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WELMEC

European cooperation in legal metrology

Measuring Instruments Directive 2004/22/EC
Assessment of Notified Bodies Designated for Module F based on EN ISO/IEC 17020

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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 the introduction to WELMEC.

WELMEC is publishing a number of Guides 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 these documents are representing 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-2001), 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.

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.

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 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. According to the case 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 AND NORMATIVE DEFINITIONS

N°	SCOPE	CHAPTERS OF EN ISO/IECIEC 17020 STANDARD (provisional column)	APPLICATION GUIDE
		1.1 This European standard specifies general criteria for the competence of impartial bodies performing inspection irrespective of the sector involved. It also specifies independence criteria	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.
		1.2 This standard is intended for the use of inspection bodies and their accreditation bodies as well as other bodies concerned with recognizing the competence of inspection bodies.	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.
		1.3 This set of criteria may have to be interpreted when applied to particular sectors, or to in-service inspection	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 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. 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”.
		1.4 This standard does not cover testing laboratories, certification bodies or the suppliers' declaration of conformity, the criteria for which are contained in other European Standards of the EN 45000 series	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: Directive 2004/22/CE on measuring instruments
			Relevant harmonised standards
			Relevant normative documents Relevant OIML RECOMMANDATIONS (testing requirements)
			Guide to the expression of uncertainty in measurement (GUM), 1995
			OIML D 14: Training of legal metrology personnel

			All relevant WELMEC guides and in particular: WELMEC guide 4.2 Elements for deciding the appropriate level of confidence in regulated measurements
			WELMEC guide 8.1 Vocabulary
			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 - DEFINITIONS

Pt n°	SCOPE	CHAPTERS OF EN ISO/IECIEC 17020 STANDARD	APPLICATION GUIDE
		2.1 Inspection Examination of a product design, product, service, process or plant, and determination of their conformity with specific requirements or, on the basis of professional judgement, general requirements. NOTE 1 Inspection of processes includes personnel, facilities, technology and methodology. NOTE 2 The results of inspection may be used to support certification	Declaration of conformity to type based on product verification (module F) is considered as inspection as far as the notified body is concerned.
		2.2 Inspection body Body, that performs inspection. NOTE A body can be an organization, or part of an organization. For other definitions those given in EN 45020:1993 are applicable	A body in charge of module F is an inspection body

3 - ADMINISTRATIVE REQUIREMENTS

Pt n°		CHAPTERS OF EN ISO/IEC 17020 STANDARD	APPLICATION GUIDE
1	**Juridical structure**	**3.1** The inspection body, or the organization of which it forms a part, shall be legally identifiable	Applicable such as described
2	**Identification**	**3.2** An inspection body that is part of an organization involved in functions other than inspection shall be identifiable within that organization.	Applicable such as described
3	**Description of activities**	**3.3** The inspection body shall have documentation which describes its functions and the technical scope of activity for which it is competent. The precise scope of an inspection will be determined by the terms of the individual contract or work order.	Declaration of conformity to type based on product verification (module F) is defined in MID. Any contract shall conform to MID.
4	**Definition of the service**		In particular the contract or the procedure shall clearly indicate if the verification will be based on examinations and testing of each instrument or application of statistical methods.
5	**Liability**	**3.4** The inspection body shall have adequate liability insurance unless its	Refer also to § 7 of article 12 in MID.

		liability is assumed by the State in accordance with national laws or by the organization of which it forms a part	
6	**Commercial conditions**	**3.5** The inspection body shall have documentation describing the conditions on which it does business unless it is part of an organization and provides inspection services only to that organization.	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.
7	**Auditable accountability**	**3.6** The inspection body, or the organization of which it forms a part, shall have independently audited accounts	Applicable such as described

