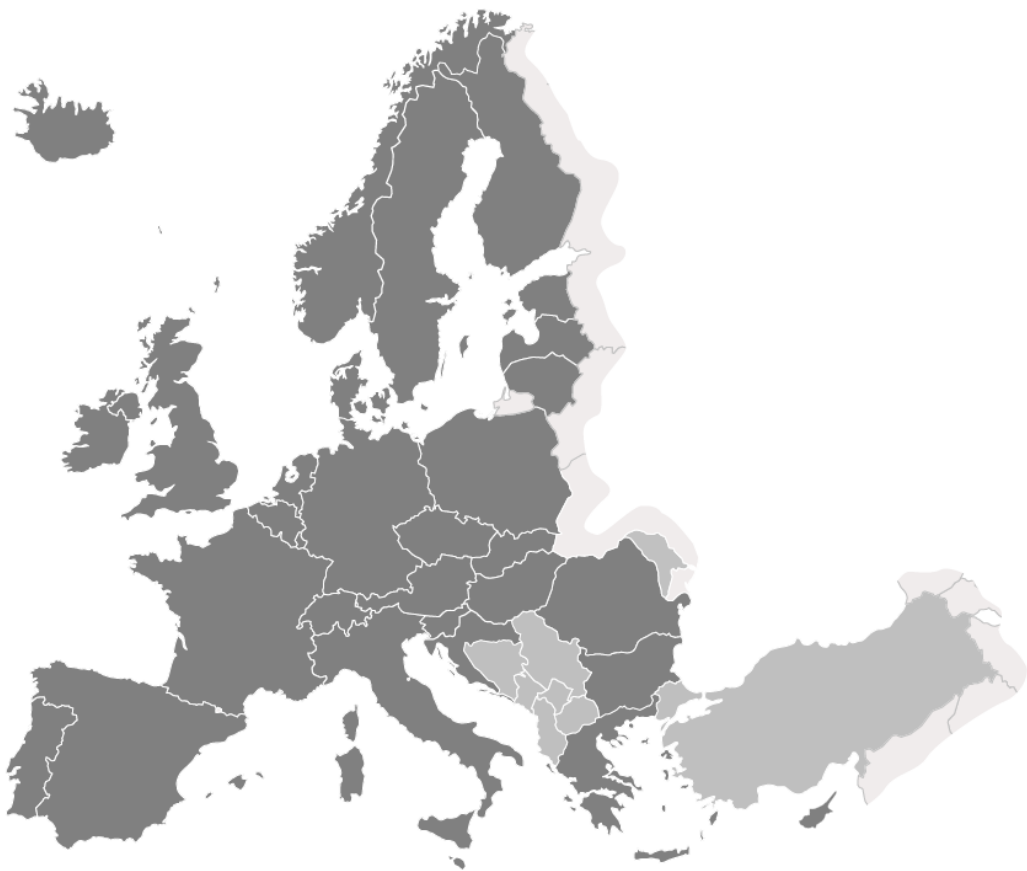


WELMEC

European Cooperation in Legal Metrology

Measuring Instruments Directive 2014/32/EU Application of Module H1



For information:

This guide is available to the Working Group Measuring Instruments for future reference on the Europa Website

WELMEC

European Cooperation in Legal Metrology

WELMEC is a cooperation between the legal metrology authorities of the Member States of the European Union and EFTA.

This document is one of a number of Guides published by WELMEC to provide guidance to manufacturers of measuring instruments and to notified bodies responsible for conformity assessment of their products.

The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EU Directives.

Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

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FORWORD

This guide is one of those which complete the general guide on the assessment and operation of notified bodies (NB) performing conformity assessment in application of the Measuring Instruments Directive (2014/32/EU; MID). Several guides have been established for the detailed application of some modules of MID. These guides should not be read without taking into consideration all relevant aspects in all the guides related to a module. In order to facilitate the understanding of the whole set of guides, a table is provided in Annex 1 of WELMEC 8.0.

This document is intended to provide guidance to all those concerned with the application of Annex II Module H1 of the Measuring Instruments Directive (2014/32/EU; MID). It provides guidance to manufacturers of measuring instruments, notified bodies (NBs) responsible for conformity assessment and the notifying authorities.

