2004/22/EC

Directive 2004/22/EC of the European Parliament and of the Council
of 31 March 2004
on measuring instruments
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission(1),

Having regard to the Opinion of the European Economic and Social Committee(2),

Acting in accordance with the procedure laid down in Article 251 of the Treaty(3),

Whereas:

(1) A number of measuring instruments are covered by specific Directives, adopted on the basis of Council Directive 71/316/EEC of 26 July 1971 on the approximation of the laws of the Member States relating to common provisions for both measuring instruments and methods of metrological control(4). Specific Directives that are technically outdated should be repealed and replaced by an independent Directive reflecting the spirit of the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards(5).

(2) Correct and traceable measuring instruments can be used for a variety of measurement tasks. Those responding to reasons of public interest, public health, safety and order, protection of the environment and the consumer, of levying taxes and duties and of fair trading, which directly and indirectly affect the daily life of citizens in many ways, may require the use of legally controlled measuring instruments.

(3) Legal metrological control should not lead to barriers to the free movement of measuring instruments. The provisions concerned should be the same in all Member States and proof of conformity accepted throughout the Community.

(4) Legal metrological control requires conformity with specified performance requirements. The performance requirements that the measuring instruments must meet should provide a high level of protection. The conformity assessment should provide a high level of confidence.

(5) Member States should as a general rule prescribe legal metrological control. Where legal metrological control is prescribed, only measuring instruments complying with common performance requirements should be used.

(6) The principle of optionality introduced by this Directive, whereby Member States may exercise their right to decide whether or not to regulate any of the instruments covered by this Directive, should be applicable only to the extent that this will not cause unfair competition.

(7) The responsibilities of the manufacturer for compliance with the requirements of this Directive should be specifically stated.

(8) The performance of measuring instruments is particularly sensitive to the environment, particular the electromagnetic environment. Immunity of measuring instruments to electromagnetic interference forms an integral part of this Directive and the immunity requirements of Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility(6) should therefore not apply.

(9) Community legislation should specify essential requirements that do not impede technical progress, preferably performance requirements. Provisions to remove technical barriers to trade should follow the

Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards.
(10) In order to take account of differences in climatic conditions or of different levels of consumer protection that may apply at national level, essential requirements may give rise to the establishment of environmental or accuracy classes.
(11) In order to ease the task of proving conformity with the essential requirements and to enable conformity to be assessed, it is desirable to have harmonised standards. Such harmonised standards are drawn up by private-law bodies and should retain their status as non-mandatory texts. To this end, the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI) are recognised as the competent bodies for the adoption of harmonised standards in accordance with the general guidelines on cooperation between the Commission and the European Standardisation bodies signed on 13 November 1984.
(12) The technical and performance specifications of internationally agreed normative documents may also comply, in part or in full, with the essential requirements laid down by this Directive. In those cases the use of these internationally agreed normative documents can be an alternative to the use of harmonised standards and, under specific conditions, give rise to a presumption of conformity.
(13) Conformity with the essential requirements laid down by this Directive can also be provided by specifications that are not supplied by a European technical standard or an internationally agreed normative document. The use of European technical standards or internationally agreed normative documents should therefore be optional.
(14) The conformity assessment of sub-assemblies should respect the provisions of this Directive. If sub-assemblies are traded separately and independently of an instrument, the exercise of conformity assessment should be undertaken independently of the instrument concerned.
(15) The state of the art in measurement technology is subject to constant evolution which may lead to changes in the needs for conformity assessments. Therefore, for each category of measurement and, where appropriate, sub-assemblies, there must be an appropriate procedure or a choice between different procedures of equivalent stringency. The procedures adopted are as required by Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the "CE" marking, which are intended to be used in the technical harmonisation Directives(7). However, derogations may have to be made for these modules in order to reflect specific aspects of metrological control. Provision should be made for the "CE" marking to be affixed during the fabrication process.
(16) Continued development in measurement technology as well as concerns expressed by stakeholders about certification, stress the need to ensure consistent conformity assessment procedures for industrial products, as requested by the Council Resolution adopted on 10 November 2003(8).
(17) Member States should not impede the placing on the market and/or putting into use of measuring instruments that carry the "CE" marking and supplementary metrology marking in accordance with the provisions of this Directive.
(18) Member States should take appropriate action to prevent non-complying measuring instruments from being placed on the market and/or put into use. Adequate cooperation between the competent authorities of the Member States is therefore necessary to ensure a Community-wide effect of this objective.
(19) Manufacturers should be informed of the grounds on which negative decisions in respect of their

products were taken, and of the legal remedies available to them.
(20) Manufacturers should be offered the possibility to exercise the rights obtained before the entry into force of this Directive, during a reasonable transitional period.
(21) National specifications concerning the appropriate national requirements in use should not interfere with the provisions of this Directive on "putting into use".
(22) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission(9).
(23) The activity of the Measuring Instruments Commmittee should include proper consultations with representatives of interested parties.
(24) Directives 71/318/EEC, 71/319/EEC, 71/348/EEC, 73/362/EEC, 75/33/EEC, as concerns the meters defined in Annex MI-001 of this Directive, 75/410/EEC, 76/891/EEC, 77/95/EEC, 77/313/EEC, 78/1031/EEC and 79/830/EEC should therefore be repealed,
HAVE ADOPTED THIS DIRECTIVE:
Article 1
Scope
This Directive applies to the devices and systems with a measuring function defined in the instrument-specific annexes concerning water meters (MI-001), gas meters and volume conversion devices (MI-002), active electrical energy meters (MI-003), heat meters (MI-004), measuring systems for continuous and dynamic measurement of quantities of liquids other then water (MI-005), automatic weighing instruments (MI-006), taximeters (MI-007), material measures (MI-008), dimensional measuring instruments (MI-009) and exhaust gas analysers (MI-010).
Article 2
1. Member States may prescribe the use of measuring instruments mentioned in Article 1 for measuring tasks for reasons of public interest, public health, public safety, public order, protection of the environment, protection of consumers, levying of taxes and duties and fair trading, where they consider it justified.
2. Where Member States do not prescribe such use, they shall communicate the reasons therefor to the Commission and the other Member States.
Article 3
Object
This Directive establishes the requirements that the devices and systems referred to in Article 1 have to satisfy with a view to their being placed on the market and/or put into use for those tasks mentioned in Article 2(1).
This Directive is a specific Directive in respect of requirements for electromagnetic immunity in the sense of Article 2(2) of Directive 89/336/EEC. Directive 89/336/EEC continues to apply with regard to emission requirements.
Article 4
Definitions
For the purposes of this Directive:
(a) "measuring instrument" means any device or system with a measurement function that is covered by Articles 1 and 3;
(b) "sub-assembly" means a hardware device, mentioned as such in the specific annexes, that functions

independently and makes up a measuring instrument together
- with other sub-assemblies with which it is compatible, or
- with a measuring instrument with which it is compatible;
(c) "legal metrological control" means the control of the measurement tasks intended for the field of application of a measuring instrument, for reasons of public interest, public health, public safety, public order, protection of the environment, levying of taxes and duties, protection of the consumers and fair trading;
(d) "manufacturer" means a natural or legal person responsible for the conformity of the measuring instrument with this Directive with a view to either placing it on the market under his own name and/or putting it into use for his own purposes;
(e) "placing on the market" means making available for the first time in the Community an instrument intended for an end user, whether for reward or free of charge;
(f) "putting into use" means the first use of an instrument intended for the end user for the purposes for which it was intended;
(g) "authorised representative" means a natural or legal person who is established within the Community and authorised by a manufacturer, in writing, to act on his behalf for specified tasks within the meaning of this Directive;
(h) "harmonised standard" means a technical specification adopted by CEN, CENELEC or ETSI or jointly by two or all of these organisations, at the request of the Commission pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services(10) and prepared in accordance with the General Guidelines agreed between the Commission and the European standards organisations;
(i) "normative document" means a document containing technical specifications adopted by the Organisation Internationale de Métrologie Légale (OIML), subject to the procedure stipulated in Article 16(1).
Article 5
Applicability to sub-assemblies
Where specific annexes exist, laying down the essential requirements for sub-assemblies, the provisions of this Directive shall apply mutatis mutandis to such sub-assemblies.
Sub-assemblies and measuring instruments may be assessed independently and separately for the purpose of establishing conformity.
Article 6
Essential requirements and assessment of conformity
1. A measuring instrument shall meet the essential requirements laid down in Annex I and in the relevant instrument-specific Annex.
Member States may require, if it is needed for correct use of the instrument, the information referred to in Annex I or in the relevant instrument-specific annexes to be provided in the official language(s) of the Member State in which the instrument is placed on the market.
2. The conformity of a measuring instrument with the essential requirements shall be assessed in accordance with Article 9.
Article 7

Conformity marking

1. The conformity of a measuring instrument with all the provisions of this Directive shall be indicated by the presence on it of the "CE" marking and the supplementary metrology marking as specified in Article 17.

2. The "CE" marking and supplementary metrology marking shall be affixed by, or under the responsibility of, the manufacturer. These markings may be affixed to the instrument during the fabrication process, if justified.

3. The affixing of markings on a measuring instrument that are likely to deceive third parties as to the meaning and/or form of the "CE" marking and the supplementary metrology marking shall be prohibited. Any other marking may be affixed on a measuring instrument, provided that the visibility and legibility of the "CE" marking and the supplementary metrology marking is not thereby reduced.

4. Where the measuring instrument is subject to measures adopted under other Directives covering other aspects which require the affixing of the "CE" marking, the marking shall indicate that the instrument in question is also presumed to conform to the requirements of those other Directives. In such a case, the publication reference of the said Directives, in the Official Journal of the European Union, must be given in the documents, notices or instructions required by those Directives and accompanying the measuring instrument.

Article 8

Placing on the market and putting into use

1. Member States shall not impede for reasons covered by this Directive the placing on the market and/or putting into use of any measuring instrument that carries the "CE" marking and supplementary metrology marking in accordance with Article 7.

2. Member States shall take all appropriate measures to ensure that measuring instruments be placed on the market and/or put into use only if they satisfy the requirements of this Directive.

3. A Member State may require a measuring instrument to satisfy provisions governing its putting into use that are justified by local climatic conditions. In such a case, the Member State shall choose appropriate upper and lower temperature limits from Table 1 of Annex I and, in addition, may specify humidity conditions (condensing or non-condensing) and whether the intended location of use is open or closed.

4. When different accuracy classes are defined for a measuring instrument:

(a) the instrument-specific annexes under the heading "Putting into use" may indicate the accuracy classes to be used for specific applications.

(b) in all other cases a Member State may determine the accuracy classes to be used for specific applications within the classes defined, subject to allowing the use of all accuracy classes on its territory.

In either case falling under (a) or (b), measuring instruments of a better accuracy class may be used if the owner so chooses.

5. At trade fairs, exhibitions, demonstrations, etc., Member States shall not prevent the showing of instruments not in conformity with this Directive, provided that a visible sign clearly indicates their non-conformity and their non-availability for placing on the market and/or putting into use until brought into conformity.

Article 9

Conformity assessment

Conformity assessment of a measuring instrument with the relevant essential requirements shall be carried out by the application, at the choice of the manufacturer, of one of the conformity assessment procedures

listed in the instrument-specific annex. The manufacturer shall provide, where appropriate, technical documentation for specific instruments or groups of instruments as set out in Article 10.

The conformity assessment modules making up the procedures are described in Annexes A to H1.

Records and correspondence relating to conformity assessment shall be drawn up in the official language(s) of the Member State where the notified body carrying out the Conformity assessment procedures is established, or in a language accepted by that body.

Article 10

Technical Documentation

1. The technical documentation shall render the design, manufacture and operation of the measuring instrument intelligible and shall permit an assessment of its conformity with the appropriate requirements of this Directive.

2. 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, and
- the integrity of the instrument.

3. 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;

(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;

(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.

(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.

Article 11

Notification

1. Member States shall notify to the other Member States and the Commission the bodies under their

jurisdiction, which they have designated to carry out the tasks pertaining to the conformity assessment modules referred to in Article 9, together with the identification numbers given to them by the Commission in accordance with paragraph 4 of this Article, the kind(s) of measuring instrument for which each body has been designated and in addition, where relevant, the instrument accuracy classes, the measuring range, the measurement technology, and any other instrument characteristic limiting the scope of the notification.

2. Member States shall apply the criteria set out in Article 12 for the designation of such bodies. Bodies that meet the criteria laid down in the national standards which transpose the relevant harmonised standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to meet the corresponding criteria. Member States shall publish the references to these national standards.

If a Member State has not introduced national legislation for tasks mentioned under Article 2, it shall retain the right to designate and notify a body for tasks relating to that instrument.

3. A Member State that has notified a body shall:

- ensure that the body continues to meet the criteria set out in Article 12,
- withdraw such notification if it finds that the body no longer meets those criteria.

It shall forthwith inform the other Member States and the Commission of any such withdrawal.

4. Each of the bodies to be notified shall be given an identification number by the Commission. The Commission shall publish the list of notified bodies, together with the information in respect of the scope of the notification referred to in paragraph 1, in the Official Journal of the European Union, C series, and shall ensure that the list is kept up to date.

Article 12

Criteria to be satisfied by designated bodies

Member States shall apply the following criteria for the designation of bodies in accordance with Article 11(1).

1. The body, its director and staff involved in conformity assessment tasks shall not be the designer, manufacturer, supplier, installer or user of the measuring instruments that they inspect, nor the authorised representative of any of them. In addition, they may not be directly involved in the design, manufacture, marketing or maintenance of the instruments, nor represent the parties engaged in these activities. The preceding criterion does not, however, preclude in any way the possibility of exchanges of technical information between the manufacturer and the body for the purposes of conformity assessment.

2. The body, its director and staff involved in conformity assessment tasks shall be free from all pressures and inducements, in particular financial inducements, that might influence their judgement or the results of their conformity assessment, especially from persons or groups of persons with an interest in the results of the assessments.

3. The conformity assessment shall be carried out with the highest degree of professional integrity and requisite competence in the field of metrology. Should the body subcontract specific tasks, it shall first ensure that the subcontractor meets the requirements of this Directive, and in particular of this Article. The body shall keep the relevant documents assessing the subcontractor's qualifications and the work carried out by him under this Directive at the disposal of the notifying authority.

4. The body shall be capable of carrying out all the conformity assessment tasks for which it has been designated, whether those tasks are carried out by the body itself or on its behalf and under its responsibility. It shall have at its disposal the necessary staff and shall have access to the necessary

facilities for carrying out in a proper manner the technical and administrative tasks entailed in conformity assessment.

5. The body's staff shall have:

- sound technical and vocational training, covering all conformity assessment tasks for which the body was designated;
- satisfactory knowledge of the rules governing the tasks which it carries out, and adequate experience of such tasks;
- the requisite ability to draw up the certificates, records and reports demonstrating that the tasks have been carried out.

6. The impartiality of the body, its director and staff shall be guaranteed. The remuneration of the body shall not depend on the results of the tasks it carries out. The remuneration of the body's director and staff shall not depend on the number of tasks carried out or on the results of such tasks.

7. The body shall take out civil liability insurance if its civil liability is not covered by the Member State concerned under national law.

8. The body's director and staff shall be bound to observe professional secrecy with regard to all information obtained in the performance of their duties pursuant to this Directive, except vis-à-vis the authority of the Member State which has designated it.

Article 13

Harmonised standards and normative documents

1. Member States shall presume conformity with the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes in respect of a measuring instrument that complies with the elements of the national standards implementing the European harmonised standard for that measuring instrument that correspond to those elements of this European harmonised standard the references in respect of which have been published in the Official Journal of the European Union, C series.

Where a measuring instrument complies only in part with the elements of the national standards referred to in the first subparagraph, Member States shall presume conformity with the essential requirements corresponding to the elements of the national standards with which the instrument complies.

Member States shall publish the references to the national standards referred to in the first subparagraph.

2. Member States shall presume conformity with the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes in respect of a measuring instrument that complies with the corresponding parts of the normative documents and lists referred to in Article 16(1)(a), the references in respect of which have been published in the Official Journal of the European Union, C series.

Where a measuring instrument complies only in part with the normative document referred to in the first subparagraph, Member States shall presume conformity with the essential requirements corresponding to the normative elements with which the instrument complies.

Member States shall publish the references of the normative document referred to in the first subparagraph.

3. A manufacturer may choose to use any technical solution that complies with the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes (MI-001 to MI-010). In addition, to benefit from the presumption of conformity, the manufacturer must correctly apply solutions mentioned either in the relevant European harmonised standards, or in the corresponding parts of the normative documents and lists as referred to in paragraphs 1 and 2.

4. Member States shall presume compliance with the appropriate tests mentioned in point (i) of Article 10 if

the corresponding test programme has been performed in accordance with the relevant documents mentioned in paragraphs 1 to 3 and if the test results ensure compliance with the essential requirements.

Article 14

Standing Committee

Where a Member State or the Commission considers that a European harmonised standard as referred to in Article 13(1) does not fully meet the essential requirements referred to in Annex I and in the relevant instrument-specific Annexes, the Member State or the Commission shall bring the matter before the Standing Committee set up under Article 5 of Directive 98/34/EC, giving its reasons for doing so. The Committee shall deliver an opinion without delay.

In the light of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw the references to the national standards from the publication referred to in the third subparagraph of Article 13(1).

Article 15

Measuring Instruments Committee

1. The Commission shall be assisted by the Measuring Instruments Committee.

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4. The Committee shall adopt its Rules of Procedure.

