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Initial verification of measuring instruments utilizing
the manufacturer's quality management system

Vérification primitive des instruments de mesure utilisant les systèmes
de gestion qualité des fabricants



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Foreword

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, of its Member States.

The two main categories of OIML publications are:

- **International Recommendations (OIML R)**, which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity; the OIML Member States shall implement these Recommendations to the greatest possible extent;
- **International Documents (OIML D)**, which are informative in nature and intended to improve the work of the metrological services.

OIML Draft Recommendations and Documents are developed by technical committees or subcommittees which are formed by the Member States. Certain international and regional institutions also participate on a consultation basis.

Cooperative agreements are established between OIML and certain institutions, such as ISO and IEC, with the objective of avoiding contradictory requirements; consequently, manufacturers and users of measuring instruments, test laboratories, etc. may apply simultaneously OIML publications and those of other institutions.

International Recommendations and International Documents are published in French (F) and English (E) and are subject to periodic revision.

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Initial verification of measuring instruments utilizing the manufacturer's quality management system

0 Introduction

0.1 The interpretation and implementation of this OIML International Document depend on the understanding and use of other international documents, standards and guides, which are indicated in the text and listed as references. Any apparent differences between this Document and its references are intended for clarification and not as contradictions in meaning.

0.2 This Document is compatible in its application with that of the ISO 9000 series of standards on "Quality management systems" and relevant ISO/IEC guides and standards related to evaluating and assessing quality management systems.

0.3 When authorizing the implementation of a manufacturer's quality management system for the metrological control of measuring instruments, national responsible bodies should take into account any agreements among or between OIML Member States regarding the mutual recognition or acceptance of "certificates of conformity". Importers or a manufacturer's agent or representative may present such certificates. Implementation of mutual recognition agreements or mutual acceptance arrangements could avoid or minimize potential trade barriers.

1 Scope

1.1 The requirements of this Document serve as a model for national responsible bodies that are considering developing, adopting and implementing regulations employing principles of quality management systems for initial verification of measuring instruments as a part of their national legal metrological control.

1.2 This Document is intended as a guideline for a national responsible body that permits manufacturers to declare conformity of measuring instruments to legal metrological requirements for initial verification, either immediately after production of the instruments or after installation and prior to their use, according to legal metrological regulations. In such cases, the national responsible body shall have in place a means for periodically validating the implementation of a manufacturer's quality management system.

1.3 This Document provides definitions and guidelines for consideration by manufacturers that choose to implement a quality management program for measuring instruments in accordance with legal metrological requirements. It provides criteria and procedures to be applied by a manufacturer that seeks authorization to declare a newly manufactured instrument to be in conformity with requirements for initial verification according to national laws or regulations for legal metrological control.

Note: The criteria and procedures may also be used by the manufacturer for production control of manufactured instruments to ensure that each manufactured instrument meets the performance requirements demonstrated during type evaluation, that is, to ensure that production meets type.

1.4 The national responsible body may recognize an existing manufacturer's quality management system for use in declaring conformity of a specific category or class of measuring instruments to performance requirements prescribed by regulations. If appropriate and relevant, the manufacturer's quality management system could be based in part on ISO 9001 [7].

1.5 This Document does not address any requirements and tests necessary to meet national safety regulations for instrument users. If such regulations exist, the manufacturer shall take the necessary actions to comply.

2 Terminology

Note 1: Other metrological terms important to the interpretation of this Document may be found in the VIM [1], VIML [2] (see References), ISO/IEC Guide 2 [3], and ISO 9000:2000 [6].

Note 2: The terms indicated in **bold text** in definitions 2.8 to 2.15 below are themselves further defined in ISO 9000:2000 [6], although their full cross-references are omitted here in the interests of clarity.

2.1 National responsible body

National organization or agency responsible for implementing laws or regulation regarding metrological control of measuring instruments.

Note: The national service of legal metrology may fall under the jurisdiction of the national responsible body referred to in this Document; therefore, when delegated the responsibility, the national service of legal metrology should be substituted for the “national responsible body” throughout the text of this Document.