The guide is intended to give general information concerning the actions of manufacturers and NBs for the application of Module H1. For more information on the requirements applicable to the quality systems of manufacturers see the specific WELMEC Guide 8.6 Presumption of conformity of the quality system of manufacturers with Modules D or H1 when EN ISO 9001:2015 is applied.

The Guide is purely advisory and does not impose any restrictions or additional technical requirements beyond those contained in the MID. Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed. However it is intended that the procedures as described in the guide must be followed if it is to be claimed that the guide has been applied.

The flow chart in Annex 1 to this guide illustrates the Module H1 process. It identifies the activities performed by the manufacturer (applicant) and those performed by the notified body. The flowchart is arranged so as to clearly show the quality system assessment processes and the design examination processes. Annex 2 to this guide contains a checklist that can be used by the manufacturer and the notified body to assist in the design examination process.

EXPLANATORY NOTES

Module H1 specifies procedures for Design Examination which are different to the Type Examination procedures specified in Module B. However, in both cases it is the responsibility of the notified body to assess conformity: Whereas in Module B it is done by testing or examination of technical documentation, in Module H1 it is done by evaluating all relevant aspects of the instrument design, which may include evaluation of test data provided by the manufacturer.

The additional procedural requirements placed on the manufacturer, and the rights given to him, result from the fact that the design examination is made in conjunction with the approval of the Quality System (QS) of the manufacturer. Module H1 is based on the quality approach, with emphasis on product related aspects, specifying a number of aspects of the quality system that clearly indicate that design and production of instruments must be systematically and thoroughly documented. (H1 3.2)

The design examination aspect of Module H1 is based on the evaluation of a technical file and does therefore not require that a "prototype" or "representative product" is available and physically examined by the Notified Body. However, nothing excludes that, when such a product is available, the manufacturer can present it to the Notified Body. However, in no circumstances can the Notified Body require a prototype or a representative product to be presented for physical examination.

The inspection visit to the manufacturer's premises, allows a Notified Body to see how the manufacturer is dealing with design and manufacture of measuring instruments. Similarly, the ongoing dialogue between manufacture and Notified Body should be seen as a basis for the correct application of the essential requirements in relating to measuring instruments.

Thus, where approval is based on a quality assurance and specific design evaluation, Notified Bodies will in practice see the premises of the manufacturer, they will see the specifications, tests etc, that allow them to obtain a clear view on the manufacturer's ability to design and produce equipment in conformity with the Directive's requirements.

In many cases, the manufacturer will already have an appropriate quality system in place. The task for the notified body will then be to build on the work done by the body certifying the quality system, taking into account all the specific requirements of Module H1, and to have a particular focus on the design examination. In this way, the notified body will avoid duplicating work that already has been done by a certification body. (See WELMEC 8.6, Presumption of Conformity of the Quality System of Manufacturers with Module D or H 1 when EN ISO 9001:2015 is applied.)

In the framework of the surveillance of the quality system, i.e. after a design examination certificate has been issued, 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. This is part of the overall system put in place by module H1. It should not be seen as part of the design evaluation and there is no implication that H1 is not sufficient to guarantee in itself a proper design examination.

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[Below is the full text of the Annex II Module H1 with *Guidance notes indicated in italics.*]

MODULE H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION

1. Conformity based on full quality assurance plus design examination

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.

Full quality assurance is where the manufacturer has in place an approved quality system for design, manufacture and final product inspection and testing of the measuring instrument with all the requirements to demonstrate a priori the ability to consistently produce a product that meets the appropriate requirements of the Directive.

Design Examination is where the notified body conducts an assessment of the conformity of the instrument, based on the technical documentation of the design and development process and the supporting evidence that is supplied by the manufacturer.

2. Manufacturing

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 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 a notified body of his choice for the measuring instruments concerned.

The notified body shall be a body designated by a notifying authority for this activity after having been found to satisfy the criteria as laid down in Article 27 of the Directive. For more information, see the WELMEC 8.0 Generalities on the assessment and operation of notified bodies performing conformity assessment.

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;

The relevant information will include the category, or sub-category if applicable, of the instrument(s) described by the specific relevant Annex III-XII (MI-OXY).

- c) the documentation concerning the quality system.

