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Guide for the market introduction of measuring instruments

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2 Aim and object

2.1 Aim of the document

The guide specifies the requirements and procedures for conformity assessment of measuring instruments and management systems for the manufacture of measuring instruments, to be performed by the certification body of the Federal Office for Metrology (METAS-Cert). It is directed at the manufacturers and persons placing measuring instruments on the market.

2.2 Objective of the certification body

METAS-Cert performs conformity assessments of designs and patterns of measuring instruments and certifies products and management systems of measuring instrument manufacturers. It thereby enables the manufacturers to place measuring instruments on the Swiss and EU market, which is ruled by legal specifications (agreement between the European Community and the Swiss Confederation on the mutual recognition of conformity assessments [SR 0.946.526.81](#) [23]). Both of METAS' metrology divisions as well as the Certification Body METAS-Cert form a notified body for conformity assessments within the EC and EFTA area (EU states plus Norway, Iceland, Liechtenstein, Switzerland) in accordance with the module listed in chart 3 in chapter 3.1 and in conformity with article 12 of the directive 2004/22/EG of the European Parliament and of the Council of 31 March 2004.

The guide provides information on legal and normative directives and the procedures for conformity assessment and certification in the legally-regulated area and according to other procedures.

2.3 Principles

The requirements for the market introduction of measuring instruments in the legally-regulated area are based on the following legal specifications and standards:

	Swiss Ordinance	European Directive
Measuring instruments	Ordinance of 15 February 2006 on Measuring Instruments (MMV) (SR 941.210) [1] and relevant specific Ordinances (see chart 2)	Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments (MID) [11]
Non-automatic weighing instruments	Ordinance of the FDJP of 26 April 2004 on Non Automatic Weighing Instruments (SR 941.213) [5].	Directive 2009/23/EC of the European Parliament and of the Council of 23 April 2009 on non-automatic weighing instruments [12].

Chart 1: Regulated area

The above-listed requirements in the Swiss ordinances are equivalent to the requirements of the corresponding European guidelines.

The requirements for the certification of measuring instruments according to other procedures are based on the following principles:

	International directive, standard
Measuring instruments according to other procedures	Organisation Internationale de Métrologie Légale (OIML), OIML Recommendation RXX (Recommendation on measuring instruments categories according to the chapter 3.3.1 Chart 6, and 3.3.2 Chart 7), SN EN ISO/IEC 17025 [16].

Chart 2: Other procedures

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The requirements for METAS-Cert are based on the ISO Standard 17021 “Conformity assessment – Requirements for bodies providing audit and certification of management systems” [15] and the Swiss standard SN EN 45011 “General requirements for bodies operating product certification systems” [18] and the according [WELMEC](#) guides.

2.4 Scope of Certification

Certifications performed in compliance with the ordinances shown in chart 1 must be recognised for the legally-regulated area in the EC and EFTA area and authorise the application of the CE label. Certification of measuring instruments according to chart 2 shall be recognised worldwide.

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3 Conformity assessment procedure

The following chapters illustrate the range of conformity assessment procedures offered by METAS-Cert.

3.1 Procedure according to Annex II of the MMV (equivalent to MID procedures)

Chart 3 lists the various possible modules to acquire the CE label. The passing of certification authorises the manufacturers to affix the corresponding CE label and additional metrology mark to the measuring instrument.

