



Assessment of Notified Bodies for Module F

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Presentation

1. The module F
2. Which standard to assess Module F Notified Bodies ?
3. WELMEC guide 8.7

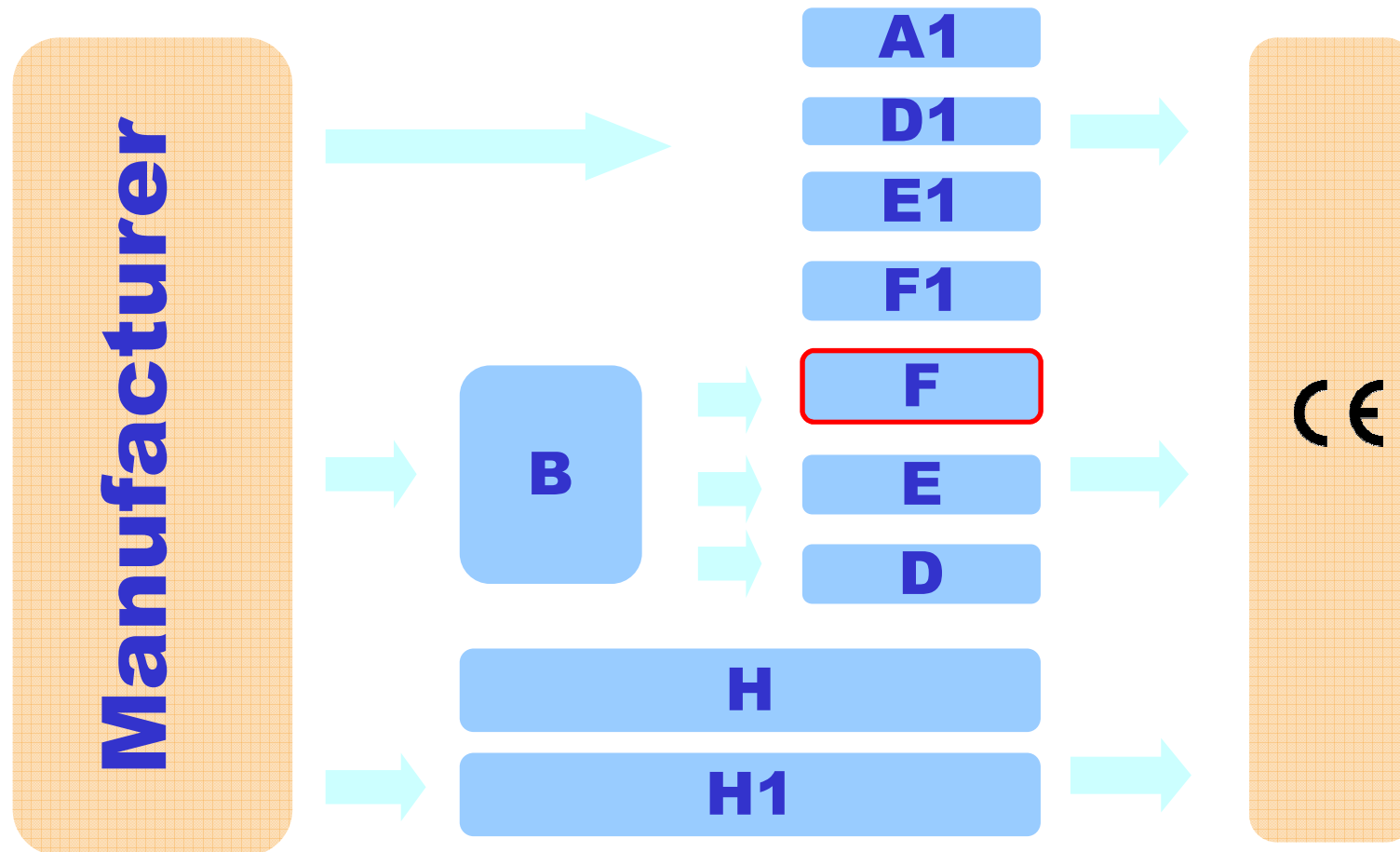


The module F

- Declaration of conformity to type based on product verification
- Part of a conformity assessment procedure (B+F)



