Survey on the Metrological Control for the Medical measurement Instruments

The Working Group on Medical Measurements
Singapore
November 15-17, 2006

• Issued: August 29, 2006
• Responded:
  – Six Member Economies, including Cambodia, Japan, Mexico, U.S.A, Vietnam, and Chinese Taipei (by October 12, 2006.)
# Medical Measurement Instruments with OIML Recommendation

## Q3-A-Responsible Authorities for Metrology control-1

<table>
<thead>
<tr>
<th>Instrument Description</th>
<th>Cambodia</th>
<th>Japan</th>
<th>Mexico</th>
<th>U.S.A</th>
<th>Viet Nam</th>
<th>Chinese Taipei</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 – Clinical thermometers, mercury-in-glass with maximum device</td>
<td>None</td>
<td>METI &amp; NMIJ/AIST</td>
<td>None</td>
<td>FDA</td>
<td>STAMEQ</td>
<td>METI &amp; NMIJ/AIST</td>
</tr>
<tr>
<td>16-1 – Mechanical non-invasive sphygmomanometers</td>
<td>None</td>
<td>METI &amp; NMIJ/AIST</td>
<td>DGN</td>
<td>FDA</td>
<td>STAMEQ</td>
<td>BSMI</td>
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<tr>
<td>16-2 – Non-invasive automated sphygmomanometer</td>
<td>None</td>
<td>METI &amp; NMIJ/AIST</td>
<td>DGN</td>
<td>FDA</td>
<td>None</td>
<td>BSMI</td>
</tr>
<tr>
<td>26 – Medical syringes</td>
<td>None</td>
<td>No Metrological Control</td>
<td>DGN</td>
<td>FDA</td>
<td>None</td>
<td>None</td>
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<tr>
<td>78 – Westergren tubes for measurement of erythrocyte sedimentation rate</td>
<td>None</td>
<td>No Metrological Control</td>
<td>DGN</td>
<td>FDA</td>
<td>None</td>
<td>None</td>
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<tr>
<td>90 – Electrocardiographs - Metrological characteristics - Methods and equipment for verification</td>
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<td>No Metrological Control</td>
<td>DGN</td>
<td>FDA</td>
<td>STAMEQ</td>
<td>None</td>
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<tr>
<td>104 - Pure-tone Audiometers</td>
<td>None</td>
<td>No Metrological Control</td>
<td>DGN</td>
<td>FDA</td>
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<tr>
<td>114 – Clinical electrical thermometers for continuous measurement</td>
<td>None</td>
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<td>FDA</td>
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<td>BSMI</td>
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<tr>
<td>115 – Clinical electrical thermometers with maximum device</td>
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<td>DGN</td>
<td>FDA</td>
<td>STAMEQ</td>
<td>BSMI</td>
</tr>
<tr>
<td>128 – Ergometers for foot crank work</td>
<td>None</td>
<td>No Metrological Control</td>
<td>DGN</td>
<td>FDA</td>
<td>None</td>
<td>None</td>
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<tr>
<td>135 – Spectrophotometers for medical laboratories</td>
<td>None</td>
<td>No Metrological Control</td>
<td>DGN</td>
<td>FDA</td>
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<td>None</td>
</tr>
</tbody>
</table>

13th APLMF, Singapore

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### Responsible Authorities

- **METI**: Ministry of Economy, Trade and Industry
- **NMIJ**: National Metrology Institute of Japan
- **AIST**: National Institute of Advanced Industrial Science and Technology
- **DGN**: DIRECCIÓN GENERAL DE NORMAS, DGN, (General Bureau of Standards, Economy)
- **FDA**: U.S. Food and Drug Administration
- **STAMEQ**: Directorate for Standards and Quality
- **BSMI**: Bureau of Standards, Metrology, and Inspection
Medical Measurement Instruments with OIML Recommendation

