



**First Second Committee Draft (12CD) – marked version**

Project: Revision of OIML D 31:2008

Title: General requirements for ~~software~~ software-controlled measuring instruments

**Commented [ME1]:** Changed throughout the document to make it a proper adjective.

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List of Changes spread through the document:

All changes discussed at the Dordrecht meeting have been implemented.

Results of Subgroup 1 “Verification methods and means” have been implemented in clause 7 and its subclauses.

Results of Subgroup 2 “Operating systems requirements” have been implemented in clause 5.2.5 and its subclauses.

The terminology surrounding examination/verification/validation has been updated to conform with current V1 and V2 definitions.

Usage of terms related to type evaluation/type examination, reports/certificates has been updated to conform to the current B18 description of the OIML certification system.

All clauses have been reviewed and changed where necessary to use valid normative vocabulary.

Usage of duplicate terms (software module, software part, program and similar) has been minimized as much as possible to use the defined terms and definitions as consistently as possible. Terms no longer used have been deleted from clause 3.1 and from Annex C.

Terms related to functions and commands have been corrected to ensure that they have the same meaning throughout the document: Commands trigger functions through an interface.

Abbreviations are only listed in clause 3.2 if they are used more than once or twice in the document. Otherwise, the full term is used.

The term “universal computer” has been updated to “universal device” to make room for current and future developments.

**Commented [ME2]:** Updated according to changes agreed at and implemented after the Dordrecht meeting.

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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 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. OIML Member States shall implement these Recommendations to the greatest possible extent;
- **International Documents (OIML D)**, which are informative in nature and which are intended to harmonize and improve work in the field of legal metrology;
- **International Guides (OIML G)**, which are also informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology; and
- **International Basic Publications (OIML B)**, which define the operating rules of the various OIML structures and systems.

OIML Draft Recommendations, Documents and Guides are developed by Technical Committees or Subcommittees which comprise representatives from the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements have been established between the OIML and certain institutions, such as ISO and the IEC, with the objective of avoiding contradictory requirements. Consequently, manufacturers and users of measuring instruments, test laboratories, etc. may simultaneously apply OIML publications and those of other institutions.

International Recommendations, Documents, Guides and Basic Publications are published in English (E) and translated into French (F) and are subject to periodic revision.

Additionally, the OIML publishes or participates in the publication of **Vocabularies (OIML V)** and periodically commissions legal metrology experts to write **Expert Reports (OIML E)**. Expert Reports are intended to provide information and advice, and are written solely from the viewpoint of their author, without the involvement of a Technical Committee or Subcommittee, nor that of the CIML. Thus, they do not necessarily represent the views of the OIML.

This publication - reference OIML D 31, edition YYYY (E) - was developed by the OIML Technical Subcommittee TC 5/SC 2 *Software*. It was approved for final publication by the International Committee of Legal Metrology in YYYY.

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## General requirements for ~~software~~ ~~software~~-controlled measuring instruments

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### 1 Introduction

The primary aim of this International Document is to provide OIML Technical Committees and Subcommittees with guidance for establishing appropriate requirements for software related functionalities in measuring instruments covered by OIML Recommendations.

Furthermore, this International Document can provide guidance to OIML Member States in the implementation of OIML Recommendations in their national laws.

### 2 Scope and field of application

**2.1** This International Document specifies the general requirements applicable to legally relevant ~~software~~-related functionality and security in measuring instruments and gives guidance for verifying the compliance of an instrument with these requirements.

Commented [ME4]: Changed to make it a proper adjective

**2.2** This Document shall be taken into consideration by the OIML Technical Committees and Subcommittees as a basis for establishing specific software requirements and procedures in OIML Recommendations applicable to particular categories of measuring instruments (hereafter termed “relevant ~~OIML~~ Recommendations”).

Commented [ME5]: Changed here for consistency with the rest of the document.

**2.3** The instructions given in this Document apply only to ~~software~~-controlled measuring instruments or their components.

#### Notes:

- This Document does not cover all the technical requirements specific to ~~software~~-controlled measuring instruments; these requirements are to be given in the relevant ~~OIML~~ Recommendation, e.g. for weighing instruments, water meters, etc.
- This Document addresses some aspects concerning data security. In addition, national regulations for this area ~~have need~~ to be considered.

Commented [ME6]: Changed here for consistency with the rest of the document.

Commented [ME7]: Changed to use valid normative language throughout the document

### 3 Terms and Definitions

Some of the definitions used in this Document are in conformity with the International Vocabulary of Metrology - Basic and General Concepts and Associated Terms 3rd Edition (OIML V 2-200:2012 [1]), with the International Vocabulary of Terms in Legal Metrology (OIML V 1:2013 ~~[8]~~[6]), with the OIML International Document *General requirements for measuring instruments – Environmental conditions* (OIML D 11:2013 ~~[3]~~[2]) and several ISO/IEC International Standards. For the purpose of this Document, the following definitions and abbreviations apply.

#### 3.1 General terminology

##### 3.1.1 audit trail

continuous data file containing a time stamped information record of events, e.g. changes in the values of the parameters of a measuring instrument or software updates, or other activities that are legally relevant and which may influence the metrological characteristics  
[OIML V 1:2013, 6.05]

##### 3.1.2 authentication

checking of the declared or alleged identity of a user, process, or measuring instrument

Note: This may be necessary when checking that downloaded software originates from the owner of the ~~type evaluation~~ certificate.

Commented [FGT8]: Related to NL-02

##### 3.1.3 authenticity

result of the process of authentication (passed or failed)

##### ~~3.1.4~~ built-for-purpose device device constructed for the specific purpose of a metrological task

Note: ~~Note:~~ Undeclared interfaces to the operating system are inaccessible or non-existent.

Commented [FGT9]: Related to FR-01

##### 3.1.4~~5~~ checking facility

facility that is incorporated in a measuring instrument and which enables ~~a~~ significant defect to be detected and acted upon

Note: “Acted upon” refers to any adequate response by the measuring instrument (luminous signal, acoustic signal, prevention of the measurement process, etc.).

~~adapted from~~ ~~adopted from~~ OIML V 1:2013, 5.07]

Commented [ME10]: Related to US-comments

### 3.1.56 communication interface

part of an instrument that enables information to be passed between measuring instruments, components of measuring instruments or other external systems

*Note 1:* Communication interfaces can be wired, optical, radio, etc. and **they** are usually designed to use a specific protocol.

Commented [ME11]: Changed for clarity.

*Note 2:* This definition does not include communication between software parts.

### 3.1.76 cryptographic certificate

dataset containing the public key belonging to a measuring instrument or a person plus a unique identification of the subject, e.g. serial number of the measuring instrument or name or Personal Identification Number (PIN) of the person, plus a date of expiry

### 3.1.78 cryptographic means

**software** means **like such as** encryption/decryption with the purpose of hiding information from unauthorized persons, e.g. cryptographic hashes, or electronic signatures (see 3.1.132)

Commented [ME12]: Related to US-comments submitted at the Dordrecht meeting

Commented [ME13]: Related to US-comments submitted at the Dordrecht meeting

Commented [ME14]: Changed to for clarity

### 3.1.89 data domain

location in memory that each program needs for processing data

*Note:* Data domains may belong to one *software module* only, or to several.

### 3.1.910 device-specific parameter

legally relevant parameter with a value that depends on the individual instrument

*Note:* Device-specific parameters comprise adjustment parameters (e.g. span adjustment or other adjustments or corrections) and configuration parameters (e.g. maximum value, minimum value, units of measurement, etc.).

[OIML V 1:2013, 4.12]

### 3.1.1011 durability

ability of the measuring instrument to maintain its performance characteristics over a period of use

[OIML V 1:2013, 5.15]

### 3.1.1112 electronic measuring instrument

measuring instrument intended to measure an electrical or non-electrical quantity using electronic means and/or equipped with electronic parts

*Note:* For the purpose of this Document, auxiliary equipment, provided that it is subject to metrological

control, is considered to be part of the measuring instrument.  
[OIML D 11:2013, 3.1]

3.1.4213  
**electronic signature**

software means which is added to software or data with the purpose to verify the origin of software or data, i.e. to prove their authenticity, or to check that the software or data are unchanged, i.e. to prove their integrity

*Note 1:* For electronic signing, a public key system is used in general, i.e. a pair of keys where only one ~~has~~ needs to be kept secret; the other may be public.

*Note 2:* The secret key is used when software or data are secured. The public key is used when software ~~are~~ or data are validated/verified before use.

*Note 3:* The ~~validating-verifying~~ instance may require a cryptographic certificate of the securing instance (see 3.1.67) to be sure of the authenticity of the public key.

Commented [ME15]: Related to NL-03.

Commented [ME16]: Changed to comply with B6-2 requirements.

Commented [ME17]: Changed to use valid normative language.

Commented [ME18]: Related to US-comments submitted at the Dordrecht meeting, CA-09

Commented [ME19]: Related to DE-07, AU-13, AU-19

Commented [ME20]: Related to DE-07, AU-13, AU-19

3.1.1443  
**error of indication**

indication minus a reference quantity value

*Note:* This reference value is sometimes referred to as a (conventional) true quantity value. See, however, also OIML V2-200:2012, 2.12, Note 1).

~~*Note:*~~ [OIML V 1:2013, 0.04]

3.1.4415  
**error log**

continuous data file containing an information record of failures ~~or significant defects~~ that have an influence on the metrological characteristics ~~of the measuring instrument~~

Commented [ME21]: Related to DE-11

Commented [ME22]: Changed for clarity

3.1.4516  
**event**

action in which a modification of a measuring instrument parameter, adjustment factor or update of software module is made

[OIML V 1:2013, 6.06]

3.1.1746  
**event counter**

non-resettable counter that increments each time an event occurs

3.1.4718  
**executable code**

~~digital information available in the software or firmware installed on the computing system of the measuring instrument/component or a measuring instrument's module file installed on the computer system of the measuring instrument or component (EPROM, hard disk, etc.). This code is interpreted by the microprocessor and transposed into certain logical, arithmetical, decoding, or data transporting operations~~

Commented [ME23]: Changed for consistency with the rest of the document

Commented [ME24]: Related to NL-04, UK-02

Commented [ME25]: Related to NL-04

*Note:* This code is interpreted by the central processing unit (CPU) of the measuring instrument and



converted into certain logical, arithmetical, decoding or data transporting operations.

Note: — This code is interpreted by the central processing unit (CPU) of the measuring instrument and converted into certain logical, arithmetical, decoding or data transporting operations.

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Commented [ME26]: Related to NL-04

### 3.1.1819

#### fault

difference between the error of indication and the intrinsic error of a measuring instrument

*Note 1:* Principally, a fault is the result of an undesired change of data contained in or flowing through an electronic measuring instrument.

*Note 2:* From the definition it follows that a "fault" is a numerical value which is expressed either in a unit of measurement or as a relative value, for instance as a percentage.

[OIML V 1:2013, 5.12]

### 3.1.1920

#### hash function

(mathematical) function which maps values from a large (possibly very large) domain into a smaller range. *Note:*

— A "good" hash function is such that the results of applying the function to a (large) set of values in the domain will be evenly distributed (and apparently at random) over the range.

[ISO/IEC 9594-8:2014] ~~[4]~~[3]

### 3.1.2021

#### integrity ~~(of programs, data, or parameters)~~

assurance that the programs, data, or parameters have not been subjected to any unauthorized or unintended changes while in use, transfer, storage, repair or maintenance

Commented [ME27]: Changed for clearer use in the rest of the document

### 3.1.2122

#### interface

shared boundary between two functional units, defined by various characteristics pertaining to the functions, physical interconnections, signal exchanges, and other characteristics of the units, as appropriate.

[ISO 2382-9:1995] ~~[5]~~[4]

### 3.1.2223

#### interruptible cumulative measurement

process of cumulative measurement of the quantity value of a substance that can be easily and rapidly stopped during normal operation

*Note 1:* Examples include: a) discontinuous totalizing automatic weighing instrument, b) fuel dispenser.

*Note 2:* See also non-interruptible cumulative measurement (3.1.2930).

Commented [ME28]: Related to JP-03

### 3.1.2324

#### intrinsic error

error of indication, determined under reference conditions

[OIML V 1:2013, 0.06]

## 3.1.2425

**legally relevant**

subject to legal control

[to be changed in OIML V 1:2013, 4.08]

**Commented [ME29]:** TC1 will be informed about the change once 2CD has been approved.

## 3.1.2526

**legally relevant parameter**

parameter of a measuring instrument/~~component~~ (electronic) device, ~~sub-assembly~~ component software or a module subject to legal control

*Note:* The following types of legally relevant parameters can be distinguished: *type-specific parameters* and *device-specific parameters*.

