

Legal Metrology in Europe: Harmonizing Requirements Through Directives and the Cooperation of Authorities Through WELMEC

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Abstract: For many measurement purposes, the authorities has found it necessary to set accuracy requirements to the measuring instruments. In Europe, there has been a development in harmonizing these requirements through directives and the latest directive, MID, will at the end of 2006 establish the same requirements for the instruments covered by this directive, in more than 30 European countries. WELMEC, the European cooperation in legal metrology, is an effective cooperation between the legal metrology authorities in these countries. WELMEC has played a major role in the contribution for developing the MID and has since 1990 when it was founded, developed guidance documents to help and improve the harmonization of the requirements for measuring instruments in Europe. It is foreseen, that the present close cooperation with the European Commission will lead to further guidance documents being of help for the authorities, the manufacturers of instruments and the users of the same.

1. Legal metrology and accuracy requirements for measuring instruments

The reason for having accuracy requirements for measurements is to establish confidence among parties involved when reliable measurements are needed. In many cases, one or more of the parties involved have no possibility to control the correctness of the measurements. Reliable in this context, means that they are sufficiently accurate. “Sufficiently accurate” will always be seen in relationship with the respective application. For example, the expectation for accuracy is different when weighing gold compared to weighing garbage.

EU has for a long time developed directives with accuracy requirements for measuring instruments that are used within the legal metrology applications. These directives where not mandatory, until the end of the 1980s, when there was a change to the “new approach” where the directives decided in the EU should be mandatory for all member states. This was the approach to get to a fully harmonized market for measuring instruments within Europe.

2. “New approach” directives for legal metrology

The first directive that provided a fully harmonized market on measuring instruments, was implemented in 1990 for non-automatic weighing instruments (NAWI). The new approach directives states the “essential requirements” and the way to comply with these requirements could either be by testing directly according to these requirements or to harmonized standards which would help the manufacturer in the development and production process. For the NAWI directive however, more detailed requirements where taken directly into the directive all based on the OIML R-76. In addition it was developed a harmonized standard (EN standard) with similar requirements as in OIML R-76.

The NAWI directive also stated for what kind of applications (use) the instrument should comply with the requirements. In addition to the accuracy requirements given for new instruments (type approval) also accuracy requirements in use (as in the OIML R-76) are given. The directive give the same accuracy classes as in OIML R-76, leaving it up to the national authorities to decide which accuracy class should be used for the different applications. For non-automatic weighing instruments, an investigation done in the early 1990's showed that there was a very good agreement between the European countries on which accuracy classes to use for which application. As a conclusion, this new directive in combination with the tradition on the use of accuracy classes, has lead to a harmonized market for NAWIs and a harmonized "level of protection" for the parties involved.

In 2006, finally, we have reached the stage of implementing a new directive of measuring instruments in Europe, covering ten different types of instruments in addition to the already established directive for NAWIs. This directive (MID – measuring instruments directive) follows the same principles for "new approach" directives giving the essential requirements and foresee that there will be either harmonized standards (EN-standards) or normative documents (OIML recommendations) that can help the manufacturer in the development and the production process to fulfil the requirements. The use of "normative documents" is a new development in the EU that for the first time was taken in use in this directive.

The MID cover the following ten groups of instruments:

- water meters
- gas meters
- electricity meters
- heat meters
- measuring systems for liquids other than water
- automatic weighing instruments
- taximeters
- material measures
- dimensional measuring instruments
- exhaust gas analysers

Unlike the NAWI directive, the MID give the national authorities the option to decide on whether or not to set legal requirements to the instruments covered by this directive. However, if the authority in one country do not find it necessary to set legal requirements to one or another instrument covered by the directive, the authorities in that country can not set different requirement for this instrument. The consequence may be two different markets in Europe, one where the countries set requirement to a particular measuring instrument and for particular applications and another market where there is no official requirements for such instruments for the same particular applications.

Furthermore, there is given the option of different accuracy classes, in particular for automatic weighing instruments, where the situation is not that harmonized as it is by the NAWI and this may also lead to a more differential market.

As for the NAWI directive, the procedures that the manufacturer has to follow to put a product on the market according to the directive, is described in the directive itself. The manufacturer can choose between the more traditional type approval and initial verification process, a process based on type approval and a quality system for the production/end-control of the instrument or a quality system for the whole process of development, production and

end-control of the instrument or other combinations of these processes. In all cases, there shall be a notified body involved in the approval procedure. The notified body shall be appointed by the national authorities according to the requirements given in the directive. (Example: shall be third party bodies, shall have a quality system etc.).

3. European structure – not only EU

When discussing Europe, this is not only EU countries, but also other cooperation like the EEA (EU and three EFTA countries), countries in negotiations to enter the EU and even other countries in cooperation with the EU. In the context of the directives we would normally include those countries that has taken on the obligation to implement the directives into there national legislation. Currently there are more than 30 countries in this situation.

4. WELMEC – European cooperation in legal metrology

Particularly based on the cooperation that developed on the NAWI directive in 1990, the WELMEC organization was established by a MoU (Memorandum of Understanding) in 1990 between the legal metrology authorities from the EU and EFTA countries (at that time 18 countries). Since that time, there has been an increase in membership and currently WELMEC has 28 members and 3 associate members, the last 3 countries being in negotiations for entering the EU.

