NMi Certification

Regulations

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Changes to the previous version

- July 2021, revised to accommodate UKCA
- June 2021, responsibility communication changes in certification requirements added
- April 2021, Chapter Sanctions added.
- January 2021, revision, updating Certification scheme "Mess- und Eichgesetz - MessEG
- January 2020, revision, updating hyperlinks §4.8 and §6
- November 2019, revision, updating NMi contact information in Delft and minor lay-out
- May 2018, revision, new NMi logo, minor lay-out and textual changes
- February 2018, revision formulation of various Modules related to criteria of ISO/IEC 17065, MID, OIML CS
- 14 July 2017, revision including OIML-B18, ISO 17065
- 1 December 2016, contents of the complete document are updated with new directive numbers
- 16 January 2009: revision of initial assessment §3.3 and validity of agreement (§1.4 and §3.3.2)
- 11 June 2008, modification of "making appeal".
- 14 April 2008, description of stage 1 and stage 2 audits.
- 10 Oct. 2007, replacement College of Experts by Advisory committee
- 4 Oct. 2007, scheme NMi Legal replaced by scheme NL Metrology
- 16/20 June 2005, addition of §4.2.2 Scope and §4.3.1 Categorising non-conformities
- 17 May 2005, correction table MID instruments

PREFACE

This document describes the organisation, the certification systems, and the assessment procedure of NMi Certification. The relevant aspects of the certification systems are described along with the rules for both the certificate holder and for NMi Certin and for the Advisory Committee.

This document was drafted primarily for current and future certificate holders in one of the certification systems of NMi Certification. These regulations are also necessary for the Advisory Committee and for the (lead) assessors of NMi Certification.

Delft, July 2021

Marc Schmidt
Director Operations

1 INTRODUCTION

1.1 APPLICATION

Inside Sales will inform the applicant of the conformity assessment procedure. The applicant will be provided with the necessary data or documents for processing the application:

- These regulations
- The application form for the requested scheme.

In the application, the applicant will indicate under which scheme and under which assessment guideline it wishes to have its product, process, or service to be certified.

The Inside Sales consult the application to the assessors and or evaluators to check whether the application requirements of the certification scheme have been met. If this is the case, the application will be accepted. Following consultation with NMi may refuse the application in case this is incomplete if there is insufficient capacity available or if the financial situation or the payment history of the applicant gives reason to do this. A refusal of an application will be provided in writing to the applicant.

1.2 AGREEMENT, ORDER AND CONFIRMATION

The agreement entered into between NMi and the applicant will be recorded in a separate order-confirmations and an certification agreements. There is an order-confirmation with respect to specific certification (product or system).

Certification Agreements can be submitted for a limited period and will be signed by both parties.

The client fulfils the certification requirements as addressed in ISO/IEC 17065: clause 4.1.2.2. These certification regulations apply to these agreements and orders.

1.3 SANCTIONS

A certification may be suspended or withdrawn by the management if the applicant does (temporarily) not comply with the requirements of the certification scheme, including the requirement of this certification regulations. The certificate holder shall immediately inform the management of NMi Certification of any circumstance which results in a severe non-conformity with the requirements.

More details about sanctions in Chapter 8.

1.4 FEEDBACK HANDLING

Customer-feedback, other than an appeal against a certificate decision of the management, about the functioning of NMi Certification or the assessment criteria, will be treated in accordance with the NMi Certin feedback procedure (www.nmi.nl/feedback)

1.5 DISPUTE CONCERNING A CERTIFICATION DECISION

In the case that an applicant or a certificate holder disagrees with a certification decision, then the certification decision can be objected.

Stakeholders may make objection towards decision of the Certification Board concerning public tasks of NMi Certin.

More details about making an appeal in Chapter 6.

1.6 PRODUCT EXPERTISE

The necessary product-specific expertise for measuring instruments in the CE or UKCA Metrology scheme and NL Metrology scheme will be provided by NMi Certin and competence can be demonstrated through accreditation in accordance with the ISO/IEC 17020, ISO/IEC 17021-1 & ISO/IEC 17025 standards.

Table 1 Reference to Accreditations

Accreditation	Reg. No.	Standard	Hyperlink to scope
Inspection	**I122**	ISO 17020:2012	https://www.rva.nl/en/alle-geaccrediteerden/i122/
Certification	**C081**	ISO 17021-1:2015	https://www.rva.nl/en/alle-geaccrediteerden/c081/
Testing	**L029**	ISO 17025:2017	https://www.rva.nl/en/alle-geaccrediteerden/l029/
Calibration	**K163**	ISO 17025:2017	https://www.rva.nl/en/alle-geaccrediteerden/k163/

1.7 CHANGES TO THE CERTIFICATION REQUIREMENTS

If changes occur in certification requirements, NMi Certin will assess the impact of these changes. In the event that these changes affect existing certifications, NMi Certin will inform the relevant certificate holders about these changes, including the period within which the certificate holder must implement the changes.

1.8 CHANGES TO THE REGULATIONS

The management of NMi Certin is authorized to make changes in these regulations which do not affect the certification status of a certificate holder[1].

Changes which do affect the certification status of a certificate holder shall be authorized by the director.

[1] For example a change which implies that a certificate of a certificate holder shall be withdrawn.

2 Certification Systems

2.1 OIML CS

The OIML-CS is a system for issuing, registering, and using OIML Certificates and their associated OIML type evaluation/test reports for types of measuring instruments (including families of measuring instruments, modules, or families of modules), based on the requirements of OIML Recommendations.

It is a single Certification System comprising two Schemes: Scheme A and Scheme B (see below).

The aim of the OIML-CS is to facilitate, accelerate and harmonize the work of national and regional bodies that are responsible for type evaluation and approval of measuring instruments subject to legal metrological control. In the same way, instrument manufacturers, who are required to obtain type approval in some countries in which they wish to sell their products, should benefit from the OIML-CS as it will provide evidence that their instrument type complies with the requirements of the relevant OIML Recommendation(s).

It is a voluntary system and OIML Member States and Corresponding Members are free to participate or not. Participating in the OIML-CS and signing the OIML-CS Declaration will commit, in principle, the signatories to abide by the rules of the OIML-CS. OIML B 18:2017 establishes these rules whereby signatories voluntarily accept and utilize OIML type evaluation and test reports, when associated with an OIML Certificate issued by an Issuing Authority, for type approval or recognition in their national or regional metrological controls.

The OIML Recommendations and the OIML CS (scheme A & B) are the basis for the technical competence of

NMi's Certification & Conformity assessment activities according to Directives 2014/31/EU and 2014/32/EU.

The requirements for the participation of Issuing Authorities and their associated Test Laboratories in Scheme A or Scheme B are the same, but the method of demonstrating compliance is different. Issuing Authorities are required to demonstrate compliance with accepted international standards, e.g. ISO/IEC 17065, and Test Laboratories are required to demonstrate compliance with ISO/IEC 17025. For participation in Scheme B, it is sufficient to demonstrate compliance based on "self-declaration" with additional supporting evidence.

For participation in Scheme A, compliance shall be demonstrated by peer evaluation, based on accreditation or peer assessment.