4 - INDEPENDANCE, IMPARTIALITY AND INTEGRITY

Pt n°	SCOPE	CHAPTERS OF EN ISO/IEC 17020 STANDARD	APPLICATION GUIDE
9 10	**Absence of commercial or financial pressure** **Absence of external pressure**	**4.1** The personnel of the inspection body shall be free from any commercial, financial and other pressures which might affect their judgement. Procedures shall be implemented to ensure that persons or organizations external to the inspection body, cannot influence the results of inspections carried out.	Refer to article 12 in MID, in particular § 1, 2 and 6.
11	**Independence**	**4.2** The inspection body shall be independent to the extent that is required with regard to the conditions under which it performs its services. Depending on these conditions it shall meet the minimum criteria stipulated in one of the normative annexes A, B or C. **4.2.1 Type A inspection body** The inspection body providing "third party" services shall meet the criteria of annex A (normative). **4.2.2 Type B inspection body** The inspection body which forms a separate and identifiable part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects and has been established to supply inspection services to its parent organization shall meet the criteria of annex B (normative). **4.2.3 Type C inspection body** The inspection body which is involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects or of similar	Refer to article 12 in MID, in particular § 1, 2 and 6. Only Type A inspection bodies may be designated for application of MID.

		competitive items and may supply inspection services to other parties not being its parent organization shall meet the criteria of annex C (normative).	

5 - CONFIDENTIALITY

Pt n°	SCOPE	CHAPTERS OF EN ISO/IEC 17020 STANDARD	APPLICATION GUIDE
12	**Confidentiality**	The inspection body shall ensure confidentiality of information obtained in the course of its inspection activities. Proprietary rights shall be protected.	Refer also to § 8 of article 12 in MID.

6 - ORGANISATION AND MANAGEMENT

Pt n°	SCOPE	CHAPTERS OF EN ISO/IEC 17020 STANDARD	APPLICATION GUIDE
13	**Organisation enabling to maintain capability**	**6.1** The inspection body shall have an organization that enables it to maintain the capability to perform its technical functions satisfactorily.	Applicable such as described
14 15	**Description of the responsibilities** **Relationships between functions**	**6.2**The inspection body shall define and document the responsibilities and reporting structure of the organization. Where the inspection body also supplies certification and/or testing services, the relationship between its functions shall be clearly defined	Applicable such as described
16	**Designation of the technical manager**	**6.3** The inspection body shall have a technical manager however named, who is qualified and experienced in the operation of the inspection body and who has overall responsibility that the inspection activities are carried out in accordance with this standard. He shall be a permanent employee. NOTE Where an inspection body consists of several divisions with different scopes of activity, there may be one technical manager per division.	The technical manager is responsible for : - the definition and qualification of testing and verification means; - the verification procedures and their implementation ; - Any other relevant technical document of the notified body.
17	**Supervision**	**6.4** The inspection body shall provide effective supervision by persons familiar with the inspection methods and procedures, the objectives of the inspection and the assessment of the examination results	Applicable such as described Supervisions are recorded. Supervision applies to subcontractors if any.
18	**Nomination of deputies**	**6.5** The inspection body shall have named persons who will deputize in the absence of any manager, however named, responsible for inspection services	Applicable such as described
19 20	**Description of positions** **Training and**	**6.6** Each position category affecting the quality of the inspection services shall be described. These job descriptions shall include the	Applicable such as described

	experience	requirements for education, training, technical knowledge and experience	

7 - QUALITY SYSTEM

Pt n°	SCOPE	CHAPTERS OF EN ISO/IEC 17020 STANDARD	APPLICATION GUIDE
21	**Definition of the quality policy**	**7.1** The inspection body's management shall define and document its policy and objectives for, and commitment to quality, and shall ensure that this policy is understood, implemented and maintained at all levels in the organization.	The quality policy declaration shall contain commitment on: - Respect of this standard; - respect of the statutory requirements and in particular: - accepting only instruments that conform to the applicable requirements; - accepting only instruments that conform to the approved type as described in the type examination certificate.
22	**Implementing an effective quality system**	**7.2** The inspection body shall operate an effective quality system appropriate to the type, range and volume of work performed	Applicable such as described
23 24 25	**Documented quality system** **Quality manual** **Content of the quality manual**	**7.3** The quality system shall be fully documented. There shall be a Quality Manual, which shall contain the information required by this standard and as listed in annex D (informative)	The quality system shall contain the necessary information for each category of instruments for which the body is designated.
26 27	**Designation of a responsible person for quality assurance**	**7.4**The management of the inspection body shall designate a person who, irrespective of other duties, shall have defined authority and responsibility for quality assurance within the inspection body. This person shall have direct access to top management	Applicable such as described
27	**Maintaining the quality system**	**7.5** The quality system shall be maintained relevant and current under the responsibility of the same person	Applicable such as described
28	**Maintaining the documentation**	**7.6** The inspection body shall maintain a system for control of all documentation relating to its activities. It shall ensure that: a) the current issues of the appropriate documentation are available at all relevant locations and to all relevant staff; b) all changes of documents or amendments to documents are covered by the correct authorization and processed in a manner which will ensure timely availability at the appropriate location; c) superseded documents are	The system of control shall include information of the notifying authority.