- Q3-B-Relative Regulations for Metrology control-1

<table>
<thead>
<tr>
<th>Medical Measurement Instruments with OIML Recommendation</th>
<th>Cambodia</th>
<th>Japan</th>
<th>Mexico</th>
<th>U.S.A</th>
<th>Viet Nam</th>
<th>Chinese Taipei</th>
</tr>
</thead>
<tbody>
<tr>
<td>R 7 – Clinical thermometers, mercury-in-glass with maximum device</td>
<td>None</td>
<td>Measurement Law</td>
<td>None</td>
<td>2</td>
<td>STAMEQ</td>
<td>The Weights and Measures, 9, and 10</td>
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<tr>
<td>R 16-1 – Mechanical non-invasive sphygmomanometers</td>
<td>None</td>
<td>Measurement Law</td>
<td>1</td>
<td>3</td>
<td>STAMEQ</td>
<td>The Weights and Measures, 9, and 11</td>
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<tr>
<td>R 16-2 – Non-invasive automated sphygmomanometer</td>
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<td>Measurement Law</td>
<td>None</td>
<td>3</td>
<td>None</td>
<td>The Weights and Measures, 1, and 12</td>
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<tr>
<td>R 26 – Medical syringes</td>
<td>None</td>
<td>No Metrological Control</td>
<td>None</td>
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<tr>
<td>R 78 – Westergren tubes for measurement of erythrocyte sedimentation rate</td>
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<td>No Metrological Control</td>
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<tr>
<td>R 90 – Electrocardiographs - Metrological characteristics - Methods and equipment for verification</td>
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<td>STAMEQ</td>
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<tr>
<td>R 104 – Pure-tone Audiometers</td>
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<td>Federal Law for Metrology and Normalization</td>
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<tr>
<td>R 114 – Clinical electrical thermometers for continuous measurement</td>
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<td>No Metrological Control</td>
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<tr>
<td>R 115 – Clinical electrical thermometers with maximum device</td>
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<td>Measurement Law</td>
<td>None</td>
<td>7</td>
<td>STAMEQ</td>
<td>The Weights and Measures, 1, and 13</td>
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<tr>
<td>R 128 – Ergometers for foot crank work</td>
<td>None</td>
<td>No Metrological Control</td>
<td>None</td>
<td>None</td>
<td>None</td>
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<tr>
<td>R 135 – Spectrophotometers for medical laboratories</td>
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<td>None</td>
<td>8</td>
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</table>

Medical Measurement Instruments with OIML Recommendation

- Q3-B-Relative Regulations for Metrology control-2


2: Section 21 CFR 880.2920 Clinical mercury thermometer

3: Section 21 CFR 870.1130 Noninvasive Blood Pressure Measurement System

4: Section 21 CFR 880.5860 Piston syringe - Recognized standards include many ISO standards

5: Waived from regulation in accordance with P.L. 100-578 The Clinical Laboratory Improvements Amendments

6: Section 21 CFR 870.2340 Electrocardiograph - Recognized standards include many ISO standards
Medical Measurement Instruments with OIML Recommendation

- **Q3-B-Relative Regulations for Metrology control-3**

7:Section 21 CFR 880.2910 Clinical electronic thermometer - Recognized standards include ASTM standards

8:P.L. 100-578 The Clinical Laboratory Improvements Amendments provides the FDA with responsibility to categorize the complexity and level of regulatory oversite to be applied. Spectrophotometers used for certain analytes has a high complexity

9:Regulations Governing Verification and Inspection of Measuring Instrument

10:Technical Specification for Verification and Inspection of Thermometers

11:Technical Specification for Verification and Inspection of Non Invasive Automated Sphygmomanometers

12:Verification will be implemented from 2009

13:Technical Specification for Verification and Inspection of Thermometers( Verification will be implemented from 2008)

<table>
<thead>
<tr>
<th>Medical Measurement Instruments with OIML Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Q4.1-A-Metrology control Procedure-Type Approval or Evaluation/Time Interval-1</td>
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</table>