The module F





The module F

➤ Obligation of the manufacturer:

- ✓ Takes all measures necessary to ensure conformity of the manufactured instruments with the approved type as described in the TEC and the requirements of the MID
- ✓ Keeps the certificates of conformity available for inspection by the NA for 10 years after the certification of the instrument.
- ✓ Affixes the CE marking and the supplementary metrology marking
- ✓ Draw up a declaration of conformity



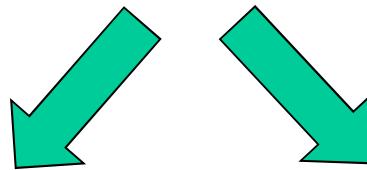
The module F

- **Obligation of the Notified Body (NB):**
 - ✓ Carries out the appropriate examinations and tests, or have them carried out, to check the conformity of the instruments with the type as described in the TEC and the requirements of the MID
 - ✓ Issues a certificate of conformity in respect of the examinations and tests carried out, and affixes its identification number to each approved instrument or have it affixed under its responsibility.



The module F

- **Verification of each instrument**
 - ✓ All instruments are individually examined and tested, as set out in normative documents or harmonised standard
 - ✓ The NB issues a certificate of conformity for each approved instrument



Unit verification

Statistical verification



The module F

➤ Statistical verification

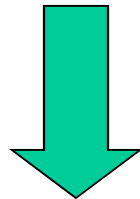
- ✓ Manufacturer takes all measures in order that the manufacturing process ensures the homogeneity of each lot produced, and presents homogeneous lots
- ✓ A random sample is drawn from each lot
- ✓ Statistical procedure shall meet the annex F §7.3 requirements (Based on attributes → see [WELMEC guide 8.10](#))
- ✓ If a lot is accepted all instruments of the lot are approved, except those that were found non conform.
- ✓ If a lot is rejected, the NB shall take measures to prevent the placing on the market of that lot. If frequent rejections of lots the NB may suspend the statistical verification.



Which standard to assess Module F NB ?

➤ § 3.4 of the blue guide draft:

- ✓ EN17025, EN 17020 or EN 17065 can be considered as the most appropriate for the assessment of the bodies seeking notification for module F.
- ✓ WELMEC proposes to use EN 17020



WELMEC guide 8.7

~~"Old Approach"~~
~~"New Approach"~~
"New Approach v2.0"

