

## Foreword

This booklet is one of the outcomes of the APEC Seminars and Training Courses in Legal Metrology titled “Training Course on Automated Sphygmomanometers” which was held on June 23-27, 2008 at the Howard International House in Taipei, Chinese Taipei.

This course, as a follow-up of “Seminar on Sphygmomanometers” conducted in August 2004 and July 2006 in Chinese Taipei, was organized by the Asia-Pacific Legal Metrology Forum (APLMF) and Bureau of Standards, Metrology and Inspection (BSMI) with a support fund of APEC Trade and Investment Liberalization and Facilitation (APEC-TILF) program (CTI-12/2008T). It was also supported by: (1) The Center for Measurement Standards (CMS), The Industrial Technology Research Institute (ITRI); (2) Electronic Testing Center (ETC), Chinese Taipei; (3) Physikalisch-Technische Bundesanstalt (PTB), Germany. Having this result, I would like to extend my sincere gratitude to Dr. Jay San Chen and all supporting staffs of BSMI, Mr. Chen-Chuan Hung of CMS, Mr. Zheng Minfu of ETC, Dr. Hsiau-Wen Huang of Cheng Hsin Rehabilitation Medical Center, Dr. Stephan Mieke of PTB Germany. Also, special thanks should be extended to the APEC Secretariat for their great contributions.

We have conducted the surveys among the APEC member economies concerning seminar and training programs in legal metrology to find their needs as well as possible resources available in the region. The survey shows that there is a strong need for a training course or seminar on medical measurements in legal metrology. Medical measurement has become a great interest of the member economies due to the extended average life expectancy. Plus, medical measuring instruments, such as sphygmomanometers are getting widely used not only in medical facilities but also at home. In particular, portable measuring devices are expected to be widely used in near future. As a matter of fact, there is one big problem concerning the reliability and mutual acceptability of measured results by such instruments. Now, standards and regulations for such instruments need to be harmonized among the APEC/APLMF economies. However, our survey also shows that there are not enough resources for developing economies to ensure reliability on medical instruments.

Main target of this training course was to assist APEC members to develop common understanding about the current standards and regulations on automated sphygmomanometers and thus meet the APEC objective to harmonize metrology legislation with OIML international recommendations. The actual contents of the training course were composed of Clinical Investigations for Automated Sphygmomanometers; European and German Requirements for Sphygmomanometers; A comparison of OIMLR16-2 (2002) and the draft of IEC 80601-2-30; OIML R 16-2 “Non-invasive Sphygmomanometer; Sphygmomanometers Marketing Management in Chinese Taipei; The Accuracy of Non Invasive Automated Sphygmomanometers and technical visits to ETC.

In this view, this training course not only meet the highly demand in the APEC / APLMF member economies, but also provided an important opportunity to the experts in the Asia-Pacific region to share the present situation on development of automated sphygmomanometer. I would like to say that this is certainly a valuable step to promote the establishment and development of metrological infrastructure for medical measurement in the developing economies.

I am really pleased to have this fruitful outcome from the training course and again express my deeply appreciate to the APEC Secretariat's generosity in contributing to the development in legal metrology among the APLMF member economies.

July 22, 2008



Mr. Pu Changcheng  
APLMF President

## Summary Report

Mercury type blood pressure meters have been in use for about 100 years and have become reliable equipment for measuring blood pressure. However, there is a serious problem when the meter breaks and the mercury spills. It is expensive and time-consuming to clean up the spill. Besides, exposure to mercury causes serious harms to the central nervous system of human body. Therefore, in order to reduce mercury levels in the environment and exposure to this hazardous substance, this type of blood pressure meter is becoming unwelcome and even is banned to be commercially manufactured or sold in some countries. The replacement goes to automated sphygmomanometers, which has been used extensively nowadays. The accuracy has been a great concern to legal metrology authority. Based on the survey on automated sphygmomanometers conducted by the Working Group on Medical Measurements, there is a need for the authority in some member economies to acquire the related expertise to regulate automated sphygmomanometers. In order to do that, a training course on automated sphygmomanometers was held from June 23 to 27 in Taipei this year, funded by APLMF and APEC, and hosted by Chinese Taipei.

