

MID

## European Directive for Measuring Instruments - A new challenge to industry and to the state

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### Summary

After nearly ten years of preparatory work, the Commission of the European Union intends to submit the draft of a general directive for measuring instruments to the European Council and the European Parliament for further handling. To start with, the draft was forwarded to the national metrology institutes responsible for issuing type approvals.

In this paper the concept of the draft directive is presented and legal aspects are dealt with. The Commission's proposals for the further harmonization of the measuring instruments market are elucidated and potential conclusions are drawn, which might be of significance particularly for the weighing instrument industry since a totally harmonized directive according to the new approach is already available for this area.

### 1 Preliminary remarks

In early January 1999, interested national metrology institutes responsible for issuing type approvals received the third draft of a directive for measuring instruments [1] from the Commission of the European Union. This directive is called the Measuring Instruments Directive (MID). The text is now available in the various national languages of the member countries and will, according to statements by the Commission, be submitted to the political voting bodies of the European Council and of the European Parliament in the course of this year.

The text has led to a considerable need for discussions among experts, and some technical annexes still present gaps. Nevertheless it may be assumed that no more substantial modifications will be made.

The first drafts of a European measuring instruments directive date back to 1991 and were referred to as METRO. Although the content has been substantially

amended since then, the most recent version - at least in its technical annexes - leaves something to be desired; examples are given under points 5 and 6 below. From the point of view of the Commission, the MID is largely completed so it can now be presented not only to European Union member states but also to a larger circle of interested parties.

### 2 Objectives in terms of economic policy

In Article 100A of the Treaty of Rome founding the European Community (which evolved into the European Union) it was prescribed that a common internal market should be created. This presupposed that barriers to trade (which are the result of differences in legal regulations, product requirements, standards etc.) are removed. This should be achieved, among other things, by reaching Europe-wide harmonization of legal regulations, including legal metrology. The latter had in part been established in the respective nations/states according to their specific features as early as 100 years ago with the goal of protecting the consumer, and in commercial transactions today legal metrology is a fixed reference for fair competition which ensures that law and order is maintained.

### 3 Concept of the MID

As a means for harmonizing national laws, in the early seventies the Commission proposed adopting individual directives, each relating to a specific kind of measuring instrument. Within the scope of the Outline Directive 71/316/EEC [2], 23 individual directives were thus adopted.

Due to the lengthy political and administrative coordination process required to bring them into force, these product directives (with their detailed technical specifications) were not able to keep pace with rapid changes in technology, and even less so as metrology increasingly began to use microprocessor technology. So this was another reason for the Commission to feel compelled to look for a new concept which has become better known by the designation "new approach".

The MID also follows this new concept. It primarily aims at completing the single market (free access to the market) and for this uses the following measures:

- For measuring instruments only *basic technical requirements* are fixed, the objective being to ensure as high a level of consumer protection as possible. These requirements are equivalent to performance require-

ments which are to codetermine (but not to interfere with) further technical development. So as regards technical requirements for instruments, general reference to standards is an integral component of the new concept.

- The member states mutually recognize the certificates issued for measuring instruments. The authorities supervising the market are not allowed to additionally define national - and perhaps conflicting - requirements for the kinds of measuring instruments subjected to the MID.

Those kinds of measuring instruments that are not covered by Community law continue to be governed by national law.

As the Commission itself admits, the legal regulations for metrology contained in the MID are limited to the free circulation of measuring instruments. Whether a measuring instrument is subjected to metrological control such as, for example, verification, continues to be at the discretion of the individual member state according to how it defines the need of its citizens for protection within the scope of its traditional legal culture. Measuring instruments will thus continue to be subjected to legal metrology controls in some member states and not in others. If, however, a member state exclusively prescribes using only officially controlled measuring instruments, the regulations of the MID are applicable without any restriction. The Directive thus regulates only the access of the measuring instruments to the market, not their type of use nor the tests they have to undergo during their useful life, i.e. subsequent verification and inspection.