NMi Certin is registered as OIML issuing authority NL1. NMi Certin is designated and approved as Issuing Authority for several categories of measuring instrument. An overview of the actual category of measuring instruments for which NMi Certin is designated can be found on the website of OIML.

References:

General information	www.oiml.org/en/oiml-cs/general-info
OIML-CS	A single OIML Certification System (OIML-CS) from 1 January 2018
OIML B18	Framework for the OIML Certification System (OIML-CS)
Issuing Authority	https://www.oiml.org/en/oiml-cs/oiml-issuing-authorities/NMi-Certin
Utilizer	https://www.oiml.org/en/oiml-cs/utilizers-and-associates
Registered	www.oiml.org/en/oiml-cs/certificat_view

OIML Certificates

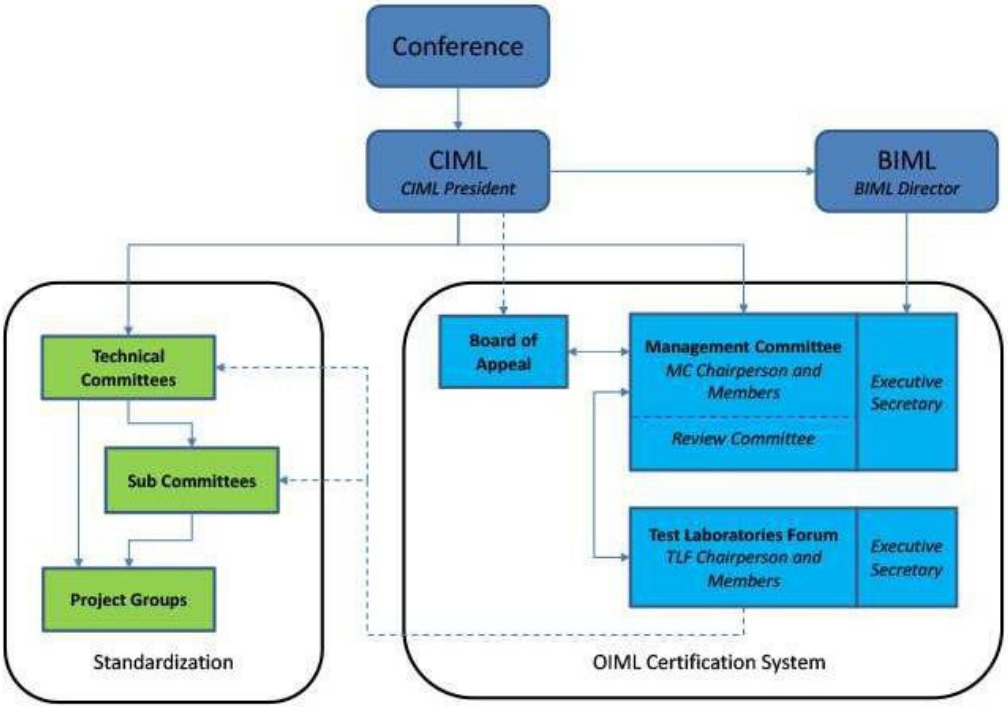

Figure 1 OIML Certification System (OIML-CS) - Structure

2.2 CERTIFICATION SYSTEM "CE OR UKCA METROLOGY"

2.2.1 INTRODUCTION

This certification system is established for measuring instruments to implement a manufacturer's conformity assessment procedure for measurement instruments within the framework of the establishment of a CE-mark or UKCA mark.

The basis is laid down in two directives for measuring instruments which describe the modules for applying a CE-mark: directive 2014/31/EU [1] and directive 2014/32/EU [2]. The equivalent provision for UKCA marks is set out in the UK Measuring Instrument Regulations 2016 (SI 1153) and Non-Automatic Weighing Instruments (NAWI) Regulations 2016 (SI 1152).

The modules for CE and UKCA conformity routes are given in Table 2.

Table 2 Modules for CE-marking according to Blue Guide of the EU. These also continue to apply for UK.

Declaration of conformity (CE or UKCA marking)	
A = internal production control	
A1 = A + Internal production control plus supervised product testing	
A2 = A + Internal production control plus supervised product checks at random intervals	
B = type examination[1]	**C = internal production control**
	C1 = C + product testing by a notified body
	D = quality assurance of the production process[1]

	E = quality assurance of final product inspection and testing[2]
	F = product verification[1]
D1 = quality assurance of the production process[1 2]	
E1 = quality assurance of final product inspection and testing[2]	
F1 = product verification[1]	
G = unit verification[1]	
H = full quality assurance[2]	
H1 = H + design examination[2]	

[1] Modules marked with 1 ae applicable to both NAWI and MID and UKCA.

[2] Modules D, D1, E, H and H1 relate to the audit of the manufactures quality system.

The manufacturer shall lodge an application for assessment of the quality system with a notified body (or approved body for UK) of his choice. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer. Additionally, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, to verify that the quality system is functioning correctly.

It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

2.2.2 *Directives 2014/31/EU and 2014/32/EU, NAWI Regulations 2016 and UK Measuring Instruments Regulations 2016*

These directives and UK regulations describe measuring instruments as given in under subsection 2.3.2

Product certification and CE/UKCA marking is the process of certifying that a product has passed performance, safety and quality assurance tests and meets the criteria specified in regulations or product specifications. CE marking provides national indigenous and multinational companies with immediate access to European and world markets which, in turn, create further employment opportunities. UKCA marking provides national indigenous and multinational companies with immediate access to the GB market. The European Union requires Member States, to appoint Notified Bodies, to work with organisations to assess whether a product meets the requisite standards under the specific directive. For UKCA, the UK government designates Approved Bodies to undertake the same tasks.

A manufacturer may apply the CE or UKCA mark if he fulfils the criteria according to a module track in Table 3. NMi Certin is a notified body and is working towards being an approved body. Notified Body number: 0122.

Table 3 Measuring instruments and the modules for conformity assessment (A1 n.a.)

	Measuring instrument	A	A2	B+C	B+C1	B+D	B+E	B+F	D1	E1	F1	G	H	H1
NAWI **UKCA**	Directive 2014/31/EU NAWI Regulations 2016													
	Non-automatic weighing instruments					●		●	●		●	●		

	Measuring instrument	A	A2	B+C	B+C1	B+D	B+E	B+F	D1	E1	F1	G	H	H1
MID **UKCA**	Directive 2014/32/EU Measuring Instruments Regulations 2016													
MI-001	Water meters					●		●						●
MI-002	Gas meters and volume conversion devices					●		●						●
MI-003	Active electrical energy meters					●		●						●
MI-004	Thermal energy meters					●		●						●
MI-005	Measuring systems for the continues and dynamic measurement of quantities of liquids other than water					●		●				●		●
MI-006	Automatic weighing instruments – Mechanical systems – Electromechanical systems – Electronic systems or systems containing software					 ● ● ●	 ● ● 	 ● ● ●	 ● 	 	 ● 	 ● ● ●	 	 ● ● ●
MI-007	Taximeters					●		●						●
MI-008	Material measures – Material measures of length – Capacity serving measures		 ●			 ● ●	 ●	 	 ● ●	 ●	 ● ●	 ● 	 ● ●	
MI-009	Dimensional measuring instruments – Mechanical or electromechanical instruments – Electronic instruments or instruments containing software					 ● ●	 ● 	 ● ●	 ● 	 ● 	 ● 	 ● ●	 ● 	 ● ●
MI-010	Exhaust gas analysers					●		●						●

2.2.3 *Measuring Instruments and the Modules to be Followed*

Accreditation as an impartial means of assessing and conveying formal demonstration of the competence (technical ability, impartiality, and professional integrity) of conformity assessment bodies, is an effective quality infrastructure tool used worldwide.