2.2 Legal metrological control [VIML 2.1]

Whole of legal metrology activities which contribute to metrological assurance.

Note: Legal metrological control includes: legal control of measuring instruments, metrological supervision, metrological assessment.

2.3 Type (pattern) evaluation [VIML 2.5]

Systematic examination and testing of the performance of one or more specimens of an identified type (pattern) of measuring instruments against documented requirements, the results of which are contained in the evaluation report, in order to determine whether the type may be approved.

Note: “Pattern” is used in legal metrology with the same meaning as “type”; in the entries below, only “type” is used.

2.4 Verification of a measuring instrument [VIML 2.13]

Procedure (other than type approval) which includes the examination and marking and/or issuing of a verification certificate, that ascertains and confirms that the measuring instrument complies with the statutory requirements.

2.5 Initial verification of a measuring instrument [VIML 2.15]

Verification of a measuring instrument which has not been verified previously.

2.6 Subsequent verification of a measuring instrument [VIML 2.16]

Any verification of a measuring instrument after a previous verification and including:

- mandatory periodic verification;
- verification after repair.

Note: Subsequent verification of a measuring instrument may be carried out before expiry of the period of validity of a previous verification either at the request of the user (owner) or when its verification mark is declared to be no longer valid.

2.7 Metrological confirmation

Set of operations required to ensure that an item of measuring and test equipment is in compliance with requirements for its intended use (see ISO 10012-1 [11]).

Note 1: Metrological confirmation normally includes calibration, any necessary adjustment or repair and subsequent recalibration, as well as any required sealing and labeling.

Note 2: In this Document, this term is referred to as “confirmation”.

2.8 Quality [ISO 9000:2000, 3.1.1]

Degree to which a set of inherent **characteristics** fulfils **requirements**.

Note 1: The term “quality” can be used with adjectives such as poor, good or excellent.

Note 2: “Inherent” as opposed to “assigned” means existing in something, especially as a permanent characteristic.

2.9 Requirement [ISO 9000:2000, 3.1.2]

Need or expectation that is stated, generally implied or obligatory.

Note 1: “Generally implied” means that it is custom or common practice for the **organization**, its **customers** and other **interested parties**, that the need or expectation under consideration is implied.

Note 2: A qualifier can be used to denote a specific type of requirement, e.g. product requirement, quality management requirement, customer requirement.

Note 3: A specified requirement is one which is stated, for example, in a **document**.

Note 4: Requirements can be generated by different interested parties.

2.10 Quality management system [ISO 9000:2000, 3.2.3]

Management system to direct and control an **organization** with regard to **quality**.

2.11 Quality control [ISO 9000:2000, 3.2.10]

Part of **quality management**, focused on fulfilling quality **requirements**.

2.12 Quality manual [ISO 9000:2000, 3.7.4]

Document specifying the **quality management system** of an **organization**.

Note: Quality manuals can vary in detail and format to suit the size and complexity of an individual organization.

2.13 Quality plan [ISO 9000:2000, 3.7.5]

Document specifying which **procedures** and associated resources shall be applied by whom and when to a specific **project, product, process** or contract.

Note 1: These procedures generally include those referring to quality management processes and to product realization processes.

Note 2: A quality plan often makes reference to parts of the **quality manual** or to procedure documents.

Note 3: A quality plan is generally one of the results of **quality planning**.

2.14 Validation [ISO 9000:2000, 3.8.5]

Confirmation, through the provision of **objective evidence**, that the **requirements** for a specific intended use or application have been fulfilled.

Note 1: The term “validated” is used to designate the corresponding status.

Note 2: The use conditions for validation can be real or simulated.

2.15 Audit [ISO 9000:2000, 3.9.1]

systematic, independent and documented **process** for obtaining **audit evidence** and evaluating it objectively to determine the extent to which **audit criteria** are fulfilled.

