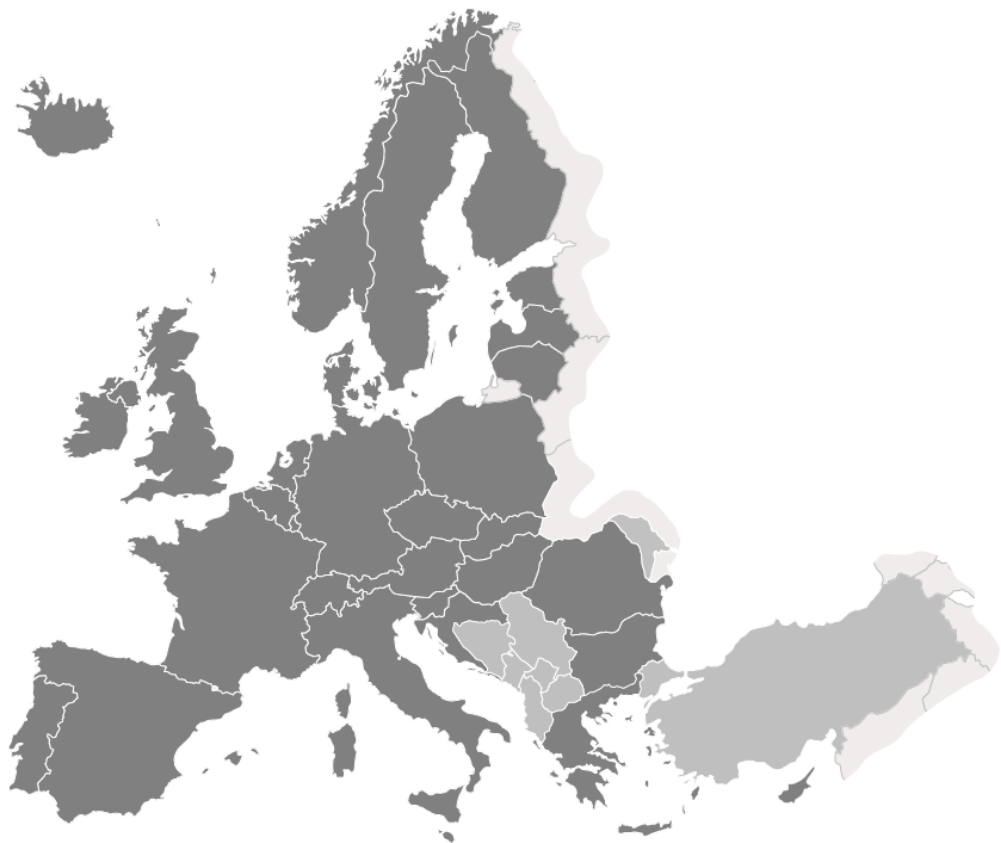


WELMEC 8.5  
2018

# WELMEC

European Cooperation in Legal Metrology

## Assessment of Notified Bodies following the EN ISO/IEC 17065



# WELMEC

European Cooperation in Legal Metrology

WELMEC is a co-operation 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 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.

Published by:  
WELMEC Secretariat

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## FOREWORD

This guide is one of those who complete the general guide on the assessment and operation of notified Bodies performing conformity assessment in application of 2014/31/EU directive (hereinafter as the “NAWID”) and 2014/32/EU directive (hereinafter as the “MID”). Several guides have been established for the detailed application of some modules of MID and NAWID. These guides should not be read without taking into consideration all relevant aspects in all the guides related to a module.

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

## INTRODUCTION

This document is intended to provide guidance in order to facilitate harmonized assessment of notified bodies (NB) following the EN ISO/IEC 17065 for the application of the following conformity assessment modules: B, D and F according to MID and NAWID and H1 according to MID.

The document is focused on these modules but the guide may also be used for other modules as foreseen in guide 8.0.

17065 is a standard which is used in order to operate a certification program according to the MID and the NAWID. Therefore accreditation/assessment bodies are encourage to take into account the relevant technical WELMEC guides which are related to the 2 directives.

As the conformity to EN ISO/IEC 17065 appears to be the most appropriate generic standard in order to give presumption of conformity for these conformity assessment modules in relation to MID and NAWID, this document is built according to the structure of this standard. For conformity assessment modules F and F1 for which EN ISO/IEC 17020 is also possible (see WELMEC guide 8.0), the WELMEC guide 8.7 could be used alternatively.

This document could be used for assessment of bodies in charge of similar conformity assessment procedures with appropriate adaptations, for instance issuing of national type examinations certificates.

