22 OPPORTUNITIES AND FUTURE TRENDS IN LEGAL METROLOGY CONTROL OF MEASURING INSTRUMENTS

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Introduction

Currently, legal metrology control generally includes type evaluation and approval and initial and subsequent verification. In the future, one can envision legal metrology control to also include:

- quality management systems for the production of instruments and the manufacturer's declaration of conformance of the individual instruments to the requirements of initial verification,
- subsequent verification of measuring instruments carried out in a manner to provide 'market surveillance', and
- exchange of field test information among nations that have established mutual acceptance arrangements with regard to 'type evaluation'.

This future will require oversight by 'national responsible officials' – legal metrology services – to ensure the competence of instrument manufacturers as well as that of participants and partners in the mutual acceptance arrangements. For maximum effectiveness, these processes should be implemented on a global basis. Thus, the OIML is expected to lead and play an important, essential role.

Legal metrological control procedures

For measuring instruments, the following procedures apply:

- **D** Type evaluation and approval:
 - o testing laboratories
 - certification bodies (issuing authorities)
- □ Initial verification:
 - o field officials
 - o manufacturer's declaration
- □ Subsequent verification:
 - \circ field officials
 - readjustment (calibration)
 - maintenance and repair
- □ Market surveillance:

- o individual instrument failures identified, recorded and notified
- recalls of instrument types displaying a record of failures
- $\circ\,$ requires manufacturers to implement adjustments in the field or in production

Current and past practices

A view of the future reflects what is happening currently and has happened in the recent past. The principles of determining the competence of calibration and testing bodies were beginning to be discussed about two decades ago and have been implemented at least during the last decade along with determining the competence of certifying bodies. These principles are being applied broadly. Out of these developments, the *OIML Certificate System for Measuring Instruments* was developed.

The *OIML Certificate System* has been a huge success since it was initiated in 1991. The challenge will now be to complete and initiate the MAA and to revise D 19 on type evaluation and approval and OIML D 20 on initial and subsequent verification, along with developing an OIML program for certifying individual instruments. The basic tools necessary for accomplishing these tasks are in place.

An OIML Technical Subcommittee TC 3/SC 5 on 'Conformity assessment' was established in 1999 under TC 3 'Metrological control' that has responsibility for the project for developing the framework for a mutual acceptance arrangement on OIML type evaluation (MAA).

The output from the various OIML Technical Committees on specific Recommendations and the guidance documents on metrological control are expected to provide a firm basis for global implementation and harmonization of national regulations.

Recommendations pertain mainly to type evaluation^{*} and incorporate the following principles providing a means for type approval and certification:

a) Metrological requirements:

- □ Accuracy class
- □ Maximum permissible errors
 - rated operating conditions, reference conditions
 - rated operating conditions, with influence factors

^{*} BIML Note: Most OIML Recommendations pertain also to verification, since initial and/or subsequent verifications belong to legal metrology activity and are thus subject to national or regional regulations.

- □ Influence factors
 - o climatic (temperature, humidity, etc.)
 - o mechanical
 - o electromagnetic
- **D** Repeatability and reproducibility
- **Discrimination and sensitivity**
- □ Reliability over time
- □ Mutual recognition and acceptance arrangements

b) Technical requirements

- □ Indication of the results
- □ Software
- □ Markings
- Operating instructions
- □ Suitability for use
- c) Test program and procedures
- d) Format of the test report
- e) Certification or declaration of conformity

Mutual recognition and acceptance arrangements

Another significant development in the past decade has been the mutual acceptance arrangement being carried out under the Treaty of the Meter which focuses on physical standards and calibrations. The successful implementation of this MRA that addresses the 'equivalence' of national physical standards could provide the necessary confidence in the 'traceability' of calibrations and measurement results. It would support OIML activities related to unifying and harmonizing the metrological control of measuring instruments globally.

The basis of these mutual arrangements and oversight functions will be the principles of determining competence that have been developed in international standardization bodies such as ISO and the IEC and member organizations. Such principles are contained in ISO/IEC Standard 17025 for calibration and testing laboratories and in ISO/IEC Guide 65 for certifying bodies. Competence of such bodies can be carried out by assessments by accreditation bodies or by peer assessment. That is:

- Bodies involved:
 - Issuing authorities
 - Testing laboratories

- □ Methods of assessment:
 - Accreditation
 - Peer assessment
- **Considerations**:
 - Availability of complete testing facilities
 - o Qualified personnel
 - Training
 - o Cost
 - Financial and human resources

It will be necessary for the OIML to incorporate such principles in those Documents directed towards national, regional, and an international harmonization of legal metrological control of measuring instruments.