The opening ceremony was held on the morning of June 23. Dr. Jay-San Chen, Director General of Bureau of Standards, Metrology and Inspection, and Ms. ZHENG Huaxin, the APLMF Secretary, delivered welcome speeches to all the trainees. There were twenty-three trainees coming from ten member economies, including Cambodia, Indonesia, Hong Kong China, PR China, Malaysia, Papua New Guinea, Philippines, Singapore, Thailand, and Chinese Taipei. Ms. ZHENG Huaxin and Mr. Guo Su from the APLMF Secretariat attended and made a great effort on this training course.

The training course focused on three parts. The first part was to introduce the development of metrology in medicine and traceability for medical devices with measuring function. The second part was to lecture on the major standards in the world such as OIML R 16-2, EN and ISO/IEC standards and comparing their differences. Those two parts were lectured by Dr. Stephan Mieke, Head of Working Group of Standards for Medical Measuring Techniques of PTB, Germany, and the Secretariat of TC 18 (Medical Measuring Instruments), as well as Mr. Chen-Chuan Hung, Researcher of the National Measurement Laboratory. Since automated sphygmomanometers are usually also subject to the control of health authority, Dr. Hsiau-Wen Huang, a senior researcher of the Health Department of Chinese Taipei, was invited to introduce the current medical control of automated sphygmomanometers in Chinese Taipei.

The third part of the training course was hand-on practice. A technical trip was arranged to the Electronics Testing Centre on June 26. Mr. Cheng, the president of the Centre, re-

ceived all participants personally and expressed his welcome. His staff members demonstrated the testing procedures for sphygmomanometers. The trainees were able to practice some of the testing procedures by themselves. During the demonstration of verification procedure for measurement instruments, Dr. Mieke gave a lot of useful comments to help participants understand the whole picture of the testing process.

One of the objectives of the training course was to exchange the experience and establish friendship among participants from different member economies. At the end of training session, the trainees presented the current status of metrological control on sphygmomanometers in their economies respectively. The presentations made by all the trainees have been posted on the APLMF website at <http://www.aplmf.org>. Dr. Jay-San Chen, the Chairperson of the Working Group on Medical Measurements hosted a welcome party on the night of June 23. All the trainees took a cruise on the Danshui River and enjoyed the amazing sunset while dining. The host also arranged a half-day tour to the National Palace Museum and Taipei 101, one of the tallest buildings in the world. After the city tour, a farewell dinner was hosted by Ms. ZHENG Huaxin at a restaurant on the 85<sup>th</sup> floor of Taipei 101 on the night of June 27, which is a perfect place to overlook the Taipei City.

This training course enhanced participants' knowledge of the metrological control on sphygmomanometers. It certainly helped to achieve the objective of APLMF to harmonize metrological standards among member economies and remove technical barriers to trade. We believe that such training courses are effective tools to promote APLMF goals, from which all member economies would benefit.

Dr. Jay-San Chen  
Chairperson of the Working Group  
on Medical Measurements



**Asia-Pacific  
Economic Cooperation**



**Asia-Pacific  
Legal Metrology Forum**

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

**Training Course on Automated  
Sphygmomanometers**

June 23-27, 2008

at the Howard International House in Taipei, Chinese Taipei

**Program**

**Organizers:**

- Asia-Pacific Economic Cooperation ( APEC )
- Asia-Pacific Legal Metrology Forum ( APLMF )

**Supporting Organizations:**

- Bureau of Standards, Metrology and Inspection ( BSMI )
- Center for Measurement Standards ( CMS ) ,  
Industrial Technology Research Institute ( ITRI )
- Physikalisch-Technische Bundesanstalt ( PTB ) , Germany
- Electronics Testing Center, Chinese Taipei ( ETC )

**Main Objective of the Seminar:**

Some portable medical measuring instruments, such as clinical electrical thermometers and automated sphygmomanometers are getting to be widely used not only in medical facilities but also in private homes. However, there remain problems concerning the reliability and mutual acceptability of measured results by such instruments. Standards and regulations for such instruments are beginning to be implemented.