[to be changed in OIML V 1:2013, 4.10]

**Commented [ME30]:** Related to CZ-01. Moved here for consistency with the rest of the document

**Commented [ME31]:** Related to CZ-01. TC1 to be informed about the modification.

## 3.1.2627

**legally relevant software part**

~~part of all software modules~~ of a measuring instrument/~~component~~ that ~~is~~ ~~are~~ ~~legally relevant~~ subject to legal control

**Commented [ME32]:** Changed for consistency with the rest of the document

**Commented [ME33]:** Related to AT-02

## 3.1.2728

**maximum permissible error (of a measuring instrument)**

extreme value of a measurement error, with respect to a known reference quantity value, permitted by specifications or regulations for a given measurement, measuring instrument, or measuring system

~~adapted from~~ [OIML V 1:2013, 0.05]

**Commented [ME34]:** Changed to “adapted from” since original note would just confuse the reader.

## 3.1.2829

**measuring instrument**

device used for making measurements, alone or in conjunction with one or more supplementary devices

~~adapted from~~ [OIML V 1:2013, 0.10]

**Commented [ME35]:** Changed to “adapted from” since original note would just confuse the reader.

## 3.1.2930

**non-interruptible cumulative measurement**

cumulative measuring process with no definite end that cannot be stopped and continued again by a user or an operator without falsifying the result of the measurement

*Note 1:* Examples include: a) continuous totalizing automatic weighing instrument, b) heat meter.

*Note 2:* See also interruptible cumulative measurement (3.1.2322)

**Commented [ME36]:** Related to JP-04

~~3.1.30~~~~performance test~~

~~test intended to verify whether the EUT is able to accomplish its intended functions~~

~~[OIML V 1:2013, 5.24]~~

**Commented [ME37]:** Deleted since it was not used anywhere in the document.

### 3.1.31 protective interface

legally relevant software module that handles all dataflow to the legally relevant software part to prevent inadmissible influences

Commented [ME38]: Changed for consistency with the rest of the document.

Commented [ME39]: Related to discussion SG2 Results (OS Requirements)

### 3.1.32 sealing

means intended to protect the measuring instrument against any unauthorized modification, readjustment, removal of parts, software, etc.

Note: This may be achieved by hardware, software or a combination of both. ~~ssd4~~

Commented [ME40]: Related to JP-02, SI-01, IR-01, UK-03, DE-12

### 3.1.33 securing

means preventing unauthorized access to hardware or software  
[OIML V 1:2013, 2.21]

### 3.1.34 significant defect

event that has an undesirable impact on the ~~properties or functions~~ compliance of the measuring instrument or a fault

Note: Examples of significant defect include: a) deletion of the audit trail; b) unauthorized parameter changes; c) unauthorized updates.

Note: Examples of significant defect include: a) deletion of the audit trail; b) unauthorized parameter changes; c) unauthorized updates.

Commented [ME41]: Related to DE-10

### 3.1.35 software examination

technical operation that consists of determining one or more characteristics of the software according to the specific procedure (e.g. analysis of technical documentation or running the program under controlled conditions)

### 3.1.36 software identification

sequence of readable characters (e.g. version number, checksum) that represents the software or software module under consideration.

Note: It can be checked on an instrument whilst in use.

### 3.1.37 software interface

program code and dedicated data domain; receiving, filtering, or transmitting data between *software modules*

Note 1: A software interface is not necessarily legally relevant.

Note 2: A software interface is an interface between two or more software modules, used to exchange data

and transmit commands.  
[OIML V 1:2013, 6.03]

3.1.3738  
software module

software entity such as a program, subroutine, library, parameter or data set, and other objects including their data domains that may be in relationship with other entities  
Note: The software of measuring instruments consists of one or more software modules.

Commented [ME42]: Related to US-comments submitted at the Dordrecht meeting

3.1.3839  
software protection

protection of measuring instrument software or data domain by a hardware or software implemented seal  
Note: The seal must be removed, damaged or broken to obtain access to change software.  
[OIML V 1:2013, 6.04]

3.1.3940  
software separation

separation of the software in measuring instruments, which can be divided into a legally relevant part and a legally non-relevant part  
Note: These parts communicate via a software interface.  
[OIML V 1:2013, 6.02]

3.1.4041  
source code

computer program written in a form (programming language) that is legible and editable. Source code is compiled or interpreted into executable code  
Note: Source code is compiled or interpreted into executable code.  
Note: Source code is compiled or interpreted into executable code.

Commented [ME43]: Modified to comply with requirements from B6-2

3.1.4142  
storage device

device used for storing measurement data after completion of the measurement and keeping it available for later legally relevant purposes (e.g. the conclusion of a commercial transaction)  
[OIML V 1:2013, 6.07]

3.1.4243  
time stamp

unique monotonically increasing time value, e.g. in seconds or a date and time string denoting the date and/or time at which a certain measurement or event or fault occurred

Commented [ME44]: Related to US-comments submitted at the Dordrecht meeting

Commented [ME45]: Related to DE-11

3.1.4344  
transmission of measurement data

transmission-electronic transportation of measurement data via communication lines or other means to a receiver

Commented [ME46]: NL comment in SG3

where they are further processed

### 3.1.445

#### type (pattern) evaluation

conformity assessment procedure on one or more specimens of an identified type (pattern) of measuring instruments which results in an evaluation report ~~or an evaluation certificate~~

[OIML V 1:2013, 2.04]

Commented [ME47]: Related to NL-01, NL-05

### 3.1.4546

#### type-specific parameter

*legally relevant parameter* with a value that depends on the type of instrument only

*Note:* Type-specific parameters are part of the legally relevant software.

[OIML V 1:2013, 4.11]

Example:

Considering a measuring instrument of liquids other than water, the range of cinematic viscosity of a turbine is a type-specific parameter, fixed by the type evaluation of the turbine. All the manufactured turbines of the same type use the same range of viscosity.

### 3.1.4647

#### universal computer device

~~computer device~~ that is not constructed for a specific purpose, but that can be adapted to ~~the a~~ metrological task by software

*Note:* ~~This kind of device might have undeclared interfaces to the operating system. In general, this software is founded on an operating system that permits loading and execution of software for specific purposes.~~

Commented [ME48]: Related to FR-01

### 3.1.4748

#### user interface

interface that enables information to be interchanged between the operator and the measuring instrument or its hardware ~~components~~ or software ~~components/modules~~

*Note:* Examples are switches, keyboard, mouse, display, monitor, printer, touch-screen, software window on a screen including the software that generates it.

[to be changed in OIML V 1:2013, 6.08]

Commented [ME49]: Changed for consistency with the rest of the document.

### ~~3.1.48~~

#### ~~validation~~

~~verification, where the specified requirements are adequate for an intended use~~

[OIML V 2-200:2012, 2.45]

Commented [ME50]: Deleted since it is not used anymore in the document.

### 3.1.49

#### verification

provision of objective evidence that a given item fulfils specified requirements

~~adapted from~~ [OIML V 2-200:2012, 2.44]

Commented [ME51]: Changed to "adapted from" since original notes and examples would just confuse the reader.

### 3.1.50\*

verification of a measuring instrument  
conformity assessment procedure (other than type evaluation) which results in the affixing of a verification  
mark and/or issuing of a verification certificate  
Note: See also OIML V2-200:2012, 2.44  
[OIML V 1:2013, 2.09]

Commented [ME52]: Related to CZ-04

3.2 Abbreviations

EUT	Equipment Under Test
IEC	International Electrotechnical Commission
<del>I/O</del>	<del>Input / Output (refers to ports)</del>
ISO	International Organization for Standardization
<del>IT</del>	<del>Information Technology</del>
MPE	Maximum Permissible Error
OIML	International Organization of Legal Metrology
<del>PCB</del>	<del>Printed Circuit Board</del>
<del>PG</del>	<del>Project Group</del>
<del>PIN</del>	<del>Personal Identification Number</del>
<del>TEC</del>	<del>Type evaluation certificate</del>

Commented [ME53]: Deleted since it is not used anymore.

Commented [ME54]: Abbreviations deleted since they are only used once or twice. Abbreviations are mentioned in brackets there.

Commented [ME55]: Only occurs in 5.1.3.2.a where full phrase is now used.

Commented [ME56]: Abbreviation deleted since it is only used twice. Abbreviations are mentioned in brackets there.

Commented [ME57]: Related to JP-05, NL-06

4 Instructions for use of this Document in drafting  
OIML Recommendations

4.1 The provisions of this Document apply only to new OIML Recommendations and OIML Recommendations under revision. The OIML ~~p~~Project groups (Technical Committees, Subcommittees) should use this guidance ~~D~~document to establish software-related requirements in addition to the other technical and metrological requirements of the applicable OIML Recommendation.

Commented [ME58]: Related to NL-07

4.2 All referred documents are subject to revision, and the users of this Document are encouraged to investigate the possibility of applying the most recent editions of the referred documents.

4.3 It is the objective of this Document to provide the project groups responsible for drawing up OIML Recommendations with a set of requirements – partly with different (risk) levels – that are suitable to cover the demands of all kinds of measuring instruments and all areas of application. The project group shall determine which risk level is suitable, and how to incorporate the relevant portions of this Document into the OIML Recommendation being drafted. In Clause 8 some aid is given for performing this task.

Commented [ME59]: Related to NL-08

4.4 PGs should define which influence is considered inadmissible for specific types of instruments.

Commented [ME60]: Related to CA-13, DE-03, AU-08

## 5 Requirements for measuring instruments with respect to the application of software

### 5.1 General requirements

At the time of publishing this Document, the general requirements represent the state of the art in information technology (IT). They are in principle applicable to all kinds of software-controlled measuring instruments and components of measuring instruments, and they should be considered in all OIML Recommendations. In contrast to these general requirements the requirements specific for configurations (5.2) deal with technical features that are not common for some kinds of instruments or in some areas of application.

In the examples, where applicable, both normal and raised risk levels are shown. Notation in this Document is as follows:

- (I) Technical solution acceptable in case of normal risk level;
- (II) Technical solution acceptable in case of raised risk level (see 8).

#### 5.1.1 Software identification

Software of a measuring instrument/component shall be clearly identified. The identification may consist of more than one part but at least one part shall be dedicated to the legal purpose.

The identification shall be displayed or printed by the measuring instrument:

- on command or
- during operation or
- at start up for a measuring instrument that can be turned off and on again.

If a measuring instrument or component has neither display nor printer, the identification shall be sent via a communication interface, in order to be displayed/printed on another component.

As an exception, an imprint of the software identification on the instrument/component shall be an acceptable solution if it satisfies all of the following conditions:

- (1) The user interface does not have any control capability to activate the indication of the software identification on the display, or the display does not technically allow the identification of the software to be shown (analog indicating device or electromechanical counter).
- (2) The instrument/component does not have an interface to communicate the software identification.
- (3) After production of the instrument/component a change of the software is not possible, or only possible if the hardware is also changed.

It shall be ensured that the software identification is correctly marked on the concerned instrument/component.

The relevant OIML Recommendation should allow or disallow this exception.

If the software is modified in any way, a new software identification is required.

The software identification and the means of identification (e.g. software version, hash value, checksum) shall be stated in the type evaluation certificate. Instructions on how to display or print the software identification shall be in the TEC certificate.

*Note:* Each measuring instrument in use has to shall conform to the approved type. The software identification enables surveillance personnel and persons affected by the measurement to determine whether the instrument under consideration is conformable.

Examples:

**Commented [ME61]:** Related to US-comments submitted at the Dordrecht meeting, CA-10, JP-06, NL-09

**Commented [ME62]:** Changed to make the sentence more easily readable.

**Commented [ME63]:** Related to UK-08

**Commented [ME64]:** Related to FR-02

**Commented [ME65]:** Changed for consistency throughout the document.

**Commented [ME66]:** Related to AU-01

**Commented [ME67]:** Related to UK-08.

**Commented [ME68]:** Related to JP-08, NL-10

**Commented [ME69]:** For consistency with previous statement in the clause.

**Commented [ME70]:** Related to JP-08, NL-10

**Commented [ME71]:** Changed to use valid normative language throughout the document.

(I) The software contains a textual string or a number, unambiguously identifying the installed version. This string is transferred to the display of the instrument when a button is pressed, when the instrument is switched on, or cyclically controlled by a timer.

A version number may have the following structure A.Y.Z. Considering a flow computer; the letter A will represent the version of the core software that is counting pulses; the letter Y will represent the version of the conversion function (none, at 15 °C, at 20 °C); the letter Z will represent the language of the user interface.

(II) The software calculates a checksum of the executable code and presents the result as the identification instead of or in addition to the string in (I).

Commented [ME72]: Related to SI-02

### 5.1.2 Correctness of algorithms and functions

The measuring algorithms and functions of a measuring instrument shall be appropriate and functionally correct for the given application and device type (accuracy of the algorithms, price calculation according to certain rules, rounding algorithms, etc.).

The measurement result and accompanying information required by specific ~~OIML~~ Recommendations or by national legislation shall be displayed or printed correctly.

Commented [ME73]: Related to UK-08.

It shall be possible to examine algorithms and functions either by metrological tests, software tests or software examination (as described in 6.3).

No hidden or undocumented functions or parameters shall exist.