The documentation shall provide information on the structure of the quality system and on conformity with an appropriate international standard, in particular EN ISO 9001, and shall contain in any case the appropriate information as laid down in this standard. It is advisable to

indicate the existence of certificates issued by other accredited certification bodies, where the scope of these certificates may be of interest or help for the approval of the QS. Also relevant to QS documentation would be alignment with the WELMEC 8.6 Presumption of Conformity of the Quality System of Manufacturers with Module D or H 1 when EN ISO 9001:2015 is applied.

If the current version of EN ISO 9001:2015 is applied, conformity of the quality system with modules D or H1 as regards the production process is presumed. The correct application concerning the directive is to be checked by the notified body.

The use of test procedures detailed in OIML recommendations or other International standards is encouraged, in particular those in normative documents and harmonised standards, in application of Point 4 in article 14 of MID.

The QS should include a statement concerning authorisation of representatives. It should be transparent under with circumstances, in which way and under which conditions an authorisation is given.

The quality system shall cover the type of instrument as described in the application and the technical documentation required by Article 18.

The scope of the QS shall be in accordance with the scope of the design and with the description of allowed developments of the design within the scope of the approved design. The approval of the QS by the NB shall either precede the approval of the first design or be conducted in conjunction with the first approval of a design.

It is up to the notified body to approve the scope of the quality system and therefore to decide whether a new instrument is covered by the scope. Therefore, an assessment of the quality system may not be required for each new model of instrument where the notified body decides it is within the scope already covered by the existing quality system

Where the quality system is modified to include an extension to the range of activities performed by the manufacturer so that new design(s) of instrument(s) can be covered by the quality system, an application shall be made, which will require a further assessment of the quality system.

The entire necessary documentation shall be 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 (Art. 17 of MID).

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

If the same application has been lodged by the manufacturer with other notified bodies, all notified bodies refuse further examination.

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 technical specifications;
- c) 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;
- 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.

The existence of the above information in the QS shall be established. This could be done through a checklist.

A cross-reference table is a helpful tool to provide access to the quality system documentation. It may be produced by the manufacturer or by the NB.

The description of the examinations and tests that are carried out by the manufacturer in the process of the evaluation of the Design for design evaluation and the evaluation of individual instruments in the process of manufacture and final control shall contain details on how the manufacturer controls the configuration of the instrument(s).

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.

To that purpose the NB shall take into account the aspects specific to legal metrology and the particular application (see WELMEC 8.6 Presumption of Conformity of the Quality System of Manufacturers with Module D or H 1 when EN ISO 9001:2015 is applied.).

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 "audit" consists of a documentation audit and an operational audit. The operational audit can only take place when the documentation audit is completed successfully.

For guidance, the time needed for the documentation and operational audit can be derived from IAF MD 5: 2015: Determination of Audit Time of Quality and Environmental Management Systems. The audit time may depend on factors such as size of the organisation, number of staff members, number of premises, etc.

Using this guide, it is not necessary to estimate the audit time from the total number of employees of the manufacturer, but only from the number of employees working on the

measuring instruments covered by the quality system to be approved. The audit time may also be reduced if the manufacturer already operates a certified QS.

The term “experience in quality management systems” means that the audit team should consist of a lead auditor who:

- *has completed an auditor/lead auditor course which is internationally recognised by the International Register of Certificated Auditors or*
- *functions as a lead auditor in an EN 17021 accredited organisation, or*
- *functions as a lead auditor in an accreditation organisation, and*
- *has demonstrated the required competence to the relevant notified body*

The term “experienced as an assessor in the relevant field and instrument technology” means that the experts (who focus on instrument specific requirements) will have:

- *completed an auditor/lead auditor or internal auditor course which is internationally recognised; or*
- *functions as an expert in an EN 17021 accredited body or*
- *functions as an expert auditor in an accreditation organisation, and have sufficient knowledge of metrology and measuring instrument technologies to enable them to assess conformity of a measuring instrument on the basis of design information supplied in accordance with Module H1 clause 4.2.*

In practice some general understanding of design, development and manufacturing processes will be a necessary competence in establishing the conformity of a product from design and manufacturing information.

Experts who undertake design assessment shall be familiar with the enabling technologies (e.g. electronics, mechanical design, software, information technology) which are applied in the measuring instrument design.

