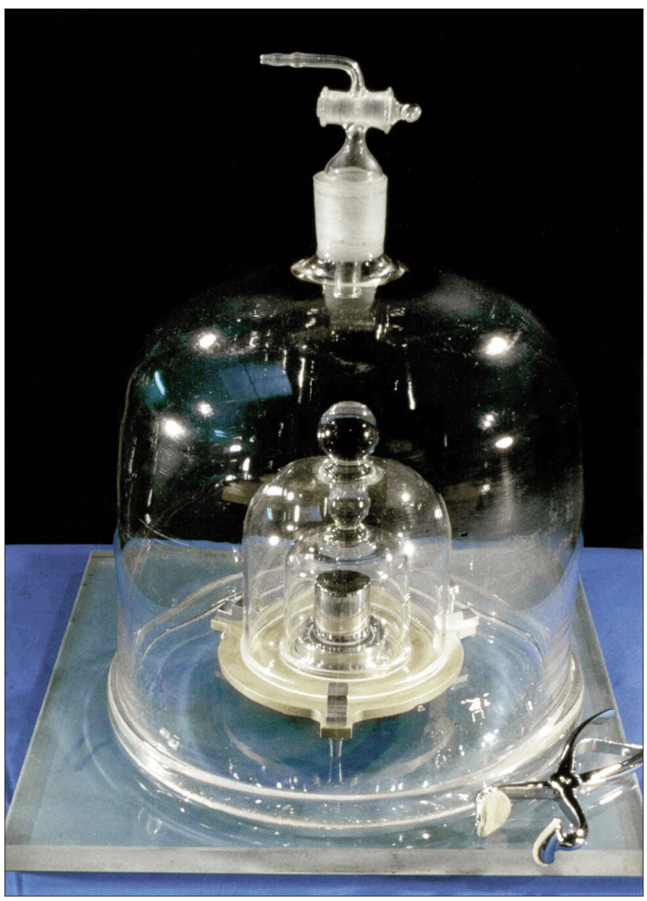
OIML BULLETIN

VOLUME LII • NUMBER 4
OCTOBER 2011

Quarterly Journal

Organisation Internationale de Métrologie Légale



ISSN 0473-2812

Towards the New SI:
Consequences for legal metrology

BULLETIN

Volume LII • Number 4

October 2011

The OIML Bulletin is the quarterly journal of the Organisation Internationale de Métrologie Légale

The Organisation Internationale de Métrologie Légale (OIML), established 12 October 1955, is an intergovernmental organization whose principal aim is to harmonize the regulations and metrological controls applied by the national metrology services of its Members.

Editor-in-Chief: Stephen Patoray
Editor: Chris Pulham

2011 Subscription Rate
60 €

ISSN 0473-2812

Printed in France

José Moyard Imprimeur
8 rue Robert Schuman
10300 Sainte Savine

OIML Secretariat

Bureau International de Métrologie Légale (BIML)

11 rue Turgot – 75009 Paris – France

Tel: 33 (0)1 4878 1282
Fax: 33 (0)1 4282 1727
Internet: www.oiml.org or www.oiml.int
www.metrologyinfo.org

OIML Member States

Albania
Algeria
Australia
Austria
Belarus
Belgium
Brazil
Bulgaria
Canada
P.R. China
Croatia
Cuba
Cyprus
Czech Republic
Denmark
Egypt
Finland
France
Germany
Greece
Hungary
India
Indonesia
Islamic Republic of Iran
Ireland
Israel
Italy
Japan
Kazakhstan
Kenya
Rep. of Korea
Macedonia, The Former Yugoslav Republic of
Monaco
Morocco
Netherlands
New Zealand
Norway
Pakistan
Poland
Portugal
Romania
Russian Federation
Saudi Arabia
Serbia
Slovakia
Slovenia
South Africa
Spain
Sri Lanka
Sweden
Switzerland
Tanzania
Tunisia
Turkey
United Kingdom
United States of America
Vietnam

OIML Corresponding Members

Argentina
Bahrain
Bangladesh
Barbados
Benin
Bosnia and Herzegovina
Botswana
Burkina Faso
Cambodia
Costa Rica
Dominican Republic
Estonia
Fiji
Gabon
Georgia
Ghana
Guatemala
Hong Kong, China
Iceland
Jordan
Dem. P. Rep. of Korea
Kuwait
Kyrgyzstan
Latvia
Libya
Lithuania
Luxemburg
Madagascar
Malaysia
Malta
Mauritius
Mexico
Moldova
Mongolia
Montenegro
Mozambique
Nepal
Oman
Panama
Papua New Guinea
Paraguay
Peru
Qatar
Rwanda
Seychelles
Singapore
Sudan
Syria
Chinese Taipei
Thailand
Trinidad and Tobago
UEMOA
Ukraine
United Arab Emirates
Uruguay
Uzbekistan
Zimbabwe

■ Contents

OIML BULLETIN
VOLUME LII • NUMBER 4
OCTOBER 2011

■ technique

■ evolutions

■ update

THE NEW SI: SEE ARTICLE, PAGE 5

Photo © BIPM - Reproduced with kind permission

Sommaire

BULLETIN OIML

VOLUME LII • NUMÉRO 4
OCTOBRE 2011

technique

évolutions

informations

■ Editorial

Stephen Patoray
Director, BIML

46th CIML Meeting: Reflections

The 46th CIML Meeting is now over and the pilot has activated the "fasten seat belts" sign. As we take off, the Prague runway becomes ever more distant and my thoughts gradually drift back to Paris, where I know the follow-up action will rapidly reach cruising speed.

This was my first CIML Meeting as BIML Director – it was a truly unique experience and one that I will certainly never forget. I was first warmly welcomed by our Czech Republic hosts, and was soon to discover that absolutely nothing had been left to chance concerning the organization of the meeting.

As the BIML staff began to arrive we finalized some of the remaining details of the meeting. Then, in turn, as the delegates began to arrive, it became clear to me the great importance this meeting was going to have, not only for me, but for *all* of the participants. The agenda was packed and the time schedule to complete all of the items was very tight. Several items had been discussed for quite some time and it had so far proven difficult to reach a consensus. But the person to person contact, I was to discover, would be key to achieving consensus and to helping us move on to the next stages of our projects.

The first major item on the agenda was the changing of the CIML President. Both Alan Johnston and Peter Mason had worked closely together during the past year, leading to a smooth transition. Then the discussions on the main agenda items began in earnest. There was a great deal of participation from CIML Members and it was a great honor for me to be a part of this very important activity.

As we progressed through the agenda items, it became clear there were a number of varying opinions on several of the major items. Coffee breaks, lunches and receptions proved to be a very important part of this meeting and so I made a great effort to listen carefully to what the Members were saying on each of the agenda items.

With all of the talking, a great deal of listening and a good dose of very hard work, on the final day of the meeting, in the final hour of the fifth session, all the Resolutions were passed.

Now I am ready to return to the Bureau to begin to work with my Team on the items identified at this very important meeting. I am proud to confirm that it is still a great honor to be the BIML Director. Together, the BIML Team looks forward to implementing the Resolutions and thus drive the Organization toward our goals.

Thank you to everyone who contributed to making this CIML Meeting such a resounding success. ■

SI UNITS

Proposed change to the definition of the kilogram: Consequences for legal metrology

Richard Davis
Consultant, International Bureau of Weights and Measures (BIPM)

The General Conference on Weights and Measures [CGPM] *invites the CIPM* [International Committee for Weights and Measures], *the Consultative Committees, the BIPM and National Metrology Institutes* [NMIs] *significantly to increase their efforts to initiate awareness campaigns aimed at alerting user communities and the general public to the intention to redefine various units of the SI and to encourage consideration of the practical, technical, and legislative implications of such redefinitions, so that comments and contributions can be solicited from the wider scientific and user communities.*

From Draft Resolution A, "On the possible future revision of the International System of Units, the SI", extract of the Convocation to the 24th meeting of the CGPM (October 2011).

Introduction

The above text is part of Draft Resolution A [1] which has been submitted for consideration and possible adoption by the meeting of the CGPM in October 2011. Note that the title of Resolution A refers only to the "possible future revision" of the SI. Nevertheless, this Resolution, if adopted, would help enlarge the debate on future redefinitions of several of the SI base units: kilogram, ampere, kelvin and mole. Although the structure of the SI will not change (the system will still be derived from the same seven base units), the proposal is that the definitions of a number of the base units should be modified once certain conditions are met. (In due course, after the conditions have been met, a new draft resolution would be presented to the CGPM to adopt and implement the new definitions).

One of these units is the kilogram. It is the purpose of this paper to examine the proposed change to the definition of the kilogram in the context of legal metrology, which is to say in the context of OIML R 111-1 [2] and OIML D 28 [3]. In addition, a brief Appendix explains why the proposed redefinition of the kelvin will have no effect on mass metrology in general and R 111-1 in particular.

This article begins by recalling the present definition of the kilogram and the practical problems it poses for mass metrology in particular and for science generally. Next, the concept of a redefinition of the kilogram based on fundamental constants is presented - this shows that any reasonable redefinition can be realized by at least two different approaches. Then the prospects for a redefinition of the kilogram in approximately five years' time, with an emphasis on the impact, if any, on legal metrology is discussed. This article should be considered to be a progress report.

1 The present definition

In the present SI, 1 kg is defined as exactly equal to the mass of an object known as the international prototype of the kilogram, now commonly abbreviated as IPK. This definition dates from 1889. The definition means that the numerical value in kg of any object, X, is equal to $m(\mathrm{X})/\boldsymbol{m}(\mathbf{IPK})$:

$$m(\mathrm{X}) = \left(\frac{m(\mathrm{X})}{\boldsymbol{m}(\mathbf{IPK})}\right)\mathrm{kg} \quad , \quad \text{or}$$

$$m(\mathrm{X})/\mathrm{kg} = \frac{m(\mathrm{X})}{\boldsymbol{m}(\mathbf{IPK})} \tag{1}$$

where $m(\mathrm{X})$ is the mass of X in kg and $\boldsymbol{m}(\mathbf{IPK})$ is the mass of the IPK.

The kilogram is the last base unit of the SI [4] which is directly defined in terms of a property - the mass, in this case - of a manufactured object or "artefact". By contrast, the metre, which was also defined in 1889 by an artefact, had already been redefined in 1960, and again in 1983. The IPK is a cylinder made of an alloy of platinum and iridium. It is conserved at the BIPM and has been used extensively during three extended periods in order to provide traceability to national prototypes of the kilogram. The last such occasion was the period from 1989 to 1991. The IPK is mentioned explicitly in OIML R 111-1, in the definition of class E_1 weights:

Class $\boldsymbol{E_1}$: *Weights intended to ensure traceability between national mass standards (with values derived from the International Prototype of the kilogram) and weights of class* E_2 *and lower...*[2].

Thus all mass values in legal metrology are ultimately traceable to the mass of the IPK.

This system worked reasonably well throughout the 20th century, but there are clearly some shortcomings for mass metrology:

- the IPK is a unique object, which is stored and used only at the BIPM. (Access to this object is strictly regulated by the CIPM);
- the IPK could, at least in principle, be damaged during use;
- after long periods when it is not used, the IPK must be carefully cleaned in order to remove accumulated surface contamination without removing the underlying alloy;
- the mass of the IPK and similar artefacts might be affected over very long periods of time by chemical or physical processes which are too slow to be easily detected;
- by convention, in the SI the mass of the IPK is always 1 kg; it was exactly 1 kg in 1889 and, after cleaning, its mass would be exactly 1 kg today.

In addition, the present definition of the ampere, which is an SI base unit, refers to a force between two current-carrying wires [4]. The unit of force contains the kilogram, and thus the kilogram definition affects electrical units as well. The electrical community recommends a new SI where two fundamental constants, the Planck constant and the elementary electrical charge, have exactly defined values [5]. Meanwhile, since 1990, the electrical community has adopted very precise "representations" of voltage and resistance units, sometimes referred to in the scientific literature as conventional 1990 electrical units (see footnote 3 in the Appendix on the need for such conventions).

Regarding the last bullet point above, it has been observed that the masses of the majority of other, similar 1 kg prototypes are increasing with respect to the mass of the IPK [5]. The relative change with time among prototypes is small, roughly 50 µg during a period of 100 years, but it is impossible to tell from measurements made on a mass comparator whether it is the mass of the IPK or that of other prototypes which have changed with respect to some fundamentally constant reference mass - it may be that the masses of all these prototypes made of the same material are also changing together with respect to a fundamental constant of mass. The need to accept the last bullet point is the major motivation in mass metrology for redefining the kilogram. Indeed OIML R 111-1 has something very relevant to say about the stability of reference weights, and the IPK is the ultimate reference weight for mass metrology:

> **The uncertainty due to instability of the reference weight ... can be estimated from observed mass changes after the reference weight has been calibrated several times. If previous calibration values are not available, the estimation of uncertainty has to be based on experience** [2].

This, of course, is excellent advice but it is impossible to apply it to the IPK, whose mass must always be exactly 1 kg by definition!

Finally, in modern physics it is illogical to measure perfectly stable physical constants - often referred to as the "fundamental" constants - in terms of some manufactured object whose long-term stability is suspect. Logically, it should be the other way around: the mass of the IPK and of all other reference weights should be traceable to the mass of a fundamentally stable constant of nature. Clearly, many problematic aspects associated with the present IPK would disappear for metrology in particular and science in general if the kilogram were somehow to be redefined in terms of fundamental constants. It must, however, be understood to what extent new problems may arise. This will be discussed in Section 4. First a brief comment is provided of how fundamental constants of mass are measured today and how one of them might serve to redefine the kilogram in the future.

2 Constraints on a new definition of the kilogram

Among the fundamental constants that can be considered, the most obvious are those which are simply masses themselves: $m(\mathrm{X})$, where X is an entity which might be chosen to be a stable atomic isotope such as carbon-12 ($^{12}\mathrm{C}$) or silicon-28 ($^{28}\mathrm{Si}$). At present, the SI value of $m(\mathrm{X})$ in all these cases must be traceable to the mass of the IPK. Say, for instance, that the most recent experimental result of such a measurement is a, so that:

$$m(\mathrm{X}) = a \qquad (2)$$

where both $m(\mathrm{X})$ and a are in kilograms. Based on traceability to the IPK as shown in (1),

$$m(\mathrm{X})/\boldsymbol{m}(\mathbf{IPK}) = a/\mathrm{kg} \qquad (3)$$

Equation (3) is useful for the purposes of this discussion because it shows both the IPK and the kilogram unit explicitly. The quantity a is measured in kg. Therefore, a/kg is dimensionless, as is the ratio on the left hand side of (3). Suppose that the measured quantity a has a standard relative uncertainty $u_r(a)$ ($k = 1$). At present, the standard relative uncertainty of $m(\mathrm{X})$, $u_r(m(\mathrm{X}))$, equals $u_r(a)$ because, by definition, $u_r(\mathrm{IPK}) = 0$.

One possibility to redefine the kilogram would be to specify that a is the exact numerical value of m(X) when this mass is expressed in kg. If that were to happen, $u_r(m(X)) = 0$ and the value of m(X) would forever be $\boldsymbol{a}$, its measured value just before the redefinition took effect. In this case, immediately after the redefinition takes effect, (3) would be rearranged to become:

$$m(\mathrm{IPK})/\boldsymbol{m}(\mathbf{X}) = \boldsymbol{a}^{-1}/\mathrm{kg} \qquad (3')$$

The value of $\boldsymbol{m}(\mathbf{X})$ in kg is defined for all time to be exactly $\boldsymbol{a}$. Remember, m(X) is a fundamental constant of physics. Its mass will not change. Suppose that sometime after the redefinition of the kilogram a new measurement of $m(\mathrm{IPK})/\boldsymbol{m}(\mathbf{X})$ does not equal $\boldsymbol{a}^{-1}$/kg. Suppose this ratio now is measured to be b^{-1}/kg and that $\boldsymbol{a} \neq b$ within the measurement uncertainty. One would conclude that m(IPK) has changed since the time it was used to determine $\boldsymbol{a}$. A change in an artefact's mass is certainly possible, and even expected (that is why they are recalibrated). With the present definition of the kilogram it would be suspected that $\boldsymbol{m}(\mathbf{IPK})$ has changed with respect to the physical constants but the present definition of the kilogram nevertheless constrains $\boldsymbol{m}(\mathbf{IPK})$ to be 1 kg exactly.

To summarize, the most important features of a new kilogram definition based on a fixed value of a fundamental constant of mass are:

- The mass of X, $\boldsymbol{m}(\mathbf{X})$, which is a fundamental constant such as the mass of a conveniently chosen atom such as carbon-12 (^{12}C) or silicon-28 (^{28}Si), will be a perfectly stable reference into the future.
- There will be no jumps in mass values measured just before and just after the redefinition. Equations (3) and (3') ensure this important feature. (Thus previous mass values traceable to the IPK are unchanged just after the redefinition).
- The mass of the IPK in kg, which by convention had zero uncertainty, acquires a known standard uncertainty, $u_r(a)$. In the future, m(IPK) must be recalibrated just as the mass of any other reference weight, i.e. the value $m(\mathrm{IPK})/\boldsymbol{m}(\mathbf{X})$ can change with time and this is now interpreted as a change in m(IPK).
- The recommendations in OIML R 111 for estimating an uncertainty component for the mass instability of a reference weight will be valid for the IPK as they are for all other reference weights. (Note however, the uncertainties of mass values which were traceable to the IPK acquire a new uncertainty component. In a sense, this component was always there but it could not be estimated accurately and, by convention, the present SI conveniently defines this uncertainty component to be zero).
- The experiment which resulted in the measurement of $\boldsymbol{a}$ can, in principle, be reproduced, and perhaps improved, wherever and whenever needed. This is important because reference weights remain artefacts and will thus need periodic recalibration.

The relative uncertainty component, $u_r(\boldsymbol{a})$ measured just before redefinition of the kilogram, will transfer to all macroscopic masses just after the redefinition. This is a crucial consideration for mass metrology and will be discussed in more detail in Section 4, below. Here it should be added that, if m(IPK) has changed over time with respect to fundamental constants of mass, then measured values of the fundamental constants of mass may appear to have changed over time with respect to m(IPK). It is important to note that no such evidence has been found. Nevertheless, experimental accuracies are continuously being improved.