### 5.1.3 Software protection

#### 5.1.3.1 Prevention of misuse

A measuring instrument shall be constructed in such a way that possibilities for unintentional, accidental, or intentional misuse are minimal. In the framework of this ~~OIML Document~~, this applies especially to the software. The presentation of the measurement results should be unambiguous for all parties affected.

Commented [ME74]: Changed for consistency with the rest of the document.

*Note:* Software-controlled instruments are often complex in their functionality. The user needs good guidance for correct use and for achieving correct measurement results.

#### Example:

The user is guided by menus. The legally relevant functions are combined into one branch in this menu. If any measurement values might be lost by an action, the user is warned and requested to perform another action before the function is executed. See also 5.2.2.

#### 5.1.3.2 ~~Fraud protection~~ Evidence of intervention

5.1.3.2.a Software shall be protected in such a way that evidence of any intervention (e.g. software updates, parameters changes) shall be available. Software shall be secured against unauthorized modification, loading, or changes by swapping the memory device. Mechanical sealing or other technical means may be necessary to secure measuring instruments.

Commented [ME75]: Related to US-comments submitted at the Dordrecht meeting

#### Example:



(I)/(II) The housing containing the memory devices is sealed or the memory device is sealed on the ~~PCB~~printed circuit board.

**Commented [ME76]:** Changed because "PCB" was deleted from the list of abbreviations.

(II) ~~If a rewritable device is used,~~ The write-enable input of the device is inhibited by a switch that can be sealed. The circuit is designed in such a way that the write protection cannot be cancelled by a short-circuit of contacts.

**Commented [ME77]:** Deleted to avoid conditional clauses in examples to make them more precise.

(I) A measuring instrument consists of two components, one containing the main metrological functions incorporated in a housing that is sealed. The other component is a universal ~~computer device~~ with an operating system. Some functions such as the indication are located in the software of this ~~computer device~~. To prevent swapping of the software on the universal ~~computer device~~, the data transfer between the component and the universal ~~computer device~~ is encrypted. The key for decryption is hidden in the ~~legally relevant~~ program ~~that is part of the legally relevant software~~ of the universal ~~computer device~~. Only this program knows the key and is able to read, decrypt and use the measurement values. Other programs cannot be used for this purpose as they cannot decrypt the measurement values (see also example in 5.2.1.2.d).

**Commented [ME78]:** Related to FR-01, CZ-05

**Commented [ME79]:** Related to FR-01, CZ-05

**Commented [ME80]:** Related to FR-01, CZ-05

**Commented [ME81]:** Related to FR-01, CZ-05

**Commented [ME82]:** For consistency with the rest of the document

**Commented [HS83]:** Related to FR-01, CZ-05

5.1.3.2.b Only clearly documented functions (see 6.1) may be activated by the user interface, which do not influence the metrological characteristics of the instrument.

**Note:** The examiner decides whether all of these documented ~~commands-functions~~ are acceptable.

**Commented [ME84]:** For consistency with the above statement.

**Example:**

(I)/(II) All inputs from the user interface are redirected to a ~~software module~~program that filters incoming commands. It only allows the ~~commands to trigger the documented functions~~documented ones and discards all others. This ~~module~~program is part of the legally relevant software.

**Commented [ME85]:** For consistency with the requirement. Commands trigger functions through an interface.

5.1.3.2.c Parameters that fix the legally relevant characteristics of the measuring instrument shall be secured against unauthorized modification. If necessary for the purpose of verification ~~of a measuring instrument~~, displaying or printing of the current parameter settings shall be possible.

**Commented [ME86]:** For consistency with definition 2.09 in V1

**Commented [ME87]:** Related CZ-04, DE-08

**Note:** ~~Some of the~~Device-specific parameters may stay adjustable or selectable after type evaluation. They should be adjustable/selectable only in a special operational mode of the instrument. ~~The~~Device-specific parameters may be classified as those that should be secured (unalterable) and those that may be accessed (adjustable/selectable parameters) by an authorized person, e.g. the instrument owner or product vendor. Type-specific parameters have identical values for all specimens of a type. They are fixed at type evaluation of the instrument.

**Commented [ME88]:** Related to US-comments submitted at the Dordrecht meeting

**Commented [ME89]:** Related to US-comments submitted at the Dordrecht meeting

**Example:**

(I)/(II) Device specific parameters to be secured are stored in a non-volatile memory. The write-enable input of the memory is inhibited by a switch that is sealed.

Refer to examples 5.1.3.2.d (1) to (3) in this clause.

5.1.3.2.d Software protection comprises appropriate sealing by mechanical, electronic and/or cryptographic means, making an unauthorized intervention impossible or evident.

**Note:** A cryptographic certificate may be used. The software is signed by a trustworthy institution with an electronic signature. The ~~assignment of a public key to a subject~~ authenticity of the signed software can be verified by using the public key of the trustworthy institution and decrypting the signature of the certificate.

Commented [ME90]: Related to JP-09

**Example:**

- (1) (I) Electronic sealing. The legally relevant parameters of an instrument can be input and adjusted by a menu item. The software recognizes each change and increments an event counter with each event of this kind. This event counter value can be indicated. The initial value of the event counter ~~is marked durably on the instrument, has to be registered in the TEC.~~ If the indicated value differs from the registered one, the instrument is in an unverified state (equivalent to a broken seal).
- (2) (I)/(II) The software of a measuring instrument is constructed such (see Example 5.1.3.2.a) that there is no way to modify the legally relevant parameters but via a switch protected menu. This switch is mechanically sealed in the inactive position, making modification of the legally relevant parameters impossible.  
To modify the legally relevant parameters, the switch ~~needs~~ has to be activated, inevitably breaking the seal by doing so.
- (3) (II) The software of a measuring instrument is constructed such that there is no way to access the legally relevant parameters but by authorized persons. If a person wants to access the parameter menu item, that person has to insert his smart card containing a personal identification number (PIN) as part of a cryptographic certificate. The software of the instrument is able to verify the authenticity of the personal identification number (PIN) by the certificate and allows the parameter menu item to be entered. The access is recorded in an audit trail including the identity of the person (or at least of the smart card used).

Commented [ME91]: Related to NL-12

Commented [ME92]: Changed to use valid normative language.

#### 5.1.4 Support of hardware features

##### 5.1.4.1 Detection of significant defects ~~Support of fault detection~~

The relevant ~~OIML Recommendation~~ may require fault-detection functions for certain faults of the instrument ~~(addressed in OIML D 11:2013 (5.1.2 (b) and 5.3)) significant defects~~. In this case, the manufacturer of the instrument shall be required to design checking facilities into the software or hardware parts or provide means by which the hardware parts can be supported by the software parts of the instrument.

Commented [ME93]: Related to DE-11

Commented [ME94]: Related to UK-08.

Commented [ME95]: Related to DE-11

If software is involved in fault-detection of significant defects, an appropriate reaction is required. For example, ~~the relevant OIML Recommendation may prescribe that the instrument --/ component is deactivated or an alarm --/ record in an error log is generated in case a~~ fault-significant defect condition is detected.

Commented [ME96]: Related to DE-11

Commented [ME97]: Related to AU-02

Commented [ME98]: Related to UK-08.

Commented [ME99]: Related to DE-11

Commented [ME100]: Related to DE-11

The documentation to be submitted for type evaluation shall contain a list of the faults-significant defects that will be detected by the software and the expected reaction and in case needed for understanding its operation, a description of the detecting algorithm.

**Example:**

(I) On each start-up the legally relevant ~~program software part~~ calculates a checksum of the program code and legally relevant parameters. The nominal value of these checksums has been calculated in advance and stored in the instrument. If the calculated and stored values do not match, the ~~program-legal relevant software part~~ stops execution.

Commented [ME101]: Changed for language accuracy. A program may be part of the legally relevant software. Software itself is split into a legally relevant and a legally non-relevant part.

~~In case of a non-interruptible cumulative measurement~~ If the measurement is cumulative and not interruptible, the checksum is calculated cyclically and controlled by a software timer. In case a

Commented [ME102]: Changed to avoid conditional clauses in examples.

failure is detected, the software displays an error message or switches on a failure indicator and records the time of the ~~fault-significant defect~~ in an error log ~~(if one exists)~~.

(II) On each start-up, the legally relevant ~~program-software part~~ calculates a ~~value produced by a cryptographic hash function~~ of the program code and legally relevant parameters. The nominal value of the hash has been calculated in advance and stored in the instrument. If the calculated and stored values do not match, the program stops execution.

~~In case of a non-interruptible cumulative measurement, if the measurement is cumulative and not interruptible, the hash value is calculated cyclically and controlled by a software timer. In case a failure is detected, the software displays an error message or switches on a failure indicator and records the time of the significant defect/fault in an error log (if one exists).~~

Commented [ME103]: Changed to avoid conditional clauses in examples.

Commented [ME104]: Changed for consistency with the terms and definitions.

Commented [ME105]: Changed to avoid conditional clauses in examples.

#### 5.1.4.2 ~~Support of~~ Durability protection

It is the manufacturer's choice to realize durability protection facilities addressed in OIML D 11:2013 [21] (5.1.3 (b) and 5.4) in software or hardware, or to allow hardware facilities to be supported by software. The relevant ~~OIML Recommendation~~ may suggest appropriate solutions.

If software is involved in durability protection, an appropriate reaction is required. ~~For example, the relevant OIML Recommendation~~ may prescribe that the instrument ~~or~~ component is deactivated or an alarm ~~or~~ report is generated in case durability is detected as being jeopardized.

Commented [ME106]: Related to DE-11

Commented [ME107]: Related to UK-08.

Commented [ME108]: Related to AU-03.

Commented [ME109]: Related to UK-08.

Example:

(I)/(II) Some kind of measuring instruments require an adjustment after a prescribed time interval, in order to guarantee the durability of the measurement. The software gives a warning when the maintenance interval has elapsed and even stops measuring, if it has been exceeded for a certain time interval.

#### 5.1.5 Time stamps

The time stamp is ~~a date/time information~~ in a consistent format, allowing for easy comparison of two different records and tracking progress over time.

The time stamp shall be read from the clock of the instrument. Depending on the kind of instrument, or area of application, setting the clock may be legally relevant and appropriate protection means shall be taken according to the risk level to be applied (see 5.1.3.2.c).

~~The internal clock of a stand-alone measuring instrument may tend to have a rather large uncertainty because there is if no means are incorporated to synchronize this clock with the universal time standard it with the global clock. But if the information concerning Where the specific field of application requires high accuracy information concerning the exact time of the measurement it might be necessary to improve for a specific field of application, the reliability of the internal clock of the measuring instrument shall be enhanced by using specific means.~~

Commented [ME110]: Related to NL-16, NL-18

Commented [ME111]: Related to NL-17, NL-18

~~Where relevant, PGs may define requirements and test methods for internal clocks.~~

Commented [ME112]: Related to AU-07, AU-09

Example:

(II) The reliability of the internal quartz-controlled clock device of the measuring instrument is enhanced by redundancy: A timer is incremented by the clock of the microcontroller that is derived from another quartz crystal. When the timer value reaches a preset value, e.g. 1 second, a specific flag of the microcontroller is set and an interrupt routine of the ~~program~~ legally relevant software part increments a second counter. At the end of e.g. one day the software reads the quartz-

Commented [ME113]: Changed for consistency with other clauses.

controlled clock device and calculates the difference in the seconds counted by the software. If the difference is within predefined limits, the software counter is reset and the procedure repeats; but if the difference exceeds the limits, the software initiates an appropriate error reaction.

Commented [ME114]: Moved from 5.2.4.5 and 5.2.3.4. Related to CA-06, JP-12, UK-07, NL-15, JP-13

## 5.2 Requirements specific for configurations

The requirements given in this clause are based on typical technical solutions in information technology, although they might not be common in all areas of legal applications. Following these requirements technical solutions are possible that show the same degree of security and conformity to a type as instruments that are not software-controlled.

The following specific requirements are needed when certain technologies are employed in measuring instruments. They ~~have to~~ shall be considered in addition to those described in 5.1.

Commented [ME115]: Related to DE-01

In the examples, where applicable, both normal and raised risk levels are shown. Notation in this document is as follows:

- (I) Technical solution acceptable in case of normal risk level;
- (II) Technical solution acceptable in case of raised risk level (see 8).

### 5.2.1 Specification and separation of legally relevant parts and specification of interfaces

This requirement applies if the measuring instrument/~~component~~ (~~component~~) has interfaces for communicating with other instruments/~~or~~ components, with the user, or with other software parts besides the legally relevant parts within a measuring instrument/~~component~~ (~~component~~).

Commented [ME116]: Changed for consistency.

Legally relevant parts of a measuring instrument – whether software or hardware parts – shall not be inadmissibly influenced by other parts of the measuring instrument.

OIML Recommendation may specify the software/~~hardware~~ data or part of the software/hardware/data that are legally relevant.

Commented [ME117]: Related to UK-08.

Commented [ME118]: Related to UK-05. Redundant spaces were deleted throughout the document.

#### 5.2.1.1 Separation of components

5.2.1.1.a Components of a measuring instrument that perform legally relevant functions shall be identified, clearly defined and documented. They form the legally relevant part of the measuring instrument.