5. The Commission shall ensure that relevant information about envisaged measures, as referred to in Article 16, is made available to interested parties in due time.

Article 16

Functions of the Measuring Instruments Committee

1. On request by a Member State or on its own initiative, the Commission, acting in accordance with the procedure referred to in Article 15(2), may take any appropriate measure to:

(a) identify normative documents drawn up by OIML and, in a list, indicate the parts thereof compliance with which gives rise to a presumption of conformity with the corresponding essential requirements of this Directive;

(b) publish the references of the normative documents and the list referred to in point (a) in the Official Journal of the European Union, C series.

2. On request by a Member State or on its own initiative, the Commission, acting in accordance with the procedure referred to in Article 15(3), may take any appropriate measure to amend instrument-specific annexes (MI-001 to MI-010) in respect of:

- the maximum permissible errors (MPEs) and accuracy classes,
- the rated operating conditions,
- the critical change values,
- disturbances,

3. Where a Member State or the Commission considers that a normative document whose references have been published in the Official Journal of the European Union, C series, in accordance with paragraph 1(b), does not fully meet the essential requirements referred to in Annex I and in the relevant instrument-specific

Annexes, that Member State or the Commission shall bring the matter before the Measuring Instruments Committee, giving the reasons for doing so.

The Commission, acting in accordance with the procedure referred to in Article 15(2), shall inform the Member States whether or not it is necessary to withdraw the references to the normative document concerned from publication in the Official Journal.

4. Member States may take appropriate measures to consult interested parties at national level about OIML work relating to the scope of this Directive.

Article 17

Markings

1. The "CE" marking referred to in Article 7 consists of the symbol "CE" according to the design laid down in paragraph I.B(d) of the Annex to Decision 93/465/EEC. The "CE" marking shall be at least 5 mm high.

2. The supplementary metrology marking consists of the capital letter "M" and the last two digits of the year of its affixing, surrounded by a rectangle. The height of the rectangle shall be equal to the height of the "CE" marking. The supplementary metrology marking shall immediately follow the "CE" marking.

3. The identification number of the notified body concerned referred to in Article 11, if prescribed by the conformity assessment procedure, shall follow the "CE" marking and supplementary metrology marking.

4. When a measuring instrument consists of a set of devices, not being sub-assemblies, operating together, the markings shall be affixed on the instrument's main device.

When a measuring instrument is too small or too sensitive to carry the "CE" marking and supplementary metrology marking, the markings shall be carried by the packaging, if any, and by the accompanying documents required by this Directive.

5. The "CE" marking and supplementary metrology marking shall be indelible. The identification number of the notified body concerned shall be indelible or self destructive upon removal. All markings shall be clearly visible or easily accessible.

Article 18

Market surveillance and administrative cooperation

1. Member States shall take all appropriate measures to ensure that measuring instruments that are subject to legal metrological control but do not comply with applicable provisions of this Directive are neither placed on the market nor put into use.

2. The competent authorities of the Member States shall assist each other in the fulfilment of their obligations to carry out market surveillance.

In particular, the competent authorities shall exchange:

- information concerning the extent to which instruments they examine comply with the provisions of this Directive, and the results of such examinations;
- EC-type examination and design examination certificates and their annexes issued by notified bodies as well as additions, amendments and withdrawals relating to certificates already issued;
- quality system approvals issued by notified bodies, as well as information on quality systems refused or withdrawn;
- evaluation reports established by notified bodies, when demanded by other authorities.

3. The Member States shall ensure that all necessary information relating to the certificates and quality system approvals is made available to bodies they have notified.

4. Each Member State shall inform the other Member States and the Commission which competent

authorities it has designated for such exchange of information.

Article 19

Safeguard clause

1. Where a Member State establishes that all or part of the measuring instruments of a particular model that bear the "CE" marking and the supplementary metrology marking do not satisfy the essential requirements relating to metrological performance set out in this Directive, when correctly installed and used in accordance with the manufacturer's instructions, it shall take all appropriate measures to withdraw these instruments from the market, prohibit or restrict their further being placed on the market, or prohibit or restrict their further being used.

When deciding on the above measures, the Member State shall take account of the systematic or incidental nature of the non-compliance. Where the Member State has established that the non-compliance is of a systematic nature, it shall immediately inform the Commission of the measures taken, indicating the reasons for its decision.

2. The Commission shall enter into consultation with the parties concerned as soon as possible.

(a) Should the Commission find that the measures taken by the Member State concerned are justified, it shall immediately inform that Member State thereof, as well as the other Member States.

The competent Member State shall take appropriate action against any person who affixed the markings and shall inform the Commission and the other Member States thereof.

If the non-compliance is attributed to shortcomings in the standards or normative documents, the Commission shall, after consulting the parties concerned, bring the matter as soon as possible before the appropriate Committee referred to in Articles 14 or 15.

(b) Should the Commission find that the measures taken by the Member State concerned are not justified, it shall immediately inform that Member State thereof, as well as the manufacturer concerned or his authorised representative.

The Commission shall ensure that the Member States are kept informed of the progress and outcome of the procedure.

Article 20

Unduly fixed markings

1. Where a Member State establishes that the "CE" marking and supplementary metrology marking have been affixed unduly, the manufacturer or his authorised representative shall be obliged:

- to make the instrument conform as regards those provisions concerning the "CE" marking and supplementary metrology marking not covered by Article 19(1) and
- to end the infringement under the conditions imposed by the Member State.

2. Should the infringement described above persist, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the instrument in question or to ensure that it is withdrawn from the market or prohibit or restrict its further use in accordance with the procedures laid down in Article 19.

Article 21

Decisions entailing refusal or restriction

Any decision taken pursuant to this Directive entailing the withdrawal from the market of a measuring instrument, or prohibiting or restricting the placing on the market or putting into use of an instrument, shall state the exact grounds on which it is based. The decision shall be notified forthwith to the party concerned,

who shall at the same time be informed of the legal remedies available to him under the law of the Member State concerned and of the time limits to which such remedies are subject.

Article 22

Repeals

The following Directives shall be repealed as from 30 October 2006 without prejudice to Article 23:

- Council Directive 71/318/EEC of 26 July 1971 on the approximation of the laws of the Member States relating to gas meters(11),
- Directive 71/319/EEC of 26 July 1971 on the approximation of the laws of the Member States relating to meters for liquids other than water(12);
- Directive 71/348/EEC of 12 October 1971 on the approximation of the laws of the Member States relating to ancillary equipment for meters for liquids other than water(13),
- Directive 73/362/EEC of 19 November 1973 on the approximation of the laws of the Member States relating to material measures of length(14),
- Directive 75/33/EEC of 17 December 1974 on the approximation of the laws of the Member States relating to cold water meters, as concerns the meters defined in Annex MI-001 of this Directive(15).
- Directive 75/410/EEC of 24 June 1975 on the approximation of the laws of the Member States relating to continuous totalising weighing machines(16),
- Directive 76/891/EEC of 4 November 1976 on the approximation of the laws of the Member States relating to electrical energy meters(17),
- Directive 77/95/EEC of 21 December 1976 on the approximation of the laws of the Member States relating to taximeters(18),
- Directive 77/313/EEC of 5 April 1977 on the approximation of the laws of the Member States relating to measuring systems for liquids other than water(19),
- Directive 78/1031/EEC of 5 December 1978 on the approximation of the laws of the Member States relating to automatic checkweighing and weight grading machines(20),
- Directive 79/830/EEC of 11 September 1979 on the approximation of the laws of the Member States relating to hot-water meters(21).

Article 23

Transitional provisions

By way of derogation from Article 8(2), Member States shall permit, for measurement tasks for which they have prescribed the use of a legally controlled measuring instrument, the placing on the market and putting into use of measuring instruments that satisfy the rules applicable before 30 October 2006 until the expiry of the validity of the type approval of those measuring instruments or, in the case of a type approval of indefinite validity, for a period of a maximum of ten years from 30 October 2006.

Article 24

Transposition

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive before 30 April 2006. They shall forthwith inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by the Member States.

Member States shall apply these provisions from 30 October 2006.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

Article 25

Revision clause

The European Parliament and the Council invite the Commission to report, before 30 April 2011, on the implementation of this Directive, inter alia, on the basis of reports provided by the Member States, and, where appropriate, to submit a proposal for amendments.

The European Parliament and Council invite the Commission to evaluate whether conformity assessment procedures for industrial products are properly applied and, where appropriate, to propose amendments in order to ensure consistent certification.

Article 26

Entry into force

This Directive shall enter into force on the day of its publication in the Official Journal of the European Union.

Article 27

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 31 March 2004.

For the European Parliament

The President

P. Cox

For the Council

The President

D. Roche

(1) OJ C 62 E, 27.2.2001, p. 1, and OJ C 126 E, 28.5.2002, p. 368.

(2) OJ C 139, 11.5.2001, p. 4.

(3) Opinion of the European Parliament of 3 July 2001 (OJ C 65 E, 14.3.2002, p. 34). Council Common Position of 22 July 2003 (OJ C 252 E, 21.10.2003, p. 1) and Position of the European Parliament of 17 December 2003 (not yet published in the Official Journal). Decision of the Council of 26 February 2004.

(4) OJ L 202, 6.9.1971, p. 1. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

(5) OJ C 136, 4.6.1985, p. 1.

(6) OJ L 139, 23.5.1989, p. 19. Directive as last amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).

(7) OJ L 220, 30.8.1993, p. 23.

(8) OJ C 282, 25.11.2003, p. 3.

(9) OJ L 184, 17.7.1999, p. 23.

(10) OJ L 204, 21.7.1998, p. 37. Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

(11) OJ L 202, 6.9.1971, p. 21. Directive as last amended by Commission Directive 82/623/EEC (OJ L 252, 27.8.1982, p. 5).

(12) OJ L 202, 6.9.1971, p. 32.

(13) OJ L 239, 25.10.1971, p. 9. Directive as last amended by the 1994 Act of Accession.

(14) OJ L 335, 5.12.1973, p. 56. Directive as last amended by Commission Directive 85/146/EEC (OJ L 54, 23.2.1985, p. 29).
(15) OJ L 14, 20.1.1975, p. 1.
(16) OJ L 183, 14.7.1975, p. 25.
(17) OJ L 336, 4.12.1976, p. 30.
(18) OJ L 26, 31.1.1977, p. 59.
(19) OJ L 105, 28.4.1977, p. 18. Directive as amended by Commission Directive 82/625/EEC (OJ L 252, 27.8.1982, p. 10).
(20) OJ L 364, 27.12.1978, p. 1.
(21) OJ L 259, 15.10.1979, p. 1.

ANNEX I

ESSENTIAL REQUIREMENTS

A measuring instrument shall provide a high level of metrological protection in order that any party affected can have confidence in the result of measurement, and shall be designed and manufactured to a high level of quality in respect of the measurement technology and security of the measurement data.

The requirements that shall be met by measuring instruments are set out below and are supplemented, where appropriate, by specific instrument requirements in Annexes MI-001 to MI-010 that provide more detail on certain aspects of the general requirements.

The solutions adopted in the pursuit of the requirements shall take account of the intended use of the instrument and any foreseeable misuse thereof.

DEFINITIONS

Measurand The measurand is the particular quantity subject to measurement.

Influence quantity An influence quantity is a quantity that is not the measurand but that affects the result of measurement.

Rated Operating Conditions The rated operating conditions are the values for the measurand and influence quantities making up the normal working conditions of an instrument.

Disturbance An influence quantity having a value within the limits specified in the appropriate requirement but outside the specified rated operating conditions of the measuring instrument. An influence quantity is a disturbance if for that influence quantity the rated operating conditions are not specified.

Critical change value The critical change value is the value at which the change in the measurement result is considered undesirable.

Material Measure A material measure is a device intended to reproduce or supply in a permanent manner during its use one or more known values of a given quantity.

Direct sales A trading transaction is direct sales if:

- the measurement result serves as the basis for the price to pay and;
- at least one of the parties involved in the transaction related to measurement is a consumer or any other party requiring a similar level of protection and;
- all the parties in the transaction accept the measurement result at that time and place.

Climatic environments Climatic environments are the conditions in which measuring instruments may be used. To cope with climatic differences between the Member States, a range of temperature limits has been defined.

Utility A utility is regarded as a supplier of electricity, gas, heat or water.

REQUIREMENTS

1. Allowable Errors

1.1. Under rated operating conditions and in the absence of a disturbance, the error of measurement shall not exceed the maximum permissible error (MPE) value as laid down in the appropriate instrument-specific requirements.

Unless stated otherwise in the instrument-specific annexes, MPE is expressed as a bilateral value of the deviation from the true measurement value.

1.2. Under rated operating conditions and in the presence of a disturbance, the performance requirement shall be as laid down in the appropriate instrument-specific requirements.

Where the instrument is intended to be used in a specified permanent continuous electromagnetic field the permitted performance during the radiated electromagnetic field-amplitude modulated test shall be within MPE.

1.3. The manufacturer shall specify the climatic, mechanical and electromagnetic environments in which the instrument is intended to be used, power supply and other influence quantities likely to affect its accuracy, taking account of the requirements laid down in the appropriate instrument-specific annexes.

1.3.1. Climatic environments

The manufacturer shall specify the upper temperature limit and the lower temperature limit from any of the values in Table 1 unless otherwise specified in the Annexes MI-001 to MI-010, and indicate whether the instrument is designed for condensing or non-condensing humidity as well as the intended location for the instrument, i.e. open or closed.

Table 1

>TABLE>

1.3.2. (a) Mechanical environments are classified into classes M1 to M3 as described below.

M1 This class applies to instruments used in locations with vibration and shocks of low significance, e.g. for instruments fastened to light supporting structures subject to negligible vibrations and shocks transmitted from local blasting or pile-driving activities, slamming doors, etc.

M2 This class applies to instruments used in locations with significant or high levels of vibration and shock, e.g. transmitted from machines and passing vehicles in the vicinity or adjacent to heavy machines, conveyor belts, etc.

M3 This class applies to instruments used in locations where the level of vibration and shock is high and very high, e.g. for instruments mounted directly on machines, conveyor belts, etc.

(b) The following influence quantities shall be considered in relation with mechanical environments:

- Vibration;
- Mechanical shock.

1.3.3. (a) Electromagnetic environments are classified into classes E1, E2 or E3 as described below, unless otherwise laid down in the appropriate instrument-specific annexes.

E1 This class applies to instruments used in locations with electromagnetic disturbances corresponding to those likely to be found in residential, commercial and light industrial buildings.

E2 This class applies to instruments used in locations with electromagnetic disturbances corresponding to those likely to be found in other industrial buildings.

E3 This class applies to instruments supplied by the battery of a vehicle. Such instruments shall comply with the requirements of E2 and the following additional requirements:

- voltage reductions caused by energising the starter-motor circuits of internal combustion engines,
- load dump transients occurring in the event of a discharged battery being disconnected while the engine is running.

(b) The following influence quantities shall be considered in relation with electromagnetic environments:
- Voltage interruptions,
- Short voltage reductions,
- Voltage transients on supply lines and/or signal lines,
- Electrostatic discharges,
- Radio frequency electromagnetic fields,
- Conducted radio frequency electromagnetic fields on supply lines and/or signal lines,
- Surges on supply lines and/or signal lines.

1.3.4. Other influence quantities to be considered, where appropriate, are:
- Voltage variation,
- Mains frequency variation,
- Power frequency magnetic fields,
- Any other quantity likely to influence in a significant way the accuracy of the instrument.

1.4. When carrying out the tests as envisaged in this Directive, the following paragraphs apply:

1.4.1. Basic rules for testing and the determination of errors

Essential requirements specified in 1.1 and 1.2 shall be verified for each relevant influence quantity. Unless otherwise specified in the appropriate instrument-specific annex, these essential requirements apply when each influence quantity is applied and its effect evaluated separately, all other influence quantities being kept relatively constant at their reference value.

Metrological tests shall be carried out during or after the application of the influence quantity, whichever condition corresponds to the normal operational status of the instrument when that influence quantity is likely to occur.

1.4.2. Ambient humidity

- According to the climatic operating environment in which the instrument is intended to be used either the damp heat-steady state (non-condensing) or damp heat cyclic (condensing) test may be appropriate.
- The damp heat cyclic test is appropriate where condensation is important or when penetration of vapour will be accelerated by the effect of breathing. In conditions where non-condensing humidity is a factor the damp-heat steady state is appropriate.

2. Reproducibility

The application of the same measurand in a different location or by a different user, all other conditions being the same, shall result in the close agreement of successive measurements. The difference between the measurement results shall be small when compared with the MPE.

3. Repeatability

The application of the same measurand under the same conditions of measurement shall result in the close agreement of successive measurements. The difference between the measurement results shall be small when compared with the MPE.

4. Discrimination and Sensitivity

A measuring instrument shall be sufficiently sensitive and the discrimination threshold shall be sufficiently low for the intended measurement task.

5. Durability

A measuring instrument shall be designed to maintain an adequate stability of its metrological characteristics over a period of time estimated by the manufacturer, provided that it is properly installed, maintained and used according to the manufacturer's instruction when in the environmental conditions for which it is intended.

6. Reliability

A measuring instrument shall be designed to reduce as far as possible the effect of a defect that would lead to an inaccurate measurement result, unless the presence of such a defect is obvious.

7. Suitability

7.1. A measuring instrument shall have no feature likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal.

7.2. A measuring instrument shall be suitable for its intended use taking account of the practical working conditions and shall not require unreasonable demands of the user in order to obtain a correct measurement result.

7.3. The errors of a utility measuring instrument at flows or currents outside the controlled range shall not be unduly biased.

