COMMITTEE DRAFT

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OIML/TC 3/SC 6/p1: ***Premarket surveillance activities*** Convener: New Zealand and the BIML BIML contact: Willem Kool (Willem.Kool@oiml.org)	Circulated to P- and O-members and liaison internal bodies and external organizations for: **Comment only** by **28 August 2014** Comments to be sent to the BIML, using the template provided.

TITLE OF THE CD (English):

OIML Dxx:201x:

Conformity to type (CTT) – Pre-market conformity assessment of measuring instruments

Scope for pre-market surveillance activities focused on the conformity assessment of measuring instruments to give assurance that the manufactured (or production) instruments meet their approved type

TITLE OF THE CD (French):

OIML Dxx: 201x:

Conformité au type (CTT) - Pré-marché évaluation de la conformité des instruments de mesure

Champ des activités de surveillance pré-marché porté sur l'évaluation de la conformité des instruments de mesure de donner l'assurance que les instruments fabriqués (ou de production) se réunissent leur type approuvé

Original version in: English

Date: 2014-05-28 Doc.No.: **TC 3/SC 6/P 1/N 011**

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Conformity to type (CTT) – Pre-market conformity assessment of measuring instruments

Scope for pre-market surveillance activities focused on the conformity assessment of measuring instruments to give assurance that the manufactured (or production) instruments meet their approved type

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1. Definition of CTT from the perspective of legal metrological control

conformity to type

conformity assessment procedure focused on assessment of measuring instruments to give assurance that manufactured (or production) instruments meet the approved type

The concept of conformity to type as considered in this document refers to a systematic procedure as a part of the pre-market conformity assessment procedures applicable to measuring instruments. It should not be confused with 'market surveillance', often performed ad-hoc by authorities based on risk assessment and user complaints[1].

2. Problem definition and justification

Generally, measuring instruments under legal control are subjected to conformity assessment before they may be legally used. Traditionally, such conformity assessment is in two stages: type evaluation (and approval) and verification.

At **type evaluation** [VIML, 2.04], one or more instruments are subjected to a wide range of tests (temperature, electromagnetic compatibility, etc.) that often require specialized and expensive test facilities and can only be meaningfully performed in a laboratory. The instruments submitted for type evaluation testing should be representative of the final production of the type of instrument, but very often they are still prototypes, or, at best, well prepared samples.

At **verification** [VIM, 2.44], each individual instrument from the production is then subjected to limited testing, typically at ambient temperature only, to verify whether the instrument performs within maximum permissible errors. Verification includes an assessment of the compliance of the design of the instrument with the approved type, as described in the type approval certificate.

When this system of conformity assessment was developed, measuring instruments under legal control were relatively simple compared to modern electronic instruments. They were mainly mechanical, while the first electrical and electronic instruments had components that were more easily recognizable and software could not be changed without breaking a physical sealing. Moreover, manufacturers operated primarily in a national market and the national (or local) legal metrology inspectors were familiar with the manufacturers and their production processes. Under these circumstances, the system of type approval and verification worked quite well to ensure that instruments under legal control complied with applicable technical and metrological requirements.

Some developments that took place over the last decades have put the reliability of this system of conformity assessment in legal metrology into question, for instance:

- New technologies make it difficult and often impossible to verify whether hardware components in production instruments have the same function or the same specifications as those in the samples that were tested for type approval.
- Software can be easily modified, often without having to break any physical sealing.
- As a result of globalization and increasingly complex supply chains, instruments may be type approved in one country, produced in another country with components from different sources, and verified and used in yet another country.

[1] UNECE publication ECE/TRADE/389 "A glossary of market surveillance terms" defines market surveillance as: The activities carried out and measures taken by designated authorities to ensure that products comply with the requirements set out in the relevant legislation and do not endanger health, safety or any other aspect of public interest protection.

The issues coming from these developments are further exacerbated by the increased use of test results obtained under bilateral and multilateral acceptance arrangements, such as the OIML Mutual Acceptance Arrangement for measuring instruments (MAA).

Nowadays, it is very difficult for the verification officer to ascertain that the instrument he is verifying is actually in conformance with the design as described in the type approval certificate, or in compliance with all applicable technical and metrological legal requirements.

The problem may be formulated in the following way: "Traditional conformity assessment in legal metrology (i.e. type approval followed by verification) no longer provides sufficient assurance that verified instruments comply with all applicable requirements".

The absence of this assurance could result in the failure of mutual acceptance arrangements and the exposure of manufacturers to unfair competition from non-compliant instruments.

The problem as defined here is illustrated by issues identified in Australia with:

- Load cells lacking temperature compensation,
- NAWI instruments with different power supplies,
- EMC components missing from instruments.