*Note:* The examiner decides whether this part is complete and whether other parts of the measuring instrument may be excluded from further evaluation.

Example:

- (1) (I)/(II) An electricity meter is equipped with an optical interface for connecting an electronic device to read out measurement values. The meter stores all the relevant quantities and keeps the values available for being read out for a sufficient time span. In this system, only the electricity meter is the legally relevant instrument. Other legally non-relevant devices may exist and may be connected to the interface that complies with clause 5.2.1.1.b. Securing of the data transmission itself (see 5.2.4) is not required.
- (2) (I)/(II) A measuring instrument consists of the following components:
  - a digital sensor calculating the weight or volume;
  - a universal ~~computer device~~ calculating the price;
  - a printer printing out the measurement value and the price to pay.

Commented [ME119]: Related to US-comments submitted at the Dordrecht meeting

Commented [ME120]: Related to FR-01, CZ-05

All components are connected by a local area network. In this case the digital sensor, the universal ~~computer device~~ and the printer are legally relevant components and are optionally connected to a merchandize system that is not legally relevant. The legally relevant components ~~have to fulfill~~ requirement 5.2.1.1.b and – because of the transmission via the network – also requirements contained in 5.2.4.

**Commented [ME121]:** Deleted to avoid normative language in examples.

5.2.1.1.b It shall be demonstrated that the functions and data of components, that are legally relevant, cannot be inadmissibly influenced by commands received via the interface ~~to from~~ the other, legally non-relevant parts.

**Commented [ME122]:** Related to SI-03

This implies that there is an unambiguous assignment of each command to all initiated functions or data changes in the component.

*Note:* If “legally relevant” components interact with other “legally relevant” components, refer to 5.2.4.

#### Example:

- (1) (I)/(II) The software of the electricity meter (see example (1) of 5.2.1.1.a above) is able to receive commands for selecting the quantities required. It combines the measurement value with additional information – e.g. time stamp, unit – and sends this dataset back to the requesting device. The software only accepts commands for the selection of valid allowed quantities and discards any other command, sending back only an error message. There may be securing means for the contents of the dataset, but they are not required, as the transmitted dataset is not subject to legal control.
- (2) (I)/(II) Inside the housing that is sealed there is a switch that defines the operating mode of the electricity meter: one switch setting indicates the secured mode and the other the free mode (securing means other than a mechanical seal are possible; see examples 5.1.3.2.a/d). When interpreting received commands, the software checks the position of the switch: in the free mode, the command set that the software accepts is extended compared to the secured mode (e.g. it may be possible to adjust the calibration factor by a command that is discarded in the secured mode).

#### 5.2.1.2 Specification and separation of software parts

5.2.1.2.a All software modules (programs, subroutines, objects, etc.) that perform legally relevant functions or that process legally relevant data form the legally relevant software part of a measuring instrument ~~component (or component)~~. The conformity requirement applies to this part and it shall be made identifiable as described in 5.1.1.

**Commented [ME123]:** Changed for consistency

If the separation of the software is not possible or needed, the software is legally relevant as a whole.

#### Example:

(I) A measuring instrument consists of several digital sensors connected to a personal computer that displays the measurement values. The legally relevant software ~~part~~ on the personal computer is separated from the legally non-relevant parts by compiling all procedures realizing legally relevant functions (including presentation of results) into a dynamically linkable library. One or several legally non-relevant applications may call ~~program procedures~~ functions in this library. These procedures receive the measurement data from the digital sensors, calculate the measurement result, and display it in a software window.

**Commented [ME124]:** Changed for consistency with other clauses.

**Commented [ME125]:** Changed for consistency with other clauses.

5.2.1.2.b If the legally relevant software part communicates with other software parts, a software interface shall be defined. All communication shall be performed exclusively via this interface. The legally relevant

software part and the interface shall be clearly documented. All legally relevant functions and data domains of the software shall be described to enable a type evaluation authority to decide on correct software separation.

The software interface consists of program code and dedicated data domains. Defined coded commands or data are exchanged between the software parts by storing to the dedicated data domain by one software part and reading from it by the other. Writing and reading program code is part of the software interface. The declared software interface shall not be circumvented.

Commented [ME126]: Changed for clarity of requirements.

Commented [ME127]: Related to DE-02

Example:

(I) In the example 5.2.1.2.a/c the legally non-relevant application controls the start of the legally relevant procedures in the library. Omitting a call of these procedures would of course inhibit the legally relevant function of the system. Therefore, the following provisions have been made in the example system to fulfill the requirement 5.2.1.2.d: The digital sensors send the measurement data in encrypted form. The key for decryption is hidden in the library. Only the procedures in the library know the key and are able to read, decrypt, and display measurement values.

Commented [ME128]: Related to CA-13

5.2.1.2.c There shall be an unambiguous assignment of each command to all initiated functions or data changes in the legally relevant software part of the software. Commands-Functions that are triggered communicate through the software interface shall be declared and documented. Only documented commands functions are allowed to shall be activated through the software interface.

Commented [ME129]: Changed for consistency with the definition.

Commented [ME130]: Changed for consistency with other clauses. Functions are triggered via interfaces by means of commands.

Commented [ME131]: Modified to use valid normative language.

Examples:

(I) In the example described in 5.2.1.2.a the software interface consists of the procedures in the library and their parameters and return values. The interface cannot be circumvented e.g. by pointers to internal data. The number and kind of procedures, parameters, and return values is fixed at compile time.

(II) Legally relevant and legally non-relevant software parts run in separate virtual machines on a universal computer device. Both machines are configured in such a way, that any communication between both software parts can only be done via the defined software interface. The setup of the virtual machines, including the method of communication between both, is part of the legally relevant software. The operating system ensures that the configuration cannot be modified without breaking a seal.

Commented [ME132]: Changed for consistency with definition.

Commented [ME133]: Related to FR-01, CZ-05

5.2.1.2.d Where the legally relevant software part has been separated from the non-relevant software part, the legally relevant software part shall have priority using the resources over non-relevant software. The legally relevant process should shall not be inadmissibly interrupted by legally non-relevant software. The measurement process (realized by the legally relevant software part) shall must not be delayed or blocked by other processes.

Commented [ME134]: Changed for consistency with definition.

Commented [ME135]: Related to DE-03

Commented [ME136]: Related to CA-13, AT-03

Commented [ME137]: Related to NL-11

Examples:

(I) In the example 5.2.1.2.a/c the legally non-relevant application controls the start of the legally relevant procedures in the library. Omitting a call of these procedures would of course inhibit the legally relevant function of the system. Therefore, the following provisions have been made in the example system to fulfill the requirement 5.2.1.2.d: The digital sensors send the measurement data in encrypted form. The key for decryption is hidden in the library. Only the procedures in the library know the key and are able to read, decrypt, and display measurement values.

(I) A priority level is assigned to the legally relevant function which is higher than for normal processes

Commented [ME138]: Related to CA-13

and which cannot be decreased by a user/operator of the measuring instrument.

Commented [ME139]: Related to NL-13

- (2) (I) The software of an electronic electricity meter reads raw measurement values from an analog-digital converter (ADC). For the correct calculation of the measurement values the delay between the “data ready” event from the ADC to finishing buffering of the measurement values is crucial. The raw values are read by an interrupt routine initiated by the “data ready” signal. The instrument is able to communicate via an interface with other electronic devices in parallel served by another interrupt routine (legally non-relevant communication). The priority of the interrupt routine for processing the measurement values is higher than that of the communication routine.

(II) Legally relevant and legally non-relevant software parts run in separate virtual machines on a universal computer device. The configuration of the operating system ensures, that the virtual machine, on which the legally relevant software part runs, has always sufficient system resources available for the legally relevant processes.

Commented [ME140]: Changed for consistency with definition

Commented [ME141]: Related to FR-01, CZ-05

Examples from 5.2.1.2.a, 5.2.1.2.b, 5.2.1.2.c (1) and 5.2.1.2.d (1)(4)/(2)(1) are acceptable as a technical solution only for a normal risk level (I). If increased protection against fraud or increased conformity is necessary (see 8), software separation alone is not sufficient and additional means are demanded or the whole software should be considered as under legal control.

Commented [ME142]: Related to CA-14, JP-10

#### 5.2.2 Shared indications

A display or printout may be employed for presenting both information from the legally relevant software part and other information. The contents and layout are specific for the kind of instrument and area of application and ~~have to shall~~ be defined in the relevant Recommendation. If a display or printout is used both for legally relevant and legally non-relevant outputs, the legally relevant information should always be readable, and clearly distinguishable from other information.

Commented [ME143]: Changed to use valid normative language.

#### Example:

(I) In the measuring instrument described in the examples 5.2.1.2.a to 5.2.1.2.d, the measurement values are displayed in a separate software window. The means described in 5.2.1.2.d guarantee that only the legally relevant software part can read and display the measurement values. The instrument has an operating system with a multiple windows user interface. The window displaying the legally relevant data is generated and controlled by procedures in the legally relevant dynamically linkable library (see 5.2.1.2). During measurement, these procedures check cyclically that the relevant window is still on top of all the other open windows; if not, the procedures put it on top.

Commented [ME144]: Changed for consistency with definition

(II) In the measuring instrument described in the examples 5.2.1.2.a to 5.2.1.2.d the measurement application runs in kiosk mode. The entire display is controlled by the legally relevant software part. Legally non-relevant data is presented in a special part of the display marked as legally non-relevant.

Commented [ME145]: Changed for consistency with definition

If increased protection against fraud is necessary (II), a printout as an indication alone may not be suitable and additional precautions in the form of hardware and/or software shall be considered. There should exist a component with increased securing means that is able to display the measurement values.

Commented [ME146]: Related to AU-04, DE-04

~~The use of a universal computer is not appropriate as part of a measuring instrument if increased protection against fraud is necessary (II). Additional precautions to prevent or minimize the risk of fraud, in the form of hardware and software, should be considered when increased protection is necessary, such as when using a universal computer (for example PC, PDA, etc.).~~

Commented [ME147]: Related to AU-04, DE-04

#### 5.2.3 Storage of data



~~If measurement values are stored before they are used for legal purposes the following requirements apply. If measurement values are stored for legal purposes the following requirements apply:~~

~~PGs may decide upon appropriate storage conditions for different applications.~~

Commented [ME148]: Related to AU-05.

5.2.3.1 The measurement value stored shall be accompanied by all relevant information necessary for future legally relevant use.

Example:

(I)/(II) A dataset includes the following entries:

- measurement value including unit;
- time stamp of measurement (see 5.2.3.4);
- place of measurement or identification of the measuring instrument that was used for the measurement;
- unambiguous identification of the measurement, e.g. consecutive numbers enabling assignment to values printed on an invoice.

5.2.3.2 The stored data shall be protected by software means to guarantee the authenticity, integrity and, if necessary, correctness of the information concerning the time of measurement. The software that displays or further processes the measurement values and accompanying data shall check the time of measurement, authenticity, and integrity of the data after having read them from the storage. If an irregularity is detected, the data shall be discarded or marked unusable.

Software modules that prepare data for storing, or that check data after reading are considered part of the legally relevant software.

Note: It is appropriate to require a raised risk level when considering a freely accessible storage.

Raised risk levels might require the application of cryptographic methods. ~~If appropriate, means shall be provided whereby cryptographic keys can only be input or read if a seal is broken. Example (I) applies to local storage and Example (II) applies to freely accessible storage and transmission of data over open networks.~~

Commented [ME149]: Related to DE-05

Commented [ME150]: Changed to avoid mentioning "transmission" in storage requirements.

Commented [ME151]: Related to O3 (CA-02)

Examples:

(I) The program of the storing device calculates a CRC32 checksum of the dataset and appends it to the dataset. It uses a secret initial value for this calculation instead of the value given in the standard. This initial value is employed as a key and stored as a constant in the program code. The reading program also has stored this initial value in its program code. Before using the dataset, the reading program calculates the checksum and compares it with that stored in the dataset. If both values match, the dataset is not falsified. Otherwise, the program assumes falsification and discards the dataset.

(II) The storing program ~~that is part of the legally relevant software~~ generates an electronic signature for the stored dataset. It is appended to the stored dataset. The private and public key used for signing are generated in a hardware security module which protects the private key against manipulation or reading and exports the public key. The reading program ~~validates~~ verifies the signature with the public key to check authenticity and integrity of the dataset. To prove the origin of the dataset the reading program ~~must needs to~~ know whether the public key really belongs to the storing program. Therefore, the public key is presented on the display of the measuring instrument and can be registered once, e.g. together with the serial number of the instrument when it is ~~legally~~ verified in the field.

Commented [ME152]: Changed for consistency with definition

Commented [ME153]: Related to DE-07, AU-13, AU-19

Commented [ME154]: Changed to avoid using normative language in examples.

Commented [ME155]: Deleted for consistency

5.2.3.3 Automatic storing

5.2.3.3.a When, considering the application, data storage is required, measurement data ~~must shall~~ be

Commented [ME156]: Related to NL-14



stored automatically when the measurement is concluded, i.e. when the final value used for the legal purpose has been generated.