3 Methods to redefine the kilogram and to provide traceability to the new definition

The previous section has introduced the basic scheme for redefining the kilogram in terms of a fixed numerical value of a fundamental constant. The example of the mass of an atom has been taken but, as will now be shown, there is another possibility. Two principal types of practical experiments which are being used to provide the necessary metrological underpinning of a new definition are described. The two methods in some ways resemble the methods a) and b) mentioned in Section 9 of OIML D 28:

> *In general, the mass of a body can be determined either:*
>
> *a) By comparison with a weight or a mass standard as a reference, using a balance or weighing instrument as a comparator, or*
>
> *b) By using a weighing instrument as a reference instrument.* [3]

3.1 Traceability of $m(^{28}Si)$ to m(IPK) - type (a) experiment

This experiment is usually referred to as measuring the Avogadro constant, N_A. For our purposes, however, it is preferable to view this experiment simply as a determination of the mass of one silicon-28 atom, $m(^{28}Si)$, in kg[(1)]. The challenge is to compare two masses as in (2) above, where a/kg is nominally about 5×10^{-26} and to carry out this comparison with a relative uncertainty that is much smaller than, for example, the class E_1 maximum permissible error (mpe) at 1 kg. This remarkable feat has required a world-wide collaboration

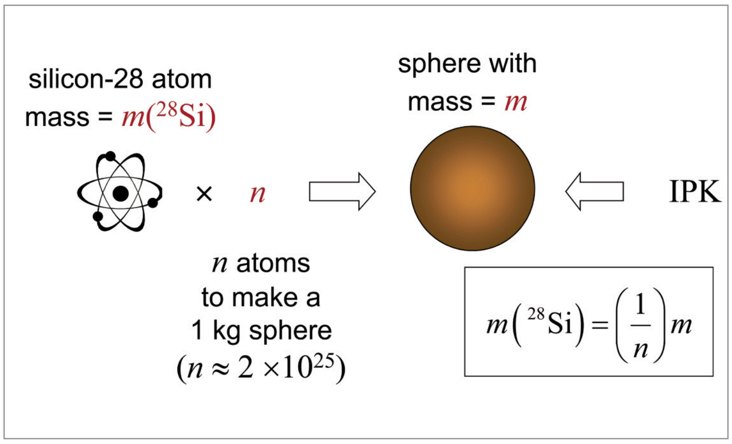


Figure 1. Linking the mass of a silicon-28 atom to the IPK. A sphere, with mass approximately 1 kg, is manufactured from a perfect crystal of silicon. Only the isotope silicon-28 is used to grow the crystal. The number of atoms, n, in the sphere is found by dividing the volume of the sphere by the average volume occupied by a single atom. Comparing the mass of the sphere to the mass of a 1 kg reference weight traceable to the IPK establishes the link between the mass of a silicon-28 atom and the IPK. There are many experimental challenges to achieving high accuracy [7].

involving many NMIs and other laboratories. The procedure was to create a nearly perfect crystal, with a mass close to 1 kg, composed entirely of silicon-28 atoms. The perfection of the crystal allows the experimenters to determine the number of atoms, n, in the crystal by a combination of innovative techniques. Thus the mass of the crystal is $n \times m(^{28}\mathrm{Si})$. The crystal is manufactured to be a sphere with mass of approximately 1 kg. Its actual mass, m, is found with respect to a reference standard, m_r, by performing a series of weighing cycles. Of course the value of m_r is traceable to the IPK (Fig. 1). Thus the ratio $m(^{28}\mathrm{Si})/\boldsymbol{m}(\mathbf{IPK})$ is known from this experiment:

$$\frac{m\left(^{28}\mathrm{Si}\right)}{\boldsymbol{m}(\mathbf{IPK})} = \left(\frac{1}{n}\right) m/\mathrm{kg} \tag{4}$$

Note that (4) has the same form as (1) and (3). The experiment consists of measuring m/n to high accuracy, and this is extremely challenging [7].

The Avogadro collaboration has determined the average of m/n in two different crystalline spheres to a standard relative uncertainty of 30×10^{-9}, or 30 µg/kg, and work continues to reduce this uncertainty even further.

3.2 Traceability of h to m(IPK) using a watt balance - type (b) experiment

Simply put, the watt balance is a weighing instrument which, after a future redefinition of the kilogram, can serve as a reference instrument to determine the mass of a weight piece. The operation of a watt balance has two parts, often referred to as "weighing" and "moving" experiments [8]. The weighing experiment is very similar to that which occurs in an analytical balance of the type well known in legal metrology. As shown schematically in Fig. 2-1, the gravitational force, $m_r g$, is balanced by an electro-magnetic force. The latter is produced by an electrical current, I_r, flowing through a length, L, of wire that is in a magnetic field, B. The current can also be thought of as the balance indication:

$$m_r = (BL/g)I_r \tag{5}$$

In an analytical balance, (BL/g) is determined by the ratio m_r/I_r. In a watt balance, however, the gravitational acceleration, g, is measured and BL is eliminated by carrying out the "moving" experiment. As shown in Fig. 2-2, BL is the ratio of a voltage, U, to a velocity v:

$$BL = U/v \tag{6}$$

so that:

$$m_r = (U/vg)I_r \tag{7}$$

or:

$$m_r vg = UI_r \tag{7'}$$

The left hand side of (7') is a mechanical power and the right hand side is an electrical power. Both powers are measured in watts, hence the name "watt balance". But (7') does not yet contain a fundamental constant.

Many NMIs now calibrate voltage and resistance standards not in terms of the SI definitions of these units, but in terms of quantum electrical devices. Hence the 1990 conventions mentioned briefly in Section 1 which are commonly used at the highest levels of electrical metrology [5]. Voltage standards are based on the "Josephson effect" and resistance standards are based on the "quantum Hall effect". (A Nobel prize was awarded for the discovery of each effect). For this article it is sufficient to state that (7) becomes:

(1) m(X) of any atomic entity X is related to the Avogadro constant, N_A, through the molar mass of X, M(X): $M(\mathrm{X}) = m(\mathrm{X})N_A$. In the present SI, the value of $M(^{12}\mathrm{C})$ is defined as exactly 0.012 kg/mol. Thus a measurement of $m(^{12}\mathrm{C})$ with relative uncertainty $u_r(m(^{12}\mathrm{C}))$ can be reported as a measurement of N_A having the same relative uncertainty. From measurements in atomic physics, the mass ratio $m(^{28}\mathrm{Si})/m(^{12}\mathrm{C})$ is already known with a negligible uncertainty. Therefore a measurement of $m(^{28}\mathrm{Si})$ can easily be converted to a value of $m(^{12}\mathrm{C})$, and hence to a measured value of N_A. (Note: In the "new" SI, it has been proposed that N_A have an exactly defined value in mol^{-1} and that, consequently, $M(^{12}\mathrm{C})$ will acquire a very small uncertainty.)

$$m_r = h\frac{f_{J,1}f_{J,2}}{vg}C_{wb} \quad (8)$$

where the constant, h, the two measured frequencies $f_{J,1}$ and $f_{J,2}$ and a dimensionless factor, C_{wb}, all arise from the use of quantum effects for measuring voltage and resistance, as shown in [8]. The constant, h, which now appears is the Planck constant, the fundamental constant of quantum physics. Its unit, kg m^2 s^{-1}, contains the kilogram. On the right hand side of (8), the kilogram unit appears only in the units of h.

At present, watt balance experiments described in (8) have already been used to measure the Planck constant with great accuracy. In analogy to (1), (3) and (4) it is seen that, in the present SI, the watt balance is a means to relate h to the IPK:

$$\frac{h}{m(\text{IPK})} = \left(\frac{vg}{f_{J,1}f_{J,2}C_{wb}}\right) m_r / \text{kg} \quad (9)$$

In the future, the kilogram could be redefined in terms of a fixed numerical value for h and (9) could be rearranged to represent a realization of the new definition.

The National Institute of Standards and Technology (NIST, USA) has been steadily improving its watt balance over the years and has continued to reduce its uncertainty. The new NIST-measured values of h remain consistent with its own historical values. At present, NIST has also achieved the lowest uncertainty of any watt balance experiment. The most recently published NIST value for h has a relative standard uncertainty of 36×10^{-9}. A number of other NMIs and the BIPM are also working actively on the "electronic kilogram" but have not yet achieved uncertainties comparable to that of NIST. However, low-uncertainty results can reasonably be expected from several of these laboratories in the near future.

3.3 Relation between $m(^{28}\text{Si})$ and h

One might think that the choice of whether to redefine the kilogram through an atomic mass, or through an exact value of the Planck constant would be a crucial decision for mass metrology. However, this is not the case. Various experimental results obtained in the realm of atomic physics can be combined to provide a value of the ratio $h/m(^{28}\text{Si})$ to a relative uncertainty less than 1×10^{-9}, (i.e., a relative uncertainty corresponding to less than 1 µg/kg). This uncertainty component is so small that both the NIST watt balance experiment to determine h and the Avogadro experiment to determine $m(^{28}\text{Si})$ provide equivalent values of h. Thus the kilogram can be redefined in terms of h but traceability of mass standards to h can in principle be achieved through $m(^{28}\text{Si})$ or through h.

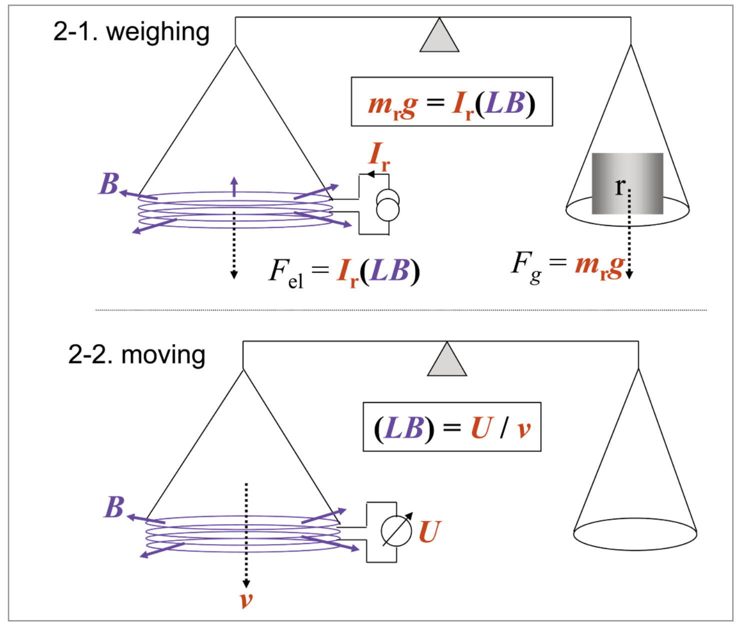


Figure 2. Linking the Planck constant to the IPK. 2-1: The "weighing" experiment is similar to the operation of a modern analytical balance: The gravitational force on a reference weight, r, is balanced by the electrical current, I_r, flowing through a coil (of length, L) placed in a magnetic field of flux density, B. 2-2: In the "moving" experiment, the same coil is made to move at constant velocity, v, through the same magnetic field. This induces a voltage U at the ends of the coil. Combining both experiments eliminates (BL) from the model equation. From (7') and (8), measuring the electrical quantities, U and I_r, by means of the Josephson and quantum Hall effects establishes a link between h and the IPK [8].

Results of the Avogadro experiment to determine $m(^{28}\text{Si})$ can easily be compared with results of watt balance experiments to determine h, with which they should agree within their combined uncertainties. Again, this is because the value of $(h/m(^{28}\text{Si}))$ is already known to 1 part in10^9. Thus a measurement of $m(^{28}\text{Si})$ to a relative uncertainty of, say, 10×10^{-9}, when multiplied by the recommended value of $(h/m(^{28}\text{Si}))$ provides a value of h to the same relative uncertainty of 10×10^{-9}. Conversely, a measurement of h made on a watt balance can easily be converted to a value of $m(^{28}\text{Si})$ or, indeed, to a value of the Avogadro constant, N_A, as explained in the footnote referenced at the beginning of 3.1.

4 The proposed new definition of the kilogram

After considering the various recommendations of its relevant consultative committees - namely the Consultative

Committee for Mass and Related Quantities (CCM), the Consultative Committee for Electricity and Magnetism (CCEM), the Consultative Committee for Metrology in Chemistry (CCQM) and the Consultative Committee for Units (CCU), the International Committee for Weights and Measures (CIPM) has concluded that a redefinition of the kilogram based on a fixed value for *h* combined with the existing definitions of the metre and the second is the optimum choice.

In large part, this decision was motivated by: (i) the central role of *h* in modern science; (ii) the fact that defining an exact value for *h*, along with an exactly defined value for the charge on the electron, would bring the quantum electrical standards (see Section 1) within the SI [5]; and (iii) the fact that the kilogram can be disseminated equally well from a new definition based on *h*, $m(^{28}Si)$ or $m(^{12}C)$. Thus the proposed draft recommendation for consideration at the October 2011 meeting of the CGPM, as cited at the start of this paper, proposes the following redefinition of the kilogram based on an exact fixed value for *h* :

> *…the SI will continue to have the present set of seven base units, in particular*
>
> - *the kilogram will continue to be the unit of mass, but its magnitude will be set by fixing the numerical value of the Planck constant to be equal to exactly 6.626 06X × 10^{-34} when it is expressed in the SI unit m^2 kg s^{-1}, which is equal to J s,…*[1]

It should be noted that the "X" in the numerical value of the Planck constant refers to digits that have yet to be determined because high-accuracy experimental work is still ongoing. As discussed above, defining the numerical value of *h* to be equal to that of its recommended value in the present SI will ensure that there will be no discontinuity in mass measurements caused by the redefinition (see Section 2). The same procedure has already been followed for successive redefinitions of the metre. It is interesting to note that since 1983 the metre has not been defined by a fundamental constant of length but by a combination of a fixed value of the speed of light in a vacuum and the SI definition of the second. Similarly, the proposed new definition of the kilogram would not be based on a fundamental constant of mass but rather on a fixed value for the Planck constant and the existing SI definitions of the second and the metre.

4.1 Our present knowledge of the value of *h* in SI units

The present values of *h* which have been determined from the Avogadro experiment and the NIST watt balance experiment do not agree as well as could be hoped. The CODATA Task Group on Fundamental Constants, which traditionally recommends values and uncertainties for the fundamental constants of physics, has examined the highly precise NIST and Avogadro determinations along with other relevant measurements.

To summarize the present situation, the available data led the Task Group to recommend a value of *h* with relative standard uncertainty of 44×10^{-9} ($k = 1$)[9]. This uncertainty takes account of the as-yet unexplained difference between *h* derived from the Avogadro measurement of $m(^{28}Si)$ and *h* derived from the NIST watt balance. Not surprisingly (see footnote (1) at the bottom of page 8), the same relative standard uncertainty, 44×10^{-9}, applies to the recommended values of N_A and $m(^{12}C)$. This means that these expanded relative uncertainties ($k = 2$) correspond to 88 µg/kg, which is already less than 1/5 the mpe for 1 kg class E_1 weights [2], and further experimental improvements can be expected relatively soon.

4.2 Practical realization of the "new" kilogram definition

At its previous meeting in November 2007, the CGPM had already recognized the importance of establishing practical realizations for the redefined units. Their view was formally expressed as part of Resolution 12:

> *The 23rd General Conference …*
>
> *Recommends that National Metrology Institutes and the BIPM … should, together with the International Committee, its Consultative Committees, and appropriate working groups, work on practical ways of realizing any new definitions based on fixed values of the fundamental constants, prepare a mise en pratique for each of them, and consider the most appropriate way of explaining the new definitions to users, …*[10].

The *mise en pratique* for the definition of a unit is a set of instructions that allows the definition to be realized in practice at the highest level of accuracy.

A number of questions naturally arise:

- When will the new definition of the kilogram take effect?
- What will be the *mise en pratique* for the proposed new definition of the kilogram?
- Who is responsible for developing the *mise en pratique*?
- What will be the uncertainty with which the new kilogram can be realized in practice?
- How will the new kilogram be disseminated?
- Does every NMI need to have a watt balance?
- And finally, what will be the effect on legal metrology?

4.2.1 *When will the new definition of the kilogram take effect?*

Operationally, the new definition of the kilogram will take effect when the General Conference (CGPM) gives its final approval. Since the CGPM traditionally meets every four years, approval could come as early as October 2015. However, a certain number of criteria must be met. Technical difficulties in realizing the new definitions must be overcome, user communities must be informed and their views considered, and as many as four redefined base units of the SI should be ready for implementation at the same time. Thus the launch date is not yet certain.

Specifically regarding redefinition of the kilogram, the CCM has been involved at least since 2005. Its most recent Recommendation, dated 2010, is available on the BIPM website [11]. In part, the CCM recommends that the following technical conditions be met before the kilogram is redefined in terms of fundamental constants of physics:

- at least three independent experiments, including work both from the watt balance and from international Avogadro collaboration projects, yield values of the relevant constants with relative standard uncertainties not larger than 5 parts in 10^8. At least one of these results should have a relative standard uncertainty not larger than 2 parts in 10^8,
- for each of the relevant constants, values provided by the different experiments be consistent at the 95 % level of confidence,
- traceability of BIPM prototypes to the international prototype of the kilogram be confirmed.

A recent publication by authors at the Physikalisch-Technische Bundesanstalt (PTB, Germany)[12] makes a detailed case that, if these recommendations are met, the added uncertainty component due to traceability to the new definition will have minimal impact on the calibration of class E_1 weights by accredited laboratories. Legal metrology will be unaffected, and the long-term stability of the kilogram unit will be assured. The importance of the uncertainties obtained by different experiments, their statistical agreement and their traceability to the IPK - all mentioned in the CCM Recommendation - have been explained in Sections 2 and 3.3 above.

4.2.2 *What will be the mise en pratique for the new kilogram? Who is responsible for the document?*

Remember that the *mise en pratique* will be a set of instructions which lead to a realization of the new kilogram to the smallest practical uncertainty. The CCM working group on changes to the SI kilogram, CCM WG-SI kg, is preparing the first draft of this document but it is premature to give further details. The terms of reference of the WG-SI kg are publicly available [13]. These include "To solicit and collate comments from a wider scientific community on the wording of the future definition and on the *mise en pratique*"[(2)].

4.2.3 *What will be the uncertainty with which the new kilogram can be realized in practice?*

This depends on the results of experiments that are still under way. If the minimum conditions recommended by the CCM can be achieved, then there should be no transitional problems when the redefinition takes effect [11, 12]. After that, one would expect the uncertainty of the realization to decrease with time as experiments are improved.

4.2.4 *Does every NMI need to construct a watt balance or a crystal of ^{28}Si?*

The answer to this question is no. At present, both the watt balance approach and the silicon crystal approach to a realization of a future definition of the kilogram are relatively costly, time consuming and metrologically demanding. The kilogram can be disseminated from any recognized source that realizes the definition of the kilogram. This will not change. For example, the BIPM plans to continue to disseminate the kilogram to its Member States whether or not the BIPM watt balance is operational at the time of the redefinition. The BIPM plans to rely on a weighted average of the realizations available at the time of the redefinition. However, a detailed dissemination scheme has not yet been defined because many experiments that have the potential to realize the new definition are still under development. Any NMI wanting to disseminate the kilogram directly from its own realization of the new definition, such as

(2) Of interest to the readership of the *OIML Bulletin* is the fact that the Chair of WG-SI kg is currently a member of the CIML Presidential Council, and a member of the WG-SI kg is currently the contact person for the Secretariat of OIML TC 9/SC 3. This Secretariat has technical responsibility for both R 111-1 and D 28.

its own watt balance, will presumably be constrained by the rules of the CIPM MRA for the international acceptance of its calibration and measurement capabilities. The BIPM will be under similar constraints.

Conclusion – What will be the effect on legal metrology?

The redefinition of the kilogram in terms of a fundamental constant of physics is still a work in progress. The BIPM has centralized much of the important information on progress towards a new SI at a publicly accessible URL [1]. The site is, of course, kept current. The redefinition of the kilogram, when it occurs, will take the needs of legal metrology into account (e.g. discussion in Section 4.2.1) so that any impact will be minimal. Nevertheless, it is important for the legal metrology community to be aware of the efforts underway and to contribute as it sees fit to this enterprise.