The main target of this training course is to assist APEC and APLMF member economies in developing common understanding about the current standards and regulations on automated sphygmomanometers and thus to meet the APEC objective of harmonizing metrology legislation with OIML international recommendations. Officials in charge of type approvals and/or regulation of automated sphygmomanometers are expected to attend the seminar. The lectures would be focused on the understanding of basic construction of automated sphygmomanometers and current international or national standards and regulations related to sphygmomanometers.

**Venue and Accommodation:**

- **Howard International House Taipei**  
30 HsinSeng South Road, Section 3, Taipei 106, Chinese Taipei

Telephone: (886-2) 8369-1155

Fax: (886-2) 8369-1177

http://3w.howard-hotels.com.tw/

### Travel Support:

- **APEC travel support**, composed of a roundtrip airfare in a discount economy class and per diem including accommodation, would be prepared for the participants from **Chile, PR China, Indonesia, Malaysia, Mexico, Papua New Guinea, Philippines, Peru, Russian Federation and Thailand**.
- **APLMF travel support** would be complementary prepared for the non-APEC and full-APLMF member economies; **Cambodia, DPR Korea and Mongolia**.
- The maximum number of supported participants is limited to **one** for each economy. The final eligible participants will be decided after an approval by the APEC / APLMF secretariat. All supported participants are required to prepare a presentation with a document during the course. The English proficiency of your selected participant will very much affect the training accomplishments, so we hope you can recommend the right participant for the right training course.
- The candidates of the **APEC support** will be requested to submit an airfare quotation and itinerary in advance and have to wait to buy air ticket until it is approved by the APEC secretariat. Basically, all payment will be reimbursed directly from APEC after the **travel is finished**. The supported participants have to pay their airfare and accommodation temporarily by themselves until the reimbursement.

### Presentation from each economy:

- At least **one trainee** from each economy will be requested to provide a **brief presentation** about the legal metrology system on **Automated Sphygmomanometers** in his/her economy. The **recommended topics** of the presentation are given below.
  - 1 Self introduction
    - 1.1 Explain about your organization and department.
    - 1.2 Explain your professional experience in your organization.
  - 2 **Automated Sphygmomanometers** in your economy
    - 2.1 What are the major purposes or targets to use **Automated Sphygmomanometers**?
    - 2.2 How many manufacturers of **Automated Sphygmomanometers** are there in your economy?
    - 2.3 If you know, please mention approximate total number of production of **Automated Sphygmomanometers**.
    - 2.4 What are the accuracy class and the maximum capacity, which are most commonly used?
  - 3 Legal metrology system in your economy
    - 3.1 Who implements the measurement law (government, metrology institute, verification body, testing laboratory, etc.)?
    - 3.2 Describe briefly the types of **Automated Sphygmomanometers** and its measur-

ing range, which are covered by the measurement law.

- 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?
- 3.4 Are type approvals required? If yes, which organization performs the type approvals? How many type approval tests are performed in a year?
- 4 Explain current situation in your economy about the compliance to the international standards/recommendations, such as OIML R 16-2? or Related ISO/IEC standards for sphygmomanometers?
- 5 Are there any other requirements from your economy? Do you have any problems in order to implement the legal metrology system (budget, human resources, etc.)?

● **Accommodations:**

Accommodation for the participants will be prepared in the Howard International House on request from the participant at a rate of NT \$ 1, 800 (about US \$ 60) . Please complete the hotel reservation form to make the reservation.