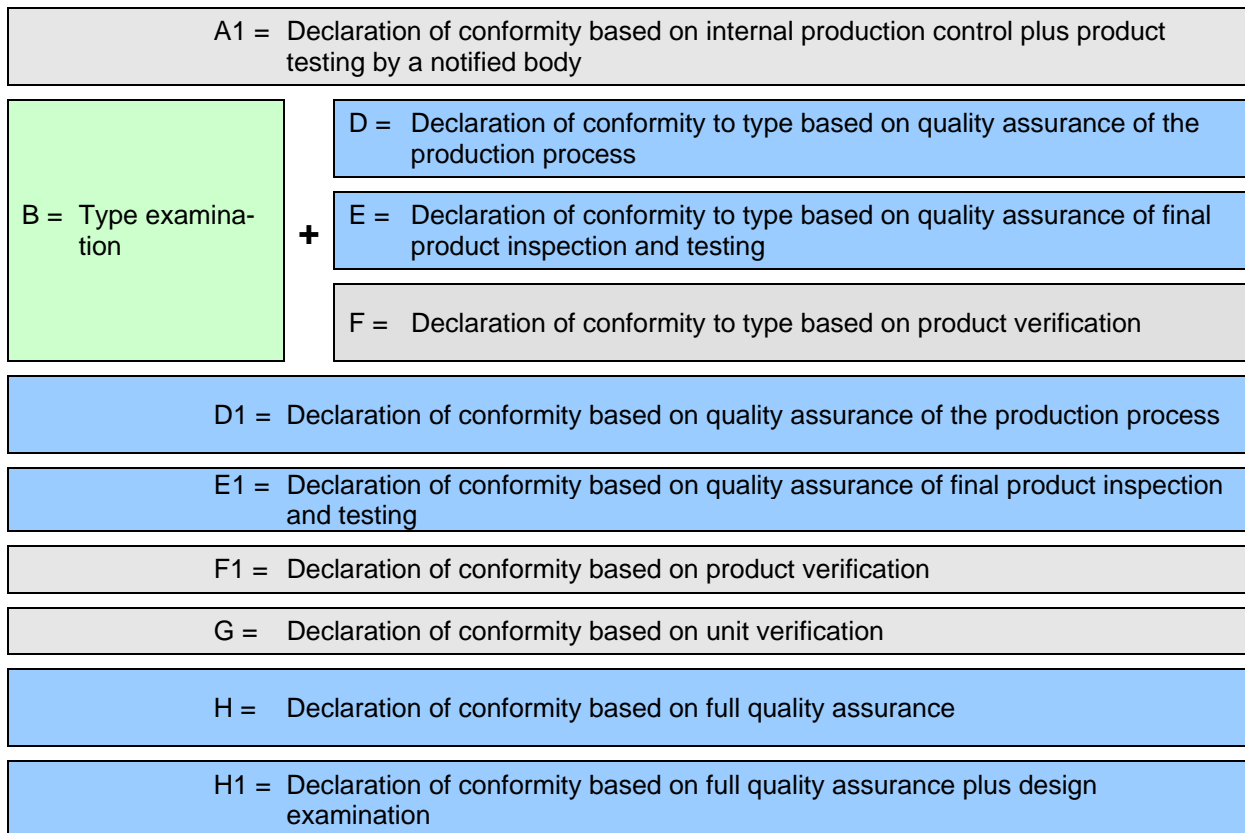


Chart 3: Modules to achieve de CE labelling according to the Ordinance on Measuring Instruments.

The modules may be divided into three groups; “**Pattern evaluation**”, “**Product examination**” and “**Assessment of the quality management system**”. A complete description of the modules is given in the MMV [1] or MID [11].

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Chart 4 shows the modules provided by METAS-Cert in the EU-harmonised area. The conformity assessments according to modules A1, D1, E1, F1, G, H and H1 are to be performed by one single body, those performed according to combinations B+D, B+E and B+F may be carried out by two different bodies.

Swiss ordinance (see chap. 0)	Annex MID	Measuring instrument	A1	B+D	B+E	B+F	D1	E1	E1	G	H	H1
941.231 [7]	MI-001	Water meters		●		●						●
941.241 [8]	MI-002	Gas meters and volume conversion devices		●		●						●
941.251 [10]	MI-003	Active electrical energy meters		●		●						●
941.231 [7]	MI-004	Heat meters		●		●						●
941.212 [4]	MI-005	Measuring systems for the continuous and dynamic measurement of quantities of liquids other than water		●		●				●		●
941.214 [6]	MI-006	Automatic weighing instruments - mechanical systems - electromechanical instruments - electronic systems containing software		●	●	●	●		●	●		●
941.201 [2] 941.211 [3]	MI-008	Material measures - material measures of length - capacity serving measures	●	●	●		●	●	●	●	●	
941.201 [2]	MI-009	Dimensional measuring instruments - mechanical or electromechanical instruments - electronic instruments or instruments containing software		●	●	●	●	●	●	●	●	●
941.242 [9]	MI-010	Exhaust gas analysers		●		●						●

Chart 4: Measuring instruments and possible conformity assessment modules

3.1.1 Pattern evaluation

The pattern evaluation, referred to in the MID as “type examination”, forms part of the conformity assessment procedure, whereby METAS-Cert examines and evaluates the pattern of a measuring instrument and declares that the technical design meets the standard requirements applicable to that particular measuring instrument.

