WELMEC 8.5
Issue 1

# WELMEC

**European cooperation in legal metrology**

# Measuring Instruments Directive 2004/22/EC

## Assessment of Notified Bodies in Charge of Type Examination
## Presumption of Conformity based on EN 45011

May 2007

# WELMEC

**European cooperation in legal metrology**

WELMEC is a co-operation 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 guide is one of those who complete the general guide on the assessment and operation of notified Bodies performing conformity assessment in application of 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 has been put at the end of each one of this series.

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 .

## INTRODUCTION

This document is intended to provide guidance in order to facilitate harmonised assessment of notified bodies (NB) in charge of type examination, that is module B of MID. As the conformity to EN 45011 appears to-day the most appropriate generic standard in order to give presumption of conformity for this activity, this document is built according to the structure of this standard.

This document should be used for specific accreditation of NBs in charge of type examination in application of MID. It could be used for accreditation of bodies in charge of similar conformity assessment procedures with appropriate adaptations, for instance issuing of national type examinations certificates.

However the right column in this document provides guidance that should be used also in the cases where the Member State or the NB have chosen other ways to prove the conformity. Provisions in this column are in fact based:

1 On the specific application to MID, that is, it concerns some requirements that are not applicable in general for similar application in legal metrology.
2 On the metrological culture (legal or general) that any good assessor in legal metrology should have, based on the standards, OIML documents or the state of the art. As it is not probable that each NB or each assessor would think to all these aspects, it has appeared necessary to establish this document in order to ensure an harmonised approach concerning assessment of NBs.

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 he takes the appropriate provisions in order to meet the requirements. This is the case for instance where this guide recalls requirements made to the manufacturer, in which case the NB will demonstrate how it ensures these requirements are met or how it informs the manufacturer of its obligations.

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.

Whether the NB does not claim conformity to the standard, whatever it is written "applicable such as described" or specific guidance is provided in the right column, he has to implement appropriate general provisions corresponding to the paragraph of the standard in his quality system when they are critical for the correct evaluation of the measuring instruments.

This guide is not intended to substitute any other guidance available on the New approach, in particular the Blue Guide (e.g. on sub-contracting). Discrepancies between this guide and guides other than those developed by WELMEC could result in particular of the fact that this guide is more specific for MID and legal metrology.

## PRELIMINARY CONSIDERATIONS ON THE PHILOSOPHY OF THE DOCUMENT

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. To some extend, tests could be performed without knowing the corresponding requirements, in particular the maximum permissible errors. 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 fraudability are concerned.

An other particularity of type examination is that the measuring instrument (MI) 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.

These preliminary considerations, specific to legal metrology and type examination, lead to the necessity to develop the following application guide of EN 45011, dealing in particular with those related to subcontracting.

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 § 2 of annex B of MID. Is 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.

