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European co-operation in legal metrology

Elements for deciding the appropriate level of confidence in regulated measurements.

(Accuracy classes, MPE in-service, non-conformity, principles of uncertainty)

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WELMEC

European cooperation in legal metrology

WELMEC is a cooperation between the legal metrology services of the Member States of the European Union and EFTA. This document is one of a number of Guides published by WELMEC to provide guidance to manufacturers of measuring instruments and to notified bodies responsible for conformity assessment of their products. The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EC Directives. Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

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1 Introduction.

In today's society, measurements are used for many applications not only in industry and science but also in our daily life. There are measurements involved such as when buying petrol or foodstuff from the shop or energy from utilities; when trying to keep within the speed limits when driving your car; in health analyses when doctors diagnose and treat on the basis of blood pressure measurements; or when authorities make measurements to control the pollution in the air that we all breathe. Common to all these situations is that the measurement results need to be accepted (with confidence) by society. If not, the result is repeated measurements, disputes and legal actions. In most cases, the consumer or even the user of the measuring instrument does not personally have either the knowledge, the opportunity or the equipment to check whether the measurement that is so important for us is correct or not. In all countries, the legislature therefore has decided to set accuracy requirements for these types of measurements; most commonly measurements in trade are regulated, but increasingly, also those within the health and environmental sectors.

Against this background, this WELMEC paper intends to reflect on the most important issues normally taken into account by authorities – specifically in relation to:

- Accuracy classes [part 3]
- The role and setting of *MPEs* in-service [part 4]
- Acceptable maximum rate of non-conforming instruments in use [part 5]
- Use of measurement uncertainty when assessing instrument conformity [part 6]
- One example is given in Annex

2 General considerations

Ongoing harmonisation in Europe has become more and more the first reference point for authorities in the establishment of requirements for measurements as requirements for new measuring instruments are stated in directives; the most important of these directives being the Measuring Instrument Directive (MID) and the directive on non-automatic weighing instruments (NAWI). For many of the instrument categories covered by the directives, there is a possibility nationally to select the prescription of different accuracy classes for different applications, and furthermore, to decide on what maximum permissible errors (*MPEs*) to apply in-service.

The goal for all interested parties will always be that all measuring instruments at any time are conforming to the legal requirements. The reality is however that it is not always possible to guarantee that a particular measuring instrument will conform or continue to conform to the requirements prescribed and authorities are faced with the task of devising strategies and assigning resources to ensure that the highest appropriate level of protection is fulfilled. In this regard the approach will be to establish an acceptable rate of non-conformity by taking account of different risk factors.

Another important issue, highlighted often in recent years, is the need in legal metrology to clarify the use of measurement uncertainty as used by the sector. A major issue when dealing with uncertainty in legal metrology is traceability of measurement and its assurance by the authority through the use of suitable test equipment of the appropriate accuracy.

3 The use of accuracy classes.

One important means of determining the acceptable protection level is the assignment of the use of accuracy classes for different purposes. Over the years accuracy classes have been introduced for many instrument categories, both for NAWIs and many of the instrument categories in the MID.

For NAWIs, coming from a long tradition in legal metrology, there is a well recognised common view in Europe on the use of the different accuracy classes. For example, class II for precious metals, class IIII for low cost materials like gravel and sand and class III for other trade purposes. For automatic weighing instruments, however, there is not such a long tradition and the approach in the MID does not give any guidance or prescriptions on how these shall be used, i.e. it is left up to the national authorities to decide. For some other instruments in the MID such as gas meters, electricity meters and heat meters where different accuracy classes have been established the directive gives some direction on how these shall be used.

There is no real contradiction in these different approaches as there may be good reasons if the national implementation of MID leads to different accuracy classes even for the same type of applications in different countries. For some a particular application (or trade) may be of great economic importance and a better accuracy class is needed to reduce the economic risk to an acceptable level. An example of one such area is the measurement (weighing) of fish caught in the sea. This is quite an important business for some countries, not only for the fisherman and the industry processing the fish, but also for the authorities concerning the international agreements on quotas for the different countries. In one country therefore a beltweigher (i.e. continuous totaliser) with 1% accuracy may be required while another, giving consideration to the important factors on its territory, may allow a 2% accuracy where this level is considered as adequate and appropriate protection.

In implementing the MID authorities have an opportunity to reflect on whether or not to prescribe different accuracy classes for different applications. If no accuracy classes are prescribed, it will then be up to the user to decide what he finds suitable from his point of view.

As matters develop, it is intended that information on prescribed accuracy classes by the WELMEC members will be put onto the WELMEC web-site as information becomes available.