**Speakers:**

- Dr. Stephan Mieke, Head, Measurement of Pressure and Flow in Medicine, Physikalisch-Technische Bundesanstalt (PTB)
- Mr. Chen-Chuan Hung, Measurement Standards & Technology Division, CMS, ITRI
- Dr. Chang-Chyi Lin, Cheng Hsin Rehabilitation Medical Center

**Registration:**

- Please complete the attached “**Registration Form**” and send it to the APLMF Secretariat by **May 26, 2008**.

**Passport, Visa and Vaccinations:**

- Every participant will be required to hold a valid passport and valid visa for entry into Chinese Taipei. Some foreign nationals are granted an automatic visa upon arrival. Please check with your local Trade and Culture Office of Chinese Taipei regarding visas and vaccinations.
- In case that a visa is required, please complete the attached “**Visa Assistance Form**” and send it to the host (BSMI) by **June 2, 2008**. On your request, the host will send an official ‘letter of invitation’ to participants for visa application at the Trade and Cultural Offices of Chinese Taipei in the participants’ countries.
- For more information, please visit the Ministry of Foreign Affairs’ website at <http://www.mofa.gov.tw/mofa91/web/welcome.html> or the Bureau of Consular Affairs’ website at <http://www.boca.gov.tw/english/index.htm>.

**Access Information:**

- **Howard International House Taipei** is about 45 kilometers from Chinese Taipei Taoyuan International Airport (the CKS Airport) . We recommend you to take the “Air Bus” that runs every 30 minutes, and it would take about 70 minutes from the CKS Airport to downtown Taipei, at a cost of NT \$ 145. You should get off at the Howard Hotel, and ask the

front desk to arrange for a taxi about NT \$ 160 to the Howard International House Taipei (公务人力发展中心, 台北市新生南路3段30号)

- **Taxis** are convenient and relatively inexpensive. However, most taxi drivers in Taipei do not speak English. It is most helpful to have your intended locations written in Chinese for the driver.

### **Currency and Credit Cards:**

The currency in Chinese Taipei is New Chinese Taipei Dollars. Coin denominations are NT \$ 1, NT \$ 5, NT \$ 10, NT \$ 20, and NT \$ 50. Bill denominations are NT \$ 100, NT \$ 200, NT \$ 500, NT \$ 1 000, and NT \$ 2 000. The current exchange rate for NT dollar is about US \$ 1 = NT \$ 30. Foreign currency and traveler's checks can be exchanged at most banks. International credit cards such as VISA, American Express, Diner Club or Master Card are accepted in most hotels, restaurants, department stores, and shops.

### **Climate and Clothing:**

The weather in Taipei in June is warm. The average temperature is about 28 Celsius degree. Please visit the website of the Central Weather Bureau (<http://www.cwb.gov.tw/V5e/index.htm>) for details.

### **Electricity Supply:**

The electricity supply in Chinese Taipei is 110V/60Hz. In some cases, 220V/60Hz might also be available. Always check the power supply if you have any questions.

### **Local Time:**

Local time in Chinese Taipei is GMT + 8hrs.

### **Contact Persons about the Seminar:**

- **APLMF Secretariat** (registration and travel support)  
Mr. Guo Su & Ms. Zheng Huaxin  
APLMF Secretariat  
AQSIQ No. 9, Madiandonglu, Haidian District, Beijing 100088, P. R. China  
Tel: +86-10-8226-0335  
Fax: +86-10-8226-0131  
E-mail: [aplmf@aqsiq.gov.cn](mailto:aplmf@aqsiq.gov.cn), [sec@aplmf.org](mailto:sec@aplmf.org)
- **Host in Chinese Taipei** (visa assistance, accommodation, venue and access information)  
Ms. Meggie Chu  
Bureau of Standards, Metrology and Inspection (BSMI)  
7F, No. 20, Nanhai Road, Taipei 100, Chinese Taipei  
Tel: +886-2-2396-3360 ext 738  
Fax: +886-2-2397-0715  
E-mail: [metrology@bsmi.com.tw](mailto:metrology@bsmi.com.tw) & [meggie.chu@bsmi.gov.tw](mailto:meggie.chu@bsmi.gov.tw)



