



International Organization of Legal Metrology

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Organisation Internationale de Métrologie Légale

# Health and Legal Metrology

## The view of OIML

Bob Joseph Mathew  
*OIML Second Vice-President*



# Agenda

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- The OIML
- Work in the area of health
- Initiative in the area of health



# International Organization of Legal Metrology

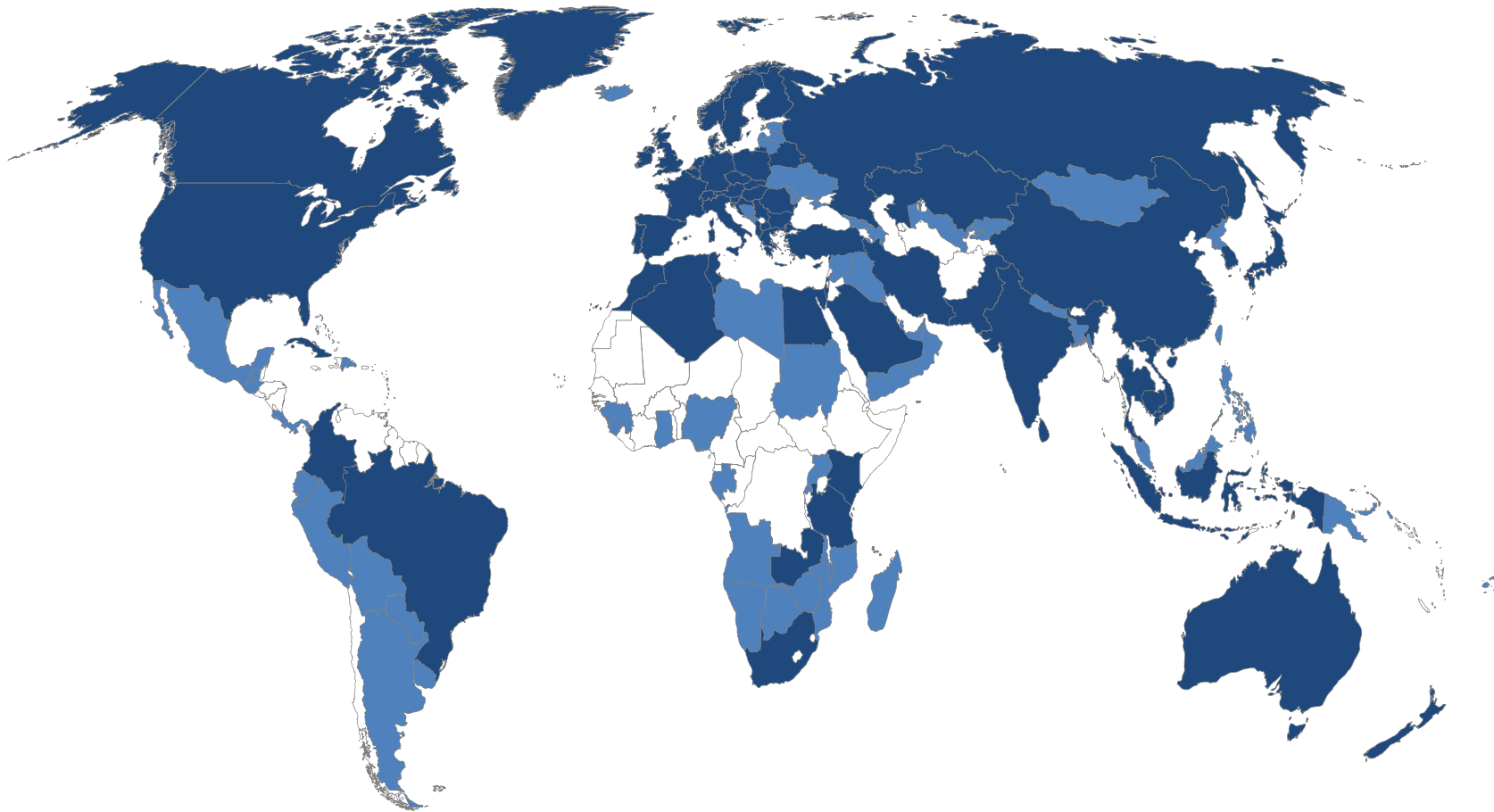
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- Develops **model regulations, standards and related documents** for use by legal metrology authorities and industry,
- Provides **mutual recognition systems** which reduce trade barriers and costs in a global market,
- Represents the **interests of the legal metrology community** within international organizations and forums concerned with metrology, standardization, testing, certification and accreditation,
- Promotes and facilitates the **exchange of knowledge and competencies** within the legal metrology community worldwide,
- Cooperates with **other metrology bodies to raise awareness** of the contribution that a sound legal metrology infrastructure can make to a modern economy.