		removed from use throughout the organization, but one copy is filed for a determined period; d) other parties, as necessary, are notified of changes.	
29	**Internal audits**	**7.7** The inspection body shall carry out a system of planned and documented internal quality audits to verify compliance with the criteria of this standard and the effectiveness of the quality system. The personnel performing the audits shall be suitably qualified and independent from the functions being audited.	The maximum periodicity for internal audits is one year. In the case of teams operating independently (for instance from different geographical locations) each team shall be audited at least every two years. All applicable statutory provisions and this guidance shall be in the scope of the internal audits.
30	**Feedback and corrective actions**	**7.8** The inspection body shall have documented procedures for dealing with feedback and corrective action whenever discrepancies are detected in the quality system and/or in the performance of inspections	It shall be foreseen that: - corrective actions are documented and placed at the disposal for the national Authority, - circumstances necessitating report to the notifying Authority are defined, - the notifying Authority is informed as quickly as possible of any discrepancy which has affected the conformity of measuring instruments, with reference to articles 19 and 20 of MID.
31	**Quality system reviews**	**7.9** The management of the inspection body shall review the quality system at appropriate intervals to ensure its continuing suitability and effectiveness. The results of such reviews shall be recorded	The maximum periodicity for these reviews is one year. All applicable statutory provisions shall be the object of the reviews.

8 - PERSONNEL

Pt n°	SCOPE	CHAPTERS OF EN ISO/IEC 17020 STANDARD	APPLICATION GUIDE
32	**Personnel available**	**8.1** The inspection body shall have a sufficient number of permanent personnel with the range of expertise to carry out its normal functions.	
33	**Qualification of the personnel**	**8.2** The staff responsible for inspection shall have appropriate qualifications, training, experience and a satisfactory knowledge of the requirements of the inspections to be carried out. They shall have the ability to make professional judgements as to conformity with general requirements using examination results and to report there on.	Refer to article 12 in MID, in particular § 3, 4 and 5.
34	**Ability to judgement**		

35 36	**Technological knowledge of the personnel** **Understanding the significance of deviations**	They shall also have relevant knowledge of the technology used for the manufacturing of the products inspected, of the way in which products or processes submitted to their inspections are used or are intended to be used, and of the defects which may occur during use or in service. They shall understand the significance of deviations found with regard to the normal use of the products or processes concerned.	
37 38	**Up-to-date training** **Adapted training**	8.3 The inspection body shall establish a documented training system to ensure that the training of its personnel, in the technical and administrative aspects of the work in which they will be involved, is kept up-to-date in accordance with its policy. The training required shall depend upon the ability, qualifications and experience of persons involved. The inspection body shall establish the necessary stages of training for each of its personnel. These may include: a) an induction period; b) a supervised working period with experienced inspectors; c) continuation training, throughout employment, to keep pace with developing technology	Refer to article 12 in MID, in particular § 5. In addition, all the personnel of the body likely to have contacts with the national Authority (reception, telephone…) shall be aware of the verification activities and of the names of the responsible persons.
39	**Recording of qualifications**	**8.4** Records of academic or other qualifications, training and experience of each member of its personnel shall be maintained by the inspection body	Applicable such as described
40	**Conducting the staff**	**8.5** The inspection body shall provide guidance for the conduct of its staff	Applicable such as described
41	**Remuneration of the personnel**	**8.6** The remuneration of persons engaged in inspection activities shall not directly depend on the number of inspections carried out and in no case on the results of such inspections	Refer also to § 6 of article 12 in MID.

