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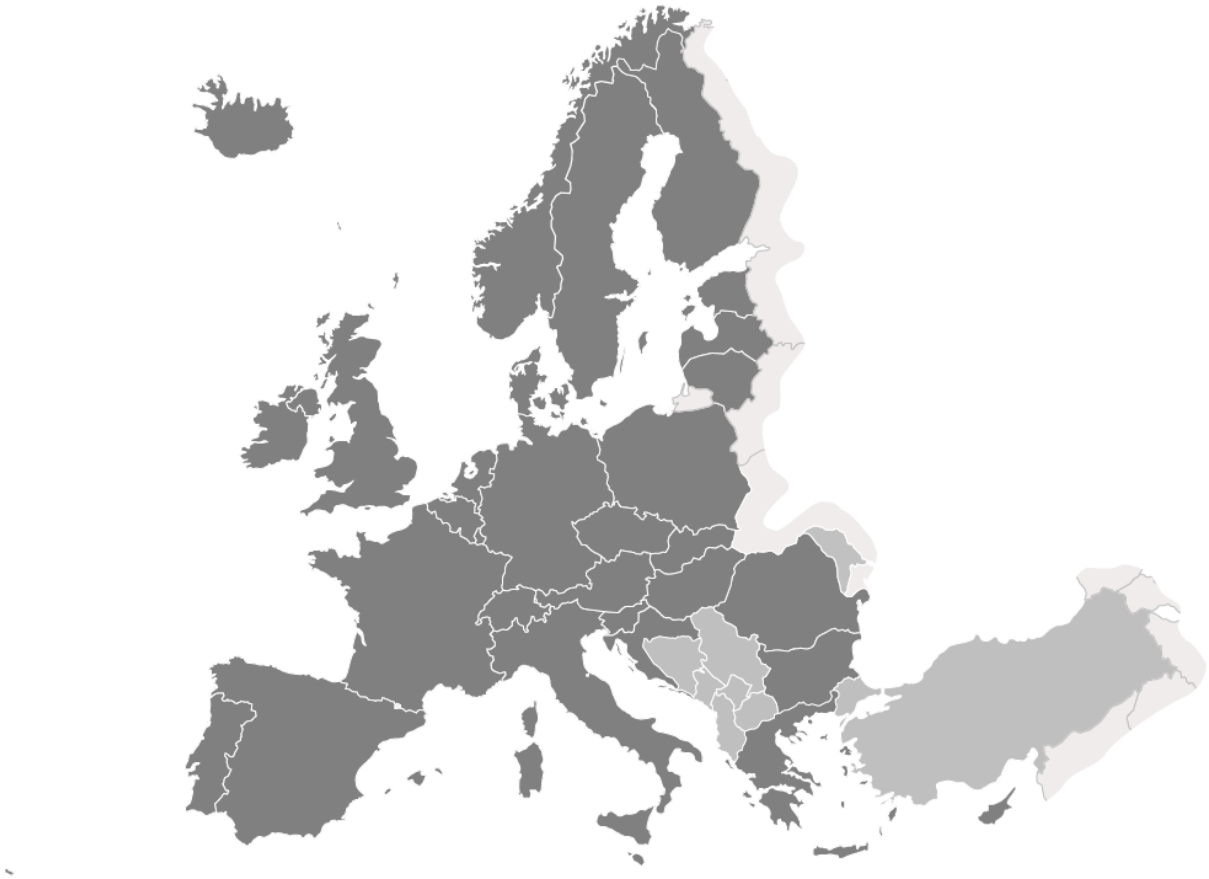
European Cooperation in Legal Metrology

Application of module D Quality assurance

Under directive 2014/32/EU (MID) or directive 2014/31/EU (NAWID)



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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Foreword

This guide is one of those which complete the general guide on the assessment and operation of notified bodies performing conformity assessment in application of the Measuring Instruments Directive (2014/32/EU; MID) and the directive on non-automatic weighing instruments (2014/31/EU; NAWID). 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 guide is intended to provide guidance to all those concerned with the application of Annex II Module D (for simplicity referred to as Module D) of MID and NAWID. It provides guidance for manufacturers, notified bodies responsible for conformity assessment and the notifying authorities.

For more information on the requirements applicable to the quality systems of manufacturers, 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 should be considered.

The Guide is purely advisory and does not impose any restrictions or additional technical requirements beyond those contained in the MID or NAWID. 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.

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 II Module D, and to have a particular focus on the legal metrology application. In this way the notified body will avoid duplicating work that already has been done by a certification body. (See 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)

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[Below is the full text of Annex II Module D marked on the sides, with Guidance notes]

MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

Quality assurance of the production process means that the manufacturer operates an approved quality system covering the manufacturing, the testing of the measuring instrument during the production process and the final product inspection. Thus the manufacturer demonstrates a priori the ability to consistently provide a product in conformity with the approved type that meets appropriate requirements of the Directive.