### 3.1 Essential requirements

According to the MID, manufacturers of measuring instruments have to ensure that their products meet essential technical requirements in order that minimum metrological standards are complied with. The compliance of a measuring instrument with the relevant essential requirements is evaluated by a conformity assessment procedure which is stated for the individual instruments in the separate annexes.

However, manufacturers may prefer to apply more detailed specifications giving presumption of conformity to the essential requirements of the MID. Two sources of presumption of conformity are provided for:

- a) The member states presume that a measuring instrument meets the essential requirements if it complies with the harmonized European Standards in force; these standards are to be published in Series C of the Official Journal of the European Union. The

presumption of conformity can apply (only) to those elements of the standards the instrument complies with.

- b) It is an important modification of the former versions of the MID that not only European Standards but also OIML Recommendations can act in the sense of the Directive. So the Commission can request the OIML to prepare a “normative document with normative elements” for the kinds of measuring instruments subjected to the Directive; if the technical requirements of these are met, the corresponding requirements of the MID will also be met (presumption effect). The respective OIML Normative Documents are also to be published in the Official Journal of the EU, Series C. The status of the OIML Recommendations has thus considerably been enhanced as regards their legal effect and will in future have decisive importance in the conformity assessment procedure.

If a member state or the Commission holds the opinion that parts of a harmonized standard do not completely comply with the essential requirements, the matter will be discussed in accordance with Directive 98/34/EC [3] of the Council on the *Standing Committee on Standards and Technical Regulations*. The reasons for deviations ascertained are to be stated; the Committee forthwith gives its opinion and the Commission informs the member states of the decision. It is one of the Committee’s tasks to establish whether national standards are in possible conflict with the essential requirements of the MID.

### 3.2 Notified bodies

According to the MID, the member states are obliged to subject measuring instruments to a conformity assessment procedure which is based on the modular approach and which has been presented in Directive 93/465/EEC [4].

The MID takes up this modular approach and (in its Annexes) describes the modules which can be taken as a basis for conformity assessment (cf. Table 1). Of the total of 14 modules among which a selection can be made, three are not, however, applied for the time being.

For a given product the manufacturer can choose the module preferred for the conformity procedure according to the instrument-specific Annexes of the MID (cf. Table 2). The manufacturer can either carry out the conformity testing in-house or can have it performed by a third party by involving a *notified body*. In any case, the responsibility is borne by the manufacturer [6].

The member states inform the Commission and the other member states which bodies they have notified for the tasks in connection with the conformity assessment

procedure. The Commission assigns an identification number to these notified bodies which must be publicized in Series C of the Official Journal of the EU in a "List of Notified Bodies". From this list it can also be ascertained for what kinds of measuring instruments the individual bodies have been notified and whether there are limitations as regards categories of instruments, range of measurement, measuring technique or other instrument features.

The MID does not require that the notified bodies should have been accredited but in Annex III it describes the criteria they must meet to carry out their tasks in connection with the conformity assessment modules. For the notified body to be fully operative the criteria, which are listed in eight short paragraphs, constitute essential requirements which need to be interpreted. As notified bodies may have either a private or a public legal status and thus follow different business principles, considerable and cost-intensive efforts will still have to be made for their work to be harmonized on a permanent basis and Europe-wide.

### 3.3 CE identification

If a measuring instrument fulfils the essential requirements, the manufacturer will be entitled (and obliged) to affix the CE mark. According to the MID, this obligation will be dropped if the measuring instrument is not subjected to legal control at the national level. But even for these instruments the manufacturer may be compelled by one or several *other, parallel, directives* (such as, for example, electromagnetic compatibility) to affix the CE conformity mark. To clearly show whether the measuring instrument meets the requirements of the MID, in addition to the CE identification, a "metrological identification" is to be applied, which is in the form of an "M" and gives the year in which the mark was applied.