Conformity assessment includes activities such as testing (carried out by laboratories), inspection, certification, etc. Inspection and product certification can be considered similar and there is some overlapping in the definitions. They both go beyond simple testing by including tasks related to the ability to assess test results and decide on conformity. They pursue the same goal (i.e. the assessment of the conformity of a product) in slightly different ways.

The “Blue Guide” describes the various modules A till H1 applicable in conformity testing and gives Guidance in choosing the appropriate accreditation standards for the various Modules under Notification.

ISO/IEC 17020, ISO/IEC 17021-1, ISO/IEC 17025, and ISO/IEC 17065 are the core standards for assessing the competence of conformity assessment bodies. ISO/IEC 17020, ISO/IEC 17065 focus on criteria for performing conformity assessment, while ISO/IEC 17025 tackles in more detail the testing aspect.

ISO/IEC 17065 covers all the various modules A till H1 and specifies the general requirements that a third party operating a product certification system shall meet if it is to be recognized as competent and reliable. Product certification entails giving assurance that a product conforms to specified requirements such as regulations, standards, or other technical specifications. A product certification system can include, e.g. type testing or examination, testing or inspection of every product or of a particular product, batch testing or inspection, design appraisal, which could be coupled with production surveillance or assessment and surveillance of the manufacturer's quality system.

Table 4 Overview of Modules

Modules	Description
A Internal production control	Covers both design and production. The manufacturer himself ensures the conformity of the products to the legislative requirements (no EU-type examination).
A1 Internal production control plus supervised product testing	Covers both design and production. A + tests on specific aspects of the product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer.
A2 Internal production control plus supervised product checks at random intervals	Covers both design and production. A + product checks at random intervals carried out by a notified body or in-house accredited body.
B EU-type examination	Covers design. It is always followed by other modules by which the conformity of the products to the approved EU-type is demonstrated. A notified body examines the technical design and or the specimen of a type and verifies and attests that it meets the requirements of the legislative instrument that apply to it by issuing an EU-type examination certificate. There are 3 ways to carry out EU-type examination: 1) production type, 2) combination of production type and design type and 3) design type.
C Conformity to EU-type based on internal production control	Covers production and follows module B. Manufacturer must internally control its production in order to ensure product conformity against the EU-type approved under module B.
C1 Conformity to EU-type based on internal production control plus supervised product testing	Covers production and follows module B. Manufacturer must internally control its production in order to ensure product conformity against the EU-type approved under module B. C + tests on specific aspects of the product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer.
C2 Conformity to EU-type based on internal production control plus supervised product checks at random intervals	Covers production and follows module B. Manufacturer must internally control its production in order to ensure product conformity against the EU-type approved under module B. C + product checks at random intervals tests on specific aspects of the product carried out by a notified body or in-house accredited body.
D Conformity to EU-type based on quality assurance of the production process	Covers production and follows module B. The manufacturer operates a production (manufacturing part and inspection of final product) quality assurance system in order to ensure conformity to EU-type. The notified body assesses the quality system.
D1 Quality assurance of the production process	Covers both design and production. The manufacturer operates a production (manufacturing part and inspection of final product) quality assurance system in order to ensure conformity to legislative requirements (no EU-type, used like D without module B). The notified body assesses the production (manufacturing part and inspection of final product) quality system.

Modules	Description
E Conformity to EU-type based on product quality assurance	Covers production and follows module B. The manufacturer operates a product quality (= production quality without the manufacturing part) assurance system for final product inspection and testing in order to ensure conformity to EU-type. A notified body assesses the quality system. The idea behind module E is similar to the one under module D: both are based on a quality system and follow module B. Their difference is that the quality system under module E aims to ensure the quality of the final product, while the quality system under module D (and D1 too) aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E is thus similar to module D without the provisions relating to the manufacturing process
E1 Quality assurance of final product inspection and testing	Covers both design and production. The manufacturer operates a product quality (= production quality without the manufacturing part) assurance system for final product inspection and testing in order to ensure conformity to the legislative requirements (no module B (EU-type), used like E without module B). The notified body assesses the quality system. The idea behind module E1 is similar to the one under module D1: both are based on a quality system. Their difference is that the quality system under module E1 aims to ensure the quality of the final product, while the quality system under module D1 aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E1 is thus similar to module D1 without the provisions relating to the manufacturing process.
F Conformity to EU-type based on product verification	Covers production and follows module B. The manufacturer ensures compliance of the manufactured products to approved EU-type. The notified body carries out product examinations (testing of every product or statistical checks) in order to control product conformity to EU-type. Module F is like C2 but the notified body carries out more systematic product checks.
F1 Conformity based on product verification	Covers both design and production. The manufacturer ensures compliance of the manufactured products to the legislative requirements. The notified body carries out product examinations (testing of every product or statistical checks) in order to control product conformity to the legislative requirements (no EU-type, used like F without module B) Module F1 is like A2 but the notified body carries out more detailed product checks.
G Conformity based on unit verification	Covers both design and production. The manufacturer ensures compliance of the manufactured products to the legislative requirements. The notified body verifies every individual product in order to ensure conformity to legislative requirements (no EU-type).
H Conformity based on full quality assurance	Covers both design and production. The manufacturer operates a full quality assurance system in order to ensure conformity to legislative requirements (no EU-type). The notified body assesses the quality system.
H1 Conformity based on full quality assurance plus design examination	Covers both design and production. The manufacturer operates a full quality assurance system in order to ensure conformity to legislative requirements (no EU-type). The notified body assesses the quality system and the product design and issues an EU design examination certificate. Module H1 in comparison to module H provides in addition that the notified body carries out a more detailed examination of the product design. The EU-design examination certificate must not be confused with the EU-type examination certificate of module B that attests the conformity of a specimen 'representative of the production envisaged', so that the conformity of the products may be checked against this specimen. Under EU design examination certificate of module H1, there is no such specimen. EU design examination certificate attests that the conformity of the design of the product has been checked and certified by a notified body.

REFERENCE

– "2016/C 272/01" COMMISSION NOTICE — THE 'BLUE GUIDE' ON THE IMPLEMENTATION OF EU PRODUCTS RULES 2016

2.3 CERTIFICATION SYSTEM "NL METROLOGY"

2.3.1 INTRODUCTION

NL Metrology is subdivided into a number of approval schemes, which have been assigned to NMi Certin on behalf of the Dutch Government.

See Notification / aanwijzing ID 7575.

Figure 2 shows this diagram.