**REQUIREMENTS FOR NOTIFIED BODIES IN CHARGE OF TYPE EXAMINATION**

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| EN 45011<br>Introduction | GUIDE FOR APPLICATION TO<br>TYPE EXAMINATION<br><br>Type examination, also called type or pattern approval for application of some regulations, is a legal metrology certification of product. However it must be considered in the exact sense of MID, with all its specificity, in particular concerning aspects such as ensuring that the manufacturer is capable of consistent productions in conformity with the type.<br><br>This document provides specific guidance to the requirements in EN 45011 in order to give confidence in the capability of a NB for type examination certificates issuing of measuring instruments (MIs) in application of MID. “Issuing of type examination certificates” is sometimes called “approval” in the remaining of the document.<br><br>This document does not cover the case where the approval is granted taking into consideration the quality-system of the manufacturer for design of MIs (module H1), but covers the case where the NB takes into consideration the test results provided by the testing laboratory of the manufacturer.<br><br>Type examination involves not only testing but also examination.<br>Note: Care must be taken on the fact that “examination” is used here to characterise any review of the technical documentation and/or of the instrument in order to assess the technical requirements are met otherwise than by testing, where “examination” is used to characterise test and examination (the latter in the above mentioned sense)in clause 2 of annex B in MID.<br><br>In general, type examination is based only on initial type examination and testing. Other certification activities in legal metrology are the subject of other control activities.<br><br>It is expected such document could be used by bodies in charge of accreditation in the course of the assessment of bodies in charge of type examination.<br><br>The appropriate documents for validating the type are type examination certificates.<br><br>Type examination is a conformity assessment module that can only be performed by a third-party. |
| **1**<br>**Scope** | |
| **1.1** | This document gives the requirements that a notified body has to fulfil in order to establish its competence.<br><br>For application to type examination, “standard” means one or more of the following :<br><br>- annexes of MID containing essential requirements,<br><br>- harmonised standards,<br><br>- normative documents,<br><br>- Other useful international standards.<br><br>Other bodies which may intervene in the scope of a type examination must be considered as subcontractors and shall fulfil the requirements laid down in ISO 17025 - general requirements for the competence of testing and calibration laboratories to testing laboratory activities. However this applies without prejudice of the possibility for a NB to take into consideration the work performed by other NBs in the framework of a WELMEC modular approach for instance, in which case these other NBs are not considered as subcontractors in the sense of the standard but as bodies having to respect themselves the rules applicable to NBs.<br><br>Note: this provision does not restrict the possibility of recognition of evaluations of the performance and characteristics of MIs performed by Issuing Authorities other than European NBs. Such recognition is under the |

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| | responsibility of NBs which should check that the rules provided in this guide have been met.<br><br>A notified body has also to fulfil the requirements in this standard when it performs tests itself.<br><br>This document does not cover the relationships between the national authority responsible for legal metrology and the notified body, where applicable. |
| **1.2** | Guidance for a)<br><br>In general type examination includes these two operations, although c) of clause 2 in annex B of MID makes clear a possibility for only paper work, which in fact has always been used in legal metrology, for instance in some cases of instruments made of parts already approved on similar instruments. This document is not intended to cover in detail where cases a), b) or c) of clause 2 in annex B are implemented. This will be the object of a specific document for application of module B. Whatever is the case implemented by the NB, the statement in "Preliminary considerations on the philosophy of the document" at the beginning of this guide shall be supposed to be fulfilled.<br><br>Guidance for b)<br><br>In general type examination does not include testing or inspection of samples taken from the market. According to the type examination procedure, it may involve sampling from the supplier's stock.<br><br>Guidance for c)<br><br>In general type examination involves a limited number of new MIs but can necessitate testing in the field of operation according to the type examination procedure (endurance test, suitability for use…).<br><br>Guidance for d)<br><br>Only for specific cases.<br><br>Guidance for e)<br><br>Type examination includes design evaluation aspects, particularly for suitability for use, fraudulent aspects and, if applicable some specific design requirements (presence of checking facilities…). |
| **2**<br><br>**References** | **Legal references or comments** |
| | Directive 2004/22/CE on measuring instruments<br><br>ISO 8402:1994 was cancelled and replaced by ISO 9000:2000, Quality management systems – Fundamentals and vocabulary<br><br>ISO 10011-1:1990 was cancelled and replaced by ISO 19011:2002, Guidelines for quality and/or environmental management systems auditing<br><br>ISO/IEC Guide 2:1996 was cancelled and replaced by ISO/IEC 17000:2004, Conformity assessment – Vocabulary and general principles, and ISO/IEC Guide 2:2004 Standardization and related activities — General vocabulary<br><br>ISO/IEC Guide 25:1990 was cancelled and replaced by ISO/IEC 17025:2005, Conformity assessment – General requirements for the competence of testing and calibration laboratories<br><br>ISO/IEC Guide 28:1982 was replaced by ISO/IEC Guide 28:2004, Conformity assessment – Guidance on a third-party certification system for products<br><br>ISO/IEC Guide 39:1988 was cancelled and replaced by ISO/IEC 17020, General criteria for the operation of various types of bodies performing inspection<br><br>Replaced by ISO/IEC Guide 53: 2005, Conformity assessment -- Guidance on the use of an organization's quality management system in product certification<br><br>Relevant harmonised standards<br><br>Relevant normative documents |