Appendix: mass metrology, legal metrology and the new kelvin

OIML R 111-1 specifies many temperature measurements. These are needed in calculations of air density (for buoyancy corrections) and of water density (for density determinations of weight pieces). As Section 3 of R 111-1 explicitly states, the temperature in kelvin or in Celsius referred to is derived from the International Temperature Scale of 1990 (ITS-90). This is generally true for all temperature measurements required by mass metrologists. The ITS-90 is a conventional scale which is a very close approximation to "thermodynamic temperature". The advantage of the ITS-90 is that temperatures defined on this scale can be efficiently disseminated with high precision and reproducibility(3). Continued use of the ITS-90 is independent of the redefinition of the kelvin [14], which is the SI base unit of thermodynamic temperature. Therefore legal metrology should be unaffected by the redefinition of the SI kelvin.

(3) In 1995 the directors of the PTB and the BIPM published an article which acknowledged that "in many fields where precise metrology is applied, for example, in industry, the uniformity and reproducibility of measurements are of greater immediate interest than compatibility with the SI" [15].

References

Note: To the extent possible, references are given as the URL addresses of freely-available sources.

[1] DRAFT Resolution A, "On the possible future revision of the International System of Units, the SI", extract of the Convocation of the CGPM (24th meeting, Oct. 2011) http://www.bipm.org/en/si/new_si/

[2] OIML R 111-1 *Weights of classes* E_1, E_2, F_1, F_2, M_1, M_{1-2}, M_2, M_{2-3} *and* M_3. *Part 1: Metrological and technical requirements* http://www.oiml.org/publications/R/R111-1-e04.pdf

[3] OIML D 28 *Conventional value of the result of weighing in air* http://www.oiml.org/publications/D/D028-e04.pdf

[4] *The International System of Units (SI)*, 8th edition http://www.bipm.org/en/si/si_brochure/

[5] CCEM, Recommendation E1 (2007) http://www.bipm.org/utils/common/pdf/CCEM25.pdf#page=23

[6] R. Davis, *Metrologia* **40**, 2003, pp. 299-305

[7] http://www.ptb.de/en/aktuelles/archiv/presseinfos/pi2011/pitext/pi110127.html

[8] See for example http://www.bipm.org/en/scientific/elec/watt_balance/wb_principle.html

[9] CODATA, *Latest (2010) values of the constants* http://physics.nist.gov/cuu/Constants/index.html

[10] Resolution 12 of the 23rd meeting of the CGPM (2007) http://www.bipm.org/en/CGPM/db/23/12/

[11] CCM, Recommendation G1 (2010) http://www.bipm.org/utils/common/pdf/CCM12.pdf#page=23

[12] M. Gläser, M. Borys, D. Ratschko, R. Schwartz, *Metrologia* **47**, 2010, pp. 419–428

[13] CCM Working Group on the SI kilogram, Terms of Reference http://www.bipm.org/en/committees/cc/ccm/tor_wgsi-kg.html

[14] See CCT, Executive Summary of "Report to the CIPM on the implications of changing the definition of the base unit, kelvin" http://www.bipm.org/wg/CCT/TG-SI/Allowed/Documents/Report_to_CIPM_2.pdf

[15] D. Kind and T. Quinn, T. *IEEE Trans. Instrum. Meas.* **44**, 1995, pp.85–89

LEATHER MEASUREMENT

Areas of leather measured for the first time according to OIML R 136

Rudolf Mascherek, Ingo Lohse, Frank Püschel, Michael Krystek, and Jürgen Hirsch,
PTB, Germany

Introduction

OIML R 136 [1] describes in detail the technical requirements for area measuring machines for the independent measurement of leather. Because leathers mainly comprise irregularly shaped areas, the technical and mathematical requirements for the exact determination of the area are very stringent. In addition, two types of leather are distinguished in the OIML Recommendation: hard and soft leather. Within the scope of the recommended tests, both leather types are to be tested at different ambient conditions, which partially deviates greatly from the conditions that usually prevail in test laboratories.

Detailed procedure

The Society for the Promotion of Applied Computer Science (Gesellschaft für angewandte Informatik (GFaI)) has presented to the Physikalisch-Technische Bundesanstalt (PTB) an area measuring machine for leather which aims to meet these high requirements. The machine of the type LQScan 1809 (see Fig. 1) allows areas of up to 162 dm² and material thicknesses of up to 5 mm to be measured, the leather type being of no importance for fully automated measurements.

The type LQScan 1809 leather measuring machine presented is scaleable, i.e. it is possible to use multiples of the system width (450 mm in this case). The model tested at the PTB contains two basic modules, allowing leather to be measured up to a width of 900 mm. The length of the area to be determined amounts to a maximum of 1800 mm. The leather measuring machine is based on a system composed of a transmitted light unit and cameras having a resolution of 1280 × 1024 pixels. With the transmitted light procedure, the contour of the leather is determined without contact, and the area is determined from the measurement values by means of special evaluation software (see Fig. 2). Up to 16 cameras detect the contour points of the leathers in the respective observation area. This technique allows leather types of any color with a translucence below 10 % in the spectrum of visible light to be measured.

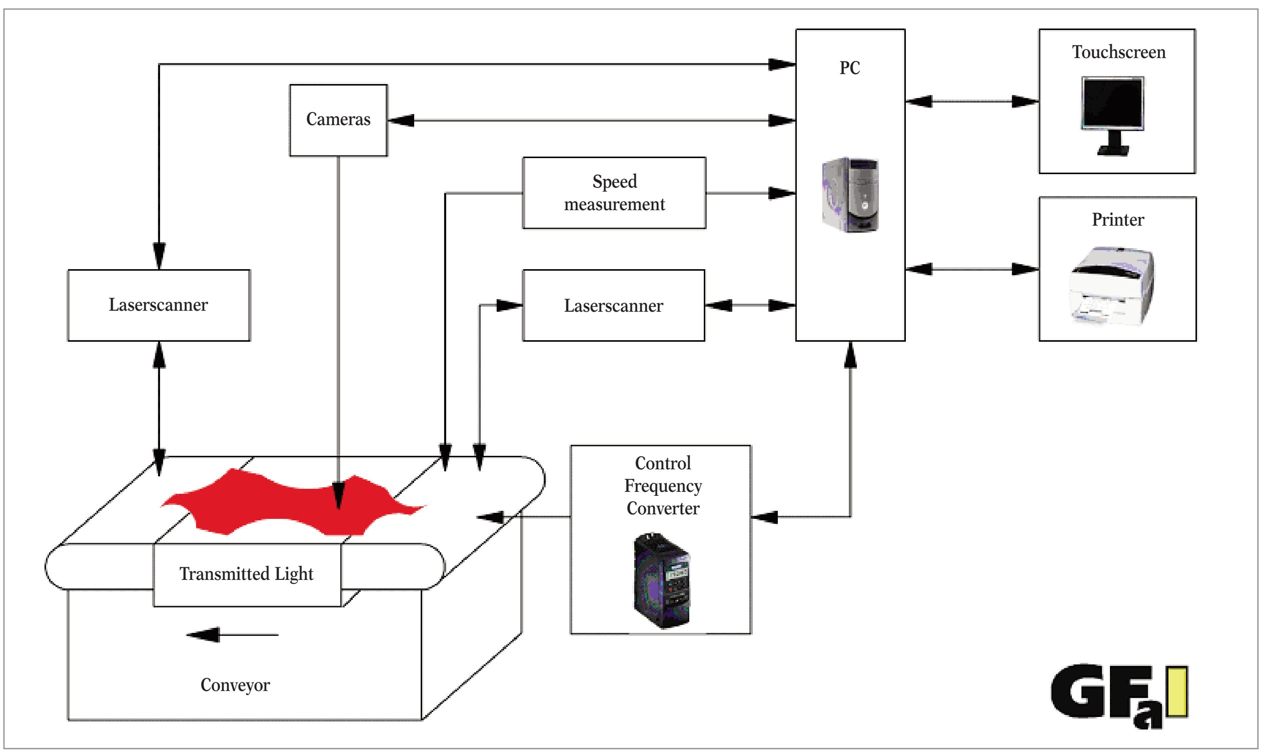


Fig. 1 Design of the area measuring machine, type LQScan 1809

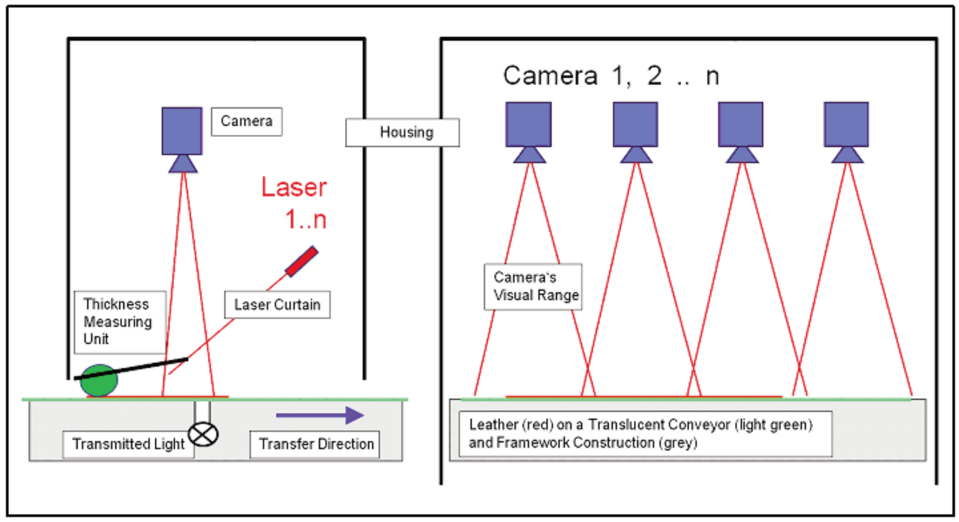


Fig. 2 Schematic view of the measurement principle

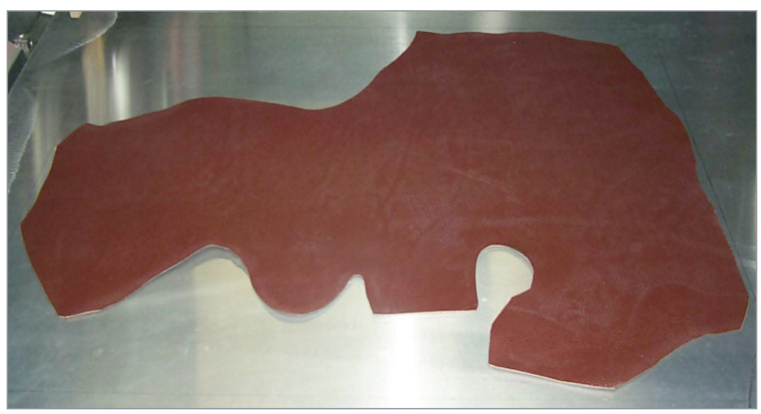


Fig. 3 Photo of the test object used "leather07"

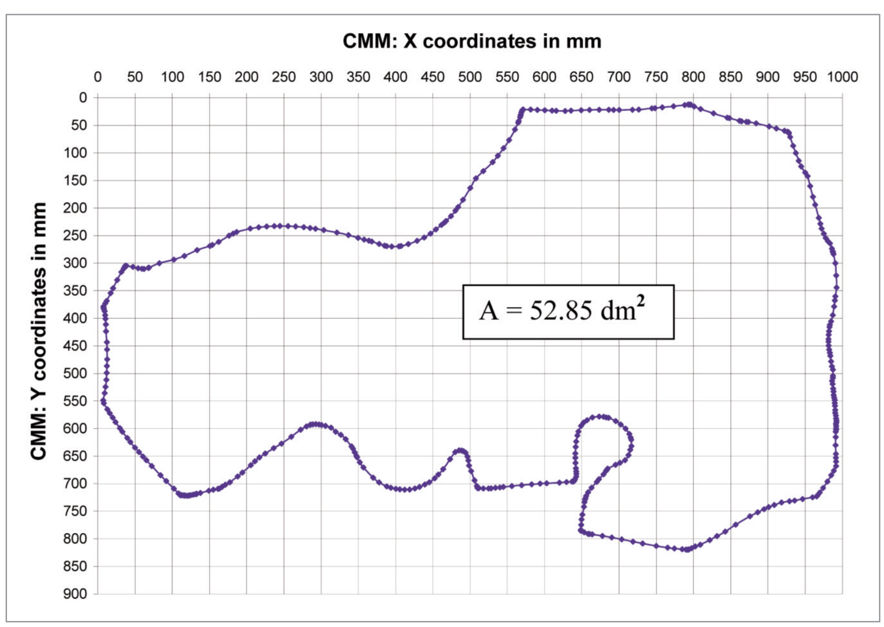


Fig. 4 x-y coordinates of the reference leather area "leather07"

```
void
polyarea
(
 unsignedn,    / * number of datapoints   */
 doublex [],   / * array of x coordinates */
 doubley [],   / * array of y coordinates */
 double *area, / * area of the polygon    */
 double *unc,  / * uncertainty            */
 )
{
 int i;
 double a, b, s, s2;

 a=x[1] - x[n-1];
 b=y[1] - y[n-1];
 s=b * x[0];
 s2= a * a+b * b;
 for ( i = 1 ; i < n, ++ i )
     {
     a = x[i + 1] - x[i - 1],
     b = y[i + 1] - y[i - 1],
     s += b * x[i];
     s2 += a * a + b * b;
     }
 a = x[0] - x[n - 2];
 b = y[0] - y[n - 2];
 s += b * x[ n - 1];
 s2 += a * a + b * b;
*area = 0.5 * fabs(s);
*unc *= 0.5 * sqrt(s2);
}
```

Fig. 5 Algorithm implemented in C programming language

A system consisting of a camera, a laser curtain and a thickness measuring unit determines the thickness of the object to be measured.

To test a machine for measuring the areas of leather within the scope of R 136, high demands had to be made on the quality of the reference areas to determine them exactly by means of independent procedures. To meet these challenges, some processes in the field of metrology and software application had to be newly developed.

To determine as exact reference values as possible, in the first step the x-y coordinates (see Fig. 4) on the circumferences of the leather areas which clearly differ in their type, color, size and thickness, were measured (see also Fig. 3). The measurements were carried out under laboratory conditions (approx. 20 °C, 40 % relative air humidity) on a coordinate measuring machine (CMM) with optical probing. To approximately reach the measurement uncertainties which are typical of CMMs in the micrometer or submicrometer range also for material measures of leather, parts of the CMM as well as the measuring strategy were adapted especially to the requirements.

In the second step, the x-y coordinates determined as above had to be evaluated by the coordinate measuring machine in such a way that an area could be calculated from these measurement values by integration.

For that purpose, all the x-y coordinates of the measured points were first classified according to the specification to form a closed circumference of the test body, based on the x-y coordinates (see Fig. 4).

The area was then calculated using the mathematical procedure "numerical calculation of the area of plane, closed contours" [2]. In addition, an in-house developed software evaluation (see Fig. 5) allowed the measurement uncertainty for the area to be determined in accordance with the GUM [3]. This uncertainty is mainly composed of the following contributions:

i) measurement uncertainty of the x-y coordinates furnished by the coordinate measuring machine,
ii) measurement uncertainty due to the application of the evaluation algorithm.

The measurement uncertainties calculated for the 12 leather reference areas were each time below 0.15 dm^2. Thus, the essential part for the evaluation of the process capability of this test procedure in accordance with OIML R 136 was complied with.

To calculate the equations for the calculation of the respective area and its measurement uncertainty from the coordinates of the measured points and their measurement uncertainty, the following algorithm was implemented in C programming language [2] (see Fig. 5).

The call of the C routine in the main program is done by `polyarea(n, x, y, &area, &unc)`, `n` being the number of data points whose x- or y- coordinates have to be transferred in the two arrays `x` and `y`. In addition, the uncertainty of the data points must be transferred in `unc`. After the calculation, the area and its uncertainty are available in `area` and `unc` (the contents of `unc` is overwritten by the C routine).

The first measurements of the 12 leather areas (see also Fig. 3) were carried out at a room temperature of 20 °C and a relative air humidity of 35 %. According to R 136, measurements must, however, be carried out at temperatures and humidities which deviate by far from the so-called standard conditions (20 °C and 50 % relative air humidity). This requirement made it necessary to check both the reference leather areas and the leather measuring machine in climatically adjustable environments. To meet this requirement, measurements were carried out in a suitable and sufficiently

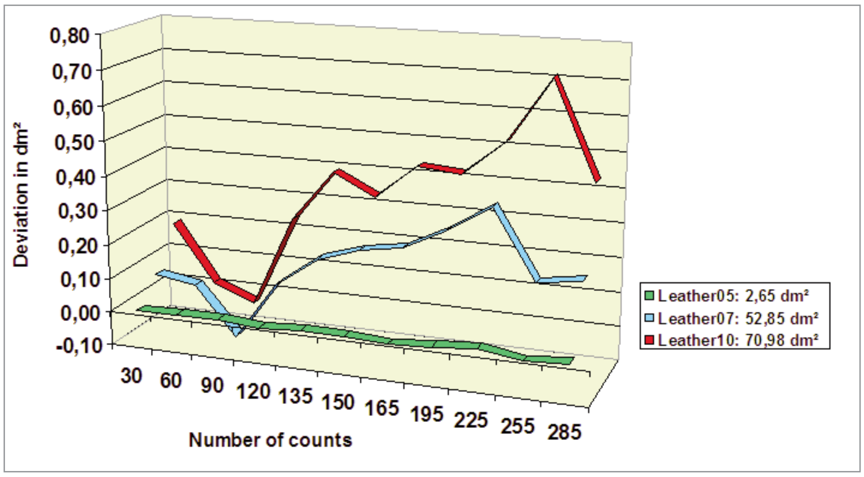


Fig. 6 Deviation from the nominal value in the case of three representative test objects

dimensioned climatic chamber. This allowed well reproducible climatic conditions to be achieved with an air relative humidity between 28 % and 80 % and air temperatures from 5 °C to 40 °C.

R 136 also provides tests for measurements carried out under the influence of extraneous light and under the influence of electromagnetic disturbances (EMC test). These measurements were carried out with the leather test objects at standard conditions (20 °C and 35 % air relative humidity).

A visualization of the measurement results for three different sized leather areas is to be used as an example of the evaluation of the OIML Recommendation (see Fig. 6): The chronological representation of the measurements performed shows a direct dependence of the area change on the total leather area. As expected, the large leather areas 07 and 10 showed the largest changes at the extreme conditions of temperature and relative humidity. The largest deviations were detected in the first third (measurements 0 to 120, temperature range 5 °C to 40 °C) and in the third third (measurements 195 to 285, temperature 40 °C and relative humidity 80 %). This influence also applies to leather area 05, where the area changes are, however, hardly measurable due to the small area.

Conclusions

The type LQScan 1809 area measuring machine meets the specified technical requirements. The test procedures selected and this technical measurement principle allow both soft and hard leather to be measured in such a way that the differentiation of the leather types made in OIML R 136-1 does not exert any influence on the result and that the error limit of ± 1 % required according to R 136 is clearly understepped.
Another metrological property is the thickness measurement of the leather areas, which R 136 does not cover. In addition, the high-resolution optics and the special evaluation software allow defects to be detected and localized - an important auxiliary means for quality assurance and the optimal cut-out of exclusive materials. Discussions and, possibly, additional tests on the basis of these additional properties, are needed by industrial companies. ■

Acknowledgement

The authors wish to thank Mr. Olaf Heuer and Mr. Holger Zimmermann for performing the measurements.