The storage device must shall have sufficient permanency to ensure that the data are not corrupted under normal storage conditions. There shall be sufficient memory storage for any particular the intended application.

When the final value used for the legal purpose results from a calculation, all data that are necessary for the calculation must shall be automatically stored with the final value.

*Note 1:* In case of cumulative measurements it may happen that the same data domain (program variable) is used repeatedly. In that case, storage capacity may not be legally relevant. Questions of storage capacity may not play a role then.

*Note 2:* Stored data does not need to be physically localized in one storage unit, as long as all requirements are met.

5.2.3.3.b Stored data may be deleted if either:

- the transaction is settled;
- these data are printed by a printing device subject to legal control.

*Note:* Other general national regulations (e.g. for tax purposes) may contain strict limitations for the deletion of stored measurement data. PGs may define alternative conditions for data deletion.

Commented [ME157]: Related to NL-14

Commented [ME158]: Related to US-comments submitted at the Dordrecht meeting

Commented [ME159]: Related to NL-14

Commented [ME160]: Related to JP-11

Commented [SR,M161]: Related to CA-03

Commented [SR,M162]: Related to AU-06, CA-03

#### 5.2.3.4 Time stamp

The time stamp is a date/time information in a consistent format, allowing for easy comparison of two different records and tracking progress over time.

The time stamp shall be read from the clock of the instrument. Depending on the kind of instrument, or area of application, setting the clock may be legally relevant and appropriate protection means shall be taken according to the risk level to be applied (see 5.1.3.2.e).

The internal clock of a stand-alone measuring instrument tends to have a large uncertainty because there is no means to synchronize it with the global clock. But if the information concerning the time of measurement is necessary for a specific field of application, the reliability of the internal clock of the measuring instrument shall be enhanced by specific means.

#### Example:

(II) The reliability of the internal quartz-controlled clock device of the measuring instrument is enhanced by redundancy: A timer is incremented by the clock of the microcontroller that is derived from another quartz crystal. When the timer value reaches a preset value, e.g. 1 second, a specific flag of the microcontroller is set and an interrupt routine of the program increments a second counter. At the end of e.g. one day the software reads the quartz-controlled clock device and calculates the difference in the seconds counted by the software. If the difference is within predefined limits, the software counter is reset and the procedure repeats; but if the difference exceeds the limits, the software initiates an appropriate error reaction.

Commented [ME163]: Moved to 5.1.5. Related to CA-06, JP-13, UK-07, NL-15

#### 5.2.4 Transmission via communication lines

If measurement values are transmitted before they are used for legal purposes the following requirements apply:

5.2.4.1 The measurement value transmitted shall be accompanied by all relevant information necessary for future legally relevant use.

Example:

(I)/(II) A dataset includes the following entries:

- measurement value including unit;
- time stamp of measurement (see 5.2.4.5.1.5);
- place of measurement or identification of the measuring instrument that was used for the measurement;
- unambiguous identification of the measurement, e.g. consecutive numbers enabling assignment to values printed on an invoice.

Commented [FGT164]: Previously known as 5.2.4.5 (Time Stamp)

5.2.4.2 The transmitted data shall be protected by software means to guarantee the authenticity, integrity and, if necessary correctness of the information concerning the time of measurement. The software that displays or further processes the measurement values and accompanying data shall check the time of measurement, authenticity, and integrity of the data received from a transmission channel. If an irregularity is detected, the data shall be discarded or marked unusable.

Software modules that prepare data for sending, or that check data after receiving, are considered part of the legally relevant software.

Note: It is appropriate to require a raised risk level when considering an open network.

Raised risk levels might require application of cryptographic methods. Means shall be provided whereby these keys can only be input or read if a seal is broken.

Example:

(I) The ~~program~~ legally relevant software part of the sending device calculates a CRC32 checksum of the dataset. ~~(algorithm such as BCC, CRC16, CRC32, etc.) and appends it~~ It is appended to the dataset. It uses a secret initial value for this calculation instead of the value given in the standard. This initial value is employed as a key and stored as a constant in the program code. The ~~receiving~~ program that is part of the legally relevant software of the receiving device also has stored this initial value in its program code. Before using the dataset, the ~~receiving~~ program calculates the checksum and compares it with that stored in the dataset. If both values match, the dataset is not falsified. Otherwise, the program assumes falsification and discards the dataset.

Commented [ME165]: For consistency with definition. A program may be part of the legally relevant software.

Commented [ME166]: Related to CA-12, FR-03

Commented [ME167]: Changed for clarity

(II) ~~The transmitting program~~ The legally relevant software part of the sending device generates an electronic signature for the transmitted dataset. It is appended to the transmitted dataset. The private and public key used for signing are ~~is~~ generated in a hardware security module which protects the private key against manipulation or reading and exports the public key. ~~The receiving~~ program that is part of the legally relevant software of the receiving device verifies the signature with the public key to check authenticity and integrity of the dataset. To prove the origin of the dataset the receiving program ~~must needs to~~ know whether the public key really belongs to the transmitting program. Therefore, the public key is presented on the display of the measuring instrument and can be registered once, e.g. together with the serial number of the instrument when it is verified in the field.

Commented [ME168]: Changed for clarity

Commented [ME169]: Changed for clarity

Commented [ME170]: Related to DE-07, AU-13, AU-19

Commented [ME171]: Changed to avoid normative language in examples.

Commented [ME172]: Changed for consistency

Example:

(II) The transmitting program generates an electronic signature for the transmitted dataset. It is

appended to the transmitted dataset. The private and public key used for signing are generated in a hardware security module which protects the private key against manipulation or reading and exports the public key. The receiving program ~~validates~~<sup>verifies</sup> the signature with the public key to check authenticity and integrity of the dataset. To prove the origin of the dataset the receiving program must know whether the public key really belongs to the transmitting program. Therefore, the public key is presented on the display of the measuring instrument and can be registered once, e.g. together with the serial number of the instrument when it is ~~legally~~ verified in the field.

Commented [ME173]: Related to DE-07, AU-13, AU-19

Commented [ME174]: Changed for consistency

#### 5.2.4.3 Transmission delay

The measurement shall not be inadmissibly influenced by a transmission delay.

#### 5.2.4.4 Transmission interruption

If network services become unavailable, no measurement data shall be lost. The measurement process should be stopped to avoid the loss of measurement data.

*Notes:* Consideration should be given to distinguish between static and dynamic measurements.

Depending on the area of application, and for cases where measurements are easily repeatable, a loss of transmitted data may be acceptable.

#### Example:

(I)/(II) The sending instrument/component waits until the receiver has sent an affirmation of correct receipt of the dataset. The sending instrument/component keeps the dataset in a buffer until this affirmation has been received. The buffer ~~may have~~<sup>has</sup> a capacity for more than one dataset, organized as a FIFO (First-in-first-out) queue.

Commented [ME175]: Changed to make the example as precise as possible.

#### 5.2.4.5 Time stamp

The time stamp is a date/time information in a consistent format, allowing for easy comparison of two different records and tracking progress over time.

The time stamp shall be read from the clock of the instrument. Depending on the kind of instrument, or area of application, setting the clock may be legally relevant and appropriate protection means shall be taken according to the risk level to be applied (see 5.1.3.2.e).

The internal clock of a stand alone measuring instrument tends to have a large uncertainty because there is no means to synchronize it with the global clock. But if the information concerning the time of measurement is necessary for a specific field of application, the reliability of the internal clock of the measuring instrument shall be enhanced by specific means.

#### Example:

(II) The reliability of the internal quartz controlled clock device of the measuring instrument is enhanced by redundancy: A timer is incremented by the clock of the microcontroller that is derived from another quartz crystal. When the timer value reaches a preset value, e.g. 1 second, a specific flag of the microcontroller is set and an interrupt routine of the program increments a second counter. At the end of e.g. one day the software reads the quartz controlled clock device and calculates the difference in the seconds counted by the software. If the difference is within predefined limits, the software counter is reset and the procedure repeats; but if the difference exceeds the limits, the software initiates an appropriate error reaction.

Commented [ME176]: Moved to 5.1.5. Related to CA-06, UK-07, NL-15, JP-13

## 5.2.5 Compatibility of operating systems and hardware

5.2.5.1 If an operating system is part of the measuring instrument, requirements according to clauses 5.2.5.2 to 5.2.5.7 shall be met.

**Commented [ME177]:** Clauses 5.2.5.1-5.2.5.7 were modified to reflect SG2 results.

Each of the following operating system requirements shall be met by measures on application level, operating system level or a combination of both. For example, the protective interface may be implemented within the legally relevant application, the operating system, the physical layer etc.

5.2.5.2 Hardware interfaces not equipped with a protective software interface shall not be able to inadmissibly influence the legally relevant software part (e.g. physical seal).

**Commented [ME178]:** Changed for consistency with definition.

### Examples:

(I) The legally relevant application routinely checks all open physical interfaces for incoming traffic. In the case of unauthorized input, it inhibits measurements.

(II) All open interfaces are physically protected or disabled by the operating system.

5.2.5.3 If a secure boot process is needed to ensure protection of the legally relevant software part, the following requirements apply.

**Commented [ME179]:** Changed for consistency with definition

5.2.5.3.a In order to ensure integrity and authenticity of the legally relevant software part, a chain of trust shall be established over the individual components of the boot process.

**Commented [ME180]:** Changed for consistency with definition

5.2.5.3.b The processing of the chain of trust can be interrupted, as long as its integrity is preserved.

5.2.5.3.c The boot configuration shall be protected against unauthorized modifications.

5.2.5.3.d Booting via open interfaces shall be protected.

### Examples:

(I) The boot loader is protected by security means, e.g. a secure password.

(II) A TPM (trusted platform module) verifies the signature of the boot loader, the boot loader then verifies the operating system, which in turn verifies and starts the legally relevant application.

5.2.5.4 The combination of legally relevant software part and operating system shall ensure that there are enough resources for the operation of the legally relevant application.

**Commented [ME181]:** Changed for consistency with definition

### Examples:

(I) The legally relevant application ensures that it has all resources it requires.

(II) The smallest number of operating system components required to ensure the measuring operation is selected.

5.2.5.5 Protection during use5.2.5.5.a The operation of software that is not legally relevant shall not inadmissibly influence the legally relevant application.5.2.5.5.b The combination of legally relevant software part and operating system shall ensure that the legally relevant display is distinguishable.**Commented [ME182]:** Changed to "part" for consistency with definition5.2.5.5.c The access control shall be configured in such way that the intended use cannot be inadmissibly influenced.5.2.5.5.d The administration tasks of the legally relevant software part shall be protected.**Commented [ME183]:** Changed to "part" for consistency with definitionExample:(I) All legally relevant files are write protected and the access permissions are routinely checked by the legally relevant software part.**Commented [ME184]:** Changed to "part" for consistency with definition(II) The legally non-relevant software runs in a virtually separated environment.5.2.5.6 Communication with the legally relevant software part shall be made via protective interfaces.**Commented [ME185]:** Changed to "part" for consistency with definitionExample:(I) A legally relevant software module interprets all commands reaching the legally relevant software part and discards the inadmissible ones.**Commented [ME186]:** Changed to "part" for consistency with definition(II) The communication via open software interfaces is protected by means of the operating system.5.2.5.7 Testability and traceability5.2.5.7.a The configuration of the operating system shall be identifiable.Example:**Commented [HS187]:** Related to JP-14, CZ-08, CA-05(1) On a UNIX-type operating system, the configuration consists of legally relevant:

- kernel modules
- list of installed packages
- libraries
- accounts and user privileges
- passwords
- configuration files
- file read/write/execute permissions

All of the above is identified by means of a checksum.2) On a WINDOWS operating system, the configuration consists of legally relevant:

- kernel modules

- list of installed packages
  - libraries
  - accounts and user privileges
  - passwords
  - configuration files
  - file read/write permissions
  - registry keys
- Each of the above is identified by means of a checksum.

5.2.5.7.b If changes to the configuration of the operating system are possible, they shall be traceable.

~~5.2.5.1 If an operating system is part of the measuring instrument, requirements according to this clause shall be met.~~

~~5.2.5.1.a The manufacturer shall state the legally relevant components of the operating system (e.g. libraries, drivers used in the measurement process, access management, security measures for interfaces). The protective features of software might rely on components of the operating system.~~

~~5.2.5.1.b The configuration of the operating system shall be identifiable.~~

~~Note 1: The access control might need to be configured in such way that the intended use of the measuring instrument cannot be inadmissibly influenced.~~

~~Note 2: Control of the data flow by the protection of interfaces (e.g. firewall configuration) shall be one of the main tasks in the configuration of a standard operating system.~~

~~5.2.5.1.c Changes to the configuration of the operating system shall be traceable.~~

Commented [ME188]: Related to NL-19

5.2.5.8<sup>2</sup> The manufacturer shall identify the hardware and software environment that is suitable. Minimum resources and a suitable configuration (e.g. processor, memory, specific communication, version of operating system, etc.) necessary for correct functioning shall be declared by the manufacturer and stated in the type evaluation certificate.