Outlined below are the tasks for which the manufacturer or its authorised representative is responsible, and the tasks which METAS-Cert is to perform.

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3.1.1.1 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 a pattern evaluation,
- provide the notified body with one (or several) specimens representative of the planned production
- inform the notified body of any modifications made to the approved instrument
- keep the technical documentation and a copy of the pattern approval certificate at the disposal of the surveillance authorities.

METAS-Cert 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 a pattern 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 pattern approval certificate.

3.1.2 Product examination

Included in this group are the modules A1, F, F1 and G. The examinations carried out or supervised by METAS-Cert relate to the manufactured product. METAS-Cert issues, with the exception of module A1, a conformity certificate (referred to in MID [11] as a declaration of conformity) and supervises the affixing of the identification number on the product.

3.1.2.1 Declaration of conformity based on internal production control plus product testing by METAS-Cert, module A1

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 assurance 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 authorised representative shall

- ensure and declare that the relevant products fulfil the requirements,
- affix the CE label to each measuring instrument and, where the notified body has intervened in the production process, behind the CE label, the identification number of the notified body,
- affix the identification number of the notified body beside the CE label
- submit a conformity declaration,

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- keep a copy of the conformity declaration and of the technical documents at the disposal of the surveillance authorities.

METAS-Cert shall

- monitor the inspections performed by the manufacturer,
- supervise the affixing of its identification number, should METAS-Cert 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.

3.1.2.2 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 assurance 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 label to each individual measuring instrument,
- affix, behind the CE label, the identification number of the notified body,
- 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 the notified body with the listed supplementary documents).

METAS-Cert 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,
- if a lot is rejected, establish appropriate measures to prevent the placing on the market of that lot
- store a register of important technical documentation,
- provide other notified bodies, upon their request, with the required information.

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3.1.2.3 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 assurance 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 label to each individual measuring instrument,
- affix, behind the CE label, the identification number of the notified body,
- submit a declaration of conformity,
- keep a copy of the conformity declaration, the technical documents and the conformity certificate of the notified body at the disposal of the surveillance authorities.

METAS-Cert 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,
- if a lot is rejected, establish appropriate measures to prevent the placing on the market of that lot,
- store a register of important technical documentation,
- provide other notified bodies, upon their request, with the required information.

3.1.2.4 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 label to each individual measuring instrument,
- affix, behind the CE label, the identification number of the notified body,
- submit a declaration of conformity,
- keep a copy of the conformity declaration and the technical documents at the disposal of the surveillance authorities.

METAS-Cert 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,

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- 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.

3.1.3 Assessment of the quality management system

Included in this group are the modules D, D1, E, E1, H and H1. The assessments performed by METAS-Cert are based on the quality management system. METAS-Cert carries out periodic audits of the manufacturer, in order to ensure that it operates and correctly applies an adequate management system.

In addition, METAS-Cert may also pay the manufacturer unexpected visits. During these visits, it may carry out any necessary product examinations, or have them carried out, to verify the correct functioning of the management system.

3.1.3.1 Declaration of conformity to type based on quality assurance of the production process, module D

The manufacturer shall

- operate an approved quality assurance 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 assurance system and its updating, technical documentation of the approved type, a copy of the pattern approval certificate and the decisions and reports of the notified body),
- submit an application for an evaluation of the quality assurance system for the products concerned,
- guarantee and declare that the products in question are in compliance 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 the notified body in its surveillance,
- keep the documentation of the quality assurance system, details of its updating and decisions and reports of the notified body at the disposal of the surveillance authorities.

The manufacturer or its authorised representative shall

- affix the CE label to each individual measuring instrument,
- affix, behind the CE label, the identification number of the notified body,
- submit a declaration of conformity,
- inform the notified body of its intention to update the quality assurance system,
- keep a copy of the conformity declaration at the disposal of the surveillance authority.