9 - FACILITIES AND EQUIPMENTS

Pt n°	SCOPE	CHAPTERS OF EN ISO/IEC 17020 STANDARD	APPLICATION GUIDE
42	**Necessary facilities and equipments**	**9.11** The inspection body shall have available to it suitable and adequate facilities and equipment to permit all activities associated with the inspection services to be carried out.	Refer also to § 4 of article 12 in MID. If the notified body uses manufacturer's facilities and equipments , 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.

43	**Rules for access to and use of facilities and equipments**	**9.2** The inspection body shall have clear rules for the access to and the use of specified facilities and equipment	Applicable such as described
44	**Continued suitability of facilities and equipments**	**9.3** The inspection body shall ensure the continued suitability of the facilities and the equipment mentioned in 9.1 for their intended use	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 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.
45	**Identification of equipments**	**9.4** All such equipment shall be properly identified	The identification shall be comprehensive, clear, without ambiguity and shall be recorded (See also § 9.15 of EN IS/IEC 17020)
46	**Maintaining equipments procedures**	**9.5** The inspection body shall ensure that all such equipment is properly maintained, in accordance with documented procedures and instructions	Applicable such as described
47	**Calibration program**	**9.6** The inspection body shall ensure that, where appropriate, equipment is calibrated before being put into service and thereafter according to an established programme.	Requirements concerning traceability should be in line with standard ISO 17025 and/or ISO 10012, and especially : - the testing facilities shall be initially qualified, - the testing facilities shall be comprehensively identified. - the testing facilities shall (in all the cases) be calibrated or verified before being put into service or back into service. - the frequency of verification and/or calibration of the testing facilities shall conform to applicable standards or WELMEC guides. - the testing facilities shall clearly carry the limit of validity of the previous verification and/or calibration. - the responsibilities of the metrological management person (as defined in the ISO 10012) shall be clearly defined and ensured.
48	**Traceability of the working standards**	**9.7**The overall programme of calibration of equipment shall be designed and operated so as to ensure that wherever applicable measurements	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).

		made by the inspection body are traceable to national and International Standards of measurement where available. Where traceability to national or International Standards measurement is not applicable, the inspection body shall provide satisfactory evidence of correlation or accuracy of inspection results	The test facilities that are critical for the conformity shall be traceable to standards according to ILAC-P 10:2002 "ILAC Policy on Traceability of Measurement Results". 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).
49 50	**Use of reference standards** **Traceability of reference standards**	**9.8** Reference standards of measurement held by the inspection body shall be used for calibration only and for no other purpose. Reference standards of measurement shall be calibrated by a competent body that can provide traceability to a national or International Standard of measurement.	The list of standards shall allow clear identification of reference and working standards. Guidance on § 9.7 of EN ISO/IEC 17020 is applicable
51	**In-service checks between recalibrations**	**9.9** Where relevant, equipment shall be subjected to in-service checks between regular recalibrations	Applicable such as described
52	**Traceability of reference materials**	**9.10** Reference materials shall where possible be traceable to national or International Standard reference materials	Applicable such as described when applicable
53	**Purchasing procedures**	**9.11** Where relevant to the quality of inspection services, the inspection body shall have procedures for: a) selection of qualified suppliers; b) issuing appropriate purchasing documents; c) inspection of received materials; d) ensuring appropriate storage facilities.	This applies in particular to purchasing of metrological equipment, as well as testing, calibration and verification of this equipment.
54	**Assessment of stored items**	**9.12** Where applicable the condition of stored items shall be assessed at appropriate intervals to detect deterioration	Applicable such as described
55	**Hardware and software equipment**	**9.13** If the inspection body uses computers or automated equipment in connection with inspections, it shall ensure that: a) computer software is tested in order to confirm that it is adequate for use; b) procedures are established and implemented for protecting the integrity of data; c) computer and automated equipment is maintained in order to ensure proper functioning; and	Applicable to testing equipment as well as to technical procedures 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 § 12.3 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