3. Scope

This document provides considerations for economies or Regional Legal Metrology Organizations (RLMOs) that are planning to develop conformity to type programs. This document also provides illustrative examples of conformity to type systems currently in operation.

4. Conformity assessment — the ISO/CASCO toolbox

Conformity assessment is defined as: demonstration that specified requirements relating to a product, process, system, person or body are fulfilled [VIML, A.1]. Typical conformity assessment activities include: **testing** [VIML, A.10], **certification** [VIML, A.18] and **inspection** [VIML, A.11]. **Accreditation** [VIML, A.9] is also considered conformity assessment (of conformity assessment bodies), while the concept of testing includes calibration and measurement, and 'certification' may relate to products, management systems and persons.

ISO/CASCO is the ISO Conformity Assessment Committee. ISO/CASCO has developed a series of standards dealing with the various aspects of conformity assessment. These standards are collectively referred to as the "ISO/CASCO toolbox". The majority of these standards are more applicable to type evaluation, but we have listed examples relevant to conformity to type in Annex 1.

For the majority of measuring instruments under legal control, the applicable legislation specifies conformity assessment procedures involving third party attestation, even if the manufacturer, or another body is authorized to do certain activities that are traditionally performed by metrological authorities. In such cases, the authorization is the third party attestation.

5. IEC conformity assessment systems

To facilitate international trade in electrical equipment, primarily intended for use in homes, offices, workshops, healthcare facilities and similar locations, for benefit of consumers, industries, authorities etc, and to provide convenience for manufacturers and other users of the services provided by various national certification bodies (NCBs), an international scheme is operated by the IECEE (IEC System for Conformity testing and Certification of Electrotechnical Equipment and Components), known as the CB Scheme.

The CB Scheme is based on the principle of mutual recognition (reciprocal acceptance) by its members of test results for obtaining certification or approval at national level.

Participation of the various NCBs within the CB Scheme is intended to facilitate certification or approval according to IEC standards. Where national standards are not yet completely based on IEC standards, declared national differences will be taken into account; however, successful operation of the CB Scheme presupposes that national standards are reasonably harmonized with the corresponding IEC standards.

Use of the CB Scheme to its fullest extent will promote the exchange of information necessary in assisting manufacturers around the world to obtain certification or approval at national level.

The CB Scheme is based on the use of CB Test Certificates which provide evidence that representative specimens of the product have successfully passed tests to show compliance with the requirements of the relevant IEC standard. [2]

A supplementary report providing evidence of compliance with declared national differences in order to obtain national certification or approval may also be attached to the CB Test Report.

The first step for an NCB, intending to operate in the CB Scheme, is to be accepted as a Recognizing NCB. Such an NCB is prepared to recognize CB Test Certificates as a basis for certification or approval at national level for one or more categories of products.

The second step for an NCB, which can be taken at the same time as the first step, is to be accepted as an Issuing and Recognizing NCB. Such an NCB is entitled to issue CB Test Certificates for the categories of equipment for which it recognizes CB Test Certificates. It should, however, be noted that an NCB may recognize CB Test Certificates for more categories of equipment than for which it is entitled to issue CB Test Certificates.

The IECEE Certification Body (CB) Full Certification Scheme (CB-FCS) is an extension of the IECEE CB Scheme and is an option to be exercised by the participants in the CB Scheme and by applicants under the same IECEE management structure.

Member NCBs to which an applicant applies for a national certification or approval (NCBs “B”) accept the "Conformity Assessment Certificate" (CAC) and associated “Conformity Assessment Report” (CAR) issued by NCB “A” as a basis for such certification or approval. As a NCB B, an NCB’s national certification procedures should as far as possible be harmonized with the CB-FCS Rules of Procedure; however, if differences exist, they are formally declared to the IECEE Secretariat for publication in order that Member NCBs are able to properly cover these certification differences when acting as NCB “A”.

CB-FCS is a product certification system 5 as defined in ISO/IEC 17065. A system 5 includes product type testing, product certification and assessment of the involved manufacturer’s quality management system. Surveillance of the quality management system is carried out and samples of the product may be taken from either the market or the point of production or both and may be assessed for ongoing conformity. The extent to which the three elements of ongoing surveillance are carried out can be adjusted for a given situation. As a result, this system provides significant flexibility for ongoing surveillance.

Whether or not the NCB A issues its certification mark, it remains responsible for the ongoing conformity of the product(s) for which the CAC has been granted.

CB-FCS includes the following for the NCB A:

a) type testing (by an accepted test laboratory) on sample(s) and issuance of a CAR;

[2] The IECEE CB Scheme for electrotechnical equipment is comparable to the OIML Mutual Acceptance Arrangement for measuring instruments (MAA).

b) initial factory inspection including the evaluation of the factory's quality management system (QMS);

c) issuance of the CAC;

d) follow-up factory inspection by NCB A that in addition to assess the product, the manufacturing process and the QMS will also include sampling of the certified product for the purpose of re-testing when applicable.