<table>
<thead>
<tr>
<th>Procedure Type Approval or Evaluation/Time Interval-1</th>
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<tr>
<td>R 7 – Clinical thermometers, mercury-in-glass with maximum device</td>
</tr>
<tr>
<td>R 16-1 – Mechanical non-invasive sphygmomanometers</td>
</tr>
<tr>
<td>R 16-2 – Non-invasive automated sphygmomanometer</td>
</tr>
<tr>
<td>R 26 – Medical syringes</td>
</tr>
<tr>
<td>R 78 – Westergren tubes for measurement of erythrocyte sedimentation rate</td>
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<td>R 115 – Clinical electrical thermometers with maximum device</td>
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<td>R 128 – Ergometers for foot crank work</td>
</tr>
<tr>
<td>R 135 – Spectrophotometers for medical laboratories</td>
</tr>
</tbody>
</table>
Medical Measurement Instruments with OIML Recommendation

- Q4.1-A-Metrology control Procedure-Type Approval or Evaluation/Time Interval-2
  a: Exempt from the Premarket procedures
  b: Subject to Premarket notification application (510K)
  c: Subject to Premarket notification application (510K) Third party eligible using recognized accredited laboratories

## Medical Measurement Instruments with OIML Recommendation

### Q4.1-B-Metrology control Procedure-Verification/Time Interval

<table>
<thead>
<tr>
<th>Instrument Description</th>
<th>Cambodia</th>
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<th>U.S.A</th>
<th>Viet Nam</th>
<th>Chinese Taipei</th>
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</thead>
<tbody>
<tr>
<td>R 7 – Clinical thermometers, mercury-in-glass with maximum device</td>
<td>No required</td>
<td>X/Not Specified (initial only)</td>
<td>No required</td>
<td>No required</td>
<td>X/Not Specified</td>
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<td>R 16-1 – Mechanical non-invasive sphygmomanometers</td>
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<td>X/Not Specified (initial only)</td>
<td>No required</td>
<td>No required</td>
<td>X/1 year</td>
<td>X</td>
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<td>No required</td>
<td>No required</td>
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<td>No required</td>
<td>No required</td>
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<tr>
<td>R 78 – Westergren tubes for measurement of erythrocyte sedimentation rate</td>
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<td>No required</td>
<td>No required</td>
<td>No required</td>
<td>No required</td>
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<td>No required</td>
<td>No required</td>
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<td>X/2 years</td>
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<td>X/2 years</td>
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<td>No required</td>
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<td>R 114 – Clinical electrical thermometers for continuous measurement</td>
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<td>X/1 year</td>
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<td>R 128 – Ergometers for foot crank work</td>
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<td>No required</td>
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<td>R 135 – Spectrophotometers for medical laboratories</td>
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<td>No required</td>
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### Medical Measurement Instruments with OIML Recommendation

**Q4.2--The level of implementing Pattern Approval or Evaluation**

<table>
<thead>
<tr>
<th>Instrument Description</th>
<th>Cambodia</th>
<th>Japan</th>
<th>Mexico</th>
<th>U.S.A</th>
<th>Viet Nam</th>
<th>Chinese Taipei</th>
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<tbody>
<tr>
<td>R 7 – Clinical thermometers, mercury-in-glass with maximum device</td>
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<td>Central/National</td>
<td>None</td>
<td>None</td>
<td>Central/National</td>
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<td>R 16-1 – Mechanical non-invasive sphygmomanometers</td>
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<td>Central/National</td>
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<td>Central/National</td>
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<tr>
<td>R 26 – Medical syringes</td>
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<tr>
<td>R 78 – Westergren tubes for measurement of erythrocyte sedimentation rate</td>
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<td>None</td>
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<td>R 90 – Electrocardiographs - Metrological characteristics - Methods and equipment for verification</td>
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<td>None</td>
<td>None</td>
<td>None</td>
<td>Central/National</td>
<td>None</td>
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<tr>
<td>R 104 - Pure-tone Audiometers</td>
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<td>Central/National</td>
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<td>R 114 – Clinical electrical thermometers for continuous measurement</td>
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<td>None</td>
<td>None</td>
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<td>R 115 – Clinical electrical thermometers with maximum device</td>
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<td>None</td>
<td>None</td>
<td>Central/National</td>
<td>None</td>
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<tr>
<td>R 128 – Ergometers for foot crank work</td>
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<td>None</td>
<td>None</td>
<td>None</td>
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<tr>
<td>R 135 – Spectrophotometers for medical laboratories</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>*</td>
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<td>None</td>
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</tbody>
</table>

*: The CLIA provides "Guidelines for Laboratories" and laboratories may be subject to accreditation requirements and proficiency testing.