The right to apply the "M" is also granted to the manufacturer whose role is "strengthened" by the Commission "to as high a degree as acceptable". This is achieved by the fact that "as little intervention as possible is required from the certification body". The manufacturer will have greatest freedom of action as regards the selection of the conformity modules if a certification center confirms that the relevant measuring instruments are manufactured under a quality system in accordance with ISO 9001.

### 3.4 Measuring Instruments Standing Committee

To reconcile diverging opinions on the interpretation of the MID or to deal with technical developments, a

"*Measuring Instruments Standing Committee*" has been created into which representatives of the member states are delegated; the Committee is presided over by a representative of the Commission. The representative submits a draft of the measures to be taken to the Committee, which is authorized to prepare - by voting, if necessary - comments on the changes it proposes for the instrument-specific Annexes, for the testing programs fixed or for normative documents. The Commission takes account of the Committee's comments to the greatest extent possible but ultimately reserves the right to take the final decision. Thus the member states irreversibly transfer their (metrological) competence to a supranational decision-making body.

### 3.5 Placing on the market and putting into use of measuring instruments, and supervision of the market

The member states are responsible for prescribing that:

- measuring instruments should be placed on the market only if they fulfil the respective performance requirements;
- for particular measuring tasks only legally controlled measuring instruments (mandatory verification) should be used; and
- that these instruments must be subjected to tests (periodic verifications and metrological evaluations) at regular intervals within the proposed period of use.

According to common understanding, the terms "placing on the market" and "putting into use" are equivalent in metrological terms. In Article 3 the Commission makes, however, a distinction by considering "placing on the market" to be the moment of the transition of a product from the manufacturing phase to that of distribution and/or utilization on the Community market. In contrast to this, "putting into use" is regarded as equivalent to the "first use of a product for the purposes for which it was intended". The difference seems to be rather of a semantic nature; from the point of view of the Commission, it is, however, of considerable importance for market supervision: only in the phase of placing on the market do the member states have the right to check measuring instruments for conformity with the essential requirements. This is meant to ensure that after having been placed on the market in other member countries instruments are not again subjected to conformity testing without a particular reason.

The member states have to take any measure necessary to ensure that the measuring instruments placed on the market and put into use under the MID comply with

Table 1 Modules for the declaration of conformity according to the MID

Module description	Declaration of conformity based on
A	Internal production control by the manufacturer
A1	Internal production control by the manufacturer plus product testing by a Notified Body
B	Type examination by an NB*
C (+ B)	Internal production control by the manufacturer
C1 (+ B)	Internal production control plus product testing by an NB
D (+ B)	Approved quality system (ISO 9002) for the production process by an NB
D1	Approved quality system (ISO 9002) for the production process by an NB and technical documentation
E (+ B)	Approved quality system for final product inspection and testing (ISO 9003) by an NB
E1	Approved quality system for final product inspection and testing (ISO 9003) by an NB and technical documentation
F (+ B)	Type approval by an NB with subsequent product verification (individually or statistically)
F1	Product verification at the choice of the manufacturer by an NB either of every instrument or statistically, and technical documentation
G	Unit verification by an NB and technical documentation
H	Approved full quality system (ISO 9001) subject to surveillance by an NB
H1	Approved full quality system (ISO 9001) plus design examination subject to surveillance by an NB including inspection visits to the manufacturers' premises

\* NB: Notified Body

Modules A / C / C1 described in the MID are not applied to the conformity assessment procedures.

the basic and measuring instrument-specific requirements and were subjected to conformity assessment. If, however, they find out that the requirements have not been met in a systematic manner (and not only occasionally), the Commission must immediately be informed of the measures taken; grounds must be given for the decision. The decision may be that the instruments are withdrawn from the market, and that the further placing on the market or putting into use is prohibited or limited.

The Commission hears those concerned and then establishes whether the measures taken were justified, but it also ensures that the member states are informed about the course and the results of the project.