		d) procedures are established and implemented for maintenance of security of data.	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.
56	**Procedures for dealing with defective equipment**	**9.14**The inspection body shall have documented procedures for dealing with defective equipment. Defective equipment shall be removed from service by segregation, prominent labelling or marking. The inspection body shall examine the effect of defects on previous inspections	Applicable such as described NOTE: the mentioned equipment is the one used by the body and not the instruments to be verified.
57	**Recording relevant information**	**9.15** Relevant information on the equipment shall be recorded. This will normally include identification, calibration and maintenance	Applicable such as described Apply standards when available

10 - INSPECTION METHODS AND PROCEDURES

Pt n°	SCOPE	CHAPTERS OF EN ISO/IEC 17020 STANDARD	APPLICATION GUIDE
58	**Defined methods and procedures**	**10.1** The inspection body shall use the methods and procedures for inspection which are defined in the requirements, against which conformity is to be determined	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: - examinations and tests to be performed on the instruments, - conditions in which the identification mark of the NB is affixed, - conditions in which the authorisation of affixing marking during the manufacturing process is delivered, - conditions in which a verification report and a certificate of conformity are established (see § 13.1 of EN ISO/IEC 17020 for more detail).
59	**Adequate inspection planning documents**	**10.2** The inspection body shall have and use adequate documented instructions on inspection planning and on standard sampling and inspection techniques, where the absence of such instructions could jeopardize the efficiency of the inspection process. Where applicable, this requires sufficient knowledge of statistical techniques to ensure statistically sound sampling procedures and the correct processing 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 F of MID are met.

60	**Non-standard methods or procedures**	**10.33** When the inspection body has to use inspection methods or procedures which are non-standard, such methods and procedures shall be appropriate and fully documented	There shall be a procedure how to deal with cases where the standard procedures cannot be used. 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.
61	**Availability of documents**	**10.4** All instructions, standards or written procedures, worksheets, check lists and reference data relevant to the work of the inspection body shall be maintained up-to-date and be readily available to the staff.	Applicable such as described
62	**Contract control system**	**10.5** The inspection body shall have a contract or work order control system which ensures that: a) work to be undertaken is within its expertise and that the organization has adequate resources to meet the requirements; b) the requirements of those seeking the inspection body's services are adequately defined and that special conditions are understood so that unambiguous instructions can be issued to staff performing the duties to be required; c) work being undertaken is controlled by regular review and corrective action; d) completed work is reviewed to confirm that requirements have been met.	Applicable such as described
63	**On time recording**	**10.6** Observations and/or data obtained in the course of inspections shall be recorded in a timely manner to prevent loss of relevant information.	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): - its identification (including the reference to the type examination certificate) - the examinations and tests performed, - the results and conclusions of these

			examinations and tests, - where applicable, conditions in which an evaluation of parts have been taken into consideration, - where applicable, conditions in which examinations and/or tests have been performed by an other body.
64	**Calculations and transfer of data**	**10.7** All calculations and data transfers shall be subject to appropriate checks	Applicable such as described
65	**Safety instructions**	**10.8** The inspection body shall have documented instructions for carrying out inspection safely.	Applicable such as described

11 - HANDLING INSPECTION SAMPLES AND ITEMS

Pt n°	SCOPE	CHAPTERS OF EN ISO/IEC 17020 STANDARD	APPLICATION GUIDE
66	**Identification of inspected items**	**11.1** The inspection body shall ensure that samples and items to be inspected are uniquely identified to avoid confusion regarding the identity of such items at any time.	Applicable such as described
67 68	**Recording of apparent abnormalities** **Consulting the client in case of doubt**	**11.2** Any apparent abnormalities notified to, or noticed by, the inspector shall be recorded before commencement of the inspection. Where there is any doubt as to the item's suitability for the inspection to be carried out, or where the item does not conform to the description provided, the inspection body shall consult the client before proceeding.	Applicable such as described
69	**Necessary preparation**	**11.3** The inspection body shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the inspection body.	In particular, conditions in which an evaluation of parts performed by an other body is taken into consideration shall be documented.
70	**Avoiding deterioration**	**11.4** The inspection body shall have documented procedures and appropriate facilities to avoid deterioration or damage to inspection items while under its responsibility.	Applicable such as described