Experience of the evaluation of measuring instruments for the purpose of type approval can contribute to the knowledge necessary for design assessment. Likewise, experience as a verification officer may contribute to the knowledge necessary for production control.

The “knowledge of the applicable requirements of the Directive” means that a member of the audit team possesses the general knowledge that relates to MID requirements that are not instrument specific, such as the concept of sub-assemblies, software security, protection against corruption and marking.

The lead auditor, the expert auditor(s) and the generalist member can be one person.

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.

The “conclusions of the audit” shall contain:

- *scope of the audit,*
- *references to the used standards , and/or recommendations and/or test procedures,*
- *examination and conclusion,*
- *summary of findings with reference to non-conformity reports; and*
- *recommendation of the audit team to the issuing authority of the Notified Body.*

The conclusions of the audit may be laid down in one or more audit reports that cover the documentation and operational audits, plus an audit report for the purpose of verifying the corrective actions implemented to clear non-conformities.

The “manufacturer or his authorised representative shall be notified” means:

- *in the case of a positive decision: a certificate issued by the issuing authority of the Notified Body based on the advice of the audit team, or*

- *in the case of a negative decision: a letter from the issuing authority of the Notified Body with reference to the audit report. This letter shall include adequate justification for the negative decision and a reference to the procedure described in Art. 37 of MID and/or its national transposition.*

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.

All changes that might affect the subjects covered by the bullets under 3.2 shall be notified to the Notified Body. Changes of manufacturer's staff members responsible for conformity assessment should be notified, but generally – an exception of key personnel to be considered - assessment for these changes is not needed.. Records of staff experience and qualifications (which may include education, training, skills, experience etc.) for the personnel concerned shall be maintained.

Changes of standards and test procedures can in many cases be evaluated based on the documentation.

Changes in subcontracting should be assessed.

Changes of locations crucial to conformity assessment should be evaluated on site.

Changes to the QS that are purely administrative e.g. spelling corrections, need not be notified.

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.

Information shall be provided as for the initial audit (3.3).

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.

In addition, Art. 38 point 2 of MID applies, requiring that "Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same measuring instruments with relevant information on issues relating to negative and, on request, positive conformity assessment results."

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.

This is part of the same procedure so the application shall be made to the same notified body as chosen by the manufacturer for assessment of the quality system, in point 3.1. An application for design examination shall either be made after, or at the same time as, the application for approval of the QS.

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

Design:

Article 18.3 provides a comprehensive list of information that is necessary for establishing conformity of a design. Note that this includes conceptual design, manufacturing procedures, descriptions of how technologies are applied (sub-paragraphs (b), (c) and (d)) and, where necessary, explanations to enable understanding of the above. (sub-paragraph (e)) Design calculations, examinations and appropriate test results shall also be provided. All this information may normally be found in a product design file. It shall be provided "insofar as relevant for assessment and identification". The checklist at Annex 2 of this guide is intended to assist the notified body and manufacturer to agree on what information may be necessary for a practical assessment.

Operation:

Some operating characteristics, such as susceptibility to fraudulent use or suitability for use, may be less apparent from design information. Manufacturers shall provide an explanation of how they have considered and complied with all such requirements. The evaluation of these aspects necessitates some judgement and is recommended to be part of the risk assessment.

The technical documentation shall include an adequate analysis and assessment of the risk(s), in which the manufacturer identifies all risks, relevant to the measuring instrument, assesses them (quantitative, qualitative or combined) and classifies them (for example - major, marginal, negligible or minor) according to the assessment.

It is recognised that if a measuring instrument complies within the rated operating conditions with the essential requirements that this would cover most of the risks associated with the measuring instruments.

It is however expected that the following aspects should be assessed:

- *Suitability of use in those cases where the use of the MI could influence conformity to the essential requirements. For example, the use of gas meters with bio gas or the use of measuring systems for the continuous and dynamic measurement of quantities of liquids other than water for cryogenic liquids or bio fuel, the use of automatic weighing instruments with heavy products.*
- *Durability, particularly for gas-, water-, thermal energy-meters as well as for liquids other than water for the cases mentioned above or if harmonised standards or normative documents⁴ are not applied for durability.*
- *Software risk assessment to establish if the legally relevant software, parameters and data are adequately protected against accidental or unintentional changes and against intentional changes by unauthorised persons.*

When the risks are classified the manufacturer produces and implements a plan with optimal measures for their limitation.