References

[1] OIML R 136-1: 2004 *Instruments for measuring the areas of leathers*

[2] Krystek, M.: *Numerische Berechnung des Flächeninhaltes ebener geschlossener Flächen*. tm - Technisches Messen 78 (2011) 2 / DOI 10.1524/teme. 2011.0059, Oldenbourg Wissenschaftsverlag

[3] *Leitfaden zur Angabe der Unsicherheit beim Messen* - Deutsche Übersetzung des "*Guide to the Expression of Uncertainty in Measurement*", Beuth Verlag, Berlin (1995)

UNCERTAINTY

Metrological traceability and uncertainty of measurement: Concepts that define the quality of measurements

ELVIRA BUZAC
Romanian Bureau of Legal Metrology

1 Introduction

The meaning of the concept of quality has always been similar to that of performance, rigor, competence, and value, whether we are talking about the quality of products and services, work, the environment, or indeed life in general.

Higher quality measurements (in conjunction with quality management based on ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*) facilitate better cooperation between testing/calibration laboratories, and they improve the exchange of information and experience as well as the harmonization of standards, procedures and other normative documents used in metrology.

A uniform approach to the concept of "quality of measurement" becomes a condition *sine qua non* of the spirit of competition.

Metrological traceability and uncertainty of measurement are concepts that are frequently used today in standards, procedures, and other technical publications. It is important to have a coherent metrological system and it is also important to use similar standards for the assessment and calculation of the uncertainty of measurement, such as the *Guide to the expression of uncertainty in measurement (GUM)* [5], which establishes general rules for evaluating and expressing uncertainty in measurement that can be followed at various levels of accuracy and in many fields - from the shop floor to fundamental research. The principles of this Guide are intended to be applicable to a broad spectrum of measurements which includes, for example, requirements for:

- maintaining quality control and quality assurance in production;
- calibrating standards and instruments and performing tests throughout a national measurement system in order to achieve traceability to national standards.

2 Traceability and uncertainty: metrological concepts that define the quality of measurements

The quality of the measuring process involves:

- providing metrological traceability by using a standard with traceable results, in accordance with the International System of Units (SI);
- using correctly trained staff to perform the calibrations;
- ensuring the correct environmental conditions;
- choosing a suitable measurement method which has been validated;
- using the correct procedure for calculating the measured value and also the uncertainty of measurement;
- choosing the correct standard for performing the calibration/verification;
- making intermediary checks to increase confidence in the measurements made. These checks are needed to maintain the confidence in the standard (reference, transfer or working standard).

The quality of products and services depends increasingly on the accuracy of the measurements made. One of the mandatory requirements for obtaining accurate measurement results is that they must be metrologically traceable. Metrological traceability represents the *"property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty"* (VIM 3, [6]). The metrological traceability chain represents the sequence of measurement standards and calibrations that is used to relate a measurement result to a reference, and is defined through a calibration hierarchy which represents a sequence of calibrations from a reference to the final measuring system, where the outcome of each calibration depends on the outcome of the previous calibration.

The concept of "traceability" was adopted relatively recently in the Romanian metrological vocabulary. In 1996 the *International vocabulary of basic and general terms in metrology (VIM)* was adopted as a Romanian standard.

It was revised and replaced in 2010 by the 3rd edition of the VIM [6].

In accordance with EN ISO/IEC 17025:2005 a calibration/test laboratory establishes the traceability of its own standards and measuring instruments to the SI by an unbroken chain of calibrations or comparisons which links them to the relevant realization of the units. The link to the SI may be achieved by reference to national measurement standards.

The metrology laboratories have to achieve all the requirements of this standard in order to demonstrate that they apply the system of quality management, that they are competent, and that they can provide valid technical results.

Measurement results have to be compatible with the results that could be obtained in any other place in the country or in the world.

This target can be accomplished if the reference standard, used in a given place, is introduced into an unbroken chain of comparisons with higher rank standards, up to the realization of the units. Thus the traceability to national and international standards is achieved.

Figure 1 shows the metrological traceability chain for a power unit, in AC, f = 50 Hz.

For each of these comparisons the uncertainty of the standard should be significantly less than the estimated measurement uncertainty for the calibrated object.

The measurement results can be verified by:

- participating in inter-laboratory comparisons or in competence-testing programs;
- replicating the calibrations using the same method or different methods;
- the re-calibration of retained items.

The result of a measurement is determined on the basis of a series of observations obtained under repeatability conditions.

When reporting the measurement result it is necessary to give some quantitative indication of the quality of the result so that those who use it can assess its reliability.

In general, the result of a measurement is only an approximation or estimate of the value of the measurand and thus is complete only when accompanied by a statement of the uncertainty of that estimate.

Without such an indication, measurement results cannot be compared, either among themselves or with reference values given in a specification or a standard. It is therefore necessary that there be a readily implemented, easily understood, and generally accepted procedure for characterizing the quality of a result of a measurement, that is, for evaluating and expressing its uncertainty.

The uncertainty of measurement comprises, in general, many components. Some of these components may be evaluated from the statistical distribution of the results of a series of measurements and can be characterized by experimental standard deviations. The other components, which can also be characterized by standard deviations, are evaluated from assumed probability distributions based on experience or other information.

The components of the measurement uncertainty may be grouped into two categories:

- the components in category A which are evaluated by statistical methods; and
- the components in category B which are evaluated by other means.

The word "uncertainty" means doubt, and thus in its broadest sense "uncertainty of measurement" means doubt about the validity of the result of a measurement.

Therefore the result of the measurement is the best estimate of the value of the measurand, and all the uncertainty components, including those arising from systematic effects such as components associated with corrections and reference standards, contribute to the dispersion.

In recent decades there has been a constant worldwide concerns to clarify some basic concepts on the theory of measurement uncertainty, in particular to unify their estimation and expression.

The result of these concerns has been the standard EN 13434:1993, replaced in 1999 by the ENV 13005:1999 *The expression of uncertainty in measurement* and, currently, the *Guide to the expression of uncertainty in measurement (GUM)* [5].

These documents were adopted as Romanian standards SR ENV 13005 and SR ISO/IEC GUIDE 98-3 respectively in 2003 and 2010.

Metrological conformity involves an analysis of the measurement results (respectively the measured value and the uncertainty of measurement) compared with the maximum permissible error (limit of error) provided by the manufacturer in the technical specification of the measuring instrument.

Figure 2 shows the curves of the measurement errors, expressed as a percentage, and the percentage error limits for single-phase active energy meters, class index C. These meters were tested under reference conditions.

The behavior of the four meters was analyzed and the accuracy of the test results obtained after the measurement was interpreted. The expanded measurement uncertainty evaluated is $U = 0.2$ for a coverage factor of $k = 2$ and a coverage probability of 95 %.

Instrument no. 1, Test 1, conforms to the technical specification of the manufacturer. The result of the

Value of current for direct connected	Power factor	Percentage error limits for meters of class index C
$I_{min} \leq I < I_{tr}$	1	± 1.0
$I_{tr} \leq I \leq I_{max}$	0.5 ind.1.cap 0.8	± 0.5

Table1 Percentage error limits at reference conditions for single-phase meters

	Meters of class index C
Permissible displacement of the zero line (%)	± 0.2

Table 2 Interpretation of test results

measurement, which includes the uncertainty of measurement, is within the technical specification percentage error limits at reference conditions which are represented in the graphic.

Instrument no. 2, Test 2, does not conform to the technical specification. The result of the measurement, which includes the uncertainty of measurement, is outside the technical specification.

Certain test results may fall outside the percentage limits indicated in Table 1, owing to uncertainties involved in the measurement process. However, if by one displacement of the zero line parallel to itself by no more than the limits indicated in Table 2, all the test results are brought within the limits, and it shall be considered that the requirements set in Table 1 are met. In this case, by displacement of the zero line parallel to itself by -0.1 (%) all the test results obtained in case no. 2 are brought within the limits and we can consider that the requirements set in Table 1 are met.

Instruments no. 3 and no. 4, Test 3 and Test 4, do not conform to the technical specification. The result of measurement is also outside the technical specification. The measurement results obtained after metrological testing of instruments no. 3 and no. 4 are illustrated in Figure 1 by curves Test 3 and Test 4. Two single-phase static meters with direct connection, class index C, were verified metrologically. As shown in Figure 1, even with one displacement of the zero line parallel to itself, with a value less than ± 0.2 %, all the measurement results cannot be brought within the limits specified in Table 1. In this case the instruments do not conform to the technical specification because the measurement result is outside the technical specification.

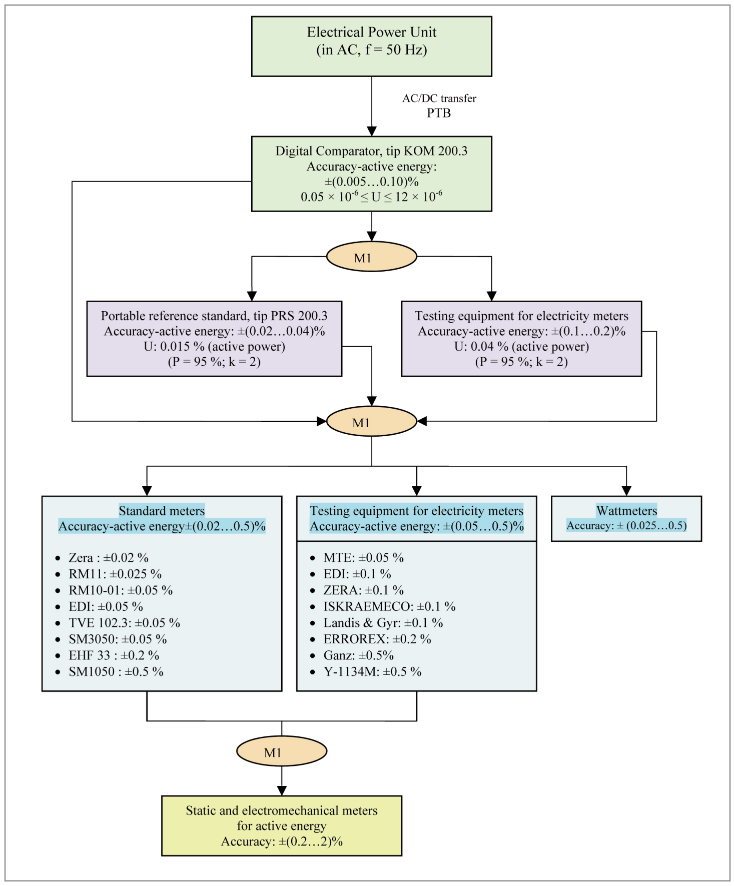


Figure 1 The metrological traceability chain for a power unit, in AC, f = 50 Hz. M1: Direct comparison method

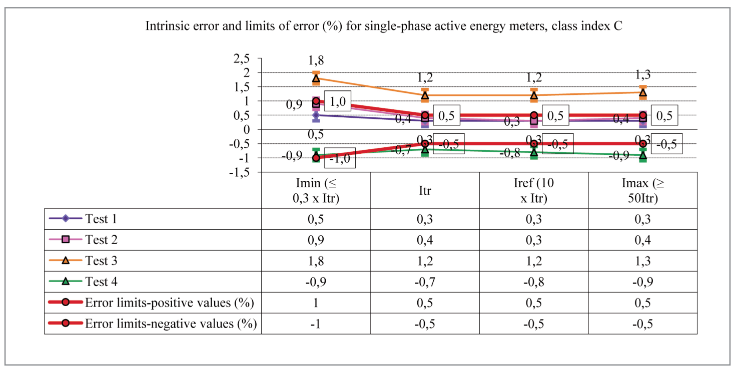


Figure 2 Intrinsic error and limits of error (%) for single-phase active energy meters, class index C, cos φ = 1

3 Conclusions

In general, society relies on a vast infrastructure, often invisible, of services, goods, transport and communication networks, whose correct functioning is essential to our everyday lives. As our economy develops and scientific and technical progress is made, the use of instruments that ensure high quality measurements becomes inevitable because metrology is a part of this invisible infrastructure.

In a modern society, metrology is a very important domain, and has the mission to create the basis of scientific and technical measurements in order to ensure uniformity and correctness of measurements in all segments of economic and social activity.

Although it is well known that obtaining accurate measurements is expensive, incorrect measurements may also have implications such as higher costs because the results of various measurements have a direct impact on the lives of every citizen. Developed countries spend significant amounts of money on measurement-related activities.

Is very important to treat the measurement results obtained at metrological verification for an active electrical energy meter carefully, and to make a correct interpretation of these results so that there is no danger of *accidentally* rejecting an instrument because the measurement result erroneously indicates that it is not in accordance with a set of technical specifications that relate to its accuracy.

A misinterpretation of the measurements results may therefore cause significant material losses, which can affect either the consumer or the electricity distributor with regard to the actual cost of the product "electricity". Making measurements and interpreting the results of these measurements after verification of electricity meters must be done with objectivity and professionalism by the staff with technical competence in the field, given that legal metrology is facing numerous complaints regarding the accuracy of records and implicitly the cost of electrical energy.

Given the definition of traceability, we can conclude that we cannot talk about traceability unless we also refer to the uncertainty of measurement.

The traceability chain involves a series of comparisons that use the standards with growing accuracy. In each comparison the uncertainty associated with the conventional true value of the reference should be noticeably lower than that of the measuring instrument.

The relation between these two uncertainties, called the "accuracy reserve", is an essential feature of the calibration process. Traceability is not possible if this parameter is not known for each step of the chain of traceability. This parameter is important to demonstrate that the chain of traceability is reliable.

Traceability and uncertainty of measurement represent the basic concepts for the quality of measurement, as stipulated in ISO/IEC 17025:2005.

In order to have a coherent metrological system it is important to use the same reference documents to express the uncertainty of measurement, for example the GUM.

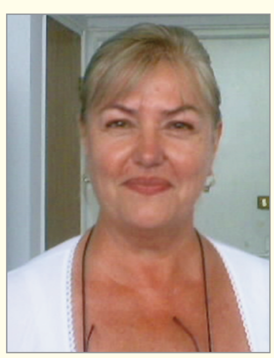
Implementation of this requirement in metrology in Romania began with the adoption of international standard ISO/IEC 17025:2005, the GUM [5] and the VIM [6].

The concept of quality, even if it relates to the quality of life, the environment, the quality of a product or a service, becomes a necessity, without which it is not possible for a country to be competitive in global international markets. ■

The Author

Elvira Buzac

Romanian Bureau of Legal Metrology
National Institute of Metrology
Vitan Barzesti street, no. 11,
Sector 4, 042122 Bucharest, Romania
e-mail: elvira.buzac@inm.ro
Phone: (4021) 334 50 60
Fax: (4021) 332 53 45



References

[1] Buzac, E., Ionescu, F., Electricity measurement, trends reflected in the Technical Committee TC 164 of the Romanian Standards Association activities, the 10th Edition of WEC Regional Energy Forum - FOREN 2010, Neptun, Romania.

[2] E. Buzac, F. Ionescu, Metrology and standardization: Infrastructure components of a modern society, OIML Bulletin vol. LI, no. 4, 2010, p. 8–12.

[3] E. Buzac, C. Cepisca, *The importance of accurate measurement of electrical energy, and the performance of modern electricity meters*, OIML Bulletin vol. XLIX, no. 1, 2008, p. 5–9.

[4] J. Zaharovitz, E. Buzac, *Consideration concerning the trend of metrology after integration of Romania in the European Union*, 9th edition FOREN 2008, Neptun, Romania.

[5] *Evaluation of measurement data - Guide to the expression of uncertainty in measurement*, Joint Committee for Guides in Metrology (JCGM), 2008. Published by the OIML as OIML G 1-100:2010.

[6] *International vocabulary of metrology - Basic and general concepts and associated terms (VIM)*, 3rd edition. Joint Committee for Guides in Metrology (JCGM). Published by the OIML as OIML V 2-200:2010.

[7] ISO/IEC Guide 99:2007, *International vocabulary of metrology - Basic and general concepts and associated terms (VIM)*.

[8] EN 50470-1:2006 – *Electricity metering equipment* (a.c.) – Part 1 – *General requirements, tests and test conditions. Metering equipment (class indexes A, B and C)*.

[9] EN 50470-2:2006 – *Electricity metering equipment* (a.c.) – Part 2 – *Particular requirements – Electromechanical meters for active energy (class indexes A and B)*.

[10] EN 50470-3:2006 – Electricity metering equipment (a.c.) – Part 3 – Particular requirements – static meters for active energy (class indexes A, B and C).

[11] F. Iacobescu, E. Buzac, C. Cepisca, *Preoccupation at national level, in Romania, concerning standardization in the field of electrical energy*, OIML Bulletin vol. XLVII, no. 4, 2006, p. 19–22.

[12] EN ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*.

[13] Directive 2004/22/EC on Measuring Instruments (MID).

[14] C. Cepisca, *Metrologie legala*, Ed. ICPE, 2004, Bucharest.

[15] A. Millea, *Trasabilitate: cerin e implica ii, efecte*, Revista Metrologie, vol.XLIV (serie nou), nr.1/1997.

MEDICAL

The role of metrology in medical devices

MARIA DO CÉU FERREIRA
Instituto Português da Qualidade, Portugal

Abstract

Medical measurements are present in everyday life and are fundamental processes in the prevention, diagnosis and treatment of diseases. There is therefore growing interest in the role of metrological decisions and conformity assessment, notably where measurements are made to safeguard health.

This paper focuses on the use of medical devices and looks to improve their metrological traceability, highlighting the specific role of metrology in the field of healthcare and the impact of legal control in the framework of the regulation of medical devices with a measuring function. A new regulatory approach for medical devices in use is proposed, in view of the fact that we are faced with increasing convergence between European policy enforcement and metrological regulations.

Keywords: Metrology, Traceability, Medical measurements

1 Introduction

The science of measurement, as a field of technical and scientific activity, comprises a range of activities with a key role in all sectors of society. In the health sector, due to the inherent potential risk to life it is necessary to measure quantities as accurately as possible.

Although measurements that are used to arrive at a medical diagnosis are only “pieces” within the complex process of medical decision-making in general, they contribute incrementally. Therefore, the accuracy and reliability of medical measurements have direct consequences on each individual’s health.

Medical decisions are often based on statistical analysis and on the conclusions of clinical studies [1]. Medical measurements are incorporated within these studies and are correlated with other medical findings. Consequently, each medical decision for an individual may be influenced by the results of previous studies, including data from medical measurements carried out previously.

Assuming that medical measurements are related to SI (International System of Units) units such as mass, temperature, length, etc., it would follow that the main concepts used in other areas in industrial and legal metrology can be adapted and used more or less directly. Following this line of reasoning, the need to improve the metrological traceability of measuring instruments (reproducibility and repeatability conditions) to make them suitable for use is obvious. Hence, quality assurance of measurements should be ensured by metrological tools (e.g. calibration, legal metrological control and reference measurement methods). Considering this analogy with other sectors of society in which legal metrological control is required, the accuracy of measurements and the traceability chain are equally essential for the reliability of medical measurement results.