Commented [ME190]: Related to NL-20

5.2.5.3<sup>9</sup> Technical means shall be provided in the legally relevant software to prevent operation, if the minimal configuration requirements are not met. The system shall be operated only in the environment specified by the manufacturer for its correct functioning.

~~For example, in case an invariant environment is specified for the correct functioning of the system, means shall be provided to keep the operating environment fixed. This especially applies to a universal computer performing legally relevant functions.~~

Fixing the hardware, operating system, or system configuration of a universal computer device or even excluding the usage of an off-the-shelf universal device/computer ~~has to~~ shall be considered in the following cases:

- if high conformity is required;
- if cryptographic algorithms or keys ~~have~~ need to be implemented (see 5.2.3 and 5.2.4).

Commented [ME191]: Related to US-comments submitted at the Dordrecht meeting (due to results of SG2)

Commented [ME192]: Related to FR-01 changed for consistency

Commented [ME193]: Related to FR-01 changed for consistency

Commented [ME194]: Changed to use valid normative language

Commented [ME195]: Changed to use valid normative language

5.2.6 Conformity of manufactured devices to the approved type

The manufacturer shall produce devices and legally relevant software that conform to the approved type and the documentation submitted.

## 5.2.7 Maintenance and re-configuration

Updating the legally relevant software part of a measuring instrument in the field should be considered as:

- a modification of the measuring instrument, when exchanging the software with another approved version;
- a repair of the measuring instrument, when re-installing the same version.

A measuring instrument which has been modified or repaired while in service may require initial or subsequent verification, dependent on national regulations.

Software which does not realize legally relevant functions of the measuring instrument does not require verification after being updated.

Commented [ME196]: Changed for consistency with definition

5.2.7.1 Only versions of the legally relevant software part that conform to the approved type are allowed for use (see 5.2.6). They shall be stated in the TECcertificate. Applicability of the following requirements depends on the kind of instrument and is to be worked out in the relevant OIML Recommendation. The following options 5.2.7.2 and 5.2.7.3 are alternatives. In case that device-specific parameters (especially calibration parameters) are concerned only verified update should be done.

This issue concerns verification of a measuring instrument in the field. Refer to Clause 7 for additional constraints.

Commented [ME197]: Changed for consistency with definition

Commented [ME198]: Related to NL-21

Commented [ME199]: Related to UK-08.

Commented [ME200]: For consistency with definition 2.09 in V1

Commented [ME201]: Related CZ-04, DE-08

## 5.2.7.2 Verified Update

The software to be updated can be loaded locally, i.e. directly on the measuring instrument or remotely via a network. Loading and installation may be two different steps (as shown in Fig. 1) or combined into one, depending on the needs of the technical solution. A physical seal needs to be broken for the update to take effect. A person should be on the installation site of the measuring instrument to check the effectiveness of the update. After the update of the legally relevant software part of a measuring instrument (exchange with another approved version or re-installation) the measuring instrument should not be employed for legal purposes before a verification of the measuring instrument as described in Clause 7 has been performed and the securing means have been renewed (if not otherwise stated in the relevant OIML Recommendation or in the TECcertificate).

Commented [ME202]: Related to AU-10

Commented [ME203]: Changed to use valid normative language.

Commented [ME204]: For consistency with definition 2.09 in V1

Commented [ME205]: Related to UK-08.

Commented [ME206]: Related to NL-22

## 5.2.7.3 Traced Update

The software is implemented in the instrument according to the requirements for Traced Update (5.2.7.3.a to 5.2.7.3.h), if it is in compliance with the relevant OIML Recommendation. Traced Update is the procedure of changing software in a verified instrument or component after which the subsequent verification by a responsible person at place is not necessary. This means the traced update shall not affect existing parameters. The software to be updated can be loaded locally, i.e. directly on the measuring instrument or remotely via a network. The software update is recorded in an audit trail (see 3.1.1). The procedure of a Traced Update comprises several steps: loading, integrity checking, checking of the origin (authentication), installation, logging and activation.

Commented [ME207]: Related to UK-08.

Commented [ME208]: Related to AU-10

5.2.7.3.a Traced Update of software shall be automatic. If some of the securing measures of the instrument are turned off to enable updating, they must shall be turned on again immediately after update, independent of the result of the update process.

Commented [ME209]: Changed to use valid normative language

Note: Triggering of the Traced Update process may require intervention/manual actions by the user of the measuring instrument.

Commented [ME210]: Related to CA-07, AU-11

5.2.7.3.b Software shall be protected in such a way that evidence of any intervention shall be available.

During an update, any existing audit trail information ~~and event counter value~~ shall be retained.

Commented [ME211]: Related to NL-23

5.2.7.3.c Technical means shall be employed to guarantee the authenticity of the loaded software, i.e. that it originates from the owner of the ~~type evaluation~~ certificate.

Commented [ME212]: Related to NL-24

Example:

(II) The authenticity check is accomplished by cryptographic means such as a public key system. The owner of the ~~type evaluation~~ certificate (in general the manufacturer of the measuring instrument) generates an electronic signature of the ~~revised~~ software or software part to be updated using the *secret key* in the manufactory. The *public key* is stored in a ~~legally relevant~~ fixed software part of the measuring instrument ~~receiving the signed revised software~~. The signature is checked using the *public key* when loading the ~~revised~~ software into the measuring instrument. If the signature of the loaded software is OK, it is installed and activated; if it fails the check, the ~~fixed loaded revised~~ software is discarded, ~~it~~ and the instrument continues to operate with ~~uses~~ the ~~previous~~ current version of the software or switches to an inoperable mode.

Commented [ME213]: Related to NL-25

Commented [ME214]: Changes adopted related to CA-01, CA-11, CZ-09

Commented [HS215]: Related to CA-01

5.2.7.3.d Technical means shall be employed to ensure the integrity of the loaded software, i.e. that it has not been inadmissibly changed before loading. This can be accomplished by adding a checksum or hash code of the loaded software and verifying it during the loading procedure.

5.2.7.3.e An audit trail shall be employed to ensure that Traced Updates of ~~the~~ legally relevant software ~~part~~ are adequately traceable within the instrument for subsequent verification and surveillance or inspection.

Commented [ME216]: Changed for consistency with definition

The audit trail shall contain at minimum the following information:

- ~~success/failure of the update procedure~~
- ~~software identification of the installed version~~
- ~~software identification of the previous installed version~~
- ~~time stamp of the event~~
- ~~identification of the downloading party if available~~

Commented [ME217]: Formatting modified according to suggestions from AU-12.

An entry is generated for each update attempt regardless of the success.

The storage device that supports the Traced Update shall have a sufficient capacity to ensure the traceability of Traced Updates of ~~legally relevant software part~~ between at least two successive verifications ~~of a measuring instrument~~ in the field/inspections. After having reached the limit of the storage for the audit trail, it shall be ensured by technical means that further downloads are impossible without breaking a seal.

Commented [ME218]: Changed for consistency with definition

Commented [ME219]: For consistency with definition 2.09 in V1

Commented [ME220]: Related to CZ-04, DE-08

Commented [ME221]: Related to NL-26

The audit trail shall be displayed or printed on command. The ~~PEC-certificate~~ shall describe how the audit trail may be displayed or printed.

*Note:* This requirement enables inspection authorities, which are responsible for the metrological surveillance of legally controlled instruments, to back-trace Traced Updates of ~~the~~ legally relevant software ~~part~~ over an adequate period of time (depending on national legislation).

5.2.7.3.f Depending on the needs and on national ~~legal~~ legislation it may be necessary for the user or owner of the measuring instrument ~~to have to~~ give his consent to a traced update. The measuring instrument shall have a feature for the user or owner to express his consent, e.g. a push button, before the update starts. It shall be possible to enable and disable the feature, e.g. by a switch that can be sealed or by a parameter. If the feature is enabled, each traced update ~~has needs to~~ be initiated by the user or owner. If it is disabled, no activity by the user or owner is necessary to perform a traced update.

Commented [ME222]: Related to UK-09

Commented [ME223]: Related to CZ-10

Commented [ME224]: Changed to use valid normative language



~~5.2.7.3.g If the requirements in 5.2.7.3.a through 5.2.7.3.f cannot be fulfilled, it is still possible to update the legally non-relevant software part. In this case the following requirements shall be met:~~

- ~~• there is a distinct separation between the legally relevant and non-relevant software according to 5.2.1;~~
- ~~• the whole legally relevant software part cannot be updated without breaking a seal;~~
- ~~• it is stated in the type evaluation certificate that updating of the legally non-relevant part is acceptable;~~

Commented [ME225]: Related to NL-27

5.2.7.3.g<sup>h</sup> If the loaded software fails integrity test (5.2.7.3.d) or authenticity test (5.2.7.3.c), the instrument shall discard the new version and use the previous version of the software or switch to an inoperable mode. In this mode, the measuring functions shall be inhibited. It shall only be possible to resume the download procedure, or to show an error. If the audit trail has no more capacity (5.2.7.3.e), or the user or owner denies consent (5.2.7.3.f), the update procedure should not start at all.

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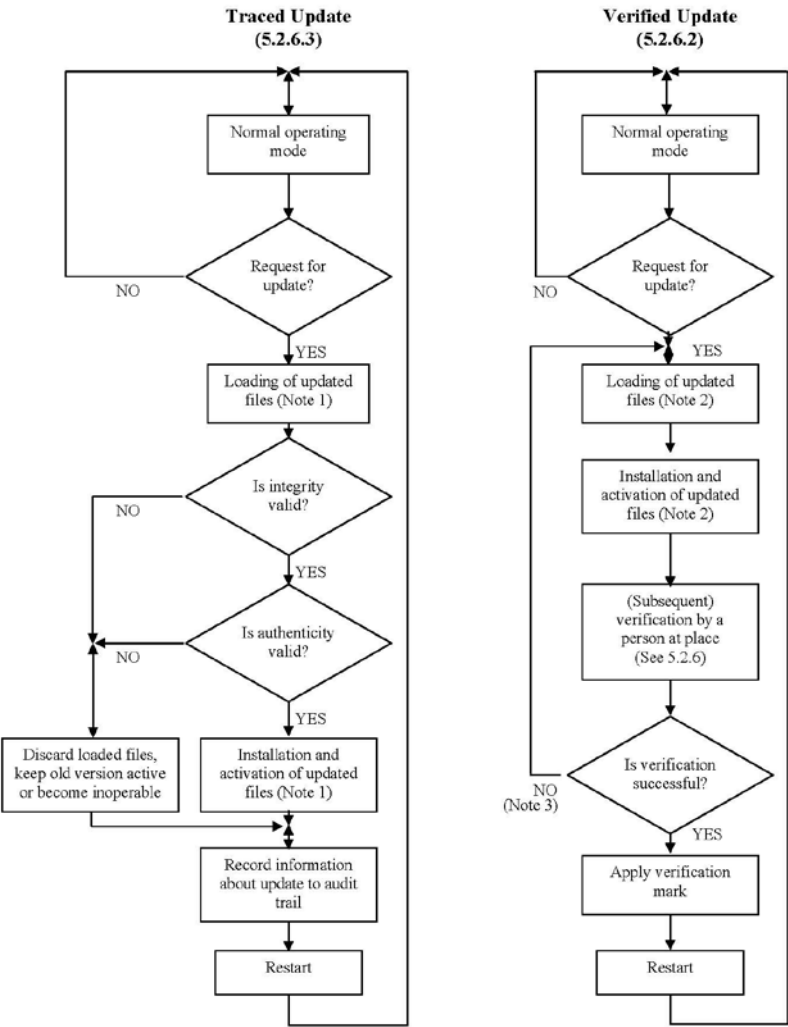


Figure 1 Software update procedure

*Notes:* (1) In the case of a Traced Update, updating is separated into two steps: “loading” and “installing/activating”. This implies that the software is temporarily stored after loading without being activated because it ~~must~~ **shall** be possible to discard the loaded software and revert to the old version, if the checks fail.

**Commented [ME226]:** Changed to use valid normative language

(2) In the case of a Verified Update, the software may also be loaded and temporarily stored before installation but depending on the technical solution loading and installation may also be accomplished in one step.

(3) Here, only failure of the verification ~~of a measuring instrument~~ due to the software update is considered. Failure due to other reasons does not require re-loading and re-installing of the software, symbolized by the NO-branch.

**Commented [ME227]:** For consistency with definition 2.09 in V1

**Commented [ME228]:** Related to CZ-04, DE-08

5.2.7.4 The relevant ~~OIML~~ Recommendation may require the setting of certain device-specific parameters to be available to the user. In such a case, the measuring instrument shall be fitted with a facility to automatically and non-erasably record any adjustment of the device-specific parameter, e.g. an audit trail. The instrument shall be capable of presenting the recorded data.

**Commented [ME229]:** Related to UK-08.

5.2.7.5 The audit trails are part of the legally relevant software ~~part~~ and should be protected as such. They should not be exchanged when the software is updated.