4 Deciding on Maximum Permissible Errors (MPE) in-service

The *MPE's* for new instruments are decided in instrument specific legislation, the primary source being the directives. In the NAWI directive, the directive itself prescribes that the *MPE's* in-service shall be twice the *MPE's* for new instruments.

In MID, the *MPE's* in-service are left completely to the discretion of the national authorities and while traditionally for many instrument categories it has been usual to set the *MPE's* in-service as twice the *MPE's* for new instruments, mostly for technical reasons. The time is now opportune for authorities to consider the approach to *MPE's* in-service as one based on the assessment of acceptable risk and decide whether it may be more or less than twice the *MPE's* for new instruments. The way *MPE's* in-service are used is a fundamental consideration to be taken into account in arriving at this decision.

For some countries, the in-service regime is one based on subsequent verification, requiring that the instrument be tested at established intervals according to the *MPE's* for new instruments. In others, it may be that any subsequent tests (provided no adjustments or repairs etc.) require an instrument to be tested according to the *MPE's* in-service. Either of these approaches is well recognised as the prerogative of the national authorities but one major factor is common to both and that is, no matter which approach is taken the authorities in all cases must decide what period of time elapses between the checks in-service in order to achieve the desired level of protection. So deciding on the *MPE's* applicable in-service and the time periods between checks is the balancing exercise that authorities must take into account in arriving at the optimum solution. Among others, the costs for the checks/ measurements have to be considered and the risk for wrong measurements due to the use of the instrument.

However, in order to decide on the appropriate intervals one other matter needs to taken into account and that is what level of non-conformity can be tolerated.

5 Criteria for deciding on an acceptable non-conformity in-service.

By fixing the requirement on the maximum permissible error for a measurement, it determines what society, through the intercession of the legislator, accepts as sufficiently correct from this measurement. The accuracy thereafter cannot be expected to be better than this, neither by the consumer nor by the industry or other parties (Note that the legislation sets only the minimum requirement to be fulfilled and from a company's business point of view higher accuracy may be necessary in which case the company may decide to bear the costs of its validation).

For the user of the measuring instrument – the person responsible for the measurement – the target must be that 100% of the measurements are conforming to the requirements. In daily life however, there is no doubt that there will always be some measurements that will exceed the maximum permissible error and instruments that will from time to time fail to conform to other requirements in legislation. To avoid or to reduce to a minimum such occurrences authorities as well as the user, need to take measures to ensure that the measurements and the measuring instruments continue to conform to the requirements. For the authorities, however, there will always be a point where the resources needed to achieve these aims exceed those justified by the risk associated with wrong measurements.

Different measurement applications.

A uniform acceptable non-conformity rate would not appear to be practicable. For example an acceptable non-conformity rate for trade may be totally unacceptable for measurements used in court cases where the result could lead to a heavy fine or worse still a prison sentence, or within the health sector where the result could lead to misdiagnosis or unsuitable treatment. In trade, the acceptance risk is generally linked to the economic risk of the different parties; in some cases the risk for the consumer could be considered as less, while the risk for the seller can be quite considerable. On the other hand, in court cases everyone would like to have virtually no risk that the court decision would be taken on the basis of a wrong measurement in such cases like traffic control or alcohol testing where no non-conformity will be accepted, unless the non-conformity is in favour of the person involved.

Such elements to be considered in such a "risk analysis" can be separated broadly into two categories. Examples of such elements will be:

- Administrative risk of non-conformity
    - Conformity assessment missing or incorrect
    - Marking either missing or wrong
    - Broken seal
    - Risk of manipulating the measurement or of exploiting the MPE

- Metrological risk of non-conformity
    - Outside the legal MPE
    - Mechanical defects
    - Instable mounting of the instrument or the instrument is used under wrong operating conditions or wrong environmental conditions

(These are no more than examples of non-conformities and there may be other reasons for non-conformity, however these are considered the most general and important and are further elaborated below.)

Establishing an acceptable Non-conformity rate

The basis for such analysis needs to be established on sufficient information of the current non-conformity situation in the market. Such information will also be of help for "designing" the optimum periods of subsequent checks.

To make such an analysis, it is necessary to know and monitor continuously the situation in the market. As a consequence authorities, either by themselves or through other means, must maintain a sufficient level of control and surveillance in the market and have unlimited access to the information derived from these activities. To date some limited information is available from the authorities in some countries that are detailed below.

Administrative non-conformity

Conformity assessment missing or incorrect – when it is not verified that an instrument has fulfilled the appropriate conformity assessment procedure, its performance could be questioned in a lot of cases and this deviation from the requirements is definitely a non-conformity and the regulations in the different countries will basically require that such an instrument is taken out of use.

Marking missing or incorrect (but correct conformity assessment performed) – this is a non-conformity particularly important where the authorities make there inspection based on marking.

