

<p style="text-align: center;"><b>ECONOMY MEMBER'S REPORT</b> Of The Kingdom of Cambodia Seminars and Training Course On Automated Sphygmomanometers From June 23 to 27,2008 In Taipei, Chinese Taipei. By Mr. CHHEANG Khin Officer, Department of Metrology ,Ministry of Industry Mines and Energy.</p> <p style="text-align: right;">1</p>	<p style="text-align: center;"><b>1- Brief History</b></p> <ul style="list-style-type: none"> <li>-1995 Establishment of Weights and Measures Unit under the Technical Department of Ministry of Industry, Mines and Energy (MIME).</li> <li>-1999 Upgraded to be the Department of Metrology (DOM), under MIME.</li> <li>-2000 Became the Corresponding Member of OIML.</li> <li>-2002 Became the Full Member of APLMF.</li> </ul> <p style="text-align: right;">2</p>
<p style="text-align: center;"><b>2-Structure of Metrology</b> Recently, the Metrology of Cambodia is split between the Department of Metrology (DOM) and Industrial Laboratory Center of Cambodia (ILCC). DOM has the responsibility for all Legal Metrology Activities and keeps the Secondary and Working Standards. ILCC keeps the Primary Standard and also implements the Industrial and Scientific Metrology requested by DOM. Our structure is in Annex No 01.</p> <p style="text-align: right;">3</p>	<p style="text-align: center;"><b>3-Situation of Automated Sphygmomanometers in Cambodia</b> In Cambodia, mostly of sphygmomanometer used in hospitals, clinics, family use are imported from China, Japan, Germany ,USA and others. These are more than 21,000 medical staffs in Cambodia used about 85 percent of aneroid sphygmomanometer and 15 percent of automated sphygmomanometer which is day to day increasing.</p> <p style="text-align: right;">4</p>

<p>4-Metrological control on Automated Sphygmomanometer  Measuring Unit used for the Automated Sphygmomanometer is Millimeter Hg (mmHg).  Presently, medical devices including Thermometer or Sphygmomanometer are not subject to any regulatory control at the moment. Pattern Approval and Verification such instruments are not legally enforced.</p> <p style="text-align: right;">5</p>	<p>DOM is interested in this matter because in the drafted law of metrology of Cambodia, There is one article has prescribed on public health safety .Now Cambodia does not have measurement standard and regulation of verification or inspection. These devices are very important for health and lives, therefore it must be inspected and verified.</p> <p style="text-align: right;">6</p>
<p>We foresee that the medical devices regulation coming force in the future. So we need to update of technical competence and capability.  The adoption of OIML recommendation in the Technical Regulation is envisaged. Therefore the participation to this training course will be very important for me to get and share experience from lectures and colleagues participants of these matters.</p> <p style="text-align: right;">7</p>	<p>5-Acknowledgement  Finally on behalf of my department of metrology , I would like to express my sincere thank to APLMF whose has supported me to this training courses and particularly all lectures and organizers who have always contacts and facilitated me before and during the training courses.  Thank you for your attention.</p> <p style="text-align: right;">8</p>

<p style="text-align: center;"><b>Annex 1</b> Organization Chart Ministry of Industry, Mines and Energy</p> <pre> graph TD     DGI[Direction General of Industry] --- DOM[DOM]     DGI --- ILCC[ILCC]     DGI --- OD[Other Department] </pre>	<p style="text-align: right;">9</p>
<p>Under DOM: 1-There are five offices a-Administration and Legislation Office b-Control –Verification Office c-Technological Development of Metrology Office d-Province Management Metrology Office e-Tax-Accounting Office</p>	<p style="text-align: right;">10</p>
<p>2-Room Verification of DOM consists of a-Mass Section b-Volume Section c-Temperature Section d-Pressure – Force Section e-Dimensional Section f-Electricity Section 3-Five Regional Verification Centers (Regional) 4-Twenty-four Provincial Metrology Offices (Local)</p>	<p style="text-align: right;">11</p>
<p>Under ILCC: There are two Laboratories: a-Food Microbiology , Chemical Lab b-Scientific, Industrial Metrology Lab. Thank you very much.</p>	<p style="text-align: right;">12</p>

## Legal Metrology System on Automated Sphygmomanometers in China

Gao Yang

Beijing Institute of Metrology  
P.R.China

## 1. Working Background

- ◆ engineer of Beijing Institute of Metrology
- ◆ member of National Pressure Metrology and Technology Committee (NPMTTC)
- ◆ Metrology Administrative Department under State Council (MADSC)
- ◆ My daily work is mainly on type evaluation and verification for the automated Sphygmomanometer

## 2.1 major purposes or targets to use Automated Sphygmomanometer

- ◆ For the hospital use including Ambulatory Blood Pressure Monitor (ABPM) multi-parameter monitor with automatic-cycling non-invasive blood pressure monitoring function (NIBP);



## 2. Automated Sphygmomanometers in China

- For the home use all kinds of electronic sphygmomanometers for the public healthcare used in families



### 2.2 Manufacturers of Automated Sphygmomanometers in China

manufacturer	Product purpose and target
PHILIPS(China)	For the hospital use, multi-parameter monitors with NIBP
GE(China)	
MINDRAY (Shenzhen)	
FUKUDA(Beijing)	
CHOICE(Beijing)	
OMRON(Dalian)	For the home use, electronic sphygmomanometers
PANASONIC(Beijing)	
MICROLIFE(Chinese Taiwan)	
NISSE(Wuxi)	
Medipro(Chinese Taiwan)	
RUIKANGY(Chinese Taiwan)	
CITIZEN(Jiangmen)	
JIUAN(Tianjin)	
NURSE(Qingdao)	

### 2.3 Market of Automated Sphygmomanometers in china

- multi-parameter monitors are getting more and more widely use in hospitals of China. Mindray(40%domestic,10% global occupation) Philips (38%); GE(26%) global occupation
- As for electronic sphygmomanometers, China has become the main product base of the world, is also the biggest potential consumption market of sphygmomanometer products.

### 2.4 Accuracy class and the maximum capacity most commonly used

- Maximum permissible errors of cuff pressure indication is used to describe the main performance of sphygmomanometer for many manufacturers, which conforms to the national regulation.
- At any point of the scale range it shall be  $\pm 0.4$  kPa ( $\pm 3$  mmHg) in the first time of verifying and  $\pm 0.5$  kPa ( $\pm 4$  mmHg) for sphygmomanometers in use.
- Commonly, most of products can reach the performance requirement in the light of the statistic for Automated Sphygmomanometer National spot test every time.

### 3. Legal metrology system in China

#### 3.1 Who implements the measurement law

- In terms of Metrology Law, generally Metrology Administrative Department under State Council (MADSC) is responsible for organization, establishment and implement of measurement law.
- Definitely, the National Pressure Metrology and Technology Committee (NPMTC) is assigned to finish the task, and responsible to organize the expert in this field to constitute the regulation of automated sphygmomanometer.

#### 3.2 Description of the measurement law

- Verification regulation applies to NIBP, ABPM and all kinds of automatic or semi-automatic electronic sphygmomanometer, all those automatically determines non-invasive blood pressure with the Oscillometric method.
- It prescribes test methods for type evaluation, initial and periodic verification and specifies metrology, Environmental performance, electrical safety and EMC requirements etc.
- Its measuring range shall meet: at least including (0~34.7) kPa ( 0~260) mmHg)

#### 3.3 Initial verification and re-verification

- Verification for sphygmomanometers as clinical medical instrument is legally enforced;  
Generally, it is provincial metrology institute with qualification to perform the verification;  
The period is one year commonly.
- Verification for the electronic sphygmomanometers used at home for healthcare is not legally enforced.
- In my working field, we finish verifying about 5,000 pieces per year.