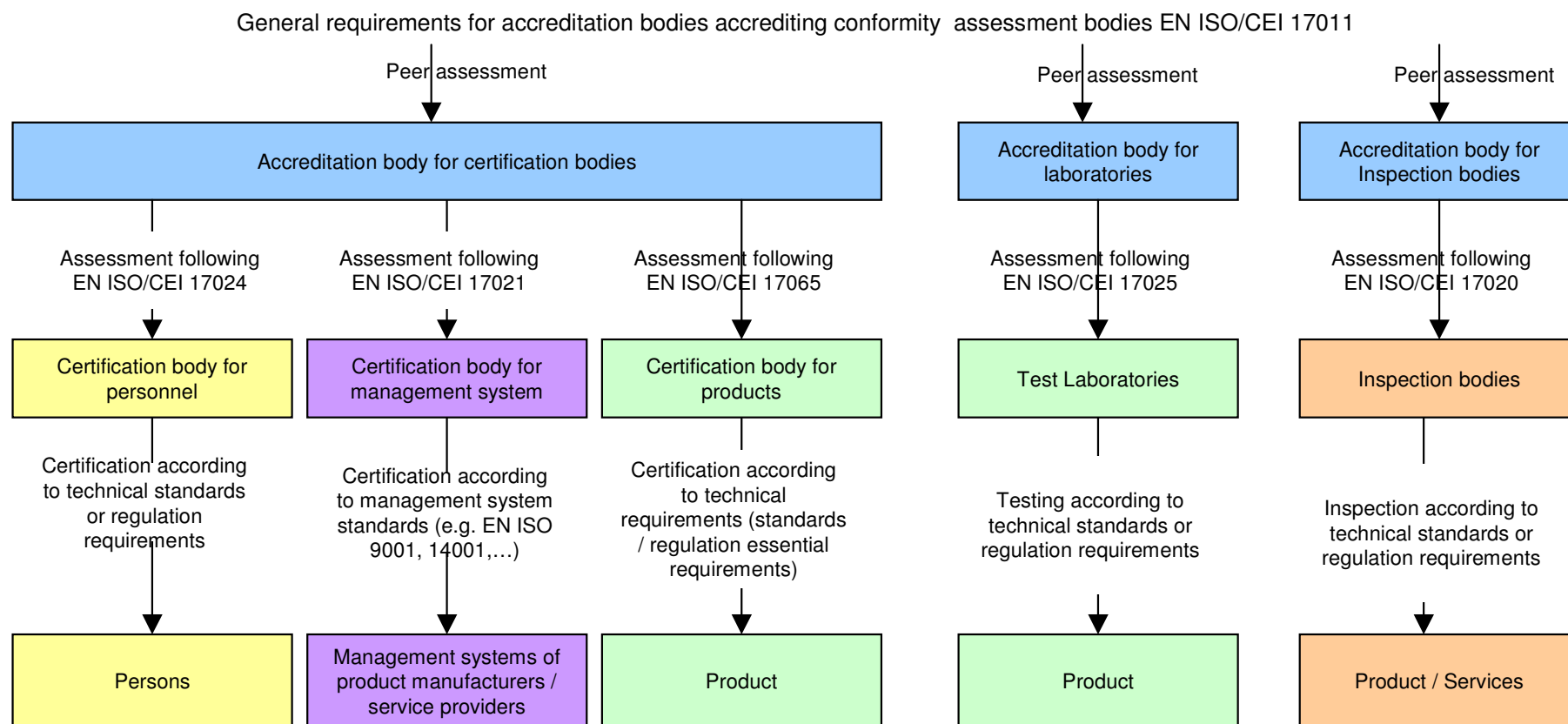


Can be used for accreditation /
assessment of the NB



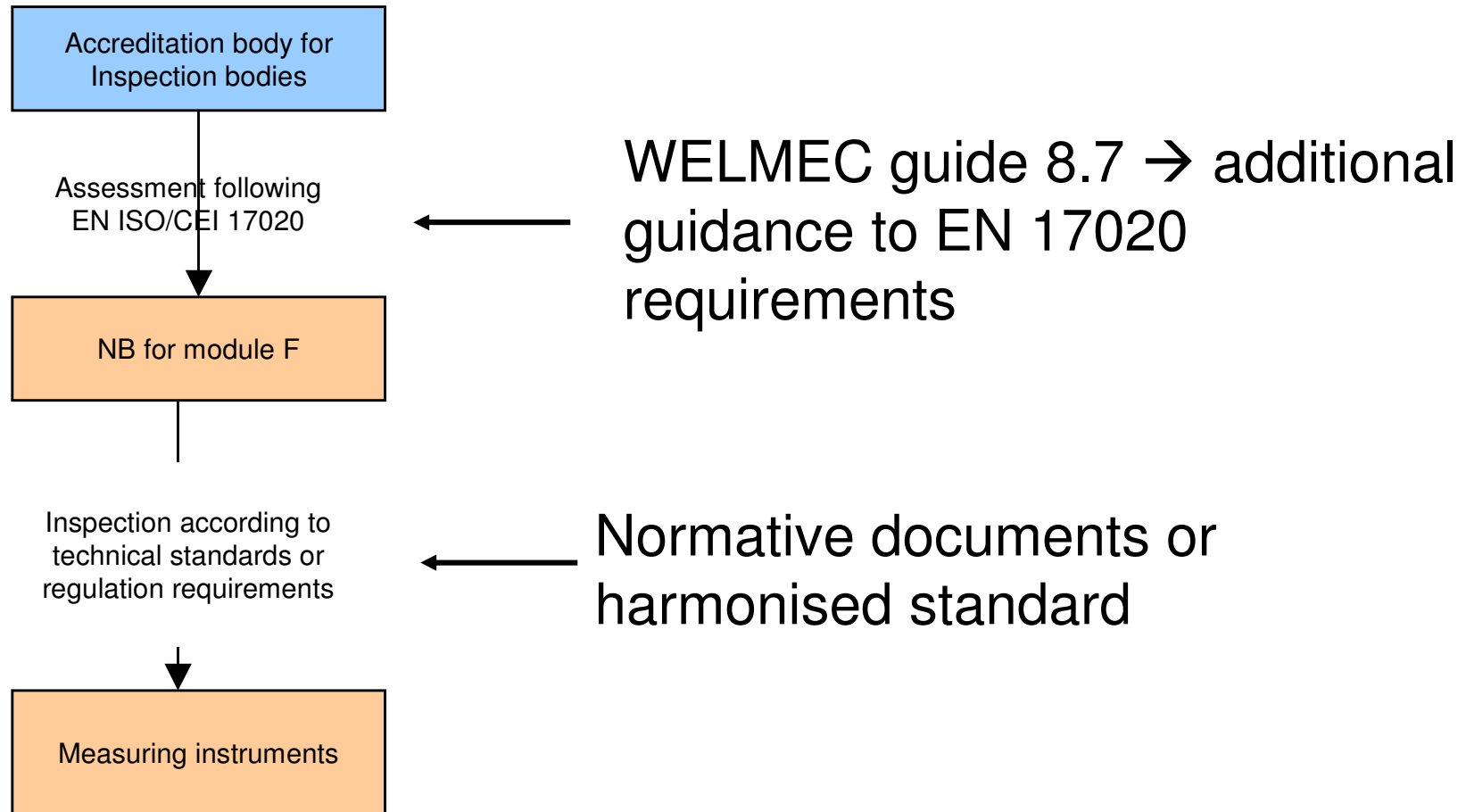
Which standard to assess Module F NB ?

If we step back and look at the global scheme...





Which standard to assess Module F NB ?

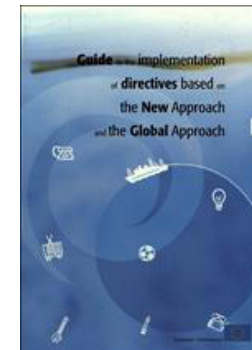




Which standard to assess Module F NB ?

➤ § 3.4 of the blue guide draft:

If EN 17020 or EN 17065 are used, and as these standards do not tackle criteria for testing/calibration, the requirements on testing activities as set out in EN 17025 must be taken into account.





WELMEC guide 8.7

➤ Structure of the guide

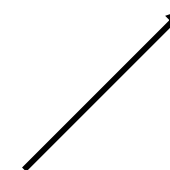
N°	SCOPE	CHAPTERS OF EN ISO/IEC 17020 STANDARD (provisional column)	APPLICATION GUIDE
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Subject of the
guidance

Ex: confidentiality,

Internal audits, ...



Provisions in the right column are based :

1 On the specific application to MID,

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.



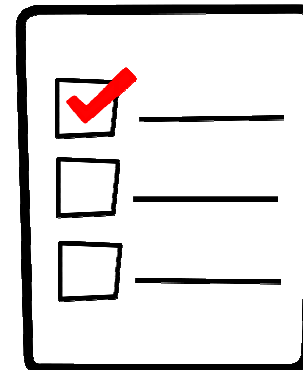
WELMEC guide 8.7

- Guide based on EN 17020 version 2005
- To be revised by WELMEC WG8 to take into consideration:
 - ✓ EN 17020 version 2012
 - ✓ The New legal framework



WELMEC guide 8.7

Let's go through some specific items of the guide...