2 Regulatory domains for medical devices

The economic integration of the European Union (EU) has led to a number of EU Directives being passed to define the essential requirements for health, safety and welfare, with the intention of gradually eliminating barriers to trade among member countries. This methodology deals with the harmonization of Member States’ legislation, contributing to the single market and developing an assurance of free circulation of goods and services.

Indeed, this scenario was achieved by the European Council resolution adopted in May 1985, which became known as the *New Approach*. Therefore, under the scope of the *New Approach* Directives technical barriers to trade were removed, thus promoting trust in economic operators and allowing for the free movement of goods within the EU.

The regulatory framework for medical devices consists of three main Directives:

- Directive 90/385/EEC regarding active implantable medical devices;
- Directive 93/42/EEC regarding medical devices; and
- Directive 98/79/EEC regarding in-vitro diagnostic medical devices.

These Directives create new responsibilities and technical requirements related to the design and manufacture of instruments prior to their being placed on the market, where each participant (manufacturer, distributer/importer, user, public and government) plays an important role.

Although many instruments are covered by the Medical Devices Directive, this sphere of regulation allows each Member State to consider additional measures to protect public health and its citizens. In fact, after placing them on the market and putting them into service no further regulated control (according to EU policy) exists for those medical devices.

Products that fall within the scope of these Directives must meet all the applicable essential requirements and must be CE marked to show that they comply. Such products may then be freely sold throughout the European Economic Area (EEA) without being subject to additional national legislation, except in the field of funding and reimbursement [2].

In line with international requirements, the three main Directives have been supplemented over time by a number of modifying and implementing Directives, including the most recent technical revision brought about by Directive 2007/47 EEC [3] which was transposed for Portuguese legislation by Law-Decree no. 145/2009, dated 17 June 2009.

2.1 Harmonization of the term «medical device»

The term *medical device* includes everything from highly sophisticated computerized medical equipment down to simple wooden tongue depressors, including a wide range of products varying in complexity and application. Several different international classification systems for medical devices are still in use in the world today [4]. However, considering its relevance in patient safety it is very important to achieve harmonization in medical device nomenclature.

According to Directive 2007/47/EC, *medical device* means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- research, replacement or modification of the anatomy or of a physiological process;
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

2.2 The impact of medical devices in the world economy

In the health sector, medical technology offers a wide range of products covered by community legislation and consequently transposed into national law. This sector has a dynamic and competitive industry within a global market of nearly 10 000 types of products.

According to the Eucomed database [5], in 2007 the community market amounted to €72 billion with an upwards trend (annual growth up to 6 %). It is the second biggest market worldwide (approx. 33 %) after the USA (± 37 %) and before Japan (± 15 %). The medical device industry employs more than 500 000 people in Europe. Table 1 shows the number of employees in the European Zone in 2007. In Portugal, it can be seen from Table 1 that the medical technology industry has a low impact on the trade balance.

Country	No. of Employees	% of European
Austria	6 000	1.4 %
Belgium	5 500	1.3 %
Czech Republic	12 760	2.9 %
Denmark	14 000	3.2 %
Finland	3 000	0.7 %
France	40 000	9.2 %
Germany	110 000	25.3 %
Greece	2 500	0.6 %
Hungary	4 250	1.0 %
Ireland	26 000	6.0 %
Italy	29 815	6.9 %
Netherlands	9 500	2.2 %
Norway	500	0.1 %
Poland	8 700	2.0 %
Portugal	3 200	0.7 %
Romania	15 000	3.5 %
Slovakia	2 198	0.5 %
Slovenia	1 237	0.3 %
Spain	25 400	5.8 %
Sweden	15 000	3.5 %
Switzerland	40 000	9.2 %
United Kingdom	60 000	13.8 %
Total Europe	**434 560**	**100 %**

Table 1 European Medical Technology Employment. Source: Eucomed, 'An introduction to the Medical Technology industry' [5]

2.3 The life-span of a medical device

The principal phases in the life-span of a medical device include the conception and development, planning, manufacturing, packaging and labeling, advertising, sale and use. Any of these may overlap and interactions can affect the safety and performance of a medical device.

Usually, the manufacturer is engaged in the first three phases of the medical device's life-span and the user is a professional in a healthcare facility (but the user may also be the patient). The manufacturer is responsible for ensuring that products conform to the applicable legal requirements, and plays an important role in a) producing the device and b) representing the principal entity (technology/industry sector) involved in the pre-marketing device.

The notified body is another *actor* with an important responsibility for carrying out tasks relating to the procedures of conformity assessment. This is a competent authority appointed by the government of each Member State with authority to act on behalf of the government in order to ensure that the requirements of the appropriate Directive(s) are transposed into national law, and that they are subsequently applied.

2.3.1 Registration, control and supervision of medical devices

Once an assessment has been made of the compliance of a medical device with the relevant requirements and the CE mark affixed to it, it can be traded freely. However, several EU Member States (including Portugal) require a registration system for products, so that the number of products that are actually in circulation in their market can be controlled.

All EU Member States are subjected to the same European regulations, up until the moment that the devices are placed on the market and put into service.

In today's global market with so many products and of such diversity, associated with limited public authority resources, more and more Member States set up surveillance systems for the users of these products in order to detect suspicious errors or failures in the field. A surveillance system for the in-service use of instruments is a requirement for all medical devices, meaning that the manufacturer has to identify all those events that are likely to cause serious injury or death to a patient, user or third party [6].

Due to this knowledge, to the politics of medicine, and also to the assessment of medical devices and health technology, manufacturers are obliged to submit a report on any such occurrences to the competent authority of the country in which the device is manufactured, in order to centrally analyze and register the event and, consequently, trigger the appropriate measures to eliminate or minimize the possibility of recurrence thereof. Regarding the undeniable importance of this approach, the impact of the metrological traceability of medical devices with measuring functions is very important and must be highlighted by the competent authorities. However, in the current situation, it seems that this matter is often somewhat neglected.

All medical devices must satisfy the systems of pre-market review, such as risk management for the requirements of safety and performance, quality system (some low-risk devices may be exempt) and labeling. However, the degree of regulatory scrutiny increases with the potential risks of the medical device, as evidenced by the risk-based device classification system [7].

In Portugal, the regulatory surveillance system for medical devices in use is still very distant from (and therefore unknown by) its main audience (i.e. users and health professionals). Any strategy for future development in this field has to pass through increased participation of users in the system, which includes governmental cooperation by developing a closer relationship between the ministries and organizations involved, which creates a benefit for the entire health and economic system. Regarding the fact that better measurements lead to reduced costs, an interdisciplinary task force must be set up with a transversal application for the field of medical devices.

3 Considerations of metrological assurance of medical measurements

The science of measurements is part of a technical community as a whole, providing tools to ensure the reliability of the technologies used. To the common user, these metrology tools can either be relevant or irrelevant, but for the safety of human lives, the benefits provided by metrology are present every day and everywhere.

Measurements are essential in medical diagnosis and the prevention and treatment of diseases, risk assessment and monitoring of patients. Such measurements are performed every day; moreover, as the measurement results become more important in medicine so they must be more accurate and also comparable in different locations over time. Only then is it possible to optimize patient care and to efficiently manage healthcare funds.

In the Portuguese health sector, a large number of initiatives have been implemented that aim at ensuring the certification/accreditation of public and private hospitals. In this context, the use of medical devices that incorporate a measuring function should not be omitted from the qualification process. However, at the present time, the requirements of the metrological traceability standard are sometimes neglected. Thus, as a part of accredited/certified activities, the measuring instruments must demonstrate compliance with the metrological traceability chain by means of their calibration/verification certificates on the basis of voluntary or policy regulation. These certificates are valid if issued by a laboratory accredited for the activities concerned, or by a national metrology laboratory (both signatories of their corresponding mutual recognition agreements).

In the context of metrology, "trust" means traceability of measurements to the SI with a certain confidence level. In the health sector, due to the inherent risk to human life it is necessary to measure quantities as accurately as possible [8].

A simple example is incorrectly measured blood pressure, which is a major risk to an individual's health. Here, metrological control has to play a key role through technical guidelines.

In order to demonstrate the impact of ensuring adequate traceability of medical equipment in public health, several studies have been conducted, mainly focusing on the accuracy of measurements and the traceability chain as an essential tool to guarantee results. The findings are worthy of reflection and consideration [9, 10, 11, 12, 13, 14] and in this same context the World Health Organization (WHO) has published information promoting good practices for the use of medical equipment. Considering the analogy with other sectors of society in which the practice of metrological traceability is supposed to be regularly enforced, so the health and medical sector should not continue to be isolated from legal metrological checks.

3.1 The role of standards and Recommendations to increase enforcement

For certain kinds of medical devices, several countries have adopted OIML Recommendations, or have developed their own regulations. This requires implementing legal metrological control, but can also be viewed as a voluntary act, in the case of calibration.

According to the recommendations of the European Community, all medical devices must meet the requirements of ISO and the IEC. In addition, there are also European and IEC standards that are specially adapted to European Community requirements [15]. These standards are developed and harmonized by the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC).

The classification of medical devices by potential risk and by methods of risk analysis is a major step towards harmonization between European policy regulations and the national metrology institutes.

The combined application of medical safety by measurement standards and reference standards reduces the potential health hazard to both patients and medical personnel to a minimum. Therefore, standardization should include requirements for technical service and calibration of medical devices, software control, etc.

On the other hand, Directive 93/42/EEC, 10th item, Annex I related to the requirements of the devices, states that those devices with a measuring function must be designed in such a way as to ensure measurement accuracy. This requirement is referred to throughout the Directive [16]. Moreover, as part of quality assurance, this Directive is relatively demanding as it is based on ISO 13485 [17] as the reference standard for the regulatory requirements. However, the 8th section of this standard introduces the requirements for measurement systems which are not that stringent. Through its supplement, the technical report ISO/TR 14969 [19] deepens the measurement requirements. In order to enforce this approach, Table 2 shows the relation between the relevant OIML Recommendations and the corresponding European standards.

3.1.1 A new approach for medical measurements

International Organizations such as the WHO and the European Commission identify medical technology and medical devices as being key to ensuring public health [20]. Training of health professionals is also essential.
Another fundamental pillar is the consolidation of metrological knowledge, which must be part of any organization's strategy. The development of this culture and its consequent application to safety and the performance of instruments require long-term actions with widespread monitoring. Probably, these aspects are as important as the concerns about the technical and legal regulatory framework.

According to the group of risk, medical devices fall into four groups [21]:

- Group I requires declaration of correspondence;
- Group IIa requires declaration of correspondence and certification of the quality system;
- Group IIb requires declaration of correspondence and independent testing and certification of the quality system; and
- Group III requires independent assessment of the design, declaration of correspondence, and independent testing and certification of the quality system.

These modules can be compared to the Directive on Measuring Instruments 2004/22/EC (MID). As we know, the philosophy of the MID was to adopt a decisively modern regulatory approach, leaving much more room for technological innovation and more choice for manufacturers in conformity assessment procedures, aligning Community legislation with international standards. The objective was to allow free movement of goods between the Member States, while allowing for

Measuring instrument	OIML	EN
Mechanical non-invasive sphygmomanometers	R 16-1 (2002)	EN1060-1:1995+A2:2009 EN 1060-2:1995+A1:2009 EN 1060-3:1997+A2:2009 EN 1060-4:2004
Non-invasive automated sphygmomanometers	R 16-2 (2002)	
Medical syringes	R 26 (1978)	EN 20594-1:1993
Standard graduated pipettes for verification officers	R 40 (1981)	EN ISO 4787:2010
Electroencephalographs - Metrological characteristics - Methods and equipment for verification	R 89 (1990)	EN 60601-2-26:2003
Electrocardiographs - Metrological characteristics - Methods and equipment for verification	R 90 (1990)	EN 60601-2-25:1995/A1:1999 EN 60601-2-27:2006
Measuring instrumentation for human response to vibration	R 103 (1992)	EN ISO 8041:2005
Pure-tone audiometers (including Annexes A to E)	R 104 (1993)	EN 60645-2:1997 EN 60645-1:2001
Clinical electrical thermometers for continuous measurement	R 114 (1995)	EN 12470-1,2,3,4:2000 + A1:2010
Clinical electrical thermometers with maximum device	R 115 (1995)	
Equipment for speech audiometry	R 122 (1996)	EN 60645-2:1997

Table 2 OIML Recommendations and European Standards for certain categories of medical devices

the possibility of continuing to manufacture in conformity with national rules for the home market. This is the same philosophy for the medical devices Directive.

However, the principle of the metrological traceability chain (which is the aim of this paper) is missing. This may be achieved by a new approach, where convergence towards a MID structure could be achieved by implementing a new dynamic and trustworthy system for the provision of reliable measurements. Indeed, this new approach will cover the specific metrological requirements for those instruments that are in use.

Each Member State should strive to improve its national legislation in order to apply the specific requirements for the instruments they are placing on the market and putting into use. Prior to being placed on the market, the devices must meet the applicable metrological requirements and if they are in use for some time then they are subject to re-verification tests. If it is demonstrated that they are operating outside their metrological limits (i.e. the maximum permissible errors) then they will be rejected.

Taking into account specific national operating conditions, Member Sates should set up a generic network to support and harmonize the metrological limits for each group of medical devices, as a holistic approach. The role of metrology in this field must also be highlighted by new International Standards, in order to improve the definition of the metrological requirements, focusing on those medical devices that have an in-built measuring function.

In this context, the verification requirements could be drawn up for each type of instrument of an enforcement system and based on specific national regulations. Special attention must be paid to all systems including software, to ensure the integrity, authenticity and privacy of the data.

Some countries have already successfully implemented metrological verification for several categories of medical devices. In the legal framework of Portuguese legislation, certain measuring instruments used in the field of x-rays are submitted to metrological control, according to national regulation No. 1106/2009, dated 24 September 2009.

4 Conclusions

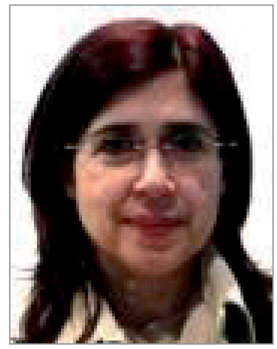
This paper has presented a brief overview of the key role of metrology and legal control in the field of medical measurements, and has also provided some suggestions for a new approach focusing on the present national and European regulatory system. Taking into account technological innovations, economic significance and technical barriers, an explanation was provided concerning the legal framework of Member States and the consequent impact of metrological regulations. The current situation in Portugal was also highlighted, where no further regulatory metrological control exists for the majority of medical devices with measuring functions exists after they are placed on the market and put into service. Undoubtedly, this issue plays an important role in the field of medical measurements. ■

Acknowledgements

The author expresses her thanks to Engº Cartaxo Reis (Director of the Legal Metrology Unit of the IPQ) for his contribution to the revision of this paper.

The Author

Engª Maria do Céu Ferreira
Portuguese Institute for Quality
Department of Metrology
Rua C. à Av. dos três Vales
2825 Monte de Caparica, Portugal
Tel.: +351 212 948 100 - Fax: +351 212 948 188
E-mail: mcferreira@mail.ipq.pt



References

[1] Brownson R.C., Baker E.A., Leet T.L., Gillespie N. (2002). *Evidence-Based Public Health*, New York: Oxford University Press

[2] Jonas S., Michael B., Reinhard B. (2009). *Balancing adoption and affordability of medical devices in Europe*. Health Policy No. 92, 218–224

[3] Council Directive 2007/47/EEC of 5 September 2007. *Official Journal L 247, 21/09/2007 P. 0021 – 0055*

[4] World Health Organization (2003). *Medical Device Regulations*. WHO. Geneva. ISBN 9241546182.http://www.who.int/medical_devices/en/

[5] http://www.eucomed.be/ press/~/media/pdf/tl/2008/portal/press/ backgrounders/mddbackgrounder.ashx

[6] Keshia M. P., Dan Morhaimb, Michael A. Williams. (2010). *The public's perspectives on advance directives: Implications for state legislative and regulatory policy.* Health Policy No. 96, 57–63

[7] Gundarov V. P., Kavalerov G. I. (2001). *Standardization and Certification of Quality of Medical Devices*. Biomedical engineering, Vol. 35, No. 3, 2001, pp.123–126

[8] Chião et al. (2008). *Metrology and Standards Needs for Some Categories of Medical Device*. J. Res. Natl. Inst. Stand. Technol, No. 113, 121–129

[9] Lucatelli M. V. et al. (2003). *Engenharia clínica e a metrologia em equipamentos eletromédicos*, in metrologia para a Vida, Sociedade Brasileira de Metrologia (SBM), Setembro 01–05, 2003, Recife, Pernambuco – Brazil

[10] Minyailik G. M. (2001): *Standardization and Certification of Medical Devices: Results and Prospects*. Biomedical Engineering, Vol. 35, No. 3, 2001, pp. 121–122. Translated from Meditsinskaya Tekhnika, Vol. 35, No. 3, 2001, pp. 3–4

[11] Monteiro E.C., Lessa M. L.(2005). *A metrologia na área de saúde: garantia da segurança e da qualidade dos equipamentos electromédicos*. Engevista, V.7, no. 2, P.51–60

[12] Sriram R.D., Fenves S. J. (2008): *Manufacturing Metrology and standards for the healthcare enterprise program summary*. National Institute of Standards and Technology. NISTIR 7487

[13] Turner M.J., Kam P.C., Baker A.B. (2004). *Metrology in Medicine*. Department of Anesthetics, University of Sydney.http://www.personal.usyd.edu.au/~mjturn er/metrology_in_med_msa_2004.pdf

[14] Council Directive 90/385/EEC of 20 June 1990 concerning the approximation of the laws of the member states relating to active implantable medical devices. Official Journal L 189, 20.7.1990, p. 17

[15] Wilson et al (1999): *An analysis of the causes of adverse events from the quality in Australia*. Healthcare Study. Med. J. Aust. 1999 170:411– 415

[16] http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm#linkBoxTools

[17] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Official Journal L 169 12/07/1993 P. 0001–004393/42/CE

[18] ISO 13485: 2003. Medical devices - Quality management systems - requirements for regulatory purposes

[19] ISO/TR 14969:2004. Medical devices - Quality management systems - guidance on the application of ISO 13485:2003

[20] Report on the functioning of the medical devices Directive. http://www.bsigroup.com/upload/Standards%20&%20Publications/Healthcare/MDDReport2002.pdf

[21] Council Directive 98/78/EEC of 27 October 1998 concerning ***in vitro* diagnostic medical devices.** Official Journal L 33, 7/12/1998

[22] http://www.eucomed.org/ press/~/media/A4261DDBBA854C7F852CA16F7AC3C716.ashx

OIML Systems

Basic and MAA Certificates registered 2011.07–2011.09

Information: www.oiml.org section "OIML Systems"

The OIML Basic Certificate System

The *OIML Basic Certificate System for Measuring Instruments* was introduced in 1991 to facilitate administrative procedures and lower the costs associated with the international trade of measuring instruments subject to legal requirements. The System, which was initially called "OIML Certificate System", is now called the "OIML Basic Certificate System". The aim is for "OIML Basic Certificates of Conformity" to be clearly distinguished from "OIML MAA Certificates".

