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WELMEC

European cooperation in legal metrology

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Application of Module H1

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WELMEC

European cooperation in legal metrology

WELMEC is a cooperation between the legal metrology services 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 EC 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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FOREWORD

This document is intended to provide guidance to all those concerned with the application of Module H1 of the Measuring Instruments Directive (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, the specific WELMEC guide on set-up and approval of quality systems of manufacturers for application of modules D and H1 [currently under development] should be considered .
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. General comparison between “type approval” (module B) and “design examination” (module H1) will be provided as an annex to the ‘top-level’ guide - MID Conformity Assessment.

Some aspects of module H1 may necessitate further consideration. A revision of the guide may therefore be necessary. This includes possible changes if EN 45 012 will be amended.

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 of the manufacturer. Module H1 (and H) 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 Annex 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 guide on set-up and approval of quality systems of manufacturers for application of modules D and H1 [currently under development])

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.

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

Annex H1

Declaration of conformity based on full quality assurance plus design examination

1. 'Declaration of conformity based on full quality assurance plus design examination' is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down hereafter and ensures and declares that the measuring instruments concerned satisfy the appropriate requirements of the Directive.

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.

Manufacturing

2. The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the measuring instrument concerned as specified in paragraph 3, and shall be subject to surveillance as specified in paragraph 5. The adequacy of the technical design of the measuring instrument shall have been examined according to the provisions of paragraph 4.

Quality system

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

The notified body is designated by a Member State for this activity after having been found to satisfy the criteria as laid down in Article 12 of the Directive. For more information see the WELMEC guide for the assessment and operation of notified Bodies performing conformity assessment according to MID [currently under development].

The application shall include:

- 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 MI-0XY.

- 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 9001:2000, 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 guide on set-up and approval of quality systems of manufacturers for application of modules D and H1 [currently under development].

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 13 of MID .

This 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.

The quality system shall cover the type of instrument as described in the application and the technical documentation required by Article 10.)

The scope of the QS shall be in accordance with the scope of the design and with the description of allowed evolutions 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.

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

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

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;
- the technical design specifications, including standards, that will be applied and, where the standards referred to in Article 9 will not be applied in full, the means that will be used to ensure that the essential requirements of the Directive that apply to the instruments will be met;
- the design control and design verification techniques, processes and systematic actions that will be used when designing the instruments pertaining to the instrument category covered;
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

- the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

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 notified body.

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 paragraph 3.2. It shall presume conformity with these requirements in respect of a quality system that complies with the corresponding specifications of the national standard that implements the relevant harmonised standard, from the moment its references have been published in the Official Journal.

To that purpose the NB shall take into account the aspects specific to legal metrology and the particular application (see WELMEC guide on set-up and approval of quality systems of manufacturers for application of modules D and H1 [currently under development]).

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

The "evaluation procedure" 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 annex 2 (auditor time) of EA 7/01 (Guideline on the application of EN45012).
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 or accredited quality system.

The audit team shall include, but need not be made up entirely, of persons having appropriate experience in the relevant field of metrology and instrument technology, and knowledge of the applicable requirements of the Directive.

The term "provide 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, or*
- *functions as a lead auditor in an EN 45012 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 "appropriate experience in the relevant field of metrology 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 45012 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 Annex 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 decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

The "conclusions of the examination" 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 examination 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 "notification to the manufacturer" 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.*

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 updating of the quality system.

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

All changes that might affect the subjects covered by the bullets under 3.2 shall be notified to the Notified Body. Changes of staff do not need to be notified, but records of staff experience

and qualifications (which may include education, training, skills, experience etc.) for the personnel concerned shall be maintained.

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

It shall notify its decision to the manufacturer. 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).

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

The Member State will inform all the Member States. They will make this information available to the bodies they have notified.

[The methods for making this information available are currently under discussion within WELMEC and the outcome will be referenced in the next revision of this guide.]

Design examination

4.1 The manufacturer shall lodge an application for examination of the design with the notified body referred to in item 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 item 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 enable understanding of the design, manufacture and operation of the instrument, and shall enable assessment of conformity with the appropriate requirements of the Directive. It shall include:

- the name and address of the manufacturer;
- a written declaration that the same application has not been lodged with any other notified body;
- the technical documentation as described in Article 10. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of the Directive. It shall, as far as relevant for such assessment, cover the design and operation of the instrument;

Design
Article 10.3 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. Further advice will be developed as soon as possible and published in the next revision of this guide.

- the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any standards that have been applied, in particular where the standards referred to in Article 9 have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

The WELMEC guide on set-up and approval of quality systems of manufacturers for application of modules D and H1 [currently under development] 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 up- grades shall also be supplied. This forms part of the technical Documentation described in Article 10.

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 provisions of the Directive that apply to the measuring instrument it shall issue an EC design examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, conclusions of the examination, conditions (if any) for its validity and the necessary data for identification of the approved instrument.

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, the Annex specific requirements (MI-0XY) and, where applicable, the instrument specific requirements.

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

A copy is kept by the notified body.

4.3.2 The certificate or its annexes shall contain all relevant information for conformity evaluation and in-service control. In particular, to allow the evaluation of conformity of the manufactured instruments with the examined design regarding the reproducibility of their

metrological performances, when they are properly adjusted using appropriate intended means. Content shall include:

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

The annexes may be split into 2 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.