### 3.4 Type approvals

- Any sphygmomanometers newly- manufactured domestically or imported for sale on the domestic market must acquire type approvals.
- Technical agency performing the type evaluation for the imported sphygmomanometers should be examined and authorized by MADSC.
- Type approvals for those domestic can be done by the provincial metrology institute qualified.
- Type approval tests number.

### 4. About the compliance to the international standards/ recommendations for sphygmomanometers?

- Our national regulation for automated sphygmomanometer is basically equivalent to OIML R16-2 except for some alterations.

### 5. Future work in this field




- electronic sphygmomanometers and NIBP, ABPM have different dynamic ranges;
- about patient simulator of R16-2 ;
- about dynamic performance control in daily verification.

Clinical test is expensive and impractical for the periodic verification; R16-2 brings forward the notion for stability of performance without definite requirement.

We put out definite requirement of blood pressure indication value stability. By comparison of automated sphygmomanometer and patient simulator "justified" mean to realize quality control for the overall system in the periodic verification.

*The End*

Thanks a lot!

# Current Situation of Legal Metrology System in Chinese Taipei




June 27, 2008  
 by Jin-Hai Yang  
 Bureau of Standards, Metrology, and Inspection





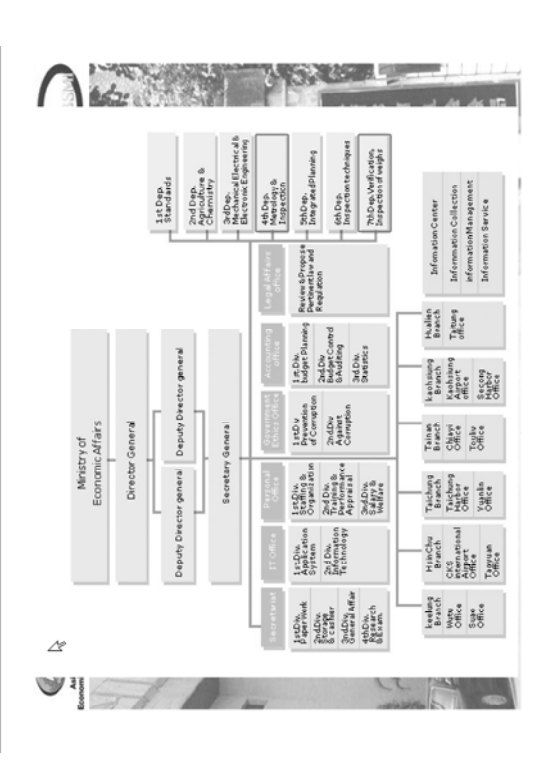
# Content

- ❖ Introduction of BSMI
- ❖ Main Task of BSMI
- ❖ Legal Metrology in Chinese Taipei
- ❖ The legal Control on Medical instruments in Chinese Taipei

# Introduction of BSMI-1

Seven Departments in Headquarter  
 ( employees : 426 )  
 Six Branches islandwide ( employees : 547 )





### Main Task of BSMI-1

- Development and promotion of Standards
- CNS Mark Certification System
- Licensing and Management of Measuring Instruments Enterprises
- Type Approval of Measuring Instruments
- Verification and Inspection of Measuring Instruments
- Calibration Service of Measuring Standards
- Inspection of Commodities
- Contracted Inspection

**Inspection of Commodities**

**Standards**

**BSMI**

**Metrology**

### Headquarters of the BSMI

Keelung Branch

Hualien Branch

Hsinchu Branch

Tai Chung Branch

Tainan Branch

Kaohsiung Branch

### Main Task of BSMI-2

- Commissioned Test and other Technical Services
- Voluntary Product Certification
- Inspection Conducted by Designated Laboratories
- Registration of Product Certification
- Management System Certification





## Legal Metrology in Chinese Taipei -2

- Licensing and Management of Measuring Instruments Enterprises
- ↳ Scope:
  - Manufacturing
  - repair
  - importation
- ↳ Legal Measuring Instruments:
  - Dimensional instruments; Weighing instruments; Force meters; Thermometers; Pressure meters (including sphygmomanometers); Volumeters; Speed meters; Calorimeters; Density meters; Concentration meters; Specific gravity meters; Watt-hour meters; Surface area meters; Lux meters; Light meters; Sound level meters; Deniermeters; and other instruments designated by the competent authority.





## Legal Metrology in Chinese Taipei -4

- Verification and Inspection
- ↳ Subject to verification:
  - Taximeters
  - Weighing instruments
  - Diaphragm gases measuring instruments
  - Water meters
  - Liquid dosage meters
  - Oil meters
  - LPG meters
  - Clinical thermometers
  - Non-invasive mechanical sphygmomanometers





## Legal Metrology in Chinese Taipei -1

- Measures of Legal Control
  - Licensing and Management of Measuring Instruments Enterprises
  - Type Approval
  - Verification and Inspection
  - Contracted Verification
  - Self-verification





## Legal Metrology in Chinese Taipei -3

- Type Approval
- ↳ Subject to Type approval:
  - Water Meters
  - Electronic Nonautomatic Weighing Instruments
  - Diaphragm Gases Measuring Instruments
  - Taximeters
- ↳ Designated Laboratory:
  - Electronics Testing Center, Chinese Taipei
  - Center for Measurement Standards
  - Aerospace Science and Technology Research Center, National Cheng Kung University





## Legal Metrology in Chinese Taipei -6



- Contracted Verification-1
  - ↳ Subject to contracted verification:
    - Electricity meters
    - Radar speedometers
    - Laser speedometers
    - Sound Level Meters
    - Illuminance Meters
    - Breath Alcohol Testers and Analyzers
    - Vehicle Exhausted Emissions Analyzers
    - Rice Grain Moisture Meters





## The legal control on Medical instruments

- Classification:
  - ↳ License
  - ↳ Manufacturers
    - ↳ Local manufacturers
    - ↳ Overseas manufacturers
- Instruments:
  - ↳ Medical Device Registration
  - ↳ Surveillance
  - ↳ Verification

## Legal Metrology in Chinese Taipei -5


- Self-verification
  - ↳ Subject to self-verification:
    - Water Meters
    - Diaphragm Gases Measuring Instruments
    - Taximeters
    - Electronic Nonautomatic Weighing Instruments
  - ↳ Qualification:
    - ISO 9000
    - ISO 17025
    - Type Approval
  - ↳ Verification facilities





## Legal Metrology in Chinese Taipei -7

- Contracted Verification-2
  - ↳ Contracted Laboratories:
    - Electronics Testing Center, Chinese Taipei
    - Center for Measurement Standards.
    - Chinese Taipei Electric Research & Testing Center



科學技術委員會  
 HONG KONG  
 TECHNOLOGY COMMISSION


## The Government of the Hong Kong China Special Administrative Region Standards and Calibration Laboratory (SCL)



科學技術委員會  
 HONG KONG  
 TECHNOLOGY COMMISSION

SCL has seven subsidiary subject laboratories:

- Direct Current/High Voltage Laboratory,
- Low Frequency Laboratory,
- Radio Frequency/Microwave Laboratory,
- Temperature/Humidity Laboratory,
- Mass Laboratory,
- Dimensional Laboratory and
- Force Laboratory.




APCC  
 Asia-Pacific  
 Economic Cooperation

APLAP  
 Asia Pacific Laboratory Accreditation Program


*Thank You*

標準及校準實驗室



科學技術委員會  
 HONG KONG  
 TECHNOLOGY COMMISSION



- maintaining the reference standards of physical measurements for Hong Kong, traceable to the International System of Units (SI).
- providing calibration services to users of measurement standards and measuring instruments to ensure accuracy and proper traceability.