2. Manufacturing

The manufacturer shall operate an approved quality system for production, 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 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 the Notifying Authority after having been found to satisfy the requirements as laid down in Art. 27 of MID or Art. 23 of NAWID for this activity. For more information see the WELMEC Guide 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) 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.

(c) 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 respective relevant specific Annex III to XII (MI-0XY).

(d) 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 the current version of 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. For more guidance on the QS documentation WELMEC Guide 8.6 should be taken into account.

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 Art. 14 of MID or Art. 12 of NAWID.

If a manufacturer makes use of the voluntary modular evaluation and producers with examined QS-systems are involved the respective documents according to WELMEC 8.8 may also be considered.

The QS-system 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 relevant TEC and the technical documentation required by Art. 18 of MID or Annex II, point 1.3 of NAWID.

The scope of the QS shall be in accordance with the scope of the manufacturing and with the description of manufactured approved types. If the scope of certification requested by the manufacturer is different from the description of manufactured approved types, this information should be included the QS approval document established by the notified body.

It is up to the notified body to approve the scope of the quality system and therefore to decide whether a new approved type of measuring instrument is covered by the scope. Therefore an assessment of the quality system may not be necessarily required for each new approved type 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 type(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.

For the NAWID the QS should include a procedure for testing in two stages when relevant. In this case more than one notified body could be indicated with the conformity marking.

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 and Art. 13 of NAWID).

(e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

Conformity assessment under Module D can only take place when Module B is completed. The approval of the QS by the notified body shall therefore not be effective before the first type of measuring instrument of the respective manufacturer is approved.

If the manufacturer has parts or the complete instrument manufactured by an organisation not covered by the quality system, then the related contracts and agreements, especially with regard to the accessibility of technical documentation have to be examined.

If a manufacturer makes use of the voluntary modular evaluation the respective documents according to WELMEC 8.8 should also be considered.

The manufacturer undertaking the Module D does not need to be the same person as the one having the EU-type examination certificate under Module B. Nevertheless he takes the entire responsibility for the conformity assessment (design & production) of the product. Consequently, he must be in possession of both certificates and the full history of the product even though the EU-type examination certificate does not have to be in his name. He must have all the administrative and technical information and data, and be able to make the technical documentation available.

3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU-type examination certificate and comply 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 product quality;

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

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

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

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

The QS shall cover all required elements. Evidence is to be collected during the evaluation. This could be done through a checklist.

A cross-reference table is a helpful tool to provide an overview of the quality system documentation. It may be produced by the manufacturer or by the notified body.

The description of examinations and tests that will be carried out evaluating the individual measuring instrument (either for every instrument or on statistical basis) during the production process and/or 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 a quality system that comply with the corresponding specifications of the relevant harmonised standard.

To that purpose the notified body shall take into account the aspects specific to legal metrology and the particular application (see 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).

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation 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 term *experience in quality management systems* means that one member of the audit team shall be a lead auditor who:

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

The term *experience of evaluation in the relevant instrument field and instrument technology concerned* 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
- function as experts in an EN 17021 accredited body, or
- function as expert auditors in an accreditation organisation, and
- have sufficient knowledge of metrology and the measuring instrument technologies to enable them to assess conformity of a measuring instrument on the basis of information supplied in accordance with Annex II Module B.

The term *knowledge of the applicable requirements of the Directive* means that a member of the audit team possesses general knowledge that relates to MID requirements that are not instrument specific, such as economic operators responsibilities, declaration of conformity, labelling etc.

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

Experience in testing of measuring instruments (type examination, verification, calibration) may contribute to the knowledge necessary for production control.

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

> The auditing team shall review the technical documentation referred to in point (e) of 3.1, to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

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.

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 decision shall be notified to the manufacturer. 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 with regard to the scope and decision about the approval.

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 decision 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 or Art. 32 of NAWID 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 of 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 quality system that are purely administrative e.g. spelling corrections, need not be notified.

It shall notify the manufacturer 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).

4. Surveillance under the responsibility of the notified body

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

4.2. The manufacturer shall, for assessment purposes allow the notified body access to the 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, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide 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 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 IAF MD 5: 2015.

4.4. 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 verify that the quality system is functioning correctly. The notified body 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 relevant economic operators, 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 mentioned 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 manufacturing sites may be restricted.

The *conclusions of the examination* shall contain:

- scope of the audit and duration,
- 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 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.

5. Conformity marking and EU declaration of conformity

5.1. 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 measuring instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

5.2. 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 was drawn up.

For the content of the declaration of conformity cf. Annex XIII of MID or Annex IV of NAWID.

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.

6. 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 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 from the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall periodically or on 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 or Art. 33 point 2 of NAWID 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.”

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

According to Art. 9 of MID or Art. 7 of NAWID the mandate has to allow a minimum scope of tasks. Chapter 2 of MID or NAWID specifies the obligations of economic operators (being either the manufacturer, authorised representatives, importers or distributors). Only for the authorised representative a written mandate is needed. Operators performing specific tasks on behalf of the manufacturer should either be covered by his QM-System or be authorised.

Art. 13 of MID and Art. 11 of NAWID 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.