Note: Internal audits, sometimes called “first-party audits”, are conducted by, or on behalf of, the **organization** itself for internal purposes and can form the basis of an organization’s self-declaration of **conformity**. External audits include what are generally termed “second-” or “third-party audits”.

Second-part audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf.

Third-party audits are conducted by external independent organizations. Such organizations provide certification or registration of conformity with

requirements such as those of ISO 9001 and ISO 14001:1996.

When quality and environmental **management systems** are audited together, this is termed a “combined audit”.

When two or more auditing organizations cooperate to audit a single **auditee** jointly, this is termed “joint audit”.

2.16 Metrological supervision [VIML 2.3]

Control exercised in respect of the manufacture, import, installation, maintenance and repair of measuring instruments and/or in respect of their use, performed in order to check that they are used correctly as regards the observance of metrology laws and regulations.

Note: Metrological supervision includes checking the correctness of the quantities indicated on and contained in prepackages.

2.17 Authorized manufacturer

Organization that has been authorized by the national responsible body to provide a declaration of conformity of a manufactured measuring instrument to legal requirements.

Note: This term may also apply to distributors, importers, assemblers, installers, repackagers, relabelers, etc. that have responsibility for assuring the quality and performance of a measuring instrument prior to its being placed in service (see ISO/IEC Guide 22 [4]).

2.18 Declaration of conformity

Statement provided under the sole responsibility of an authorized manufacturer, having a validated quality management system, that a measuring instrument meets the legal metrological requirements for initial verification according to its approved type, if required.

Note: Legal requirements may be issued as laws or regulations or in documentary standards (norms) referenced in them.

2.19 Verification mark [VIML 3.7]

Mark applied to a measuring instrument certifying that the verification of the measuring instrument was carried out with satisfactory results.

Note: The verification mark may also identify the body responsible for verification and/or indicate the year or date of verification or its expiry date.

2.20 Verification certificate [VIML 3.3]

Document certifying that the verification of a measuring instrument was carried out with a satisfactory result.

3 Metrological control by the national responsible body

3.1 A manufacturer's quality management system applied to ensure that measuring instruments meet the necessary legal metrological requirements for initial verification shall be under the control of the national responsible body. An authorized manufacturer shall be obliged to assist the national responsible body in the implementation of the control of quality management system.

3.2 The national responsible body shall have a procedure for authorizing a manufacturer and for the renewal of that authorization. The authorization shall specify requirements for initial and periodic validation of the manufacturer's quality management system (see ISO/IEC 17025 [5] and ISO 10011-1 [9]).

3.3 The manufacturer shall submit an application to the appropriate national responsible body for validation of its quality management system for the measuring instruments to be covered. The application shall include:

- all relevant information concerning the category, class or complexity of the measuring instruments;
- the type approval certificate and test report, if required;
- identification of any subcontracting arrangements for inspections and tests; and
- the complete documentation of the quality management system to be implemented.

3.4 The procedure for initial validation by the national responsible body according to its metrological supervision shall include the following:

3.4.1 Determining whether the manufacturer has received type approval, if required, for the category and class of measuring instruments covered.

3.4.2 Determining that the manufacturer has the necessary qualified personnel, facilities, measuring and test equipment, and control procedures for ensuring compliance of manufactured instruments with legal metrological performance requirements.

3.4.3 Determining the suitability of the manufacturer's quality management system through inspections or assessment.

3.5 The procedure for periodic validation by the national responsible body according to its metrological supervision shall include the following:

3.5.1 Determining the effectiveness of the manufacturer's quality management system at specified intervals through inspection, surveillance and testing that includes reviewing required records and, when applicable, witnessing the procedures required by the system.

3.5.2 Providing for unannounced inspections, surveillance and testing.

3.5.3 Conducting more frequent or detailed inspections, surveillance and testing when a need is indicated.

3.5.4 Determining the responsibilities, qualifications and requirements for any third party authorized to undertake the auditing of any part of the manufacturer's quality management system (see ISO 10011-2 [10]).