METAS-Cert 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.

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3.1.3.2 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 assurance 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 assurance system and its updating together with the decisions and reports of the notified body),
- submit an application for an evaluation of the quality assurance 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 in its surveillance,
- keep the documentation of the quality system, details of its possible updating and decisions and reports of the notified body at the disposal of the surveillance authorities.

The manufacturer or its authorised representative shall

- affix the CE label to each individual measuring instrument,
- affix, behind the CE label, the identification number of the notified body,
- submit a declaration of conformity,
- inform the notified body of its intention to update the quality assurance system,
- keep a copy of the conformity declaration at the disposal of the surveillance authorities.

METAS-Cert 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 assurance systems.

3.1.3.3 Declaration of conformity to type based on the quality assurance of final 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.

METAS-Cert shall

- obligations as in module D.

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3.1.3.4 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.

METAS-Cert shall

- obligations as in module D.

3.1.3.5 Conformity declaration based on full quality assurance, module H

The manufacturer shall

- operate an approved quality assurance 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 assurance system and its updating together with the decisions and reports of the notified body,
- submit an application for evaluation of the quality assurance 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 the notified body in its surveillance,
- keep the documentation of the quality system, details of its possible updating and decisions and reports of the notified body at the disposal of the surveillance authorities.

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The manufacturer or its authorised representative shall

- obligations as in module D.

METAS-Cert shall

- obligations as in module D.

3.1.3.6 Declaration of conformity based on full quality assurance plus design examination, module H1

The manufacturer shall

- operate an approved quality assurance 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 assurance system and its updating together with the decisions and reports of the notified body),
- submit an application for evaluation of the quality assurance 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 the notified body in its surveillance,
- keep the documentation of the quality system, details of its possible updating and decisions and reports of the notified body at the disposal of the surveillance authorities,
- apply for the examination of the design,
- provide the notified body up-to-date information on modifications of the approved design.

The manufacturer or its authorised representative shall

- obligations as in module D.

METAS-Cert 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.

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3.2 Procedure for non-automatic weighing instruments (NAWI)

Chart 5 shows the eligible modules to achieve CE labelling. Successful passing of the examinations according to these modules entitles the manufacturer to affix the CE label to the weighing instrument.

Weighing instruments placed on the market in the legally-regulated area shall complete all levels of the conformity assessment procedure selected by the manufacturer, and shall bear the required conformity label. The procedures according to the Ordinance of the FDPJ on Non-Automatic Weighing Instruments of 16 April 2004 ([SR 941.213](#)) [5] are:

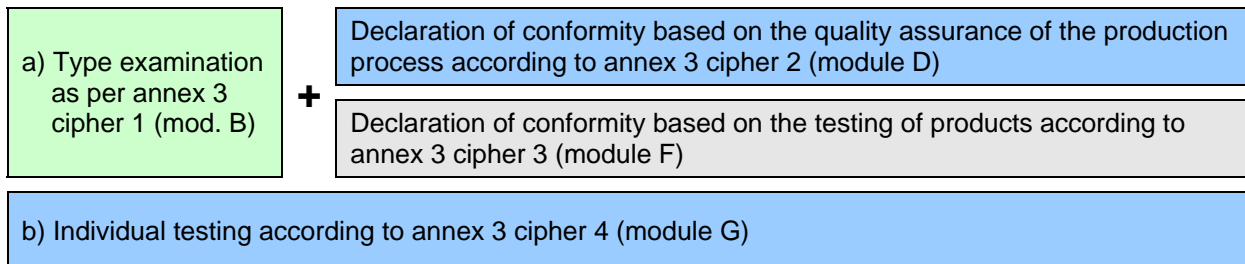


Chart 5: Modules to achieve the CE labelling according to the Ordinance of the FDJP of 16 April 2004 on Non-Automatic Weighing Instruments.

Non-automatic weighing instruments without electronic equipment, whose load-measuring device does not use a spring to balance the load, necessitate, in the case of choosing procedure according to letter a) only the declaration of conformity based on the quality assurance of production process in compliance with [annex 3 cipher 2](#) or the examination of the product according to [annex 3 cipher 3](#). Should the manufacturer submit an application for the assessment of his management system, METAS-Cert shall perform periodic audits in compliance with chapter 0 of this guide, in order to ensure that it operates and correctly applies an adequate management system.