## Program

<b>June 23 Monday</b> (Room 101)	09:00-09:30	Registration
	09:30-09:40	Welcoming address ( Dr. Jay-San Chen, Director General of BSMI) *
	09:40-09:50	Opening ceremony ( APLMF Secretariat)
	09:50-10:00	Taking a group picture
	10:00-10:15	Coffee break
	10:15-11:15	Presentation by trainees from each economic
	11:15-12:00	Metrology in medicine ( Dr. Mieke)
	12:00-13:30	<i>Lunch break</i>
	13:30-15:20	OIML R 16-2 ( Dr. Mieke)
	15:20-15:40	<i>Coffee break</i>
	15:40-17:00	OIML R 16-2 ( Dr. Mieke)
	18:00	<i>Leave hotel lobby for the welcome dinner by bus</i>
	18:30-21:00	<i>Welcome Dinner hosted by the BSMI</i>
	<b>June 24 Tuesday</b> (Room 101)	09:00-10:20
10:20-10:40		<i>Coffee break</i>
10:40-12:00		OIML R 16-2 ( Dr. Mieke)
12:00-13:30		<i>Lunch break</i>
13:30-15:20		ISO/IEC standards for sphygmomanometers ( Dr. Mieke)
15:20-15:40		<i>Coffee break</i>
15:40-17:00		ISO/IEC standards for sphygmomanometers ( Dr. Mieke)
<b>June 25 Wednesday</b> (Room 101)	09:00-09:50	Clinical application of blood pressure measurement ( Dr. Lin)
	09:50-10:10	<i>Coffee break</i>
	10:10-11:00	The accuracy and traceability of Non-invasive automated sphygmomanometers ( Mr. Hung)
	11:00-12:00	Clinical investigations for automated sphygmomanometers ( Dr. Mieke)
	12:00-13:30	<i>Lunch break</i>
	13:30-15:20	Current situation in Germany on sphygmomanometers ( Dr. Mieke)
	15:20-15:40	<i>Coffee Break</i>
	15:40-17:00	Current situation in Germany on sphygmomanometers ( Dr. Mieke)
<b>June 26 Thursday</b>	09:30	<i>Leave hotel lobby for the technical visit by bus</i>
	09:30-12:00	Technical visit to Electronics Testing Center ( ETC) , Chinese Taipei ( Dr. Mieke & host staffs)
	12:00-13:30	<i>Lunch break</i>
	13:30-16:30	Practical demonstration at Electronics Testing Center ( ETC) , Chinese Taipei ( Dr. Mieke & host staffs)
	16:30	<i>Go back to the hotel</i>

<b>June 27 Friday</b>	09:00-10:20	Summary, including country report, by a trainee from each economy
	10:20-10:40	<i>Coffee break</i>
	10:40-11:00	Closing ceremony (Dr. Jay-San Chen & APLMF Secretariat) : Presentation of certificates to all trainees & closing remarks
	11:00-12:00	Visit to Chinese Taipei Handicraft Promotion Centre (host staffs)
	12:00-13:30	<i>Lunch break</i>
	13:30-18:00	City tour of Taipei (host staffs)
	18:30-21:00	<i>Farewell Dinner hosted by the APLMF</i>

\* Persons in ( ) are the speakers or instructors.