**T. K. Chan**  
**Electrical and Mechanical Engineer**  
**Responsible for Mass Laboratory**  
**for**  
**mass and related measurements –**  
**mass, pressure, volume, density,**  
**hardness, torque, rotational speed**



**Automated Sphygmomanometer**  
**in Hong Kong China**

*Finger model type*  
*Arm model type*  
*Wrist model type*



**Purposes:**

- 1) Diagnostic purpose as used in clinics and hospitals
- 2) Monitoring blood pressures by patients at home

**Targets:**

- 1) Increased use of automated sphygmomanometers due to
  - (i) user-friendly as compared with mercury sphygmomanometers
  - (ii) increased users due to increase with fat people and aged people
- 2) To perform the intended function satisfactorily, i.e. measure blood pressure accurately.

**Customs and Excise Department:**

**Implementation of the measurement law**

**At this point in time there is no measurement law pertaining to sphygmomanometers.**

**Problem to implement law on automated sphygmomanometers:**

**No standard equipment available to verify the automated sphygmomanometers.**



Thank you  
for  
your attention

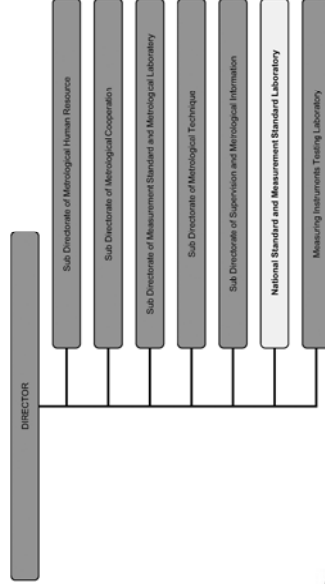
LEGAL METROLOGY SYSTEM ON  
AUTOMATED  
SPHYGMOMANOMETERS

M. HENDRO PURNOMO  
INDONESIA

Organization

- ▶ DIRECTORATE OF METROLOGY IS INSTITUTIONS THAT HANDLES LEGAL METROLOGY , UNDER THE DIRECTORATE GENERAL OF DOMESTIC TRADE, MINISTRY OF TRADE

DIRECTORATE of METROLOGY



## Experience

- ▶ 19 years in legal metrology
- ▶ Inspector of Metrology Legal

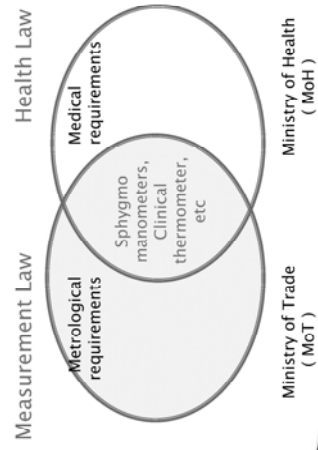
## Automated Sphygmomanometer

- ▶ Manufacture in Indonesia : 1
- ▶ The accuracy class and the maximum capacity of the most commonly used sphygmomanometer are 2 mmHg and 300mmHg (aneroid and mercury type)

## Legal Metrology system

- ▶ Metrology System in Indonesia is supported by the Measurement Law No. 2, 1981
- ▶ DIRECTORATE OF METROLOGY IS INSTITUTIONS THAT HANDLES LEGAL METROLOGY , UNDER THE DIRECTORATE GENERAL OF DOMESTIC TRADE, MINISTRY OF TRADE
- ▶ THERE ARE 58 RVOs, WHICH CARRY OUT VERIFICATION AND REVERIFICATION MEASURING INSTRUMENT

## Current position and situation





## Progress

- ▶ Developing consolidation and cooperation with Ministry of Health to undertake verification and reverification of measuring instrument
- ▶ Establishing Memorandum of Understanding between MoH and MoT concerning verification and reverification of measuring instrument

## Problems

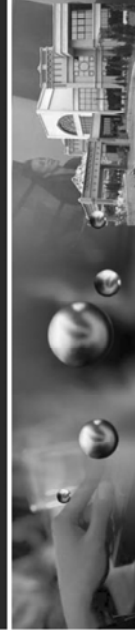
- ▶ The measurement law in Indonesia gives responsibility to DoM and RVOs in legal metrology aspect but ratio between measuring instrument and human resource in those institutions are too big, that's make services in metrology are not optimum
- ▶ Need third parties to involve in this work to increase services in metrology, but the measurement law in Indonesia do not support

Thank you

APEC/APLMF Seminars and Training Course in Legal Metrology:

**Training Course on Automated Sphygmomanometers**

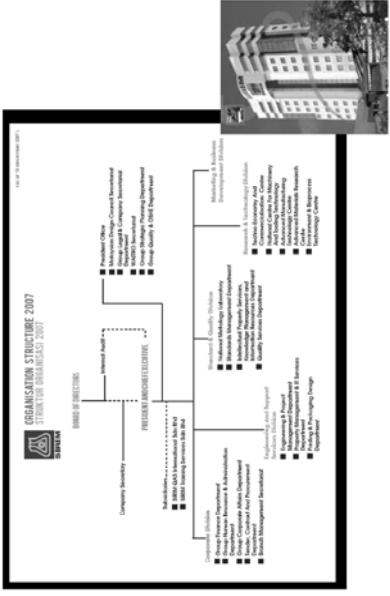
23 - 27 June 2008; Howard International House in Taipei, Chinese Taipei



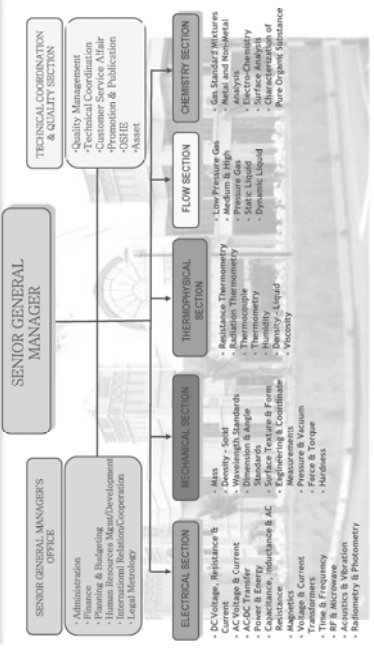
Dr. Wan Abd Malik Wan Mohamed  
Senior Metrologist  
National Metrology Laboratory  
SIRIM Berhad, MALAYSIA



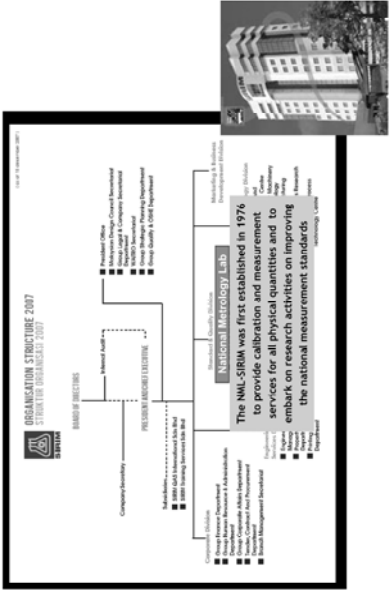
Organizational Structure Of SIRIM Berhad 1. Self Introduction



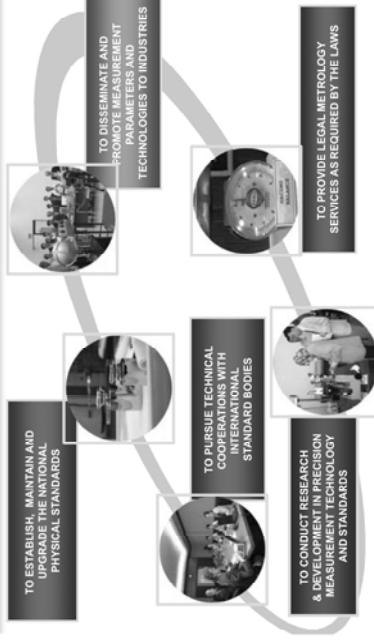
Organizational Structure of NML-SIRIM 1. Self Introduction