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| | Guide to the expression of uncertainty in measurement (GUM), 1995<br>OIML D19: Pattern evaluation and pattern approval, 1988<br>OIML D 14: Training of legal metrology personnel<br>WELMEC guide 4.2 Elements for deciding the appropriate level of confidence in regulated measurements<br>WELMEC guide 8.1 Vocabulary<br>WELMEC Guide 8.0 Generalities on the assessment and operation of notified Bodies performing conformity assessment |
| **3**<br>**Definitions** | |
| | For the purposes of this Guide, the relevant definitions given in ISO/IEC Guide 2, ISO 9000 and ISO/IEC 17000 apply, together with the following definitions.<br>For type examination the terminology is completed by :<br>- VIML International vocabulary of terms in legal metrology, 2000,<br>- International vocabulary of basic and general terms in metrology (VIM), 1993,<br>- OIML D 11 General requirements for electronic measuring instruments,<br>- Terminology in MID,<br>- Terminology in each appropriate harmonised standard or normative document,<br>- WELMEC WG 8's document on vocabulary (in the course of elaboration)...<br>**Type (pattern) evaluation (VIML 2.5)**<br>Systematic examination and testing of the performance of one or more specimens of an identified type (pattern) of measuring instruments against documented requirements, the results of which are contained in the evaluation report, in order to determine whether the type may be approved.<br>Note: "Pattern" is used in legal metrology with the same meaning as "type"…<br>**Evaluator**<br>Person of the staff of the notified body who is in charge of the type evaluation of a MI.<br>**Supervisor**<br>Person of the managerial staff of the notified body who is in charge of validating the work of evaluators and who has an appropriate knowledge of legal metrology.<br>**Testing laboratory**<br>A laboratory that performs tests intended for the type evaluation of an MI, under the responsibility of a notified body.<br>Note : This may be an independent laboratory, a formal part of the notified body or an informal part of the notified body (for example tests may be performed by the evaluator himself/herself), or even if appropriate the testing laboratory of the manufacturer. |
| **3.1**<br>**Supplier** | For this application, "supplier" must be understood as "manufacturer".<br>Note : Although the manufacturer may designate an authorised representative to carry out under his behalf and responsibility some very specific actions as specified in MID, the manufacturer always remains responsible for the conformity of the MI. |

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| **4 Certification body** | |
| **4.1 General provisions** | |
| **4.1.1** | Applicable such as described |
| **4.1.2** | Applicable such as described |
| **4.1.3** | The certification criteria are:<br>- essential requirements in MID,<br>- harmonised standards if applicable,<br>- normative documents if applicable,<br>- other ways to demonstrate the conformity to essential requirements if applicable. |
| **4.1.4** | Applicable such as described |
| **4.2 Organisation** | |
| | Guidance for (others applicable such as described):<br>General: This requirement is applicable for each category of MIs for which the body is notified.<br>2) of c): The policy shall include a commitment to approve only types of MIs which fulfil the full set of applicable essential requirements.<br>f): This is one of the reasons why the concepts of evaluator and supervisor have been introduced.<br>o): In cases where the body practices consultancy for the design of MIs, people in charge of tests, examination or evaluation in general of MIs shall not be under the responsibility of managerial personnel in charge of such advice.<br>Note : It is considered that indicating whether or not a MI complies with requirements in the course of type evaluation or providing explanations on the requirements and on their interpretations is not design consultancy.<br>If the operators are both in charge of examination or evaluation in general and of advising, they may not take part in examination or evaluation related to MIs for which they have advised.<br>The confidentiality of information must not be opposed to the designating authority for purposes of assessment and surveillance |
| **4.3 Operations** | |
| | Before issuing a certificate, the notified body shall ensure that the MI(s) is (are) able to fulfil any requirement without any unauthorised adjustment or modification.<br>Note : In this document "without adjustment" means "without adjustment except those which are intended to be left at the disposal of the user".<br>As far as possible or practicable, the full set of tests should be performed on the same individual instrument. This is particularly important as far as influence factors (See OIML D 11, equivalent to rated operating conditions in MID) are concerned (that is as far as respect of maximum permissible errors is relevant for influence quantities). |