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**Q4.3--The level of implementing Verification**

<table>
<thead>
<tr>
<th>Instrument Description</th>
<th>Cambodia</th>
<th>Japan</th>
<th>Mexico</th>
<th>U.S.A</th>
<th>Viet Nam</th>
<th>Chinese Taipei</th>
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<tbody>
<tr>
<td>R 7 – Clinical thermometers, mercury-in-glass with maximum device</td>
<td>None</td>
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<td>1,2,3</td>
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<td>2</td>
<td>1,2,3</td>
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<td>1</td>
</tr>
<tr>
<td>R 26 – Medical syringes</td>
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<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>R 78 – Westergren tubes for measurement of erythrocyte sedimentation rate</td>
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<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
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<td>R 90 – Electrocardiographs - Metrological characteristics - Methods and equipment for verification</td>
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<td>None</td>
<td>2</td>
<td>1,2,3</td>
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<td>R 104 – Pure-tone Audiometers</td>
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<td>None</td>
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<tr>
<td>R 114 – Clinical electrical thermometers for continuous measurement</td>
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<td>1*</td>
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<td>None</td>
<td>1,2,3</td>
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<tr>
<td>R 128 – Ergometers for foot crank work</td>
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<td>None</td>
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</table>

## Q5.1-A–Other Control (e.g. health concerned) Responsible Authorities

<table>
<thead>
<tr>
<th>Instrument Description</th>
<th>Cambodia</th>
<th>Japan</th>
<th>Mexico</th>
<th>U.S.A</th>
<th>Viet Nam</th>
<th>Chinese Taipei</th>
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<tbody>
<tr>
<td>R 7 – Clinical thermometers, mercury-in-glass with maximum device</td>
<td>None</td>
<td>MHLW</td>
<td>None</td>
<td>Hospital and accredited health facility Requirements</td>
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<td>Dep. Of Health</td>
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<tr>
<td>R 16-1 – Mechanical non-invasive sphygmomanometers</td>
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<td>Health Dep.*</td>
<td>Hospital and accredited health facility Requirements</td>
<td>None</td>
<td>Dep. Of Health</td>
</tr>
<tr>
<td>R 16-2 – Non-invasive automated sphygmomanometer</td>
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<td>MHLW</td>
<td>None</td>
<td>Hospital and accredited health facility Requirements</td>
<td>None</td>
<td>Dep. Of Health</td>
</tr>
<tr>
<td>R 26 – Medical syringes</td>
<td>None</td>
<td>MHLW</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Dep. Of Health</td>
</tr>
<tr>
<td>R 78 – Westergren tubes for measurement of erythrocyte sedimentation rate</td>
<td>None</td>
<td>MHLW</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Dep. Of Health</td>
</tr>
<tr>
<td>R 90 – Electrocardiographs - Metrological characteristics - Methods and equipment for verification</td>
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<td>MHLW</td>
<td>None</td>
<td>Hospital and accredited health facility Requirements</td>
<td>None</td>
<td>Dep. Of Health</td>
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<tr>
<td>R 104 – Pure-tone Audiometers</td>
<td>None</td>
<td>MHLW</td>
<td>Health Dep. &amp; Labor Dep.</td>
<td>None</td>
<td>None</td>
<td>Dep. Of Health</td>
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<tr>
<td>R 114 – Clinical electrical thermometers for continuous measurement</td>
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<td>None</td>
<td>None</td>
<td>Dep. Of Health</td>
</tr>
</tbody>
</table>

*: SECRETARÍA DE SALUD, SS, (Health Department, Federal Government)

## Q5.1-B–Other Control (e.g. health concerned) Relatives Regulations

<table>
<thead>
<tr>
<th>Instrument Description</th>
<th>Cambodia</th>
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<th>Chinese Taipei</th>
</tr>
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<tbody>
<tr>
<td>R 7 – Clinical thermometers, mercury-in-glass with maximum device</td>
<td>None</td>
<td>Medicines Act</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Pharmacetic Law</td>
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### Q5.2–Other Control Procedure