The System provides the possibility for manufacturers to obtain an OIML Basic Certificate and an OIML Basic Evaluation Report (called "Test Report" in the appropriate OIML Recommendations) indicating that a given instrument type complies with the requirements of the relevant OIML International Recommendation.

An OIML Recommendation can automatically be included within the System as soon as all the parts - including the Evaluation Report Format - have been published. Consequently, OIML Issuing Authorities may issue OIML Certificates for the relevant category from the date on which the Evaluation Report Format was published; this date is now given in the column entitled "Uploaded" on the Publications Page.

Other information on the System, particularly concerning the rules and conditions for the application, issue, and use of OIML Certificates, may be found in OIML Publication B 3 *OIML Certificate System for Measuring Instruments* (Edition 2003, ex. P 1) and its *Amendment* (2006) which may be downloaded from the Publications page. ■

The OIML MAA

In addition to the Basic System, the OIML has developed a *Mutual Acceptance Arrangement* (MAA) which is related to OIML Type Evaluations. This Arrangement - and its framework - are defined in OIML B 10-1 (Edition 2004) and its Amendment (2006), and B 10-2 (2004).

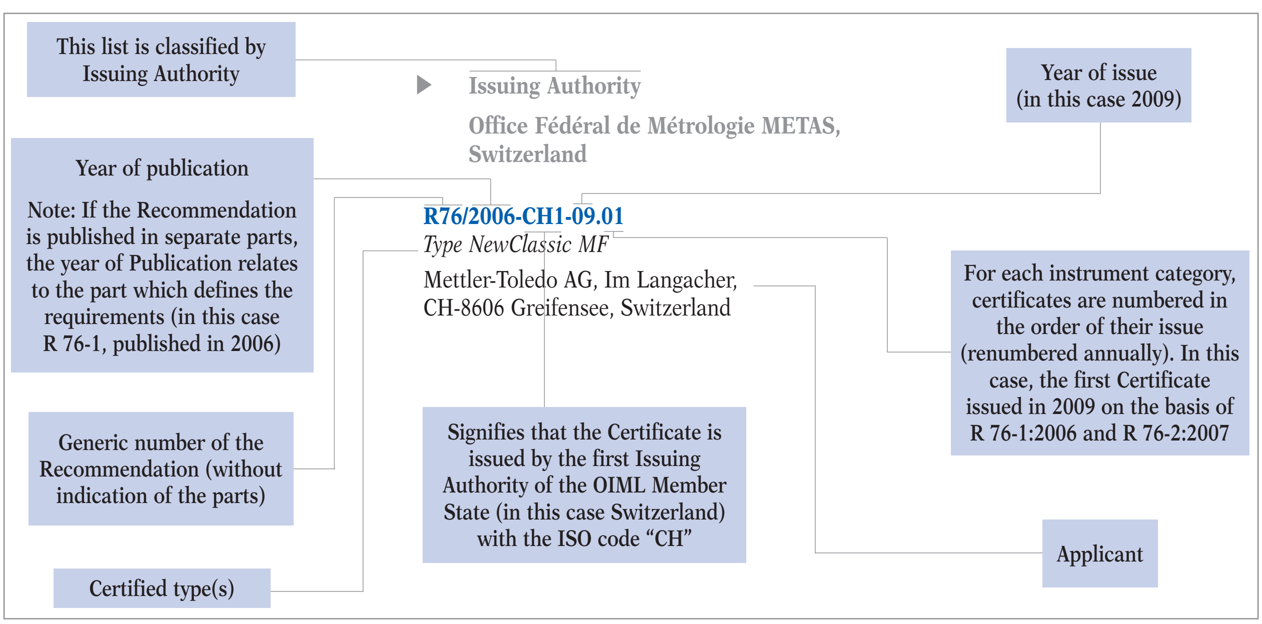
The OIML MAA is an additional tool to the OIML Basic Certificate System in particular to increase the existing mutual confidence through the System. It is still a voluntary system but with the following specific aspects:

- Increase in confidence by setting up an evaluation of the Testing Laboratories involved in type testing;
- Assistance to Member States who do not have their own test facilities;
- Possibility to take into account (in a Declaration of Mutual Confidence, or DoMC) additional national requirements (to those of the relevant OIML Recommendation).

The aim of the MAA is for the participants to accept and utilize MAA Evaluation Reports validated by an OIML MAA Certificate of Conformity. To this end, participants in the MAA are either Issuing Participants or Utilizing Participants.

For manufacturers, it avoids duplication of tests for type approval in different countries.

Participants (Issuing and Utilizing) declare their participation by signing a Declaration of Mutual Confidence (Signed DoMCs). ■



INSTRUMENT CATEGORY
CATÉGORIE D'INSTRUMENT

Water meters intended for the metering of cold potable water

R 49 (2006)

▶ Issuing Authority / *Autorité de délivrance*

Czech Metrology Institute (CMI), Czech Republic

R049/2006-CZ1-2011.01
Magnetic Flow Meter - Type: Transmitter type 8732 and Flow Sensor types 8705 and 8711
Emerson Process Management/ Rosemount Flow Division, 12001 Technology Drive, US-553 44 MN Eden Prairie, United States

▶ Issuing Authority / *Autorité de délivrance*

Laboratoire National de Métrologie et d'Essais, Certification Instruments de Mesure, France

R049/2006-FR2-2009.01 Rev. 1
Water meters types 171 A and 171 B
Hydrometer GmbH, Industriestrasse 13, DE-91522 Ansbach, Germany

R049/2006-FR2-2011.04
Water meters ITRON type FLOSTAR TU1 65, 80, 100 & 150
Itron France, 11, Boulevard Pasteur, FR-67500 Haguenau, France

▶ Issuing Authority / *Autorité de délivrance*

Physikalisch-Technische Bundesanstalt (PTB), Germany

R049/2006-DE1-2007.03 Rev. 4
Water meter intended for the metering of cold potable water - Type: SM100VR, SM150VR
Elster Metering Ltd., 130 Camford Way, Sundon Park, Luton LU3 3AN, Bedfordshire, United Kingdom

R049/2006-DE1-2011.02
Water meter intended for the metering of cold potable water and hot water - Type: M200, M210, M210 genius
Elster messtechnik GmbH, Otto-Hahn Strasse 25, DE-68623 Lampertheim, Germany

INSTRUMENT CATEGORY
CATÉGORIE D'INSTRUMENT

Automatic catchweighing instruments
Instruments de pesage trieurs-étiqueteurs à fonctionnement automatique

R 51 (2006)

▶ Issuing Authority / *Autorité de délivrance*

Physikalisch-Technische Bundesanstalt (PTB), Germany

R051/2006-DE1-2007.07 Rev. 2
Automatic catchweighing instrument - Type: AB C
Mettler-Toledo Garvens GmbH, Kampstr. 7, DE-31180 Giesen, Germany

INSTRUMENT CATEGORY
CATÉGORIE D'INSTRUMENT

Metrological regulation for load cells (applicable to analog and/or digital load cells)
Réglementation métrologique des cellules de pesée (applicable aux cellules de pesée à affichage analogique et/ou numérique)

R 60 (2000)

▶ Issuing Authority / *Autorité de délivrance*

Dansk Elektronik, Lys & Akustik (DELTA), Denmark

R060/2000-DK3-2011.01
Stainless steel, compression load cell with digital output - Type: TZD
Societa Cooperativa Bilanciai s.r.l, Via S. Ferrari, 16, IT-41011 Campogalliano (Modena), Italy

▶ Issuing Authority / *Autorité de délivrance*

International Metrology Cooperation Office, National Metrology Institute of Japan (NMIJ) National Institute of Advanced Industrial Science and Technology (AIST), Japan

R060/2000-JP1-2010.04 Rev. 1 (MAA)
Compression Load cells - Type: LCC11T010-KC, LCC11T020-KC, LCC11T030-KC,
A&D Company Ltd., 3-23-14 Higashi-Ikebukuro, Toshima-Ku, JP-170-0013 Tokyo, Japan

R060/2000-JP1-2010.16 Rev. 1 (MAA)
DC002-10T, DC002-20T, DC002-25T, DC002-30T, DC002-40T,
Minebea Co. Ltd., 1-1-1 Katase Fujisawa-shi,
JP-251-8531 Kanagawa-ken, Japan

R060/2000-JP1-2011.05 (MAA)
LCM19K500, LCM19T001, LCM19T1,5, LCM19T002
A&D Company Ltd., 3-23-14 Higashi-Ikebukuro, Toshima-Ku,
JP-170-0013 Tokyo, Japan

R060/2000-JP1-2011.06 (MAA)
DCC-20T, DCC11-24T, DCC11-36T
Yamato Scale Co. Ltd., 5-22 Saenba-cho, JP-673-8688 Akashi,
Hyogo, Japan

R060/2000-JP1-2011.07 (MAA)
Beam (shear) load cell - Type: C2T1-1T-M1
Minebea Co. Ltd., 1-1-1 Katase Fujisawa-shi,
JP-251-8531 Kanagawa-ken, Japan

R060/2000-JP1-2011.08 (MAA)
DC003-10T, DC003-20T, DC003-30T, DC003-40T, KDC003-10T,
KDC003-20T, KDC003-30T, KDC003-40T,
Minebea Co. Ltd., 1-1-1 Katase Fujisawa-shi,
JP-251-8531 Kanagawa-ken, Japan

INSTRUMENT CATEGORY
CATÉGORIE D'INSTRUMENT

Nonautomatic weighing instruments
Instruments de pesage à fonctionnement non automatique

R 76-1 (1992), R 76-2 (1993)

▶ **Issuing Authority / *Autorité de délivrance***

National Measurement Office (NMO), United Kingdom

R076/1992-GB1-2011.01 Rev. 2 (MAA)
XT Series, Models XT 100, XT 101, XT 200, XT 300, XT 400,
XT 410 and XT 420 non-automatic weighing instruments
Avery Berkel, Foundry Lane, Smethwick,
West Midlands B66 2LP, United Kingdom

R076/1992-GB1-2011.02 (MAA)
PDI
CAS Corporation, #19, Ganap-Ri, Gwangjuk-Myoun, Yangju-Si,
KR-482-841 Kyunggi-Do, Korea (R.)

▶ **Issuing Authority / *Autorité de délivrance***

Physikalisch-Technische Bundesanstalt (PTB), Germany

R076/1992-DE1-2007.08 Rev. 2 (MAA)
Non-automatic price-computing weighing instrument for direct sales to the public - Type: BC II..
Bizerba GmbH & Co. KG, Wilhelm-Kraut-Strasse 65,
DE-72336 Balingen, Germany

INSTRUMENT CATEGORY
CATÉGORIE D'INSTRUMENT

Non-automatic weighing instruments
Instruments de pesage à fonctionnement non automatique

R 76-1 (2006), R 76-2 (2007)

▶ **Issuing Authority / *Autorité de délivrance***

Dansk Elektronik, Lys & Akustik (DELTA), Denmark

R076/2006-DK3-2011.06
Non-automatic weighing instrument - Type: FT-11 / FT-11D / FT-12 / FT-13 / FT-15 / FT-15D / FT-16 / FT-16D
Flintec GmbH, Bemannsbruch 9, DE-74909 Meckesheim,
Germany

▶ **Issuing Authority / *Autorité de délivrance***

National Measurement Office (NMO), United Kingdom

R076/2006-GB1-2011.01 (MAA)
OP-960+
Atrax Group (NZ) Ltd., 390 A Church Street, Penrose, Auckland,
New Zealand

▶ **Issuing Authority / *Autorité de délivrance***

Physikalisch-Technische Bundesanstalt (PTB), Germany

R076/2006-DE1-2009.01 Rev. 2
Nonautomatic electromechanical weighing instrument - Type: MSX
SARTORIUS Weighing Technology GmbH,
Weender Landstrasse 94-108, DE-37075 Gottingen, Germany

INSTRUMENT CATEGORY
CATÉGORIE D'INSTRUMENT

Automatic level gauges for fixed storage tanks
Jaugeurs automatiques pour les réservoirs de stockage fixes

R 85 (2008)

▶ Issuing Authority / *Autorité de délivrance*

Czech Metrology Institute (CMI), Czech Republic

R085/2008-CZ1-2011.01
Magnetostrictive level gauge - Type: AMT (probe) / MASTER LEVEL AT06907 (console)
Assytech S.r.l., Via Val d'Aosta 169, I-23018 Talamona (SO), Italy

R085/2008-CZ1-2011.02
Magnetostrictive level gauge - Type: XMT (probe) / MAGLINK32 (console)
Start Italiana srl., via Napoli 29A, I-20030 Bovisio Masciago (MB), Italy

R085/2008-CZ1-2011.03
Magnetostrictive level gauge - Type: XMT-SI-485 / MAGLINK32 (console)
Start Italiana srl., via Napoli 29A, I-20030 Bovisio Masciago (MB), Italy

▶ Issuing Authority / *Autorité de délivrance*

National Measurement Office (NMO), United Kingdom

R085/2008-GB1-2011.01
AMETEK 7100 PSU Controller and AMETEK Petro-Stik probe
Dem. G. Spyrides S.A., 24 Athinon Avenue, GR-10441 Athens, Greece

INSTRUMENT CATEGORY
CATÉGORIE D'INSTRUMENT

Fuel dispensers for motor vehicles
Distributeurs de carburant pour véhicules à moteur

R 117 (1995) + R 118 (1995)

▶ Issuing Authority / *Autorité de délivrance*

International Metrology Cooperation Office, National Metrology Institute of Japan (NMIJ) National Institute of Advanced Industrial Science and Technology (AIST), Japan

R117/1995-JP1-2011.01
Fuel dispenser for motor vehicles, A series
Tokico Technology Ltd., 3-9-27 Tsurumi Chuo, Tsurumi-ku, Yokohama City, Kanagawa, Japan

▶ Issuing Authority / *Autorité de délivrance*

Slovak Legal Metrology (Banska Bystrica), Slovakia

R117/1995-SK1-2011.01
Measurement Transducer (to be used as a part of LPG dispenser) - Type: PRIMA
2 A Mühendislik A.S., Kagithane Cad. N°: 2 Kagithane, 34400 Istanbul, Turkey

OIML CERTIFICATE SYSTEM

List of OIML Issuing Authorities

The list of OIML Issuing Authorities is published in each issue of the OIML Bulletin. For more details, please refer to our web site: www.oiml.org/certificates.
There are no changes since the last issue of the Bulletin.

		R 16	R 21	R 31	R 49	R 50	R 51	R 58	R 60	R 61	R 75	R 76	R 81	R 85	R 88	R 93	R 97	R 98	R 99	R 102	R 104	R 105	R 106	R 107	R 110	R 112	R 113	R 114	R 115	R 117/118	R 122	R 126	R 128	R 129	R 133	R 134	R 136
AT1	Bundesamt für Eich- und Vermessungswesen (BEV)					■	■	■		■		■		■	■		■	■		■	■		■	■	■			■	■	■							
AU1	National Measurement Institute (NMI)				■	■	■		■			■		■									■	■						■		■		■			
BE1	SPF Economie, PME, Classes Moyennes et Energie											■					■	■																			
BG1	State Agency for Metrology and Technical Surveillance (SAMTS)											■						■																			
BR1	Instituto Nacional de Metrologia, Normalização e Qualidade Industrial (INMETRO)											■																									
CH1	Office Fédéral de Métrologie (METAS)	■		■	■	■	■		■	■		■					■	■				■	■	■						■							
CN1	General Administration of Quality Supervision, Inspection and Quarantine of P. R. China (AQSIQ)								■			■					■	■																			
CZ1	Czech Metrology Institute (CMI)				■							■	■	■								■								■						■	
DE1	Physikalisch-Technische Bundesanstalt (PTB)	■		■	■	■	■	■	■	■		■		■	■		■	■	■	■	■	■	■	■	■			■	■	■		■	■	■	■		■
DK1	The Danish Accreditation and Metrology Fund (DANAK)					■	■		■	■		■						■				■	■	■						■				■		■	
DK2	FORCE Certification A/S				■																																
DK3	Dansk Elektronik, Lys & Akustik (DELTA)					■	■		■	■		■											■	■										■		■	
ES1	Centro Español de Metrología (CEM)				■		■		■	■		■					■	■														■					
FI1	Inspecta Oy					■	■		■	■		■		■									■	■						■							
FR1	Ministère de l'Economie, de l'Industrie et de l'Emploi (MEIE)	*All activities and responsibilities were transferred to FR2 in 2003*																																			
FR2	Laboratoire National de Métrologie et d'Essais (LNE)			■	■	■	■	■	■	■		■		■	■		■	■		■		■	■	■	■			■	■	■		■		■			
GB1	National Measurement Office (NMO) - Formerly NWML		■		■	■	■		■	■	■	■		■				■				■	■	■						■				■		■	
GB2	National Physical Laboratory (NPL)																■																				
HU1	Hungarian Trade Licensing Office (MKEH)											■																									
JP1	National Metrology Institute of Japan / National Institute of Advanced Industrial Science and Technology (NMIJ / AIST)								■			■																	■	■							
KR1	Metrology and Measurement Division (KATS)											■																									
NL1	NMi Certin B.V.		■	■	■	■	■		■	■		■	■	■			■		■			■	■	■						■		■	■	■		■	
NL2	KIWA Nederland B.V.				■																																
NO1	Norwegian Metrology Service (Justervesenet)					■	■			■		■										■	■	■						■				■			
NZ1	Measurement and Product Safety Service (MAPSS Wellington)											■																									
PL1	Central Office of Measures (GUM)											■						■		■																	
RO1	Bureau Roumain de Métrologie Légale (B.R.M.L.)																■	■							■			■	■								
RU1	Russian Research Institute for Metrological Service (VNIIMS)			■	■	■	■	■	■	■		■		■	■	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	
SE1	Swedish National Testing and Research Institute AB (S.P.)					■	■		■	■		■		■				■					■	■						■							
SI1	Metrology Institute of the Republic of Slovenia (MIRS)											■																									
SK1	Slovak Legal Metrology				■							■																		■							
US1	NCWM, Inc.								■			■																									
VN1	Directorate for Standards and Quality (STAMEQ)											■																									

MEETING REPORT

OIML TC 12
Instruments for measuring electrical quantities

22–24 June 2011
London, United Kingdom

DR. PHILLIP MITCHELL, NMI Australia

A meeting of OIML TC 12 was held in London on 22–24 June 2011, hosted by the NMO (United Kingdom). The purpose of the meeting was to discuss the 5th Committee Draft (5CD) for the revision of OIML R 46 *Active electrical energy meters*.

There were 21 delegates in attendance representing 11 P-Members and 1 O-Member, as well as BIML Assistant Director Willem Kool. The meeting was chaired by Dr. Grahame Harvey (NMI Australia).

The meeting opened with a welcome from David Moorhouse (NMO, UK) followed by an introduction, brief history and outline of the agenda provided by Grahame Harvey. It was stated that, based on the maturity of the Committee Draft and the comments received, the aim was to produce a draft that could be considered for a draft Recommendation.

The agenda was divided into two parts: an initial discussion of major issues and then discussions on each specific comment. This report presents the major issues discussed at the meeting.