If a member state establishes that the CE mark and the additional metrological mark have unlawfully been affixed to a measuring instrument, it will bind the manufacturer or his agent having residence in the Community to remedy this situation. This has to take place under specified conditions which have been fixed by the member state in question. If no corrections are made, the member state will take all measures it considers fit.

How these targets can practically be achieved has to be clarified in further discussions.

## 4 Structure of the MID

It was originally the Commission's intention to present a directive for measuring instruments which (as for other regulated products) primarily harmonizes the procedure for market access, leaving the technical specifications largely to the standardization bodies or to the OIML.

Only at a relatively late date could hearings before the Commission show that for the use of measuring instruments not only the objective of free access to the market but also some other goals are to be taken into account. These - particularly consumer protection - had been largely neglected by previous draft directives. This protection goal manifests itself, among other things, in far-reaching safety of the measuring instruments from manipulation and as long a period of use as possible.<sup>1</sup> The MID takes account of consumer protection insofar as the Annexes relevant to metrology contain regulations which are to ensure that the measuring instruments are capable of complying with the maximum permissible errors over as long a period of use as possible. The

<sup>1</sup> Correctness of operation within the legally defined maximum permissible errors in service.

subdivision of the Annexes will, however, trigger off further discussions.

So Annex I: “*Essential Requirements*” specifies climatic and mechanical ambient conditions and combinations of these which (just as the electromagnetic ambient conditions) correspond to a theoretical schematization rather than to the practical conditions of use for the various kinds of measuring instruments.

Annex II deals with the general test programs corresponding to different test levels to which the kinds of measuring instruments are subjected for conformity assessment in accordance with the manufacturers’ specifications. This is just one of the weak points of the MID; the test program selection which has been proposed on a general basis is not appropriate in all cases for the concrete applications of the kinds of measuring instruments.

Annex IV describes the *Technical Documentation* to be submitted by the manufacturer; these are to enable the notified body or the national authorities to assess whether the measuring instrument complies with the applicable MID requirements and particularly comprise documents on the design, manufacture and functioning of the product.

The *Conformity Assessment Annexes* describe the eight modules of the relevant Directive 93/465/EEC [4] (referred to as A to H) with their respective amendments (cf. Table 1). As a supplementary characterization, six modules bear a “1” and are variants of the basic module. For the manufacturer they in part imply an increase in the severity of testing (for example, modules A1, C1 and H1); in the other cases (D1, E1 and F1) these variants reduce the severity. This means that the modules of the MID and those of the so-called Module Directive [4] of 1993 are not in all cases congruent. So for variants D1, E1 and F1 a section has been added to the technical documents that manufacturers must hold at the disposal of the national authorities for ten years.

The rather general formulations not only call for interpretation but in view of the potential heterogeneity of the notified bodies in Europe, might rather have the opposite effect.

The last part of the MID contains the *Instrument-Specific Annexes*. These not only list the respective kinds of measuring instruments but also assign to them those modules which the manufacturer can select for conformity assessment (cf. Table 2). In the case of material measures of length or automatic weighing instruments, for example, the selection can comprise up to eight modules. For capacity serving measures the MID allows the manufacturer to choose among seven modules. In practice however, this great number will be reduced to the procedure which from the administrative point of view is most simple and least expensive for the manufacturer.

## 5 MID proposals for “automatic weighing instruments”

With the Directive 90/384/EEC for non-automatic weighing instruments [7], the Commission accounted for the first kind of measuring instruments harmonized in accordance with the new approach. For manufacturers of weighing instruments it implied that under certain boundary conditions they can themselves carry out “initial verification”. It is, however, bindingly prescribed that a notified body must first perform a type evaluation.