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| | However there are several cases where it may be envisaged not to perform all tests and examinations on the same instrument without adjustment or modification during type evaluation:<br>- the request concerns a family of MIs and it is not economically possible to make all tests on all instruments,<br>- some tests may be destructive,<br>- unfortunately the MI needs to be readjusted in the course of tests,<br>- unfortunately the MI needs modifications in the course of tests or examination,<br>- there is a need to share tests between two (or more) MIs in order to be able to issue quickly a type examination certificate,<br>- the normative test procedure gives specific provisions on the matter,<br>- the request concerns the modification of a type already approved and for economical and technical reasons it is not planned to submit the modified type to the full set of examinations and tests,<br>- …<br>Each time a body in charge of type examination does not perform (or does not require) the full set of examinations and tests on any concerned MI (in particular in the case of a family of MIs) and/or each time adjustments or modifications are performed in the course of type approval, this body must have established a clear policy in order to be sure that any MI covered by the application is able to fulfil all applicable provisions without any non-allowed adjustment and/or modification.<br>There are also cases were testing and examination of the instrument are not necessary.<br>This shall be established in conformity with the 3 possibilities for type examination as laid down into clause 2 of annex B in MID. |
| **4.4 Subcontracting** | |
| | The notified body shall not subcontract the activities concerning judging on the conformity.<br>Only tasks that are clearly identified and described may be subcontracted to a testing laboratory. This leads subcontracting to be limited to tests or part of examination of same nature than testing, that is for which clear and exhaustive procedures are available and validated by the notified body.<br>Subcontracting in series (subcontractors subcontracting to other subcontractors) is prohibited.<br>Where the laboratory that performed the tests is not fully independent of the manufacturer this shall clearly appear in the type evaluation report.<br>Traditionally, tests performed for type evaluation were performed by third-party laboratories.<br>However, the introduction of the concepts of quality assurance may allow the possibility for tests performed by the laboratory of the manufacturer to be recognised sufficient for demonstrating the conformity to the corresponding essential requirements, provided he can give confidence (by the way of accreditation in particular) for the specific task, that is for the very tests applicable at type examination and for the very MI. For more information on the recognition of tests provided by the manufacturer refer to the top level guide 8.0 and also to the specific WELMEC Guide 8.3 Application of module B.<br>In all the cases, when the NB accepts tests performed by an external testing laboratory, the tests shall be performed by a laboratory accredited for the specific task or by a laboratory having demonstrated its competence in an equivalent way. There shall be provisions to ensure that:<br>- the MI subjected to tests is the one being the object of type examination,<br>- the MI subjected to tests has not been adjusted or modified in a non-authorised way,<br>- the test conditions were those applicable to type evaluation,<br>- the communicated test report is in conformity with the original version. |

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| | The best way to provide evidence of the appropriate competence for testing is conformity to ISO/IEC 17025, but in any case the evidence concerning compliance with the provisions in ISO/IEC 17025 shall exist and shall be sufficiently clear and established.<br><br>The contractor (in the sense the one who decides what tests to be performed and how to perform them) is considered to be the notified body even if tests are ordered directly by the manufacturer to a test laboratory which is not the notified body.<br><br>Note : The acceptance of test reports delivered to the manufacturer outside the scope of a type examination (before the first examination has been made by the notified body) may be a problem because it is often very difficult to be sure which MI was tested. |
| **4.5**<br>**Quality system** | |
| **4.5.1** | Applicable such as described |
| **4.5.2** | The documentation includes in particular:<br>- MID,<br>- all relevant harmonised standards,<br>- all relevant normative document,<br>- all relevant WELMEC guides,<br>- any relevant standard relative to metrology, and quality assurance,<br>- any document interpreting or modifying the above documents,<br>- test procedures and examination procedures (as far as the later may exist), criteria for acceptance of tests and examinations. |
| **4.5.3** | Guidance for (others applicable such as described):<br><br>h): The role and responsibilities of evaluators and supervisors shall be clearly described for all categories of MIs.<br><br>j): Participants in mutual recognition programmes on type examination shall be part of this list. The NB has not to assess the competence of such participants in the case of recognition programmes organised at the WELMEC level or at the EU Commission level.<br>See also 4.4<br><br>l): Testing procedures shall be available. They shall be in conformity with international standardised procedures when applicable.<br><br>Formal examination procedures may be difficult to establish as far as suitability for use or fraudability are concerned. This is why special experience and competence of the staff in this field is necessary and why subcontracting of these aspects is not possible in general.<br><br>The procedures shall cover the following particular aspects:<br><br>- sharing tests on two or more MIs,<br><br>- general conditions for determining the list of tests to be performed in the case of a modification to a similar type previously approved,<br><br>- general conditions for determining the list of tests to be performed in the case of a family of MIs.<br><br>In the case where tests are started before examination, this shall be documented.<br><br>There shall be a policy and procedures on how to assess that the manufacturer is capable to ensure consistent productions. This is a specific aspect of MID and could be limited to aspects ensuring conformity to the type and that instruments conforming to the type do not demand non reasonable operations to be put in conformity with applicable requirements, on accuracy in particular. |