The right column in this document provides guidance that can also be used in the cases where the Notifying authorities have chosen other ways than accreditation to prove the conformity.

In all the cases, where a provision exists in the right column, it must correspond to a provision in the quality system of the NB, demonstrating that it takes the appropriate provisions in order to meet the requirements.

Where it is written "Applicable such as described" in the right column, this means that the standard applies as such and does not need additional specific guidance.

This guide is not intended to substitute any other guidance available on the new approach, in particular the Blue Guide.

## **PRELIMINARY CONSIDERATIONS ON TYPE EXAMINATION (module B)**

The tests performed in the scope of a type examination constitute essential aspects of the procedure (when they are necessary). Nevertheless reliable tests may be performed by any laboratory having the necessary procedures and competencies and having demonstrated a sufficient impartiality. On the contrary, the assessment of conformity performed by the NB necessitates a very good knowledge of all the applicable requirements and of legal metrology in general, in particular as far as some specific aspects such as suitability for use and fraud resistance are concerned.

Another particularity of type examination is that the measuring instrument must be capable of meeting all the applicable requirements without non-allowed adjustments or modification. When tests are used for demonstrating the conformity, they must be performed under conditions which give confidence on the respect of this fundamental principle. When test are not performed, this assumption remains also valid.

Is it pointed out that when tests are referred to in this documents, this does not mean that they are necessary in any case. In such an occurrence, a reference to tests is made without prejudice of the three possibilities provided in the module B (Module B section 2 of MID and module B section 1.2 of NAWID). It may be also noticed that these three possibilities are traditional solutions used in legal metrology (see the WELMEC Guide 8.3 Application of module B for more information).

It is also pointed out that the tests referred to in this document are those which are considered necessary by the NB for the demonstration of conformity according to module B and not those performed by the manufacturer as the supporting evidence being part of his technical documentation (see the WELMEC Guide 8.3 Application of module B for more information).

## **PRELIMINARY CONSIDERATIONS ON CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS (module D) AND CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION (module H1)**

A NB performing assessment and approval on quality assurance of the production process or on full quality assurance may use assessors that are not of its staff, provided the audit team fulfils the necessary requirement on the level of qualification and expertise of the assessor(s), as referred to in the MID and NAWID.

The assessors shall have adequate knowledge of the technology and applications of the instruments that are to be examined. An expert in legal metrology having the appropriate knowledge of the category of instruments shall be part of the assessment teams.

Concerning H1 where there is a combination of design examination and full quality assurance, members of the assessment team all together shall have competence in both fields and shall exchange information during the assessment process.

EN ISO/IEC 17065 chapter	Guidance
1 Scope	Applicable such as described
2 Normative references	<p>Harmonized standards and normative documents, the list of which has been published in the Official Journal of the European Union, are necessary for the implementation of conformity assessment in the frame of the MID and NAWID.</p> <p>The following WELMEC guides should be considered:</p> <ul style="list-style-type: none"> <li>- WELMEC guide 8.0 Notified bodies directive 2014/31/EC and Directive 2014/32/EC Generalities on Assessment and Operation</li> <li>- WELMEC guide 4.2 Elements for deciding the appropriate level of confidence in regulated measurements</li> <li>- Guide to the expression of uncertainty in measurement (GUM).</li> <li>- Relevant technical WELMEC guides and 8.8 for modular evaluation</li> </ul> <p>For the implementation of the conformity assessment modules, the following WELMEC guides should also be considered:</p> <ul style="list-style-type: none"> <li>- guide 8.2 for module H1</li> <li>- guide 8.3 for module B</li> <li>- guide 8.4 for module D.</li> </ul>
3 Terms and definitions	<p>The terminology is completed by :</p> <ul style="list-style-type: none"> <li>- VIML International vocabulary of terms in legal metrology,</li> <li>- International vocabulary of basic and general terms in metrology (VIM),</li> <li>- WELMEC guide 8.1 Terms and definitions in MID and their relation to terms defined in other international metrologically relevant documents</li> <li>- Terminology listed or referred to in annexes of the MID and the NAWID</li> </ul>
4 General requirements	
4.1 Legal and contractual matters	<p>Requirements of article 27 of MID or article 23 of NAWID shall be considered, in particular:</p> <p><i>“A conformity assessment body shall be established under national law of a Member State and have legal personality.”</i></p>
4.2 Management of impartiality	<p>Requirements of article 27 of MID or article 23 of NAWID shall be considered, in particular:</p> <p>Section 3:</p> <p><i>“A conformity assessment body shall be a third-party body independent of the organisation or the measuring instrument it assesses.”</i></p> <p>Section 4:</p> <p><i>“A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the measuring instruments which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed measuring instruments that are necessary</i></p>