In the MID for *automatic weighing instruments*, this requirement need no longer be followed in the selection of module H or H1. The manufacturer rather can choose from among several procedures or combinations of modules. The choice depends on whether mechanical or electromechanical construction is concerned or whether the instrument is of the electronic type and/or software-controlled (cf. Table 2, MI-006). Chapter I defines the requirements valid for automatic weighing instruments, particularly the ambient conditions and the conditions of use under which the weighing instruments have to work. These are to be specified by the manufacturer who must also fix under which class the weighing instrument falls. In the following chapters the requirements for the different kinds of weighing instruments are specified. The maximum permissible errors of measurement are stated for the possible device classes depending on the weight of the load. These chapters also give the conformity assessment procedures; it may be noted that the same “mechanical” and “electronic” subdivisions are used as in other instrument-specific Annexes:

- Chapter II Automatic catchweighers
- Chapter III Automatic gravimetric filling instruments
- Chapter IV Discontinuous totalizers
- Chapter V Continuous totalizers
- Chapter VI Automatic rail weighbridges.

### Module H1 (H)

For all kinds of measuring instruments the Commission grants the manufacturer the option to decide - besides other modules - in favor of module H1. This is also valid for automatic weighing instruments. For the mechanical or electromechanical design of automatic catchweighers, module H and for other kinds of weighing instruments, modules H1 can be selected.

This illustrates the Commission’s “program” for economic policy, i.e. to comply as far as possible with the manufacturer’s wishes as regards the liberalization of the “approval market”.

Table 2 Choice of modules for specific kinds of measuring instruments

Annex numbering	Chapter	Kind of measuring instrument	Declaration of conformity according to module
MI-001		Water meters	B + F / B + D / H1
MI-002		Gas meters	B + F / B + D / H1
MI-003		Active electrical energy meters and measurement transformers	B + F / B + D / H1
MI-004		Heat meters (meters and sub-assemblies)	B + F / B + D / H1
MI-005		Measuring systems for the continuous and dynamic measurement of quantities of liquids other than water - for mechanical or electromechanical systems - for electronic systems or systems containing software	B + F / B + E / B + D / G / H1 B + F / B + D / G / H1
MI-006	I	Automatic weighing instruments (specific requirements for all)	F1 / E1 / D1 / B + F / B + E / B + D / G / H
	II	Automatic catchweighers - for mechanical or electromechanical instruments - for electronic instruments containing software	B + F / B + D / G / H1
	III	Automatic gravimetric filling instruments - for mechanical or electromechanical instruments - for electronic instruments containing software	B + F / B + E / B + D / G / H1 B + F / B + D / G / H1
	IV	Discontinuous totalizers - for mechanical or electromechanical instruments - for electronic instruments or instruments containing software	B + F / B + E / B + D / G / H1 B + F / B + D / G / H1
	V	Continuous totalizers - for mechanical or electromechanical instruments - for electronic instruments or instruments containing software	B + F / B + E / B + D / G / H1 B + F / B + D / G / H1
	VI	Automatic rail weighbridges - for mechanical or electromechanical instruments - for electronic instruments or instruments containing software	B + F / B + E / B + D / G / H1 B + F / B + D / G / H1
MI-007		Taximeters	B + F / B + E / B + D / G / H1
MI-008	I	Material measures	A1 / D1 / E1 / F1 / B + E / B + D / G / H
	II	Material measures of length Capacity serving measures	A1 / D1 / E1 / F1 / B + E / B + D / H
MI-009	I	Dimensional measuring instruments Requirements common to all dimensional measuring instruments - for mechanical or electromechanical instruments - for electronic instruments or instruments containing software	F1 / E1 / D1 / B + E / B + D / G / H B + F / B + D / G / H1
	II	Length measuring instruments	Modules as Chapter I
	III	Area measuring instruments	Modules as Chapter I
	IV	Multidimensional measuring instruments	Modules as Chapter I
MI-010		Evidential breath analyzers	B + F / G / H1
MI-011		Exhaust gas analyzers	B + F / B + D / H1

## 6 An instrument-specific example from the MID

Those who are familiar with the political scene suppose that the deliberations on the MID in the subsequent bodies will take between 2–3 years. In addition, the Commission has provided a transition period of two and a half years until the Directive comes into force.