- 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.

The WELMEC 8.6 Presumption of Conformity of the Quality System of Manufacturers with Module D or H 1 when EN ISO 9001:2015 is applied shall be considered. Some aspects are pointed out below.

If test results are submitted by the manufacturer, the tests shall be carried out in accordance with the principles of EN ISO 17025. The uncertainty of measurement shall be in line with the WELMEC guide 4.2. Where a subcontractor is used for carrying out all (or part of) the testing, the subcontractor shall provide evidence of his competence to the manufacturer (e.g. by accreditation for testing according to EN ISO 17025) and in the case of a non-accredited body the manufacturer must be capable of assessing this competence.

Details regarding software, version, status and upgrades shall also be supplied. This forms part of the technical documentation described in Article 18.

Although some information might be provided by the operating manual, it is necessary that the manufacturer also supplies an "examination report" which explains how conformity to the Directive, or where applicable to the appropriate harmonised standard or normative document, has been made for technical requirements or aspects not covered by test results.

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. The certificate shall give the name and address of the manufacturer, 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.

The Design Examination will consist of an assessment of the conformity of the design, as contained in the technical documentation and the supporting evidence, in meeting the Essential Requirements as laid down in Annex 1 and the applicable instrument specific requirements in Annex III-XII (MI-OXY)

The certificate or 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 annexes may be split into two parts:

1 *One available to everybody involved in the legal metrology control, including in service controls. This part includes all information for identifying at least externally the design of the*

instrument, performing the metrological controls and a minimum of information to assist in efficient market surveillance and surveillance of instruments in service.

2 *One containing more information on the description of the instrument, allowing full market surveillance, in particular for checking the complete conformity to design of produced 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 such a refusal.

The evaluation report shall include an assessment of suitability for use, susceptibility to fraudulent use, arrangements for sealing/securing.

The evaluation report, or the Technical file which is to be retained by the notified body, shall include a description or reference to the test procedures involved.

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.

Any modification to the approved design or change to the technical documentation as described in Article 18 of MID or the supporting evidence for the adequacy of the technical design, as supplied with the application in 4.2, and which may affect the metrological performance or metrological characteristics of the instrument, must be declared to the notified body who will determine if the change is considered to have a metrological effect on the instrument. Based on the information supplied the notified body will determine if the modification requires an "addition" to the original design examination or for a new design examination certificate to be issued.

WELMEC 8.0 Generalities on the assessment and operation of notified bodies performing conformity assessment gives information on possible evolutions of an approved design.

An "addition" to the original design examination may also be in the form of a "revision" which replaces the original 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.

The "additions" may also be in the form of "revisions" which replace the original certificate. Each notified body shall immediately inform the Member State that designated it of the withdrawal of an EU design examination 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.

After the initial audit (see 3) a periodic surveillance takes place with a scope generally limited to the areas which are critical for the conformity of instruments. The frequency of periodic audits may vary according to the past performance of the manufacturer, the frequency of any changes to the quality system, and the complexity of the products.

It is advisable to have these audits performed regularly for example once every calendar year as in ISO 17021-1 (2015).

The conclusions of the periodic audit shall contain:

- *scope of the audit,*
- *references to the used harmonised standards and/or normative documents*
- *examination and conclusion,*
- *summary of findings with reference to non-conformity reports; and*
- *recommendation of the audit team to the issuing authority of the NB.*

The conclusions of the periodic audit shall be laid down in an audit report which references the initial (documentation and operational) audit reports.

The conclusions of the re-assessment may be laid down in a separate audit report or as additions to the initial (documentation and operational) audit reports.

For guidance, the time needed for the documentation and operational audit can be derived from IAF MD 5: 2015: Determination of Audit Time of Quality and Environmental Management Systems.

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.

The necessity and frequency of such unexpected visits will be determined by the Notified Body after consideration of the initial assessment of the QS, previous information relating to the manufacturer, the manufactured instruments and any complaints received. To minimise costs such visits should focus on points where further assurance is required in the light of the above considerations.

The practicality of performing such unexpected visits and of obtaining suitable results shall be taken into consideration before deciding approval of the QS, in particular where access to a manufacturer may be restricted.