EN ISO/IEC 17065 chapter	Guidance
	<p><i>for the operations of the conformity assessment body or the use of such measuring instruments for personal purposes.</i></p> <p><i>A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those measuring instruments, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services. This does not, however, preclude the possibility of exchanges of technical information between the manufacturer and the body for the purposes of conformity assessment.</i></p> <p><i>Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.”</i></p> <p>Section 5: <i>“Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.”</i></p> <p>Section 8: <i>“The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.”</i></p>
4.3 Liability and financing	<p>Requirements of article 27 of MID or article 23 of NAWID shall be considered, in particular:</p> <p>Section 8: <i>“The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.”</i></p> <p>Section 9: <i>“Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.”</i></p>
4.4 Non-discriminatory conditions	Applicable such as described
4.5 Confidentiality	The confidentiality of information is applicable except as far as the notifying authority is concerned for the purpose of assessment and surveillance of the NB, and except concerning information obligations applicable to the NB.

EN ISO/IEC 17065 chapter	Guidance
	<p>Requirements of article 27 of MID or article 23 of NAWID shall be considered, in particular:</p> <p>Section 10:  <i>“The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex II or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.”</i></p> <p>Section 9 Annex II, module B of MID or section 1.8 Annex II, module B of NAWI and Section 4.5 Annex II, module H1 of MID:  <i>“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.”</i></p>
4.6 Publicly available information	Applicable such as described
5 Structural requirements	
5.1 Organizational structure and top management	Applicable such as described
5.2 Mechanism for safeguarding impartiality	Applicable such as described
6 Resource requirements	
6.1 Certification body personnel	<p>The criteria for the competence of the personnel in charge of examinations, tests and judgement should include a good knowledge of the relevant harmonized standard and/or normative documents.</p> <p>The following requirements shall be considered:  Section 7, article 27 of MID or section 7, article 23 of NAWID:  <i>“The personnel responsible for carrying out conformity assessment tasks shall have the following:</i></p> <ul style="list-style-type: none"> <li><i>(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;</i></li> <li><i>(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;</i></li> <li><i>(c) appropriate knowledge and understanding of the essential requirements set out in Annex I and in the relevant instrument-specific Annexes, of the applicable harmonised standards and normative documents and of the relevant provisions of Union harmonisation legislation and of national legislation;</i></li> <li><i>(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.”</i> <p>Section 11, article 27 of MID or section 11, article 23 of NAWID:  <i>“Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant</i></p> </li></ul>

EN ISO/IEC 17065 chapter	Guidance
	<p><i>Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group."</i></p> <p>It should in particular be verified that the NB has a good knowledge of the WELMEC guides and of the work done at the level of NOBOMET, where applicable.</p> <p>For module D and H1, 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 the MID/NAWID.</p>
6.2 Resources for evaluation	<p>EN ISO/IEC 17025 sets out the general requirements a laboratory must meet if it is to be recognised as competent to carry out testing and/or calibration during type examination (module B) and design examination (module H1).</p> <p>For module D and H1, the management system assessment aspects have to be carried out in accordance with the applicable requirement ISO/IEC 17021 namely paragraph 9.</p> <p>Article 27 of MID and article 23 of NAWID, section 6 in particular last paragraph shall be considered:  <i>"A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities."</i></p> <p>As regard the Subsidiaries of and subcontracting by notified bodies, the requirements of article 29 of the MID and 25 of the NAWID shall be considered:  <i>"1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 27 and shall inform the notifying authority accordingly.  2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.  3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.  4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex II."</i></p>
7 Process requirements	
7.1 General	Applicable such as described
7.2 Application	For Modules B, D and H1 the technical documentation as described in article 18 of the MID or annex II 1.3.c of the NAWID is part of the necessary information to complete the certification process.