7.4. Where a measuring instrument is designed for the measurement of values of the measurand that are constant over time, the measuring instrument shall be insensitive to small fluctuations of the value of the measurand, or shall take appropriate action.

7.5. A measuring instrument shall be robust and its materials of construction shall be suitable for the conditions in which it is intended to be used.

7.6. A measuring instrument shall be designed so as to allow the control of the measuring tasks after the instrument has been placed on the market and put into use. If necessary, special equipment or software for this control shall be part of the instrument. The test procedure shall be described in the operation manual.

When a measuring instrument has associated software which provides other functions besides the measuring function, the software that is critical for the metrological characteristics shall be identifiable and shall not be inadmissibly influenced by the associated software.

8. Protection against corruption

8.1. The metrological characteristics of a measuring instrument shall not be influenced in any inadmissible way by the connection to it of another device, by any feature of the connected device itself or by any remote device that communicates with the measuring instrument.

8.2. A hardware component that is critical for metrological characteristics shall be designed so that it can be secured. Security measures foreseen shall provide for evidence of an intervention.

8.3. Software that is critical for metrological characteristics shall be identified as such and shall be secured. Software identification shall be easily provided by the measuring instrument.

Evidence of an intervention shall be available for a reasonable period of time.

8.4. Measurement data, software that is critical for measurement characteristics and metrologically important parameters stored or transmitted shall be adequately protected against accidental or intentional corruption.

8.5. For utility measuring instruments the display of the total quantity supplied or the displays from which the total quantity supplied can be derived, whole or partial reference to which is the basis for payment, shall not be able to be reset during use.

9. Information to be borne by and to accompany the instrument

9.1. A measuring instrument shall bear the following inscriptions:

- manufacturer's mark or name;
- information in respect of its accuracy,

plus, when applicable:

- information in respect of the conditions of use;
- measuring capacity;
- measuring range;
- identity marking;
- number of the EC-type examination certificate or the EC design examination certificate;
- information whether or not additional devices providing metrological results comply with the provisions of this Directive on legal metrological control.

9.2. An instrument of dimensions too small or of too sensitive a composition to allow it to bear the relevant information shall have its packaging, if any, and the accompanying documents required by the provisions of this Directive suitably marked.

9.3. The instrument shall be accompanied by information on its operation, unless the simplicity of the measuring instrument makes this unnecessary. Information shall be easily understandable and shall include where relevant:

- rated operating conditions;
- mechanical and electromagnetic environment classes;
- the upper and lower temperature limit, whether condensation is possible or not, open or closed location;
- instructions for installation, maintenance, repairs, permissible adjustments;
- instructions for correct operation and any special conditions of use;
- conditions for compatibility with interfaces, sub-assemblies or measuring instruments.

9.4. Groups of identical measuring instruments used in the same location or used for utility measurements do not necessarily require individual instruction manuals.

9.5. Unless specified otherwise in an instrument-specific annex, the scale interval for a measured value shall be in the form 1×10n, 2×10n, or 5×10n, where n is any integer or zero. The unit of measurement or its symbol shall be shown close to the numerical value.

9.6. A material measure shall be marked with a nominal value or a scale, accompanied by the unit of measurement used.

9.7. The units of measurement used and their symbols shall be in accordance with the provisions of Community legislation on units of measurement and their symbols.

9.8. All marks and inscriptions required under any requirement shall be clear, non-erasable, unambiguous and non-transferable.

10. Indication of result

10.1. Indication of the result shall be by means of a display or hard copy.

10.2. The indication of any result shall be clear and unambiguous and accompanied by such marks and inscriptions necessary to inform the user of the significance of the result. Easy reading of the presented result shall be permitted under normal conditions of use. Additional indications may be shown provided they cannot be confused with the metrologically controlled indications.

10.3. In the case of hard copy the print or record shall also be easily legible and non-erasable.

10.4. A measuring instrument for direct sales trading transactions shall be designed to present the measurement result to both parties in the transaction when installed as intended. When critical in case of direct sales, any ticket provided to the consumer by an ancillary device not complying with the appropriate requirements of this Directive shall bear an appropriate restrictive information.

10.5. Whether or not a measuring instrument intended for utility measurement purposes can be remotely read it shall in any case be fitted with a metrologically controlled display accessible without tools to the consumer. The reading of this display is the measurement result that serves as the basis for the price to pay.

11. Further processing of data to conclude the trading transaction

11.1. A measuring instrument other than a utility measuring instrument shall record by a durable means the measurement result accompanied by information to identify the particular transaction, when:

- the measurement is non-repeatable and;
- the measuring instrument is normally intended for use in the absence of one of the trading parties.

11.2. Additionally, a durable proof of the measurement result and the information to identify the transaction shall be available on request at the time the measurement is concluded.

12. Conformity evaluation

A measuring instrument shall be designed so as to allow ready evaluation of its conformity with the appropriate requirements of this Directive.

ANNEX A

DECLARATION OF CONFORMITY BASED ON INTERNAL PRODUCTION CONTROL

1. The "declaration of conformity based on internal production control" is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments concerned satisfy the appropriate requirements of this Directive.

Technical documentation

2. The manufacturer shall establish the technical documentation as described in Article 10. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the instrument.

3. The manufacturer shall keep the technical documentation at the disposal of the national authorities for ten years after the last instrument has been manufactured.

Manufacturing

4. The manufacturer shall take all measures necessary to ensure conformity of the manufactured instruments with the appropriate requirements of this Directive.

Written declaration of conformity

5.1. The manufacturer shall affix the "CE" marking and the supplementary metrology marking to each measuring instrument that satisfies the appropriate requirements of this Directive.

5.2. A declaration of conformity is drawn up for an instrument model and shall be kept at the disposal of the national authorities for ten years after the last instrument has been manufactured. It shall identify 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. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

Authorised representative

6. The manufacturer's obligations contained in paragraphs 3 and 5.2 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Where the manufacturer is not established within the Community and where he does not have an authorised representative, the obligations contained in paragraphs 3 and 5.2 shall be the responsibility of the person who places the instrument on the market.

ANNEX A1

DECLARATION OF CONFORMITY BASED ON INTERNAL PRODUCTION CONTROL PLUS PRODUCT TESTING BY A NOTIFIED BODY

1. "Declaration of conformity based on internal production control plus product testing by a notified body" is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex, and ensures and declares that the measuring instruments concerned satisfy the appropriate requirements of this Directive.

Technical documentation

2. The manufacturer shall establish the technical documentation as described in Article 10. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the instrument.

3. The manufacturer shall keep the technical documentation at the disposal of the national authorities for ten years after the last instrument has been manufactured.

Manufacturing

4. The manufacturer shall take all measures necessary to ensure conformity of the manufactured instruments with the appropriate requirements of this Directive.

Product checks

5. A notified body, chosen by the manufacturer, shall carry out product checks or have them carried out in appropriate intervals determined by it, in order to verify the quality of the internal checks of the product, taking into account inter alia the technological complexity of the instruments and the quantity of production. An adequate sample of the final products, taken by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant document(s) referred to in Article 13, or equivalent tests, shall be carried out to check the conformity of the instruments with the appropriate requirements of this Directive. In the absence of a relevant document, the notified body concerned shall decide on the appropriate tests to be carried out.

In those cases where a relevant number of instruments in the sample do not conform to an acceptable quality level, the notified body shall take appropriate measures.

Written declaration of conformity

6.1. The manufacturer shall affix the "CE" marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 5, the latter's identification number to each measuring instrument that satisfies the appropriate requirements of this Directive.

6.2. A declaration of conformity is drawn up for each instrument model and shall be kept 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.

However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

Authorised representative

7. The manufacturer's obligations contained in paragraphs 3 and 6.2 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Where the manufacturer is not established within the Community and where he does not have an authorised representative, the obligations contained in paragraphs 3 and 6.2 shall be the responsibility of the person who places the instrument on the market.

ANNEX B

TYPE EXAMINATION

1. "Type examination" is the part of a conformity assessment procedure whereby a notified body examines the technical design of a measuring instrument and ensures and declares that the technical design meets the appropriate requirements of this Directive.

2. Type examination may be carried out in either of the following manners. The notified body decides on the appropriate manner and the specimens required:

(a) examination of a specimen, representative of the production envisaged, of the complete measuring instrument;

(b) examination of specimens, representative of the production envisaged, of one or more critical parts of the measuring instrument, plus assessment of the adequacy of the technical design of the other parts of the measuring instrument through examination of the technical documentation and supporting evidence referred to in paragraph 3;

(c) assessment of the adequacy of the technical design of the measuring instrument through examination of the technical documentation and supporting evidence referred to in paragraph 3, without examination of a specimen.

3. The application for type examination shall be lodged by the manufacturer with a notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition;
- a written declaration that the same application has not been lodged with any other notified body;
- the technical documentation as described in Article 10. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the instrument;
- the specimens, representative of the production envisaged, as required by the notified body;
- the supporting evidence for the adequacy of the technical design of those parts of the measuring instrument for which no specimens are required. This supporting evidence shall mention any relevant documents that have been applied, in particular where the relevant documents referred to in Article 13 have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall:

For the specimens:

4.1. examine the technical documentation, verify that the specimens have been manufactured in conformity with it and identify the elements which have been designed in accordance with the relevant provisions of the relevant documents referred to in Article 13, as well as the elements which have been designed without applying the relevant provisions of those documents;
4.2. carry out the appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant documents referred to in Article 13, these have been applied correctly;
4.3. carry out the appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen not to apply the solutions in the relevant documents referred to in Article 13, the solutions adopted by the manufacturer meet the corresponding essential requirements of this Directive;
4.4. agree with the applicant on the location where the examinations and tests shall be carried out.
For the other parts of the measuring instrument:
4.5. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the other parts of the measuring instrument.
For the manufacturing process:
4.6. examine the technical documentation to assure that the manufacturer has adequate means to ensure consistent production.
5.1. The notified body shall draw up an evaluation report that records the activities as undertaken in accordance with paragraph 4 and their outcomes. Without prejudice to Article 12(8), the notified body shall release the content of this report, in full or in part, only with the agreement of the manufacturer.
5.2. Where the technical design meets the requirements of this Directive that apply to the measuring instrument, the notified body shall issue an EC-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer and, if appropriate, of his authorised representative, conclusions of the examination, conditions (if any) for its validity and the necessary data for identification of the instrument. The certificate may have one or more annexes attached.
The certificate and its annexes shall contain all relevant information for conformity evaluation and in-service control. In particular, to allow the conformity of manufactured instruments to be evaluated with the examined type regarding the reproducibility of their metrological performances, when they are properly adjusted using appropriate means, content shall include:
- the metrological characteristics of the type of instrument;
- measures required for ensuring the integrity of the instruments (sealing, identification of software, etc.);
- information on other elements necessary for the identification of the instruments and to check their visual external conformity to type;
- if appropriate, any specific information necessary to verify the characteristics of manufactured instruments;
- in the case of a sub-assembly, all necessary information to ensure the compatibility with other sub-assemblies or measuring instruments.
The certificate shall have a validity of ten years from the date of its issue, and may be renewed for subsequent periods of ten years each.
5.3. The notified body shall establish an evaluation report in this regard and keep it at the disposal of the Member State that designated it.
6. The manufacturer shall inform the notified body 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. Such modifications require additional approval in the form of an addition to the original EC-type examination certificate.

7. Each notified body shall immediately inform the Member State that designated it about:

- EC-type examination certificates and annexes issued;
- additions and amendments relating to certificates already issued.

Each notified body shall immediately inform the Member State that designated it of the withdrawal of an EC-type examination certificate.

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.

8. 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.

9. The manufacturer's authorised representative may lodge the application referred to in paragraph 3 and carry out the obligations mentioned in paragraphs 6 and 8. Where the manufacturer is not established within the Communities and where he does not have an authorised representative, the obligation to make the technical documentation available on request shall be the responsibility of the person designated by the manufacturer.

ANNEX C

DECLARATION OF CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

1. "Declaration of conformity to type based on internal production control" is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments concerned are in conformity with the type as described in the EC-type examination certificate and satisfy the appropriate requirements of this Directive.

Manufacturing

2. The manufacturer shall take all measures necessary to ensure conformity of the manufactured instruments with the type as described in the EC-type examination certificate and with the appropriate requirements of this Directive.

Written declaration of conformity

3.1. The manufacturer shall affix the "CE" marking and the supplementary metrology marking to each measuring instrument that is in conformity with the type as described in the EC-type examination certificate and satisfies the appropriate requirements of this Directive.

3.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for 10 years after the last instrument has been manufactured. It shall identify the instrument model for which it was drawn up.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

Authorised representative

4. The manufacturer's obligations contained in paragraph 3.2 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Where the manufacturer is not established within the Community and where he does not have an authorised representative, the obligation mentioned in paragraph 3.2 shall be the responsibility of the

person who places the instrument on the market.

ANNEX C1

DECLARATION OF CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS PRODUCT TESTING BY A NOTIFIED BODY

1. "Declaration of conformity to type based on internal production control plus product testing by a notified body" is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments concerned are in conformity with the type as described in the EC-type examination certificate and satisfy the appropriate requirements of this Directive.

Manufacturing

2. The manufacturer shall take all measures necessary to ensure conformity of the manufactured instruments with the type as described in the EC-type examination certificate and with the appropriate requirements of this Directive.

Product checks

3. A notified body, chosen by the manufacturer, shall carry out product checks or have them carried out in appropriate intervals determined by it, in order to verify the quality of the internal checks of the product, taking into account inter alia the technological complexity of the instruments and the quantity of production.

An adequate sample of the final products, taken by the notified body before the placing on the market, shall be examined and appropriate tests, as identified by the relevant documents referred to in Article 13, or equivalent tests, shall be carried out to check the conformity of the product with the type as described in the EC-type examination certificate and the appropriate requirements of the Directive. In the absence of a relevant document, the notified body concerned shall decide on the appropriate tests to be carried out.

In those cases where a relevant number of instruments in the sample do not conform to an acceptable quality level, the notified body shall take appropriate measures.

Written declaration of conformity

4.1. The manufacturer shall affix the "CE" marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 3, the latter's identification number, to each measuring instrument that is in conformity with the type as described in the EC-type examination certificate and satisfies the appropriate requirements of this Directive.

4.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for 10 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. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

Authorised representative

5. The manufacturer's obligations contained in paragraph 4.2 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Where the manufacturer is not established within the Community and where he does not have an authorised representative, the obligations mentioned in paragraph 4.2 shall be the responsibility of the person who places the instrument on the market.

ANNEX D

DECLARATION OF CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. "Declaration of conformity to type based on quality assurance of the production process" is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments concerned are in conformity with the type as described in the EC-type examination certificate and satisfy the appropriate requirements of this Directive.

Manufacturing

2. The manufacturer shall operate an approved quality system for production, final product inspection and testing of the measuring instrument concerned as specified in paragraph 3 and shall be subject to surveillance as specified in paragraph 4.

Quality system

3.1. The manufacturer shall lodge an application for assessment of the quality system with a notified body of his choice.

The application shall include:

- all relevant information for the instrument category envisaged;
- the documentation concerning the quality system;
- the technical documentation of the approved type and a copy of the EC-type examination certificate.

3.2. 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 this Directive.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc;
- the means to monitor the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It shall presume conformity with these requirements in respect of a quality system that complies with the corresponding specifications of the national standard that implements the relevant harmonised standard, from the moment its references have been published.

In addition to experience in quality management systems, the auditing team shall possess appropriate experience in the relevant field of metrology and instrument technology, and knowledge of the applicable requirements of this Directive. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the changed quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations of manufacture, inspection, testing and storage, and shall provide it with all necessary information, in particular:

- the quality system documentation;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, to verify that the quality system is functioning correctly. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

Written declaration of conformity

5.1. The manufacturer shall affix the "CE" marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 3.1, the latter's identification number to each measuring instrument that is in conformity with the type as described in the EC-type examination certificate and satisfies the appropriate requirements of this Directive.

5.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for 10 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. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

6. The manufacturer shall, for 10 years after the last instrument has been manufactured, keep at the disposal of the national authorities:

- the documentation referred to in paragraph 3.1, second indent;
- the change referred to in paragraph 3.5, as approved;
- the decisions and reports from the notified body referred to in paragraphs 3.5, 4.3 and 4.4.

7. Each notified body shall periodically make available to the Member State that designated it the list of quality system approvals issued or refused, and shall immediately inform the Member State that designated it of the withdrawal of a quality system approval.

Authorised representative

8. The manufacturer's obligations contained in paragraphs 3.1, 3.5, 5.2 and 6 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

ANNEX D1

DECLARATION OF CONFORMITY BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. "Declaration of conformity based on quality assurance of the production process" is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments concerned satisfy the appropriate requirements of this Directive.

Technical documentation

2. The manufacturer shall establish the technical documentation as described in Article 10. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design and operation of the instrument.

3. The manufacturer shall keep the technical documentation at the disposal of the national authorities for 10 years after the last instrument has been manufactured.

Manufacturing

4. The manufacturer shall operate an approved quality system for production, final product inspection and testing of the measuring instrument concerned as specified in paragraph 5 and shall be subject to surveillance as specified in paragraph 6.

Quality system

5.1. The manufacturer shall lodge an application for assessment of the quality system with a notified body of his choice.

The application shall include:

- all relevant information for the instrument category envisaged;
- the documentation concerning the quality system;
- the technical documentation referred to in paragraph 2.