CB-FCS includes the following for the NCB B:

a) evaluation of CAC and CAR including, if necessary, direct separate consultation with NCB A to ensure validity, initial inspection, follow up inspection, QMS surveillance and completeness of CAC and CAR;

b) not to require test sample(s) if CAC and CAR are complete and determined to be valid;

c) Issuance of the NCB's certification mark and implementation of its certification procedure.

6. Considerations for a CTT program

Conformity to type is an integral part of **legal metrological control** [VIML, 2.01] for measuring instruments for which national legislation requires **type evaluation** [VIML, 2.04] and **type approval** [VIML, 2.05] before such instruments may be placed on the market.

Legal metrological control systems may be considered as consisting of a sequence of conformity assessment procedures covering the various phases of the life cycle of measuring instruments: the design phase, the production phase, and the in-service phase.

Legal metrological control systems may exist in different forms, i.e. consist of different conformity assessment procedures. Conformity to type may appear as a separate conformity assessment procedure, or be part of another conformity assessment procedure (initial verification, surveillance), but always in the production phase. This is illustrated by considering three different legal metrological control systems: A, B and C (see Figure 1).

System A includes

- type evaluation, with tests performed on one or more specimen instruments and resulting in a national or regional type approval certificate. The tests may be covered by an OIML (MAA or Basic) certificate;
- **initial verification** [VIML, 2.12], where individual instruments are assessed for compliance with the technical and metrological requirements that apply to them and resulting in the application of a **verification mark** [VIML, 3.04] on the instruments. For those requirements for which compliance cannot be assessed during initial verification, the assessment of the conformity of the instrument with the approved type (i.e. conformity to type) should ensure that the instrument complies with those requirements;
- conformity assessment procedures after **placing on the market** [VIML, 2.24], as part of market surveillance and in-service inspection by **metrological authorities** [VIML, 1.05], or **subsequent verification** [VIML, 2.13].

Examples of a 'system A' legal metrological control:

- traditional type approval and verification procedures for measuring instruments used for trade: weighing instruments, petrol pumps, etc.
- European measuring instruments directive (MID) conformity assessment modules B (Type examination) + F (Declaration of conformity to type based on product verification). See 8.2 and Annex 2 for details.

System B includes

- type evaluation, as in system A;
- conformity to type as a separate conformity assessment procedure, resulting in the affixing of a conformity marking on the instrument;
- initial verification, where the conformity of the instrument to the approved type is demonstrated by the conformity marking on the instrument, resulting in the application of a verification mark on the instrument;
- conformity assessment procedures after placing on the market, as in system A.

This system may apply to a regionally based conformance system where a conformity mark is agreed and utilized by participating economies. Typically, the type approval would take place in one jurisdiction and production (and initial verification) in another. This could result in the need for a conformity mark.

System C includes

- type evaluation (as in system A) and surveillance of the production by the body that issued the type approval certificate. Here, conformity to type would be part of the surveillance. A conformity marking would be affixed during the production of the instruments,
- initial verification, as in system B,
- conformity assessment procedures after placing on the market, as in systems A and B.

Example of system C:

- The Verified Conformity Assessment Program of the National Type Evaluation Program (NTEP/VCAP) administered by the National Conference on Weights and Measures (NCWM) in the US. For details, see 8.1 and Annex 3.

A variation of system C would be the case where the manufacturer has a certified quality system covering both the design and production phases and is authorized to apply a verification mark. In this case, conformity to type is part of the certified quality system.

Example:

- The European Measuring instruments directive (MID), conformity assessment module H1 (Declaration of conformity based on full quality assurance plus design examination). For details see 8.2 and Annex 4.

Other variations of the systems considered here may exist. For instance: verifications may be performed either by metrological authorities, or, under certain conditions, by the manufacturer or authorized private certification bodies. Such variations, however, would not affect the role of conformity to type.