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| **4.6** | |
| **4.6.1** | It shall be taken into consideration of provisions in MID and in the national regulation. |
| **4.6.2** | Guidance for:<br><br>a) It shall be taken into consideration of provision in MID and of national regulation.<br><br>b) In particular the rules concerning complementary type examination for MIs whose type is already approved (modification…) shall be established.<br><br>c) Provisions shall ensure that the manufacturer is informed of its responsibilities when he uses an authorised representative, in particular concerning conformity to type.<br><br>There shall be provisions to inform the recipient that any significant modification to an approved type must be notified to the notified body. There shall be at least examples of significant and non-significant modifications. |
| **4.7 Internal audits and management reviews** | |
| **4.7.1** | Applicable such as described |
| **4.7.2** | Applicable such as described |
| **4.8 Documentation** | |
| **4.8.1** | Applicable such as described |
| **4.8.2** | Applicable such as described |
| **4.9 Records** | |
| **4.9.1** | Applicable such as described |
| **4.9.2** | Records related to type examination should be kept available at least ten years after the end of validity of the type examination certificate. |
| **4.10 Confidentiality** | |
| **4.10.1** | Applicable such as described |
| **4.10.2** | Applicable such as described |

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| **5**<br>**Certification body personnel** | |
| **5.1**<br>**General** | |
| **5.1.1** | Examinations, tests and judgement shall be performed by evaluators having the required competence. The outcome of these tasks shall be validated by a supervisor.<br><br>A list shall be kept up-to-date, indicating for each category of measuring instruments:<br>- the qualified supervisor,<br>- the qualified evaluators,<br>- the staff in process to be qualified.<br>**NOTE :** The person in charge of signing the type examination certificates may be different from the supervisor. |
| **5.1.2** | This provision applies to any activity critical for type examination.<br>If the notified body subcontracts tests, the corresponding requirements are transferred to the subcontractor's laboratory.<br>Personnel in the course of training or support personnel (in process to be qualified) shall be in charge of only simple activities or activities that are sufficiently described. They may take part in tests or examination but they cannot have the responsibility for this.<br>The traceability of personnel involved in each type evaluation, including the supervisor, shall be ensured.<br>**NOTE :** It is not necessary that all elements of the type evaluation report are validated by the supervisor but this report shall show all elements taken into consideration. |
| **5.2**<br>**Qualification criteria** | |
| **5.2.1** | The personnel in charge of type examination activities shall have the competence as described in … (WELMEC WG 8's documents n° 1-4 and 1-5) |
| **5.2.2** | Applicable such as described |
| **5.2.3** | Training methods for the personnel include in particular the necessity :<br>- for the body to participate actively in international work in the field of legal metrology (OIML or WELMEC activities, international meetings and seminars),<br>- for the participants in this international activity, to inform the rest of the relevant personnel.<br>Traceability of these participations and information shall be ensured. |
| **6**<br>**Changes in the certification requirements** | |
| | The changes in the requirements shall be in conformity with MID. |