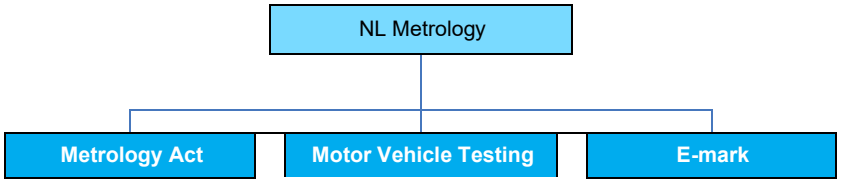

Figure 2 Overview of the sectors of the NL Metrology System

2.3.2 *Metrology Act*

The Metrology Act is based on:

- *Metrologiewet*
- *Besluit Meetinstrumenten En Marktdeelnemers*
- *Regeling gebruik en installatie EU-meetinstrumenten*
- *Regeling nationaal autonoom geregelde meetinstrumenten*

This certification scheme, based on measuring instruments offers companies the possibility of being authorised to carry out verification on measuring instruments up to and including the application of approval and rejection marks. An applicant for verification authority shall be approved by NMi Certin before he may start verification activities. A major part of the approval is the assessment of the verification system selected by the applicant and which is described in a quality manual. These are formal quality system aspects and the establishment of technical competence.

2.3.3 *Motor Vehicle Testing*

Motor Vehicle Testing is based on:

- *Regeling Voertuigen*

This is a certification scheme based on the Road Traffic Act (entitlement to carry out inspections) which specifies an inspection system for motor vehicles (Periodic Vehicle Check Act). All vehicles are checked regularly for safety and environmental requirements. The measuring instruments to be used for this (including CO meters and brake test benches) must also be checked regularly. This may be carried out by those entitled to carry out inspections who have to be approved by NMi Certin.

2.3.4 *Quantity Indication Act – Pre-packaging*

This is a certification scheme based on the Consumer Goods Act (quantity indication act) which specifies a control system for companies which manufacture pre-packaging according to the averaged principle.

This also includes companies which import from outside the EU.

A major component of approval is the assessment of the control system which is laid down in the system description.

A candidate company will receive provisional recognition following NMi Certification approval. Advice will be provided to the supervisory authority following an assessment or re-assessment.

2.4 Certification System "Mess- und Eichgezetz-Messeg"

This certification system is established for measuring instruments covered by the national German Mess- und Eichgesetz.

The basis is laid down in the Mess- und Eichgesetz – MessEG and the Mess- und Eichverordnung – MessEV. In the MessEV, Appendix 4, part B, the same conformity modules are stated as in the MID (2014/32/EU), as described above.

The modules for the conformity routes are given in a document published by the Regelermittlungsausschuss, "Ermittelte Regeln und Erkenntnisse des Regelermittlungsausschusses nach § 46 des Mess- und Eichgesetzes". In Table 5 an overview is given for several measuring instruments.

Table 5 Measuring instruments and the modules for conformity assessment for the German Mess- und Eichgesetz

	Measuring instrument	A	A2	B+C	B+C1	B+D	B+E	B+F	D1	E1	F1	G	H	H1
6.2	Wirkverbrauchszähler soweit nicht EU-Elektrizitätszähler					●		●						
6.3	Blindverbrauchszähler					●		●						
6.5	Gleichstromzähler					●		●						
6.6	Zusatzeinrichtungen [1)]					●		●						
6.8	Messgeräte und Zusatzeinrichtungen im Anwendungsbereich E-Mobilität [2)]					●		●						

1) For Zusatzeinrichtungen NMi is appointed for module D only.
2) Item "6.8 Messgeräte und Zusatzeinrichtungen im Anwendungsbereich E-Mobilität" covers EV Charging Systems for both DC and AC applications.

NMi Certin is appointed as Notified Body (Konformitätsbewertungsstelle) by the Bundesministerium für Wirtschaft und Energie (BMWi), with Notified Body no. DE-0122.

A manufacturer may place products on the German market for the above-mentioned instruments if he fulfils the criteria according to a module track in Table 5.

3 Product Certification

3.1 Introduction

Product Certification is known as type examination of the instrument and involves rigorous testing of the instrument to ensure it meets the requirements. Type examination is done in accordance with the applicable regulations.

Technical Documentation to be submitted

The technical documentation required to be submitted will depend on the directive that applies. However, the below gives a good generic summary of the sort of documentation that must be submitted:

a) The technical documentation shall render the design, manufacture and operation of the measuring instrument intelligible and shall permit an assessment of its conformity with the appropriate requirements of the relevant directive / regulation.
b) The technical documentation shall be sufficiently detailed to ensure:
   - the definition of the metrological characteristics,
   - the reproducibility of the metrological performances of produced instruments when properly adjusted using appropriate intended means,
   - the integrity of the instrument

3.2 OIML Type Evaluation

Not approved yet for ISO/IEC 17065. Performed under ISO/IEC 17020.

3.3 EU/UKCA Type Examination, Module B

The manufacturer shall:

- establish the technical documentation on the design, manufacture and operation of the product.

The manufacturer or its authorised representative shall:

- submit application for an evaluation;
- provide NMi Certin with one (or several) specimens representative of the planned production;
- inform NMi Certin of any modifications made to the approved instrument;
- keep the technical documentation and a copy of the approval certificate at the disposal of the surveillance authorities.

NMi Certin shall:

- perform the relevant examinations and necessary tests, or has them carried out, to examine whether the specimen(s) fulfil the essential requirements and have been manufactured in compliance with the technical documents;
- issue an approval certificate;
- keep a copy of the certificate and a register of other important technical documentation;
- provide other notified bodies upon their request, with the intended information on the approval certificate.

3.4 EU/UKCA Product Examination

3.4.1 Introduction

Included in this group are the modules A2, F, F1 and G. The examinations carried out or supervised by NMi Certin relate to the manufactured product. NMi Certin issues, except for module A1, a conformity certificate as a declaration of conformity and supervises the affixing of the identification number on the product.

3.4.2 Declaration of Conformity based on Internal Control plus Supervised Product Checks at Random Intervals, Module A2

The manufacturer shall:

- establish technical documentation on the design, manufacture, and operation of the product,
- take all action necessary to ensure that the production process guarantees conformity of the manufactured products with the technical documents and the corresponding requirements (i.e. it shall maintain a quality system),
- perform one or several random inspections of the product, or have them carried out at its expense,
- appoint a notified body to be responsible for the performance of the checks.

The manufacturer or its authorized representative shall:

- ensure and declare that the relevant products fulfil the requirements,
- affix the CE or, where relevant, the UKCA label to each measuring instrument and, where NMi Certin has intervened in the production process, behind the CE label, the identification number of NMi Certin,
- affix the identification number of NMi Certin beside the CE label (or the NMi Certin UK identification number for the UKCA label),
- submit a conformity declaration,
- keep a copy of the conformity declaration and of the technical documents at the disposal of the surveillance authorities.

NMi Certin shall:

- monitor the inspections performed by the manufacturer,
- supervise the affixing of its identification number, should NMi Certin have been involved in the conformity assessment during the production process,
- store the specified documentation,
- provide other notified bodies, upon their request, with the required information.

3.4.3 Declaration of Conformity to Type Based on Product Verification, Module F

The manufacturer shall:

- take all measures necessary in order that the manufacturing process ensures conformity of the manufactured products with the pattern described in the pattern approval certificate and the applicable requirements (i.e. it shall operate a quality system and draw up the necessary documents).
- in the case of a statistical examination, present its products in homogeneous lots and take all measures to ensure the homogeneity of each lot produced.