## 6 Type evaluation

### 6.1 Software documentation to be supplied for type evaluation

For type evaluation the manufacturer of the measuring instrument shall declare and document all ~~program~~ functions, relevant data structures and software interfaces of the legally relevant software part that are implemented in the instrument. All commands and their effects shall be described completely in the software documentation to be submitted for type evaluation.

**Commented [ME230]:** Changed for consistency with other clauses

Furthermore, the application for type evaluation shall be accompanied by a document or other evidence that supports the assumption that the design and characteristics of the software of the measuring instrument comply with the requirements of the relevant ~~OIML~~ Recommendation, in which the general requirements of this Document have been incorporated.

**Commented [ME231]:** Related to UK-08.

6.1.1 Typical documentation (for each measuring ~~instrument/-component~~) basically includes:

**Commented [ME232]:** Changed for consistency

- a description of the legally relevant software and how the requirements are met:
  - list of software modules that belong to the legally relevant part;
  - description of the software interfaces of the legally relevant software part and of the commands and data flows via this interface;
  - depending on the ~~validation~~ **evaluation** method chosen in the relevant ~~OIML~~ Recommendation (see 6.3 and 6.4) the source code shall be made available to the type evaluation authority if raised risk level is required by the relevant ~~OIML~~ Recommendation;
  - list of parameters to be protected and description of protection means;
- a description of suitable system configuration and minimal required resources (see 5.2.5);
- a description of security means of the operating system (password, etc. if applicable);

**Commented [ME233]:** Related to DE-07

**Commented [ME234]:** Related to UK-08.

**Commented [ME235]:** Related to UK-08.

- a description of the (software) sealing method(s);
- an overview of the system hardware, e.g. topology block diagram, type of computer(s), type of network, etc. Where a hardware component is deemed legally relevant or where it performs legally relevant functions, this should also be identified;
- a description of the accuracy of the algorithms (e.g. filtering of A/D conversion results, price calculation, rounding algorithms, etc.);
- a description of the user interface, menus and dialogues;
- the software identification and instructions for obtaining it from an instrument in use;
- list of commands of each hardware interface of the measuring instrument/-component;
- list of durability errors that are detected by the software and if necessary for understanding, a description of the detecting algorithms;
- a description of datasets stored or transmitted;
- if ~~fault~~ detection of significant defects is realized in the software, a list of ~~faults~~ significant defects that are detected and a description of the detecting algorithm;
- if an audit trail is realized in the software, a description on how to access the audit trail;
- the operating manual.

Commented [ME236]: Related to DE-11

## 6.2 Requirements on the evaluation procedure

Test procedures in the framework of the type evaluation are based on well-defined test setups and test conditions and can rely on precise comparative measurements. ~~“Testing” and “validating” software are different activities.~~ The accuracy or correctness of software in general cannot be measured in a metrological sense, though there are standards that prescribe how to “measure” software quality [e.g. [ISO/IEC 25040:2011 series](#) ~~5~~ [ISO/IEC 14598](#)]. The procedures described here take into consideration both the legal metrology needs and also well-known ~~validation and test~~ evaluation and verification methods in software engineering but which do not have the same goals (e.g. a software developer who searches for errors but who also optimizes performance). As shown in 6.4 each software requirement needs individual adaptation of suitable ~~validation-evaluation~~ procedures. The effort for the procedure should reflect the risk level.

Commented [ME237]: No longer needed because of changes done related to DE-07, AU-13, AU-19

Commented [ME238]: Related to US-comments submitted at the Dordrecht meeting

Commented [ME239]: Related to DE-07, AU-13, AU-19

Commented [ME240]: Related to DE-07

The aim is to ~~validate-verify~~ the fact that the instrument to be approved complies with the requirements of the relevant ~~OIML~~ Recommendation. For software-controlled instruments the ~~validation-evaluation~~ procedure comprises examinations, analysis, and tests and the relevant ~~OIML~~ Recommendation shall include an appropriate selection of methods described below.

Commented [ME241]: Related to DE-07, AU-13, AU-19

Commented [ME242]: Related to UK-08.

Commented [ME243]: Related to DE-07

Commented [ME244]: Related to UK-08.

The methods described below focus on the type ~~examination-evaluation~~ Verifications of every single instrument in use in the field are not covered by those ~~validation-evaluation~~ methods. Refer to Clause 7 Verification of a measuring instrument for more information.

Commented [ME245]: Related to DE-07, AU-13, AU-19

Commented [ME246]: Related to DE-07

The methods specified for ~~software evaluation-validation~~ are described in 6.3. Combinations of these methods forming a complete ~~validation-software evaluation~~ procedure adapted to all requirements defined in Clause 5 are specified in 6.4.

Commented [ME247]: Related to DE-07

Commented [ME248]: Related to DE-07, AU-13, AU-19 and for consistency within the clause

The manufacturer shall attest that no hidden or undocumented properties exist. (e.g. parameters, commands, functions, backdoors.)

~~This document does not ask manufacturers for extra declarations that documentation is correct and complete. However, any country may require this declaration, as a part of the specified software examination process.~~

Commented [ME249]: Changed for consistency

Commented [SR,M250]: Related to JP-01

### 6.2.1 Information to be included in the ~~PEC~~ certificate

Commented [ME251]: Related to NL-24 and NL-28

- The software identification of all approved versions.
- The method to display the current software identification on the approved instrument in use.

- The securing means and the method to check them (e.g. hardware seals, event counters, audit trails.)

### 6.3 Validation-Verification and evaluation methods (software examination)

#### 6.3.1 Overview of methods and their application

The selection and sequence of the following methods are not prescribed and may vary in a validation-software evaluation procedure from case to case.

This is a rough overview. For more details, see 6.3.2.

Abbreviation	Description	Application	Preconditions, tools for application	Special skills for performing
AD	Analysis of the documentation and validation-evaluation of the design (6.3.2.1)	Always	Documentation	-
VFTM	Validation-Verification by functional testing of metrological functions (6.3.2.2)	Correctness of the algorithms, uncertainty, compensating and correcting algorithms, rules for price calculation	Documentation, specimen	-
VFTSw	Validation-Verification by functional testing of software functions (6.3.2.3)	Correct functioning of communication, indication, evidence of intervention, fraud protection, protection against operating errors, protection of parameters, fault-detection of significant defects	Documentation, specimen	-
DFA	Metrological data flow analysis (6.3.2.4)	Software separation, evaluation of the impact of commands on the instrument's functions	Source code, tools for analyzing source code	Knowledge of programming languages
CIWT	Code inspection and walkthrough (6.3.2.5)	All purposes	Source code, tools for analyzing source code	Knowledge of programming languages
SMT	Software module testing (6.3.2.6)	All purposes when input and output can clearly be defined	Source code, testing environment	Knowledge of programming languages

Table 1: Overview of the proposed selected validation-verification and evaluation methods

**Commented [ME252]:** Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

**Commented [ME253]:** Related to DE-07, AU-13, AU-19

**Commented [ME254]:** Related to DE-07, AU-13, AU-19

**Commented [ME255]:** Related to DE-07, AU-13, AU-19

**Commented [ME256]:** Related to DE-07, AU-13, AU-19

**Commented [ME257]:** Related to US-comments submitted at the Dordrecht meeting

**Commented [ME258]:** Related to DE-11

**Commented [ME259]:** Related to DE-07, AU-13, AU-19

6.3.2 Description of selected ~~validation-verification and evaluation~~ methods

**Commented [ME260]:** Related to DE-07, AU-13, AU-19

6.3.2.1 Analysis of Documentation and Specification and ~~Validation-Evaluation~~ of the Design (AD)

**Commented [ME261]:** Related to DE-07, AU-13, AU-19

Application:

Basic procedure for software ~~validationevaluation~~.

**Commented [ME262]:** Related to DE-07, AU-13, AU-19

Preconditions:

The procedure is based on the manufacturer's documentation of the measuring instrument. Depending on the demands this documentation shall have adequate scope:

- (1) Specification of the externally accessible functions of the instrument in a general form (Suitable for simple instruments with no interfaces except a display, all features verifiable by functional testing, low risk of fraud);
- (2) Specification of software functions and interfaces (necessary for instruments with interfaces and for instrument functions that cannot be functionally tested and in case of increased risk of fraud). The description shall make evident and explain all software functions that may have an impact on metrological features;
- (3) Concerning interfaces, the documentation shall include a complete list of commands or signals that the software is able to interpret. The effect of each command shall be documented in detail. The way in which the instrument reacts on undocumented commands shall be described;
- (4) Additional documentation of the software for complex measuring algorithms, cryptographic functions, or crucial timing constraints shall be provided, if necessary for understanding and evaluating the software functions;

A general precondition for examination is the completeness of the documentation and the clear identification of the EUT, i.e. of the software packages that contribute to the metrological functions (see 6.1.1).

Description:

The examiner evaluates the functions and features of the measuring instrument using the documentation and decides whether they comply with the requirements of the relevant ~~OIML~~ Recommendation. Metrological requirements as well as software-functional requirements defined in Clause 5 (e.g. ~~fraud protectionevidence of intervention~~, protection of adjustment parameters, disallowed functions, communication with other devices, update of software, ~~fault-detection of significant defects~~, etc.) shall be considered and evaluated. This task may be supported by the Software Evaluation Report Format (see Annex B ~~Checklist~~).

**Commented [ME263]:** Related to UK-08.

**Commented [ME264]:** Related to US-comments submitted at the Dordrecht meeting

**Commented [ME265]:** Related to DE-11

Result:

The procedure gives a result for all characteristics of the measuring instrument, provided that the appropriate documentation has been submitted by the manufacturer. The result should be documented in a clause related to software in a Software Evaluation Report (see Annex B) included in the Evaluation Report Format of the relevant ~~OIML~~ Recommendation.

**Commented [ME266]:** Related to UK-08.

Complementary procedures:

Additional procedures should be applied, if examining the documentation cannot provide substantiated ~~validation-evaluation~~ results. In most cases "~~Validating-Verifying~~ the metrological functions by functional testing" (see 6.3.2.2) is a complementary procedure.

**Commented [ME267]:** Related to DE-07, AU-13, AU-19

**Commented [ME268]:** Changed for consistency with other clauses

## References:

IEC 61508-5:2010 [94][7].5

Commented [ME269]: Related to IR-03

6.3.2.2 Validation-Verification by Functional Testing of the Metrological Functions (VFTM)

Commented [ME270]: Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

## Application:

For validating-verifying correctness of algorithms for calculating the measurement value from raw data, for linearization of a characteristic, compensation of environmental influences, rounding in price calculation, etc.

Commented [ME271]: Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

## Preconditions:

Operating manual, functioning specimen, metrological references, test equipment, test cases, instructions for test equipment.

When it is not clear how to validate-verify a function of a software part/program the onus to develop a test method should be placed on the manufacturer. In addition, the services of the programmer should be made available to the examiner for the purposes of answering questions.

Commented [ME272]: Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

Commented [ME273]: Changed for consistency with other clauses

## Description:

Most of the evaluation and test-verification methods described in OIML Recommendations are based on reference measurements under various conditions. Their application is not restricted to a certain technology of the instrument. Although it does not aim primarily at validating-verifying the software, the test result can be interpreted as a validation-verification of some software parts, in general even the metrologically most important. If the tests described in the relevant OIML Recommendation cover all the metrologically relevant features of the instrument, the corresponding software parts can be regarded as being validated-verified. In general, no additional software analysis or test has needs to be applied to validate-verify the metrological features of the measuring instrument.

Commented [ME274]: Related to DE-07, AU-13, AU-19 and for consistency with clauses 6.2, 7.1

Commented [ME275]: Related to UK-08.

Commented [ME276]: Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

Commented [ME277]: Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

Commented [ME278]: Related to UK-08.

Commented [ME279]: Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

Commented [ME280]: Changed to use valid normative language

Commented [ME281]: Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

## Result:

Algorithms are correct or not correct. Measurement values under all conditions are within the maximum permissible error (MPE) or not.

## Complementary procedures:

The method is normally an enhancement of 6.3.2.1. In certain cases, it may be easier or more effective to combine the method with examinations based on the source code (6.3.2.5) or by simulating input signals (6.3.2.6) e.g. for dynamic measurements.

## References:

Various specific OIML Recommendations.

Commented [ME282]: Related to UK-08.

6.3.2.3 Validation-Verification by Functional Testing of the Software Functions (VFTSw)

Commented [ME283]: Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

## Application:

For validation-evaluation of e.g. protection of parameters, indication of a software identification, software supported fault detection of significant defects, configuration of the system (especially of the software environment), etc.

Commented [ME284]: Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

Commented [ME285]: Related to DE-11

## Preconditions:

Operating manual, software documentation, functioning specimen, test equipment, test cases,



instructions for test equipment.

When it is not clear how to ~~validate-verify~~ a function of a software ~~part/program~~, the onus to develop a test method should be placed on the manufacturer. In addition, the services of the programmer should be made available to the examiner for the purposes of answering questions.