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| **7**<br>**Appeals, complaints and disputes** | |
| **7.1** | Applicable such as described |
| **7.2** | Applicable such as described |
| **8**<br>**Application for certification** | |
| **8.1**<br>**Information on the procedure** | |
| **8.1.1** | The NB shall have, for each category, a detailed list of documents that the manufacturer has to provide with the type approval request. It shall also have a procedure for checking that any required document is provided.<br>There shall be a clear policy on what is allowed to do the Authorised representative on behalf of the manufacturer, established in conformity with § 9 of annex B. |
| **8.1.2** | Applicable such as described |
| **8.1.3** | Applicable such as described |
| **8.1.4** | Applicable such as described |
| **8.2**<br>**The application** | Title only |
| **8.2.1** | Guidance for (others applicable such as described):<br>b): The manufacturer shall provide the technical documentation has described in MID; the policy of the NB shall be in principle to start the instruction of the request only when the complete technical documentation has been provided. In particular cases where this principle may not be respected, reason for this will be recorded with further analysis of the consequences in particular on the validity of the list of examination and tests to be performed. |
| **8.2.2** | Guidance for (others applicable such as described):<br>b) The manufacturer shall indicates if it has implemented an harmonised standard, a normative document or an other solution to give presumption of conformity to essential requirements.<br>Any change on this approach during the process of evaluation shall be documented. |
| **9**<br>**Preparation for evaluation** | |
| **9.1** | This concerns in particular the acceptability of the type examination request.<br>Guidance for:<br>a) As far as necessary the manufacturer shall be asked to clarify his request.<br>b) This applies also to subcontracted tests and test facilities of the manufacturer when applicable.<br>c) The national regulation may impose the language. However if the regulation allows the NB to accept other languages, there shall be consideration on the possibility to demonstrate to the |

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| | State Authority that the action of the NB is correct. |
| **9.2** | Applicable such as described |
| **9.3** | Applicable such as described |
| **9.4** | Applicable such as described |
| **10 Evaluation** | Applicable such as described |
| **11 Evaluation report** | |
| | When the evaluation report includes two or more parts (examination report(s), test report(s), final judgement on the evaluation) this shall be indicated.<br>In particular, the following shall appear if applicable:<br>- whether all applicable tests were performed,<br>- whether tests where shared between two or more MIs,<br>- whether adjustment and/or modifications were performed during the tests.<br>If such procedures were allowed, reasons leading to the conclusion that they had no influence on the judgement on the MI shall be provided in the type evaluation report.<br>Analogous considerations apply in the case of a complementary type evaluation for a modification of a MI already approved or in the case of a family of instruments.<br>The evaluation report shall be clearly documented on the capacity for the instrument of meeting all the requirements where no test and no examination of the instrument were performed.<br>The evaluation report shall at least bear the name and signature of :<br>- the evaluator,<br>- the supervisor.<br>The description in the evaluation report, together with the technical documentation describing the MI as provided by the manufacturer, shall enable the conclusion that the characteristics of the evaluated MI conforms to those of the MI for which the type examination is requested. This description is of the greatest importance in the case where the request concerns a family or group of MIs rather than a single MI. |
| **12 Decision on certification** | |
| **12.1** | The reasons shall be only metrological. |
| **12.2** | Applicable such as described |
| **12.3** | For more information refer to the specific WELMEC Guide 8.3 Application of module B for the presentation of an EC type examination certificate (under consideration for H1 although Guide 8.3 may provide useful information).<br>Guidance for (others applicable such as described):<br>2) of b): This provision may be understood in the way that only the reference to MID or to the national regulation transposing MID is necessary. However when the fact that the manufacturer has decided to follow other routes than the conformity to European harmonised standards or to OIML normative documents results in specific procedures for testing and/or |