The manufacturer or its authorised representative shall:

- submit application for a conformity certificate,
- guarantee and declare, that the products are in compliance with the pattern described in the pattern approval certificate and satisfy the applicable requirements,
- affix the CE or, where relevant, the UKCA label to each individual measuring instrument,

- affix, behind the CE label, the identification number of NMi Certin (or the NMi Certin UK identification number for the UKCA label),
- submit a declaration of conformity,
- keep a copy of the conformity declaration and technical documents at the disposal of the surveillance authorities (i.e. the conformity certificate of NMi Certin with the listed supplementary documents).

NMi Certin shall:

- carry out the appropriate evaluations and tests, either through examination and testing of each individual product or by examination and testing of the products on a statistical basis, to check the conformity of the product to the relevant requirements,
- supervise the affixing of its identification number,
- issue a conformity certificate for the examinations performed,
- store a register of important technical documentation,
- provide other notified bodies, upon their request, with the required information.

3.4.4 Declaration of Conformity based on Product Verification, Module F1

The manufacturer shall:

- establish technical documentation on the design, production and operation of the product,
- take all action necessary in order that the manufacturing process ensures conformity of the manufactured products with the applicable requirements (i.e. it shall operate a quality system and draw up the necessary documents),
- in the case of a statistical examination, present its products in homogeneous lots and take all measures to ensure the homogeneity of each lot produced.

The manufacturer or its authorised representative shall:

- submit application for a conformity certificate,
- guarantee and declare that the products satisfy the applicable requirements,
- affix the CE or, where relevant, the UKCA label to each individual measuring instrument,
- affix, behind the CE label, the identification number of NMi Certin (or the NMi Certin UK identification number for the UKCA label),
- submit a declaration of conformity,
- keep a copy of the conformity declaration, the technical documents and the conformity certificate of NMi Certin at the disposal of the surveillance authorities.

NMi Certin shall:

- carry out the appropriate evaluations and tests, either through examination and testing of each individual product or by examination and testing of the products on a statistical basis, to check the conformity of the product to the relevant directive requirements,
- supervise the affixing of its identification number,
- issue a conformity certificate for the examinations performed,
- store a register of important technical documentation,
- provide other notified bodies, upon their request, with the required information.

3.4.5 Declaration of Conformity based on Unit Verification, Module G

The manufacturer shall:

- establish technical documentation on the design, production and operation of the product,
- guarantee and declare that the products satisfy the applicable requirements.

The manufacturer or its authorised representative shall:

- submit application for a conformity certificate,
- affix the CE or, where relevant, the UKCA label to each individual measuring instrument,
- affix, behind the CE label, the identification number of NMi Certin (or the NMi Certin UK identification number for the UKCA label),
- submit a declaration of conformity,
- keep a copy of the conformity declaration and the technical documents at the disposal of the surveillance authorities.

NMi Certin shall:

- examine the product and carry out the appropriate tests to check the conformity of the product to the relevant specified requirements,
- supervise the affixing of its identification number,
- store a register of important technical documentation,
- issue a conformity certificate for the examinations performed,
- provide other notified bodies, upon their request, with the required information.

3.5 Execution

The technical procedures for type approval are laid down in internal procedures. NMi Certin provides the customer with a quotation and a test plan.

NMi Certin provides the customer with a Certification Agreement. The tests will be performed by qualified staff.

3.6 Deliverables

- EU or UKCA-type examination Certificate (valid 10 years)
- Test certificate
- Parts certificate
- Test / Parts certificate
- Evaluation Certificate
- Test report
- Evaluation report
- (Software) report Welmec 7.2
- Type evaluation report
- (Parallel) certificate
- Documentation folder
- OIML certificate, scheme A or B
- Certificate of Conformity (Module F en G)
- Module H is not practically applicable

4 System Certification

4.1 Introduction

Included in this group are the modules D, D1, E, E1, H and H1 (as defined in the Blue Guide of the EU). The assessments performed by NMi Certin as based on the quality system. NMI Certin carries out periodic audits of the manufacturer, to ensure that it operates and correctly applies an adequate quality system.

Module D is applicable in 95 % of all situations. The differences between the various Modules are explained in detail in the Annex V of the BLUE GUIDE_2016_EN

4.2 EU/UKCA Quality System examination

4.2.1 Declaration of Conformity to Type Based on Quality Assurance of the Production Process, Module D

The manufacturer shall:

- operate an approved quality system for production, final product inspection and testing, which incorporates the establishing of technical documentation (i.e. defined information on the product category envisaged, documentation of the quality system and its updating, technical documentation of the approved type, a copy of the pattern approval certificate and the decisions and reports of NMi Certin),
- submit an application for an evaluation of the quality system for the products concerned,
- guarantee and declare that the products in question comply with the type approval certificate and satisfy the applicable requirements,
- undertake to fulfil the obligations defined by the approved quality system and to guarantee its correct and efficient functioning at all times,
- support NMi Certin in its surveillance,
- keep the documentation of the quality system, details of its updating and decisions and reports of NMi Certin at the disposal of the surveillance authorities.

The manufacturer or its authorized representative shall:

- affix the CE or, where relevant, the UKCA label to each individual measuring instrument,
- affix, behind the CE label, the identification number of NMi Certin (or the NMi Certin UK identification number for het UKCA label),
- submit a declaration of conformity,
- inform NMi Certin of its intention to update the quality system,
- keep a copy of the conformity declaration at the disposal of the surveillance authority.

NMi Certin shall:

- evaluate the quality system, in order to establish whether it fulfils the relevant requirements and shall meet an assessment decision,
- supervise the affixing of its identification number,
- monitor the manufacturer by periodic and unannounced visits,
- store a register of important technical documentation,
- provide other notified bodies, upon their request, with the required information on granted or withdrawn approvals of quality systems.

4.2.2 *Declaration of Conformity based on Quality Assurance of the Production Process, Module D1*

The manufacturer shall:

- establish technical documentation on the design, production and operation of the product,
- operate an approved quality system for production, final product inspection and testing, which incorporates the establishing of technical documentation (i.e. defined information on the planned product category, documentation of the quality system and its updating together with the decisions and reports of NMi Certin),
- submit an application for an evaluation of the quality system for the products concerned,
- guarantee and declare that the products in question satisfy the applicable requirements
- undertake to fulfil the obligations arising from the approved quality system and to guarantee its correct and efficient functioning at all times,
- support the notified body or, for UKCA the approved body, in its surveillance,
- keep the documentation of the quality system, details of its possible updating and decisions and reports of NMi Certin at the disposal of the surveillance authorities.

The manufacturer or its authorized representative shall:

- affix the CE or, where relevant, the UKCA label to each individual measuring instrument,
- affix, behind the CE label, the identification number of NMi Certin (or the NMi Certin UK identification number for the UKCA label),
- submit a declaration of conformity,
- inform NMi Certin of its intention to update the quality system,
- keep a copy of the conformity declaration at the disposal of the surveillance authorities.

NMi Certin shall:

- evaluate the quality system, in order to establish whether it fulfils the relevant requirements and meet an assessment decision,
- supervise the affixing of its identification number,
- monitor the manufacturer by periodic and unannounced visits,
- store a register of important technical documentation,
- provide other notified bodies, upon their request, with the required information on granted or withdrawn approvals of quality systems.

