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WELMEC

European cooperation in legal metrology

Measuring Instruments Directive 2004/22/EC

Generalities on the Assessment and Operation of Notified Bodies performing Conformity Assessment

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WELMEC is a co-operation between the legal metrology services of the Member States of the European Union and EFTA. This document is one of a number of Guides published by WELMEC to provide guidance to manufacturers of measuring instruments and to notified bodies responsible for conformity assessment of their products. The Guides are purely advisory and do not themselves impose any restrictions or additional technical requirements beyond those contained in relevant EC Directives. Alternative approaches may be acceptable, but the guidance provided in this document represents the considered view of WELMEC as to the best practice to be followed.

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FOREWORD

This document is intended to provide guidance to all those concerned with the application of the Measuring Instruments Directive (MID).

The guide must be considered as the general guide on the assessment and operation of notified Bodies performing conformity assessment in application of MID. Several other 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.

This 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 to the best practice to be followed. In principal this Guide shall be followed entirely when reference is made to it. However if some specific points of this Guide are not followed, reference to it may be made provided that these specific points are clearly identified and reasons for given.

1. SCOPE

1.1 This guide is developed to assist all parties involved in the application of the directive 2004/22/EC (MID):

- Member States in appointment and supervision of notified bodies (NB),
- NBs in assessment of products and quality (management) systems, and
- Manufacturers to meet the applicable requirements.

The NBs should be assessed and should operate according to this guide whether they are private bodies or part of a national or local authority.

1.2 This guide gives advice on the use of particular quality standards within the EN 45000 or EN ISO/IEC 17000 series for each conformity assessment module. The overall aim is that all valid combinations of the quality standards and modules featured here is giving the same confidence in the work performed by the notified body.

1.3 This guide is not self-applicable. It is a top-level guide, supplemented by specific guidance. In addition to the directive itself, operation according to this WELMEC guide may necessitate referring up to 5 types of documents that are useful and recommended for the implementation of a module of conformity assessment, here after called « module » :

a) Concerning assessment of NBs :

- the most appropriate international standard(s) applicable for the assessment of the competence of the Body,
- a specific WELMEC guide for the application of the combination of the relevant international standard for the assessment of the competence of the Body and the relevant module (eg Guide 8.5 Assessment of notified bodies in charge of type examination Presumption of conformity based on EN 45011),

b) Concerning operation of NBs :

- the relevant standard for bodies in charge of testing,
- a specific WELMEC guide on the global application of a module (until now availble for H1- guide 8.2, B- guide 8.3 and D-guide 8.4),
- where appropriate, a specific WELMEC guide on the requirements applicable to quality-systems (QS) of manufacturers (eg Guide 8.6 Presumption of conformity of the quality system of manufacturers with modules D or H1 when EN ISO 9001 : 2000 is applied).

Annex 1 gives a table summarising all applicable documents for a module.

1.4 At this stage, this guide is mainly focussing on the modules corresponding to the following main procedures of conformity assessment that appear the most useful for application of MID (one procedure corresponds either to one single module or to a combination of two modules):

- module B + module F,
- module B + module D,
- module H1,
- module G.

However some considerations on application of other modules may also be provided, in particular in annex 1. See also 3.9.

1.5 In addition annex 2 provides guidance on how:

- facilitating the designation of bodies to be notified for the first time for the implementation of MID, but taking into consideration their past action in legal metrology, in particular for application of the NAWI directive,
- facilitating the designation of bodies already notified for some applications of MID, to be notified for other applications.

2. ASSESSMENT AND APPOINTMENT OF NOTIFIED BODIES

2.1 General consideration

Bodies are designated by the competent authority in the member State. The member State is responsible for their assessment, designation and notification. The assessment shall be effective although all past action may be taken into account in order to facilitate the designation, according to annex 2.

An expert on legal metrology shall always be a part of the assessment team (See article 12 of MID and the relevant § in the annexes defining the conformity assessment modules). A legal metrology expert must have the competence with regard to the functioning and use of measuring instruments within the relevant field of application, to applicable assessment module(s) and to evaluation of measuring uncertainties. He must also have the knowledge of the legal requirements which are laid down for the instruments according to the directive.