A simplified audit may be performed of applicants performing only the second stage of the conformity assessment procedure ([annex 3, cipher 5](#)).

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3.3 Procedures according to OIML

3.3.1 OIML certification system for measuring instruments

In order to promote the mutual recognition of pattern evaluations of measuring instruments the Organisation Internationale de Métrologie Légale (OIML) has developed a certification system (see also OIML publication [OIML B 3](#)) [21] and met an agreement on mutual recognition. Within this system, the following OIML test reports, test results and certificates of pattern evaluations can be issued for the following categories of measuring instrument.

OIML Recommendation R 16 (Non-invasive sphygmomanometers) [34]
OIML Recommendation R 49 (Water meters) [36]
OIML Recommendation R 50 (Continuous totalizing automatic weighing instruments) [28]
OIML Recommendation R 51 (Automatic catchweighing instruments) [29]
OIML Recommendation R 61 (Automatic gravimetric filling instruments) [30]
OIML Recommendation R 97 (Barometers) [35]
OIML Recommendation R 98 (High precision line measures of length) [24]
OIML Recommendation R 105 (Direct mass flow measuring systems) [25]
OIML Recommendation R 106 (Automatic rail weighbridges) [32]
OIML Recommendation R 107 (Discontinuous totalizing automatic weighing instruments) [33]
OIML Recommendation R 117 (Measuring systems for liquids other than water) [26]
OIML Recommendation R 137 (Gas meters) [27]

Chart 6: Measuring instruments categories for which METAS-Cert issues OIML documents.

The signatories of the agreement are obliged to recognise OIML test reports, test results and certificates and to use them for their national approvals.

3.3.2 OIML framework agreement (Mutual Acceptance Arrangement, MAA)

The OIML certification system has been amended by a framework agreement on the mutual recognition of OIML pattern evaluations (see also OIML publication [OIML B 10 1](#)) [22]. Conformity certificates issued by member states within this certification system verify that the tests have been carried out in accordance with the internationally harmonised procedures, and that the examined instrument types satisfy the requirements specified by the recommendation.

Pattern evaluations according to the OIML recommendation R 60 (load cells) [13]
Pattern evaluations according to the OIML recomm. R 76 (Non automatic weighing instruments) [31]

Chart 7: Measuring instrument categories for which METAS-Cert issues conformity certificates within the scope of the OIML MAA.

After successful testing, an OIML "Certificate of Conformity" is issued. The recognition of these certificates is binding for the MAA signatories.

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3.4 Other procedures

METAS-Cert also offers conformity assessments according to Swiss regulations or other requirements (e.g. standards) for measuring instruments and other products. The tests are usually performed by METAS laboratories, whose range of services can be found in the [service database](#).

4 Certification of patterns and management systems

4.1 Application for certification

On receiving an application for the certification of a pattern or management system, METAS-Cert shall inform the applicant of the procedure and deliver an application form ([application forms can be found on the METAS-Cert internet page](#)).

On the application form, the applicant shall state the standards to which he wishes to have his product or management system certified.

In justified cases, METAS-Cert may refuse an application for certification, and shall inform the applicant accordingly.

4.2 Certification contract, commission

The basis of the assignment is the written certification contract between the applicant and METAS-Cert. This is established on the basis of the application. It contains inter alia the following agreements on:

- the product or management system and the specifications to be satisfied by certification,
- the auditors, which are to perform the evaluation,
- the date of evaluation,
- fees,
- the general terms of contract.

The applicant is obliged to inform METAS-Cert immediately in writing of any modifications of the product or management system, which are of consequence to the certification.

4.3 Appointment of auditors and technical experts

Once the application for certification has been completed, the head of METAS-Cert appoints a lead assessor and, depending on the size and complexity of the certification, additional auditors and technical experts. The minimum personnel requirement is one lead assessor, who is to be a member of the certification commission. The requirements on the auditors are defined by the Ordinance on Measuring Instruments and the standard SN EN ISO 19011 [17].

