WELMEC 8.7
2018

# WELMEC

European Cooperation in Legal Metrology

# Measuring Instruments Directive (2014/32/EU):

## Assessment of Notified Bodies Designated for Module F based on EN ISO/IEC 17020

# 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 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 (annex B).

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 (in particular see Blue-Guide-2006), but the guidance provided in this document represents the considered view of WELMEC as being the best practice to be followed. This Guide shall be followed entirely when reference is made to it.

## INTRODUCTION

This document is intended to provide guidance in order to facilitate harmonised assessment of notified bodies (NB) in charge of declaration of conformity to type based on product verification that is module F of MID.

As the conformity to EN ISO/IEC 17020 appears to be one of the two most appropriate generic standards in order to give presumption of conformity for this activity, this document is built according to the structure of this standard.

The other appropriate generic standard in order to give presumption of conformity for these conformity assessment modules in relation to MID and NAWID is the EN ISO/IEC 17065. For conformity assessment modules F for which EN ISO/IEC 17065 is also possible (see WELMEC guide 8.0), the WELMEC guide 8.5 could be used alternatively.

In addition, accreditation bodies should be invited to use the provisions in this document for specific accreditation of bodies in charge of module F in application of MID. It could be used also for accreditation of bodies in charge of similar conformity assessment procedures with appropriate adaptations, for instance initial verifications.

This document applies to inspection bodies of type A (inspection body providing third party inspections) only, even if the EN ISO/IEC17020 refers also to type B or C bodies. – *refer to MID article 27 §3 (A conformity assessment body shall be a third-party body independent of the organisation or the measuring instrument it assesses.)*

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 on:

1. the specific application to MID, that is, it concerns some requirements that are not applicable in general for similar application in legal metrology.
2. 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 a harmonised approach concerning assessment of NBs.

In all the cases, where a provision exists in the right column, it shall 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 makes reference to 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.

The expression "national Authority” is used in this document. This may mean "notifying authority", "authority responsible for assessment and surveillance of notified bodies", "market surveillance authority" or "authority responsible for metrological supervision of instruments in use". This may also cover a single authority or two or more authorities (for example a central authority and a local authority). The appropriate authority depends on the organisation of the State and of the type of responsibility of course.

# REQUIREMENTS FOR NOTIFIED BODIES IN CHARGE OF MODULE F

## 1 - SCOPE

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
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| | | This International Standard contains requirements for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities. | This document provides specific guidance on the application of EN ISO/IEC 17020 in order to give confidence in the capability of a notified body (NB) to implement the conformity assessment module “Declaration of conformity to type based on product verification” (module F) for application of MID. Except specific aspects it is not intended to recall obligations made to manufacturers. |
| | | It applies to inspection bodies of type A, B or C, as defined in this International Standard, and it applies to any stage of inspection<br><br>NOTE The stages of inspection include design stage, type examination, initial inspection, in-service inspection or surveillance. | These requirements are established for the bodies to be notified and government services in charge of designation, notification, and surveillance of these bodies. It is also expected that provisions in line with this document will be used by accreditation bodies for accreditation of bodies in charge of module F.<br><br>Declaration of conformity to type based on product verification, similar to operations called initial verification for application of some regulations, is a legal metrology certification of a product. However, it shall be considered in the exact sense of MID, with all its specificity, in particular concerning aspects such as marking affixed by the manufacturer.<br><br>In the following guidance, examinations, tests and judgement performed by a NB in the framework of declaration of conformity to type based on product verification are simply called “verification”. |
| | | | These requirements do not cover aspects on testing that are specified in EN ISO 17025. |
| | | | The following documents shall also be considered as far as relevant:<br>Directive 2014/32/CE on measuring instruments<br>Relevant harmonised standards<br>Relevant normative documents<br>Relevant OIML RECOMMANDATIONS (testing requirements)<br>Guide to the expression of uncertainty in measurement (GUM), 1995<br>OIML D 14: Training of legal metrology personnel<br>All relevant WELMEC guides and in particular:<br>WELMEC guide 4.2 Elements for deciding the appropriate level of confidence in regulated measurements<br>WELMEC guide 8.1 Vocabulary |