12 - RECORDS

Pt n°	SCOPE	CHAPTERS OF EN ISO/IEC 17020 STANDARD	APPLICATION GUIDE
71	**Record system**	**12.1** The inspection body shall maintain a record system to suit its particular circumstances and to	Applicable such as described

		comply with applicable regulations.	
72	**Recordings content**	**12.2** The records shall include sufficient information to permit satisfactory evaluation of the inspection	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. 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.
73	**Records storage**	**12.3** All records shall be safely stored for a specified period, held secure and in confidence to the client, unless otherwise required by law.	All ercords shall be kept at the disposal of the national Authority for a duration identical to the one applicable to the certificate of conformity (at least ten years).

13 - INSPECTION REPORTS AND INSPECTION CERTIFICATES

Pt n°	SCOPE	CHAPTERS OF EN ISO/IEC 17020 STANDARD	APPLICATION GUIDE
74	**Report and certificate**	**13.1** The work carried out by the inspection body shall be covered by a retrievable inspection report and/or inspection certificate	A distinction is made between : - 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 - 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 F in MID), and called in this guide the « certificate of conformity ». 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
75	**Content of the report or certificate**	**13.2** The inspection report and/or inspection certificate shall include all the results of examinations and the determination of conformity made from these results as well as all information needed to understand and interpret them. All this information shall be reported correctly, accurately, and clearly. Where the inspection report or	The verification report and the certificate of conformity shall conform to provisions in annex A. The verification reports shall be kept at the disposal of the national Authority for at least ten years The copy of the certificates of conformity shall be

		inspection certificate contains results supplied by subcontractors, these results shall be clearly identified.	kept at the disposal of the national Authority for at least ten years (4.2 and 5.4 of Annex F in MID).
76	**Approval and signature of reports and certificates**	**13.3** Inspection reports and inspection certificates shall be signed or otherwise approved by authorized staff members only.	Applicable such as described
77	**Correction and additions to reports and certificates**	**13.4** Corrections or additions to an inspection report or inspection certificate after issue shall be recorded and justified in accordance with the relevant requirements of this section.	Amended certificates are uniquely identified and include a statement referring to the original certificate (serial number).

14 - SUBCONTRACTING

Pt n°	SCOPE	CHAPTERS OF EN ISO/IEC 17020 STANDARD	APPLICATION GUIDE
78	**General policy for subcontracting**	**14.1** The inspection body shall itself normally perform the inspections which it contracts to undertake	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. Conditions in which this delegation is possible shall be clearly established. In any case the NB shall have the competence to perform himself the subcontracted activities (see point 4 of article 12 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.
79 80	**Competence of subcontractors** **Acceptance of subcontracting by the client**	**14.2** When an inspection body subcontracts any part of the inspection, it shall ensure and be able to demonstrate that its subcontractor is competent to perform the service in question and where applicable complies with the criteria stipulated in the relevant standard of the EN 45000 series. The inspection body shall advise the client of its intention to subcontract any part of the inspection. The subcontractor shall be acceptable to the client.	See article 12 points 3 and 4 of MID
81	**Recording all subcontracting**	**14.3** The inspection body shall record and retain details of its investigation of the competence and compliance of its subcontractors. The inspection body shall maintain a register of all subcontracting.	Applicable such as described
82	**Assessment of**	**14.4** Where the inspection body subcontracts certain specialized activities, it shall have access to a	Applicable such as described

	subcontractors	qualified and experienced person who is able to form an independent assessment of the results of these subcontracted activities. The responsibility for the determination of conformity with the requirements rests with the inspection body itself.	See also 14.1 of EN ISO/IEC 17020