METAS-Cert may, where necessary, engage external auditors and/or technical experts. Auditors or technical experts may be refused by the applicant on presentation of solid justification. However, for economical reasons, attempts should be made to maintain the auditors and experts for the duration of the 3-year validity of certification. Any essential changes in the audit team are to be undertaken by METAS-Cert only in agreement with the applicant/certificate holder.

4.4 Task of the lead assessor

The lead assessor is responsible for the audit and establishes the audit programme together with the auditors and technical experts. He guarantees the coordination of the tasks with the applicant, in the audit team and with the head of METAS-Cert. Furthermore, he is responsible for the prompt drafting of the audit report.

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First-time audits shall be performed in two stages; stage 1 audit and stage 2 audit (see sections 4.13.3 and 4.13.4).

4.5 Confidentiality

The employees of the federal government are sworn to secrecy according to art. 94 par. 1 of the Ordinance of 3 July 2001 on the Staff of the Confederation (SR 172.220.11.3) [20] on professional and business issues, which, depending on their nature or due to legal provisions or directives, are to be held secret. The external auditors and technical experts shall be bound by a non-disclosure contract. Should information be required to be passed on due to legally-compelling reasons, the affected persons are to be informed.

4.6 Audit report and decision on certification

After completion of the initial audit, the audit team shall use the gained information to draft its audit report. It shall include a recommendation on the granting of certification, observations to support the decision on recommendation and, where necessary, restrictions to be followed during the period of validity. The audit report shall be forwarded to the applicant for statement and to the certification commission (CC) for evaluation. After evaluation, the report shall be passed on by the CC to the head of METAS-Cert. He then decides on the basis of the audit report, the applicant's statement and the CC's recommendation on the granting of the certification.

In the case of non-conformities and restrictions, the applicant shall be requested to correct the deficient points of its management system within an agreed period.

Should the requirements not be satisfied within the agreed period, then the contract between METAS-Cert and the applicant may be terminated. The costs incurred up until this point shall be charged to the applicant.

4.7 Certificate and validity

Once all the requirements have been fulfilled, the applicant shall receive from the head of METAS-Cert a signed and numbered certificate. Certificates issued for quality management systems shall bear reference to the binding pattern approval certificate, or may be supplemented with a scope of application for the valid pattern approval certificates. The certificates for quality management systems are valid for a period of 3 years and may, if requested by the applicant and following successful renewal of certification, be extended for a further 3-year period.

Certificates for pattern evaluation according to module B are valid for 10 years.

4.8 Surveillance audit

During the periods between renewals of certification, a surveillance audit shall be carried out by METAS-Cert at least once a year. If the situation is in keeping with the certification, this shall then be conveyed in writing to the certification holder.

If, during a surveillance audit, a divergence from the requirements for certification is detected, the head of METAS-Cert may then adopt one of the following measures:

- the change in situation is justifiable; the certification may be extended or renewed, where necessary, after fulfilment of relevant requirements,
- the situation is unacceptable; this represents a temporary suspension or withdrawal of certification.

The head of METAS-Cert may, where necessary, define a shorter period for the surveillance audits.

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4.9 Extension and withdrawal of a certificate

4.9.1 Extension

Should a firm request an extension of the scope of certification, the evaluation shall be carried out following the same procedures as previously described. If all requirements are fulfilled, a new certificate shall be issued.

4.9.2 Suspension and withdrawal of a certificate

If a review of certification is established on the grounds of a surveillance audit, or should non-conformity with the constraints of certification be detected due to any other reason, the certification may be suspended or the scope may be restricted during this period. The imposed measure may be lifted once an audit verifies that the discordance has been corrected.

The applicant may appeal against the decision to suspend certification (see chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**).

4.10 Publication of certificates

METAS-Cert keeps a register of the certificates issued, which is published on its website.

4.11 Cancellation of a certification procedure

Should the applicant fail to submit the required documentation on schedule, the head of METAS-Cert is entitled to postpone certification or to annul the certification contract, whilst stating the grounds for his decision.

4.12 Complaints, appeals and civil action

4.12.1 Complaints

Complaints shall be addressed to the certification body. They shall be treated in accordance with the procedure "Treatment of complaints and non-conformities" (W004) of METAS.