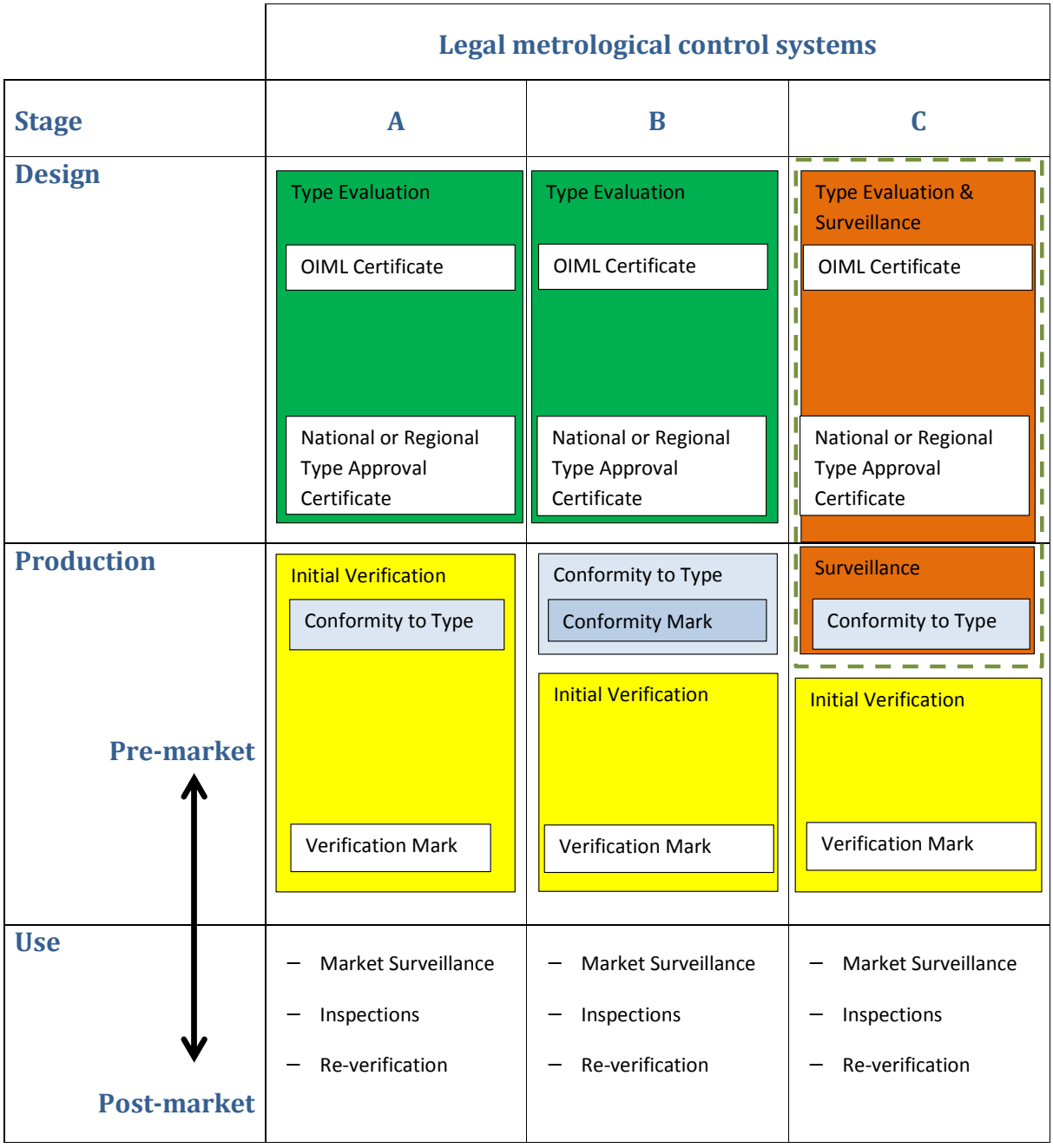

Figure 1

Note:

'Surveillance' during the production phase in system C is performed as part of the certification (type evaluation) process where non-compliances may lead to the withdrawal of the certificate. It should not be confused with 'market surveillance' performed by authorities.

Elements to be considered for inclusion in a conformity to type procedure:

- comparing production instruments with the design of the approved type as described in the type approval documentation (for an example of requirements for type approval documentation, see Annex 5);
- repeating (part of the) type evaluation tests on one or more production instruments, as part of a surveillance and sampling program. The sampling may be ad-hoc, or based on a statistical sampling plan. The extent of such a program may be based on a risk assessment, or take account of the number of instruments placed on the market;
- production of instruments under an appropriate certified quality system;
- affixing a mark on the instrument to demonstrate its conformity to the approved type;
- sealing of the instrument to ensure that it cannot be modified until its initial verification;
- linking the renewal of a type approval certificate (sunset clause) to the testing of production instruments (formal conformity to type assessment);
- regionally or internationally sharing the results of conformity to type surveillance and testing.

For consideration by economies in a region that do not have the capabilities to do type evaluation:

- to develop a separate CTT procedure (as in system B) as described in ISO/IEC 17067, type 3.

7. Issues identified and possible mitigation strategies

a) The description of the approved type in the type approval certificate may not be detailed enough to identify critical parts or components of the instrument.

   → Provide guidance on the details of the description of the type in the type approval certificate.

b) Possible conflicts of interest where private bodies perform conformity to type paid for by the manufacturer.