Annex 2 provides detailed information on the necessary knowledge of the NBs or its staff and how to assess it.

2.2 Accreditation

The member State should consider the possibility to take advantage of the competence of the accreditation bodies for the assessment of a notified body.

Accreditation is now considered as the best way for a body to demonstrate its competence. It is insisted that accreditation in general can not be regarded as sufficient : to take the accreditation into account a NB must be accredited for the specific task (for the specific measuring instrument category and the specific module of conformity assessment as laid down in MID).

However, if accreditation for the specific task is taken into account by the member State and is of nature of facilitating its checking and decision, this cannot discharge the member State from its responsibility regarding the evaluation of competence, decision on appointment and surveillance of the NB: the member State or an authority in charge by a member State may carry out a minimum of supplementary actions by itself.

Where the member State decides not to require accreditation for its NBs, it shall assess their competencies on a similar basis. This generally implies that the NB will implement and maintain a QS.

2.3 Relevant standards

The recommended relevant standards for assessment of the competence of NBs are referred to in Annex 1.

2.4 Specific guidance

This document indicates (see overview in annex 1) where a specific WELMEC guide on how assessing exists or is needed. In this case this specific WELMEC guide shall be taken into consideration when it exists.

Where no specific WELMEC guide exists for application to a module and of the most appropriate international standard applicable for the assessment of the competence of a Body, the relevant provisions in the existing specific WELMEC guides applies by analogy and shall be taken into account.

Where the member State accepts to perform the assessment of the competence of a Body on an other basis than the most appropriate international standard, the relevant provisions in the existing specific WELMEC guides applies and shall be taken into account.

2.5 Supervision of Notified Bodies

In the course of action, the member State shall supervise the action of the NBs, and provide them all appropriate necessary assistance. The member State shall ensure that the NBs are aware of all interpretation made on the application of the directive that are of interest for their action.

The member State shall check that the NBs they have notified continue to meet the applicable criteria, and shall withdraw the notification if these criteria are no longer fulfilled (MID, § 3 of article 11). This checking should be made at intervals not exceeding one year.

3 OPERATION OF NOTIFIED BODIES

3.1 General

3.1.1 A NB performing product assessment decision may subcontract activities for which clear procedures have been established. This is in particular possible for metrological tests in order to demonstrate the performance of the instruments. Where interpretation of these procedures are necessary, the subcontractor shall contact the NB. In no case a NB may subcontract activities that necessitate:

- its expertise for which it is notified,
- interpretations, in particular of the here above referred procedures,
- judgement on conformity of individual requirements and/or on the global acceptance of the instrument.

The “Blue guide” provides general useful information on subcontracting and should be considered.

3.1.2 A NB performing assessment and approval of quality (management) systems may use assessors that are not of its staff, provided the audit team fulfils the necessary requirement on the level of qualification and expertise of the assessor(s), as referred to in § 3.3 in annexes D, E, H and H1 of MID and § 5.3 in annexes D1 and E1of MID.

The conformity to EN ISO 9001, complemented with the appropriate specific WELMEC guide (Guide 8.6 Presumption of conformity of the quality system of manufacturers with modules D or H1 when EN ISO 9001 : 2000 is applied), and to EN ISO/IEC 17025 for tests, gives

presumption of conformity to the corresponding requirements applicable to QS of manufacturers in MID. However the manufacturer is allowed to proceed to exclusions of the appropriate paragraphs, as foreseen in EN ISO 9001, in order to meet the level of requirements corresponding to the relevant module: final control, production + final control or full quality.

Where the manufacturer decides to prove the conformity on other basis than EN ISO 9001 and EN ISO/IEC 17025, the NB shall at least take into account the relevant provisions in the specific guidance documents here above referred to, which apply.

It should be assessed that the NB have procedure to treat manufacturers in third countries and daughter companies in an equivalent and appropriate manner than respectively manufacturers established in the European Union and mother companies. This takes into account aspects referring to surveillance (expected and unexpected).