1 Temperature influence

There were two separate requirements for temperature: limits on temperature coefficients, and limits on error shifts due to the influence of temperature (which effectively clamp the maximum permissible error at temperate extremes).

It was agreed at the previous TC 12 meeting in 2009 (Bled, Slovenia) that the limits of error shift should be removed, and consideration given to temperature extremes. With no progress prior to the meeting, it was agreed at the meeting that a small working group (Netherlands and USA) would work on this and report back before the end of the meeting. This working group cooperated very successfully and proposed a solution that was agreed by all at the meeting. The requirements for temperature coefficients were modified slightly to allow double the limits for class D meters below –10 °C.

2 Parameterisation of current

There are several definitions related to current used in R 46. In order of decreasing magnitude, there are: I_{max}, I_{tr}, I_{min}, and I_{st}, corresponding to maximum, transitional, minimum and starting currents respectively. Meters are expected to perform best above I_{tr}, and manufacturers are required to specify all parameters.

However, the requirements in the 5CD set fixed ratios for I_{min} and I_{st} relative to I_{tr}. The USA raised concerns over this parameterisation, arguing that ANSI meters may perform within the maximum permissible errors over the entire current range, but would fail against R 46 because of the way the current is parameterised. To resolve this, it was agreed to modify Tables 1 and 2 to firstly remove the fixed ratios, and secondly to parameterise relative to I_{max}.

3 Poly-phase measurement

Following a comment by Austria, it was agreed to remove a sentence stating that for poly-phase meters, the mean flow shall be over the sum of all phases. This is because mean flow may be defined differently where flow is recorded for individual phases or directions of flow.

4 Maximum permissible errors

The maximum permissible errors (mpe) in Table 2 were specified slightly differently over different current ranges. It was proposed to extend the table to explicitly state maximum permissible errors for unity and non-unity power factors separately. This was agreed and values were proposed and agreed upon by all present.

5 Disturbances

Some of the limits of error shift for disturbances were given as 1/10 base maximum permissible error. The USA commented that this is difficult to assess in practice particularly for class C and D meters where this corresponds to 0.05 % and 0.02 %. Furthermore, an imbalance was recognised by Japan in some tests, where a factor of 1/10 was applied for classes A and B, and 1/2 for classes C & D, because the actual limit was tighter for class B than class C.

To resolve these issues, changes were made for the relevant disturbances so that the limits are now 1/3 base mpe for classes A, B, and C and 1/2 base mpe for class D.

6 Interval and multi-tariff meters

The participants discussed the great variety of intervals and billing systems used for interval metering throughout the world. It was therefore agreed that minimum storage periods for interval data should be determined by the national authority.

There was also agreement with the Canadian suggestion to add requirements for multi-tariff registration. Essentially, registration occurs in the correct register, and the sum of the multi-tariff register shall equate to the cumulative register.

7 Protection of metrological properties

There are several references to authorised personnel, so following a Canadian proposal it was agreed to state that levels of authorised access shall be determined by the national authority.

The software requirements are largely based on OIML D 31, but the section on software updates had not been included. It was suggested by France that these requirements should be added. France produced draft text based on OIML D 31 and it was agreed that the text would be included.

8 Testability

It was suggested by France that additional requirements should be added for the wavelength and strength of test pulse outputs to avoid issues that have been encountered in reliably sensing the pulses. France proposed requirements based on IEC 62052.11 (EN 50470-01). The USA also provided draft ANSI requirements. Both were considered, but the IEC requirements were deemed simpler, and so it was agreed to include them.

9 Durability

The durability test (based on draft IEC 62059-32-1) was considered by some to be quite onerous (1000 hours) and also not suitable for ANSI meters given their high maximum current values. It was agreed to remove the test procedure and replace it with: "The test procedure for durability shall be taken from either IEC or ANSI standards for durability of electricity meters."

Participants attending the OIML TC 12 meeting

10 Validation procedures

Validation procedures based on OIML D 31 have been included in this Committee Draft, but it was agreed that any validation procedure that requires analysis of source code is not justifiable for electricity meters. The cost and added complexity would greatly outweigh the benefits. Therefore, the validation procedures have been limited to only AD (Analysis of Documentation) and VFTSw (Validation by Functional Testing of the Software Functions).

11 Starting current

An Austrian comment on the verification test for checking the starting current led to discussions about how long to wait to see if the meter has started. Austria provided a formula and test procedure which it was agreed would be added.

12 Impulse voltage test

For the impulse voltage test, multiple test voltages are specified for different rated systems voltages. A source energy of 10 J is also specified, and it was agreed that this is an important parameter to retain, so a source series impedance is not specified. Given the need for different test setups in each case, it was agreed that reference to IEC 61000-4-5 is not always appropriate and should be removed.

Concluding remarks

The Secretariat would like to thank all the participants for the high level of cooperation and technical expertise provided during the meeting. It believes that the text is now essentially complete, although further work may be needed in future to address issues not included in the draft such as the use of modular meters and current and voltage transformers. It is planned to circulate a 6th Committee Draft for voting prior to proceeding to Draft Recommendation status. ■

MEETING REPORT

OIML TC 5/SC 1 *Environmental conditions*

27–28 June 2011 Centraal Museum, Utrecht, The Netherlands

George Teunisse, OIML TC 5/SC 1 Secretariat

A meeting of OIML TC 5/SC 1 *Environmental conditions* took place in Utrecht, the Netherlands, on 27 and 28 June 2011, in conjunction with a meeting of the CIML Presidential Council and the first OIML Seminar on *Conformity to Type*. The meeting discussed the most important topics from the comments received on the first Committee Draft (1 CD) of the revision of OIML D 11:2004 *General requirements for electronic measuring instruments*.

Revision of OIML D 11

OIML D 11 is a horizontal document, which serves as a tutorial and catalog to support OIML Technical Committees and Subcommittees in selecting the appropriate environmental immunity requirements for measuring instruments and related harmonized test methods simulating environmental influences. Since the publication of the current version in 2004, the world has experienced significant innovations in wireless and wire-bound communication technology. International standards laying down requirements and test methods to prevent mutual incompatibility or interference between instruments have been amended or further developed since then. This is one of the reasons why the CIML approved the revision of OIML D 11:2004 at its meeting in 2008 in Sydney.

Moreover, it was decided at that CIML Meeting to widen the scope of the Document. The new scope covers the requirements and tests concerning the exposure of all kinds of measuring instruments (electronic as well as non-electronic) to environmental quantities.

At the beginning of 2011 the TC 5/SC 1 Secretariat produced a first CD, which was circulated for comments with a deadline of 16 May 2011. Twelve out of the 19 P-members and three O-members responded to the request for comments on the 1 CD. A synthesis report of these comments, including observations and responses by the Secretariat, was circulated a few weeks prior to the TC 5/SC 1 meeting. That report also highlighted the most important items for discussion during the meeting.

Besides discussions concerning the title, scope and terminology of the Document, much attention was paid to the inclusion of new requirements and tests related to disturbances on the mains power supply caused by non-sinusoidal disturbances and the level of immunity required for mobile communication devices such as mobile phones. Another discussion item was the appropriate requirements for battery-powered measuring instruments on board vehicles.

Although the scope of the Document is clear, the suggested title was also a point of discussion.

Close contact between the Secretariats of OIML TC 5/SC 1 and OIML TC 1 *Terminology* will be maintained because the VIML (*International Vocabulary of Legal Metrology*) is also being revised and attention has been paid to keeping terminology synchronized.

The introduction of an additional environmental class similar to the one prescribed in the European Union's Measuring Instruments Directive (MID) for battery-powered instruments (E3) was discussed. It was considered that the potentially disturbing electromagnetic phenomena on battery-powered instruments may differ considerably from those directly powered by AC mains, and that creating a separate environmental class may help in the selection of the appropriate requirements and test methods.

Today's mains power supply voltages suffer disturbances caused by analog and digital mains power line communication means (audio telecommunication or LAN) and also from local energy sources (photovoltaic cell converters) and switched-mode power supplies.

In international standardization there is a focus on developing standardized test methods for the simulation of this kind of disturbance. As soon as such methods have sufficiently matured, the appropriate requirements and tests should be included in OIML D 11 because many types of measuring instruments may be affected. This is particularly true for electrical energy meters which have the most direct connection to the mains and therefore need to be immune to such phenomena.

The views of the participants in the TC 5/SC 1 meeting were quite diverse concerning the level of immunity against the influence of electromagnetic fields produced by mobile phones. Dr. Thorsten Schrader (PTB, Germany) presented test results on the susceptibility of on-site weigh bridges and the further approach to this subject in Germany. This served as a good starting point for the discussion, after which a widely supported compromise was reached.

An ad-hoc working group (comprising NL, US and DK) was set up and was given the task of studying the differences between the standardized requirements and methods for testing on-board battery powered instruments in order to produce well-founded advice on which requirements and tests to include in OIML D 11.

It is the intention of the Secretariat to produce the 2 CD of the revision of OIML D 11:2004 and to circulate it for comments and vote well before the end of 2011. ■

Participants atending the OIML TC 5/SC 1 meeting

MoU

New MoU between the OIML and the IEC

13 October 2011
Prague, Czech Republic

The OIML and the IEC (International Electrotechnical Commission) have concluded an agreement, in the form of a "Memorandum of Understanding" (MoU), covering the relationship between the two organizations in matters of technical cooperation, conformity assessment and the development and application of standards.

The MoU was signed during a special ceremony that took place in Prague on 13 October 2011, as part of the 46th CIML Meeting. Signing the MoU were Mr. Pierre de Ruvo on behalf of the Secretary General and CEO of the IEC, Mr. Aharon Amit, who could not be present and Peter Mason, CIML President. Mr. De Ruvo is the Executive Secretary of the IECEE, the IEC's conformity assessment system for electrotechnical equipment.

Mr. De Ruvo also represented the IEC in the working group that drafted the MoU. The OIML representatives on that group were Roman Schwartz, CIML Vice-President, and Ian Dunmill and Willem Kool of the BIML.

The text of the MoU was reviewed by the members of CIML Presidential Council and discussed at their meeting in March 2011. The Presidential Council agreed with the text, but felt that the following clarifications should be provided to the OIML community:

- *Note 1*. In this MoU the term 'jointly developed publications' refers to the result of a process whereby the two organizations cooperate in the development of technical requirements or guidance documents, for instance in a joint working group, while each of the organizations publish separate, but equivalent publications, following their own adoption procedures. This should not be confused with a 'joint publication' which is to be understood as one publication, published by two (or more) organizations.
- *Note 2*. The term 'equivalent' in this MoU refers to the situation where the application of the provisions of either the IEC publication, or the OIML publication on the same topic leads to the same result, although the (relevant parts of) both publications may not be identical.

The text of the MoU was then submitted to the CIML for approval. With Resolution No. 10 of its 46th Meeting (11–14 October 2011), the CIML approved the MoU and instructed the BIML to commence the drawing up of a joint OIML-IEC work program. Some possible elements of such a work program have already been identified by the working group that drafted the MoU and include:

- Joint press release on the signature of the MoU;
- Cross-reference list of relevant OIML and IEC Technical Committees;
- List of OIML experts appointed to participate in IEC TCs/SCs;
- List of IEC/IEC conformity assessment experts appointed to participate in OIML TCs/SCs;
- IECEE participation in the OIML CTT (conformity to type) Seminar;
- OIML participation in IECEE PTP (proficiency testing program) workshop.

Signing of a new MoU between the OIML and the IEC in Prague during the 46th CIML Meeting.
Left: Mr. Pierre de Ruvo - Right: Mr. Peter Mason

MEMORANDUM of UNDERSTANDING

between

The INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC)
and the IEC CONFORMITY ASSESSMENT SYSTEMS

and

The INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

concerning

LIAISONS and COLLABORATION BETWEEN BOTH ORGANIZATIONS

The scope of this Memorandum of Understanding (MoU) covers the relationship between the OIML and IEC in matters of relevant technical cooperation, conformity assessment, standards development and practices.

The **International Organization of Legal Metrology (OIML)** and the **International Electrotechnical Commission (IEC) and its Conformity Assessment Systems (IECEE, IECEx and IECQ)**:

- CONSIDERING that the OIML is an Intergovernmental Organization which was established to harmonize legal metrology regulations and methods of control, to solve, at the international level, technical and administrative issues as they relate to legal metrology concerning the manufacture, the use and the control of measuring instruments and to facilitate the coordination of the efforts of its Member States in this field,
- CONSIDERING that the IEC is an International Standardization Organization which was established to promote the development of standardization and conformity assessment in the Electrotechnical Sector with a view to facilitating international exchange of goods and services and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity,
- CONSIDERING that the OIML and the IEC are international standards-setting bodies as stipulated in the Technical Barriers to Trade (TBT) Agreement of the World Trade Organization,
- CONSIDERING that both Organizations are involved in certain related technical activities which it would be desirable to harmonize,
- CONSIDERING that the IEC provides global conformity assessment services in the electrotechnical field, and that the OIML develops systems for the acceptance and mutual recognition of conformity assessment in the field of legal metrology,
- DESIRING to coordinate their efforts to attain their joint objectives and to this end, to define the terms and conditions of their liaisons and collaboration,

HAVE AGREED AS FOLLOWS,

Preliminary provisions

Article I

The OIML and the IEC shall maintain mutual liaisons and collaboration through:

- the International Bureau of Legal Metrology and the Central Secretariat of the International Electrotechnical Commission,
- the Secretariats of OIML Technical Committees and Subcommittees and IEC Technical Committees and Subcommittees, and
- the relevant conformity assessment systems of both Organizations.

Article II

The OIML and the IEC shall consult each other on any technical issues of joint interest and shall provide each other with any information or documentation concerning matters of mutual interest, particularly concerning legal metrology related to standardization and conformity assessment.

Liaisons

Article III

In accordance with the IEC's policy on liaison given in the ISO/IEC Directives, the OIML can make an effective contribution by participating in the metrology-related work of IEC Technical Committees or Subcommittees (category A- liaison).

In accordance with the IEC's policy on options for development of a project, as a Liaison with IEC Committees, the OIML may submit OIML Recommendations or Documents for consideration to be processed according to the ISO/IEG Directives.

Article IV

In accordance with the OIML Policy paper on liaisons between the OIML and other bodies and the OIML Directives, the IEC can make an effective contribution by participating in the technical work of the OIML.

Article V

The IEC and the OIML may agree to jointly develop publications. Such development shall be in accordance with the procedures of the respective Organizations. The IEC and the OIML shall also coordinate the maintenance of such publications.

Publications

Article VI

An OIML Recommendation or Document that has been processed under IEC procedures, including the Fast-Track procedure, may be published by the IEC as an IEC Standard or Guide under the IEC's normal sales, copyright and exploitation conditions. Such an IEC Standard or Guide shall include appropriate indication of the equivalent OIML Recommendation or Document as its source.

Article VII

An IEC Standard or Guide that has been processed under OIML procedures may be published by the OIML as a Recommendation or Document under the OIML's normal translation, copyright and distribution conditions. Such an OIML Recommendation or Document shall include appropriate indication of the equivalent IEC Standard or Guide as its source.

Article VIII

In the case of jointly developed publications, both Organizations shall apply their own rules and procedures. Appropriate indication of the joint development shall be included in the publications.

Conformity assessment systems

Article IX

IEC Conformity Assessment Systems may participate as liaisons in relevant OIML Technical Committees and Subcommittees.

Relevant OIML TCS/SCs may participate as liaisons in the work of IEC Conformity Assessment Systems whose work is of interest to them.

Article X

The IEC and the OIML, in their attempt to avoid duplication of effort in their technical work, agree to the normative referencing of each other's publications as far as possible.

A portion of the technical content of one of the Organizations' publications may be reproduced in the other's publications on condition that formal permission has been granted and due credit is given.

Article XI

Both Organizations shall take the utmost account of existing publications of, and ongoing work in the other Organization.

Article XII

The OIML and the IEC may work together to prepare, release and jointly publicize external communications on matters of common interest.

External communications in the name of both Organizations shall be mutually agreed prior to their publication.

Implementation

Article XIII

The effectiveness of this MoU shall be monitored during the period of its implementation.

Article XIV

To facilitate the implementation and maintenance of this MoU, Liaison Officers shall be appointed by each Organization.

Liaison Officers shall be responsible for drawing up a joint work programme and ensuring its acceptance for implementation by their respective Organization.

The joint work programme shall be reviewed at least once a year.

Final provisions

Article XV

This MoU cancels and supersedes the prior MoU between the IEC and the OIML established in 1968.

Article XVI

This MoU does not make any legal or otherwise enforceable commitments on behalf of any of the parties.

Article XVII

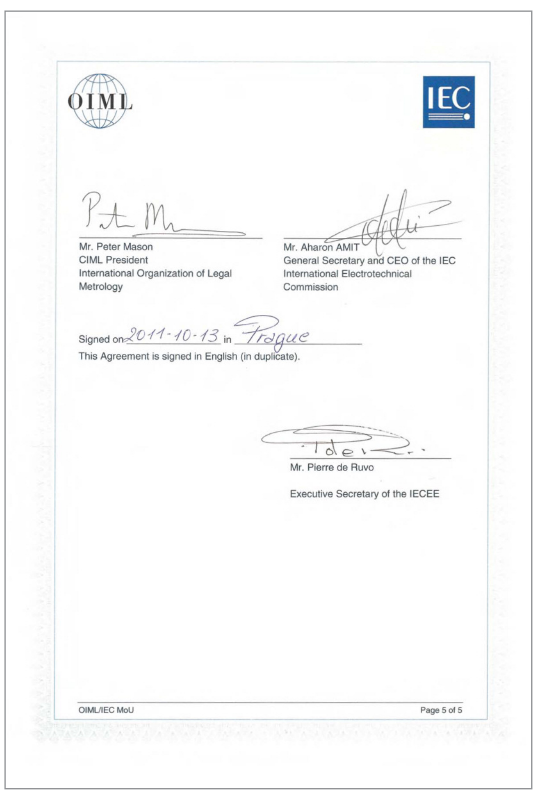
Initially, this MoU is established for a period of three years from the date of signature.

This MoU may be amended and/or renewed with the approval of both Organizations.

Each party may terminate this MoU by giving the other party at least six months' written notice.

Article XVIII

This MoU shall be signed by the duly authorized representatives of the International Organization of Legal Metrology and the International Electrotechnical Commission and shall become effective from the date of signature.



OIML IEC

Mr. Peter Mason
CIML President
International Organization of Legal Metrology

Mr. Aharon AMIT
General Secretary and CEO of the IEC
International Electrotechnical Commission

Signed on 2011-10-13 in Prague
This Agreement is signed in English (in duplicate).