   → Develop an industry code of practice (voluntary) for the manufacturer to sign up to, clearly defining roles and responsibilities, including requirements on sharing of information.

c) Funding of conformity to type activities.

   → Start small; prove benefits to manufacturers. Consider starting with a national, bilateral or regional approach. Focus on specific types of instrument or industry (e.g. water meter code of practice developed in New Zealand[3]).

d) Sharing of information between regulators on a national and international basis raises privacy issues and issues to do with securing intellectual property rights.

   → Set up an information sharing system such as RAPEX in Europe, sharing info using templates and limiting access to participating issuing authorities and regulators nominated by the CIML Member. Operation based on a code of practice with voluntary participation.

[3] New Zealand Water and Waste Association (NZWWA): *Water meter code of Practice*, 2003, see: http://www.nzwwa.org.nz/Folder?Action=View%20File&Folder_id=101&File=110118_water_meter_cop.pdf

e) Lack of market surveillance, so that existing CTT procedures cannot be adequately evaluated for their effectiveness.

→ Increase sharing and coordination of market surveillance activities between authorities

8. Examples of existing systems in the field of legal metrology

8.1 The NTEP/VCAP in the US

In the US, the National Conference on Weights and Measures (NCWM) administers the National Type Evaluation Program (NTEP). NTEP performs type evaluations of measuring instruments and issues Certificates of Conformance. In addition, NTEP has developed conformity assessment procedures to ensure conformance of production instruments with their approved type. One of the elements is the NTEP VCAP (Verified Conformity Assessment Program). The scope of this program is currently restricted to weighing equipment. Manufacturers of instruments or components within the scope of VCAP and which are subject to influence factors as defined in *NIST Handbook 44*, must have in place a Verified Conformity Assessment Program, to ensure that these instruments and components are produced at a level consistent with that of the previously certified instrument or component.

The VCAP requirements are detailed in NCWM/NTEP Publication 14: *Administrative policy*, Section S: *Conformity Assessment*, 1.c: *NTEP Verified Conformity Assessment Procedures* (See Annex 3).

Non-compliance with the VCAP requirements may result in the Certificate of Conformance becoming "inactive".

8.2 The European NAWI-directive and MID

The Member States of the European Union are required to implement the European directive on non-automatic weighing instruments (NAWI Directive)[4] and the European measuring instruments directive (MID)[5] when exercising legal control on measuring instruments for the applications mentioned in those directives.

The NAWI Directive and the MID provide for the affixing of the CE marking on the measuring instruments within their scope that will be placed on the market of the European Economic Area (EEA)[6] and Turkey.

The manufacturer is responsible for the conformity of the instruments with the provisions of all applicable European Union legislation and for the affixing of the CE marking. By affixing the CE marking, a manufacturer is declaring conformity, irrespective of whether or not a third party has been involved in the conformity assessment process.

Conformity assessment procedures are composed of one or two conformity assessment modules, covering both design and production phases. For more information about the conformity assessment procedures for products by European legislation providing for the

[4] Directive 2014/31/EU of the European Parliament and the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments.

[5] Directive 2014/32/EU of the European Parliament and the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of measuring instruments.

[6] The EEA consists of the European Union Member States, Norway, Iceland and Lichtenstein.

affixing of the CE marking, see paragraph 5.1 of the 2014 edition of the "Blue Guide" on the implementation of EU product rules.[7]

Manufacturers generally may choose one from several alternative conformity assessment procedures. The procedures most frequently provided for in the MID are

- module B (EU-type examination) followed by module D (Conformity to EU-type based on quality assurance of the production process),
- module B (EU-type examination) followed by module F (Conformity to EU-type based on product verification), see Annex 2,
- module G (Conformity based on unit verification), and
- module H1 (Conformity based on full quality assurance plus design examination), see Annex 4.

In all cases, conformity to type is assessed on the basis on the technical documentation that the manufacturer has submitted to the notified body for the purpose of type (or design) examination and that has been included or referenced in the type (or design) approval certificate.

The requirements for the technical documentation are contained in article 18 of the MID (see Annex 5).

[7] Available for download from the EU Commission, DG Enterprise and Industry web site at: http://ec.europa.eu/enterprise/policies/single-market-goods/documents/internal-market-for-products/new-legislative-framework/index_en.htm#h2-3

Annex 1 The ISO/CASCO toolbox

Standards under the responsibility of ISO/CASCO (the ISO/CASCO toolbox) with relevance to CTT.