WELMEC guide 8.7

Independence

EN 17020 : 3 types of inspection bodies are foreseen

Guide 8.7 : Only type A inspection bodies may be designated (See article 12 in MID, in particular § 1, 2 and 6.)



WELMEC guide 8.7

Technical manager

EN 17020 : The inspection body shall have a technical manager (...)

Guide 8.7 : 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.

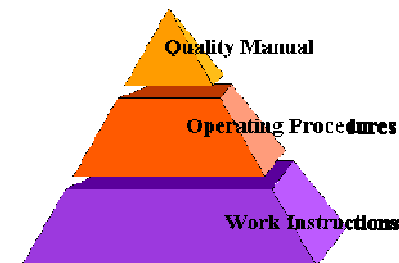


WELMEC guide 8.7

Documented quality system

EN 17020 : The quality system shall be fully documented.
(...)

Guide 8.7 : The quality system shall contain the necessary information for each category of instruments for which the body is designated.





WELMEC guide 8.7

Feedback and corrective actions

EN 17020 : The inspection body shall have documented procedures for dealing with feedback and corrective action (...)

Guide 8.7 : It shall be foreseen that:

- corrective actions are documented and 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 MI (art. 19 & 20 of MID.)



WELMEC guide 8.7

Facilities and equipments

EN 17020 : The inspection body shall have available suitable and adequate facilities and equipment (...)

Guide 8.7 : If the NB uses manufacturer's facilities and equipments , this shall be documented and recorded in the contract as defined in § 3.3 of EN 17020. In this case, it remains the responsibility of the NB to ensure that test means are suitable and traceable to standards.





WELMEC guide 8.7

Calibration program

EN 17020 : The inspection body shall ensure that, where appropriate, equipment is calibrated (...)

Guide 8.7 : Requirements concerning traceability should be in line with ISO 17025 and/or 10012, and especially :

- the testing facilities shall be initially qualified,
- the testing facilities shall be comprehensively identified.
- the testing facilities shall be calibrated or verified before being put into service or back into service.
- the frequency of verification/calibration shall conform to applicable standards or WELMEC guides.
- the testing facilities shall clearly carry the limit of validity of the previous verification/calibration.
- the responsibilities of the metrological management person shall be clearly defined and ensured.



WELMEC guide 8.7

Methods & Procedures

EN 17020 : The inspection body shall use the methods and procedures for inspection which are defined in the requirements, against which conformity is to be determined

Guide 8.7 : The verification methods and procedures shall be described & shall conform to most suitable standards or WELMEC guides or OIML IR. 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



WELMEC guide 8.7

Records

EN 17020 : Observations and/or data obtained in the course of inspections shall be recorded (...)

Guide 8.7 : The recording procedures shall apply to each verified instrument.

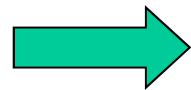
They shall allow to determine retrospectively, for each instrument (or group):

- its identification (including the reference to the TEC)
- 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 (see WELMEC guide 8.8),
- where applicable, conditions in which examinations and/or tests have been performed by an other body.



WELMEC guide 8.7

How to deal with the evaluation of parts of a measuring instruments?



WELMEC guide 8.8 § 4.2.5 :

Special attention should be made to the conformity of the production of the part delivered by a producer. The manufacturer of the measuring instrument may not transfer its responsibility regarding the conformity of the production of the part to the producer.

If applicable, **evaluation of the compatibility sheets** that indicate the relevant quantities and characteristics identified, which together establish the conformity of the complete instrument to the essential requirements and the conditions for compatibility with other parts, interfaces and sub-assemblies, **is recommended**.



WELMEC guide 8.7

Other WELMEC guide to consider...

- Guide 8.3 : Application of module B
- Guide 8.8 : General and Administrative Aspects of the Voluntary System of Modular Evaluation of Measuring instruments
- Guide 8.10 : Guide for generating sampling plans for statistical verification according to Annex F and F1 of MID
- Guide 8.21 : Directive 2004/22/EC Common application

And all guides related to each measuring instrument categories ...



WELMEC guide 8.7

Thank you for your attention !

For any other questions ...



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