3.2 Use of standards and other WELMEC guides

WELMEC develops guides of general or specific interest other than those specific to MID, which shall be also taken into account. The use of standards of general interest in metrology is recommended.

3.3 General guidance for product testing

A body fulfilling the EN ISO/IEC 17025 standard for the applicable methods, will give the necessary confidence in the test results to be taken into account for the conformity assessment decision. This is applicable to tests directly performed by the NB or subcontracted, but also to tests performed by the manufacturer in the framework of its approved QS.

General conditions on the uncertainty in the test results specified in the WELMEC Guide 4.2 Elements for deciding the appropriate level of confidence in regulated measurements shall be considered. The uncertainty in the test results may be evaluated a priori, to be valid for all intended conditions of tests, but may also be calculated case by case, for each particular test condition. Further consideration on how to handle uncertainty is given here under for each conformity assessment module.

3.4 Type examination (module B)

3.4.1 The notified body operates according to EN 45011, complemented by the specific WELMEC guide (Guide 8.5 Assessment of notified bodies in charge of type examination Presumption of conformity based on EN 45011) and according to the specific general WEMEC guide on type examination (Guide 8.3 Application of Module B).

In particular, the personnel of the notified body shall have adequate knowledge of the technology and applications of the instruments that are to be examined and also of the subsequent verification process. The competence of each person shall be documented.

3.4.2 Type examination under MID is very similar to the well known concept of type/pattern approval in legal metrology, with the particularity of two aspects that must be taken into account. The technical documentation accompanying the request for the type approval certificate shall include:

1 The necessary test results proving the conformity to the required metrological performances (see i) of article 10 in MID).

Whatever are these test results, for application of solutions a) and b) of § 2 of Annex B of MID, the NB has to decide what tests it will perform for evaluating the conformity. The possibility not to repeat all or part of the test program is encouraged when the testing laboratory (that has performed the tests provided with the technical documentation) is accredited according to EN ISO/IEC 17025, in which case it has demonstrated its competence and its impartiality (not to be confused with independence). It is also possible not to repeat the tests when the tests were performed by a non-accredited laboratory which has demonstrated it's competence and its impartiality for all the necessary actions to the notified body. In this case, EN ISO/IEC 17025 should be considered to determine these necessary actions.

In all the cases, it must also be assumed that all the necessary conditions are met: that is in particular, it can be demonstrated or assumed that the instrument is capable to meet all the metrological requirements without modification or non-allowed adjustment in the course of the test program. The NB must be able to ensure and demonstrate that this assumption is fulfilled. If he accepts results of tests in the course of which modifications or non-allowed adjustments were performed, the NB shall have a procedure to consider the acceptability of tests performed before a modification or an adjustment took place during the process.

2 The manufacturing procedures to ensure consistent production of instruments (see 3 c) of article 10 in MID).

This should be considered in the spirit of preventing the concept of the "golden instrument" subject to type approval, and should be limited to this consideration.

3.4.3 Records of approved instruments and technical files which include test results and the evaluation report shall be kept for as long as the instruments are likely to be subject to further conformity assessment modules in application of MID, for application of 5.3 in annex B of MID but also in order to be capable to face manufacturer requests concerning evolution of the approved type.

3.4.5 The WELMEC Guide 4.2 Elements for deciding the appropriate level of confidence in regulated measurements foresee that the general rule on management on uncertainties is such that the uncertainty on the test results is not greater than 1/3 of the maximum permissible error, excepted in the case of particular situation admitted in an international standard for example. It has to be noticed that, taking into consideration the importance of test results at the type examination stage, several International Recommendations foresee that the uncertainty in the test results shall not be greater than 1/5 of the maximum permissible error. In such a case excepted when duly justified this particular ratio applies.

3.4.6 Where appropriate the NB should take into account tests and examination performed on parts of measuring instruments performed in the framework of the WELMEC guide establishing a voluntary system of modular evaluation (draft 1-10 of WG 8).