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*: Type Approval/Evaluation and Verification

### Q5.3–The level of Implementation for other Control

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### Q3-A- Responsible Authorities for Metrology control

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### Q3-B- Relative Regulations for Metrology control

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### Q4.1-A-Metrology control Procedure-Type Approval or Evaluation/Time Interval

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### Q4.1-B-Metrology control Procedure-Verification Approval or Evaluation/Time Interval

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### Q4.2--The level of implementing Pattern Approval or Evaluation

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1. Central/National,  2. State/Regional  3. Local/Municipal

### Q4.3--The level of implementing Verification

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Medical Measurement Instruments without OIML Recommendation

Q5.1-A–Other Control (e.g. health concerned) Responsible Authorities

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</tr>
</tbody>
</table>

MHLW: Ministry of Health, Labour and Welfare

*: Health Department (Subsecretary of Innovation and Quality, CENTEC, COFEPRIS, Programs of Technology Assessment for Health

Medical Measurement Instruments without OIML Recommendation

Q5.1-B–Other Control (e.g. health concerned) Relatives Regulations

<table>
<thead>
<tr>
<th></th>
<th>Cambodia</th>
<th>Japan</th>
<th>Mexico</th>
<th>U.S.A</th>
<th>Viet Nam</th>
<th>Chinese Taipei</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tonometer</td>
<td>None</td>
<td>Medicines Act</td>
<td>None</td>
<td>None</td>
<td>None</td>
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</tr>
<tr>
<td>Ultrasound equipment – ultrasonography units</td>
<td>None</td>
<td>Medicines Act</td>
<td>Mandatory Std. NOM-208-SSA1-2003</td>
<td>None</td>
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<tr>
<td>Electroencephalography</td>
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<td>Medicines Act</td>
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<td>Electrotherapy</td>
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<td>Medicines Act</td>
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<td>None</td>
</tr>
<tr>
<td>Cobal-60 Teletherapy</td>
<td>None</td>
<td>Medicines Act</td>
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### Q5.2–Other Control Procedure

<table>
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<tr>
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<th>U.S.A</th>
<th>Viet Nam</th>
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<td>None</td>
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<td>None</td>
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<td>Ultrasound equipment – ultrasonography units</td>
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<td>Electroencephalography</td>
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<td>None</td>
</tr>
<tr>
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<td>None</td>
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<td>None</td>
<td>None</td>
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<tr>
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<td>None</td>
</tr>
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<td>Cobal-60 Teletherapy</td>
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Medical device market distributions require authorization from the Federal Commission for the Prevention of Sanitary Risks (COFEPRIS- Comision Federal para la Protection)

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### Q5.3–The level of Implementation for other Control

<table>
<thead>
<tr>
<th></th>
<th>Cambodia</th>
<th>Japan</th>
<th>Mexico</th>
<th>U.S.A</th>
<th>Viet Nam</th>
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<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Ultrasound equipment – ultrasonography units</td>
<td>None</td>
<td>None</td>
<td>Central/National</td>
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</tr>
<tr>
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<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Electrotherapy</td>
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</tr>
<tr>
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<td>None</td>
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<tr>
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</table>
### Q6.1—Kind of medical measurement instruments the WG on Medical Measurements should work