5.2. The quality system shall ensure compliance of the instruments with the appropriate requirements of this Directive.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain, in particular, an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

- the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;
- the means to monitor the achievement of the required product quality and the effective operation of the quality system.

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 5.2. It shall presume conformity with these requirements in respect of a quality system that complies with the corresponding specifications of the national standard that implements the relevant harmonised standard, from the moment its references have been published.

In addition to experience in quality management systems, the auditing team shall possess appropriate experience in the relevant field of metrology and instrument technology, and knowledge of the applicable requirements of this Directive. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

5.5. The manufacturer shall keep the notified body that has approved the quality system periodically informed of any intended change of the quality system.

The notified body shall evaluate the changes proposed and decide whether the changed quality system will still satisfy the requirements referred to in paragraph 5.2 or whether a re-assessment is required.

It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the notified body

6.1. The purpose of surveillance is to make sure that the manufacturer fulfils the obligations arising out of the approved quality system.

6.2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations of manufacture, inspection, testing and storage, and shall provide it with all necessary information, in particular:

- the quality system documentation;
- the technical documentation referred to in paragraph 2;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

6.4. Additionally, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, to verify that the quality system is functioning correctly. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

Written declaration of conformity

7.1. The manufacturer shall affix the "CE" marking, the supplementary metrology marking and, under the

responsibility of the notified body referred to in paragraph 5.1, the latter's identification number to each measuring instrument that satisfies the appropriate requirements of this Directive.

7.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for 10 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. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

8. The manufacturer shall, for 10 years after the last instrument has been manufactured, keep at the disposal of the national authorities:

- the documentation referred to in paragraph 5.1, second indent;
- the change referred to in paragraph 5.5, as approved;
- the decisions and reports from the notified body referred to in paragraphs 5.5, 6.3 and 6.4.

9. Each notified body shall periodically make available to the Member State that designated it the list of quality system approvals issued or refused, and shall immediately inform the Member State that designated it of the withdrawal of a quality system approval.

Authorised representative

10. The manufacturer's obligations contained in paragraphs 3, 5.1, 5.5, 7.2 and 8 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

ANNEX E

DECLARATION OF CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF FINAL PRODUCT INSPECTION AND TESTING

1. "Declaration of conformity to type based on quality assurance of final product inspection and testing" is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments concerned are in conformity with the type as described in the EC-type examination certificate and satisfy the appropriate requirements of this Directive.

Manufacturing

2. The manufacturer shall operate an approved quality system as specified in paragraph 3 for final product inspection and testing of the measuring instrument concerned and shall be subject to surveillance, as specified in paragraph 4.

Quality system

3.1. The manufacturer shall lodge an application for assessment of the quality system with a notified body of his choice.

The application shall include:

- all relevant information for the instrument category envisaged;
- the documentation concerning the quality system;
- the technical documentation of the approved type and a copy of the EC-type examination certificate.

3.2. 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 this Directive.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality

system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- the examinations and tests that will be carried out after manufacture;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;
- the means to monitor the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It shall presume conformity with these requirements in respect of a quality system that complies with the corresponding specifications of the national standard that implements the relevant harmonised standard, from the moment its references have been published.

In addition to experience in quality management systems, the auditing team shall possess appropriate experience in the relevant field of metrology and instrument technology, and knowledge of the applicable requirements of this Directive. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.

The notified body shall evaluate the changes proposed and decide whether the changed quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations of inspection, testing and storage, and shall provide it with all necessary information, in particular:

- the quality system documentation;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, to verify that the quality system is functioning correctly. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

Written declaration of conformity

5.1. The manufacturer shall affix the "CE" marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 3.1, the latter's identification number to each measuring instrument that is in conformity with the type as described in the EC-type examination certificate and satisfies the appropriate requirements of this Directive.
5.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for 10 years after the last instrument has been manufactured. It shall identify the instrument model for which it was drawn up. A copy of the declaration shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.
6. The manufacturer shall, for 10 years after the last instrument has been manufactured, keep at the disposal of the national authorities:
- the documentation referred to in the second indent of paragraph 3.1;
- the change referred to in the second subparagraph of paragraph 3.5, as approved;
- the decisions and reports from the notified body which are referred to in paragraph 3.5, final subparagraph, paragraph 4.3 and paragraph 4.4.
7. Each notified body shall periodically make available to the Member State that designated it the list of quality system approvals issued or refused, and shall immediately inform the Member State that designated it of the withdrawal of a quality system approval.
Authorised representative
8. The manufacturer's obligations contained in paragraphs 3.1, 3.5, 5.2 and 6 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.
ANNEX E1
DECLARATION OF CONFORMITY BASED ON QUALITY ASSURANCE OF FINAL PRODUCT INSPECTION AND TESTING
1. "Declaration of conformity based on quality assurance of final product inspection and testing" is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments concerned are in conformity with the appropriate requirements of this Directive.
Technical documentation
2. The manufacturer shall establish the technical documentation as described in Article 10. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the instrument.
3. The manufacturer shall keep the technical documentation at the disposal of the national authorities for 10 years after the last instrument has been manufactured.
Manufacturing
4. The manufacturer shall operate an approved quality system for final product inspection and testing of the measuring instrument concerned as specified in paragraph 5 and shall be subject to surveillance as specified in paragraph 6.
Quality system
5.1. The manufacturer shall lodge an application for assessment of the quality system with a notified body

of his choice.
The application shall include:
- all relevant information for the instrument category envisaged;
- the documentation concerning the quality system;
- the technical documentation referred to in paragraph 2.
5.2. The quality system shall ensure compliance of the instruments with the appropriate requirements of this Directive.
All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.
This documentation shall contain in particular an adequate description of:
- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- the examinations and tests that will be carried out after manufacture;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc;
- the means to monitor the effective operation of the quality system.
5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 5.2. It shall presume conformity with these requirements in respect of a quality system that complies with the corresponding specifications of the national standard that implements the relevant harmonised standard, from the moment its references have been published.
In addition to experience in quality management systems, the auditing team shall possess appropriate experience in the relevant field of metrology and instrument technology, and knowledge of the applicable requirements of this Directive. The evaluation procedure shall include an inspection visit to the manufacturer's premises.
The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.
The notified body shall evaluate the changes proposed and decide whether the changed quality system will still satisfy the requirements referred to in paragraph 5.2 or whether a re-assessment is required.
It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
Surveillance under the responsibility of the notified body
6.1. The purpose is to make sure that the manufacturer fulfils the obligations arising out of the approved quality system.
6.2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations of inspection, testing and storage, and shall provide it with all necessary information, in particular:
- the quality system documentation;

- the technical documentation referred to in paragraph 2;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

6.4. Additionally, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, to verify that the quality system is functioning correctly. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

Written declaration of conformity

7.1. The manufacturer shall affix the "CE" marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 5.1, the latter's identification number to each measuring instrument that satisfies the appropriate requirements of this Directive.

7.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for 10 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. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

8. The manufacturer shall, for 10 years after the last instrument has been manufactured, keep at the disposal of the national authorities:
- the documentation referred to in paragraph 5.1, second indent;
- the change referred to in paragraph 5.5, as approved;
- the decisions and reports from the notified body referred to in paragraphs 5.5, 6.3 and 6.4.

9. Each notified body shall periodically make available to the Member State that designated it the list of quality system approvals issued or refused, and shall immediately inform the Member State that designated it of the withdrawal of a quality system approval.

Authorised representative

10. The manufacturer's obligations contained in paragraphs 3, 5.1, 5.5, 7.2 and 8 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

ANNEX F

DECLARATION OF CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION

1. "Declaration of conformity to type based on product verification" is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments that have been subjected to the provisions of paragraph 3 are in conformity with the type as described in the EC-type examination certificate and satisfy the appropriate requirements of this Directive.

Manufacturing

2. The manufacturer shall take all measures necessary to ensure conformity of the manufactured instruments with the approved type as described in the EC-type examination certificate and the appropriate requirements of this Directive.

Verification

3. A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests, or have them carried out, to check the conformity of the instruments with the type as described in the EC-type examination certificate and the appropriate requirements of this Directive.
The examinations and tests to check the conformity with the metrological requirements will be carried out, at the choice of the manufacturer, either by examination and testing of every instrument as specified in paragraph 4, or by examination and testing of the instruments on a statistical basis as specified in paragraph 5.
4. Verification of conformity with the metrological requirements by examination and testing of every instrument.
4.1. All instruments shall be individually examined and appropriate tests as set out in the relevant documents referred to in Article 13, or equivalent tests, shall be carried out to verify their conformity with the metrological requirements that apply to them. In the absence of a relevant document, the notified body concerned shall decide on the appropriate tests to be carried out.
4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.
The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the certification of the instrument.
5. Statistical verification of conformity with the metrological requirements.
5.1. The manufacturer shall take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced, and shall present his instruments for verification in the form of homogeneous lots.
5.2. A random sample shall be drawn from each lot according to the requirements of paragraph 5.3. All instruments in the sample shall be individually examined and appropriate tests as set out in the relevant documents referred to in Article 13, or equivalent tests, to establish their conformity with the metrological requirements that apply to them shall be carried out to determine whether the lot is accepted or rejected. In the absence of a relevant document, the notified body concerned shall decide on the appropriate tests to be carried out.
5.3. The statistical procedure shall meet the following requirements:
The statistical control will be based on attributes. The sampling system shall ensure:
- a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity of less than 1 %;
- a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity of less than 7 %.
5.4. If a lot is accepted, all instruments of the lot are approved, except for those instruments from the sample that were found not to satisfy the tests.
The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.
The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the certification of the instrument.
5.5. If a lot is rejected, the notified body shall take appropriate measures to prevent the placing on the market of that lot. In the event of frequent rejection of lots the notified body may suspend the statistical

verification and take appropriate measures.

Written declaration of conformity

6.1. The manufacturer shall affix the "CE" marking and the supplementary metrology marking to each measuring instrument that is in conformity with the approved type and satisfies the appropriate requirements of this Directive.

6.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for 10 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. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

If agreed upon by the notified body referred to in paragraph 3, the manufacturer shall also affix the notified body's identification number to the measuring instruments under the notified body's responsibility.

7. The manufacturer may, if agreed upon by the notified body and under its responsibility, affix the notified body's identification number to the measuring instruments during the manufacturing process.

Authorised representative

8. The manufacturer's obligations may be fulfilled, on his behalf and under his responsibility, by his authorised representative except for the obligations contained in paragraphs 2 and 5.1.

ANNEX F1

DECLARATION OF CONFORMITY BASED ON PRODUCT VERIFICATION

1. "Declaration of conformity based on product verification" is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments that have been subjected to the provisions of paragraph 5 are in conformity with the appropriate requirements of this Directive.

Technical documentation

2. The manufacturer shall establish the technical documentation as described in Article 10. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the instrument.

3. The manufacturer shall keep the technical documentation at the disposal of the national authorities for 10 years after the last instrument has been manufactured.

Manufacturing

4. The manufacturer shall take all measures necessary to ensure conformity of the manufactured instruments with the appropriate requirements of this Directive.

Verification

5. A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests, or have them carried out, to check the conformity of the instruments with the appropriate requirements of this Directive.

The examinations and tests to check the conformity with the metrological requirements will be carried out, at the choice of the manufacturer, either by examination and testing of every instrument as specified in paragraph 6, or by examination and testing of the instruments on a statistical basis as specified in paragraph 7.

6. Verification of conformity with the metrological requirements by examination and testing of every instrument.

6.1. All instruments shall be individually examined and appropriate tests, as set out in the relevant documents referred to in Article 13, or equivalent tests, shall be carried out to verify their conformity with the metrological requirements that apply to them. In the absence of a relevant document, the notified body concerned shall decide on the appropriate tests to be carried out.

6.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the certification of the instrument.

7. Statistical verification of conformity with the metrological requirements.

7.1. The manufacturer shall take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced, and shall present his instruments for verification in the form of homogeneous lots.

7.2. A random sample shall be drawn from each lot according to the requirements of paragraph 7.3. All instruments in the sample shall be individually examined and appropriate tests as set out in the relevant documents referred to in Article 13, or equivalent tests, to establish their conformity with the metrological requirements that apply to them, shall be carried out to determine whether the lot is accepted or rejected. In the absence of a relevant document, the notified body concerned shall decide on the appropriate tests to be carried out.

7.3. The statistical procedure shall meet the following requirements:

The statistical control will be based on attributes. The sampling system shall ensure:

- a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity of less than 1 %;
- a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity of less than 7 %.

7.4. If a lot is accepted all instruments of the lot are approved, except for those instruments from the sample that were found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the certification of the instrument.

7.5. If a lot is rejected, the notified body shall take appropriate measures to prevent the placing on the market of that lot. In the event of frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

Written declaration of conformity

8.1. The manufacturer shall affix the "CE" marking and the supplementary metrology marking to each measuring instrument that satisfies the appropriate requirements of this Directive.

8.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for 10 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. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.
If agreed upon by the notified body referred to in paragraph 5, the manufacturer shall also affix the notified body's identification number to the measuring instruments under the notified body's responsibility.
9. The manufacturer may, if agreed upon by the notified body and under its responsibility, affix the notified body's identification number to the measuring instruments during the manufacturing process.
Authorised representative
10. The manufacturer's obligations may be fulfilled, on his behalf and under his responsibility, by his authorised representative, except for the obligations contained in paragraphs 4 and 7.1.
ANNEX G
DECLARATION OF CONFORMITY BASED ON UNIT VERIFICATION
1. "Declaration of conformity based on unit verification" is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that a measuring instrument that has been subjected to the provisions of paragraph 4, is in conformity with the appropriate requirements of this Directive.
Technical documentation
2. The manufacturer shall establish the technical documentation as described in Article 10 and make it available to the notified body referred to in paragraph 4. The technical documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive and shall, as far as relevant for such assessment, cover the design, manufacture and operation of the instrument.
The manufacturer shall keep the technical documentation at the disposal of the national authorities for ten years.
Manufacturing
3. The manufacturer shall take all measures necessary to ensure conformity of the manufactured instrument with the appropriate requirements of this Directive.
Verification
4. A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests as set out in the relevant documents referred to in Article 13, or equivalent tests, to check the conformity of the instrument with the appropriate requirements of this Directive, or have them carried out. In the absence of a relevant document, the notified body concerned shall decide on the appropriate tests to be carried out.
The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and affix its identification number to the approved instrument, or have it affixed under its responsibility.
The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the certification of the instrument.
Written declaration of conformity
5.1. The manufacturer shall affix the "CE" marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 4, the latter's identification number to each measuring instrument that satisfies the appropriate requirements of this Directive.
5.2. A declaration of conformity shall be drawn up and kept at the disposal of the national authorities for 10 years after the instrument has been manufactured. It shall identify the instrument for which it was drawn up.
A copy of the declaration shall be supplied with the measuring instrument.

Authorised representative

6. The manufacturer's obligations contained in paragraphs 2 and 4.2 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

ANNEX H

DECLARATION OF CONFORMITY BASED ON FULL QUALITY ASSURANCE

1. "Declaration of conformity based on full quality assurance" is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments concerned satisfy the appropriate requirements of this Directive.

Manufacturing

2. The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the measuring instrument concerned as specified in paragraph 3, and shall be subject to surveillance as specified in paragraph 4.

Quality system

3.1. The manufacturer shall lodge an application for assessment of the quality system with a notified body of his choice.

The application shall include:

- all relevant information for the instrument category envisaged;
- the documentation concerning the quality system.