Seal broken – basically, the instrument could be tested and found to conform to the requirements. A broken seal, however, may be a sign that the instrument is adjusted or components may have been replaced. It is therefore is a risk that the instrument is non-conforming.

Risk for manipulating the measurement or for exploiting the MPE – the risk of manipulation or wrong use of the instrument has to be individually analysed depending on the situation and may be different depending on the sector of the society. Exploiting the MPE could be considered not to be a non-conformity (no legal actions taken when inside +/- MPE). In some countries, however, this will not be accepted according to national regulations.
The user of an instrument might be interested in exploiting the MPE by charging a repair company to adjust the instrument asymmetrically to positive indications but inside the MPE. In several countries authorized repair companies adjust instruments after repair so that the instrument can be used with broken seals or with the repair companys own sealing, until the next re-verification. When the repair companies are obliged by national legislation to adjust symmetrically they will follow this requirement otherwise they will loose their licence when the wrong practice is recognized by the surveillance authority. The authorities in such cases have to monitor the repairers and could reduce the surveillance of the users of the instruments.

Metrological non-conformity

Outside the legal MPE – this is an obvious non-conformity and actions need to be taken but again the authority must decide whether the breach is so significant as to put the instrument immediately out of use or whether a warning for repair will suffice in the first instance.

Mechanical defects – in these cases, it has to be judged on the basis of sufficient competence by the authority, if the nature of the defects are such that wrong measurement could occur.

Mounting of the instrument not stable or instrument used under wrong operating conditions – again, it needs to be considered by an authority with sufficient competence, if the situation could lead to wrong measurements. An example of wrong operating conditions, is if an instrument is used under industrial electromagnetic environment (Class E2 in MID) and has only been assessed for Class E1.

By considering this kind of data and the number of times these types of breaches occur, authorities can decide on what levels of non-compliance are tolerable for different instruments and/or activities or inversely what levels of compliance need to be achieved in order that users, the wider public and the authorities can have confidence in that area.

6 Measurement uncertainty and decision-making

As in general in conformity assessment, uncertainties associated with measurement and sampling may need to be evaluated and accounted for when making decisions about conformity in the context of legal metrology. This is mainly because test uncertainty can increase the risk of making incorrect decisions, such as failing a conforming instrument or passing a non-conforming instrument when the test result is close to a specification limit. This is important for instruments in use and also for Notified Bodies to have a uniform way of handling uncertainty so the risk for the manufacturer of a measuring instrument is the same regardless of which Notified Body is used.

General requirements on measurement uncertainty

In order to make a decision of conformity assessment based on quantitative testing of an instrument, the result of a reading of a particular measuring instrument should be accompanied by its measurement uncertainty, usually a so-called 'expanded' uncertainty U. The interval of measurement uncertainty is often $y \pm U$.

Decision-making with measurement uncertainty

The two main stages in handling uncertainty in decision-making:

(i) setting a limit on a maximum permissible measurement uncertainty (*MPU*);
(ii) allowing for risks due to uncertainty by 'sharing' risks

Accounting for uncertainty in decision-making

The two main stages in handling uncertainty in decision-making identified above can be applied to conformity assessment for both new instruments and instruments in-service.

Conclusion

The following principles to deal with measurement uncertainty in legal metrology are recommended:

1. A clear statement of how uncertainty has been treated in conformity assessment shall be given
2. Measurement uncertainty shall be evaluated accounting for all relevant contributions to the test result (including resolution and repeatability of instrument under test)[1]

[1] When the parameter measured is the variability (repeatability) of an instrument, the intrinsic reproducibility obviously should not be accounted for when determining measurement uncertainty. This is also the case when conducting several measurements, and the requirement is that all of the measurements should be inside MPE. (e.g. Catch weighing instruments Y(y).)

3. Shared risk principle can be applied when MPU not greater than MPE/3. (The uncertainty is then not taken into account when deciding on the conformity)

Where practically possible:

MPU ≤ *MPE*/3 at each measuring point, expanded uncertainty (k = 2; 95%)[2]

This shared risk principle is a general approach for applications in trade but not necessarily applicable for measurements in court cases or within the health sector.

7 SUMMARY

When it was first decided that regulation was necessary, we must assume that some kind of considerations of acceptable risk for wrong measurements was made. If there were no risk – or if the acceptance level is high – then there would presumably be no need for regulations.

So far, mainly the economic risk has been the issue for consideration. Today we would also, for certain applications, consider the risk for health, environment and juridical security. These, however, are more difficult to calculate and quantify.