15 - COMPLAINTS AND APPEALS

Pt n°	SCOPE	CHAPTERS OF EN ISO/IEC 17020 STANDARD	APPLICATION GUIDE
83	**Procedure for dealing with complaints**	**15.1** The inspection body shall have documented procedures for dealing with complaints received from clients or other parties about the inspection body's activities	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, warnings or complaints issued by the Authorities from other member States.
84	**Procedure for appeals**	**15.2**The inspection body shall have documented procedures for the consideration and resolution of appeals against the results of its inspections, where these are carried out under legally delegated authority	Applicable such as described
85	**Records of complaints and appeals**	**15.3** A record shall be maintained of all complaints and appeals and of the actions taken by the inspection body.	Applicable such as described

16 - COOPERATION

Pt n°	SCOPE	CHAPTERS OF EN ISO/IEC 17020 STANDARD	APPLICATION GUIDE
86	**Co-operation and exchanges**	The inspection body is expected to participate in an exchange of experience with other inspection bodies and in the Standardization processes as appropriate	The body shall have implemented provisions in order to recall with appropriate efficiency the obligations made to manufacturers in application of module F. Co-operation with the national Authority shall be provided for purposes of surveillance and audits of the body. This includes means and information necessary for the statutory surveillance. If applicable co-operation shall be also provided to accreditation bodies.

87	**technical co-operation**		The NB shall commit himself in participating into intercomparisons organised at the European level.

ANNEX A

Content of the verification report

A verification report (whether it is established on a paper sheet or an electronic file) shall bear at least the following information:

- *title « Verification report » in respect of the examinations and tests carried out »*
- *specific identification of the report*
- *name and address of the notified body*
- *name and address of the manufacturer*
- *address of the verification location (if different)*
- *date of the verification and if relevant issue date*
- *identification of the instrument(s) subject to verification*
- *reference to the type examination certificate*
- *main statutory identification elements of the instrument*
- *any other useful information on the verification (verification of every instrument or statistical verification…)*
- *reference to the verification procedure*
- *any other useful information on the test conditions (method ,conditions, means…) together with either uncertainties of measurements or reference to documents establishing these uncertainties*
- *detailed results of the examinations ant tests performed*
- *conclusion versus conformity to the type examination certificate*
- *conclusion versus conformity to essential requirements*
- *clear identification of the person who has performed the verification and (when applicable) identification and signature of the authorized person to issue the document*

The document shall be paginated (number of the page/total number of pages) and shall bear on each page an unambiguous identification of the report .

Content of the certificate of conformity

A certificate of conformity shall bear at least the following information:

- *title « certificate of conformity in respect of the examinations and tests carried out »*
- *specific identification of the certificate*
- *name and address of the notified body*
- *name and address of the manufacturer*
- *address of the verification location (if different)*
- *date of the verification and if relevant issue date*
- *identification of the instrument(s) subject to verification including identification of main elements*
- *reference to the type examination certificate*
- *list of examination and tests performed, reference to the verification procedure, identification of the batch if statistical verification, reference of the associated test report*
- *conclusion versus conformity to the type examination certificate*
- *conclusion versus conformity to appropriate essential requirements*
- *identification and signature of the authorized person to issue the document and optionally identification of the person who has performed the verification*

The document shall be paginated (number of the page/total number of pages) and shall bear on each page an unambiguous identification of certificate.

ANNEX B

Overview of documents useful for the application of MID

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

	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
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		ISO/IEC 17021	No	Application of module D	EN ISO 9001 + EN ISO/IEC 17025 for tests	Presumption of conformity of the quality system of manufacturers
D1		ISO/IEC 17021	No	?	EN ISO 9001+ EN ISO/IEC 17025 for tests	?
E		ISO/IEC 17021	No	?	EN ISO 9001+ EN ISO/IEC 17025 for tests	?
E1		ISO/IEC 17021	No	?	EN ISO 9001+ EN ISO/IEC 17025 for tests	?
F		EN ISO/IEC 17020 or EN 45011 *	Assessment of notified bodies in charge of module F	?	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		ISO/IEC 17021	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: ISO/IEC 17021	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.

** 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.