Organizational Structure Of SIRIM Berhad 1. Self Introduction



NML's Core Activities 1. Self Introduction



<p><b>2. Automated Sphygmomanometers in Malaysia</b></p> <p><b>Q 2.1:</b> Major Purposes or Targets to use Automated Sphygmomanometers</p> <ul style="list-style-type: none"> <li>As a blood pressure measuring device, commonly used by hospitals and clinics</li> </ul> <p><b>Q 2.2:</b> No. of manufacturers of Automated Sphygmomanometers in Malaysia?</p> <ul style="list-style-type: none"> <li>Nil</li> </ul>	<p><b>2. Automated Sphygmomanometers in Malaysia</b></p> <p><b>Q 2.3:</b> No. of production of Automated Sphygmomanometers in Malaysia?</p> <ul style="list-style-type: none"> <li>Nil</li> </ul> <p><b>Q 2.4:</b> Accuracy class &amp; Maximum capacity commonly used</p> <ul style="list-style-type: none"> <li>No information available</li> </ul>
<p><b>3. Legal Metrology System in Malaysia</b></p> <p><b>Q 3.1 :</b> Who implements the measurement law ?</p> <p><b>WEIGHTS AND MEASURES ACT, 1972 (WMA 72)</b></p> <ul style="list-style-type: none"> <li>Regulated and governed by Enforcement Division under the Ministry of Domestic Trade and Consumers Affairs (MTDCA).</li> <li>Section 14 of WMA72 requires mandatory verification and re-verification for all weighing and measuring instruments used for trade.</li> <li>Enforcement of the Act were initially been carried out by Weights and Measures Inspector under the Enforcement Division.</li> <li>From April 2005, the service were privatized and done by a company, namely Metrology Corporation Malaysia (MCM). Weights and Measures Inspector only enforces the WMA and oversee the company performance.</li> <li>Each standard used to perform the verification is traceable to national standards maintained by NML-SIRIM.</li> </ul>	<p><b>3. Legal Metrology System in Malaysia</b></p> <p><b>Q 3.1 :</b> Who implements the measurement law ?</p> <p><b>WEIGHTS AND MEASURES ACT, 1972 (WMA 72)</b></p> <p>Measuring instruments for medical use such as clinical thermometers, sphygmomanometers, haemocytometer dilution pipettes, etc are not subject to any regulatory control at the moment. Pattern approval and verification of such instruments are as such not legally enforced.</p> <p>The Ministry of Health however is currently drafting an Act on Medical Devices which will emphasize on the need for all medical devices procured to meet with certain standards.</p> <p>Common Type of Sphygmomanometer used by medical practitioners in Malaysia :</p> <ul style="list-style-type: none"> <li>(i). Mercury Manometer</li> <li>(ii) Elastic Sensing Element (e.g Dial Type)</li> </ul>

### 3. Legal Metrology System in Malaysia

#### WEIGHTS AND MEASURES ACT 1972 (WMA 72)

Main legislation regulating weights, measures and measuring instruments in Malaysia. The Act is enforced by the Ministry of Domestic Trade and Consumer Affairs.

### 3. Automated Sphygmomanometers in Malaysia

Q 3.2: Types and ranges covered by the measurement law

- Nil

Q 3.3: Initial verification & re-verification required?

- No

Q 3.4: Type approval required?

- No

### 3. Legal Metrology System in Malaysia

The main provisions of the Act are briefly described as below:

1. The Act prescribes the use of the International System of Units (S.I.) as the only legal units to be used in Malaysia.
2. It provides for the appointment of a Custodian of Weights and Measures to realise, establish and maintain national measurement standards to provide traceability of measurement to verification standards used for legal enforcement.  
The NML-SIRIM carries out the duties and responsibilities of the Custodian.
3. A system of metrological control of measuring instruments for trade use is regulated under this Act. It is effected through the requirement for pattern approval of new instruments by the Custodian and the verification and re-verification of the measuring instruments by the Inspectors of Weights and Measures.

### 4. Current Situation in Malaysia

Current Direction

- ↘ Joined the International Organization of Legal Metrology (OIML) as a corresponding member in 1989 and has since gradually adopted a number of OIML international recommendations and guidelines for its pattern evaluation and verification procedures.
- ↘ A member of the Asia Pacific Legal Metrology Forum and has participated in a number of training courses, workshops, meetings since its inception in November 1994.
- ↘ Will continue to maintain liaison and cooperation with regional and international organizations to keep abreast with the developments in legal metrology in its effort to achieve harmonization, mutual recognition and upgrading of technical competence and capability.

#### 4. Current Situation in Malaysia

##### Future Direction

- It is foreseen that with the Medical Devices Act coming into force in the near future some regulatory control on sphygmomanometers including other medical instruments will be enforced. The adoption of OIML recommendations in the technical regulations is envisaged.

#### 5. Other requirements from Malaysia

- Malaysia looks forward to more training opportunities to upgrade the technical competence and knowledge of legal metrology personnel.
- Funding support from donor countries and funding agencies is very much appreciated.

Thank You  
FOR YOUR ATTENTION



### APEC/APLMF Seminars and Training Courses in Legal Metrology Training Course on Automated Sphygmomanometers (CTI-12/2008T)

June 23 - 27, 2008

Howard International House in Taipei,  
Chinese Taipei

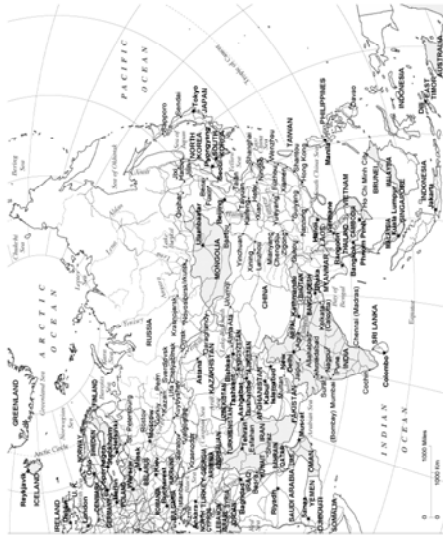
Maryness I. Salazar  
National Metrology Laboratory (NML)  
Industrial Technology Development Institute (ITDI)  
Department of Science and Technology (DOST)  
Metrology Bldg. DOST Compound, Gen. Santos Avenue  
Bicutan, Taguig City, Metro Manila, Philippines

1

### Outline of Presentation

- About the Philippines
- Department Of Science and Technology (DOST) Organizational Chart
- Industrial Technology Development Institute (ITDI) Organizational Chart
- Brief History of ITDI
- About ITDI
- National Metrology Laboratory (NML) Organizational Chart
- About NML
- Participant
- Automated Sphygmomanometer in the Philippines
- Philippine Laws on Weights and Measures
- Current Situation
- Future Plans

2

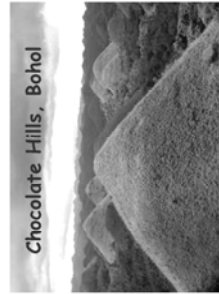


3



## About The Philippines

Official name : Republic of the Philippines  
 Capital : Manila  
 Language : Filipino; English is widely spoken and taught in schools  
 Population : about 90 million  
 Religion : 92 percent Christian; 80% Roman Catholic  
 Area : 7,107 islands; 300,000 sq km  
 17 Regions, 81 provinces and 136 cities