# Membership

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-  61 OIML Member States
-  64 OIML Corresponding Members



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# Major fields of activity of the OIML

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- Technical Work:
  - 18 TCs / 45 SCs /  $\approx$  50 Project Groups
  - Global harmonization of metrological requirements and test procedures (e.g. R 149: Non-invasive automated sphygmomanometers )
- OIML Certification System (OIML-CS):
  - 39 MI categories / 12 Issuing Authorities / 32 Utilizers
  - Global harmonization of conformity assessment procedures and mutual recognition of test results
- Support of Countries & Economies with Emerging Metrology Systems (CEEMS)
- International Cooperation



# OIML Certification System (OIML-CS)

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The OIML-CS is a certification system which:



- Strengthens trust in measuring instruments and measurement results
- Enables certification of measuring instruments, avoiding duplicate testing and acceptance on an international level
- Facilitates international trade of measuring instruments
- Makes the work of legal metrology authorities more efficient
- Certified once, accepted everywhere



# Added value for different stakeholders

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- Compliance with requirements is examined by competent certification bodies (“OIML Issuing Authorities”)
- Consumers can rely on certified measuring instruments, which fulfill internationally agreed requirements
- Manufacturers can get testing services for their measuring instruments from competent and recognized OIML Issuing Authorities
- National authorities can rely on internationally accepted OIML certificates without duplicate testing and can issue national or regional type approvals







# Benefits of OIML work

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- Adoption of Recommendations in 2020
  - Non-invasive non-automated sphygmomanometers (R 148)
  - Non-invasive automated sphygmomanometers (R 149)
- R 148 and R 149 were added to the OIML-CS on 1 January 2021
- OIML developed model regulations for use by legal metrology authorities and industry
- Facilitates through the OIML-CS the international acceptance of these measuring instruments





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- Initiatives in the area of health



# OIML Task Group on Medical Devices

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- OIML members expressed needs for the regulation of medical devices with a measuring function in the context of the COVID-19 pandemic.
- Legal metrology requirements are important in the field of medical devices
- Participants from all continents
- Large number of medical devices, for instance
  - Medical weighing instruments
  - Syringes
  - Clinical thermometers
  - Audiometer
  - Computed tomography X-ray equipment



# Challenges

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- Regulatory regime can vary from country to country
  - Medical devices regulation, Standards etc.
- Inconsistencies in post-market legal metrology activities of verification and inspection in many countries
- Digitalisation and use of data



# Actions initiated

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- Infrared thermometers

- Possible project to revise R 115 *Clinical electrical thermometers with maximum device*, or to develop a new OIML Recommendation, to cover Infrared thermometers (ISO 80601-2-56:2017).



- Pulse oximeters

- Possible project on pulse oximeters (ISO 80601-2-61:2017)
- In the context of TC 18 *Medical measuring instruments*,
- Restricted to those instruments used by professionals, wearable devices for use by the general public not covered.



- Sphygmomanometers

- Possible revision of R 148:2020 and R 149:2020 to cover verification and inspection in more detail



## Conclusion

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- OIML also develops model regulations, standards and related documents in the area of health for use by legal metrology authorities and industry
- OIML-CS facilitates the international acceptance of measuring instruments (medical devices)
- Facilitates the exchange of knowledge and competencies within the legal metrology community worldwide (Task groups, Technical groups)
- Cooperates with other organization to raise awareness of the contribution that a sound legal metrology infrastructure can make in the area of health (eg. WHO, Unido)



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Gracias por su atención