ISO/IEC Guide 28:2004	Conformity assessment -- Guidance on a third-party certification system for products
ISO/IEC Guide 53:2005	Conformity assessment -- Guidance on the use of an organization's quality management system in product certification
ISO/IEC Guide 60:2004	Conformity assessment -- Code of good practice
ISO/IEC 17011:2004	Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies
ISO/IEC 17020:2012	Conformity assessment -- Requirements for the operation of various types of bodies performing inspection
ISO/IEC 17021:2011	Conformity assessment -- Requirements for bodies providing audit and certification of management systems
ISO/IEC DIS 17021-1	Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 1: Requirements
ISO/IEC TS 17022:2012	Conformity assessment -- Requirements and recommendations for content of a third-party audit report on management systems
ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories
ISO/IEC 17025:2005/Cor 1:2006	
ISO/IEC AWI TR 17026	Conformity assessment -- Guidance on a third-party certification system for products
ISO/IEC 17030:2003	Conformity assessment -- General requirements for third-party marks of conformity
ISO/IEC 17065:2012	Conformity assessment -- Requirements for bodies certifying products, processes and services
ISO/IEC 17067:2013	Conformity assessment -- Fundamentals of product certification and guidelines for product certification schemes
ISO Guide 27:1983	Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity

Annex 2 MID conformity assessment modules B and F

A2.1 Module B: EU-type examination

1. 'EU-type examination' is the part of a conformity assessment procedure in which a notified body examines the technical design of an instrument and verifies and attests that the technical design of the instrument meets the requirements of this Directive that apply to it.

2. EU-type examination may be carried out in either of the following manners:

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

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

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

The notified body decides on the appropriate manner and the specimens required.

3. The manufacturer shall lodge an application for EU-type examination with a single notified body[8] of his choice.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) the technical documentation as described in Article 18[9]. The technical documentation shall make it possible to assess the instrument's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

The application shall in addition contain, wherever applicable:

(d) the specimens, representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;

(e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards, and/or normative documents have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications 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 instrument:

[8] A notified body is a certification body designated by national authorities to perform certain certification activities prescribed in European legislation (such as the NAWI-directive and the MID) and subsequently notified according to a procedure detailed in the appropriate European legislation.

[9] See Annex 6.

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the instrument;

For the specimen(s):

4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or normative documents, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and normative documents, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards, and/or normative documents have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Directive;

4.5. agree with the manufacturer on the location where the examinations and tests will be carried out.

For the other parts of the measuring instrument:

4.6. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the other parts of the measuring instrument.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis, the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Directive, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured measuring instruments with the examined type to be evaluated and to allow for 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 EU-type examination certificate shall have a validity of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself appraised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

8. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the instrument with the essential requirements of this Directive or the conditions for validity of that certificate Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

9. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of that certificate.

10. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

11. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 8 and 10, provided that they are specified in the mandate.

A2.2 Module F: Conformity to type based on product verification

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5.1 and 6, and ensures and declares on his sole responsibility that the measuring instruments concerned, which have been subject to the provisions of point 3, are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured measuring instruments with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. Verification

A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests, or have them carried out, to verify the conformity of the instruments with the type as described in the EU-type examination certificate and the appropriate requirements of this Directive.

The examinations and tests to verify the conformity of the measuring instruments with the appropriate requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every instrument as specified in point 4, or by examination and testing of the measuring instruments on a statistical basis as specified in point 5.

4. Verification of conformity by examination and testing of every instrument

4.1. All measuring instruments shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or normative documents, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of a harmonised standard or normative 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 instrument has been placed on the market.

5. Statistical verification of conformity

5.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his measuring instruments for verification in the form of homogeneous lots.

5.2. A random sample shall be taken from each lot according to the requirements of point 5.3. All measuring instruments in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or normative document(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the type described in the EU-type examination certificate and with the applicable requirements of this Directive, and to determine whether the lot is accepted or rejected. In the absence of such harmonised standard or normative 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) a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity of less than 1 %;

(b) 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 measuring instruments of the lot shall be considered approved, except for those measuring instruments from the sample that have been 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 at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

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.

6. Conformity marking and EU declaration of conformity

6.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual instrument that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

6.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity 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 y the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the measuring instruments.

7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the measuring instruments during the manufacturing process.

8. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 2 and 5.1.

Annex 3 NTEP/VCAP requirements and procedures

National Conference on Weights and Measures / National Type Evaluation Program

Publication 14 Administrative policy: Section S. Conformity Assessment

S. Conformity assessment process

(…)

S.1 Main elements

a. Initial verification

(…)

[The tests performed at initial verification] offer an invaluable means to check production devices and many, but not all, of their features against the current requirements of *NIST Handbook 44* and to verify the information provided in the NTEP Certificate of Conformance is both accurate and correct.

NTEP will use [feedback from the initial verification] to assist in the process of verifying that production devices remain in compliance and that the information on the NTEP Certificate of Conformance remains accurate.

b. Administrative review of a NTEP Certificate of Conformance

The administrative review of all NTEP Certificates of Conformance will be periodically conducted by NTEP.