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| | | | WELMEC guides referred to in the table provided in the annex to this guide and in particular guide 8.0 „Generalities on the assessment and operation of notified Bodies performing conformity assessment” |

## 2 - NORMATIVE REFERENCES

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
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| | | The following referenced documents are indispensable for the application of this document.<br><br>ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles* | |

## 3 – TERMS AND DEFINITIONS

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
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| 1 | | 3.1 inspection | Declaration of conformity to type based on product verification (module F) is considered as inspection as far as the notified body is concerned. |
| 2 | | 3.5 inspection body | A body in charge of module F is an inspection body |

## 4 - GENERAL REQUIREMENTS

## 4.1 – IMPARTIALITY AND INDEPENDANCE

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
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| 3 | Absence of commercial or financial pressure<br><br>Absence of external pressure | 4.1.1<br>4.1.2<br>4.1.3<br>4.1.4<br>4.1.5<br>4.1.6 | Refer to article 27 in MID<br><br>**Requirements relating to notified bodies** in particular § 4, 5 and 8<br><br>4. 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 for the operations of the conformity assessment body or the use of such measuring instruments for personal purposes.<br>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 |

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| | | | 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.<br>The second subparagraph does not, however, preclude the possibility of exchanges of technical information between the manufacturer and the body for the purposes of conformity assessment.<br>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.<br><br>5. 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.<br><br>8. 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. 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. |

## 4.2 – CONFIDENTIALITY

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
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| | **Confidentiality** | 4.2.1<br>4.2.2.<br>4.2.3 | Refer to article 27 in MID<br>**Requirements relating to notified bodies** in particular § 10<br><br>10. 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. |

## 5 - STRUCTURAL REQUIREMENTS

## 5.1 – ADMINISTRATIVE REQUIREMENTS

| N° | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
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| | Juridical structure | 5.1.1 | Applicable such as described |
| | Identification | 5.1.2 | Applicable such as described |
| | Desciption of activities | 5.1.3 | Declaration of conformity to type based on product verification (module F) is defined in MID. Any contract shall conform to MID. |
| | Liability | 5.1.4 | Refer to article 27<br>**Requirements relating to notified bodies** in particular § 9<br>9. 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. |
| | Commercial conditions | 5.1.5 | The documentation shall be conforming to the scope of the designation and shall indicate in particular the nature of the work for which the body is designated as well as the references to his designation. |

## 5.2 – ORGANISATION AND MANAGEMENT

| N° | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
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| | Organisation enabling to maintain capability | 5.2.1 | Applicable such as described |
| | | 5.2.2 | Applicable such as described |
| | Description of the responsibilities | 5.2.3. | Applicable such as described |
| | Relationships between functions | 5.2.4 | Applicable such as described |
| | Designation of the technical manager | 5.2.5 | The technical manager is responsible for :<br>- the definition and qualification of testing and verification means;<br>- the verification procedures and their implementation ;<br>- any other relevant technical document of the notified body |
| | Nomination of deputies | 5.2.6. | Applicable such as described |
| | Description of positions | 5.2.7 | Applicable such as described |

## 6 - RESOURCE REQUIREMENTS

## 6.1 – PERSONEL

| N° | SCOPE | CHAPTERS OF | APPLICATION GUIDE |
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| | | ISO/IEC 17020:2012 STANDARD | |
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| | | 6.1.1 | Applicable such as described |
| | Personnel available | 6.1.2 | Applicable such as described |
| | Qualification of the personnel | 6.1.3 | Refer to article 27 in MID<br>**Requirements relating to notified bodies** in particular § 5, 6 and 7<br><br>5. 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.<br><br>6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex II and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.<br>At all times and for each conformity assessment procedure and each kind or category of measuring instruments in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:<br>(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;<br>(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;<br>(c) procedures for the performance of activities which take 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.<br>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.<br><br>7. The personnel responsible for carrying out conformity assessment tasks shall have the following: |