Chocolate Hills, Bohol



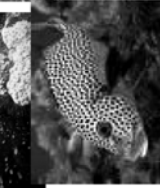
Mt. Mayon, Bicol

5



## About The Philippines

National anthem : "Lupang Hinirang."  
 Government : Constitutional democracy with two legislative houses  
 Chief of state : President  
 Head of Government : President  
 Currency : Philippine Peso  
 Weights and measures : Metric system



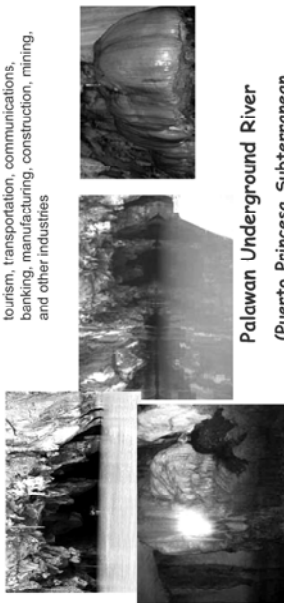
Tubbataha Reef (Palawan)

6

## About The Philippines

**Climate**  
 : wet or rainy season (June – Oct.)  
 : cool, dry season (Nov. – Feb.)  
 : hot, dry season (Mar. – May)

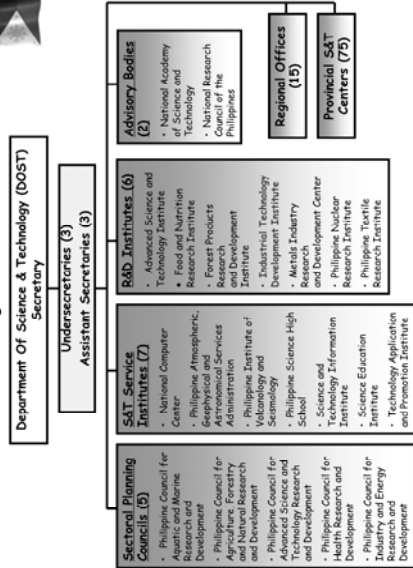
**Industry**  
 : Farming, rice, sugar, coconuts, pineapples, forestry, fishing, education, health, trade, tourism, transportation, communications, banking, manufacturing, construction, mining, and other industries



**Palawan Underground River**  
 (Puerto Princesa Subterranean River National Park)

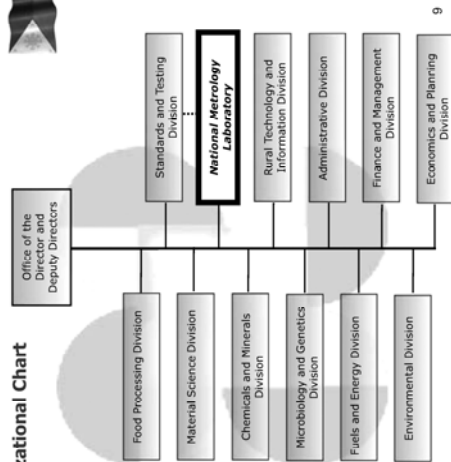
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## DOST Organizational Chart



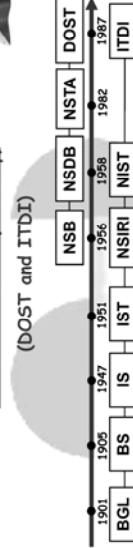
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## ITDI Organizational Chart



9

## Historical Timeline (Summary)



BGL - Bureau of Government Laboratories  
 BS - Bureau of Science  
 IS - Institute of Science  
 IST - Institute of Science and Technology  
 NSIRI - National Scientific and Industrial Research Institute  
 NIST - National Institute of Science and Technology  
 ITDI - Industrial Technology Development Institute  
 NSB - National Science Board  
 NSDB - National Science Development Board  
 NSTA - National Science and Technology Authority  
 DOST - Department Of Science and Technology

10



### Brief History of the ITDI

• **1987 to Present** - The NSTA was reorganized into the Department of Science and Technology (DOST) by virtue of Executive Order Number 128 dated 30 January 1987.

Under this reorganization, NIST was renamed **Industrial Technology Development Institute (ITDI)** and remained one of the R&D institutes under the DOST.

**ITDI is mandated by Batas Pambansa Bilang 8 (An Act Defining the Metric System and Its Units, Providing for its Implementation and For Other Purposes)** under section 6 to establish and maintain the national standards for the SI units of quantities such as mass, length, time, electric current, thermodynamic temperature, pressure and luminous intensity; and the Science Act of 1958, pertaining to the test and analyses of products and materials and the calibration of weights and measures.

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The Industrial Technology Development Institute or ITDI is one of the research and development institutes (RDIs) under the Department of Science and Technology (DOST). By virtue of Executive Order No. 128 dated January 30, 1987, ITDI is mandated to render variety of services to local industries. It is the flagship agency of DOST generating a large pool of technologies while providing technical services to industry.

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### Industrial Technology Development Institute (ITDI)



#### Vision:

Excellence in propelling development as provider of technologies and services for the industry

#### Mission:

To make local industries globally competitive

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ITDI provides various services or interventions to industry to help modernize the production sector and improve their productivity such as:

- » Research and development
- » Technology transfer and contract projects
- » Test and analyses
- » Food engineering services
- » Metrology
- » Process engineering
- » Post harvest handling/near farm processing/packaging
- » Packaging research and development
- » Cleaner production
- » Enterprise module
- » Energy audit
- » Industry training and skills development
- » Scale-up production facilities
- » Technical information and promotion
- » Library service.

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## National Metrology Laboratory



**VISION :**  
NML of internationally recognized competence and nationally sought for traceability of calibrations.

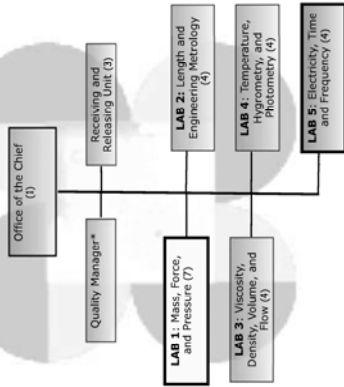


**MISSION :**  
We shall establish and disseminate national standards of units and measurements to calibration laboratories and other sectors to provide international traceability to measurements done in the country. We shall do this by reliably conducting calibration and measurements at accuracy levels appropriate to the needs of the clients.

As national custodian for weights and measures, ITDI's program on metrology responds to the call for accuracy and traceability in the units of measurement (e.g. mass, length, volume) for product standardization, higher quality and competitiveness of local products, and protection of the consumers.



### NML Organizational Chart



The NML is equipped with high precision standards and measuring instruments for use in its calibration and measurement activities. National standards are regularly calibrated abroad to ensure international traceability.

The NML also regularly participates in international intercomparison of measurement standards to further enhance confidence in its measurement results. Personnel qualification is kept up to date through attendance in training programs, seminar and workshops conducted by the international metrology community.



The National Measurement Laboratory of the Philippines (NML) is the organization responsible for establishing and maintaining national physical standards for basic and derived quantities such as mass, length, temperature, time interval, voltage and resistance. Dissemination of standard values to users at the best uncertainty levels attainable is performed through the calibration and measurement services offered by the Laboratory.



## INTERNATIONAL LINKAGES

The Philippines through NML-ITDI is a full member of the Asia Pacific Metrology Program (APMP) and Asia Pacific Legal Metrology Forum (APLMF) and an Associate Member of the General Conference On Weights and Measures (CGPM). It is also a signatory to the Global Mutual Recognition Arrangement (MRA) among national metrology institutes.

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NML has five major labs, which keep and maintain the national standards in the different fields of metrology. Each of these laboratories disseminates the standard units of measurement through our calibration services.