<table>
<thead>
<tr>
<th>Country</th>
<th>Instruments</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambodia</td>
<td>Clinical thermometers, mercury-in-glass with maximum device; Mechanical non-invasive sphygmomanometers; Non-invasive automated sphygmomanometer; Clinical electrical thermometers for continuous measurement</td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td>Clinical electrical contact thermometers; Clinical electrical infrared ear-thermometers; Non-invasive automated sphygmomanometer</td>
<td>We expect that such automated portable measuring devices will be widely used in the future.</td>
</tr>
<tr>
<td>Mexico</td>
<td>Locally, the metrological control of measuring devices has been focused on industrial applications, neglecting the metrological control of medical devices. Either because of the lack of regulations or limited measuring capabilities to evaluate the conformance of such devices. Traceability of ultrasound measurements to the International System of Units. Are current medical ultrasound measurements traceable to national standards? Do we care? National regulations regarding water quality measurements: NOM 002-SEMARNAT-1996, NOM 052-SEMARNAT-2005</td>
<td></td>
</tr>
<tr>
<td>U.S.A</td>
<td>This is a low priority subject for the U.S.</td>
<td></td>
</tr>
<tr>
<td>Viet Nam</td>
<td>Automated sphygmomanometers; Clinical electrical thermometers</td>
<td></td>
</tr>
<tr>
<td>Chinese Taipei</td>
<td>Automated sphygmomanometers; Clinical electrical thermometers</td>
<td></td>
</tr>
</tbody>
</table>

### Q6.2—Activities on medical measurement instruments APLMF should provide

<table>
<thead>
<tr>
<th>Country</th>
<th>Training</th>
<th>Seminar</th>
<th>Presentation</th>
<th>Others</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambodia</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>Medical devices are described above mostly used in Cambodia. The other devices are used in the modern hospitals</td>
</tr>
<tr>
<td>Japan</td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td>We expect the WG will continue to organize seminars and present survey results on medical measurements.</td>
</tr>
<tr>
<td>Mexico</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X (Creation of an electronic web site to promote the exchange of technical experiences and scientific developments on metrological issues associated to medical devices)</td>
</tr>
<tr>
<td>U.S.A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>This is a low priority subject to the U.S.A.</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>Especially, for automated sphygmomanometer with digital indicator: - How to verify - How to calibrate/ adjust</td>
</tr>
<tr>
<td>Chinese Taipei</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
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</table>
### Q6.3–Number of people who would participate in the activities

<table>
<thead>
<tr>
<th>Country</th>
<th>Training</th>
<th>Seminar</th>
<th>Presentation</th>
<th>Others</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambodia</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td></td>
<td>3</td>
<td>2</td>
<td></td>
<td>We hope to support the activities of WG by preparing speakers for seminars.</td>
</tr>
<tr>
<td>Mexico</td>
<td></td>
<td>4</td>
<td>4</td>
<td></td>
<td></td>
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<tr>
<td>U.S.A</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viet Nam</td>
<td>5</td>
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<tr>
<td>Chinese Taipei</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

### Q6.4–Number of expert(s) contribute as a trainer.

<table>
<thead>
<tr>
<th>Country</th>
<th>Training</th>
<th>Seminar</th>
<th>Presentation</th>
<th>Others</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambodia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td></td>
<td>2</td>
<td></td>
<td></td>
<td>We hope to support the activities of WG by preparing speakers for seminars.</td>
</tr>
<tr>
<td>Mexico</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>U.S.A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Depending on the subject the US will make inquires as to the availability of the trainers.</td>
</tr>
<tr>
<td>Viet Nam</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chinese Taipei</td>
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<td></td>
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</tbody>
</table>
Q6.5–Other comments

<table>
<thead>
<tr>
<th></th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambodia</td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td>We wish the WG will continue present activities such as organizing seminars and survey on medical measurements.</td>
</tr>
<tr>
<td>Mexico</td>
<td></td>
</tr>
<tr>
<td>U.S.A</td>
<td></td>
</tr>
<tr>
<td>Viet Nam</td>
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<tr>
<td>Chinese Taipei</td>
<td></td>
</tr>
</tbody>
</table>

Survey on the Metrological Control for the Medical measurement Instruments

Conclusion:

1. According to the responses, basically, only the health authority and metrological authority pay their attention to the medical measurements instruments affairs, though the labour authority may involve in this issue.

2. According to the surveys conducted by this WG during past years, the relative regulations in member economies still quite differ from member economy to economy. Therefore, we encourage member economies make their efforts to harmonize their regulation with OIML and to reduce the technical barrier to trade which is one of the main objects of APLMF.

3. This WG would like to organize training courses in the near future if we could get the support from APLMF and member economies.