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| | | | (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;<br>(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;<br>(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;<br>(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out. |
| | | 6.1.4 | Applicable such as described |
| | | 6.1.5 | Applicable such as described |
| | Up-to-date training | 6.1.6 | Refer to article 27 in MID<br><br>**Requirements relating to notified bodies** in particular § 7<br>7. The personnel responsible for carrying out conformity assessment tasks shall have the following:<br>(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;<br>(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;<br>(c) appropriate knowledge and understanding of the essential requirements set out in Annex I and in the relevant instrumentspecific Annexes, of the applicable harmonised standards and normative documents and of the relevant provisions of Union harmonisation legislation and of national legislation;<br>(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out. |
| | | 6.1.7 | Applicable such as described |
| | | 6.1.8 | Applicable such as described |
| | | 6.1.9 | Applicable such as described |
| | Recording of qualifications | 6.1.10 | Applicable such as described |
| | Remuneration of the personnel | 6.1.11 | Refer to article 27 in MID<br>**Requirements relating to notified bodies** in particular § 6<br><br>6. The impartiality of the body, its director and staff shall be guaranteed. The remuneration of the body shall not depend on the results of the tasks it carries out. The remuneration of the body's director and staff shall not depend on the number of tasks carried out or on the results of such tasks. |

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| | | 6.1.12 | Applicable such as described |
| | Confidentiality | 6.1.13 | Refer to article 27 in MID<br>**Requirements relating to notified bodies** in particular § 10<br><br>10. 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. |

## 6.2 – FACILITIES AND EQUIPMENT

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
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| | Necessary facilities and equipment | 6.2.1 | Refer to article 27 in MID<br>**Requirements relating to notified bodies** in particular § 4<br>4. The body shall be capable of carrying out all the conformity assessment tasks for which it has been designated, whether those tasks are carried out by the body itself or on its behalf and under its responsibility. It shall have at its disposal the necessary staff and shall have access to the necessary facilities for carrying out in a proper manner the technical and administrative tasks entailed in conformity assessment.<br><br>If the notified body uses manufacturer's facilities and equipment, this shall be documented and recorded in the contract as defined in § 3.3 of EN IS/IEC 17020. In this case, it remains the responsibility of the notified body to ensure that test means are suitable and traceable to standards. |
| | Rules for access to and use of facilities and equipment | 6.2.2 | Applicable such as described |
| | Continued suitability of facilities and equipment | 6.2.3 | The verification is carried out in suitable locations and conditions as MID does not provide information on this. As far as available or relevant, the NB shall apply the applicable provisions in the most suitable standards or WELMEC guides or normative documents or OIML recommendations and documents. In any case the verification will be performed in a location and conditions ensuring that the MI in use will meet the applicable requirements were properly installed. The notified body shall ensure that all environmental conditions applicable to the instrument are adapted, especially regarding the statutory regulations, and if applicable, regarding the type examination certificate. This applies whether the verification is carried out on the location of installation of the |