3.5 Declaration of conformity to type based on product verification (module F)

Basically, the necessary confidence will be provided by a notified body operating as a type A inspection body as defined in EN ISO/IEC 17020, complemented by the specific WELMEC guide (draft under preparation). However conformity to EN 45011 is also possible, in which case the here above referred specific WELMEC Guide shall also be taken into account.

In particular, the personnel shall have the necessary competence in the functioning and operation of the instrument to be verified and in the legal requirements as stated in MID, and the applicable harmonised standards or normative documents (See also article 12 of MID).

Where appropriate the notified body shall issue a certificate of conformity and ensure that the instrument is marked correctly according to the requirements in MID and, if applicable, the applicable harmonised standards or normative documents.

The certificate shall be kept by the manufacturer, or by agreement with the manufacturer, by the notified body.

The notified body shall keep a record of certificates that are issued.

If the notified body considers that an instrument does not fulfil the requirements, the reasons for this shall be given to the manufacturer and may be accompanied by test results.

Where appropriate the NB should take into account tests and examination performed on parts of measuring instruments performed in the framework of the WELMEC guide establishing a voluntary system of modular evaluation (draft 1-10).

3.6 Declaration of conformity to type based on quality assurance of the production process (module D)

3.6.1 Operation of the notified body

The notified body operates according to EN 45012 (as long as it is not replaced by ISO/IEC 17021) and to the specific WELMEC guide (WELMECGuide 8.4 Application of Module D).

The personnel of the notified body shall have adequate knowledge of the technology and applications of the instruments that are to be examined (see also article 12 of MID). The competence of each person shall be documented.

An expert in legal metrology having the appropriate knowledge of the category of instruments shall be part of the assessment teams.

3.6.2 Assessment of the manufacturer

In addition to what is laid down in 3.1.3, the exclusion of § 7.3 in EN ISO 9001 applies.

The manufacturer shall have documented traceability for all instruments and standards used for testing. All test results shall be recorded and available for the notified body responsible for the assessment.

The manufacturer shall keep the test results that are appropriate for the assessment of the product for a period of at least 3 years. It is pointed out that this is without prejudice of the necessary documentation to be let at the disposal of the National Authorities for 10 years in application of § 6 of annex D in MID.

3.6.3 Manufacturer certified according to ISO 9001

If the manufacturer already has a quality (management) system approved in accordance with EN ISO 9001, then the notified body should take this into account in assessing compliance with

the requirements for declaration of conformity of products to MID. However the notified body must assess the quality (management) system to ensure that it covers all aspects of the production and quality control that are relevant to the declaration of conformity for the products concerned, and the particular aspects of legal metrology applicable for module D. These aspects must be assessed by a team which includes an expert on legal metrology.

See also WELMEC Guide 8.6 Presumption of conformity of the quality system of manufacturers with modules D or H1 when EN ISO 9001 : 2000 is applied.

3.6.4 Surveillance

After the initial audit, a periodic surveillance takes place, possibly with a limited scope, in particular those which are critical for the conformity of instruments. The frequency of periodic audits may vary according to the past performance of the manufacturer, the frequency of any changes to the quality (management) system, and the complexity of the products, but should take place in a period not exceeding 12 months since the last audit.

Once every three years a re-assessment takes place with a similar scope as the initial audit.

The necessity to perform unexpected visits will be considered taking into consideration the previous information available on the manufacturer, the manufactured measuring instruments, the QS and review of complaints. It is expected that a NB will perform unexpected visits to at least 10 % of the approved QS in each year. The choice of the manufacturers that will be visited unexpectedly will not depends on criteria such as: location of the factory, difficulty or price for travelling.

3.7 Declaration of conformity based on full quality assurance plus design examination (module H1)

3.7.1 General

The NB shall take into account the specific WELMEC Guide 8.2 Application of Module H1.

The implementation of module H1 necessitates 2 approvals from the same NB:
- the approval of the QS of the manufacturer,
- the issuing of a design examination certificate for each manufactured design.