Experience has shown that such principles will need to be updated and revised on a periodic basis. Thus, it will also be necessary to revise accordingly those Documents for which such principles have been adopted in Documents for international application such as fields of legal metrology.

The principles that should be observed by international standards bodies in the development of their projects are as follows:

Transparency – all essential information available to interested parties

Openness - participation open on a non-discriminatory basis

Impartiality and consensus – consider all views and attempt to resolve differences

Effectiveness and relevance – respond to needs and performance rather than design based to promote development

Coherence – avoid duplication and establish cooperation with relevant work of others

Development dimension - consider the needs of developing countries

Future trends

The principles of a 'Framework for mutual acceptance arrangement on OIML type evaluation' (MAA) are in the process of being finalized. Much has yet to be learned after the approval and implementation of the MAA. Based on the experience gained in its implementation, the MAA will require continued development and maintenance.

In the harmonization of metrological requirements in mutual arrangements for type evaluation, agreement will need to be established on metrological and technical performance requirements, examination and testing procedures, and the format of the test report. For metrological requirements, agreement should be achieved on accuracy classes, maximum permissible errors under rated operating conditions at reference conditions and under applicable influence quantities. For technical requirements, agreement should be on features necessary for the instrument to perform correctly and display accurately and including labeling, except for some specialized national and regional requirements.

Trends in the field of verification are expected to include the use of remote monitoring of measuring instruments in service. The use of Internet services should facilitate much of this monitoring. However, local radio-wave devices may also be employed. Software specific to operating such services should also be available.

Future opportunities

A future challenge based on the experience gained in the implementation of the MAA will be the development of an 'OIML certification program for individual measuring instruments'. Such a program will have as the basis the existing principles provided in OIML D 27 on initial verification based on the manufacturer's quality management system.

The benefits of these efforts will be to facilitate the marketing of 'type approved' measuring instruments for carrying out measurements under legal metrological control globally. The areas affected will be equity in trade of the quantity of products, the protection of public health and worker safety, and the monitoring and protection of the environment. These efforts will provide protection of the consumer and establish broad confidence in the quantity and quality of goods and services.

The areas of legal metrology control of instruments may be summarized as follows:

- **□** Equity in the quantity or quality of products marketed:
 - buyer and seller
 - consumers of products
 - o labeling of quantities of products in packages
- **D** Public and worker health and safety:
 - medical diagnostic instruments
 - o clinical instruments used in analysis
 - monitoring of workers' exposure to potential harmful conditions
 - o monitoring of the workplace environment
- **D** Environment:
 - monitoring pollutants in the air, water, and soil
 - o determining the level of pollutants (contaminates) in food products
 - verifying and maintaining analytical instruments used for analysis

Conclusions

Future developments in legal metrology control of measuring instruments will depend on the application of the principles laid down in significant publications. Some of those publications that include vocabularies, requirements for competence for testing and calibration laboratories, requirements for bodies operating certification systems, quality management systems, type approval, initial and subsequent verification, and the framework for a mutual acceptance arrangement for type evaluation are as follows:

OIML VIML: 2000 International vocabulary of terms in legal metrology

BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML VIM:1993 International vocabulary of basic and general terms in metrology

ISO/IEC Guide 2:1996 Standardization and related activities – General vocabulary

ISO/IEC Guide 17025: 1999 general requirements for the competence of testing and calibration laboratories

ISO/IEC Guide 65: 1996 General requirements for bodies operating product certification systems

ISO/IEC CD 17040: 2001 General requirements for per assessment of conformity assessment bodies

ILAC-G10: 1996 Harmonized procedures for surveillance and reassessment of accredited laboratories

ISO 9000 Series: Quality management systems

OIML D 19:1988 Pattern evaluation and pattern approval

OIML D 20: 1988 Initial and subsequent verification of measuring instruments and processes

OIML D 27: 2001 Initial verification of measuring instruments utilizing the manufacturer's quality system

OIML P 1: 2003 OIML Certificate System for Measuring Instruments

OIML Draft Document Framework for a mutual acceptance arrangement for OIML type evaluation (MAA)

OIML Draft Document Checklists used by issuing authorities and testing laboratories involved in type evaluation

Discussion

- **Comment:** In one of the illustrations shown during the lecture, only two ways for establishing confidence are mentioned, accreditation and peer assessment. However, knowing each other, long lasting experience and facts may establish confidence as well.
- **Reaction:** This is quite true. However, accreditation or peer evaluation of a given laboratory have benefits not only for other partners, but for the laboratory itself by giving good advice on how to improve the management, the staff, etc.