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| | | | instrument or not. If the environmental conditions are not suitable, in particular when the MI is tested on site, the body shall refuse to carry out the verification. |
| | Identification of equipment | 6.2.4. | The identification shall be comprehensive, clear, without ambiguity and shall be recorded (See also § 6.2.15 of EN IS/IEC 17020) |
| | Maintaining equipment procedures | 6.2.5 | Applicable such as described |
| | Calibration program | 6.2.6 | Requirements concerning traceability should be in line with standard ISO 17025 and/or ISO 10012, and especially:<br>- the testing facilities shall be initially qualified,<br>- the testing facilities shall be comprehensively identified.<br>- the testing facilities shall (in all the cases) be calibrated or verified before being put into service or back into service.<br>- the frequency of verification and/or calibration of the testing facilities shall conform to applicable standards or WELMEC guides.<br>- the testing facilities shall clearly carry the limit of validity of the previous verification and/or calibration.<br>- the responsibilities of the metrological management person (as defined in the ISO 10012) shall be clearly defined and ensured. |
| | Traceability of the working standards | 6.2.7 | The test facilities used for verification shall be identified distinguishing those that are critical for the conformity of MIs (in particular those used for calibration of the intended measurand).<br>The test facilities that are critical for the conformity shall be traceable to standards according to ILAC-P 10:2013 “ILAC Policy on Traceability of Measurement Results”.<br><br>Those that are not critical (for instance a chronometer used to determine the duration of a test) may be qualified and verified according to internal rules ensuring appropriate results. This shall be recorded. In all the cases the calibration uncertainties shall be compatible with the applicable metrological requirements (WELMEC guide 4.2, Elements for deciding the appropriate level of confidence in regulated measurements, may be considered). |
| | Use of reference standards<br><br>Traceability of reference standards | 6.2.8 | The list of standards shall allow clear identification of reference and working standards.<br><br>Guidance on § 6.2 of EN ISO/IEC 17020 is applicable |
| | In-service checks between recalibrations | 6.2.9 | Applicable such as described |

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| | Traceability of reference materials | 6.2.10 | Applicable such as described when applicable |
| | Purchasing procedures | 6.2.11 | This applies in particular to purchasing of metrological equipment, as well as testing, calibration and verification of this equipment. |
| | Assessment of stored items | 6.2.12 | Applicable such as described |
| | Hardware and software equipment | 6.2.13 | Applicable to testing equipment as well as to technical procedures.<br><br>The provisions shall ensure in any case that the previous data will be still available during the period of validity of the calibration or verification of the test facilities and/or the period defined in § 6.2 of EN ISO/IEC 17020, even if the hardware or the operating system has been replaced. If the documents are computerised, the specific and critical software shall be initially, then periodically qualified under the body's responsibility. When a specific application in made from a general commercial software (e.g. Excel), this applies only to the specific application of the general commercial software. |
| | Procedures for dealing with defective equipment | 6.2.14 | Applicable such as described<br><br>NOTE: the mentioned equipment is the one used by the body and not the instruments to be verified. |
| | Recording relevant information | 6.2.15 | Applicable such as described.<br>Apply standards when available. |

## 6.3 – SUBCONTRACTING

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
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| | General policy for subcontracting | 6.3.1 | The NB may delegate only part of examinations and tests for which he has established clear procedures and formats of reports, and which do not result in delegating his capacity of judgement even partially.<br>Conditions in which this delegation is possible shall be clearly established.<br><br>In any case the NB shall have the competence to perform himself the subcontracted activities (see point 6 of article 27 in MID). If parts of the procedures established by the NB are based on procedures established by a subcontractor, these parts shall be the object of a careful review by the NB prior he may accept them.<br><br>6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex II and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. |

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| | | | At all times and for each conformity assessment procedure and each kind or category of measuring instruments in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:<br>(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;<br>(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;<br>(c) procedures for the performance of activities which take 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.<br><br>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. |
| | Acceptance of subcontracting by the client | 6.3.2 | Refer to article 27 in MID<br>**Requirements relating to notified bodies** in particular § 5<br><br>5. 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<br><br>The subcontractor shall be acceptable by the client and this acceptance is recorded. |
| | | 6.3.3 | Refer to article 27 in MID<br>**Requirements relating to notified bodies** in particular § 6<br><br>6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex II and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. |

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| | Recording all subcontracting | 6.3.4 | Applicable such as described |