The NB shall not issue a design examination certificate before having approved the QS under H1.

Annex 3 gives a comparison between the modules B and H1, focussed on the aspect concerning the flexibility offered to the manufacturer by module H1 for performing some evolution within a same design.

3.7.2 Approval of the QS

What is laid down in 3.6 is applicable with the exception that, by nature, § 7.3 in EN ISO 9001 is fully applicable.

Excepted particular situation admitted at international level (eg in the case where it is well established it is impossible to meet this provision), taking into consideration the importance of

test results at the design examination stage, the uncertainty in the test results shall not be greater than 1/5 of the maximum permissible error.

See also WELMEC Guide 8.6 Presumption of conformity of the quality system of manufacturers with modules D or H1 when EN ISO 9001 : 2000 is applied.

3.7.3 Design examination certificate

The notified body shall work according to EN 45011, complemented by the specific WELMEC guide (Under consideration; Some provisions in WELMEC Guide 8.5 Assessment of notified bodies in charge of type examination Presumption of conformity based on EN 45011may be relevant).

In particular, the personnel shall have adequate knowledge of the technology and applications of the instruments that are to be examined and also of the subsequent verification process. The competence of each person shall be documented.

3.7.4 Surveillance

The WELMEC guide on application of module H1 gives general information on the surveillance of the QS. The following may be added.

The necessity to perform unexpected visits will be considered taking into consideration the previous information available on the manufacturer, the manufactured measuring instruments, the QS and review of complaints. It is expected that a NB will perform unexpected visits to at least 10 % of the approved QS in each year. The choice of the manufacturers that will be visited unexpectedly will not depends on criteria such as: location of the factory, difficulty or price for travelling.

3.8 Declaration of conformity based on unit verification (module G)

Basically, the necessary confidence will be provided by a notified body operating in accordance with EN 45011, complemented by the specific WELMEC guide (Under consideration). However a notified body operating as a type A inspection body as defined in EN ISO/IEC 17020 is also possible, in which case the here above referred specific WELMEC guide shall also be taken into account.

In particular, the personnel shall have the necessary competence in the functioning and operation of the instrument to be verified and in the legal requirements, as stated in MID, the applicable harmonised standards or normative documents (see also article 12 of MID).

Records of approved instruments and technical files which include test results and reports shall be kept for as long as the instruments are likely to be in use.

The notified body shall keep a record of certificates that are issued.

It would be logical, at least for some kind of instruments, that the unit verification is only possible if the NB takes into account tests and examination performed on parts of measuring instruments performed in the framework of the WELMEC guide establishing a voluntary system of modular evaluation (draft 1-10).

3.9 Other modules

Where no specific guidance is provided for a module, in this guide or in an other one, relevant guidance in existing guides applies by analogy.

Refer also to annex 1.

ANNEX 1
Overview of documents useful for the application of mid

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

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

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

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

*** See foreword of this Guide

For testing refer to 3.3

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

ANNEX 2
Facilitating assessment of competence of notified bodies

Introduction

This annex provides detailed information on the knowledge on MID that a NB must have.

Most of the member States already have Bodies designated for metrological tasks and for measuring instrument categories. Some of these bodies are accredited for tasks similar to the specific tasks applicable for MID. It is justified in this case that member States do not carry out a complete investigation on the competence of the bodies they want to notify for application of MID and to provide a harmonised guidance approach on this aspect.

To this aim, this annex intends to cover two aspects:
- facilitating the designation of bodies to be notified for the first time for the implementation of MID (see paragraphs IV),
- facilitating the designation of bodies already notified for some applications of MID, to be notified for other applications (see paragraphs V *Will be developed later*).

The body shall fulfil the general requirements in article 12 in MID and all specific requirements resulting of MID (see paragraphs II and III). In the course of the assessment of competence of the body, a particular consideration shall be made to all specific requirements of the module(s) and to the specific instrument annex(es) for which it shall be notified. Each individual operator involved in the conformity assessment procedures shall have a suitable knowledge of items in paragraphs II and a good knowledge of items in paragraphs III.