3.6 The national responsible body shall establish suitable regulations for the following:

3.6.1 Authorizing a manufacturer to issue a declaration of conformity of a measuring instrument to national, regional or international legal requirements for initial verification.

3.6.2 Providing a means by which the authorized manufacturer may request permission to withdraw a declaration of conformity.

3.6.3 Establishing a procedure to withdraw an authorization if a manufacturer fails to meet the requirements of this Document.

3.6.4 Establishing a fair and equitable appeals mechanism by which a manufacturer may request resolution of any disputes that arise in an appraisal of the implementation and maintenance of its quality management system and in the issuing of a declaration of conformity.

3.7 If applicable and in accordance with national regulations, the national responsible body shall specify the period of validity of a declaration of conformity for initial verification of a measuring instrument according to its type, if required, and applicable category and class. The owner of the measuring instrument, and not its manufacturer, is responsible for obtaining any necessary subsequent verification.

4 Requirements for the manufacturer's quality management system

4.1 General

Participating manufacturers shall establish and maintain a documented quality management system approved by the national responsible body for the category of measuring instruments that will assure compliance of such instruments with legal metrological requirements for initial verification according to an approved type, if required, and to relevant international standards and guides.

4.2 Quality manual

A quality manual, or document, shall be developed for a quality management system applicable for relevant categories and classes of measuring instruments. It shall include management methods, procedures, controls, records, and maintenance practices that provide continuing assurance of compliance of an authorized quality management system with appropriate legal metrological laws and regulations. Any

change or update of the quality management system shall be incorporated in the quality manual and reported to the national responsible body.

4.3 Authority and responsibility

A manufacturer shall designate a person to have the authority and responsibility for ensuring the implementation and maintenance of the quality management system. The quality management system shall be reviewed periodically and updated as appropriate by this designated person.

4.4 Organizational structure and trained personnel

A manufacturer shall have in place an adequate organizational structure and trained personnel to ensure that the measuring instruments are produced in accordance with appropriate legal metrological performance requirements.

4.4.1 The organizational structure shall identify personnel responsible for making decisions regarding testing and declaration of conformity of the applicable measuring instruments.

4.4.2 The responsible personnel shall have the technical knowledge and experience of relevant activities and the knowledge of legal metrology requirements necessary to carry out the testing required for declaration of conformity. The technical training, knowledge and experience and the basis for each shall be documented for all personnel.

Note: Personnel may be qualified by attending appropriate training courses recognized by the national responsible body.

4.5 Inspection

An inspection system shall be established for accepting or rejecting instrument components and materials and for segregating nonconforming and incorrect components from work in process.

4.6 Test methods and procedures

All test methods and procedures, including a written justification of any statistical methods used, shall be documented and maintained.

4.7 Measuring and test equipment

The manufacturer shall establish and document procedures for metrological confirmation of all measuring and test equipment used in determining the conformity of a manufactured instrument to legal metrological requirements (see ISO 10012-1 [11]).

These documented procedures shall include:

4.7.1 Having appropriate measuring and test equipment, a suitable testing environment, and trained and qualified personnel for conducting each test as well as current instructions, manuals, relevant data and test and record report forms for use by personnel.

Note: The testing environment shall be controlled to the extent possible in order to be able to minimize or to account for any interference that may be caused by influence quantities such as temperature, humidity, vibrations and electromagnetic interference.

4.7.2 Having documented performance criteria including a statement of the maximum permissible errors or uncertainty for all necessary measuring and test equipment.

4.7.3 Calibrating or qualifying all measuring and test equipment used for relevant measurements or evaluations in the testing process at specified intervals by comparison with reference standards that are traceable with a stated uncertainty to either national or international measurement standards. Where such standards do not exist, defined and identified local or in-house standards may be used. Reference standards shall normally be used only for the purpose of calibrating or confirming working standards used in ensuring that the measuring instruments conform to legal performance requirements for initial verification. If reference materials or certified reference materials are applied in this process, then their method of use and reconstitution, if appropriate, shall be documented.

