The implementation of general international guides and standards on regional level in the field of metrology

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Abstract. This paper describes the basis for development of regional documents in the field of metrology and a state of harmonization of those general international guides and standards on regional levels as for example in European region.

1. Introduction

Today’s global economy depends on reliable measurements and tests, which are trusted and accepted internationally. They should not create technical barriers to trade and to precondition for this is a widely utilized and robust metrological infrastructure. Metrology is one of not many industries, where rational is a high degree of international, regional and national co-ordination.

Metrology is the scientific study of measurement. Measurements have always been essential in supporting international trade and regulation. They are required for the underpinning of conformity with written standards, and measurements have also stimulated innovation and advances in technology as well as in human well-being.

Metrology delivers the basis for the comparability of test results, e. g. by defining the units of the measurement and by providing traceability and associated uncertainty of the measurement results. Measurement results may be used provided that the corresponding characteristics of measurement errors or uncertainty are known.

2. Basis for development of regional documents in field of metrology

In order to ease the task of proving conformity with the essential requirements and to enable conformity to be assessed, it is desirable to have harmonized documents. The harmonization of regional metrological systems to requirements of international guides and standards in the field of metrology is a very complicated task not only due to differences in economical development, but due to distinguishes in regional ideology and structure.

The tasks of the Joint Committee for Guides in Metrology (JCGM) are to maintain and promote the use of the Guide to the Expression of Uncertainty in Measurement (known as the GUM) and the International Vocabulary of Basic and General Terms in Metrology (known as the VIM). The JCGM has taken over responsibility for these two documents, who originally published them under the auspices of the International Bureau of Weights and Measures (BIPM), the International Organization of Legal Metrology (OIML), the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), the International Union of Pure and Applied Chemistry (IUPAC),
the International Union of Pure and Applied Physics (IUPAP), the International Laboratory Accreditation Cooperation (ILAC). The JCGM have a two Working Groups (WG).

The JCGM/WG 1 on the GUM has the task of promoting the use of the GUM and preparing Supplements to the GUM for broad application. The GUM is now used worldwide at all levels of the measurement chain from NMIs to industry. An updated version of the GUM has been prepared under the name JCGM 100 [1] (GUM 1995 with minor corrections). In addition, the JCGM-WG1 has decided to produce series of complementary documents to cover some topics of interest in more detail (JCGM 101 [2] – propagation of distributions using a Monte Carlo method, JCGM 104 [3] – an introduction to the GUM and related documents). The GUM and complementary documents are also published by ISO (ISO/IEC Guide 98 [4]) and OIML (OIML G1-100 [5], OIML G1-104 [6]). In this era of the global marketplace, it is imperative that the method for evaluating and expressing uncertainty be uniform throughout the world so that measurements performed in different countries can be easily compared.

The JCGM/WG 2 on the VIM has the task of revising the VIM (JCGM 200 [7] – VIM, 3rd edition) and promoting its use. The VIM-3 is also published by ISO (ISO/IEC Guide 99 [8]) and OIML (OIML V2-200 [9]). The JCGM/WG 2 is composed of up to two representatives of each member organization, supplemented by a limited number of experts. VIM is meant to be a common reference for scientists and engineers (physicists, chemists, medical scientists, etc) as well as for both teachers and practitioners involved in planning or performing measurements, irrespective of the level of measurement uncertainty and irrespective of the field of application. It is also meant to be a reference for governmental and intergovernmental bodies, trade associations, accreditation bodies, regulators, and professional societies. Concepts used in different approaches to describing measurement are presented together. The member organizations of the JCGM can select the concepts and definitions in accordance with their respective terminologies. Nevertheless, VIM is intended to promote global harmonization of terminology used in metrology.

The General Conference on Weights and Measures (CGPM) adopted the name International System of Units (SI) [10], for the recommended practical system of units of measurement. The system of quantities, including the equations relating the quantities, to be used with the SI, is in fact just the quantities and equations of physics that are familiar to all scientists, technologists, and engineers. They are listed in many textbooks and in many references, but any such list can only be a selection of the possible quantities and equations, which is without limit. Just as the nearly universal use of the SI has brought coherence to all scientific and technological measurements, a worldwide consensus on the evaluation and expression of uncertainty in measurement would permit the significance of a vast spectrum of measurement results in science, engineering, commerce, industry, and regulation to be readily understood and properly interpreted.

Many of the quantities, their recommended names and symbols, and the equations relating them, are listed in the international standards ISO 31 and IEC 60027. The revised harmonized standard will be known as ISO/IEC 80000, in which it is proposed that the quantities and equations used with the SI. The IUPAP recognizes the SI for expressing the quantitative results of measurements in physics. The IUPAC serves to advance the worldwide aspects of the chemical sciences and to contribute to the application of chemistry in the service of Mankind.