4.2.3 *Declaration of Conformity to Type Based on the Quality System of the Product Inspection, Module E*

The manufacturer shall:

- Obligations as in module D, the operated and approved quality system only applies to final product inspection and testing.

The manufacturer or its authorised representative shall:

- Obligations as in module D.

NMi Certin shall:

- Obligations as in module D.

4.2.4 *Declaration of Conformity based on Quality Assurance of Final Product Inspection and Testing, Module E1*

The manufacturer shall:

- Obligations as in module D1, the operated and approved quality system only applies to final product inspection and testing.

The manufacturer or its authorised representative shall:

- Obligations as in module D.

NMi Certin shall:

- Obligations as in module D.

4.2.5 *Declaration of Conformity based on Full Quality Assurance, Module H*

The manufacturer shall:

- operate an approved quality system for design, production, final product inspection and testing, which includes the establishing of technical documentation (i.e. defined information on the design, the planned instrument category, documentation of the quality system and its updating together with the decisions and reports of NMi Certin,
- submit an application for evaluation of the quality system for the relevant products,
- guarantee and declare that the products in question satisfy the applicable requirements,
- undertake to fulfil the obligations arising from the approved quality system and to guarantee its correct and efficient functioning at all times,
- support NMi Certin in its surveillance,
- keep the documentation of the quality system, details of its possible updating and decisions and reports of NMi Certin at the disposal of the surveillance authorities.

The manufacturer or its authorised representative shall:

- Obligations as in module D.

NMi Certin shall:

- Obligations as in module D.

4.2.6 *Declaration of Conformity based on Full Quality Assurance plus Design Examination, Module H1*

The manufacturer shall:

- operate an approved quality system for design, production, final product inspection and testing, which includes the establishing of technical documentation (i.e. defined information on the design, the planned instrument category, documentation of the quality system and its updating together with the decisions and reports of NMi Certin),
- submit an application for evaluation of the quality system for the related products,
- guarantee and declare that the products in question satisfy the applicable requirements,
- undertake to fulfil the obligations as defined by the approved quality system and to guarantee its correct and efficient functioning at all times,
- support NMi Certin in its surveillance,
- keep the documentation of the quality system, details of its possible updating and decisions and reports of NMi Certin at the disposal of the surveillance authorities,
- apply for the examination of the design,
- provide NMi Certin up-to-date information on modifications of the approved design.

The manufacturer or its authorised representative shall:

- Obligations as in module D.

NMi Certin shall:

- evaluate the quality system, in order to establish whether it fulfils the relevant requirements and shall meet an assessment decision,
- supervise the affixing of its identification number,
- monitor the manufacturer by periodic and unannounced visits,
- store a register of important technical documentation,
- provide other notified bodies, upon their request, with the required information on granted or withdrawn approvals of quality assurance systems,
- examine the design,
- issue a design approval certificate where the design satisfies the requirements,
- keep a register of the design approval certificates,
- provide other notified bodies, upon their request, with the required information on the design approval certificate.

4.3 EXECUTION

4.3.1 INTRODUCTION

Once NMi Certification has received an order for a system audit then NMi Certification will assign an audit team.

4.3.2 THE AUDIT TEAM

COMPOSITION OF THE AUDIT TEAM

An audit team will consist of at least one lead assessor. In addition, one or more assessors and/or technical assessors may be added to the team. The lead assessor is the leader of the team and takes care of all communication between the team and management.

The qualifications required of the lead assessor, the assessor and the technical assessor shall be according to ISO/IEC 17021.

In addition to the qualifications specified, the members of the team should meet the following requirements:

- no interest in (results of) the audit (impartial); and
- not have acted as a consultant to the manufacturer being audited during the two years prior to the audit.

The members of the team will normally be employees of NMi Certin. If this is, however, not possible then external auditors will be contracted in.

ASSIGNMENT OF LEAD ASSESSOR

After an initial audit there will be a reaudit after three years unless there is any reason to do this earlier. Two annual audits will be carried out in the intervening period. These are called surveillances.

The lead assessor who has carried out an initial audit or a reaudit will also generally carry out the two subsequent annual surveillances. This is set as a cycle of three years.

The assessor and the technical assessor assigned by the lead assessor to carry out parts of the audit independently. It is preferable if the assessor(s) and technical assessor(s) are the same people for each cycle. Because of the desire to rotate the available lead assessors, a subsequent cycle may be done by a different lead assessor.

ACCEPTANCE TEAM

Once management has assigned or changed an audit team this will be presented to the applicant. The applicant may indicate whether he agrees to the team presented by management. If the applicant does not agree to the team then management will set up a new team.

4.3.3 Execution of the Audit

Preparation

The lead assessor oversees the audit. Together with the assessor(s), he or she will set up the assessment plan and will send it in advance to the manufacturer to acknowledge the practicality. He is also responsible for the audit report.

The time spent on the audit depends on the following factors:

- If the manufacturer to be audited has relevant certification (ISO 9001 for example).
- The language in which the manual and the job instructions are written.
- The scope.
- The number of employees within the scope of the audit.
- The number of branches/sites of the manufacturer to be visited.

Scope

The audit will shall be confined to the considered scope for certification. This implies that matters which are not relevant in relation to the decision of issuing the certificate shall not be audited.

Pre-audit

If a manufacturer so desires, a pre(liminary)-audit can take place prior to the initial certification audit.

A preliminary audit is only applicable for an initial audit and is intended to assess the quality manual and to make proper agreements on the method of working and the scope of the audit.

The time between the preliminary audit and an initial audit depends on the time required by the company to correct the non-conformities observed during the preliminary audit. The person who carries out the preliminary audit will not be the lead assessor of the initial audit.

The result of the preliminary audit will not be taken into consideration during the initial audit.

4.3.4 Initial Audit and Certification

Introduction

The initial audit consists of stage I and stage II. Stage I will be partly carried out prior to on-site activities and partly on-site to get a suitable overview of available information before initiating stage II.

The main objective of stage I is to determine whether the manufacture is ready to undergo the certification audit. After stage I no non-conformities will be reported, but the audit team can report areas of concern. These are situations which could lead to nonconformities during stage II.

Categorizing Non-Conformities

The audit team has three possibilities for indicating if a requirement of a standard has been fulfilled.

C Conform

By this result a remark can be added which gives an indication of an improvement.

D Deviation

An isolated shortcoming or misstep regarding the requirements of the standard that has no influence on the functioning of the quality system or the conformity with the requirements of the product or the service.

The deviation shall be corrected within an agreed term.

N Nonconformity

The lack of an effective implementation of a system requirement of the standard, or a situation in which there is little or no assurance that the product of the service complies with the established requirements.

The non-conformity shall be corrected within a very short term to prevent withdrawal of the quality system certificate.

In the case of a "D" or "N" finding, a non-conformity (NCF) form will be written. At an initial audit, no certificate will be issued until all NCFs have been resolved.

ISSUING AN CERTIFICATE

If all the audit criteria have been met then an agreement and a certificate (in accordance with the certification scheme in question) will be drawn up, given a number and signed by management. For UKCA purposes the decision to certify (or otherwise) will be made by the UK representative and documented accordingly.