4.7.4 Maintaining records of the comparisons and results according to 4.7.3 for each item of test and measurement equipment. The record shall bear the signature of the responsible person and the date.

4.7.5 Having a record system for all necessary measuring and test equipment, on which the procedures of 4.7.3 have been carried out, that includes relevant documents, if necessary, exhibiting or containing the following information:

- equipment that meets the criteria of 4.7.2 - the date of the comparisons of 4.7.3, the period of validity and the signature of the responsible person;
- equipment that does not meet the criteria of 4.7.2 - a notice not to use, the date of the notice, and the signature of the responsible person;
- equipment that meets the criteria of 4.7.2 but only after the comparisons of 4.7.3 are carried out immediately before use - notice to use only after calibration or qualification and signature of the responsible person.

Note: Some or all of this information may be marked or labeled on the measuring and test equipment if physically possible.

4.7.6 Having a documented procedure for withdrawing measuring and test equipment at the expiry of its period of validity or when an incident or experience suggests that the criteria of 4.7.2 are not met.

4.7.7 Maintaining records that provide a justification for not marking or labeling measuring and test equipment used in the testing and inspection process when calibration or confirmation is not required for such equipment.

4.7.8 Preparing a documented analysis of the probable effect on measuring instruments produced and declared to be in conformity during the period in which some units of necessary measuring and test equipment were determined not to be within their limits of adjustment or calibration of either maximum permissible errors or uncertainty, respectively. This analysis includes documenting the action taken with respect to both instruments produced and the non-conforming measuring and test equipment.

4.8 Measuring instrument testing

The testing shall be carried out either for each measuring instrument or by sampling from a lot according to documented sampling plans and procedures.

4.9 Measuring instrument identity

Each tested measuring instrument (or lot of instruments) that conforms to the legal metrological requirements shall be identified with appropriate information (see clause 5 for details). All measuring instruments found to be non-conforming shall also be identified clearly.

4.10 Subcontracting

A manufacturer shall identify a subcontractor for any part of the manufacturing, inspection or testing of the production process and shall be responsible for ensuring that the subcontractor is subjected to all relevant elements of the quality management system. A subcontractor shall be approved by the national responsible body and shall be subjected to the same requirements as the manufacturer.

4.11 Handling, storage and transport

The manufacturer shall implement reasonable and tested procedures that ensure the integrity of the metrological characteristics and identification of newly produced and tested measuring instruments during handling, transport and storage.

4.12 Records

A manufacturer shall establish and maintain records of inspection of the measuring instrument as specified by the national responsible body. Records shall be maintained for the required period, and all test records shall contain sufficient information to permit the tests to be repeated. Records shall include at least the following information:

4.12.1 Type approval record, if required

4.12.2 Design record

This record shall be maintained for each instrument category and contain relevant information about its design and specifications including observations, calculations, derived data and test reports. It shall identify the design for which the instrument was provided type approval, if required. A chronological record of any changes in its design and specifications shall also be included along with a rationale and evidence that the performance of the instrument has been maintained in conformity with its type. The signature of the person responsible and the effective date of each design record shall be provided.

4.12.3 Production record

This record shall contain a complete history of the information obtained for each unit or lot of instruments produced during production including any intermediate and all final tests necessary to support the metrological integrity of the instrument.

4.12.4 In-service record

This record shall contain any information received from users in the field regarding any performance problems of the measuring instrument in legal metrological applications. This information may be obtained through testing including subsequent verification, if required. Any necessary actions taken in response to such information from the field, especially regarding changes in design and/or in the production process, shall be recorded. This record shall identify the responsible person(s), including signatures and dates.

4.13 Audits

A manufacturer shall carry out audits of an authorized quality management system.

4.13.1 Documented audit procedures for the quality management system shall be prepared and include specified intervals for confirming and ensuring conformity with legal metrological requirements.

4.13.2 Internal audits shall be conducted in accordance with documented procedures by trained persons not having direct responsibility for the areas being audited, and the results of audits shall be recorded and retained for the specified period.

