OIML Seminar on Conformity to Type (CTT)

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Information about EU system

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Overview of the presentation

- Useful terms and principles
- Content of documentation
- Role of manufacturers and notified bodies
- Role of market surveillance authorities, cooperation, legal actions
- Present EU experiences

Basic principles of legal metrology

- For a list of regulated uses (transactions and others)
- Ensure that instruments in normal operation give correct and safe results
- By fixing metrological requirements that instruments have to fulfil all along their life cycle
- By setting up a system of controls from design to production and later in service with adapted level of testing and MPEs
- All the system is based on the principle that initial conformity to requirements and to type is ensured

European and national regulation

Due to the fact that European directives are limited

- To only some categories (NAWI and 10 MID instruments)
- To the stage of putting on the market and putting into service,

the national legislation in the EU member states is a mixture of national and European requirements

Legal aspects such as penalties for non conforming instruments belongs to the national legislation

Vocabulary used

MID : measuring instrument directive 2004/22

NAWI directive : Non automatic weighing instrument directive (90/384 now codified version 2009

NB : notified bodies, bodies designated by the member states to perform certain activities defined in the directives

MI measuring instrument

WELMEC european cooperation in legal metrology

Assessment according to MID

Conformity assessment procedure : 1 or 2 modules of control applicable to a category of MI

13 different modules (A, B, C, C1,D,D1,E, E1, F, F1, H, H1)

The possible choice is defined in the annexes specific to categories of instruments and they depend upon the complexity of the instrument

Main modules : B type examination, D Quality assurance of production, F verification of the product (also H1 design examination which covers also production phase)

Link with OIML

Requirements for MI are writen in a format of essential requirements (only some of them are precisely defined)

Principle of presumption of conformity by using harmonised standards or OIML normative documents but it is not possible to claim that conformity with OIML recommendation is mandatory

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Documentation

- Whatever are the modules used MID requires that the manufacturer establishes the technical documentation described in article 10 of MID

- This technical document is the basis for conformity evaluation : “it render the design, manufacture and operation of the MI intelligible and permit an assessment of its conformity with requirements of MID”

Content of the documentation

The technical documentation shall be sufficiently detailed to ensure:

— the definition of the metrological characteristics,

— the reproducibility of the metrological performances of produced instruments when properly adjusted using appropriate intended means,

— the integrity of the instrument.

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Content of the documentation

The technical documentation shall include insofar as relevant for assessment and identification of the type and/or instrument:

(a) a general description of the instrument;

(b) conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits, etc;

(c) manufacturing procedures to ensure consistent production;

Content of the documentation

(d) if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;

(e) descriptions and explanations necessary for the understanding of paragraphs (b), (c) and (d), including the operation of the instrument;

(f) a list of the standards and/or normative documents referred to in Article 13, applied in full or in part;

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Content of the documentation

(g) descriptions of the solutions adopted to meet the essential requirements where the standards and/or normative documents referred to in Article 13 have not been applied;

(h) results of design calculations, examinations, etc;

(i) the appropriate test results, where necessary, to demonstrate that the type and/or instruments comply with: the requirements of this Directive under declared rated operating conditions and under specified environmental disturbances, the durability specifications for gas-, water-, heat-meters as well as for liquids other than water.

Content of the documentation

(j) the EC-type examination certificates or EC design examination certificates in respect of instruments containing parts identical to those in the design.

4. The manufacturer shall specify where seals and markings have been applied.

5. The manufacturer shall indicate the conditions for compatibility with interfaces and sub-assemblies, where relevant.

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Who has access to this documentation? Where is it kept ?

The manufacturer establishes it (even if he uses a representative for certain tasks he cannot delegate the establishment of the documentation)

He provides it to the NB (s) he has chosen for the conformity assessment procedure (art 9 of MID)

He shall inform the NB that holds the technical documentation concerning the EC-type examination certificate of all modifications to the instrument that may affect the conformity of the instrument with

the essential requirements or the conditions for validity of the certificate.

Who has access to the documentation? Where is it kept ?