## Participants List

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

No.	Category	Economy	Name	Organization
1	APLMF	PR China	Mr. Guo Su	APLMF Secretary, Department of Metrology, AQSIQ
2	APLMF	PR China	Ms. Zheng Huaxin	APLMF Secretary, Department of Metrology, AQSIQ
3	Trainer	Germany	Dr. Stephan Mieke	Head, Measurement of Pressure and Flow in Medicine, Physikalisch Technische Bundesanstalt (PTB)
7	Trainer	Chinese Taipei	Dr. Hsiau-Wen Huang	Senior Researcher, Bureau of Pharmaceutical Affairs, Department of Health
5	Trainer	Chinese Taipei	Dr. Chang-Chyi Lin	Cheng Hsin Rehabilitation Medical Center
6	Trainer	Chinese Taipei	Mr. Chen-Chuan Hung	Measurement Standards&Technology Division, CMS, ITRI
7	Trainee	PR China	Mr. Cui Qi-Ming	The Secretariat of OIML TC18/SC1, Shanghai Institute of Measurement and Testing Technology (SIMT)
8	Trainee	PR China	Mr. Tu Li-Meng	National Pressure Metrology Technical Committee, Shanghai Institute of Measurement and Testing Technology (SIMT)
9	Trainee	Hong Kong China	Mr. Chan Tak-kin	Standards and Calibration Laboratory (SCL)
10	Trainee	Singapore	Mr. Wing Gang Seet	Health Sciences Authority
11	Trainee	PR China	Ms. Gao Yang	Beijing Institute of Metrology, National Pressure Metrology Technical Committee
12	Trainee	Papua New Guinea	Mr. Joe Magur Panga	Papua NEW Guinea National Institute of Standards&Industrial Technology (PNGNISIT)
13	Trainee	Malaysia	Dr. Wan Abd Malik Wan Mohamed	National Metrology Laboratory, SIRIM Berhad (NML-SIRIM)
14	Trainee	Philippines	Ms. Maryness Salazar	National Metrology Laboratory, Industrial Technology Development Institute (ITDI)
15	Trainee	Indonesia	Mr. M. Hendro Purnomo	Directorate of Metrology, Ministry of Trade

16	Trainee	Thailand	Mr. Peerayuth Chamrak	Northern weights and Measures Center (Chiang Mai)
17	Trainee	Cambodia	Mr. Khin CHHEANG	Department of Metrology, Ministry of Industry Mines and Energy
18	WG/Host	Chinese Taipei	Dr. Jay-San Chen	Section Chief, 3rd Section, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)
19	WG/Host	Chinese Taipei	Mr. Jhi-Sien Jiang	Director, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)
20	WG/Host	Chinese Taipei	Mr. Brain C. S. Shu	Senior Specialist, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)
21	WG/Host	Chinese Taipei	Mr. Jenn-Chyi Yang	Section Chief, 3rd Section, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)
22	WG/Host	Chinese Taipei	Ms. Meggie Chu	3rd Section, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI), Ministry of Economic Affairs
23	WG/Host	Chinese Taipei	Ms. Ching-Ru Lu	3rd Section, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)
24	Local Trainee	Chinese Taipei	Mr. DING-FU HUANG	Hsinchu Branch, Bureau of Standards, Metrology and Inspection (BSMI)
25	Local Trainee	Chinese Taipei	Mr. Chang-Chih Chen	Tainan Branch, Bureau of Standards, Metrology and Inspection (BSMI)
26	Local Trainee	Chinese Taipei	Mr. Sheng-Chieh Huang	Bureau of Food and Drug Analysis Department of Health
27	Local Trainee	Chinese Taipei	Mr. CB Liu	7th Division, Bureau of Standards, Metrology and Inspection (BSMI)
28	Local Trainee	Chinese Taipei	Mr. Yu-chou Hung	7th Division, Bureau of Standards, Metrology and Inspection (BSMI)
29	Local Trainee	Chinese Taipei	Mr. Jin-Hai Yang	2nd Section, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)
30	Local Trainee	Chinese Taipei	Mr. LI-CHUNG CHEN	Hualien Branch, Bureau of Standards, Metrology and Inspection (BSMI)
31	Local Trainee	Chinese Taipei	Mr. Alex Kou	Chinese Taipei, Medical and Biothec Industry Association

32	Local Trainee	Chinese Taipei	Mr. Chien-Hui Liu	Taichung Branch, Bureau of Standards, Metrology and Inspection (BSMI)
33	Local Trainee	Chinese Taipei	Mr. Ming-CHI Su	Medical Metrology Department Measurement standards & Legal Metrology Division