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

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

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

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

Any fundamental modification to the approved design or change to the technical documentation as described in Article 10 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.

The WELMEC guide for the assessment and operation of notified Bodies performing conformity assessment according to MID gives information on possible evolutions of an approved design [under development].

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 periodically make available to the Member State that designated it:

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

Each Member State will make this information available to the bodies which it has notified.

[The methods for making this information available are currently under discussion within WELMEC and will referred to in the next revision of this guide when agreed.]

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 EC design examination certificate.

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

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

<u>Surveillance under the responsibility of the notified body</u>

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

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

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

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, but shall l take place in a period not exceeding 12 months since the last audit.

The conclusions of the periodic audit shall contain:

- *scope of the audit,*
- *references to the used standards,*
- *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 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 periodic audit can be derived from annex 2 (auditor time) of EA 7/01 (Guideline on the application of EN45012).

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

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.

Written declaration of conformity

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

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

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

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

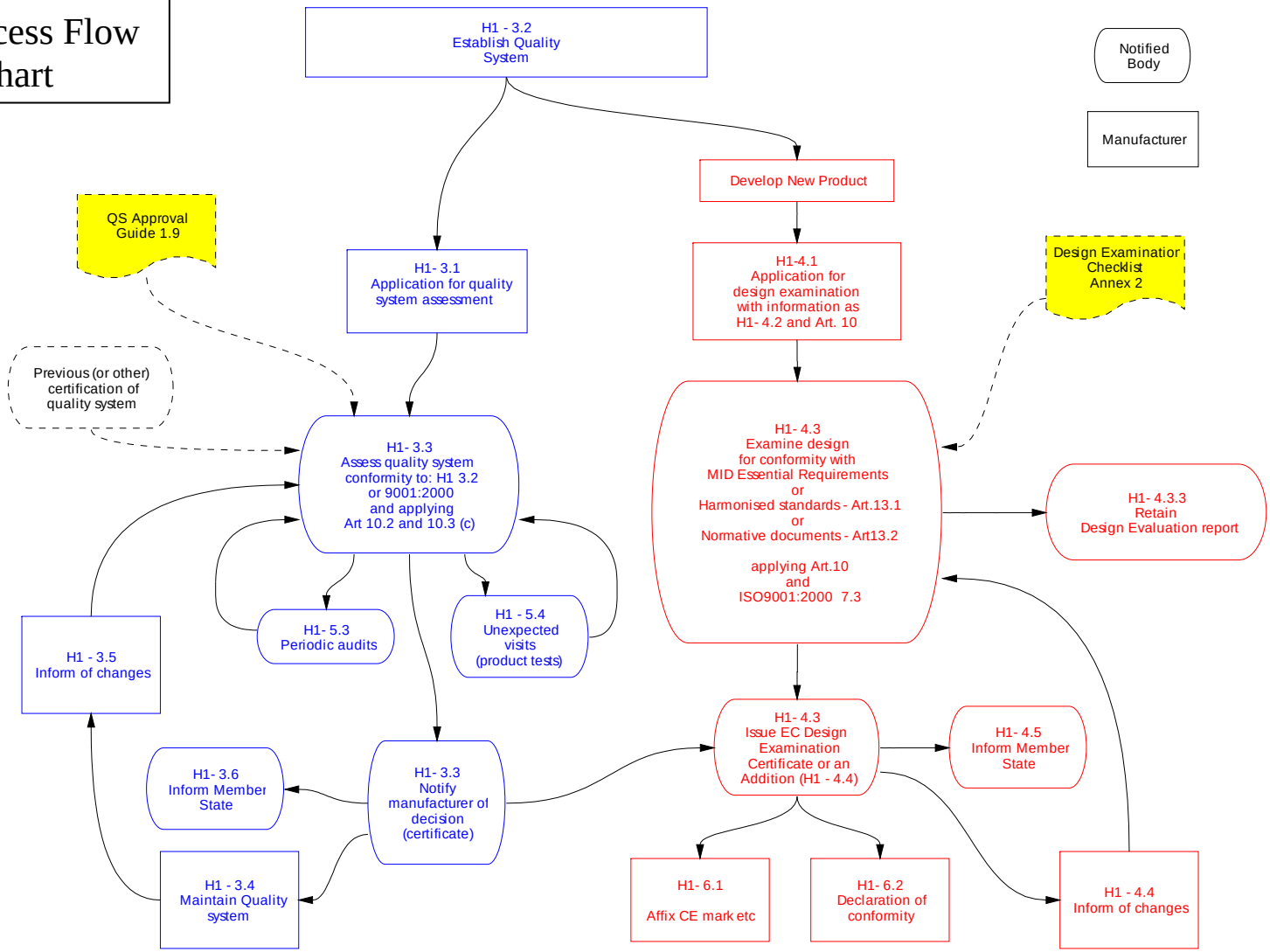
- the documentation referred to in 3.1, second indent;
- the updating referred to in paragraph 3.5, as approved;
- the decisions and reports from the notified body referred to in paragraphs 3.5, 5.3 and 5.4.

Authorised representative

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

ANNEX 1

H1 Process Flow Chart



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.