### 1. Lab 1 – Mass, Force and Pressure

Lab 1 maintains two 1 kg stainless steel cylinders as the national standard for mass and it's traceable to NIMT, Thailand and KRISS, Korea. NML also maintain sets of 1 mg to 20 kg weights in turn are used to calibrate against the 1 kg national mass standards. These sets of weights in turn are used to calibrate other mass standards, balances and are also used in measurement of related quantities such as force, pressure, volume and density.

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### 2. Lab 2 – Length and Engineering Metrology

Lab 2 maintain line end standards. Its meter bar and gage blocks are calibrated at NMI, Australia and SPRING, Singapore to maintain traceability to international standards.

### 3. Lab 3 – Viscosity, Density, Volume and Flow

Lab 3 maintains standards to calibrate volumetric measures, hydrometers for measuring liquid densities, viscosity of oil, and moisture measurement. Its volume measurements use the gravimetric method and are traceable to the 1 kg national standard.

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### 4. Lab 4 – Thermometry, Hygrometry and Photometry

Lab 4 maintains fixed-point cell to derive the International Temperature Scale (ITS90). Sets of temperature measuring instruments are calibrated against these fixed-point cells and are used as reference and working standards.

### 5. Lab 5 – Electricity, Time and Frequency

Lab 5 maintains the national standards for dc voltage, ac-dc difference and resistance and are traceable to SPRING, Singapore, NIMT, Thailand, and KRISS, Korea. Lab 5 maintains the country's primary standard for the time interval based on atomic properties (Cesium Beam Frequency Standard) and is continuously compared with the national frequency standard of NMIA, Australia through GPS Common-View (CV) method.

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## Major Projects

### 1. GAPS Identification

A nationwide comprehensive survey of the manufacturing, processing and service industries; R&D organizations and schools; municipal inspector's office; and other institutions was conducted and determined their calibration needs.

### 2. Assistance to Laboratories Outside the DOST System

Under this project, in-house calibration laboratories, commercial laboratories and municipal inspection laboratories were continually targeted for improvement. Manufacturing laboratories were encouraged to have small calibration laboratories of their own to calibrate their own measuring instruments. The local government unit on the other hand will continue to exercise their regulatory power with respect to fair trade by conducting verification test of weights and measures. Seminars, trainings and consultancy services are continuously given to help them.

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### 3. DOST Regional Calibration Laboratories

Existing DOST Regional Calibration centers are, from time to time upgraded to meet the ever growing demand for calibration services while new ones will be established in regions where these services are critically needed.

### 4. DOST Upgrading of Laboratories in the National Capital Region

a. *Philippine Atmospheric, Geophysical and Astronomical Services Administration (PAG-ASA)*, DOST – PAG-ASA has the capabilities for maintaining the epoch time (time of the day) for the country. A Rubidium-Based Time Standard was acquired and it is continuously compared to NML-ITDI and other NMIs through GPS-Common View (CV) method. A cooperative work with NML-ITDI maintains the traceability of this facility to international standards.

b. *Philippine Nuclear Research Institute (PNRI)*, DOST – In the area of ionizing radiation, ITDI delegated its national standards keeping function to PNRI. Among health and safety related functions of PNRI is the dissemination of standards on radiation through calibration and measurements on survey meters, area monitors, personnel dosimeters, environmental monitors and contamination monitoring instruments.

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### 4. DOST Upgrading of Laboratories in the National Capital Region (cont...)

c. *National Metrology Laboratory (NML), ITDI, DOST* – The NML-ITDI shall continue to take charge of the establishment, maintenance, and dissemination of the national standards of units of measurement.

NML developed an interface and program for the semi-automatic operation of a 1 kg mass comparator. It also acquired a 10 kg high resolution mass comparator to improve the build-up, and build down from the 1 kg national standard. OJML class E1 masses were also acquired. Most of the calibration in the Electricity laboratory were already automated through software programs developed by the lab's staff through GPIB, serial and parallel port control. Computer system (purchased under a Japan MITI project) and networking hardware were acquired to improve management of information. Equipment and instruments for the Photometry section were delivered and installed, and experts from China and NMISA, South Africa conducted series of trainings and visits.

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### 5. Metrology Training Center

The Metrology Training Center conducts on-site trainings and in-house trainings on metrology. On-site trainings are conducted at the premises of the requesting company while in-house trainings are conducted at NML-ITDI. This project has served over 500 participants from various sectors such as the academe, private calibration laboratories, local government units (LGUs), food manufacturers, traders of agricultural products, manufacturing industries, etc.

### 6. Laboratory Proficiency Evaluation Program

Interlaboratory comparisons in field of mass, length, volume, thermometry, pressure and electricity were conducted. These intercomparisons involved mostly of private calibration laboratories and DOST regional calibration laboratories. Also intercomparisons among semiconductor and electronic companies was also done. Moreover, proficiency of market inspectors nationwide was also tested.

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### 7. NML-ITDI ISO/IEC 17025 Accreditation

The NML is currently preparing for ISO/IEC 17025 Accreditation. All major laboratories are being primed for accreditation with specific concentration for two laboratories, LAB 1 (Mass, Force and Pressure) and LAB 4 (Thermometry, Hygrometry and Photometry). These two major laboratories are foremost in the plans of NML accreditation with the other major laboratories to follow suit.

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### • About the participant

- **Maryness I. Salazar**
  - Science Research Specialist
  - Lab 1: Mass, Force and Pressure Laboratory
    - Performs measurements and calibrations specifically on pressure gauges, pressure calibrators, analog and mercurial sphygmomanometers.
    - Maintain and conducts functional tests on standards of the laboratory.
    - Maintains laboratory's good condition.
    - Responsible for preparing quality and technical documents for ISO 17025 accreditation specially in pressure section.

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### Automated Sphygmomanometers in the Philippines

- Major purpose of using automated sphygmomanometers is for monitoring blood pressures, this however is practiced usually on households since it is easier to use compared to the aneroid or mercurial sphygmomanometers where expertise is required before use. This is important for health reasons specially with high rates of death caused by heart failures.
- Target users are the hospitals since they are the main user of these medical equipment. Mercurial and/or aneroid sphygmomanometers are still widely used since these can be calibrated and verification procedures are available at NML-ITDI and at other test or calibration laboratories.

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### Automated Sphygmomanometers in the Philippines

- There is no known manufacturer of these.
- Availability to the public is vast which is usually imported.
- Common automated sphygmomanometers uses the unit mmHg. Usually it can accommodate up to 260mmHg of pumped pressure. Accuracy classes are not given special attention since the use is not really encouraged due to unavailability of verification/calibration procedures.

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## Philippine Laws on Weights and Measures

### Republic Act No. 9236 (National Metrology Act of 2003)

- An act establishing a National Measurement Infrastructure System (NMIS) providing measurement standards that are internationally traceable and consistent with the Meter Convention.
- It shall cover units of measurement, measuring instruments, their application and metrological controls, establishment of a laboratory accreditation system, and a system of appropriate penalties.
- With this Act, a National Metrology Board is created to be chaired by the Secretary of DOST with members from other government agencies. Representative from the business sector, professional metrology association and the academe shall be appointed.

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## Philippine Laws on Weights and Measures

### ...(continued) Republic Act No. 9236 (National Metrology Act of 2003)

- With this Act, a National Metrology Board is created to be chaired by the Secretary of DOST and it shall be composed of the Secretaries of the following agencies or their duly authorized representatives with the rank of Undersecretary:
  - a) Department of Trade and Industry (DTI)
  - b) Department of Transportation and Communications (DOTC)
  - c) Department of Health (DOH)
  - d) Department of Interior and Local Government (DILG)
  - e) Department of Justice (DOJ)
  - f) Department of Environmental and Natural Resources (DENR)
  - g) Department of Agriculture (DA)
- One (1) representative from the business sector, the professional metrology association and the academe, shall be appointed by the President upon the recommendation of the Secretary of the DOST.