3.2. The quality system shall ensure compliance of the instruments with the appropriate requirements of this Directive.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;
- the technical design specifications, including standards, that will be applied and, where the relevant documents referred to in Article 13 will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the instruments will be met;
- the design control and design verification techniques, processes and systematic actions that will be used when designing the instruments pertaining to the instrument category covered;
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the examinations and tests that will be carried out before, during and after manufacture, and their frequency;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;
- the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It shall presume conformity with these requirements in respect of a quality system that complies with the corresponding specifications of the national standard that implements the

relevant harmonised standard, from the moment its references have been published.
In addition to experience in quality management systems, the auditing team shall possess appropriate experience in the relevant field of metrology and instrument technology, and knowledge of the applicable requirements of this Directive. The evaluation procedure shall include an inspection visit to the manufacturer's premises.
The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.
The notified body shall evaluate the changes proposed and decide whether the changed quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.
It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
Surveillance under the responsibility of the notified body
4.1. The purpose of surveillance is to make sure that the manufacturer fulfils the obligations arising out of the approved quality system.
4.2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations of manufacture, inspection, testing and storage, and shall provide it with all necessary information, in particular:
- the quality system documentation;
- the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.;
- the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.
4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.
4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out under its responsibility, to verify that the quality system is functioning correctly. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
Written declaration of conformity
5.1. The manufacturer shall affix the "CE" marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 3.1, the latter's identification number to each measuring instrument that satisfies the appropriate requirements of this Directive.
5.2. A declaration of conformity is drawn up for an instrument model and shall be kept at the disposal of the national authorities for 10 years after the last instrument has been manufactured. It shall identify the instrument model for which it was drawn up.
A copy of the declaration shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

6. The manufacturer shall, for 10 years after the last instrument has been manufactured, keep at the disposal of the national authorities:
- the documentation concerning the quality system referred to in paragraph 3.1, second indent;
- the change referred to in paragraph 3.5, as approved;
- the decisions and reports from the notified body referred to in paragraphs 3.5, 4.3 and 4.4.
7. Each notified body shall periodically make available to the Member State that designated it the list of quality system approvals issued or refused, and shall immediately inform the Member State that designated it of the withdrawal of a quality system approval.
Authorised representative
8. The manufacturer's obligations contained in paragraphs 3.1, 3.5, 5.2 and 6 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.
ANNEX H1
DECLARATION OF CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION
1. "Declaration of conformity based on full quality assurance plus design examination" is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in this Annex and ensures and declares that the measuring instruments concerned satisfy the appropriate requirements of this Directive.
Manufacturing
2. The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the measuring instrument concerned as specified in paragraph 3, and shall be subject to surveillance as specified in paragraph 5. The adequacy of the technical design of the measuring instrument shall have been examined according to the provisions of paragraph 4.
Quality system
3.1. The manufacturer shall lodge an application for assessment of the quality system with a notified body of his choice.
The application shall include:
- all relevant information for the instrument category envisaged;
- the documentation concerning the quality system.
3.2. The quality system shall ensure compliance of the instruments with the appropriate requirements of this Directive.
All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall contain in particular an adequate description of:
- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;
- the technical design specifications, including standards, that will be applied and, where the relevant documents referred to in Article 13 will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the instruments will be met;
- the design control and design verification techniques, processes and systematic actions that will be used when designing the instruments pertaining to the instrument category covered;

- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;
- the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It shall presume conformity with these requirements in respect of a quality system that complies with the corresponding specifications of the national standard that implements the relevant harmonised standard, from the moment its references have been published in the Official Journal.
In addition to experience in quality management systems, the auditing team shall possess appropriate experience in the relevant field of metrology and instrument technology, and knowledge of the applicable requirements of this Directive. The evaluation procedure shall include an inspection visit to the manufacturer's premises.
The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.
The notified body shall evaluate the changes proposed and decide whether the changed quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.
It shall notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
3.6. Each notified body shall periodically make available to the Member State that designated it the list of quality system approvals issued or refused, and shall immediately inform the Member State that designated it of the withdrawal of a quality system approval.
Design examination
4.1. The manufacturer shall lodge an application for examination of the design with the notified body referred to in paragraph 3.1.
4.2. The application shall enable understanding of the design, manufacture and operation of the instrument, and shall enable assessment of conformity with the appropriate requirements of this Directive. It shall include:
- the name and address of the manufacturer;
- a written declaration that the same application has not been lodged with any other notified body;
- the technical documentation as described in Article 10. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design and operation of the instrument;
- the supporting evidence for the adequacy of the technical design. This evidence shall mention any documents that have been applied, in particular where the relevant documents referred to in Article 13 have

not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4.3. The notified body shall examine the application, and where the design meets the provisions of the Directive that apply to the measuring instrument it shall issue an EC design examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, any conditions for its validity and the necessary data for identification of the approved instrument.

4.3.1. All relevant parts of the technical documentation shall be annexed to the certificate.

4.3.2. The certificate or its annexes shall contain all relevant information for conformity evaluation and in-service control. It shall to allow the evaluation of conformity of the manufactured instruments with the examined design regarding the reproducibility of their metrological performances, when they are properly adjusted using appropriate means, including:

- the metrological characteristics of the design of the instrument;
- measures required for ensuring the integrity of the instruments (sealing, identification of software ...);
- information on other elements necessary for the identification of the instrument and to check its visual external conformity to the design;
- if appropriate, any specific information necessary to verify the characteristics of manufactured instruments;
- in the case of a sub-assembly, all necessary information to ensure the compatibility with other sub-assemblies or measuring instruments.

4.3.3. The notified body shall establish an evaluation report in this regard and keep it at the disposal of the Member State that designated it. Without prejudice to Article 12(8), the notified body shall release the content of this report, in full or in part, only with the agreement of the manufacturer.

The certificate shall have a validity of ten years from the date of its issue, and may be renewed for subsequent periods of ten years each.

If the manufacturer is denied a design examination certificate, the notified body shall provide detailed reasons for the denial.

4.4. The manufacturer shall keep the notified body that has issued the "EC" design examination certificate informed of any fundamental modification to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the "EC" design examination certificate where such changes may affect the conformity with the essential requirements of this Directive, the conditions for validity of the certificate or the prescribed conditions for use of the instrument. This additional approval is given in the form of an addition to the original "EC" design examination certificate.

4.5. Each notified body shall periodically make available to the Member State that designated it:

- "EC" design examination certificates and annexes issued;
- additions and amendments relating to certificates issued.

Each notified body shall immediately inform the Member State that designated it of the withdrawal of an EC design examination certificate.

4.6. The manufacturer or his authorised representative shall keep a copy of the "EC" design examination certificate, its annexes and additions with the technical documentation for 10 years after the last measuring instrument has been manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to make the technical documentation available on request shall be the responsibility of the person designated by the manufacturer.

Surveillance under the responsibility of the notified body

5.1. The purpose of surveillance is to make sure that the manufacturer fulfils the obligations arising out of the approved quality system.

5.2. The manufacturer shall allow the notified body entrance for inspection purposes to the locations of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, in particular:

- the quality system documentation;
- the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc;
- the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

5.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

5.4. Additionally, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out under its responsibility, to verify that the quality system is functioning correctly. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

Written declaration of conformity

6.1. The manufacturer shall affix the "CE" marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 3.1, the latter's identification number to each measuring instrument that satisfies the appropriate requirements of this Directive.

6.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for 10 years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up and shall mention the number of the design examination certificate.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

7. The manufacturer shall, for 10 years after the last instrument has been manufactured, keep at the disposal of the national authorities:

- the documentation referred to in 3.1, second indent;
- the change referred to in paragraph 3.5, as approved;
- the decisions and reports of the notified body referred to in paragraphs 3.5, 5.3 and 5.4.

Authorised representative

8. The manufacturer's obligations contained in paragraphs 3.1, 3.5, 6.2 and 7 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

ANNEX MI-001

WATER METERS

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity

assessment procedures listed in this Annex, apply to water meters intended for the measurement of volumes of clean, cold or heated water in residential, commercial and light industrial use.

DEFINITIONS

Water Meter An instrument designed to measure, memorise and display the volume at metering conditions of water passing through the measurement transducer.

Minimum Flowrate (Q1) The lowest flowrate at which the water meter provides indications that satisfy the requirements concerning the maximum permissible errors (MPEs.)

Transitional Flowrate (Q2) The transitional flowrate is the flowrate value occurring between the permanent and minimum flowrates, at which the flowrate range is divided into two zones, the "upper zone" and the "lower zone". Each zone has a characteristic MPE.

Permanent Flowrate (Q3) The highest flowrate at which the water meter operates in a satisfactory manner under normal conditions of use, i.e. under steady or intermittent flow conditions.

Overload Flowrate (Q4) The overload flowrate is the highest flowrate at which the meter operates in a satisfactory manner for a short period of time without deteriorating.

SPECIFIC REQUIREMENTS

Rated Operating Conditions

The manufacturer shall specify the rated operating conditions for the instrument, in particular;

1. The flowrate range of the water.

The values for the flowrate range shall fulfil the following conditions:

Q3/Q1 >= 10

Q2/Q1 = 1,6

Q4/Q3 = 1,25

For 5 years from the date of entry into force of this Directive the ratio Q2/Q1 may be: 1,5, 2,5, 4 or 6,3.

2. The temperature range of the water.

The values for the temperature range shall fulfil the following conditions:

0,1 °C to at least 30 °C, or

30 °C to at least 90 °C.

The meter may be designed to operate over both ranges.

3. The relative pressure range of the water, the range being 0,3 bar to at least 10 bar at Q3.

4. For the power supply: the nominal value of the AC voltage supply and/or the limits of DC supply.

MPE

5. The MPE, positive or negative, on volumes delivered at flowrates between the transitional flowrate (Q2) (included) and the overload flowrate (Q4) is:

2 % for water having a temperature <= 30 °C,

3 % for water having a temperature > 30 °C.

6. The MPE, positive or negative, on volumes delivered at flowrates between the minimum flowrate (Q1) and the transitional flowrate (Q2) (excluded) is 5 % for water having any temperature.

Permissible Effect of Disturbances

7.1. Electromagnetic immunity

7.1.1. The effect of an electromagnetic disturbance on a water meter shall be such that:

- the change in the measurement result is no greater than the critical change value as defined in 8.1.4, or
- the indication of the measurement result is such that it cannot be interpreted as a valid result, such as a

momentary variation that cannot be interpreted, memorised or transmitted as a measuring result.
7.1.2. After undergoing an electromagnetic disturbance the water meter shall:
- recover to operate within MPE, and
- have all measurement functions safeguarded, and
- allow recovery of all measurement data present just before the disturbance.
7.1.3. The critical change value is the smaller of the two following values:
- the volume corresponding to half of the magnitude of the MPE in the upper zone on the measured volume;
- the volume corresponding to the MPE on the volume corresponding to one minute at flowrate Q3.
7.2. Durability
After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criteria shall be satisfied:
7.2.1. The variation of the measurement result after the durability test, when compared with the initial measurement result, shall not exceed:
- 3 % of the metered volume between Q1 included and Q2 excluded;
- 1,5 % of the metered volume between Q2 included and Q4 included.
7.2.2. The error of indication for the volume metered after the durability test shall not exceed:
- ± 6 % of the metered volume between Q1 included and Q2 excluded;
- ± 2,5 % of the metered volume between Q2 included and Q4 included for water meters intended to meter water with a temperature between 0,1 °C and 30 °C,
- ± 3,5 % of the metered volume between Q2 included and Q4 included for water meters intended to meter water with a temperature between 30 °C and 90 °C.
Suitability
8.1. The meter shall be able to be installed to operate in any position unless clearly marked otherwise.
8.2. The manufacturer shall specify whether the meter is designed to measure reverse flow. In such a case, the reverse flow volume shall either be subtracted from the cumulated volume or shall be separately recorded. The same MPE shall apply to both forward and reverse flow.
Water meters not designed to measure reverse flow shall either prevent reverse flow or shall withstand an accidental reverse flow without any deterioration or change in metrological properties.
Units of Measurement
9. Metered volume shall be displayed in cubic metres.
Putting into Use
10. The Member State shall ensure that the requirements under 1, 2 and 3 are determined by the distributor or the person legally designated for installing the meter, so that the meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.
CONFORMITY ASSESSMENT
The conformity assessment procedures referred to in Article 9 that the manufacturer can choose between are:
B + F or B + D or H1.
ANNEX MI-002
GAS METERS AND VOLUME CONVERSION DEVICES
The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to gas meters and volume conversion devices defined

below, intended for residential, commercial and light industrial use.

DEFINITIONS

Gas meter An instrument designed to measure, memorise and display the quantity of fuel gas (volume or mass) that has passed it.

Conversion device A device fitted to a gas meter that automatically converts the quantity measured at metering conditions into a quantity at base conditions.

Minimum flowrate (Qmin) The lowest flowrate at which the gas meter provides indications that satisfy the requirements regarding maximum permissible error (MPE.)

Maximum flowrate (Qmax) The highest flowrate at which the gas meter provides indications that satisfy the requirements regarding MPE.

Transitional flowrate (Qt) The transitional flowrate is the flowrate occurring between the maximum and minimum flowrates at which the flowrate range is divided into two zones, the "upper zone" and the "lower zone". Each zone has a characteristic MPE.

Overload Flowrate (Qr) The overload flowrate is the highest flowrate at which the meter operates for a short period of time without deteriorating.

Base conditions The specified conditions to which the measured quantity of fluid is converted.

PART I - SPECIFIC REQUIREMENTS - GAS METERS

1. Rated operating conditions

The manufacturer shall specify the rated operating conditions of the gas meter, taking into account:

1.1. The flowrate range of the gas shall fulfil at least the following conditions:

>TABLE>

1.2. The temperature range of the gas, with a minimum range of 40 °C.

1.3. The fuel/gas related conditions

The gas meter shall be designed for the range of gases and supply pressures of the country of destination. In particular the manufacturer shall indicate:

- the gas family or group;
- the maximum operating pressure.

1.4. A minimum temperature range of 50 °C for the climatic environment.

1.5. The nominal value of the AC voltage supply and/or the limits of DC supply.

2. Maximum permissible error (MPEs)

2.1. Gas meter indicating the volume at metering conditions or mass

Table 1

>TABLE>

When the errors between Qt and Qmax all have the same sign, they shall all not exceed 1 % for class 1,5 and 0,5 % for Class 1,0.

2.2. For a gas meter with temperature conversion, which only indicates the converted volume, the MPE of the meter is increased by 0,5 % in a range of 30 °C extending symmetrically around the temperature specified by the manufacturer that lies between 15 °C and 25 °C. Outside this range, an additional increase of 0,5 % is permitted in each interval of 10 °C.

3. Permissible effect of disturbances

3.1. Electromagnetic immunity

3.1.1. The effect of an electromagnetic disturbance on a gas meter or volume conversion device shall be

such that:
- the change in the measurement result is no greater than the critical change value as defined in 3.1.3, or
- the indication of the measurement result is such that it cannot be interpreted as a valid result, such as a momentary variation that cannot be interpreted, memorised or transmitted as a measuring result.

3.1.2. After undergoing a disturbance, the gas meter shall:
- recover to operate within MPE, and
- have all measurement functions safeguarded, and
- allow recovery of all measurement data present just before the disturbance.

3.1.3. The critical change value is the smaller of the two following values:
- the quantity corresponding to half of the magnitude of the MPE in the upper zone on the measured volume;
- the quantity corresponding to the MPE on the quantity corresponding to one minute at maximum flowrate.

3.2. Effect of upstream-downstream flow disturbances

Under installation conditions specified by the manufacturer, the effect of the flow disturbances shall not exceed one third of the MPE.

4. Durability

After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criteria shall be satisfied:

4.1. Class 1,5 meters

4.1.1. The variation of the measurement result after the durability test when compared with the initial measurement result for the flow rates in the range Qt to Qmax-shall not exceed the measurement result by more than 2 %.

4.1.2. The error of indication after the durability test shall not exceed twice the MPE in paragraph 2.

4.2. Class 1,0 meters

4.2.1. The variation of the measurement result after the durability test when compared with the initial measurement result shall not exceed one-third of the MPE in paragraph 2.

4.2.2. The error of indication after the durability test shall not exceed the MPE in paragraph 2.

5. Suitability

5.1. A gas meter powered from the mains (AC or DC) shall be provided with an emergency power supply device or other means to ensure, during a failure of the principal power source, that all measuring functions are safeguarded.

5.2. A dedicated power source shall have a lifetime of at least five years. After 90 % of its lifetime an appropriate warning shall be shown.

5.3. An indicating device shall have a sufficient number of digits to ensure that the quantity passed during 8000 hours at Qmax does not return the digits to their initial values.

5.4. The gas meter shall be able to be installed to operate in any position declared by the manufacturer in its installation instruction.

5.5. The gas meter shall have a test element, which shall enable tests to be carried out in a reasonable time.

5.6. The gas meter shall respect the MPE in any flow direction or only in one flow direction clearly marked.

6. Units

Metered quantity shall be displayed in cubic metre, or in kilogram.

PART II - SPECIFIC REQUIREMENTS - VOLUME CONVERSION DEVICES

A volume conversion device constitutes a sub-assembly according to Article 4, definition (b), second indent. For a volume conversion device, the essential requirements for the gas meter shall apply, if applicable. In addition, the following requirements shall apply:

7. Base conditions for converted quantities

The manufacturer shall specify the base conditions for converted quantities.

8. MPE

- 0,5 % at ambient temperature 20 °C ± 3 °C, ambient humidity 60 % ± 15 %, nominal values for power supply;
- 0,7 % for temperature conversion devices at rated operating conditions;
- 1 % for other conversion devices at rated operating conditions.

Note:

The error of the gas meter is not taken into account.

9. Suitability

9.1. An electronic conversion device shall be capable of detecting when it is operating outside the operating range(s) stated by the manufacturer for parameters that are relevant for measurement accuracy. In such a case, the conversion device must stop integrating the converted quantity, and may totalise separately the converted quantity for the time it is operating outside the operating range(s).

9.2. An electronic conversion device shall be capable to display all relevant data for the measurement without additional equipment.

PART III - PUTTING INTO USE AND CONFORMITY ASSESSMENT

Putting into use

10. (a) Where a Member State imposes measurement of residential use, it shall allow such measurement to be performed by means of any Class 1,5 meter, and by Class 1,0 meters which have a Qmax/Qmin ratio equal or greater than 150.

(b) Where a Member State imposes measurement of commercial and/or light industrial use, it shall allow such measurement to be performed by any Class 1,5 meter.

(c) As regards the requirements under paragraphs 1.2 and 1.3, Member States shall ensure that the properties be determined by the distributor or the person legally designated for installing the meter, so that the meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 9 that the manufacturer can choose between are

B + F oder B + D or H1.

ANNEX MI-003

ACTIVE ELECTRICAL ENERGY METERS

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to active electrical energy meters intended for residential, commercial and light industrial use.

Note:

Electrical energy meters may be used in combination with external instrument transformers, depending upon the measurement technique applied. However, this Annex covers only electrical energy meters but

not instrument transformers.

DEFINITIONS

An active electrical energy meter is a device which measures the active electrical energy consumed in a circuit.

I= the electrical current flowing through the meter;

In= the specified reference current for which the transformer operated meter has been designed;

Ist= the lowest declared value of I at which the meter registers active electrical energy at unity power factor (polyphase meters with balanced load);

Imin= the value of I above which the error lies within maximum permissible errors (MPEs) (polyphase meters with balanced load);

Itr= the value of I above which the error lies within the smallest MPE corresponding to the class index of the meter;

Imax= the maximum value of I for which the error lies within the MPEs;

U= the voltage of the electricity supplied to the meter;

Un= the specified reference voltage;

f= the frequency of the voltage supplied to the meter;

fn= the specified reference frequency;

PF= power factor = cosφ = the cosine of the phase difference φ between I and U.