But the “measuring instruments market” for weighing instruments will not be completely harmonized even after this date.

So the Commission does not intend in the foreseeable future to include non-automatic weighing instruments in the MID regulations. As a consequence, the EC law for measuring instruments as a whole increasingly becomes more complex and difficult to handle.

The harmonization takes place horizontally for individual kinds of measuring instruments and thus implies that depending on the intended use and the definition, there may be three different conformity assessment procedures for a measuring instrument of more or less the same design, which are based on different requirements and in part are governed by differing legal regulations:

- Directive for Non-automatic Weighing Instruments 90/384/EEC [7];
- MID for Automatic Weighing Instruments; and
- national regulations.

Up to now, except for a committee draft OIML Recommendation, internationally harmonized standards for *in-motion road vehicle weighing instruments* are not available. Neither does the MID deal with them, so these measuring systems will continue to be governed by national regulations. This could also apply to the kinds of measuring instruments which are not directly covered by the EC Directives. Among these would be, for example, combined measuring instruments for the determination of the postage of packages for which multidimensional measuring instruments are combined with weighing instruments.

At the same time, the EEC type approvals which have been granted on the basis of the 23 individual directives in accordance with the Outline Directive 71/316/EEC [2] remain valid for a maximum of ten years. Of these 23 individual directives only eleven will be abolished, the rest will remain in force.

As a consequence of this, besides the many new conformity assessment procedures, the previous EEC approval procedures according to the “old approach” will be maintained for a number of kinds of measuring instruments.

It remains to be seen in what direction the future consultations on the MID in the European Parliament and in the Council will lead. The experts place great hopes in the consultations within the *European Cooperation in Legal Metrology* (WELMEC) which with its Working Group 8 has a suitable forum for discussions.

## 7 New challenges for the economy and for the state

For some years, owing to the implementation of the Directive for Non-automatic Weighing Instruments [7], the weighing instruments industry, as the first group of manufacturers of measuring instruments, has had broad experience with directives following the new approach. To conclude from this that the implementation of the MID would not lead to substantial changes would do no justice to the changes in the general conditions for the state and for the economy. The changes are essentially characterized by a shift from a metrology system shaped by preventive measures to a rather repressive system. This means that industry will have greater leeway under certain conditions but that it will also have more responsibilities and risks. Whether the advantages and disadvantages of these structural changes will balance each other out will depend on the degree to which it will be possible to come to an EU-wide uniform interpretation and application of the requirements for measuring instruments. This primarily concerns the severity of testing and the procedures of the notified bodies but also the public authorities responsible for the surveillance of the market.

If it is not possible to ensure fair competitive conditions for all those involved in the market, there will be a risk that the objective of legal metrology is increasingly jeopardized. ■

## References

- [1] Proposal for a Directive of the European Parliament and the Council for measuring instruments, draft of the European Commission, December 1998
- [2] EEC Outline Directive - 71/316/EEC
- [3] Directive of the European Parliament and the Council of June 22, 1998, on an information procedure in the field of standards and technical regulations - 98/34/EC

- [4] Resolution of the Council of July 22, 1993, on the technical harmonization guidelines for the modules to be used for the different phases of the conformity assessment procedure and the rules for the application and use of the EC conformity mark - 93/465/EEC
- [5] Directive "A global concept for certification and testing" (F. No. C 267 of October 19, 1989, p. 3)
- [6] Kochsiek, M., Roesner, P., Schulz, W.: Harmonisierung des gesetzlichen Messwesens in Europa, PTB-Mitteilungen, vol. 1/93, p. 73 foll.
- [7] Directive for Non-automatic Weighing Instruments - 90/384/EEC



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