(…)

c. NTEP Verified Conformity Assessment Program Procedures

Introduction

Many NTEP certified devices must meet *NIST Handbook 44* requirements for influence factors. It is not possible to verify these requirements during the initial verification in the field. Therefore, manufacturers of metrological devices (instruments) and/or components (modules) which are subject to influence factors, as defined in *NIST Handbook 44*, must have a Verified Conformity Assessment Program (VCAP) in place to ensure that these metrological devices and/or components are produced to perform at a level consistent with that of the device and/or component previously certified.

The Verified Conformity Assessment Program audit will be at one or more sites as required to verify compliance.

For weighing devices that are subject to influence factors, NTEP will require an initial on-site audit of the manufacturer's quality system and on-site random testing and/or review of a production device(s) (instrument(s)) by the Registrar to verify that all items listed below are currently implemented and functioning to verify compliance to the appropriate sections of *NIST Handbook 44*.

Devices that must meet this requirement are limited to the list below:

(…)

Requirements:

1. The NTEP CC Holder's control facility responsibilities

1.1. A documented Quality Management System governing the design and manufacturer of the device. (…)

1.2. Appropriate statistical methods are implemented to ensure that the process is in control as defined by the NTEP CC holder's quality management system.

1.3. An appropriate sampling plan, and acceptance criteria is in place and operating. (…)

1.4. Required operator's manuals and calibration procedures or other controlled documentation for all appropriate devices and components (either manufacturered or purchased).

1.5. A non-conforming material system to control non-conforming/noncompliant devices and components (either manufactured or purchased). (…)

1.6. Adequate control over subcontractors and sub-tier suppliers shall be defined in the NTEP CC holder's quality management system. (…)

1.7. Appropriate corrective action system to deal with non-conforming/non-compliant devices. (…)

1.8. An engineering change system to control engineering/design changes affecting any MSCs. (…)

1.9. A document and data control (including software and firmware) system to control changes affecting any MSCs or components of the VCAP program. (…)

1.10. A production control system to control changes affecting any MSCs. (…)

1.11. An identification and traceability system (including serialization and lot/batch control as applicable) applied, as a minimum, to MSCs.

1.12. Documentation that personnel have been properly trained.

1.13. If the NTEP CC holder contracts with an outside testing facility to conduct the influence factor testing, that facility will be subject to all pertinent VCAP requirements.

1.14. The NTEP CC holder shall plan and implement a program of internal self-assessment. (…)

1.15. Subsequent audits will be held on-site to verify conformance to these standards. Subsequent audits will be conducted every three years until objective evidence is obtained to move to a maximum of every five years. (…)

2. Certification Body's responsibilities:

2.1. The selected certification body is to be accredited by ANSI-ASQ National Accreditation Board (ANAB). The ANSI-ASQ National Accreditation Board is the U.S. accreditation body for management systems. ANAB accredits certification bodies (CBs) for ISO 9001 quality management systems (QMS) and ISO 14001 environmental management systems (EMS), as well as a number of industry-specific requirements, or equivalent.

2.2. With accreditation to Standard Industry Classification (SIC) codes (3596/3821) or equivalent. (…)

2.3. The selected certification body shall have international auditors available.

2.4. The certification body is required to notify NCWM when a major breakdown of the NTEP CC holder's VCAP program is found.

2.5. The certification body shall submit a completed "Systems Audit Checklist" to NCWM. Submitted documents must contain a clear statement of compliance as a result of the VCAP audit.

3. NCWM Responsibilities

3.1. For new certificate holders, ensure that VCAP certification has been completed, within a one year cycle of the first maintenance fee, but not to exceed 18 months (example: if NTEP certified in July 2011, VCAP certification would be required by November 2012).

3.2. As part of annual maintenance, NCWM shall ensure that VCAP audit reports are on file, current, and that all non-conformances have been addressed.

3.3. Ensure that an appeals process is in place and made available to certificate holders.

4. Sample sizes

4.1. The following sample sizes are to be used based on annual production. (…)

S.2. Consequences

If a certificate holder fails to submit an application for the administrative review, when requested, by the review date specified, the NTEP Certificate of Conformance will be inactive.

If a certificate holder of a device subject to influence factors fails to submit documentation, by the required date, indicating that it has and continues to maintain a VCAP for influence factors, the NTEP Certificate of Conformance will be inactive.

Annex 4 MID conformity assessment module H1

Module H1: Conformity based on full quality assurance plus design examination

1. Conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the measuring instruments concerned as specified in point 3, and shall be subject to surveillance as specified in point 5.

The adequacy of the technical design of the measuring instruments shall have been examined in accordance with point 4.

3. Quality system

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

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) all relevant information for the instrument category envisaged;

(c) the documentation concerning the quality system;

(d) a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.