The manufacturer shall keep a copy of the EC-type examination certificate, its annexes and additions with the technical documentation for 10 years after the last measuring instrument has been manufactured (at the disposal of the national authorities).

The notified body shall hold the technical file including the documentation submitted by the manufacturer for a period up to the end of the validity of the certificate (art 12 of MID covers professional secrecy except vis-à-vis the authority of the Member State which has designated it)

Documentation - summary

- It is mandatory in all cases
- It is very detailed
- The description prevents that it is non representative of the future production and that the MI supplied for type evaluation is a “golden sample” or a “MI still under development”
- It has to be updated
- It is available for later checks by the NB
- When needed it is available for authorities

Responsibilities of manufacturers

Whatever is the conformity assessment and module used by the manufacturer it is always mentioned in the definition of the module that the manufacturer is responsible for the conformity to the requirements

And for all instruments where certification of the type is required the responsibility covers the conformity to the type

Even when a manufacturer nominates a representative to perform some tasks, he cannot delegate his responsibility concerning conformity

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Paper declaration by the manufacturer and markings

Whatever is the conformity assessment used the manufacturer puts the CE marking and M on the instruments and issues a paper declaration of conformity

This declaration is kept by the manufacturer at the disposal of the national authorities for ten years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market.

Responsibilities of notified bodies

They have to fulfil the requirements that applies to them

Their tasks are described in the respective module annexes of MID

Their responsibility is limited to the task they have to performed (no general responsibility for the conformity of the instruments themselves)

The member state that have notified them shall ensure that they work correctly

Module B

The manufacturer provides the documentation and in most cases a specimen representative

The NB studies the file and the specimen, in particular he has to examine the technical documentation to assure that the manufacturer has adequate means to ensure consistent production.

The NB delivers an EC type examination certificate valid 10 years (valid in all EU and even wider)

The manufacturer has to keep the NB informed of changes

Module D

The manufacturer operates a quality system (QS)

The quality system shall ensure compliance of the instruments with the type as described in the EC-type examination certificate and the appropriate requirements of the Directive.

He asks a NB to assess this QS

When it is done the NB is also responsible of the surveyance of the QS (regular audits but also possibly unexpected visits)

Module F

The manufacturer shall ensure conformity to the type and the requirements

The NB makes tests on individual instruments (visual inspection and tests)

And delivers a certificates of conformity in respect of the tests he has performed

Responsibility of member states

Transposition of the directives in the national regulation

Correct implementation (designation and surveillance of notified bodies, market surveillance)

Take appropriate actions so that instruments are brought back in conformity by the manufacturer or anyone who has put non conforming instrument on the market or in service

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Market surveillance

Several types of operation contribute to MS

- General information of all stakeholders
- Visits of manufacturers
- Examination of accompanying papers and simple tests
- Complete testing in laboratory

(See WELMEC guide 5.2)

Market surveillance and synergy

- Exchange of information is foreseen in article 18 of MID (it covers type approval certificates, certificates of approval of QS and reports of notified bodies
- In legal metrology instruments are also submitted to controls in service or after repair. At this occasion one may discover a non compliance which dates from the time the instrument was put on the market and in service, this will also contribute to market surveillance
- Information could also come from federations of manufacturers

Experience

- WELMEC is supporting the harmonised correct implementation of MID
- WG 5 of WELMEC is a platform of cooperation and exchange of information (guidance documents available on welmec.org)
- Since 2008 a new EU regulation gives more duties to members states in market surveillance field. It also covers accreditation

Conclusion

- Content of documentation
- Conformity assessment procedures
- Responsibility of notified bodies
- Responsibility of manufacturers
- Declaration of conformity
- Market surveillance and exchange of information
- Legal actions to bring instruments in conformity (possibility of removing it from the market)
- Legal obligation for the manufacturer to bring in conformity instruments
- Controls of instruments in service

conclusion

The whole system contributes to ensure that the directive is correctly implemented and that only instruments in conformity with the requirements and with the type if applicable are put on the market

but all actors have to contribute continously

Thank you

Merci de votre attention

Questions ?

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