## 7 - PROCESS REQUIREMENTS
## 7.1 – INSPECTION METHODS AND PROCEDURES

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
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| | Defined methods and procedures | 7.1.1 | The verification methods and procedures shall be described with an appropriate level of details and shall conform to most suitable standards or WELMEC guides or normative documents or OIML recommendations and documents where available. They shall contain information on:<br>- examinations and tests to be performed on the instruments,<br>- conditions in which the identification mark of the NB is affixed,<br>- conditions in which the authorisation of affixing marking during the manufacturing process is delivered,<br>- conditions in which a verification report and a certificate of conformity are established (see § 13.1 of EN ISO/IEC 17020 for more detail) |
| | Adequate inspection planning documents | 7.1.2 and interpretation of results. | In the case of verifications based on statistical methods it shall be established that the criteria laid down in the point 5.3 of Annex II module F of MID are met. |
| | Non-standard methods or procedures | 7.1.3 | There shall be a procedure how to deal with cases where the standard procedures cannot be used.<br><br>Deviation from standard procedures shall be described in the verification report. The reasons for these procedures shall be justified, as well as their relevance and the estimation of the measurement uncertainties. Depending on the level of flexibility accepted by the notifying authority, information of this authority about the new procedures developed shall be made in advance or the information shall be available afterwards Non-standard procedures for permanent application are to be reported to the national authority. |
| | Availability of documents | 7.1.4 | Applicable such as described |
| | Contract control system | 7.1.5 | Applicable such as described |
| | | 7.1.6 | Applicable such as described |
| | On time recording | 7.1.7 | The recording procedures shall apply to each verified instrument (or group of instruments as foreseen in MID). They shall allow to determine retrospectively, for each instrument (or group):<br>- its identification (including the reference to the type examination certificate)<br>- the examinations and tests performed, |

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| | | | - the results and conclusions of these examinations and tests,<br>- where applicable, conditions in which an evaluation of parts have been taken into consideration,<br>- where applicable, conditions in which examinations and/or tests have been performed by another body. |
| | Calculations and transfer of data | 7.1.8 | Applicable such as described |
| | Safety instructions | 7.1.9 | Applicable such as described |

## 7.2 – HANDLING INSPECTION ITEMS AND SAMPLES

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
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| | Identification of inspected items<br><br>Consulting the client in case of doubt | 7.2.1 | Applicable such as described |
| | Necessary preparation | 7.2.2 | In particular, conditions in which an evaluation of parts performed by another body is taken into consideration shall be documented. The content of the TEC shall be taken into consideration if specific measures have to be taken. |
| | Recording of apparent abnormalities | 7.2.3 | Applicable such as described |
| | Avoiding deterioration | 7.2.4 | Applicable such as described |

## 7.3 – INSPECTION RECORDS

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
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| | Record system | 7.3.1<br>7.3.2 | Applicable such as described |

## 7.4 – INSPECTION REPORTS AND INSPECTION CERTIFICATES

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
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| | Report and certificate | 7.4.1 | A distinction is made between:<br>- the document recording the results of examinations and tests performed in the course of verifications, let at the disposal of the national Authority for surveillance purposes, and called in this guide the « verification report », and<br>- the certificate of conformity in respect of the examinations and tests carried out by the NB, delivered to the manufacturer (see 4.2 of Annex II module F in MID), and called in this guide the « certificate of conformity ». |

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| | | | The verification report and the certificate of conformity are two different documents in the sense of this guide, even if they may use common elements. However, this does not prevent having one combined document bearing all the information and with one copy delivered to the manufacturer and another one kept by the NB at the disposal of the National Authority. |
| | Recordings content | 7.4.2 | The recordings include the results of the examination and testing of the instruments but also on the conclusion on the conformity of the instrument to the type examination certificate. If applicable, the body shall keep a record of the authorisations he gives to manufacturers concerning apposition of his identification number on the instruments and on the possibility to apply marking during the process of manufacturing.<br><br>The NB should keep records for statistical data (for instance, number of verified instruments, refusal rate, average error and variance of these errors) in order to be capable to cooperate with the national Authority. |
| | | 7.4.3 | Applicable such as described |
| | Content of the report or certificate | 7.4.4 | The verification report and the certificate of conformity shall conform to provisions in annex A.<br><br>The verification reports shall be kept at the disposal of the national Authority for at least ten years.<br><br>The copy of the certificates of conformity shall be kept at the disposal of the national Authority for at least ten years (4.2 and 5.4 of Annex II module F in MID).<br><br>Where the verification report or certificate of conformity contains results supplied by subcontractors, these results shall be clearly identified. |
| | Correction and additions to reports and certificates | 7.4.5 | Amended certificates are uniquely identified and include a statement referring to the original certificate (serial number). |