The report of the unexpected visit shall contain:

- *scope of the unexpected visit,*
- *references to the used standards and/or normative documents and/or test procedures,*
- *examination and conclusion,*
- *summary of findings with reference to non conformity reports,*
- *recommendation of the audit team to the issuing authority of the Notified Body; and*
- *test reports, if tests have been carried out.*

The result of the unexpected visit and the tests (when carried out) may be laid down in a separate report or as additions to the initial (documentation and operational) audit reports. Report formats from European Standards, WELMEC or OIML Recommendations shall be used if available.

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 measuring 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.

For the content of the declaration of conformity cf. Annex XIII of MID

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

A copy of the EU 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.

The declaration of conformity may also be made available on the manufacturers website.

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 related 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.

According to Art. 9 of MID the mandate has to allow a minimum scope of tasks. Chapter 2 of MID specifies the obligations of economic operators (being either the manufacturer, authorized representatives, importers or distributors). Only for the authorised representative written mandate is needed. Operators performing specific tasks on behalf of the manufacturer should either be covered by his QS or be authorised.

Art. 13 of MID establish the obligation for economic operators to identify any economic operator who has supplied them with as well as to whom they have supplied a measuring instrument.

ANNEX 2: CHECKLIST FOR DESIGN EXAMINATION

APPLICATION NOTES

The design assessment checklist is intended to enhance consistency and provide a basis for recording the examination. However, the first objective must be to prove to the (full) satisfaction of the NB that the measuring instrument conforms to the requirements of the directive (if chosen by the manufacturer by way of conformity to a harmonised standard or normative document). The Directive requires that the application for examination shall enable understanding of the design, manufacture and operation; and that the documentation shall cover the design and operation as far as relevant for the assessment. The checklist should therefore be applied only as far as it is relevant.

Therefore, it is not intended that the entire checklist should be applied in every case. In general the practical scope of the checklist should be agreed with the manufacturer, taking account of the type of product, the use of standards, the maturity of the design (e.g. similar to established design or using previously certified technology) and the extent to which it utilises established technology and previously approved modules. The modified checklist, as appropriately applied, may then be recorded as part of the evaluation report.

The complete list encompasses most of the elements of a product design process. Not all of them will be necessary to establish conformity. In particular, there is the possibility that variants of designs and new designs which are heavily based on previous work can be examined efficiently with minimal effort.

It is anticipated that manufacturers may use the list in preparing the documentation for the design examination and conversely that they may propose modifications to the list in the light of their experience of the design process.

LIST OF TECHNICAL DOCUMENTATION THAT MAY BE APPLICABLE FOR DESIGN ASSESSMENT

1. Functional specification
 - includes any optional functionality
 - enables correct classification of the instrument
 - to be checked against essential functional requirements
 - essential for correct interpretation of all the following documents
2. Performance specification
 - to be checked against essential requirements or against harmonised standard or normative document if this route is used by the manufacturer
 - reference for evaluation and test programme
3. Implementation scheme or design philosophy
 - Principles
 - Technology
 - Modularity
4. Standards applied
 - Harmonised standards or normative documents
 - Features not covered by standards or normative documents
5. Design methodology (particularly for software)
 - Design tools (software design tools, design oriented....)
 - Structure
 - Process
6. Critical calculations – regarding design concept
7. Evidence of detailed design (e.g. log book, “prototype report” etc)
 - Calculations
 - Drawings
 - Prototype tests
8. Major function Original Equipment Manufacturer components
 - Specifications
 - Approvals (of product or manufacturer)
9. Sub-assemblies with prior approval
 - Scope of approval
 - Compatible interfaces
10. Manufacturing documentation
 - Is it capable of consistent manufacture?
11. Design evaluation test programme
 - To prove 1, 2, and 3
12. Where necessary, design evaluation test results which shall confirm
 - Performance
 - Functionality (software)
 - Security (sealing included here)
 - Durability
 - Flexibility within the design (variants of model)
13. Production test regime (documentation)

- Processes
- Automatic Testing Equipment
- Static
- Functional
- Documentation – test specification
- Results record
- Analysis and feedback

14. Prior approval of a similar instrument (if part of the documents to be taken into account)

15. Results coming from application of other directives (LVD, EMC, machinery, ...) if relevant.