Mr. Pierre de Ruvo

Executive Secretary of the IECEE

OIML/IEC MoU Page 5 of 5

INTERNATIONAL

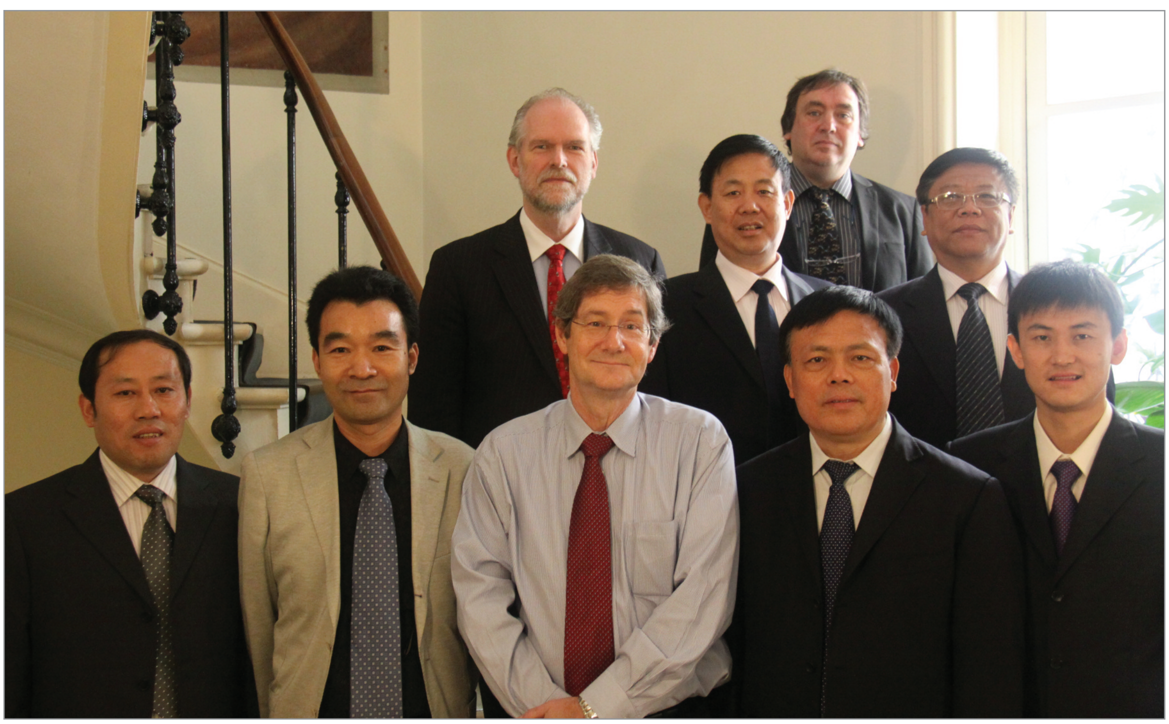
Chinese delegation visits the BIML

21 June 2011
BIML, Paris

On 21 June 2011, a delegation of Chinese metrology officials visited the BIML as part of their European tour. The objective of the tour was to receive information and exchange ideas on the issue of establishing a suitable metrology system to sustain economic growth and technology development, in order to guarantee the safety of people's lives and property in the Beijing region. Their specific interest concerned the developments in Europe on smart metering and smart grids.

The delegation consisted of:

- Mr. Ling Zhiyi, Deputy Director of the Bejing Bureau of Quality and Technology Supervision (Head of the delegation),
- Mr. Lu Jianzhong, Chairperson, Division of Metrology and Supervision, Bejing Bureau of Quality and Technology Supervision,
- Mr. Tan Yunchao, Staff Member, Division of Metrology and Supervision, Bejing Bureau of Quality and Technology Supervision,
- Mr. Zhang Baozhu, Director Senior Engineer, Bejing Institute of Metrology,
- Mr. Sun Mingchuan, Director, Bejing Huairou Qu Bureau of Quality and Technology Supervision,
- Mr. Li Jinsi, Administrative Deputy Director, Centre of Energy Measurement and Verification, Bejing Institute of Metrology.



Front left to right: Mr. Lu Jianzhong, Mr. Li Jinsi, Mr. Stephen Patoray, Mr. Ling Zhiyi, Mr. Tan Yunchao;
Back left to right: Mr. Willem Kool, Mr. Sun Mingchuan, Mr. Luis Mussio, Mr. Zhang Baozhu.

RLMO NEWS

27th WELMEC Committee Meeting

12–13 May 2011 Valletta, Malta

Grega Kovačič, WELMEC Secretary

Introduction

The 27th WELMEC Committee Meeting was opened by Ms. Nataša Mejak-Vukovič (WELMEC Chairperson), who thanked Malta for its invitation to hold the meeting in Valletta.

The Committee elected Ms. Anneke van Spronssen (The Netherlands) as the new WELMEC Chairperson for the next three years, and expressed its thanks to Ms. Nataša Mejak-Vukovič for her work as Chairperson during the previous three-year period.

The financial report for 2010 was approved and the revision of the "Financial Guidelines on Travel Expenses" was adopted.

The Committee approved the document summarizing the implementation to date of the 2010 Strategy Document and also the proposed follow-up actions. A new version of the Strategy Document is scheduled to be issued in 2012.

Ms. Mejak-Vukovič gave a presentation of the events at the most recent meeting of the Focus Group in December 2010 in Budva, Montenegro, at which the formal establishment of the Joint EURAMET-WELMEC Focus Group on Facilitating National Metrology Infrastructure Development was approved. On this occasion the Action Plan for 2011, which also covers legal metrology activities, was adopted.

The Committee took note of the report on the WELMEC Seminar "Legal Metrology & EU Directives, specific issue of national legislation" which took place last November in Zagreb, Croatia. It supported the proposal to organize a WELMEC Workshop on specific issues related to the implementation of the MID in the autumn of 2011 in Croatia.

The report on the management of the WELMEC web site was presented; the main improvement is the possibility for the Working Groups to create their own pages on the WELMEC intranet, and the fact that various forums could be opened up for internal discussion and debate.

The new e-mail address of the WELMEC Secretariat is secretary@welmec.org, the advantage of this new address being that any future changes in the Secretariat will not require a change in e-mail address each time.

The following representatives of WELMEC Observer Organizations gave presentations on the key developments in the activities of their organizations over the last year:

EURAMET	Mr. Joseph Bartolo;
OIML	Mr. Stephen Patoray;
EA	Mr. Claudio Boffa;
EMLMF	Mr. Osama Melhem.

Working Group Reports

Working Group 2 (Directive Implementation 2009/23/EC and Directive 2004/22/EC with regard to AWIs)

Mr. Gulian Couvreur presented the report and the working program. Members agreed to liaise with the EC and CEN/CENELEC to speed up the revision of EN 45501. Mr. Couvreur was confirmed as Convenor of WG2.

Working Group 4 (General Aspects of Legal Metrology)

Mr. Knut Lindløf presented the report and the working program. Due to the fact that no new tasks are planned for WG4 during 2011, the Committee agreed to disband WG4.

Working Group 5 (Metrological Supervision)

The report and working program were presented by Mr. Lindløf.

WELMEC Guide 5.3 "Risk Assessment Guide for Market Surveillance: Weighing and Measuring Instruments" was adopted.

Ms. Pia Larsen and Ms. Ann Nilsson Frödeen were elected as the new conveners.

Working Group 6 (Prepackages)

Mr. Howard Burnett presented the report and the working program.

WELMEC Guide 6.10 "Information on Controls on Prepacked Products" was adopted. This Document is not written as a Guide but has rather been produced to provide collated information regarding national implementation and requirements.

The guidance "Requirements for pre-packages whose quantity changes after packing" was approved and forwarded to the European Commission with a recommendation that it be published for guidance.

WELMEC Guide 6.5 (Issue 2) "Guidance on Controls by Competent Department's on "e" marked Pre-packages" was approved (except Annex E). It was agreed to vote on Annex E by e-mail, and if approved to publish the completed document.

Committee members confirmed Mr. Howard Burnett as Convenor for the next three years.

Working Group 7 (Software)

Mr. Dieter Richter presented the report and the working program.

WELMEC Guide 7.2 (Issue 5) "Software Guide (Measuring Instruments Directive 2004/22/EC)" was adopted.

Mr. Richter reported on the *Workshop on software issues in legal metrology* which was organized by the PTB and WELMEC last November and which had been very successful. WG 7 recommended continuing such workshops in conjunction with WG 7 meetings, since this allows for people outside the WELMEC community to be included in the technical discussions, and also to immediately draw conclusions in the subsequent Working Group meeting.

Working Group 8 (Measuring Instruments Directive)

The report and working program were presented by Ms. Corinne Lagauterie.

Guide 8.8 (Issue 2) "General and Administrative Aspects of the Voluntary System of Modular Evaluation of Measuring Instruments under the MID" and Guide 8.10 "Measuring Instruments Directive (2004/22/EC): Guide for generating sampling plans for statistical verification according to Annex F and F1 of MID 2004/22/EC" were adopted.

It was agreed to ask the other WGs to take into account the evolution of Guide 8.8 and to develop the necessary technical papers.

The Committee confirmed Ms. Corinne Lagauterie as Convenor and Mr. Thomas Lommatzsch as Secretary for the coming three years.

Working Group 10 (Measuring Equipment for Liquids other than Water)

The report and working program were presented by Ms. Anneke van Spronssen on behalf of Mr. Wim Volmer.

Guide 10.7 "Guide on evaluating purely digital self-service devices for direct sales to the public" was adopted.

The Committee approved the principles of "Harmonized EU Approach on Self-Service Devices for Fuel Dispensers" and supported its development into a WELMEC Guide.

Working Group 11 (Utility Meters)

The report and working program were presented by Mr. Rainer Kramer. WG11 should appoint a co-Convenor who will work with Mr. Rainer Kramer.

Main decisions of the 27th WELMEC Committee Meeting

- Accepted the Chairperson's Report.
- Approved the financial report for 2010.
- Approved the subscriptions for 2012 to be the same as in 2011.
- Approved the proposed amendment to the financial guidelines on travel expenses.
- Elected Ms. Anneke van Spronssen as the new WELMEC Chairperson.
- Approved the payment to Verispect of the actual costs for running the WELMEC Secretariat.
- Took note of the Progress Report on actions arising from the WELMEC Strategy Document 2010 and the need to prepare a new version of the Strategy Document by the next Committee meeting in 2012.
- Took note of the information on the WELMEC Seminar "Legal Metrology & EU Directives, specific issues of national legislation" which took place on 3 and 4 November 2010 in Zagreb, Croatia.
- Took note of the report on the EURAMET-WELMEC Focus Group on Facilitating National Metrology Infrastructure Development and asked interested WELMEC Members to nominate contact persons.
- Approved the project to study the possibility to establish a permanent WELMEC Secretariat in one of the WELMEC Member countries and present the proposal for a decision at the Committee Meeting in 2012.
- Proposed NoBoMet to pass market surveillance issues to WG5.
- Took note of the new Comitology Rules.
- Took note of all WG Reports and Programs with a few modifications (WG).
- Confirmed the need to liaise with EC and CEN/CENELEC to speed up the revision of EN 45501
- Recognized the question from multiple manufacturers, discussed in WG2, as being a horizontal issue and decided to pass it to WG8.

- Confirmed Mr. Gulian Couvreur (Switzerland) as WG2 Convenor for the next three years.
- Agreed to disband WG4 and to accept the proposed addition to "Country Info" on the WELMEC web site for the use of accuracy classes from the MID.
- Elected Ms. Pia Larsen and Ms. Ann Nilsson Frödeen as new WG5 Convenors.
- Decided not to accept CECIP's offer of 50.000 EUR to fund a market surveillance project.
- Approved WELMEC Guide 5.3 "Risk Assessment Guide for Market Surveillance: Weighing and Measuring Instruments", Issue 1.
- Confirmed Mr. Howard Burnett (UK) as WG6 Convenor for next three years.
- Approved the WELMEC Document "Information on Controls on Prepackaged Product, Including Implementation of Council Directive 76/211/EEC", Issue 1 after having considered the comments from DK.
- Approved "Guidance for prepackages whose quantity changes after packing" with the recommendation to the EC for publication.
- Approved WELMEC Guide 6.5 "Guidance on Controls by Competent Departments on "e" marked Prepackages", Issue 2, except Annex E which will later be put to electronic vote.
- Approved WELMEC "Software Guide (Measuring Instruments Directive 2004/22/EC) 7.2", Issue 5.
- Asked the Commission to address a questionnaire to NBs on software issues.
- Confirmed Ms. Corinne Lagauterie as WG8 Convenor for the next three years.
- Approved WELMEC Guide 8.10 "MID (2004/22/EC): Guide for generating sampling plans for statistical verification according to Annex F and F1 of the MID".
- Approved the revision of WELMEC Guide 8.8 on the modular approach ("Guide on the General and Administrative Aspects of the Voluntary System of Modular Evaluation of Measuring Instruments").
- Asked other WGs to take into account the evolution of Guide 8.8 and to develop the necessary technical papers.
- Approved the principles of the "Harmonized EU Approach on Self-Service Devices for Fuel Dispensers" and approved its development into a WELMEC Guide.;
- Asked WG10 to prepare the guidance document on the basis of the "living guide" to be adopted in 2012.
- Approved WELMEC Guide 10.7 on evaluating purely digital self-service devices for direct sales to the public. It will be revised if the EC will not reference it.
- Asked to further develop the draft revision of WELMEC Guide 11.1 on Common Application for utility meters.

Delegates attending the 27th WELMEC Committee Meeting in Valletta, Malta (12–13 May 2011)

Contact details: WELMEC Secretariat - p.a. Verispect B.V. - Att. Mr. Lex Rooijers
Postbus 654 - NL-2600 AR Delft - The Netherlands
secretary@welmec.org

COOMET NEWS

"20th Anniversary of COOMET" Workshop and the Competition for the "Best Young Metrologist of COOMET – 2011"

Moscow, 15–17 June 2011

PROF. DR. MANFRED KOCHSIEK
Germany

COOMET, the Euro-Asian Cooperation of National Metrology Institutions, comprises the NMIs of 18 countries, mainly members of the former COMECON block.

The event was opened by V. Krutikov, Vice-President of Rosstandart Russia which is the umbrella organization of the Russian NMIs. He welcomed the participants from eight countries to the "20th Anniversary of COOMET" Workshop and the Competition for the "Best Young Metrologist of COOMET – 2011".

The "20th Anniversary of COOMET" Workshop covered the foundation of COOMET in 1991, and the development and progress made over the last 20 years. Presentations were given by V. Belotserkovski (former president of COOMET), M. Kochsiek (one of the founders of COOMET), and H.-D. Velfe (former Vice-President of COOMET).

The lectures on the occasion of the competition for the "Best Young Metrologist of COOMET – 2011" were given in Russian or in English by 18 preselected participants up to the age of 35, from nine countries (see Figure 1). The competition was organized by staff of VNIIMS, one of the Russian NMIs, and the PTB.

The topics presented covered a wide variety of metrological issues. In the field of legal metrology, such topics were addressed as:

- measuring electrical energy;
- mass concentration of components in liquid and solid substances;
- flow of liquified gases;
- diagnostic dosimeters;
- metrological assurance.

The competition was chaired by L. Issaev (see Figure 2). A high ranking jury comprising experts from five countries assessed the presentations according to a predefined basis of seven criteria to evaluate both innovation and quality of presentation. The jury noted a remarkable increase in the quality of the papers and their presentation.

The winners were:

- 1st prize: Sergey Golubev (VNIIMS Russia), on Metrological Assurance of Scanning Probe Microscopes (see Figure 3);
- 2nd prize: Fatemeh Yaghobian (guest scientist at the PTB from Iran), on Primary Reference Method for the Quantification of Biomarkers;
- 3rd prize: Tobias Klein (PTB Germany), on Traceable Measurement of Nanoparticle Sizes using a Scanning Transmission Electron Microscope.
- Special prize for the best lecture in English: Tatyana Sosnovskaya (BelGIM, Belarus), on the National Electric Capacitance Standards.

The prize money was donated by the PTB and VNIIMS. The winner of the special prize is invited for a study tour to Braunschweig and/or Berlin.

The young metrologists also took the initiative to assess their presentations among themselves. It was a pleasure to note that they elected Fatemeh Yaghobian as their favorite lecturer.

A COOMET seminar to train young metrologists in presentation techniques was held in Minsk in 2010. Some of the competition participants took part in that seminar; obviously they were able to draw benefits from that training.

It has been proposed that the 5th competition for young metrologists should be held in Braunschweig, Germany, in 2013. ■

Figure 1: Participants at the workshop "20th Anniversary of COOMET" and "Competition for the best young metrologist"

Figure 2: S. Kononogov, New CIML Member for Russia (left), L. Issaev, M. Kochsiek

Figure 3: (Left to right) Winner of the competition, Sergey Golubev, Tobias Klein (3rd prize, PTB Germany), Fatemeh Yaghobian (2nd prize, guest scientist at the PTB from Iran)

The OIML is pleased to welcome the following new

CIML Members

- **Cyprus**
  Mr. Christodoulos Christodoulou
- **India**
  Mr. B.N. Dixit
- **Republic of Korea**
  Mr. Dong ho KIM
- **Slovak Republic**
  Mr. Martin Halaj

Corresponding Member

- **Georgia**

OIML Meeting

TC 8/SC 5 (Water meters)
8–10 November (NIST, Gaithersburg, MD, USA)

Committee Drafts

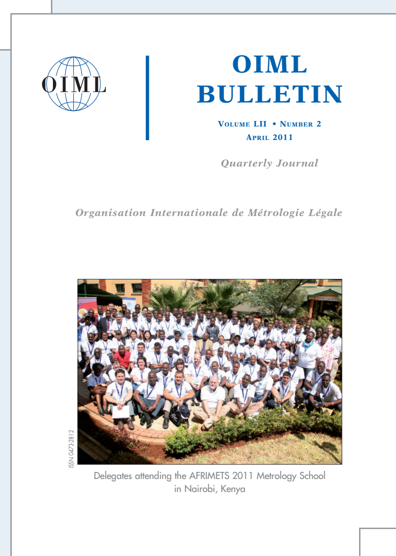
Received by the BIML, 2011.06 – 2011.09

Revision OIML R 46 Active electrical energy meters	E	6CD	TC 12	AU
Revision OIML D 1 "Considerations for a Law on metrology"	E	1CD	TC 3	US

Call for papers

OIML Members
RLMOs
Liaison Institutions
Manufacturers' Associations
Consumers' & Users' Groups, etc.

- Technical articles on legal metrology related subjects
- Features on metrology in your country
- Accounts of Seminars, Meetings, Conferences
- Announcements of forthcoming events, etc.



The **OIML Bulletin** is a forum for the publication of technical papers and diverse articles addressing metrological advances in trade, health, the environment and safety - fields in which the credibility of measurement remains a challenging priority. The Editors of the Bulletin encourage the submission of articles covering topics such as national, regional and international activities in legal metrology and related fields, evaluation procedures, accreditation and certification, and measuring techniques and instrumentation. Authors are requested to submit:

- a titled, typed manuscript in Word or WordPerfect either on disk or (preferably) by e-mail;
- the paper originals of any relevant photos, illustrations, diagrams, etc.;
- a photograph of the author(s) suitable for publication together with full contact details: name, position, institution, address, telephone, fax and e-mail.

Note: Electronic images should be minimum 150 dpi, preferably 300 dpi.

Technical articles selected for publication will be remunerated at the rate of 23 € per printed page, provided that they have not already been published in other journals. The Editors reserve the right to edit contributions for style, space and linguistic reasons and author approval is always obtained prior to publication. The Editors decline responsibility for any claims made in articles, which are the sole responsibility of the authors concerned. Please send submissions to:

The Editor, OIML Bulletin
BIML, 11 Rue Turgot, F-75009 Paris, France
(chris.pulham@oiml.org)