I GENERAL CRITERIA (ARTICLE 12)

1. The body, its director and staff involved in conformity assessment tasks shall not be the designer, manufacturer, supplier, installer or user of the measuring instruments that they inspect, nor the authorised representative of any of them. In addition they may not be directly involved in the design, manufacture, marketing or maintenance of the instruments, nor represent the parties engaged in these activities. The preceding criterion does not, however, preclude in any way the possibility of exchanges of technical information between the manufacturer and the body for purposes of conformity assessment..

2. The body, its director and staff involved in conformity assessment tasks shall be free from all pressures and inducements, in particular financial inducements, that might influence their judgement or the results of their conformity assessment work, especially from persons or groups of persons with an interest in the results of the assessments.

3. The conformity assessment shall be carried out with the highest degree of professional integrity and requisite competence in the field of metrology.

   Should the body subcontract specific tasks, it shall first ensure that the subcontractor meets the requirements of this Directive, and in particular of this Article *(12 in MID)*. The body shall keep the relevant documents assessing the subcontractor's qualifications and the work carried out by him under this Directive at the disposal of the notifying authority.

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 have

access to the necessary facilities for carrying out in a proper manner the technical and administrative tasks entailed in conformity assessment.

5. The body's staff shall have:

   – sound technical and vocational training, covering all conformity assessment tasks for which the body was designated;

   – satisfactory knowledge of the rules governing the tasks which it carries out, and adequate experience of such tasks;

   – the requisite ability to draw up the certificates, records and reports demonstrating that the tasks have been carried out.

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, nor on the results of such tasks.

7. The body shall take out civil liability insurance, if its civil liability is not covered by the Member State concerned under national law.

8. The body's director and staff shall be bound to observe professional secrecy with regard to all information obtained in the performance of their duties pursuant to this Directive, except vis-à-vis the authority of the Member State which has designated it.

II GENERAL KNOWLEDGE ON MID

Scope : Families in the specific annexes and subject to legal metrology control (art. 1, specific annexes)
Particular policy versus EMC, status of Directive 89/336/EEC (to be replaced by Directive 2004/108/EC) (art. 3, § 1.3.3 and 1.3.4 of annex I)
General policy concerning sub-assemblies (art. (b) of 4, 5, particular clauses in specific annexes)
General policy concerning conformity assessment ((h) and (i) of art. 4, 6, 9, 13, annex I, specific annexes, nature of different conformity assessment procedures)
Marking and inscriptions (art. 7, 17, § 9 of annex I)
Notification (art. 11, 12)
Respective roles of members States and NBs (art. 18, 19, 20)
Implementation (art. 22, 23, 24, 26)

In addition the NB shall have knowledge about:
- the national legislation transposing MID in the country where the notified body is based,
- available harmonised standards and normative documents,
- and general WELMEC guides.

A body performing approval of quality-systems shall have expert knowledge in auditing concerning the relevant field of metrology and instrument technology, and knowledge of the applicable requirements on approval of quality (management) systems (modules D and H1 in particular).

III SPECIFIC KNOWLEDGE ON MID

Each conformity assessment procedure for which the body requests its notification

Annex I

Each relevant specific annex or part of an annex (example : a particular AWI in MI 006)

In addition the NB shall have a good knowledge about:
- appropriate harmonised standard and/or normative documents,
- and the general and specific relevant WELMEC guides.

IV INITIAL NOTIFICATION OF BODIES

4.1 Situation before notification

4.1.1 Versus conformity assessment procedures

The body has never been in charge of a metrological activity: situation C0

The body is already in charge of a metrological activity in the country but not for an equivalent conformity assessment procedure and the relevant specific category: situation C1

The body is already in charge of a metrological activity in the country for an equivalent conformity assessment procedure but not for the relevant specific category: situation C2

The body is already in charge of a metrological activity in the country for the relevant specific category but not for an equivalent conformity assessment procedure: situation C3

The body is already in charge of a metrological activity in the country for an equivalent conformity assessment procedure and the relevant specific category : situation C4