Once the relevant agreement has been signed the certificate will be issued to the applicant.

The agreement is for a limited period of time. The period of validity of the certificate is three years and will be renewed if the criteria for the certification scheme are met in a reaudit. Management will take care of publication of the initial issuing of a certificate.

4.3.5 SURVEILLANCE AUDIT

In between the reaudits a periodic audit visit will be made at least once per year. This is called a surveillance audit. Management will determine where a surveillance audit will have to be carried out more often.

If acceptable changes are observed during a surveillance audit then the certificate will, if necessary, be amended or renewed.

If a non-conformity is observed during a surveillance audit, then a period of time will be agreed within which the non-conformity is to be corrected.

During this period restrictions may be imposed on the company with respect to the exercising of rights arising from certification. Once corrective measures have been carried out by the company an extra audit of these corrective measures will take place. This extra audit can be a document review (performed on the NMi Certin office) or an extra visit to the manufacturer's premises.

It may be decided that:

- The situation is in order in accordance with the existing certification.
- The situation has changed but is acceptable and the certificate will have to be amended or renewed.
- The situation is still not acceptable which will mean suspension or withdrawal of the certificate.

4.3.6 CHANGES TO THE QUALITY SYSTEM

According to the obligations a part of modules D, D1, E, E1, H and H1, the certificate holder is obliged immediately to report to the lead assessor any interim changes (which means between the surveillance audits) which may be of importance for the certification of the quality system.

4.3.7 Confidentiality

The members of the audit team are obliged to maintain confidentiality through their contract of employment with NMi Certin. Externally contracted auditors shall sign a confidentiality agreement.

4.3.8 Extension and Amendment of a Certificate

Expansion

If a certified manufacturer wishes to have new activities or locations included in the certification then the same procedure will be followed for these activities or locations as described earlier for the audit procedure. If all the audit criteria are met, a new certificate will be issued.

Amendment

If changes have taken place in a certified manufacturer which are not in accordance with the details specified on the certificate then, following assessment and approval of the amended situation, a new certificate will be issued and the old one will be withdrawn.

5 Advisory Committee

5.1 Introduction

This chapter contains the rules which apply for the Advisory Committee.

5.2 Establishment of the Advisory Committee

Initial the director, board and scheme manager determine the members of the Advisory Committee and invite them to take place into the committee.

The Advisory Committee will advise director, board and scheme manager on the implementation of the certification scheme and related tasks, with focus on impartiality, independency and reliability of the certificate system. This may be a binding advice.

5.3 Assignment

The members of the Advisory Committee will be assigned by the director.

5.4 Composition

5.4.1 Members of the Advisory Committee

The members of the Advisory Committee will consist of external stakeholders of the certificate system, taking account a balanced participation of interests. (See also ISO 17065 clauses 4.2.12; 5.1.3; 5.1.4).

For UKCA purposes the Advisory Committee will also include the UK Representative as a member.

5.4.2 Selection of the Chairman

The chairman will be chosen by the members of the Advisory Committee out of the Advisory Committee.

5.4.3 Secretariat

The secretariat of the Advisory Committee will be provided by the scheme manager of NMi Certification. As such he will act as secretary and may speak but does not have the right to vote.

5.4.4 Impartial Advices

The Advisory Committee must always be composed in such a way that impartial advice is guaranteed (see also subsection 5.7.5 required quorum).

5.5 Duration of Membership

An assignment in the Advisory Committee is valid for a period of 3 years. Re-assignment is allowed.

5.6 Termination of Membership

Membership of the advisory committee will cease in each of the following cases:

- At the request of the person involved;
- If there is a lack in the duty of confidentiality (see paragraph 5.8).

5.7 MEETINGS

5.7.1 FREQUENCY

The advisory committee will meet at least once per year. In addition, the management may call for a meeting when a specific issue must be discussed.

5.7.2 PROVISION OF INFORMATION

The management of NMi Certification will provide, in advance of a meeting, a report over the past year to the advisory committee, which consists of:

- The functioning of the certification systems;
- Results of certification audits;
- A list of actual certificate holders;
- A list of withdrawn certificate holders in the past year;
- A list of received customer feedback;
- Financial evaluation over the past year.

5.7.3 REQUESTED ADVICE

If requested so to do the Advisory Committee will provide advice on the ethics of:

- Policy development and the basic principles with respect to the content and the functioning of the certification system.

5.7.4 BINDING ADVICE

The Advisory Committee may indicate that its advice should be considered as binding. The director may not ignore such advice.

If the director does not follow such advice, the Advisory Committee has the right to take independent action (e.g., informing authorities, accreditation bodies, stakeholders). In taking appropriate action, the confidentiality requirements of paragraph 4.8 relating to the manufacturer and NMi Certin will be respected.

Advice that conflicts with the operating procedures of NMi Certin or other mandatory requirements will not be followed. Management of NMi Certin will document the reasoning behind the decision to not follow the advice and maintain the document for review by the Quality and Compliance Officer.

5.7.5 REQUIRED QUORUM FOR DECISIONS

The required quorum for decision making must always be more than 50% of the total number of members entitled to vote (present and not present during the meeting). If this percentage is not attained among the members present, then the members who are not present must also vote later in writing.

5.8 CONFIDENTIALITY

The members of the Advisory Committee are obliged to maintain confidentiality with respect to information whose confidential nature may be assumed. If this rule is broken, the director may decide during the session to terminate the membership of the person involved of the Advisory Committee.

5.9 CHANGES

These regulations apply to the work of the Advisory Committee. These regulations may not be set aside by the Advisory Committee even unanimously.

6 Making an Appeal

6.1 Introduction

In case a (potential) certificate holder disagrees with a certification decision; the applicant or certificate holder can file an appeal.

When certification decisions of the Certification Board concern public tasks performed by NMi Certin, stakeholders can file an appeal as well.

The specific procedures for appealing, which apply at NMi Certin, can be found in the "Regulation feedback procedure NMi Certin" document which is available on NMi website. The appeal procedure also covers the NMi Certin UK and its UKCA services.

6.2 Administrative Decision or Order versus Civil Decision

6.2.1 General

Please note that there is a difference between an administrative decision or an order and a civil decision.

Administrative Decision or Order

An 'order' is a written decision of an administrative authority constituting a public law act. It concerns decisions taken by government bodies or by bodies performing (a) public task(s). Orders are based on administrative law: it concerns orders, as meant in the General Act on Administrative Law. All orders can be subject to appeal.

For UK purposes this includes any decision from an UK court or an appointed, legal enforcement agency.

Civil Decision

Civil decisions are decisions based on private law (civil law). These are not decisions taken whilst fulfilling a governmental task (in which case the decision would be based on administrative law).

Filing an appeal is not regularly possible when decisions are civil decisions. However, for cases in which 'civil decisions' are also certification decisions, NMi Certin does provide the possibility to file an appeal. The way in which such an appeal can be filed and will be processed is described in paragraph 6.3.

6.2.2 Administrative Decision or Order versus Civil Decision

The distinction between a civil decision and an order can be difficult. A certification decision can occur when performing a legal task (which makes it an order on which appeal as meant in the General Act on Administrative Law is possible), or a certification decision can occur because of a civil activity of NMi Certin (as result of which the decision is a civil one). Because of this sometimes difficult distinction, civil decisions and orders will be processed in the same way.