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| | examining measuring instruments, these specific procedures shall be indicated in the type approval certificate or its annexes. This apply to verification procedures for new, repaired or in service measuring instruments, and to necessary information for market surveillance as well.<br>c) The validity is imposed by MID. |
| **12.4** | Applicable such as described |
| **13<br>Surveillance** | |
| **13.1** | A NB in charge of type examination has no surveillance to perform. |
| **13.2** | Applicable such as described within the following limits.<br>MID makes obligation to the manufacturer to ensure the conformity to the type. It is the responsibility of the manufacturer to ask for complementary approvals in the case of modifications to the approved type.<br>The responsibility of the NB is limited in putting the limit of validity of the approval in the certificate. In addition, for application of this guide, the NB shall have provisions for recalling the manufacturers of the near end of validity of the certificates at an appropriate time. This provision is intended to limit the risk of production of measuring instruments not covered by a valid certificate.<br>There is no quality system to take in consideration. |
| **13.3** | Not applicable |
| **13.4** | Not applicable |
| **14<br>Use of licences, certificates and marks of conformity** | |
| **14.1** | The use of type examination certificates shall be in conformity with MID. |
| **14.2** | Applicable such as described |
| **14.3** | Applicable such as described |
| **15<br>Complaints to suppliers** | Applicable such as described |

Annexe : Overview of documents useful for the application of MID

(This document is indicated as white in between shaded areas)

| Module | General guide | QS of NB according to | Specific guide for assessment of bodies | Specific guide for application of the module | QS of manufacturer according to | Specific guide for QS of manufacturers |
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| **A** | **Generalities on the assessment and operation of notified bodies performing conformity assessment *** | **No NB** | **Not applicable** | **No** | **Not applicable** | **Not applicable** |
| **A1** | | **EN ISO/IEC 17020 or EN 45011 *** | **?** | **?** | **Not applicable** | **Not applicable** |
| **B** | | **EN 45011 *** | **Assessment of notified bodies in charge of type examination *** | **Application of module B** | **Not applicable** | **Not applicable** |
| **C** | | **No NB** | **Not applicable** | **No** | **Not applicable** | **Not applicable** |
| **C1** | | **EN ISO/IEC 17020 or EN 45011 *** | ? | **?** | **Not applicable** | **Not applicable** |
| **D** | | **EN 45012 **** | **No** | **Application of module D** | **EN ISO 9001 + EN ISO/IEC 17025 for tests** | **Presumption of conformity of the quality system of manufacturers** |
| **D1** | | **EN 45012 **** | **No** | **?** | **EN ISO 9001+ EN ISO/IEC 17025 for tests** | **?** |
| **E** | | **EN 45012 **** | **No** | **?** | **EN ISO 9001+ EN ISO/IEC 17025 for tests** | **?** |
| **E1** | | **EN 45012 **** | **No** | **?** | **EN ISO 9001+ EN ISO/IEC 17025 for tests** | **?** |
| **F** | | **EN ISO/IEC 17020 or EN 45011 *** | **To be drafted** | **?** | **Not applicable** | **Not applicable** |
| **F1** | | **EN ISO/IEC 17020 or EN 45011 *** | **?** | **?** | **Not applicable** | **Not applicable** |
| **G** | | **EN 45011 or EN ISO/IEC 17020 *** | **?** | **?** | **Not applicable** | **Not applicable** |
| **H** | | **EN 45012 **** | **No** | **?** | **EN ISO 9001+ EN ISO/IEC 17025 for tests** | **?** |
| **H1** | | **DEC: EN 45011** | **?** | **Application of module H1** | **EN ISO 9001+ EN ISO/IEC 17025 for tests** | **Presumption of conformity of the quality system of manufacturers** |
| | | **QS: EN 45012 **** | **No** | | | |

* The following can be said concerning the alternative for A1, C1, F, F1 and G. In general the choice of one of these two standards is depending on whether the NB practices most of its activities on design certification of products (EN 45011) or product verification (EN ISO/IEC 17020 ; only type A inspection bodies). But in practice a specific consideration should be paid on the complexity of the instrument's category: in the case where the study of the design is complex for application of module G, preference should be given to EN 45011.

** As long as it is not replaced by ISO/CEI 17021

*** See foreword of Guide 8.0

For testing refer to 3.3 of Guide 8.0

A question mark indicates that until now no need was identified or no decision was taken.