In the same way, when trying to define an acceptable non-conformity rate, we should start with defining the acceptable risk for wrong measurements for the different parties involved (consumer, industry, authorities, others). However, as we have information on the present non-conformity rate, it may be easier to go the other way around: First to calculate the present non-conformity rate and then decide, if this is acceptable or not.

The risk for wrong measurements or the acceptable accuracy for a measurement depends on:

- the maximum permissible error, *MPE*, required for new instruments (accuracy class if relevant)
- the *MPE* required for instruments in-service
- a possible acceptable non-conformity rate
- the way uncertainty in the conformity assessment is accounted for

It is possible to make calculations on the economical effect of the decisions taken by the authorities for each of these different steps.

It is recommended, unless otherwise stated in the harmonised standard or normative document, that decision-making in conformity assessment when accounting for uncertainty in testing follows the shared risk principle under the condition that the uncertainty of the complete measurement system **–** *MPU* – is less than 1/3 of the maximum permissible error – *MPE* – for the actual conformity assessment.

[2] In some cases the resolution of the instrument tested is large compared to MPU, and MPU<1/3 MPE is not possible. While some instruments can be set to a higher “test resolution” this is not always possible or practical. In those cases it can be justified to not account for resolution while determining total measurement uncertainty.

ANNEX

An example of non-conformity and a simplified calculation of the added risk of non-conformity for petrol pumps:[3]

Accuracy requirement in-service is *MPE* = ± 0,5%.
Present status (information from verifications and surveillance):

- 96% of the meters are within the requirements of 0,5%
- 4% are within 1,0%
- only few meters are outside 1,0%

The risk for manipulation/fraud is considered rather low but there is a risk that the petrol station in cooperation with the service company will try to exploit the +/- tolerance.

Administrative non-conformity

Conformity assessment missing or incorrect
In 0,80% of the cases, the meter had not been initial verified. Only in 1 case, the meter was not type approved. (As this presently is subject to national regulations, the authority shall perform the initial verification which in all these cases was successful.)

Marking missing or incorrect
When not initial verified as described above, the marking was not correct. However, not recorded as wrong marking.

Seal broken
Without any notice to the authority, as required, was detected in 1,1% of the cases. It is obvious that the maintenance companies have to be monitored more strongly.

Risk for exploiting the MPE
When looking at the deviation from zero by the different companies, the overall figures are not far from a normal distribution.

Metrological non-conformity

Outside the legal in-service MPE
4% of the meters are outside 0,5% but still inside 1,0%. In no cases, the instrument was required to be taken out of use.

Mechanical defects
Was detected in 0,3% of the cases, mostly leakage which did not affect the measurements.

[3] Case of petrol pumps in Norway 2005.

We could make a simple calculation on the "average risk" for the consumer, the petrol station and from the taxation point of view:

Consumer risk
Yearly consumption is in average approx. 2000 l or € 2500
If we anticipate that the consumer will use different petrol stations and petrol pumps when filling, the risk for wrong measurements should also be 4%. If we simplify our findings and say that 4% of the measurements are wrong and these 4% deviate by 0,8% (average deviation for the 4%) from the correct value, the added risk (addition to the accepted required *MPE* of 0,5%) will be 2500x4%x(0,8 – 0,5)% which is *less than 1 €/year*.

Petrol station risk
In average, the petrol station would sell 2.000.000 l of petrol/year or for approx. € 2.500.000. Here the risk for having more than 4% of the measurements outside the *MPE* is present, as one or more of the pumps may be wrong. However, if we calculate on an average, a typical petrol station has 8 meters and if only one of these is outside the MPE, the added risk for wrong measurements (in addition to the accepted required *MPE*) will be 2.500.00/8x(0,8 – 0,5)% which is *940 €/year*.

Taxation risk (national risk)
The total sale of petrol/diesel is a bit more than 5 thousand million liter or € 6,5 thousand million. Tax at the selling point is 25% or € 1,6 thousand millon/year. Making the same calculation, the economic risk for the State, in addition to the accepted *MPE*, will be 1,6 thousand millionx4%x(0,8 – 0,5)% or *approx.200 000 €/year*. For this calculation, however, we have to look into the total distribution of the non-conformity from measurements outside the in-service MPE. As stated above, these are not far from a normal distribution and the risk will probably be rather low.

Conclusion
From this rather simple calculations, one could draw the conclusion that the present situation is satisfactory for the consumer. For the petrol stations, the added risk will be higher for those having dispensers giving wrong measurements and they can not "spread" the risk as the consumer normally do by using different petrol stations. Taking the distribution of non-conformity into account and assuming this is an almost normal distribution with the peak not far from zero error, the risk for authorities will be clearly less than the calculated figure.

Looking into the Administrative non-conformity, it seems obvious that stronger focus and monitoring of the maintenance companies are needed.