The objectives for the WELMEC cooperation can be summarized as:

- develop and maintain mutual confidence between legal metrology services in Europe
- achieve and maintain the equivalence and harmonization of legal metrology activities taking into account the relevant guidelines
- organize the exchange of information for legal metrology applied at national and local level
- identify and promote the removal of technical or administrative barriers to trade in the field of measuring instruments
- promote consistency of interpretation and application of normative documents
- maintain working links with all relevant bodies
- maintain channels for a continuous flow of knowledge

The WELMEC organization is based on the committee who elects a chairman and his secretariat. Both the members and the associate members are committee members. Observer organisations (EU, EFTA, OIML, Euromet, EA) are also invited to the committee meetings. In addition, there are corresponding organisations that are organisations for the manufacturer of measuring instruments in Europe and APLMF (Asia-Pacific Legal Metrology Forum). The chairman has the possibility to establish a Chairman Group with a few members to help the chairman in particular to prepare the committee meetings. The committee establish Working Groups for the different instrument groups and for more “horizontal” issues. There are currently 10 working groups developing different guidance documents used by the authorities, the manufacturers and the notified bodies:

- WG2, weighing instruments. Is developing guidelines for implementing the NAWI directive and has started to develop technical guidance and application documents for automatic weighing instruments according to the MID.
- WG4, general aspects of legal metrology. This is not basically a working group for technical issues, but is working on guidance documents for the use of uncertainty

in legal metrology, and elements for deciding the appropriate level of confidence in regulated measurements. For the last part, in particular the accuracy classes, the use of MPE in service and the acceptable non-conformity rate in use is all important when the authority shall decide the right “level of protection”.

- WG5, metrological supervision. In addition to being responsible for the directory of legal metrology in Europe, this working-group are responsible for a guidance document on market surveillance. This is considered as an important activity to ensure that only instruments that fulfil all the requirements of directives are put on the market.
- WG6, prepackages. There are some directives on prepackages, none of them however, are “new approach”. The working-group has developed a number of guidance documents both for the authorities and for the manufacturers of prepackages, to help a consistent implementation of the existing directives and to help the manufacturers to fulfil the requirements. Proposals for amendments to the directives are discussed and a WELMEC opinion is given to the European Commission after discussion in the WELMEC Committee.
- WG7, software. The use of software in measuring instruments is an increasing challenge and this working-group has developed a couple of guidelines on how software solutions can be divided into different risk categories and the requirements that should be fulfilled for the same.
- WG8, measuring instruments directive. This is a working-group particular working on the conformity assessment modules and the criteria for appointing notified bodies according to the MID. It is also responsible for doing a comparison between the relevant OIML recommendations and the requirements in the MID in order to establish OIML recommendations as normative documents.
- WG10, liquids other than water. The main work is on different technical questions and the working group has developed some guidelines to harmonize the implementation of the requirements in the MID which in fact is similar to the requirements in OIML R-117/R-105.
- WG11, utility meters. This is a rather new working-group established after the MID was finalised and has as a working program to draft necessary technical guidelines for the implementation of the requirements for the utility meters. The working-group shall further clarify if there are issues regarding utility meters that are not covered by the MID.
- Ad hoc WG for information exchange. This working-group is set up to establish a sufficient information exchange between the WELMEC members, in particular analyze an internet platform for this task

All members and associate members have the right to participate in the working groups. In addition, the manufacturers organisations can be invited. In fact, they are invited to take part in most of the working groups.

A number of guidance documents have been established through the years, which are available on www.welmec.org.

5. WELMEC and the European Commission (EU)

WELMEC has through the years entered into a very close cooperation with the European Commission and has played a major part in developing the MID. WELMEC has no legally formal status, but in 2004, a letter was developed by the European Commission stating the

importance of the work in WELMEC and their cooperation with the European Union, a letter which is available on the web site for the EU. The European Commission is always invited and present at the committee meetings in WELMEC and take as far as possible part in many of the working-groups of WELMEC, particularly in working-group 2, 5, 6 and 8. The WELMEC guidelines shall never introduce additional requirements in addition to the directives but develop guidance on unclear issues that may be the result of the directive and propose interpretations of the same. Formal interpretations is however always the task and responsibility of the European Commission.

The work in WELMEC and the cooperation with the European Commission has been based on a voluntary basis with the MoU from 1990 as the background. It has been discussed, but so far decided not, to establish a legal entity for WELMEC. WELMEC is a cooperation between the legal metrology authorities where a close cooperation give the necessary confidence in each others operations, a cooperation which so far has been successful.

6. WELMEC and the near future

The most important task for WELMEC in the near future is to support the implementation of the measuring instruments directive (MID). This will be done through identifying unclear issues and developing guidance documents that can be of help both for the authorities, the notified bodies, the manufacturer of instruments and the user of the instruments. An increasing challenge is the use of software in instruments and the application of software requirements needs to be developed continuously. WELMEC will continue to organize seminars/workshops concerning issues particularly on the MID. It will be of great benefit, both for WELMEC and the European Commission, to continue the good cooperation that has been established.