4.1.2 Versus evidence of competence

The body is not accredited or has no quality-system accepted by the member State : situation A0

The body is accredited or has a quality-system accepted by the member State for activities having no relation with the relevant application: situation A1

The body is accredited or has a quality-system accepted by the member State for similar applications and declares operating in the same conditions: situation A2

The body is accredited or has a quality-system accepted by the member State for an equivalent application (ex: type examination of NAWIs or national type approval of other instruments for EC type examination in application of MID): situation A3

Note : Concerning accreditation, the aim is the accreditation for the specific task (for the specific measuring instrument category and the specific module of conformity assessment as laid down in MID)

4.2 Action of Member States in order to check the competence and capability

4.2.1 Versus capability of the body (general criteria) and knowledge (of operators) on MID

Situation	General criteria	General knowledge of MID	Knowledge on particular aspects
C0	Exhaustive checking	Exhaustive checking (1)	Exhaustive checking (1)
C1	Exhaustive checking	Exhaustive checking (1)	Exhaustive checking (1)
C2	Check adaptation for the category and to MID	Exhaustive checking (1)	Exhaustive checking (1)
C3	Exhaustive checking	Exhaustive checking (1)	Check adaptation for the conformity assessment procedure and to MID
C4	Check adaptation for the category and to MID	Exhaustive checking (1)	Check adaptation for the conformity assessment procedure and to MID

1) This does not mean that the Member State has to check that each operator of the body knows each item but this checking shall involve a sufficient number of operators in order to assume that each item is known by each operator.

4.2.2 Versus evidence of competence

Situation	Organisational aspects	Technical aspects
A0	Exhaustive checking (1)	Exhaustive checking (1)
A1	Exhaustive checking (1)	Exhaustive checking (1)
A2	Exhaustive supervision of adaptation to MID	Exhaustive supervision of adaptation to MID
A3	Selective supervision of adaptation to MID	Selective supervision of adaptation to MID

1) This does not mean that the Member State has to check that each operator of the body knows each item but this checking shall involve a sufficient number of operators in order to assume that each item is known by each operator.

V COMPLEMENTARY NOTIFICATION OF BODIES

To be developed later : case of a notified body which wants to extend his field of competence (module and /or category of instrument)

ANNEXE 3
Comparison between
"type examination" (module B) and "design examination" (module H1)

Design examination is a new concept for legal metrology. It is intended to give more flexibility to the manufacturer than Type examination.

This annex has been established in order to present the possible flexibility of a Design approved according to module H1, making a comparison with a Type approved according to module B, in particular on the conformity to Type/Design aspects. It is intended that only some general considerations are covered as examples, and that the specific WELMEC WGs could have some specific considerations on the concept.

Comparison

Theme	Module B	Design evaluation under Module H1
Conformity	Established by examination and tests performed or accepted by the NB	Established by examination of the application (based in principle on the design full QA information and the information on the design)
Competence of the manufacturer	No demonstration needed Giving confidence in the competence to demonstrate the conformity to essential requirements is optional and does not commit the NB (see 1 in § 3.4.2 of this guide for the conditions in which the NB may have confidence in the test results provided by the manufacturer)	As far as the design of an instrument is concerned the 2 main added values of H1 compared to B are: 1 Giving confidence in the competence to demonstrate the conformity to essential requirements, 2 Giving confidence in the capability to define the instrument with an appropriate level of flexibility, allowing within the scope of the same design: - development of various alternative instruments, - modifications of the design.
Quality-system (QS)	No	Here above competencies are demonstrated via the QS
Document	The NB issues a type examination certificate for each type	The NB issues a design examination certificate for each design
Evolutions and conformity to the type/design	The manufacturer shall ensure the conformity to the type and has to declare all significant/fundamental modifications to the approved type. As far as necessary, the notified body shall issue a new certificate or an addition to the original EC type examination certificate. This constitutes a new type or a modified type.	The manufacturer has to declare all fundamental modifications to the approved design. The notified body shall issue a new certificate in the form of an addition to the original EC design examination certificate. It is not explicitly written that the manufacturer shall ensure conformity to the design, but it may be concluded that this is implicit, because any fundamental modification results in