4.12.2 Appeals

If an applicant is dissatisfied with the reply to his complaint, he may appeal against this to the management of METAS within 30 days.

4.12.3 Civil action

If the applicant disagrees with the decision on certification or with METAS' verdict, he may file a civil lawsuit at a Bernese civil court.

4.13 Performance of a management system audit

4.13.1 Preparation

The lead assessor shall forward the scheduled audit programme to the applicant for approval.

The time required for the audit depends, among other things, on the following factors:

- already existing certification (e.g. ISO 9001 [14]),
- language, in which the handbook and the work directives are written (German, French, Italian and English are accepted for the handbook),
- number of personnel within the scope to be assessed,
- number of the firm's branches to be visited.

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4.13.2 2-stage procedure

The first certification audit of a management system is carried out in two stages; stage 1 and stage 2. Parts of the management system, which are audited during audit stage 1 and have been established as complete, effective and in compliance with the requirements, do not necessitate further assessment during audit stage 2. METAS-Cert shall inspect that the already audited parts of the management system continue to satisfy the certification requirements. The report on audit stage 2 shall contain verification of this and clearly state that conformity was established during audit stage 1.

4.13.3 Stage 1

The stage 1 audit serves as orientation and preparation for the stage 2 main audit. In particular the following examinations shall be made:

1. Obtaining of sufficient information on the business and its management system in order to plan the scale and focal points of the stage 2 audit.
2. What is the scale of the management system? Which processes and locations does this cover? Do business regulations or legal specifications exist? How are they respected?
3. Do the business processes of the various locations and the prevailing conditions at the specific locations satisfy the standard requirements?
4. Does the state of the business and the compliance with the standard requirements meet expectations, particularly in terms of recognition of essential services, processes and objectives, and also the operation of the management system?
5. Is the documentation of the management system in order?
6. Does the planning and performance of the internal audits and of the management assessment fulfil the standard requirements? Is introduction of the management system sufficiently advanced to carry out the stage 2 audit?
7. Is the staff adequately prepared for the main audit? Are the resources necessary to perform the main audit (stage 2) available?

The results of the stage 1 audit shall be documented in writing and communicated to the applicant. It shall specify the areas that still give cause for reservation and could be found inadequate by the stage 2 audit.

The date for the stage 2 audit shall be defined to allow the applicant enough time to correct the areas queried during the stage 1 audit.

4.13.4 Stage 2

The stage 2 audit shall be performed in accordance with an audit plan agreed with the applicant. This shall be based on ISO/IEC 19011 [17] and take into consideration the information gained at the stage 1 audit.

The stage 2 audit serves to examine whether the management system has been implemented and whether it achieves its intended impact. The assessment shall take place at the applicant's premises and comprise at least the following aspects:

1. information and verification of conformity with all requirements of the applicable normative documents;
2. monitoring of performance, i.e. measurement, reporting and evaluation related to the most essential performance objectives (in agreement with the applicable standard requirements);
3. management system and its effectiveness concerning all the legal specifications;

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4. process control;
5. internal auditing and management assessment;
6. management responsibility for the essential operational regulations;
7. verification of compliance of the proceedings of the internal audit(s) with the standard requirements, internal directives, performance objectives, legal specifications, responsibilities, personnel expertise, processes, procedures and specifications.

The stage 2 audit shall be documented in an audit report. Further procedures shall take place as described in chapter 4.6.

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Index of headwords

Audit

Systematic and documented examination procedure to ascertain whether organisations and processes comply with specified requirements and guidelines.

Pattern approval certificate / EC declaration of type examination

See chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**

Design approval certificate / EC design examination certificate

See chapter 3.1.3.6

Conformity certificate / declaration of conformity

See chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**

Non-conformity

Non-fulfilment of a requirement.

Management system

All management methods that are not applied individually, but are linked together to pursue a superior shared objective.

System audit

Assessment of a management system by an independent third body, to examine the compliance of the declared qualities of final products or services.

Certification

Process, by which a certification organisation verifies that a measuring instrument satisfies the legal specifications, a management system fulfils all of the standard requirements and the applicant meets the internally defined directives.