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 shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents 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 measuring instruments will be met, applying other relevant technical specifications;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;

(g) the means of monitoring 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 point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the audit 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 to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It shall notify the manufacturer or his authorised representative of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.6. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

4. Design examination

4.1. The manufacturer shall lodge an application for examination of the design with the notified body referred to in point 3.1.

4.2. The application shall make it possible to understand the design, manufacture and operation of the instrument, and to assess the conformity with the requirements of this Directive that apply to it.

It shall include:

(a) the name and address of the manufacturer;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) the technical documentation as described in Article 18. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). It shall, as far as relevant for such assessment, cover the design and operation of the instrument;

(d) the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or normative documents have not been applied in full, and shall include, where necessary, the results of tests carried out in accordance with other relevant

technical specifications, 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 requirements of this Directive that apply to the instrument it shall issue an EU design examination certificate to the manufacturer. That certificate shall give the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. That certificate may have one or more annexes attached.

That certificate and its annexes shall contain all relevant information to allow the conformity of manufactured measuring instruments with the examined design to be evaluated and to allow for in-service control. It shall 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:

(a) the metrological characteristics of the design of the instrument;

(b) measures required for ensuring the integrity of the instruments (sealing, identification of software, etc.);

(c) information on other elements necessary for the identification of the instrument and to check its visual external conformity to the design;

(d) if appropriate, any specific information necessary to verify the characteristics of manufactured instruments;

(e) in the case of a sub-assembly, all necessary information to ensure the compatibility with other sub-assemblies or measuring instruments.

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 27(10), 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 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each.

Where the design does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU design examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

4.4. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall keep the notified body that has issued the EU design examination certificate informed of any modification to the approved design that may affect the conformity with the essential requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval – from the notified body that issued the EU design examination certificate – in the form of an addition to the original EU design examination certificate.

4.5. Each notified body shall inform its notifying authority of the EU design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU design examination certificates and/or additions thereto. On request, the

Commission and the Member States may obtain a copy of the technical documentation and of the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EU design examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of the certificate.

4.6. The manufacturer shall keep a copy of the EU design examination certificate, its annexes and additions with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

5. Surveillance under the responsibility of the notified body

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

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

(a) the quality system documentation;

(b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;

(c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on 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 the manufacturer with an audit report.

5.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

6. Conformity marking and EU declaration of conformity

6.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.

6.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up and shall mention the number of the design examination certificate.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity 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 a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation concerning the quality system referred to in point 3.1,

(b) the information relating to the change referred to in point 3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4.

8. Authorised representative

The manufacturer's authorised representative may lodge the application referred to in points 4.1 and 4.2 and fulfil the obligations set out in points 3.1, 3.5, 4.4, 4.6, 6 and 7, on his behalf and under his responsibility, provided that they are specified in the mandate.

Annex 5 Technical documentation

As an example of the requirements for technical documentation of a measuring instrument, refer to the European MID (Measuring instruments directive), Annex B (EU-type examination).

When applying for type (or design) examination, the manufacturer has to submit the technical documentation as described in article 18 of the MID (see below). The documentation shall enable assessment of the conformity of the instrument and shall, as far as relevant for such assessment, cover the design, manufacture and operation of the instrument.

"*Article 18*

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 applicable requirements of this Directive.

2. The technical documentation shall be sufficiently detailed to ensure compliance with the following requirements:

(a) the definition of the metrological characteristics;

(b) the reproducibility of the metrological performances of produced measuring instruments when properly adjusted using appropriate intended means;

(c) the integrity of the measuring instrument.

3. The technical documentation shall insofar as relevant for assessment and identification of the type and/or the measuring instrument include the following information:

(a) a general description of the measuring 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 the information referred to in points (b), (c) and (d), including the operation of the measuring instrument;

(f) a list of the harmonised standards and/or normative documents[10] referred to in Article 14, applied in full or in part, the references of which have been published in the Official Journal of the European Union;

(g) descriptions of the solutions adopted to meet the essential requirements where the harmonised standards and/or normative documents referred to in Article 14 have not been applied, including a list of other relevant technical specifications applied;

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

[10] The MID (not the NAWI Directive) recognizes 'normative documents' as equivalent to harmonized (European) standards providing presumption of conformity to the relevant essential requirements of the directive. A number of OIML Recommendations serve as normative documents under the MID.

(i) the appropriate test results, where necessary, to demonstrate that the type and/or the measuring instruments comply with the following:

— the requirements of this Directive under declared rated operating conditions and under specified environmental disturbances,

— the durability specifications for gas-, water-, thermal energy-meters as well as for liquids other than water;

(j) the EU-type examination certificates or EU design examination certificates in respect of measuring 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."