SPECIFIC REQUIREMENTS

1. Accuracy

The manufacturer shall specify the class index of the meter. The class indices are defined as: Class A, B and C.

2. Rated operating conditions

The manufacturer shall specify the rated operating conditions of the meter; in particular:

The values of fn, Un, In, Ist, Imin, Itr and Imax that apply to the meter. For the current values specified, the meter shall satisfy the conditions given in Table 1;

Table 1

>TABLE>

The voltage, frequency and power factor ranges within which the meter shall satisfy the MPE requirements are specified in Table 2. These ranges shall recognise the typical characteristics of electricity supplied by public distribution systems.

The voltage and frequency ranges shall be at least:

0,9· Un <= U <= 1,1· Un

0,98· fn <= f <= 1,02· fn

power factor range at least from cosö = 0,5 inductive to cosö = 0,8 capacitive.

3. MPEs

The effects of the various measurands and influence quantities (a, b, c,...) are evaluated separately, all other measurands and influence quantities being kept relatively constant at their reference values. The error of measurement, that shall not exceed the MPE stated in Table 2, is calculated as:

Error of measurement =

>REFERENCE TO A GRAPHIC>

When the meter is operating under varying-load current, the percentage errors shall not exceed the limits

given in Table 2.

Table 2

MPEs in percent at rated operating conditions and defined load current levels and operating temperature

>TABLE>

For electromechanical polyphase meters the current range for single-phase load is limited to 5Itr <= I <= Imax

When a meter operates in different temperature ranges the relevant MPE values shall apply.

4. Permissible effect of disturbances

4.1. General

As electrical energy meters are directly connected to the mains supply and as mains current is also one of the measurands, a special electromagnetic environment is used for electricity meters.

The meter shall comply with the electromagnetic environment E2 and the additional requirements in 4.2 and 4.3.

The electromagnetic environment and permissible effects reflect the situation that there are disturbances of long duration which shall not affect the accuracy beyond the critical change values and transient disturbances, which may cause a temporary degradation or loss of function or performance but from which the meter shall recover and shall not affect the accuracy beyond the critical change values.

When there is a foreseeable high risk due to lightning or where overhead supply networks are predominant, the metrological characteristics of the meter shall be protected.

4.2. Effect of disturbances of long duration

Table 3

Critical change values for disturbances of long duration

>TABLE>

4.3. Permissible effect of transient electromagnetic phenomena

4.3.1. The effect of an electromagnetic disturbance on an electrical energy meter shall be such that during and immediately after a disturbance

- any output intended for testing the accuracy of the meter does not produce pulses or signals corresponding to an energy of more than the critical change value

and in reasonable time after the disturbance the meter shall

- recover to operate within the MPE limits, and
- have all measurement functions safeguarded, and
- allow recovery of all measurement data present prior to the disturbance, and
- not indicate a change in the registered energy of more than the critical change value.

The critical change value in kWh is m· Un· Imax· 10-6

(m being the number of measuring elements of the meter, Un in Volts and Imax in Amps).

4.3.2. For overcurrent the critical change value is 1,5 %.

5. Suitability

5.1. Below the rated operating voltage the positive error of the meter shall not exceed 10 %.

5.2. The display of the total energy shall have a sufficient number of digits to ensure that when the meter is operated for 4000 hours at full load (I = Imax, U = Un and PF = 1) the indication does not return to its initial value and shall not be able to be reset during use.

5.3. In the event of loss of electricity in the circuit, the amounts of electrical energy measured shall remain

available for reading during a period of at least 4 months.

5.4. Running with no load

When the voltage is applied with no current flowing in the current circuit (current circuit shall be open circuit), the meter shall not register energy at any voltage between 0,8· Un and 1,1 Un.

5.5. Starting

The meter shall start and continue to register at Un, PF = 1 (polyphase meter with balanced loads) and a current which is equal to Ist.

6. Units

The electrical energy measured shall be displayed in kilowatt-hours or in megawatt-hours.

7. Putting into use

(a) Where a Member State imposes measurement of residential use, it shall allow such measurement to be performed by means of any Class A meter. For specified purposes the Member State is authorised to require any Class B meter.

(b) Where a Member State imposes measurement of commercial and/or light industrial use, it shall allow such measurement to be performed by any Class B meter. For specified purposes the Member State is authorised to require any Class C meter.

(c) The Member State shall ensure that the current range be determined by the distributor or the person legally designated for installing the meter, so that the meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 9 that the manufacturer can choose between are:

B + F or B + D or H1.

ANNEX MI-004

HEAT METERS

The relevant requirements of Annex I, the specific requirements and the conformity assessment procedures listed in this Annex, apply to heat meters defined below, intended for residential, commercial and light industrial use.

DEFINITIONS

A heat meter is an instrument designed to measure the heat which, in a heat exchange circuit, is given up by a liquid called the heat-conveying liquid.

A heat meter is either a complete instrument or a combined instrument consisting of the sub-assemblies, flow sensor, temperature sensor pair, and calculator, as defined in Article 4(b), or a combination thereof

θ= the temperature of the heat-conveying liquid;

θin= the value of θ at the inlet of the heat exchange circuit;

θout= the value of θ at the outlet of the heat exchange circuit;

Δθ= the temperature difference θin - θout with Δθ >= 0;

θmax= the upper limit of θ for the heat meter to function correctly within the MPEs;

θmin= the lower limit of θ for the heat meter to function correctly within the MPEs;

Δθmax= the upper limit of Δθ for the heat meter to function correctly within the MPEs;

Δθmin= the lower limit of Δθ for the heat meter to function correctly within the MPEs;

q= the flow rate of the heat conveying liquid;

qs= the highest value of q that is permitted for short periods of time for the heat meter to function correctly;
qp= the highest value of q that is permitted permanently for the heat meter to function correctly;
qi= the lowest value of q that is permitted for the heat meter to function correctly;
P= the thermal power of the heat exchange;
Ps= the upper limit of P that is permitted for the heat meter to function correctly.
SPECIFIC REQUIREMENTS
1. Rated operating conditions
The values of the rated operating conditions shall be specified by the manufacturer as follows:
1.1. For the temperature of the liquid: θmax, θmin,
- for the temperature differences: Δθmax, Δθmin,
subject to the following restrictions: Δθmax/Δθmin >= 10; Δθmin = 3 K or 5 K or 10 K.
1.2. For the pressure of the liquid: The maximum positive internal pressure that the heat meter can withstand permanently at the upper limit of the temperature.
1.3. For the flow rates of the liquid: qs, qp, qi, where the values of qp and qi are subject to the following restriction: qp/qi >= 10.
1.4. For the thermal power: Ps.
2. Accuracy classes
The following accuracy classes are defined for heat meters: 1, 2, 3.
3. MPEs applicable to complete heat meters
The maximum permissible relative errors applicable to a complete heat meter, expressed in percent of the true value for each accuracy class, are:
- For class 1: E = Ef + Et + Ec, with Ef, Et, Ec according to paragraphs 7.1 to 7.3.
- For class 2: E = Ef + Et + Ec, with Ef, Et, Ec according to paragraphs 7.1 to 7.3.
- For class 3: E = Ef + Et + Ec, with Ef, Et, Ec according to paragraphs 7.1 to 7.3.
4. Permissible influences of electromagnetic disturbances
4.1. The instrument shall not be influenced by static magnetic fields and by electromagnetic fields at mains frequency.
4.2. The influence of an electromagnetic disturbance shall be such that the change in the measurement result is not greater than the critical change value as laid down in requirement 4.3 or the indication of the measurement result is such that it cannot be interpreted as a valid result.
4.3. The critical change value for a complete heat meter is equal to the absolute value of the MPE applicable to that heat meter (see paragraph 3).
5. Durability
After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criteria shall be satisfied:
5.1. Flow sensors: The variation of the measurement result after the durability test, when compared with the initial measurement result, shall not exceed the critical change value.
5.2. Temperature sensors: The variation of the measurement result after the durability test, when compared with the initial measurement result, shall not exceed 0,1 °C.
6. Inscriptions on a heat meter
- Accuracy class
- Limits of flow rate

- Limits of temperature
- Limits of temperature difference
- Place of the flow sensor installation: flow or return
- Indication of the direction of flow

7. Sub-assemblies

The provisions for sub-assemblies may apply to sub-assemblies manufactured by the same or different manufacturers. Where a heat meter consists of sub-assemblies, the essential requirements for the heat meter apply to the sub-assemblies as relevant. In addition, the following apply:

7.1. The relative MPE of the flow sensor, expressed in %, for accuracy classes:

- Class 1: Ef = (1 + 0,01 qp/q), but not more than 5 %,
- Class 2: Ef = (2 + 0,02 qp/q), but not more than 5 %,
- Class 3: Ef = (3 + 0,05 qp/q), but not more than 5 %,

where the error Ef relates the indicated value to the true value of the relationship between flow sensor output signal and the mass or the volume.

7.2. The relative MPE of the temperature sensor pair, expressed in %:

- Et = (0,5 + 3· Δθmin/Δθ),

where the error Et relates the indicated value to the true value of the relationship between temperature sensor pair output and temperature difference.

7.3. The relative MPE of the calculator, expressed in %:

- Ec = (0,5 + Δθmin/Δθ),

where the error Ec relates the value of the heat indicated to the true value of the heat.

7.4. The critical change value for a sub-assembly of a heat meter is equal to the respective absolute value of the MPE applicable to the sub-assembly (see paragraphs 7.1, 7.2 or 7.3).

7.5.

Inscriptions on the sub-assemblies

>TABLE>

PUTTING INTO USE

8. (a) Where a Member State imposes measurement of residential use, it shall allow such measurement to be performed by means of any Class 3 meter.

(b) Where a Member State imposes measurement of commercial and/or light industrial use, it is authorised to require any Class 2 meter.

(c) As regards the requirements under paragraphs 1.1 to 1.4, Member States shall ensure that the properties be determined by the distributor or the person legally designated for installing the meter, so that the meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 9 that the manufacturer can choose between are:

B + F or B + D or H1.

ANNEX MI-005

MEASURING SYSTEMS FOR THE CONTINUOUS AND DYNAMIC MEASUREMENT OF QUANTITIES OF LIQUIDS OTHER THAN WATER

The relevant essential requirements of Annex I, the specific requirements of this Annex and the conformity

assessment procedures listed in this Annex, apply to measuring systems intended for the continuous and dynamic measurement of quantities (volumes or masses) of liquids other than water. If appropriate, the terms "volume, and L" in this Annex can be read as: "mass and kg".

DEFINITIONS

Meter An instrument designed to measure continuously, memorise and display the quantity at metering conditions of liquid flowing through the measurement transducer in a closed, fully charged conduit.

Calculator A part of a meter that receives the output signals from the measurement transducer(s) and possibly, from associated measuring instruments and displays the measurement results.

Associated measuring instrument An instrument connected to the calculator for measuring certain quantities which are characteristic of the liquid, with a view to make a correction and/or conversion.

Conversion Device A part of the calculator which by taking account of the characteristics of the liquid (temperature, density, etc.) measured using associated measuring instruments, or stored in a memory, automatically converts:

- the volume of the liquid measured at metering conditions into a volume at base conditions and/or into mass, or
- the mass of the liquid measured at metering conditions into a volume at metering conditions and/or into a volume at base conditions

Note:

A conversion device includes the relevant associated measuring instruments.

Base conditions The specified conditions to which the measured quantity of liquid at metering conditions is converted.

Measuring System A system that comprises the meter itself and all devices required to ensure correct measurement or intended to facilitate the measuring operations.

Fuel dispenser A measuring system intended for the refuelling of motor vehicles, small boats and small aircraft.

Self-service arrangement An arrangement that allows the customer to use a measuring system for the purpose of obtaining liquid for his own use.

Self-service device A specific device that is part of a self-service arrangement and which allows one of more measuring systems to perform in this self-service arrangement.

Minimum measured quantity (MMQ) The smallest quantity of liquid for which the measurement is metrologically acceptable for the measuring system.

Direct indication The indication, either volume or mass, corresponding to the measure and that the meter is physically capable of measuring.

Note:

The direct indication may be converted into another quantity using a conversion device.

Interruptible/non interruptible A measuring system is considered as interruptible/non interruptible when the liquid flow can/cannot be stopped easily and rapidly.

Flowrate range The range between the minimum flowrate (Qmin) and maximum flowrate (Qmax).

SPECIFIC REQUIREMENTS

1. Rated operating conditions

The manufacturer shall specify the rated operating conditions for the instrument, in particular;

1.1. The flowrate range

The flowrate range is subject to the following conditions:
(i) the flowrate range of a measuring system shall be within the flowrate range of each of its elements, in particular the meter.
(ii) meter and measuring system:
Table 1
>TABLE>
1.2. The properties of the liquid to be measured by the instrument by specifying the name or type of the liquid or its relevant characteristics, for example:
- Temperature range;
- Pressure range;
- Density range;
- Viscosity range.
1.3. The nominal value of the AC voltage supply and/or limits of the DC voltage supply.
1.4. The base conditions for converted values.
Note:
Paragraph 1.4 is without prejudice to the Member States' obligations to require use of a temperature of either 15 °C in accordance with Article 3(1) of Council Directive 92/81/EEC of 19 October 1992 on the harmonisation of the structures of excise duties on mineral oils(1) or, for heavy fuel oils, LPG and methane, another temperature pursuant to Article 3(2) of that Directive.
2. Accuracy classification and maximum permissible errors (MPEs)
2.1. For quantities equal to or greater than 2 litres the MPE on indications is:
Table 2
>TABLE>
2.2. For quantities less than two litres the MPE on indications is:
Table 3
>TABLE>
2.3. However, no matter what the measured quantity may be, the magnitude of the MPE is given by the greater of the following two values:
- the absolute value of the MPE given in Table 2 or Table 3,
- the absolute value of the MPE for the minimum measured quantity (Emin).
2.4.1. For minimum measured quantities greater than or equal to 2 litres the following conditions apply:
Condition 1
Emin shall fulfil the condition: Emin >= 2 R, where R is the smallest scale interval of the indication device.
Condition 2
Emin is given by the formula: Emin = (2MMQ) × (A/100), where:
- MMQ is the minimum measured quantity,
- A is the numerical value specified in line A of Table 2.
2.4.2. For minimum measured quantities of less than two litres, the above mentioned condition 1 applies and Emin is twice the value specified in Table 3, and related to line A of Table 2.
2.5. Converted indication
In the case of a converted indication the MPEs are as in line A of Table 2.
2.6. Conversion devices

MPEs on converted indications due to a conversion device are equal to ± (A - B), A and B being the values specified in Table 2.

Parts of conversion devices that can be tested separately

(a) Calculator

MPEs on quantities of liquid indications applicable to calculation, positive or negative, are equal to one-tenth of the MPEs as defined in line A of Table 2.

(b) Associated measuring instruments

Associated measuring instruments shall have an accuracy at least as good as the values in Table 4:

Table 4

>TABLE>

These values apply to the indication of the characteristic quantities of the liquid displayed by the conversion device.

c) Accuracy for calculating function

The MPE for the calculation of each characteristic quantity of the liquid, positive or negative, is equal to two fifths of the value fixed in (b).

2.7. The requirement (a) in paragraph 2.6 applies to any calculation, not only conversion.

3. Maximum permissible effect of disturbances

3.1. The effect of an electromagnetic disturbance on a measuring system shall be one of the following;

- the change in the measurement result is not greater than the critical change value as defined in paragraph 3.2, or

- the indication of the measurement result shows a momentary variation that cannot be interpreted, memorised or transmitted as a measuring result. Furthermore, in the case of an interruptible system, this can also mean the impossibility to perform any measurement, or

- the change in the measurement result is greater than the critical change value, in which case the measuring system shall permit the retrieval of the measuring result just before the critical change value occurred and cut off the flow.

3.2. The critical change value is the greater of MPE/5 for a particular measured quantity or Emin.

4. Durability

After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criterion shall be satisfied:

The variation of the measurement result after the durability test, when compared with the initial measurement result, shall not exceed the value for meters specified in line B of table 2.

5. Suitability

5.1. For any measured quantity relating to the same measurement, the indications provided by various devices shall not deviate one from another by more than one scale interval where devices have the same scale interval. In the case where the devices have different scale intervals, the deviation shall not be more than that of the greatest scale interval.

However, in the case of a self-service arrangement the scale intervals of the main indicating device on the measuring system and the scale intervals of the self-service device shall be the same and results of measurement shall not deviate one from another.