4.13.3 Audit results shall be reviewed by the person who is responsible for the audited areas. An effective and timely solution shall be sought for each problem identified, and all corrective actions taken in response to an audit shall be recorded.

4.13.4 The audit procedures, a record of the dates of audits, and the results of audits shall be available for review by the national responsible body.

4.13.5 The manufacturer shall allow the national responsible body, or its representative, access for inspection and observation to all locations of manufacturing, inspection, testing and storage and shall provide all relevant information about the documentation of the quality management system and all relevant records including qualifications of personnel and calibration and test data.

4.13.6 A subcontractor for any part of the manufacturing, inspection or testing of the production process shall be subject to the audit requirements.

5 Declaration of conformity

5.1 The declaration of conformity by a manufacturer shall be in the form of a label, mark or a certificate according to national regulations.

Note: A certificate for “Declaration of conformity” is a declaration that a newly produced measuring instrument conforms to relevant legal metrological laws, regulations or standards specifying the minimum performance requirements for initial verification. A manufacturer, however, may implement the requirements of this Document to ensure that “production meets type”, that is, each instrument produced meets the requirements achieved by its model subjected to type evaluation and approval.

5.2 A label or mark indicating conformity shall be attached to the instrument according to national regulations. Labeling shall also include the manufacturer's identity or logo and a serial number, lot number or date code. If such marks or labels cannot be placed on the instrument, then this information shall be on the package containing an individual instrument.

5.3 A certificate shall provide the following information:

- manufacturer's name and address;
- authorization number;
- common name, trade name and type of the measuring instrument including its serial number, lot number or date code for explicit identification;

- identification of legal metrological laws, regulations, standards (including OIML Recommendations and Documents), specifications and type approval certificate, if required;
- identification or description (if necessary) of test methods or procedures used and a statement of the traceability of measurement standards and reference materials;
- location of supporting test data;
- name and signature of the responsible person;
- date of the declaration of conformity; and
- authorizing organization (national responsible body).

Note: A model certificate of declaration of conformity is provided in Annex A.

Annex A

Format for a certificate of declaration of conformity

A.1 Manufacturer's name:

Address:

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A.2 Authorization number:

A.3 Instrument's common name:

Trade name or type:

Serial or model number:

Date code:

A.4 Applicable laws and regulations:

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Documentary standards:

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Type approval certificate (if required):

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A.5 Test methods and procedures:

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A.6 Measuring and test equipment:

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Reference or working standards (traceability):

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Reference materials (certification):

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A.7 Location of supporting data (if different than reported in A.1):

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A.8 Name of responsible person:

Signature:

A.9 Date of declaration:

A.10 Date of expiration (if applicable):

A.11 Authorizing organization (national responsible body):

Name:

.....

Address:

.....

References

- [1] **VIM (1993)**
International Vocabulary of Basic and General Terms in Metrology
BIPM/IEC/IFCC/ISO/IUPAC/IUPAP/OIML (ISO)
- [2] **VIML (2000)**
International Vocabulary of Terms in Legal Metrology
OIML
- [3] **ISO/IEC Guide 2 (1996)**
Standardization and related activities – General vocabulary
- [4] **ISO/IEC Guide 22 (1996)**
General criteria for suppliers' declaration of conformity
- [5] **ISO/IEC 17025 (1999)**
General requirements for the competence of testing and calibration laboratories
- [6] **ISO 9000 (2000)**
Quality management systems – Fundamentals and vocabulary
- [7] **ISO 9001 (2000)**
Quality management systems – Requirements
- [8] **ISO 9004 (2000)**
Quality management systems – Guidelines for performance improvements
- [9] **ISO 10011-1 (1990)**
Guidelines for auditing quality systems – Part 1: Auditing
- [10] **ISO 10011-2 (1991)**
Guidelines for auditing quality systems – Part 2: Qualification criteria for quality systems auditors
- [11] **ISO 10012-1 (1992)**
Quality assurance requirements for measuring equipment – Part 1: Metrological confirmation system for measuring equipment