EN ISO/IEC 17065 chapter	Guidance
	<p>For module B, the notified body shall obtain the application in line with section 3 Annex II, module B of MID or section 1.3 Annex II, module B of NAWID.</p> <p>For module D, the notified body shall obtain the application in line with section 3.1 Annex II, module D of MID or section 2.3.1 Annex II, module D of NAWID.</p> <p>For module H1, the notified body shall obtain the application in line with section 3.1 and 4.2 Annex II, module H1 of MID.</p> <p>The application for type examination can be supported by evaluation, part (or tests for NAWI or AWI) certificates according to the provisions of the WELMEC guide 8.8. In this case, the associated evaluation reports are part of the necessary information to complete the certification process.</p>
7.3 Application review	Applicable such as described
7.4 Evaluation	<p>When an application for type examination is supported by evaluation, part (or test for NAWI or AWI) certificates, the provisions of the WELMEC guide 8.8 are applicable.</p> <p>For module B and F, the notified body shall draw up an evaluation report that records the results of all evaluation activities. When relevant, evaluation report and/or test reports should use the format prescribed in OIML recommendation or WELMEC guides.</p> <p>For module D and H1, the results of the evaluation of the management system should be gathered in an audit or evaluation report.</p> <p>A list should be kept up-to-date, indicating for each category of measuring instruments, the qualified persons that perform each evaluation tasks.</p>
7.5 Review	Applicable such as described
7.6 Certification decision	<p>For type examination certificate (module B), the requirements of section 6 Annex II module B of MID or section 1.6 Annex II module B of NAWID shall be considered.</p> <p>For module F, the requirements of section 3 Annex II module F of MID or section 4.3 Annex II module F of NAWID shall be considered.</p> <p>For design examination certificate (module H1), the requirements of section 4.3 Annex II module H1 of MID shall be considered.</p>
7.7 Certification documentation	Applicable such as described
7.8 Directory of certified products	For type examination certificate (module B), the requirements of section 9 Annex II module B of MID or section 1.8 Annex II module B of NAWID shall be considered.

EN ISO/IEC 17065 chapter	Guidance
	<p>For module D, the requirements of section 7 Annex II module D of MID or section 2.7 Annex II module D of NAWID shall be considered.</p> <p>For module F, the requirements of section 3 Annex II module F of MID or section 4.3 Annex II module F of NAWID shall be considered.</p> <p>For module H1, the requirements of section 3.6 and 4.5 Annex II module H1 of MID shall be considered.</p> <p>For MID certificates according to modules B, D and H1, the notified body shall participate to the WELMEC information exchange system based on national databases.</p>
7.9 Surveillance	<p>For module D, the requirements of section 4 Annex II module D of MID or section 2.4 Annex II module D of NAWID shall be considered.</p> <p>Module F no activities by the notified body are required.</p> <p>For module H1, the requirements of section 5 Annex II module H1 of MID shall be considered.</p>
7.10 Changes affecting certification	Applicable such as described
7.11 Termination, reduction, suspension or withdrawal of certification	<p>For type examination certificate (module B), the requirements of section 9 Annex II module B of MID or section 1.8 Annex II module B of NAWID shall be considered.</p> <p>For module D, the requirements of section 7 Annex II module D of MID or section 2.7 Annex II module D of NAWID shall be considered.</p> <p>For module H1, the requirements of section 3.6 and 4.5 Annex II module H1 of MID shall be considered.</p> <p>The requirements of article 36 and 38 of the MID and article 31 and 33 of the NAWID shall be considered.</p> <p><b><i>“Operational obligations of notified bodies</i></b></p> <p><i>1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex II.</i></p> <p><i>2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.</i></p> <p><i>Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the measuring instrument technology in question and the mass or serial nature of the production process.</i></p> <p><i>In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the measuring instrument with this Directive.</i></p>

EN ISO/IEC 17065 chapter	Guidance
	<p>3. Where a notified body finds that the essential requirements set out in Annex I and in the relevant instrument-specific Annexes or corresponding harmonised standards, normative documents or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.</p> <p>4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a measuring instrument no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.</p> <p>5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.”</p> <p><b>“Information obligation on notified bodies</b></p> <p>1. Notified bodies shall inform the notifying authority of the following:</p> <p>(a) any refusal, restriction, suspension or withdrawal of a certificate;</p> <p>(b) any circumstances affecting the scope of or conditions for notification;</p> <p>(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;</p> <p>(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.</p> <p>2. 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.”</p>
7.12 Records	Applicable such as described
7.13 Complaints and appeals	<p>The requirements of article 37 of MID or article 32 of NAWID shall be considered.</p> <p><i>“Appeal against decisions of notified bodies</i></p> <p><i>Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.”</i></p>
<b>8 Management system requirements</b>	
8.1 Options	The management system shall include the procedures and policies foreseen in article 27 section 6.b & 6.c of the MID or article 23 section 6.b & 6.c of the NAWID.
8.2 General management system documentation (Option A)	Applicable such as described
8.3 Control of documents (Option A)	
8.4 Control of records (Option A)	
8.5 Management review (Option A)	
8.6 Internal audits (Option A)	
8.7 Corrective actions (Option A)	
8.8 Preventive actions (Option A)	