5.2. It shall not be possible to divert the measured quantity in normal conditions of use unless it is readily apparent.

5.3. Any percentage of air or gas not easily detectable in the liquid shall not lead to a variation of error greater than:
- 0,5 % for liquids other than potable liquids and for liquids of a viscosity not exceeding 1 mPa.s, or
- 1 % for potable liquids and for liquids of a viscosity exceeding 1 mPa.s.
However, the allowed variation shall never be smaller than 1 % of MMQ. This value applies in the case of air or gas pockets.
5.4. Instruments for direct sales
5.4.1. A measuring system for direct sales shall be provided with means for resetting the display to zero. It shall not be possible to divert the measured quantity.
5.4.2. The display of the quantity on which the transaction is based shall be permanent until all parties in the transaction have accepted the measurement result.
5.4.3. Measuring systems for direct sales shall be interruptible.
5.4.4. Any percentage of air or gas in the liquid shall not lead to a variation of error greater than the values specified in paragraph 5.3.
5.5. Fuel Dispensers
5.5.1. Displays on fuel dispensers shall not be capable of being reset to zero during a measurement.
5.5.2. The start of a new measurement shall be inhibited until the display has been reset to zero.
5.5.3. Where a measuring system is fitted with a price display, the difference between the indicated price and the price calculated from the unit price and the indicated quantity shall not exceed the price corresponding to Emin. However this difference need not be less than the smallest monetary value.
6. Power supply failure
A measuring system shall either be provided with an emergency power supply device that will safeguard all measuring functions during the failure of the main power supply device or be equipped with means to save and display the data present in order to permit the conclusion of the transaction in progress and with means to stop the flow at the moment of the failure of the main power supply device.
7. Putting into use
Table 5
>TABLE>
Note:
However, the manufacturer may specify a better accuracy for a certain type of measuring system.
8. Units of measurement
The metered quantity shall be displayed in millilitres, cubic centimetres, litres, cubic metres, grams, kilograms or tonnes.
CONFORMITY ASSESSMENT
The conformity assessment procedures referred to in Article 9 that the manufacturer can choose between are:
B + F or B + D or H1 or G.
(1) OJ L 316, 31.10.1992, p. 12. Directive abolished by Directive 2003/96/EC (OJ L 283, 31.10.2003, p. 51).
ANNEX MI-006
AUTOMATIC WEIGHING INSTRUMENTS
The relevant essential requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in Chapter I of this Annex, apply to automatic weighing instruments defined

below, intended to determine the mass of a body by using the action of gravity on that body.

DEFINITIONS

Automatic weighing instrument An instrument that determines the mass of a product without the intervention of an operator and follows a predetermined programme of automatic processes characteristic of the instrument.

Automatic catchweigher An automatic weighing instrument that determines the mass of pre-assembled discrete loads (for example prepackages) or single loads of loose material.

Automatic checkweigher An automatic catchweigher that subdivides articles of different mass into two or more subgroups according to the value of the difference of their mass and a nominal set-point.

Weight labeller An automatic catchweigher that labels individual articles with the weight value.

Weight/price labeller An automatic catchweigher that labels individual articles with the weight value, and price information.

Automatic gravimetric filling instrument An automatic weighing instrument that fills containers with a predetermined and virtually constant mass of product from bulk.

Discontinuous totaliser (totalising hopper weigher) An automatic weighing instrument that determines the mass of a bulk product by dividing it into discrete loads. The mass of each discrete load is determined in sequence and summed. Each discrete load is then delivered to bulk.

Continuous totaliser An automatic weighing instrument that continuously determines the mass of a bulk product on a conveyor belt, without systematic subdivision of the product and without interrupting the movement of the conveyor belt.

Rail-weighbridge An automatic weighing instrument having a load receptor inclusive of rails for conveying railway vehicles.

SPECIFIC REQUIREMENTS

CHAPTER I - Requirements common to all types of automatic weighing instruments

1. Rated Operating Conditions

The manufacturer shall specify the rated operating conditions for the instrument as follows:

1.1. For the measurand:

The measuring range in terms of its maximum and minimum capacity.

1.2. For the electrical supply influence quantities:

In case of AC voltage supply: the nominal AC voltage supply, or the AC voltage limits.

In case of DC voltage supply: the nominal and minimum DC voltage supply, or the DC voltage limits.

1.3. For the mechanical and climatic influence quantities:

The minimum temperature range is 30 °C unless specified otherwise in the following chapters of this Annex.

The mechanical environment classes according to Annex I, paragraph 1.3.2 are not applicable. For instruments which are used under special mechanical strain, e.g. instruments incorporated into vehicles, the manufacturer shall define the mechanical conditions of use.

1.4. For other influence quantities (if applicable):

The rate(s) of operation.

The characteristics of the product(s) to be weighed.

2. Permissible effect of disturbances - Electromagnetic environment

The required performance and the critical change value are given in the relevant Chapter of this Annex for

each type of instrument.
3. Suitability
3.1. Means shall be provided to limit the effects of tilt, loading and rate of operation such that maximum permissible errors (MPEs) are not exceeded in normal operation.
3.2. Adequate material handling facilities shall be provided to enable the instrument to respect the MPEs during normal operation.
3.3. Any operator control interface shall be clear and effective.
3.4. The integrity of the display (where present) shall be verifiable by the operator.
3.5. Adequate zero setting capability shall be provided to enable the instrument to respect the MPEs during normal operation.
3.6. Any result outside the measurement range shall be identified as such, where a printout is possible.
4. Conformity assessment
The conformity assessment procedures referred to in Article 9 that the manufacturer can choose between are:
For mechanical systems:
B + D or B + E or B + F or D1 or F1 or G or H1.
For electromechanical instruments:
B + D or B + E or B + F or G or H1.
For electronic systems or systems containing software:
B + D or B + F or G or H1.
CHAPTER II - Automatic Catchweighers
1. Accuracy Classes
1.1. Instruments are divided into primary categories designated by:
X or Y
as specified by the manufacturer.
1.2. These primary categories are further divided into four accuracy classes:
XI, XII, XIII & XIV
and
Y(I), Y(II), Y(a) & Y(b)
which shall be specified by the manufacturer.
2. Category X Instruments
2.1. Category X applies to instruments used to check prepackages made up in accordance with the requirements of Council Directive 75/106/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to the making-up by volume of certain prepackaged liquids(1) and of Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products(2) applicable to prepackages.
2.2. The accuracy classes are supplemented by a factor (x) that quantifies the maximum permissible standard deviation as specified in paragraph 4.2.
The manufacturer shall specify the factor (x), where (x) shall be <= 2 and in the form 1 × 10k, 2 × 10k or 5 × 10k, where k is a negative whole number or zero.
3. Category Y Instruments
Category Y applies to all other automatic catchweighers.

4. MPE
4.1. Mean error Category X / MPE Category Y instruments
Table 1
>TABLE>
4.2. Standard deviation
Maximum permissible value for the standard deviation of a class X (x) instrument is the result of the multiplication of the factor (x) by the value in Table 2 below.
Table 2
>TABLE>
For class XI and XII (x) shall be less than 1.
For class XIII (x) shall be not greater than 1.
For class XIV (x) shall be greater than 1.
4.3. Verification scale interval - single interval instruments
Table 3
>TABLE>
4.4. Verification scale interval - multi-interval instruments
Table 4
>TABLE>
Where:
i= 1, 2, ... r
i= partial weighing range
r= total number of partial ranges
5. Measurement Range
In specifying the measurement range for class Y instruments the manufacturer shall take account that the minimum capacity shall not be less than:
class Y(I): 100 e
class Y(II): 20 e for 0,001 g <= e <= 0,05 g, and 50 e for 0,1 g <= e
class Y(a): 20 e
class Y(b): 10 e
Scales used for grading, e.g. postal scales and garbage weighers: 5 e
6. Dynamic Setting
6.1. The dynamic setting facility shall operate within a load range specified by the manufacturer.
6.2. When fitted, a dynamic setting facility that compensates for the dynamic effects of the load in motion shall be inhibited from operating outside the load range, and shall be capable of being secured.
7. Performance Under Influence Factors And Electromagnetic Disturbances
7.1. The MPEs due to influence factors are:
7.1.1. For category X instruments:
- For automatic operation; as specified in Tables 1, and 2,
- For static weighing in non-automatic operation; as specified in Table 1.
7.1.2. For category Y instruments
- For each load in automatic operation; as specified in Table 1,
- For static weighing in non-automatic operation; as specified for category X in Table 1.

7.2. The critical change value due to a disturbance is one verification scale interval.
7.3. Temperature range:
- For class XI and Y(I) the minimum range is 5° C,
- For class XII and Y(II) the minimum range is 15° C.
CHAPTER III - Automatic Gravimetric Filling Instruments
1. Accuracy classes
1.1. The manufacturer shall specify both the reference accuracy class Ref(x) and the operational accuracy class(es) X(x).
1.2. An instrument type is designated a reference accuracy class, Ref(x), corresponding to the best possible accuracy for instruments of the type. After installation, individual instruments are designated for one or more operational accuracy classes, X(x), having taken account of the specific products to be weighed. The class designation factor (x) shall be <= 2, and in the form 1 × 10k, 2 × 10k or 5 × 10k where k is a negative whole number or zero.
1.3. The reference accuracy class, Ref(x) is applicable for static loads.
1.4. For the operational accuracy class X(x), X is a regime relating accuracy to load weight and (x) is a multiplier for the limits of error specified for class X(1) in 2.2.
2. MPE
2.1. Static weighing error
2.1.1. For static loads under rated operating conditions, the MPE for reference accuracy class Ref(x), shall be 0,312 of the maximum permissible deviation of each fill from the average; as specified in Table 5; multiplied by the class designation factor (x).
2.1.2. For instruments where the fill may be made up from more than one load (e.g. cumulative or selective combination weighers) the MPE for static loads shall be the accuracy required for the fill as specified in 2.2 (i.e. not the sum of the maximum permissible deviation for the individual loads).
2.2. Deviation from average fill
Table 5
>TABLE>
Note:
The calculated deviation of each fill from the average may be adjusted to take account for the effect of material particle size.
2.3. Error relative to pre-set value (setting error)
For instruments where it is possible to pre-set a fill weight; the maximum difference between the pre-set value and the average mass of the fills shall not exceed 0,312 of the maximum permissible deviation of each fill from the average, as specified in Table 5.
3. Performance Under Influence Factor And Electromagnetic Disturbance
3.1. The MPE due to influence factors shall be as specified in paragraph 2.1.
3.2. The critical change value due to a disturbance is a change of the static weight indication equal to the MPE as specified in paragraph 2.1 calculated for the rated minimum fill, or a change that would give equivalent effect on the fill in the case of instruments where the fill consists of multiple loads. The calculated critical change value shall be rounded to the next higher scale interval (d).
3.3. The manufacturer shall specify the value of the rated minimum fill.
CHAPTER IV - Discontinuous Totalisers

1. Accuracy Classes
Instruments are divided into four accuracy classes as follows: 0,2, 0,5, 1, 2.
2. MPEs
Table 6
>TABLE>
3. Totalisation scale interval
The totalisation scale interval (dt) shall be in the range:
0,01 % Max <= dt <= 0,2 % Max
4. Minimum Totalised Load (Ómin)
The minimum totalised load (Ómin) shall be not less than the load at which the MPE is equal to the totalisation scale interval (dt) and not less than the minimum load as specified by the manufacturer.
5. Zero Setting
Instruments that do not tare weigh after each discharge shall have a zero setting device. Automatic operation shall be inhibited if zero indication varies by:
- 1 dt on instruments with automatic zero setting device;
- 0,5 dt on instruments with a semi-automatic, or non-automatic, zero setting device.
6. Operator Interface
Operator adjustments and reset function shall be inhibited during automatic operation.
7. Printout
On instruments equipped with a printing device, the reset of the total shall be inhibited until the total is printed. The printout of the total shall occur if automatic operation is interrupted.
8. Performance under influence factors and electromagnetic disturbances
8.1. The MPEs due to influence factors shall be as specified in Table 7.
Table 7
>TABLE>
8.2. The critical change value due to a disturbance is one totalisation scale interval for any weight indication and any stored total.
CHAPTER V - Continuous Totalisers
1. Accuracy classes
Instruments are divided into three accuracy classes as follows: 0,5, 1, 2.
2. Measurement Range
2.1. The manufacturer shall specify the measurement range, the ratio between the minimum net load on the weighing unit and the maximum capacity, and the minimum totalised load.
2.2. The minimum totalised load Σmin shall not be less than
800 d for class 0,5,
400 d for class 1,
200 d for class 2.
Where d is the totalisation scale interval of the general totalisation device.
3. MPE
Table 8
>TABLE>
4. Speed of the belt

The speed of the belt shall be specified by the manufacturer. For single-speed beltweighers, and variable-speed beltweighers having a manual speed setting control, the speed shall not vary by more than 5 % of the nominal value. The product shall not have a different speed than the speed of the belt.

5. General Totalisation Device

It shall not be possible to reset the general totalisation device to zero.

6. Performance under influence factors and electromagnetic disturbances

6.1. The MPE due to influence factor, for a load not less than the Σmin, shall be 0,7 times the appropriate value specified in Table 8, rounded to the nearest totalisation scale interval (d).

6.2. The critical change value due to a disturbance shall be 0,7 times the appropriate value specified in Table 8, for a load equal to Σmin, for the designated class of the beltweigher; rounded up to the next higher totalisation scale interval (d).

CHAPTER VI - Automatic Rail Weighbridges

1. Accuracy classes

Instruments are divided into four accuracy classes as follows:

0,2, 0,5, 1, 2.

2. MPE

2.1. The MPEs for weighing-in-motion of a single wagon or a total train are shown in table 9.

Table 9

>TABLE>

2.2. The MPEs for the weight of coupled or uncoupled wagons weighing-in-motion shall be one of the following values, whichever is the greatest:

- the value calculated according to Table 9, rounded to the nearest scale interval;
- the value calculated according to Table 9, rounded to the nearest scale interval for a weight equal to 35 % of the maximum wagon weight (as inscribed on the descriptive markings);
- one scale interval (d).

2.3. The MPEs for the weight of train weighing-in-motion shall be one of the following values, whichever is the greatest:

- the value calculated according to Table 9, rounded to the nearest scale interval;
- the value calculated according to Table 9, for the weight of a single wagon equal to 35 % of the maximum wagon weight (as inscribed on the descriptive markings) multiplied by the number of reference wagons (not exceeding 10) in the train, and rounded to the nearest scale interval;
- one scale interval (d) for each wagon in the train, but not exceeding 10 d.

2.4. When weighing coupled wagons; the errors of not more than 10 % of the weighing results taken from one or more passes of the train may exceed the appropriate MPE given in paragraph 2.2, but shall not exceed twice the MPE.

3. Scale interval (d)

The relationship between the accuracy class and the scale interval shall be as specified in Table 10.

Table 10

>TABLE>

4. Measurement range

4.1. The minimum capacity shall not be less than 1 t, and not greater than the value of the result of the minimum wagon weight divided by the number of partial weighings.

4.2. The minimum wagon weight shall not be less than 50 d.
5. Performance under influence factor and electromagnetic disturbance
5.1. The MPE due to an influence factor shall be as specified in Table 11.
Table 11
>TABLE>
5.2. The critical change value due to a disturbance is one scale interval.
(1) OJ L 42, 15.2.1975, p. 1. Directive as last amended by Directive 89/676/EEC (OJ L 398, 30.12.1989, p. 18).
(2) OJ L 46, 21.2.1976, p. 1. Directive as last amended by the EEA Agreement.
ANNEX MI-007
TAXIMETERS
The relevant requirements of Annex 1, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex apply to taximeters.
DEFINITIONS
Taximeter
A device that works together with a signal generator(1) to make a measuring instrument.
This device measures duration, calculates distance on the basis of a signal delivered by the distance signal generator. Additionally, it calculates and displays the fare to be paid for a trip on the basis of the calculated distance and/or the measured duration of the trip.
Fare
The total amount of money due for a trip based on a fixed initial hire fee and/or the length and/or the duration of the trip. The fare does not include a supplement charged for extra services.
Cross-over speed
The speed value found by division of a time tariff value by a distance tariff value.
Normal calculation mode S (single application of tariff)
Fare calculation based on application of the time tariff below the cross-over speed and application of the distance tariff above the cross-over speed.
Normal calculation mode D (double application of tariff)
Fare calculation based on simultaneous application of time tariff and distance tariff over the whole trip.
Operating position
The different modes in which a taximeter fulfils the different parts of its functioning. The operating positions are distinguished by the following indications:
"For Hire": The operating position in which the fare calculation is disabled
"Hired": The operating position in which the fare calculation takes place on the basis of a possible initial charge and a tariff for distance travelled and/or time of the trip
"Stopped": The operating position in which the fare due for the trip is indicated and at least the fare calculation based on time is disabled.
DESIGN REQUIREMENTS
1. The taximeter shall be designed to calculate the distance and to measure the duration of a trip.
2. The taximeter shall be designed to calculate and display the fare, incrementing in steps equal to the resolution fixed by the Member State in the operation position "Hired". The taximeter shall also be designed to display the final value for the trip in the operating position "Stopped".