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## Philippine Laws on Weights and Measures

### ...(continued) Republic Act No. 9236 (National Metrology Act of 2003)

- The ITDI is mandated to serve as the Board's Secretariat and the National Metrology Laboratory (NML) as the institute's laboratory arm shall carry out the technical, calibration and laboratory functions to effectively implement the provisions of this Act.
- Thus, with this act, an important and critical role of NML in the development of National Standards is greatly anticipated.

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## Philippine Laws on Weights and Measures

### ...(continued) Republic Act No. 9236 (National Metrology Act of 2003)

- The Laboratory accreditation body shall establish a national standard for accreditation, testing and/or calibration laboratories following ISO/IEC GUIDE 58 "Calibration and testing laboratory accreditation systems – General requirements for operation and recognition" and ISO/IEC 17025 and other relevant International guidelines and standards.

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## Philippine Laws on Weights and Measures

...**(continued) Republic Act No. 9236 (National Metrology Act of 2003)**

- The Laboratory accreditation body shall have the following government agencies of offices as members:

- a) Department of Trade and Industry (DTI)
- b) Department Science and Technology (DOST)
- c) Bureau of Food and Drugs (BFAD)
- d) Fertilizer and Pesticide Authority (FPA)
- e) Environment Management Bureau (EMB)
- f) National Telecommunications Commission (NTC)
- g) Department of Energy (DOE)
- h) Bureau of Health Devices and Technology (BHDT)
- i) Department of National Defense (DND)

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## On Automated Sphygmomanometer

- There is no measurement law governing the use of automated sphygmomanometers yet. Moreover, the use of mercurial thermometers and sphygmomanometers are being discouraged due to health hazards it may cause.
- Verification of these instruments are usually described by manufacturers, however, re-verification will be required by DOH and technical procedure of this will usually be assigned to NML of ITDI-DOST.

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## Current Situation

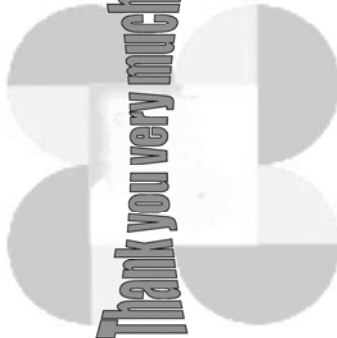
- International standards/recommendations are being followed by NML-ITDI. They are on the process of acquiring ISO 17025 accreditation from an international accrediting body.
- Calibration of aneroid and mercurial sphygmomanometers were done in NML by comparison with a pressure balance with a divider. Unfortunately at present, it was found that the divider needs overhauling (repair), thus a suspension of the service offered.
- OIML R16-2 was earlier studied and the possibility of setting up the verification procedure are on future plans since the priority were set on the accreditation of the Mass and Thermometry Laboratory. Also, the possibility of having the Pressure Laboratory be accredited on gauge pressure measurements are being prepared.
- Moreover, the increasing demand for verification procedure on automated sphygmomanometers is one of the things that must be considered and developed as soon as possible.

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## Future Plans

- Having trained staff for verification of sphygmomanometers, setting up would be easier and transfer of knowledge to other staff, old or newly hired will be done to answer the increasing demand of the general public.
- The development of the verification set-up and procedure for automated sphygmomanometers were earlier discussed in the laboratory. However, due to limited resources (budget), it was not fully developed and realized.
- Human resources is also one of the problem sought to be solved since the laboratory is already under-staffed and if be given another responsibility like setting up this facility, it would mean additional workload for the present staff, thus prioritization was opted instead of accommodating everything all at once.

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**APEC/APLMF Seminars and Training Courses in Legal Metrology**  
(CTI-12/2008T)

Seminar on Sphygmomanometers

23-27 June, 2008

Howard International House, Chinese Taipei

**Introduction**

- Name: Mr. Joe Panga
- Position: Metrologist (Legal)
- Division: Metrology (MSL)
- Organization: Papua New Guinea National Institute of Standards Industrial Technology (PNG NISIT)
- Economy: Papua New Guinea

**PNG NISIT**

- Established by an Act of Parliament, NISIT Act, 1993
- The national agency responsible for spearheading Standards and Conformance in PNG
- Operates four (4) Technical Divisions (at present)
  - Technical Standards
  - Laboratory Accreditation
  - Certification
  - Metrology

<p style="text-align: center;"><b><u>Metrology Division</u></b></p> <ul style="list-style-type: none"> <li>• Is in charge of Physical and Legal Metrology Programs in PNG</li> <li>• Operates the accredited Measurement Standards Laboratory (MSL)</li> <li>• Provides Calibration &amp; Verification Services</li> </ul>	<p style="text-align: center;"><b><u>Measurement Standards Laboratory (MSL)</u></b></p> <ul style="list-style-type: none"> <li>• Maintains the National Measurement System</li> <li>• Disseminates the National Measurement Standards</li> <li>• The only accredited Calibration &amp; Measurement Laboratory in PNG (accredited by NATA, Australia)</li> <li>• Participates in Proficiency Testing</li> <li>• Custodian of the National Primary Standards (PNG Measurement Standards)</li> </ul>
<p style="text-align: center;"><b><u>MSL Scope of Responsibilities (P1)</u></b></p> <ul style="list-style-type: none"> <li>• MSL responsibilities are covered under the NISIT Act, 1993.</li> <li>• Part (vi) Units and standards of measurement</li> <li>• Sections 33 -Application of this part</li> <li>• Section 34 -Papua New Guinea legal units of measurements</li> <li>• Section 35 -Contracts</li> <li>• Section 36- Conversion factors</li> </ul>	<p style="text-align: center;"><b><u>MSL Scope of Responsibilities (P2)</u></b></p> <ul style="list-style-type: none"> <li>• Section 37- Standards of measurements</li> <li>• Section 38- Verification of standards of measurement</li> <li>• Section 39- Measurements to be ascertained in accordance with appropriate standards of measurement</li> <li>• Section 40- Verification of Means of measurement</li> </ul>



**Other Legislative Instruments that Empower the field (Medical Measurement)**

- Trade Measurement Act
- PNG Power Act
- Public Health Act

**MSL Services (Current)**

Calibration and Verification Services provided are not directly linked but within the scope of medical instruments

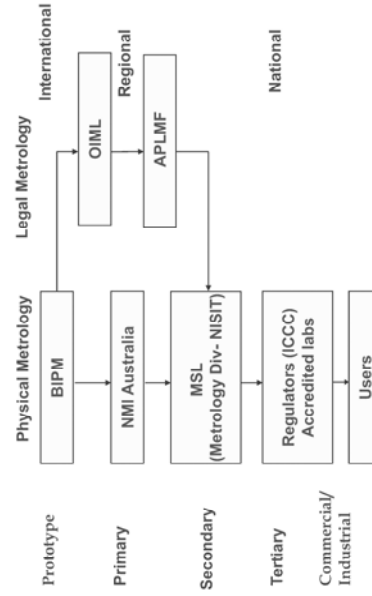
- Temperature sensors (Clinical thermometers)

**MSL Services (Future Areas)**

Calibration and Verification Services which are being looked at:

- Electrical (currently researched and at the establishment stage)
- Time and Frequency (currently researched)
- Medical (possibility)