## 7.5 – COMPLAINTS AND APPEALS

| N° | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
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| | Procedure for dealing with complaints | 7.5.1 | This procedure shall be part of the designation request. Its existence shall be mentioned in the contract specified in § 3.3 of EN ISO/IEC 17020. This procedure concerns also the demands, |

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| | | | warnings or complaints issued by the Authorities from other member States. |
| | Procedure for appeals | 7.5.2 | Applicable such as described |
| | | 7.5.3 | Applicable such as described |
| | | 7.5.4 | Applicable such as described |
| | | 7.5.5 | Applicable such as described |

## 7.6 – COMPLAINTS AND APPEALS PROCESS

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
|---|---|---|---|
| | Procedure for appeals | 7.6.1 | Applicable such as described |
| | | 7.6.2 | Applicable such as described |
| | | 7.6.3 | Applicable such as described |
| | | 7.6.4 | Applicable such as described |
| | | 7.6.5 | Applicable such as described |

## 8 – MANAGEMENT SYSTEM REQUIREMENTS

## 8.1 – OPTIONS

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
|---|---|---|---|
| | | 8.1. General<br>8.1.2 Option A | The quality policy declaration shall contain commitment on:<br>- respect of this standard;<br>- respect of the statutory requirements and in particular:<br>- accepting only instruments that conform to the applicable requirements;<br>- accepting only instruments that conform to the approved type as described in the type examination certificate. |
| | | 8.1.3 Option B | Applicable such as described |

## 8.2 – MANAGEMENT SYSTEM DOCUMENTATION (OPTION A)

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
|---|---|---|---|
| | | 8.2.1 | Applicable such as described |
| | | 8.2.2 | Applicable such as described |
| | | 8.2.3 | Applicable such as described |
| | | 8.2.4 | Applicable such as described |
| | | 8.2.5 | Applicable such as described |

## 8.3 – CONTROL OF DOCUMENTS (OPTION A)

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
|---|---|---|---|

| | | | |
|---|---|---|---|
| | | 8.3.1 | Applicable such as described |
| | | 8.3.2 | Applicable such as described |

## 8.4 – CONTROL OF RECORDS (OPTION A)

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
|---|---|---|---|
| | | 8.4.1 | Applicable such as described |
| | | 8.4.2 | (which is 10 years from the date the product has been put on the market according to Annex II module F point 4.2) |

## 8.5 – MANAGEMENT REVIEW (OPTION A)

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
|---|---|---|---|
| | | 8.5.1 | Applicable such as described |
| | | 8.5.2 | Applicable such as described |
| | | 8.5.3 | Applicable such as described |

## 8.6 – INTERNAL AUDITS (OPTION A)

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
|---|---|---|---|
| | | 8.6.1 | Applicable such as described |
| | | 8.6.2 | Applicable such as described |
| | | 8.6.3 | Applicable such as described |
| | | 8.6.4 | Applicable such as described |
| | | 8.6.5 | Applicable such as described |

## 8.7 – CORRECTIVE ACTIONS (OPTION A)

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
|---|---|---|---|
| | | 8.7.1 | Applicable such as described |
| | | 8.7.2 | Applicable such as described |
| | | 8.7.3 | Applicable such as described |
| | | 8.7.4 | Applicable such as described |

## 8.8 – PREVENTIVE ACTIONS (OPTION A)

| Nº | SCOPE | CHAPTERS OF ISO/IEC 17020:2012 STANDARD | APPLICATION GUIDE |
|---|---|---|---|
| | | 8.8.1 | Applicable such as described |
| | | 8.8.2 | Applicable such as described |
| | | 8.8.3 | Applicable such as described |