3. A taximeter shall be able to apply the normal calculation modes S and D. It shall be possible to choose between these calculation modes by a secured setting.
4. A taximeter shall be able to supply the following data through an appropriate secured interface(s):
- operation position: "For Hire", "Hired" or "Stopped";
- totaliser data according to paragraph 15.1;
- general information: constant of the distance signal generator, date of securing, taxi identifier, real time, identification of the tariff;
- fare information for a trip: total charged, fare, calculation of the fare, supplement charge, date, start time, finish time, distance travelled;
- tariff(s) information: parameters of tariff(s).
National legislation may require certain devices to be connected to the interface(s) of a taximeter. Where such a device is required; it shall be possible, by secured setting, to inhibit automatically the operation of the taximeter for reasons of the non-presence or improper functioning of the required device.
5. If relevant, it shall be possible to adjust a taximeter for the constant of the distance signal generator to which it is to be connected and to secure the adjustment.
RATED OPERATING CONDITIONS
6.1. The mechanical environment class that applies is M3.
6.2. The manufacturer shall specify the rated operating conditions for the instrument, in particular:
- a minimum temperature range of 80 °C for the climatic environment;
- the limits of the DC power supply for which the instrument has been designed.
MAXIMUM PERMISSIBLE ERRORS (MPEs)
7. The MPE, excluding any errors due to application of the taximeter in a taxi, are:
- For the time elapsed: ± 0,1 %
minimum value of mpe: 0,2s;
- For the distance travelled: ± 0,2 %
minimum value of mpe: 4 m;
- For the calculation of the fare: ± 0,1 %
minimum, including rounding: corresponding to the least significant digit of the fare indication.
PERMISSIBLE EFFECT OF DISTURBANCES
8. Electromagnetic immunity
8.1. The electromagnetic class that applies is E3.
8.2. The MPE laid down in paragraph 7 shall also be respected in the presence of an electromagnetic disturbance.
POWER SUPPLY FAILURE
9. In case of a reduction of the voltage supply to a value below the lower operating limit as specified by the manufacturer, the taximeter shall:
- continue to work correctly or resume its correct functioning without loss of data available before the voltage drop if the voltage drop is temporary, i.e. due to restarting the engine;
- abort an existing measurement and return to the position "For Hire" if the voltage drop is for a longer period.
OTHER REQUIREMENTS
10. The conditions for the compatibility between the taximeter and the distance signal generator shall be

specified by the manufacturer of the taximeter.

11. If there is a supplement charge for an extra service, entered by the driver on manual command, this shall be excluded from the fare displayed. However, in that case a taximeter may display temporarily the value of the fare including the supplementary charge.

12. If the fare is calculated according to calculation mode D a taximeter may have an additional display mode in which only the total distance and duration of the trip are displayed in real time.

13. All values displayed for the passenger shall be suitably identified. These values as well as their identification shall be clearly readable under daylight and night conditions.

14.1. If the fare to be paid or the measures to be taken against fraudulent use can be affected by the choice of functionality from a pre-programmed setting or by free data setting, it shall be possible to secure the instrument settings and data entered.

14.2. The securing possibilities available in a taximeter shall be such that separate securing of the settings is possible.

14.3. The provisions in paragraph 8.3 of Annex I apply also to the tariffs.

15.1. A taximeter shall be fitted with non-resettable totalisers for all of the following values:

- The total distance travelled by the taxi;
- The total distance travelled when hired;
- The total number of hirings;
- The total amount of money charged as supplements;
- The total amount of money charged as fare.

The totalised values shall include the values saved according to paragraph 9 under conditions of loss of power supply.

15.2. If disconnected from power, a taximeter shall allow the totalised values to be stored for one year for the purpose of reading out the values from the taximeter to another medium.

15.3. Adequate measures shall be taken to prevent the display of totalised values from being used to deceive passengers.

16. Automatic change of tariffs is allowed due to the:

- distance of the trip;
- duration of the trip;
- time of the day;
- date;
- day of the week.

17. If properties of the taxi are important for the correctness of the taximeter, the taximeter shall provide means to secure the connection of the taximeter to the taxi in which it is installed.

18. For the purpose of testing after installation, the taximeter shall be equipped with the possibility to test separately the accuracy of time and distance measurement and the accuracy of the calculation.

19. A taximeter and its installation instructions specified by the manufacturer shall be such that, if installed according to the manufacturer's instructions, fraudulent alterations of the measurement signal representing the distance travelled are sufficiently excluded.

20. The general essential requirement dealing with fraudulent use shall be fulfilled in such a way that the interests of the customer, the driver, the driver's employer and the fiscal authorities are protected.

21. A taximeter shall be designed so that it can respect the MPEs without adjustment during a period of one

year of normal use.
22. The taximeter shall be equipped with a real-timeclock by means of which the time of the day and the date are kept, one or both can be used for automatic change of tariffs. The requirements for the real-time clock are:
- The timekeeping shall have an accuracy of 0,02 %;
- The correction possibility of the clock shall be not more than 2 minutes per week. Correction for summer and wintertime shall be performed automatically;
- Correction, automatic or manually, during a trip shall be prevented.
23. The values of distance travelled and time elapsed, when displayed or printed in accordance with this Directive, shall use the following units:
Distance travelled:
- in the United Kingdom and Ireland: until the date which will be fixed by these Member States according to Article (1)(b) of Directive 80/181/EEC: kilometres or miles;
- in all other Member States: kilometres.
Time elapsed:
- seconds, minutes or hours, as may be suitable; keeping in mind the necessary resolution and the need to prevent misunderstandings.
CONFORMITY ASSESSMENT
The conformity assessment procedures referred to in Article 9 that the manufacturer can choose between are:
B + F or B + D or H1.
(1) The distance signal generator is outside the scope of this Directive.
ANNEX MI-008
MATERIAL MEASURES
CHAPTER I - Material measures of length
The relevant essential requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this chapter, apply to material measures of length defined below. However, the requirement for the supply of a copy of declarations of conformity may be interpreted as applying to a batch or consignment rather than each individual instruments.
DEFINITIONS
Material measure of length An instrument comprising scale marks whose distances are given in legal units of length.
SPECIFIC REQUIREMENTS
Reference Conditions
1.1. For tapes of length equal to or greater than five metres, the maximum permissible errors (MPEs) are to be met when a tractive force of fifty newtons or other force values as specified by the manufacturer and marked on the tape accordingly, or in the case of rigid or semi-rigid measures no tractive force is needed, is applied.
1.2. The reference temperature is 20 °C unless otherwise specified by the manufacturer and marked on the measure accordingly.
MPEs
2. The MPE, positive or negative in mm, between two non-consecutive scale marks is (a + bL), where:

- L is the value of the length rounded up to the next whole metre; and
- a and b are given in Table 1 below.

When a terminal interval is bounded by a surface, the MPE for any distance beginning at this point is increased by the value c given in Table 1.

Table 1

>TABLE>

Dip tapes may also be of Classes I or II in which case for any length between two scale marks, one of which is on the sinker and the other on the tape, the mpe is ± 0,6 mm when application of the formula gives a value of less than 0,6 mm.

The MPE for the length between consecutive scale marks, and the maximum permissible difference between two consecutive intervals, are given in Table 2 below.

Table 2

>TABLE>

Where a rule is of the folding type, the jointing shall be such as not to cause any errors, supplementary to those above, exceeding: 0,3 mm for Class II, and 0,5 mm for Class III.

Materials

3.1. Materials used for material measures shall be such that length variations due to temperature excursions up to ± 8 °C about the reference temperature do not exceed the MPE. This does not apply to Class S and Class D measures where the manufacturer intends that thermal expansion corrections shall be applied to observed readings where necessary.

3.2. Measures made from material whose dimensions may alter materially when subjected to a wide range of relative humidity, may only be included in Classes II or III.

Markings

4. The nominal value shall be marked on the measure. Millimetre scales shall be numbered every centimetre and measures with a scale interval greater than 2 cm shall have all scale marks numbered.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 9 that the manufacturer can choose between are:

F 1 or D1 or B + D or H or G.

CHAPTER II - Capacity serving measures

The relevant essential requirements of Annex I, and the specific requirements and the conformity assessment procedures listed in this chapter, apply to capacity serving measures defined below. However, the requirement for the supply of a copy of declarations of conformity may be interpreted as applying to a batch or consignment rather than each individual instrument. Also, the requirement for the instrument to bear information in respect of its accuracy shall not apply.

DEFINITIONS

Capacity serving measure A capacity measure (such as a drinking glass, jug or thimble measure) designed to determine a specified volume of a liquid (other than a pharmaceutical product) which is sold for immediate consumption.

Line measure A capacity serving measure marked with a line to indicate nominal capacity.

Brim measure A capacity serving measure for which the internal volume is equal to the nominal capacity.

Transfer measure A capacity serving measure from which it is intended that the liquid is decanted prior to

consumption.
Capacity The capacity is the internal volume for brim measures or internal volume to a filling mark for line measures.
SPECIFIC REQUIREMENTS
1. Reference Conditions
1.1. Temperature: the reference temperature for measurement of capacity is 20 °C.
1.2. Position for correct indication: free standing on a level surface.
2. MPEs
Table 1
>TABLE>
3. Materials
Capacity serving measures shall be made of material which is sufficiently rigid and dimensionally stable to maintain capacity within the MPE.
4. Shape
4.1. Transfer measures shall be designed so that a change of contents equal to the MPE causes a change in level of at least 2 mm at the brim or filling mark.
4.2. Transfer measures shall be designed so that the complete discharge of the liquid being measured will not be impeded.
5. Marking
5.1. The nominal capacity declared shall be clearly and indelibly marked on the measure.
5.2. Capacity serving measures may also be marked with up to three clearly distinguishable capacities, none of which shall lead to confusion one to the other.
5.3. All filling marks shall be sufficiently clear and durable to ensure that MPEs are not exceeded in use.
CONFORMITY ASSESSMENT
The conformity assessment procedures referred to in Article 9 that the manufacturer can choose between are:
A1 or F1 or D1 or E1 or B + E or B + D or H.
ANNEX MI-009
DIMENSIONAL MEASURING INSTRUMENTS
The relevant essential requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to dimensional measuring instruments of the types defined below.
DEFINITIONS
Length measuring instrument A length measuring instrument serves for the determination of the length of rope-type materials (e.g. textiles, bands, cables) during feed motion of the product to be measured.
Area Measuring Instruments An area measuring instrument serves for the determination of the area of irregular shaped objects, e.g. for leather.
Multi-dimensional Measuring Instruments A multi-dimensional measuring instrument serves for the determination of the edge length (length, height, width) of the smallest enclosing rectangular parallelepiped of a product.
CHAPTER I - Equirements common to all dimensional measuring instruments
Electromagnetic immunity

1. The effect of an electromagnetic disturbance on a dimensional measuring instrument shall be such that:
- the change in measurement result is no greater than the critical change value as defined in paragraph 2.3; or
- it is impossible to perform any measurement; or
- there are momentary variations in the measurement result that cannot be interpreted, memorised or transmitted as a measuring result; or
- there are variations in the measurement result severe enough to be noticed by all those interested in the measurement result.
2. The critical change value is equal to one scale interval.
CONFORMITY ASSESSMENT
The conformity assessment procedures referred to in Article 9 that the manufacturer can choose between are:
For mechanical or electromechanical instruments:
F1 or E1 or D1 or B + F or B + E or B + D or H or H1 or G.
For electronic instruments or instruments containing software:
B + F or B + D or H1 or G.
CHAPTER II - Length measuring instruments
Characteristics of the product to be measured
1. Textiles are characterised by the characteristic factor K. This factor takes the stretchability and force per unit area of the product measured into account and is defined by the following formula:
K= ε· (GA + 2,2 N/m2), where
ε is the relative elongation of a cloth specimen 1 m wide at a tensile force of 10 N,
GA is the weight force per unit area of a cloth specimen in N/m2.
Operating conditions
2.1. Range
Dimensions and K-factor, where applicable, within the range specified by the manufacturer for the instrument. The ranges of K-factor are given in Table 1:
Table 1
>TABLE>
2.2. Where the measured object is not transported by the measuring instrument, its speed must be within the range specified by the manufacturer for the instrument.
2.3. If the measurement result depends on the thickness, the surface condition and the kind of delivery (e.g. from a big roll or from a pile), corresponding limitations are specified by the manufacturer.
MPEs
3. Instrument
Table 2
>TABLE>
Where Lm is the minimum measurable length, that is to say the smallest length specified by the manufacturer for which the instrument is intended to be used.
The true length value of the different types of materials should be measured using suitable instruments (e.g. tapes of length). Thereby, the material which is going to be measured should be laid out on a suitable underlay (e.g. a suitable table) straight and unstretched.

Other requirements

4. The instruments must ensure that the product is measured unstretched according to the intended stretchability for which the instrument is designed.

CHAPTER III - Area measuring instruments

Operating conditions

1.1. Range

Dimensions within the range specified by the manufacturer for the instrument.

1.2. Condition of the product

The manufacturer shall specify the limitations of the instruments due to the speed, and thickness of the surface conditions if relevant, of the product.

MPEs

2. Instrument

The MPE is 1,0 %, but not less than 1 dm2.

Other requirements

3. Presentation of the product

In the case of pulling back or stopping the product, it should not be possible to have an error of measurement or the display must be blanked.

4. Scale interval

The instruments must have a scale interval of 1,0 dm2. In addition, it must be possible to have a scale interval of 0,1 dm2 for testing purposes.

CHAPTER IV - Multidimensional measuring instruments

Operating conditions

1.1. Range

Dimensions within the range specified by the manufacturer for the instrument.

1.2. Minimum dimension

The lower limit of the minimum dimension for all values of the scale interval is given in Table 1.

Table 1

>TABLE>

1.3. Speed of the product

The speed must be within the range specified by the manufacturer for the instrument.

MPE

2. Instrument:

The MPE is ± 1,0 d.

ANNEX MI-010

EXHAUST GAS ANALYSERS

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to exhaust gas analysers defined below intended for inspection and professional maintenance of motor vehicles in use.

DEFINITIONS

Exhaust gas analyser An exhaust gas analyser is a measuring instrument that serves to determine the volume fractions of specified components of the exhaust gas of a motor vehicle engine with spark ignition at the moisture level of the sample analysed.

These gas components are carbon monoxide (CO), carbon dioxide (CO2), oxygen (O2) and hydrocarbons (HC).
The content of hydrocarbons has to be expressed as concentration of n-hexane (C6H14), measured with near-infrared absorption techniques.
The volume fractions of the gas components are expressed as a percentage (% vol) for CO, CO2 and O2 and in parts per million (ppm vol).
Moreover, an exhaust gas analyser calculates the lambda value from the volume fractions of the components of the exhaust gas.
Lambda Lambda is a dimensionless value representative of the burning efficiency of an engine in terms of air/fuel ratio in the exhaust gases. It is determined with a reference standardised formula.
SPECIFIC REQUIREMENTS
Instrument Classes
1. Two classes (0 and I) are being defined for exhaust gas analysers. The relevant minimum measuring ranges for these classes are shown in Table 1.
Table 1
Classes and measuring ranges
>TABLE>
Rated operating conditions
2. The values of the operating conditions shall be specified by the manufacturer as follows:
2.1. For the climatic and mechanical influence quantities:
- A minimum temperature range of 35 °C for the climatic environment;
- The mechanical environment class that applies is M1.
2.2. For the electrical power influence quantities:
- The voltage and frequency range for the AC voltage supply;
- The limits of the DC voltage supply.
2.3. For the ambient pressure:
- The minimum and the maximum values of the ambient pressure are for both classes: pmin <= 860 hPa, pmax >= 1060 hPa.
Maximum permissible errors (MPEs)
3. The MPEs are defined as follows:
3.1. For each of the fractions measured, the maximum error value permitted under rated operating conditions according to paragraph 1.1 of Annex I is the greater of the two values shown in Table 2. Absolute values are expressed in % vol or ppm vol, percentage values are percent of the true value.
Table 2
MPEs
>TABLE>
3.2. The MPE on lambda calculation is 0,3 %. The conventional true value is calculated according to the formula defined in point 5.3.7.3 of Annex I of Directive 98/69/EC of the EP and the Council relating to measures to be taken against air pollution by emissions from motor vehicles and amending Council Directive 70/220/EEC(1).
For this purpose, the values displayed by the instrument are used for calculation.
Permissible effect of disturbances

4. For each of the volume fractions measured by the instrument, the critical change value is equal to the MPE for the parameter concerned.
5. The effect of an electromagnetic disturbance shall be such that:
- either the change in the measurement result is not greater than the critical change value laid down in paragraph 4;
- or the presentation of the measurement result is such that it cannot be taken for a valid result.
Other requirements
6. The resolution shall be equal to or of one order of magnitude higher than the values shown in Table 3.
Table 3
Resolution
>TABLE>
The lambda value shall be displayed with a resolution of 0,001.
7. The standard deviation of 20 measurements shall not be greater than one third of the modulus of the MPE for each applicable gas volume fraction.
8. For measuring CO, CO2 and HC, the instrument, including the specified gas handling system, must indicate 95 % of the final value as determined with calibration gases within 15 seconds after changing from a gas with zero content, e.g. fresh air. For measuring O2, the instrument under similar conditions must indicate a value differing less than 0,1 % vol from zero within 60 seconds after changing from fresh air to an oxygen-free gas.
9. The components in the exhaust gas, other than the components whose values are subject to the measurement, shall not affect the measurement results by more than the half of the modulus of the MPEs when those components are present in the following maximum volume fractions:
6 % vol CO,
16 % vol CO2,
10 % vol O2,
5 % vol H2,
0,3 % vol NO,
2000 ppm vol HC (as n-hexane),
water vapor up to saturation.
10. An exhaust gas analyser shall have an adjustment facility that provides operations for zero-setting, gas calibration and internal adjustment. The adjustment facility for zero-setting and internal adjustment shall be automatic.
11. For automatic or semi-automatic adjustment facilities, the instrument shall be unable to make a measurement as long as the adjustments have not been made.
12. An exhaust gas analyser shall detect hydrocarbon residues in the gas handling system. It shall not be possible to carry out a measurement if the hydrocarbon residues, present before any measurement, exceeds 20 ppm vol.
13. An exhaust gas analyser shall have a device for automatically recognising any malfunctioning of the sensor of the oxygen channel due to wear or a break in the connecting line.
14. If the exhaust gas analyser is capable to operate with different fuels (e.g. petrol or liquefied gas), there shall be the possibility to select the suitable coefficients for the Lambda calculation without ambiguity concerning the appropriate formula.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 9 that the manufacturer can choose between are:

B + F or B + D or H1.

(1) OJ L 350, 28.12.1998, p. 17.