		an addition to the original EC design examination certificate. It may be considered that such modified design being the object of an addition to the original certificate constitutes a new design.
Documentation relevant to the conformity to the type/design Validation by the NB	The conformity to the type shall be ensured. This concerns in particular the architecture of the instrument and the components that are critical. Art. 10.2 in MID gives the appropriate level of detail for this. Under a classical approach, only components that have been validated by the NB are allowed. They shall be identified at least in the technical documentation explicitly by their own type. However in some particular cases, it may be acceptable to identify the components by generic characteristics when this is sufficient to ensure that the 2nd hyphen of art. 10.2 is fulfilled. This might be the case when the components are purely digital. The modular approach that has been developed for NAWIs can also be considered corresponding to this case: a necessary framework specifying the condition for compatibility has been established and each module is validated by a NB (with the exception of mechanical parts of classical design). The manufacturer has flexibility only within this framework. The architecture remains the same.	The conformity to the design shall be ensured. But the module H1 allows (under controlled conditions) some evolutions to the design, in particular of the components that may be critical and possibly of the architecture of the instrument. Art. 10.2 in MID gives the appropriate level of detail for this, provided the design remains unchanged. This will depend on the capability of the manufacturer: - to define the design with sufficient flexibility, - to demonstrate its competence in order to make some evolutions or modifications to the design.

Practical aspects

The manufacturer may:
- establish a list of evolutions or modifications he want to perform without having to ask for a new approval,
- demonstrate his competence for performing the assessment of conformity (if necessary) for each kind of these evolutions or modifications.

The NB shall:
- check the adequacy of the demonstration and of the allowed evolutions or modifications,
- describe the instrument in the EC design examination certificate (or annexes) so that the appropriate flexibility is ensured, but also (if necessary in annexes being not confidential) so that the external (visual) conformity to the design can be checked by any people in charge of further metrological activities.

Generic examples of evolutions and modifications

Although the module H1 allows evolutions of the design, it seems difficult to admit without conditions that the design might correspond to all the instruments of a measuring category manufactured by one manufacturer.

Depending on the nature of the evolutions and modifications, it will be more or less easy for the manufacturer to describe the design with sufficient flexibility and to demonstrate its competence for modifying the instrument without considering that this constitutes a new design.

This demonstration will involve factual aspects (requirements and test procedures), which constitute an easy aspect, but also interpretative aspects, in particular:

- what examination and tests to perform if the full set of tests and examination is not intended to be performed, for each type of evolution/modification,
- is suitability for use or fraudability affected by the evolution/modification ?

In the following table we have used:

- "High probability" to indicate that in general it should be easy to the manufacturer to describe the design with sufficient flexibility and to demonstrate its competence for modifying the instrument without considering that this constitutes a new design,
- "Low probability" to indicate that in general this should be difficult (or impossible in some cases) to make the flexible description and the a priori demonstration,
- "Possibility" to indicate that the probability will be medium or will depend on the actual case.

	High probability	Possibility	Low probability
Replacement of a component by an other one of the same technology and according to the same definition documents (plans, schemes, drawings describing the architecture of the MI)	X		
Replacement of a component by an other one of an other technology and according to the same definition documents		X Depending	
Use of the same main components but according to new definition documents for example ….		X?	X ?
New types of instruments of equivalent design but with interpolated characteristics (example: a new meter with a Qmax within the range already approved for the design)	X		
New types of instruments of similar design but with extrapolated characteristics (example: a new meter where the Q max is increased above that stated in the original certificate)		X depending	
Modification of the number and/or location of seals			X Always necessary to change the certificate (see 4.3.2 in annex H1)
Modification of the technology of seals (mechanical to software, mechanical to stickers…)			X Same reason
Modification of the metrological part of the software			X Same reason
Modification of the non-metrological part of the software, the manufacturer having previously demonstrated the clear distinction with the metrological part	X		