In addition to this it is noted that, to make an appeal admissible, the use of terminology (either 'decision', 'administrative decision', 'civil decision', or else) is not relevant. It is however important that making and processing an appeal follow the described procedure.

6.3 PROCEDURE

6.3.1 TO APPEAL AN ADMINISTRATIVE DECISION OR ORDER

On orders (as defined in the General Act on Administrative Law), the appeal procedure always applies. This procedure has been described in "Regulation feedback procedure NMi Certin" document (only available in Dutch).

6.3.2 TO APPEAL A CIVIL DECISION

Although the General Act on Administrative Law does not apply to civil decisions, NMi Certin has determined that the procedures in articles 2 till 6 of the "Regulation appeal procedure NMi Certin" document do apply to certification decisions, including sanctions and withdrawal.

This means that filing an appeal on a decision must be done in the same manner as an appeal on an order or administrative decision and that this appeal will be processed in the same way as an appeal on an order or administrative decision.

In addition to this, the 'hearing committee' decides on matters in which the procedural provisions in Article 2 till do not foresee.

7 USE OF THE CERTIFICATION MARK

7.1 INTRODUCTION

The CE Metrology mark, UKCA mark and NL Metrology mark are subject to rules concerning the use of the marks.

7.2 DESIGN

The design of the mark shall be left unchanged by the certificate holder, regarding the mark which has been initially given by NMi to the certificate holder.

7.3 USE OF THE CERTIFICATION MARK (OR OTHER REFERENCES TO CERTIFICATION)

The certification mark may not become a part of the house style of the certificate holder.

The mark may only be used in product flyers or other publications in direct relation to the certification scope as given on the certificate.

The use of the certification mark will be part of the audit.

Those situations for which were not foreseen, the Certification Board of NMi Certification has the right to give further rules or to correct misuse.

The certificate holder is not allowed to use the NMi Certin company logo.

7.4 CONSEQUENCES AFTER ENDING CERTIFICATION

From the date the certification agreement has ended. The former certificate holder shall immediate stop using the mark in all her publications.

8 SANCTIONS

8.1 INTRODUCTION

The Certification Board is authorized to suspend or withdraw a certificate. When required by the certification scheme, or other normative document, NMi Certin will also inform other bodies like Certification Bodies, Notified Bodies (accredited or approved for the related scope) or regulators.

NMi Certin will establish a Certification Board for UKCA purposes. This section also applies to certificates issued by NMi Certin UK.

8.2 SUSPENSION OF A CERTIFICATE

8.2.1 REASONS FOR SUSPENSION

NMi Certin can suspend a certificate for a certain period of time. Reasons for suspension can be:

- the certificate holder can not demonstrate adequate corrective measure to nonconformities reported by NMi Certin;
- the Certification Board of NMi Certin had to make a negative (recertification) decision;
- improper use of the registration, the certificate and/or the certification mark (or other reference to certification)
- the certificate holder lacks to fulfil its financial obligations to NMi Certin;
- NMi Certin is not able to execute it required surveillance activities within the prescribed period.

8.2.2 SUSPENSION PROCEDURE

NMi Certin shall notify the certificate holder of the suspension in a registered letter. This letter shall specify the conditions to be met by the certificate holder to overturn the suspension of the certificate. The period during which the certificate is suspended is a maximum of six (6) weeks and depends on the stated and defined reasons, the letter announcing the suspension indicates the period in force in the specific situation. As soon as the conditions regarding the stated reasons are met within the specified period, NMi Certin will reverse the suspension of the certificate and inform the certificate holder accordingly.

8.2.3 UNDO SUSPENSION

To overturn a suspension, the certificate holder shall take appropriate (correction and/or corrective) measures without undue delay to enable NMi Certin to lift the suspension. The certificate holder shall approach NMi Certin in writing (on paper or digitally) about the proposed measure(s). NMi Certin verifies the measure(s) at the location of the certificate holder by means of a re-audit.

8.3 WITHDRAWAL OF A CERTIFICATE

8.3.1 REASONS FOR WITHDRAWAL

The Certification Board is authorized to revoke the certificate, and the use of the certification mark of NMi Certin, in the following cases:

- the measures mentioned in subsection 8.2.3 Undo suspension are not adequate;
- the normative documents and/or processes have changed, and the organisation cannot demonstrably meet the new requirements;
- the certificate holder shall not enable NMi Certin to carry out the necessary audits within the time limit set;

- the certificate holder ceases to provide the products and/or services, or processes, for more than six (6) months;
- the Certificate Holder fails to fulfil its financial obligations to NMi Certin;
- for other reasons, provided that this reason is specifically included in these certification regulations or this reason has been formally agreed between NMi Certin and the Certificate Holder.

8.3.2 Withdrawal Procedure

NMi Certin shall notify the certificate holder of the withdrawal of the certificate in a registered letter. This is first a provisional withdrawal and after one (1) week this withdrawal becomes final. NMi Certin may publish the notification of the revocation of the certificate. If requested, NMi Certin always informs third parties of the status of the certificate (valid/suspended/revoked/restricted).

8.3.3 Undo Withdrawal

The organization cannot undo the revocation of a certificate. If an organization still wants to demonstrate that it meets all the requirements of the normative document, it must go through a completely new certification audit.

9 Reference list

[1] Directive 2014/31/EU of The European Parliament and of The Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments.

[2] Directive 2014/32/EU of The European Parliament and of The Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments.

[3] The 'Blue Guide' on the implementation of EU products rules, July 2016.

[4] ISO/IEC 17020:2012, General criteria for the operation of various types of bodies performing inspection, March 2012. *RvA accreditation* I122

[5] ISO/IEC 17021-1:2015, Conformity assessment – Requirements for bodies providing audit and certification of management systems, July 2015. *RvA accreditation* C081

[6] ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories, May 2005. *RvA accreditation* L029

[7] ISO/IEC 17065:2012, Conformity assessment - Requirements for bodies certifying products, processes and services.

[8] ISO 9001, Quality management systems – Requirements, October 2015.

[9] Metrologiewet, law of 20-04-2016 concerning regulations regarding measurement units and regarding putting on the market and the use of measuring instruments.

10 Support Organisations for Legal Metrology

THE EUROPEAN ASSOCIATION OF NATIONAL METROLOGY INSTITUTES (EURAMET)

Global harmonisation of measuring instruments is fairly advanced. To achieve even higher efficiency in this field, the EURAMET was established. It represents the national metrological organisations of EU and EFTA countries. The association coordinates the metrological activities of its members.

THE INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY (OIML)

OIML is an intergovernmental organisation promoting the global harmonisation of legal metrology procedures. It ensures the certification of measuring devices is compatible around the world. This facilitates trade in measuring devices and the products relying on them. The EU recognises standards issued by OIML by publishing them in the Official Journal of the European Union.

EUROPEAN COOPERATION IN LEGAL METROLOGY (WELMEC)

The EU's policy on legal metrology is supported by WELMEC, a body set up to promote European cooperation in legal metrology. WELMEC members are the national authorities responsible for legal metrology in EU and EFTA countries. Close cooperation with WELMEC and stakeholders is the main source of the EU's guidance documents and is essential for the application of EU law.