The OIML has developed a worldwide technical structure that provides its Members with metrological guidelines for the elaboration of national and regional requirements concerning the manufacture and use of measuring instruments for legal metrology applications. The purpose of OIML D 2 [11] is to facilitate the drafting of national regulations relating to legal units of measurement. OIML D 2 is drawn up according to the following principles: SI is used as the basis for national regulations concerning legal units of measurement; as a general rule, units other than SI units should be eliminated; for practical reasons it is sometimes necessary to extensively use other units as legal units of measurement.

The world-wide reference ISO/IEC 17025 [12] standard for the accreditation of laboratories specifies that testing and calibration laboratories shall have and shall apply procedures for estimating the
uncertainty of measurement and that test report, when the uncertainty affects compliance to a specification limit, shall include a statement on the estimated uncertainty of measurement. In fact, the very large majority of measurements in the world are made in industry and without any kind of accreditation. Industry is using measurements for the control of the quality of their products. The economical consequence of these measurements is much larger than the few accredited measurements. So, the same requirements concerning the uncertainty of measurement can be applied.

ILAC-G17 [13] describes how the concept of uncertainty of measurement should be introduced taking into account present state of the art understanding. It is realized that during the course of the implementation of ISO/IEC 17025, suitable sector-specific guidance will be needed. However, the harmonization of the application of the principles of uncertainty of measurement in testing between different disciplines, industry sectors and economies should remain the main goal. ILAC-G19 [14] is intended to provide guidance for laboratories involved in forensic analysis and examination by providing application of ISO/IEC 17025.

An important aspect for maintaining the capability of a laboratory to produce traceable and reliable measurement results is a determination of the maximum period that should be permitted between successive calibrations (recalibrations) of the reference or working standards and measuring instruments used. The purpose of ILAC-G24/OIML 10 [15] is to give laboratories, particularly while setting up their calibration system, guidance on how to determine calibration intervals. ILAC-G19/OIML 10 identifies and describes the methods that are available and known for the evaluation of calibration intervals. OIML 10 [16] aims to be a guide for assessing the conformity to ISO/IEC 17025 of any testing laboratories involved in legal metrology testing.

ISO 9000 series standards [17, 18] specifies the use of suitable equipment, the approval of equipment and where necessary to ensure valid results, measuring equipment shall: be calibrated or verified at specified intervals or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded; be adjusted or re-adjusted as necessary, etc.

A state of implementation of general guides and standards in documents of International organizations which have activity in the field of metrology is shown in Table 1.

| Guide, standard, document/organization | BIPM | OIML | ISO | IEC | ILAC | IFCC | IUPAC | IUPAP |
|----------------------------------------|------|------|-----|-----|------|------|-------|-------|
| Vocabulary (VIM)                       | JCGM 200 | OIML | ISO/IEC | Guide 99 | JCGM 200 |
| Measurement uncertainty (GUM)         | JCGM 100, 101, 104 | OIML G1-100, 104 | ISO/IEC | Guide 98 | JCGM 100, ILAC-G17 |
| International System of Units (SI)     | SI-8 | OIML D2 | ISO/IEC 31, 80000, IEC 60027 | – | – |
| Laboratory accreditation              | – | OIML D10, 30 | ISO/IEC 17025 | ILAC-G17, 19, 24 | – |
| Quality management systems             | – | | ISO 9000, 9001 | – | – |
3. Harmonization of regional documents in field of metrology
The European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) are recognized as the competent bodies for the adoption of harmonized standards (for examples, ISO 9000, 9001, ISO/IEC 17025, EN ISO/IEC 80000) in accordance with the general guidelines on cooperation between the European Commission and the European Standardization bodies. The European Association of National Metrology Institutes (EURAMET) and the Euro-Asian cooperation of national metrology institute (COOMET) are a regional organizations originally establishing cooperation of national metrology institutions (NMI) for solving problems of the uniformity of measures, uniformity and required accuracy of measurements. The European Cooperation in Legal Metrology (WELMEC) achieve harmonization of legal metrology activities and promote consistency of interpretation and application of normative documents and propose actions to facilitate implementation. The European Cooperation for Accreditation (EA) is the European network of nationally recognized accreditation bodies located in the European geographical area.

COOMET R/AQ/13 [19] determines the procedure for the assessment of quality management systems in NMI of COOMET Member states. Specific nonconformity with references to the corresponding article of international standard ISO/IEC 17025 and opinion of the applicant on this nonconformity must be recorded in these Protocols.

WELMEC 8.6 [20] is intended to provide guidance in order to facilitate harmonized approvals of quality systems of manufacturers for application of module D or of module H1 of MID. As the conformity to EN ISO 9001 appears to-day the most appropriate generic standard in order to give presumption of conformity, this document is built according to the structure of this standard.

CEN technical bodies and other relevant bodies to implement the CEN Guidance 2004 [21] and recommendations about measurement uncertainty within the limits allowed by available resources and without compromising the need to deliver European standards as quickly as possible. Consequently, this document gives guidance to all technical bodies in charge of drafting standards. It provides a checklist to assess the need for implementation of the uncertainty of measurement concept in standards and guide them through their decision process.

