supervision is defined as control exercised in respect of the manufacture, import, installation, use, maintenance and repair of a measuring instrument and/or in respect of its use, performed in order to check that it is used correctly as regards the observance of metrology laws and regulations (from OIML D9)

- 3.1.3 Conformity assessment of a measuring instrument

Testing and evaluation of a measuring instrument to ascertain whether or not a single instrument, an instrument lot or a production series of instruments comply with all statutory requirements applicable to this instrument type.

Note: Conformity assessment does not only concern metrological requirements but may also cover requirements relating to: safety, EMC, software identification, ease of

use, marking, etc.

3.2 Abbreviations

OIML	International Organization of Legal Metrology
ISO	International Organization for Standardization
IMDRF	International Medical Device Regulators Forum
GHTF	Global Harmonization Task Force

4 General concepts

The main purpose of metrological supervision is to ensure community confidence in measurement of regulation and trade. To ensure the high level of protection of public health, safety, and accuracy, the legal metrological supervision should designate which medical devices are under regulatory controls. The technical requirements of medical devices should be addressed on accuracy, safety, EMC, and clinical evaluation. Conformity assessment elements are uniform to each device.

Compared with the metrological and medical supervision, technical requirements of medical devices under medical supervision are based on safety and performance. Conformity assessment elements are dependent on the criticality of potential risks to human health as well.

The different regulatory control methods (during the lifecycle of medical devices includes registration, design, manufacturing, and service) between metrological and medical supervision are shown in the table below.

Table 4.1 The Typical Difference Between Metrological And Medical Regulatory Controls

Lifecycle of medical devices / Legal measures	Pre-manufacturing	Manufacturing	In-service
Health supervision	● Registration, including manufacturer and medical devices, relevant documents needed.	● Quality management system (ISO 13485) ● Technical documentation	● Adversary event report and market surveillance. ● Accreditation for laboratories that using medical

			devices (in some member economies)
Metrological supervision	● Licensing for manufacturer if required, ● Type approval if required	● Initial verification	● Inspection ● Market surveillance ● Field surveillance ● Re-verification

Note：The QMS of medical regulatory controls in most nations are based on the ISO 13485.

5 Recommendation

5.1 Accuracy

The regulatory controls of medical devices taken by health supervision on medical conformity assessment methods include quality management system (QMS), technical documentation (device safety and performance), and registration. Despite these methods are effective and sufficient in medical regulatory controls, it still had some uncertainties on the consistency of performance, stability, and sufficient accuracy of medical devices.

Legal metrological supervision provides different controls (including type approval, initial verification, re-verification, inspection, market surveillance, etc..) to ensure the continuous accuracy and stability of the device. Accredited laboratories, supervised by health supervision and metrological supervision, should be accredited and recognized by international certification and build mutual recognition agreements with other organizations. Besides, laboratories for medical devices testing should be accredited under a quality system in compliance with the ISO 17025 and measurement standards used for verifying instruments shall be traceable to the national legal units of measurement for appropriate uncertainties as well.

5.2 Post-Market Surveillance

To ensure high level of safety and performance of medical device, the post-market management and reporting system for the recall of medical equipment need to be established. The post-market management mechanism of medical supervision mainly focuses on avoiding the hazards of medical equipment. Through legal metrological control, market surveillance that includes supervising the accuracy of measuring

instruments used to detect deviations at an early stage would assist to supervise medical devices in the market and eliminate potential risks to human health.

5.3 Avoid Duplicate control

The goals of APLMF are the promotion of free and open trades in the regions through harmonizing and coordinating the legal metrological activities. To avoid TBT, the metrological supervision should review all the regulations that related to medical device to prevent overlaps between metrological and other supervisions before any legislation. Negotiation between metrological and medical supervision on the legislation and control procedure could be and should be reached. Metrological supervision should work with medical supervision on minimizing duplicate control to reduce the burden of the manufacturers of medical devices. A one-stop window for pre-manufacturing stage could be a practice approach. Re-verification and in-use inspection taken by metrological supervision could help to ensure the accuracy of medical devices on the market.

6 References

6.1 Publications

1. Elements for a Law on Metrology, OIML D1, 2004 edition
2. Principles of Metrological Supervision, OIML D9, 2004 edition
3. Medical Devices – Quality Management Systems – Requirements for Regulatory Purpose, ISO 13485, 2007 second edition
4. Principles of Conformity Assessment for Medical Devices, SGI Final Document GHTF/SG1/N40：2006, Global Harmonization Task Force
5. Information Document Concerning the Definition of the Term ”Medical Device(GHTF/SG1/N29：2005)

6.2 Web links

1. http://oiml.org/
2. http://www.imdrf.org

3. http://www.fda.gov/MedicalDevices/default.htm
4. ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/medical-devices/