**Measurement Traceability maintained by MSL**



<p style="text-align: center;"><b><u>General Overview of Sphygmomanometers In PNG</u></b></p> <p>Organization(s) that regulate all medical instruments in PNG are:</p> <ul style="list-style-type: none"> <li>• <b>Department of Health (Biomedical Engineering Unit)</b> Installation, Service delivery and Regulatory functions, i.e., maintenance, verification.</li> <li>• <b>ICCC</b> Consumer rights and protection</li> <li>• <b>NISIT</b> For standards and Conformance</li> </ul>	<p style="text-align: center;"><b><u>Department of Health (DoH) and Sphygmomanometers In PNG</u></b></p> <ul style="list-style-type: none"> <li>• Regulate the machine in terms of purchasing, importation, installation, usage and installation</li> <li>• Ensures that Sphygmomanometers and other medical devices follow the AS/NZ3551:2004 Technical management programs for medical devices</li> <li>• Initial verification is done upon installation, re-verification is not done as planned</li> <li>• Sphygmomanometers used in the country are mostly donated – lack of proper funding</li> <li>• Does not cover calibration and verification of medical devices comprehensively</li> </ul>
<p style="text-align: center;"><b><u>NISIT and Sphygmomanometers In PNG</u></b></p> <ul style="list-style-type: none"> <li>• MSL is not providing this services to date</li> <li>• Possibility to look into providing calibration and verification services for these instruments</li> </ul>	<p style="text-align: center;"><b><u>Way Forward</u></b></p> <ul style="list-style-type: none"> <li>• This Training/Seminar to provide a starting point to NISIT to spearhead this agenda back in PNG (at seminar)</li> <li>• NISIT to initiate dialogue with DoH in establishing a legal framework that can support this activities in the medical field</li> </ul>

**END**

**Thank you for your Attention**

APEC/APLMF Seminars and Training Courses in Legal Metrology  
Training Course on Automated Sphygmomanometers  
23 - 27 June 2008, Chinese Taipei

**Automated Sphygmomanometers**  
- Singapore

## Legal Metrology System

Enhance & Assure Quality of Products and Services  
Facilitate Trade

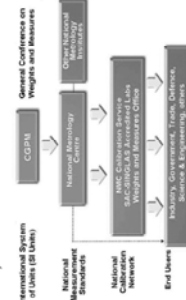
### STANDARDS AND CONFORMANCE FRAMEWORK



SPRING is the *National Standards Body & National Accreditation Body*  
NIMC, A\*Star, is the *National Metrology Authority*  
\*, private sector

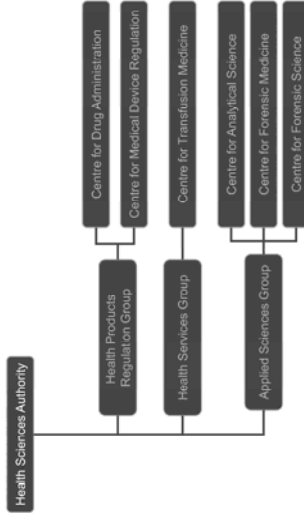
## Legal Metrology System

- National Metrology Centre, Agency for Science, Technology and Research (A\*STAR)
  - National measurement authority, custodian of the national physical measurement standards.
  - responsible for establishing and maintaining the nation's highest level physical measurement standards which can be traced to the International System of Units (SI) upheld in the General Conference of Weights and Measures (CGPM)



## Health Sciences Authority

- Statutory board of the Singapore Ministry of Health



## Status of Automated Sphygmomanometers

- No manufacturing plant of automated sphygmomanometers
- Automated sphygmomanometers is currently not regulated

## Regulation of Automated Sphygmomanometers

- Automated Sphygmomanometer is a medical device
  - Will be subjected to control under a new regulation: Health Products (Medical Devices) Regulations
- Regulation is based on regulatory principles of Global Harmonization Task Force (GHTF)

## Global Harmonization Task Force



An international forum for medical device regulators and medical device trade associations

### Objective

To develop harmonised principles relating to the regulation of medical devices

## Definition of Medical Device

**“Medical device”** means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

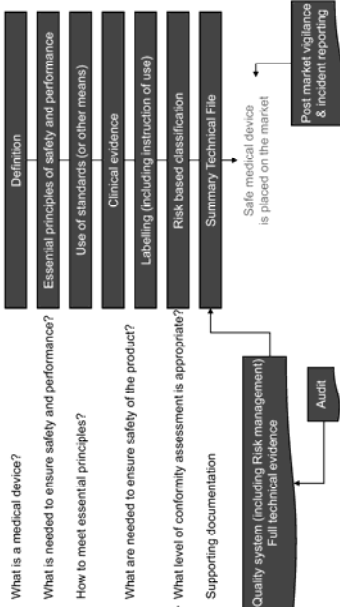
a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- 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 or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body;

and

b) 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 intended function by such means.

## Areas of Regulatory Concern



## Essential Principles of Safety and Performance

**General Requirements** - The apparatus must be designed and manufactured so that it is safe during use in its normal operating environment, under its normal conditions and for the lifetime of the device.

**Requirements regarding design and construction** - The following are specific requirements which need addressing:

- Chemical/physical and biological properties
- Infection and microbial contamination
- Construction and environmental properties
- Devices with a measuring function
- Protection against radiation
- Electrical safety
- Labelling and instructions

## How to meet essential principles

- GHTF/SG1/N044:2008 Roles of Standards in the Assessment of Medical Devices
- International consensus standards are a tool for harmonizing regulatory processes to assure the safety, quality and performance of medical devices
- encourage manufacturers to conform with appropriate international standards as a method of demonstrating conformity with the GHTF harmonized Essential Principles

APEC/APLMIF Seminars and Training Courses in Legal Metrology  
Training Course on Automated Sphygmomanometers  
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## Automated Sphygmomanometers - Thailand

Thank you

### *Self introduction*

- *1.1 Explain about my organization and department*
- My name is Peerayuth Chamrak. I work in Northern Weights and Measures, Bureau of Weights and Measures Department of Internal Trade, Ministry of Commerce.
- Bureau of Weights and Measures is an organization responsible for supervising manufactures, importers, repairers, and seller of weighing and measuring instruments including weighing or measuring service providers; the functions of the Bureau include establishing the standards of weighing and measuring instruments, providing verification services for weighing and measuring instruments, prescribing the displaying methods of net content of packaged goods, and inspecting the net content of packaged goods for the impartiality of the commodity transaction.

- *1.2 Explain my professional experience*
- My professional experience is responsible for verification of weighing and measuring instruments which are manufactured, repaired, and imported and supervision of the uses of weighing and measuring instruments to ensure that no taking advantage of abuse of such instruments takes place. I will go to inspect and examine the conditions, properties, and accuracy of weighing and measuring instruments used at markets, stores, and purchasing places and make public understanding regarding a correct means on the use of weighing and measuring instruments.

## *Automated Sphygmomanometers in Thailand*

- 2.1 What are the major purposes or targets to use **Automated Sphygmomanometers**?  
For Public Health.
- 2.2 How many manufactures of **Automated sphygmomanometers** are there in Thailand.  
None.
- 2.3 Approximate total number of production of **Automated Sphygmomanometers**.  
100,000
- 2.4 What are the accuracy class and the maximum capacity, which are most commonly used?  
N/A

## *Legal metrology in Thailand*

- 3.1 Who implements the measurement law.  
Government.
- 3.2 Describe briefly the types of **Automated Sphygmomanometers** and its measuring range, which are covered by the measurement law.  
N/A
- 3.3 Are initial verification and re- verification required? If yes, which organization performs the verification? How long is the re- verification period? How much verification is performed in a year? Are they increasing or decreasing?  
N/A
- 3.4 Are type approvals required? If yes, which organization performs the type approvals? How many type approval tests are performed in a year?  
N/A

*Explain current situation in Thailand about the compliance to the international standards/recommendations, such as OIML R 16-2? or Related ISO/IEC standards for Sphygmomanometers?*  
N/A

Thank you