EN ISO 9001 is, by design, generic in nature and is intended to be used for all economic sectors. Some economic sectors, however, have considered it useful to develop additional requirements and/or specific guidance on the implementation of EN ISO 9001. Such documents have been developed and justified in different ways, and could undermine what the EN ISO 9000 series has achieved as the common denominator for quality assurance and as an instrument for global trade.

GUM is recognized by EA as the master document on measurement uncertainty. Therefore, consistency with the GUM is generally required for specific guidance or recommendations for the evaluation of measurement uncertainty in any field of application associated with EA activity (EA-4/16 [22]). EA-4/02 [23] sets down the principles of and the requirements on the evaluation of the measurement uncertainty in calibration and the statement of this uncertainty in calibration certificates. The treatment is kept on a general level to suit all fields of calibration. In developing such supplementary guidelines the general principles stated in this document should be followed to ensure harmonization between the different fields. EA publications [24] are arranged in 9 series, corresponding to the type of documents (informative, application etc.) or to a standard used for accreditation. Application documents relating to ISO/IEC 17025 for laboratories sets down in series 3 EA publications.

A state of implementation of general guides and standards in documents of European organizations which have activity in the field of metrology is shown in Table 2.

Implementation international standards ISO/IEC 17025 and ISO 9001 in documents of International and European organizations are shown on Figure 1, as for example.
Table 2. Implementation of general international guides and standards in documents of European organizations

| Guide, standard, document/organization | EURAMET | COOMET | WELMEC | CEN | CENELEC | EA |
|----------------------------------------|---------|--------|--------|-----|---------|----|
| Vocabulary (VIM)                       |         |        |        | CEN |         | EA-4/16, 4/02 |
| Measurement uncertainty (GUM)          | –       | –      |        |     | –       |    |
| International System of Units (SI)     | –       | –      |        |     | EN ISO/IEC 80000 | –     |
| Laboratory accreditation               | –       | COOMET | R/AQ/13|     | EN ISO/IEC 17025 | EA-10/… |
| Quality management systems             | –       | –      | WELMEC |     | EN ISO 9000, 9001 | –     |

Figure 1. Implementation international standards ISO/IEC 17025 and ISO 9001 in documents of International and European organizations

4. Conclusion
The following are the conclusions obtained from investigation:
(1) As base for development of regional documents in the field of metrology are general international guides and standards on questions implementation of metrological terminology, measurement uncertainty, International System of Units – SI, laboratory accreditation and quality systems.
(2) Harmonization of regional documents in the field of metrology with requirements of those international guides and standards must be used.
References

[1] JCGM 100:2008 Evaluation of measurement data – Guide to the expression of uncertainty in measurement
[2] JCGM 101:2008 Evaluation of measurement data – Supplement 1 to the “Guide to the expression of uncertainty in measurement” – Propagation of distributions using a Monte Carlo method
[3] JCGM 104:2009 Evaluation of measurement data – An introduction to the “Guide to the expression of uncertainty in measurement” and related documents
[4] ISO/IEC Guide 98-3:2008 Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement
[5] OIML G-100:2008 Evaluation of measurement data – Guide to the expression of uncertainty in measurement
[6] OIML G-104:2009 Evaluation of measurement data – An introduction to the “Guide to the expression of uncertainty in measurement” and related documents
[7] JCGM 200:2008 International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM)
[8] ISO/IEC Guide 99:2007 International vocabulary of metrology – Basic and general concepts and associated terms
[9] OIML V2-200:2007 International vocabulary of metrology – Basic and general concepts and associated terms
[10] The International Systems of Units (SI) 8th Edition BIPM 2006.
[11] OIML D2:1999 Legal units of measurement
[12] ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories
[13] ILAC-G17:2002 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025
[14] ILAC-G19:2002 Guidelines for Forensic Science Laboratories
[15] ILAC-G24/OIML D 10:2007 Guidelines for the determination of calibration intervals of measuring instruments
[16] OIML D30:2008 Guide for the application of ISO/IEC 17025 to the assessment of testing laboratories involved in legal metrology
[17] ISO 9000:2005 Quality management systems – Fundamentals and vocabulary
[18] ISO 9001:2008 Quality management systems – Requirements
[19] COOMET R/AQ/13:2008 Procedure for the assessment of quality management systems in National Metrology Institutes
[20] WELMEC 8.6:2007 Measuring Instruments Directive 2004/22/EC Presumption of Conformity of the Quality System of Manufacturers with Module D or H 1 when EN ISO 9001:2000 is applied
[21] CEN Guidance 2004 Uncertainty of measurement concept in European Standards
[22] EA-4/16:2003 EA Guidelines on the expression of uncertainty in quantitative testing
[23] EA-4/02:1999 Expression of the uncertainty of measurement in calibration
[24] EA-1/01:2010 List of EA Publications