**Commented [ME286]:** Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

**Commented [ME287]:** Changed for consistency with other clauses

#### Description:

Required features described in the operating manual, instrument documentation or software documentation are checked practically. If they are software-controlled, they are to be regarded as ~~validated-verified~~ if they function correctly without any further software analysis. Features addressed here are e.g.:

**Commented [ME288]:** Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

- Normal operation of the instrument, if its operation is software-controlled. All switches or keys and described combinations should be employed and the reaction of the instrument evaluated. In graphical user interfaces, all menus and other graphical elements should be activated and checked;
- Effectiveness of parameter protection may be checked by activating the protection means and trying to change a parameter;
- Effectiveness of the protection of stored data may be checked by changing some data in the file and then checking whether this is detected by the ~~software-program~~;
- Indication of the software identification may be ~~validated-verified~~ by practical checking;
- If ~~fault~~-detection ~~of significant defects~~ is software supported, the relevant software parts may be ~~validated-verified~~ by provoking, implementing or simulating a fault and checking the correct reaction of the instrument;
- Protection means can be checked by making unauthorized changes. The software should inhibit these changes or should cease to function.

**Commented [ME289]:** Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

**Commented [ME290]:** Related to DE-11

**Commented [ME291]:** Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

#### Result:

Software-controlled feature under consideration is ~~acceptableOK~~ or not ~~acceptableOK~~.

**Commented [ME292]:** Related to AU-14, UK-10

#### Complementary procedures:

Some features or functions of a software-controlled instrument cannot be practically ~~validated-verified~~ as described. If the instrument has interfaces, it is in general not possible to detect unauthorized commands only by trying commands at random. Besides that, a sender is needed to generate these commands. For the normal ~~validation-examination~~ level method 6.3.2.1 may cover this requirement. For the extended examination level, a software analysis such as 6.3.2.4 or 6.3.2.5 is necessary.

**Commented [ME293]:** Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

**Commented [ME294]:** Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

#### References:

WELMEC Guide 2.3 Section 3 ~~[8+9]~~; WELMEC Guide 7.2 Sections 4.2 and 5.2~~[9+]~~.

**Commented [ME295]:** Related to JP-15

#### 6.3.2.4 Metrological Dataflow Analysis (DFA)

##### Application:

For analysis of the software design concerning the control of the data flow of measurement values through the data domains that are subject to legal control, including the examination of the software separation.

##### Preconditions:

Software documentation, source code, editor, text search program or special tools. Knowledge of programming languages.

**Description:**

It is the aim of this method to find all parts of the software that are involved in the calculation of the measurement value or that may have an impact on it. Starting from the hardware port where measurement raw data from the sensor are available, the subroutine that reads them is searched. This subroutine will store them in a variable after possibly having done some processing. From this variable the intermediate value is read by another subroutine and so forth until the completed measurement value is output to the display. All variables that are used as storage for intermediate measurement values and all subroutines processing and transporting these values can be found in the source code simply by using a text editor and a text search program to find all other occurrences of variable or subroutine name.

Other data flows can be found by this method, e.g. from **software** interfaces to the interpreter of received commands. Furthermore, circumvention of a software interface (see 5.2.1.2) can be detected.

**Commented [ME296]:** Modified for clarity

**Result:**

It can be **validated-verified** whether software separation according to 5.2.1.2 is **acceptableOK** or not **acceptableOK**.

**Commented [ME297]:** Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

It can be **validated-verified** whether the documented list of commands for each interface is complete or not.

**Commented [ME298]:** Related to UK-11, AU-16

**Commented [ME299]:** Related to DE-07, AU-13, AU-19 and for consistency with clause 6.2

**Complementary procedures:**

This method is recommended if software separation is realized and if high conformity or strong protection against manipulation is required. It is an enhancement to 6.3.2.1 through 6.3.2.3 and to 6.3.2.5.

**Reference:**

IEC 61131-3.

**6.3.2.5 Code Inspection and Walk Through (CIWT)****Application:**

Any feature of the software may be **validated-verified** with this method if **enhanced-extended** examination intensity is necessary.

**Commented [HS300]:** Related to DE-07

**Commented [ME301]:** For consistency with clause 6.4

**Preconditions:**

Source code, text editor, tools. Knowledge of programming languages.

**Description:**

The examiner walks through the source code assignment by assignment, evaluating the respective part of the code to determine whether the requirements are fulfilled and whether the **program** functions and features are in compliance with the documentation.

**Commented [ME302]:** Deleted for consistency with other clauses

The examiner may also concentrate on algorithms or functions that he has identified as complex, error-prone, insufficiently documented, etc. and inspect the respective part of the source code by analyzing and checking.

Prior to these examination steps the examiner will have identified the legally relevant software part, e.g. by applying the metrological data flow analysis (see 6.3.2.4). In general code inspection or walk through is limited to this part.

## Result:

Implementation compatible with the software documentation and in compliance with the requirements or not.

## Complementary procedures:

This is an enhanced method, additional to 6.3.2.1 and 6.3.2.4. Normally it is only applied in spot checks.

## Reference:

IEC 61508-5:2010 ~~49~~71.

Commented [ME303]: Related to JP-16, IR-04

## 6.3.2.6 Software Module Testing (SMT)

## Application:

~~This method is only used in if a high conformity and protection against fraud is required exceptional cases. This method~~ It is applied when functions of a ~~program software module~~ cannot be examined exclusively on the basis of written information. It is appropriate and effective in ~~the verification-validation~~ of dynamic measurement algorithms.

Commented [ME304]: Changed for consistency with other clauses

Commented [ME305]: Related to DE-07, AU-13, AU-19

Commented [ME306]: Related to AU-18

## Preconditions:

Source code, development tools, functioning environment of the software module under test, input dataset and corresponding nominal output dataset or tools for automation. Skills in ~~information technology-IT~~, knowledge of programming languages. Co-operation with the programmer of the module under test is advisable.

Commented [ME307]: Changed since "IT" was deleted from abbreviation list.

## Description:

The software module under test is integrated in a test environment, i.e. a specific test program that calls the module under test and provides it with all necessary input data. The test program receives actual output data from the module under test and compares them with the nominal values.

## Result:

Module under test is correct or not.

## Complementary procedures:

This is an enhanced method, additional to 6.3.2.2 or 6.3.2.5. ~~It is only effective in exceptional cases.~~

Commented [ME308]: Related to AU-18

## Reference:

IEC 61508-5:2010 ~~49~~71.

Commented [ME309]: Related to JP-17, IR-04

6.4 ~~Validation-Software evaluation~~ procedure

The ~~validation software evaluation~~ procedure consists of a combination of ~~analysis methods and test evaluation and verification methods~~. The relevant ~~OIML~~ Recommendation may specify details concerning the ~~software evaluation-validation~~ procedure, including:

Commented [ME310]: Related to DE-07, AU-13, AU-19

Commented [ME311]: Related to DE-07, AU-13, AU-19

Commented [ME312]: Related to UK-08.

- (a) which of the ~~validation evaluation and verification~~ methods described in 6.3 shall be carried out for the requirement under consideration;

Commented [ME313]: For consistency with clause 6.3

- (b) how the evaluation of test results shall be performed;

- (c) ~~which result should be included in the software test report, which result should be included in the evaluation report~~ and which ~~result~~ should be integrated in the ~~test~~-certificate (see Annex B).

Commented [ME314]: Related to JP-18 according to B18

In Table 2 two alternative examination levels [Normal \(A\)](#) and [Extended \(B\)](#) for the [validation software evaluation](#) procedures are defined. DFA, CIWT and SMT methods are only suggested for level B. –Level B implies an extended examination compared to A. [The selection of level B shall be justified by the PGs together with evidence of mitigated risk.](#) A selection between A and B [type validation examination levels procedures](#) may be made in the relevant [OIML Recommendation](#) – different or equal for each requirement – in accordance with the expected:

- risk of fraud;
- area of application;
- required conformity to approved type;
- risk of wrong measurement result due to operating errors.

Commented [ME315]: Related to DE-07, AU-13, AU-19

Commented [SR,M316]: Related to AU-20

Commented [ME317]: For consistency

Commented [ME318]: Related to UK-08.

Requirement		Validation procedure Examination level A (normal examination level)	Validation procedure Examination level B (extended examination level)	Comment
5.1.1	Software identification	AD + VFTSw	AD + VFTSw + CIWT	Select "B" if high conformity is required
5.1.2	Correctness of algorithms and functions	AD + VFTM	AD + VFTM + CIWT/SMT	
Software protection				
5.1.3.1	Prevention of misuse	AD + VFTSw	AD + VFTSw	
5.1.3.2	Evidence of intervention/Fraud-protection	AD + VFTSw	AD + VFTSw + DFA/CIWT/SMT	Select "B" in case of high risk of fraud
Support of hardware features				
5.1.4.1	Support of fault-detection of significant defects	AD + VFTSw	AD + VFTSw + CIWT + SMT	Select "B" if high reliability is required
5.1.4.2	Support of durability protection	AD + VFTSw	AD + VFTSw + CIWT + SMT	Select "B" if high reliability is required
5.1.5	Time stamps	AD + VFTSw	AD + VFTSw + SMT	
Specifying and separating relevant parts and specifying interfaces of partsSpecification and separation of legally relevant parts and specification of interfaces				
5.2.1.1	Separation of components	AD	AD + DFA/CIWT	
5.2.1.2	Specification and separation of software parts	AD	AD + DFA/CIWT	
5.2.2	Shared indications	AD + VFTM/ VFTSw	AD + VFTM/ VFTSw + DFA/CIWT	
5.2.3	Storage of data	AD + VFTSw	AD + VFTSw + CIWT/SMT	Select "B" if storage of measurement data in unsecure storages is foreseen
5.2.3.1	The measurement value stored shall be accompanied by all relevant information necessary for future legally relevant use	AD + VFTSw	AD + VFTSw + CIWT/SMT	Select "B" in case of high risk of fraud
5.2.3.2	The stored data shall be protected by software means to guarantee the authenticity, integrity and, if necessary, correctness of the information concerning the time of measurement	AD + VFTSw	AD + VFTSw + SMT	
5.2.3.3	Automatic storing	AD + VFTSw	AD + VFTSw + SMT	
5.2.3.4	Time stamp	AD + VFTSw	AD + VFTSw + SMT	
5.2.4	Transmission via communication lines	AD + VFTSw	AD + VFTSw + CIWT/SMT	Select "B" if transmission of measurement data in open system is foreseen
5.2.4.1	The measurement value transmitted shall be accompanied by all relevant information necessary for future legally relevant use.	AD + VFTSw	AD + VFTSw + CIWT/SMT	Select "B" in case of high risk of fraud
5.2.4.2	The transmitted data shall be protected by software means to guarantee the authenticity, integrity and, if necessary, correctness of the information concerning the time of measurement.	AD + VFTSw	AD + VFTSw + SMT-/	
5.2.4.3	Transmission delay	AD + VFTSw	AD + VFTSw + SMT	Select "B" in case of high risk of fraud, e.g. transmission in open systems

Commented [ME319]: For consistency with clause 6.4

Commented [ME320]: Related to US-comments submitted at the Dordrecht meeting

Commented [ME321]: Related to DE-11

Commented [ME322]: Related to DE-11

Commented [ME323]: Moved from 5.2.4.5 and 5.2.3.4. Related to CA-06, JP-12, UK-07, NL-15, JP-13

Commented [ME324]: For consistency with 5.2.1

Commented [ME325]: Related to DE-13

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Commented [ME326]: Changed for consistency with 5.1.2.1

Commented [ME327]: Changed for consistency with 5.2.3.2

Commented [ME328]: Related to CA-06, JP-12, UK-07, NL-15, JP-13

5.2.4.4	Transmission interruption	AD + VFTSw	AD + VFTSw + SMT	Select "B" in case of high risk of fraud, e.g. transmission in open systems
<del>5.2.4.5</del>	<del>Time stamp</del>	<del>AD + VFTSw</del>	<del>AD + VFTSw + SMT</del>	
5.2.5	Compatibility of operating systems and hardware	AD + VFTSw	AD + VFTSw + SMT	
5.2.5.2	Hardware interfaces not equipped with a protective software interface shall not be able to inadmissibly influence the legally relevant software part.	AD + VFTSw	AD + VFTSw + SMT	
5.2.5.3	If a secure boot process is needed to ensure protection of the legally relevant software part, the following requirements apply.	AD + VFTSw	AD + VFTSw + SMT	
5.2.5.4	The combination of legally relevant software part and operating system shall ensure that there are enough resources for the operation of the legally relevant application.	AD + VFTSw	AD + VFTSw + SMT	
5.2.5.5	Protection during use	AD + VFTSw	AD + VFTM/ VFTSw + DFA	
5.2.5.6	Communication with legally relevant software part shall be made via protective interfaces.	AD + VFTSw	AD + VFTM/ VFTSw + DFA	
5.2.5.7	Testability and traceability	AD + VFTSw	AD + VFTSw + SMT	
5.2.5.8	The manufacturer shall identify the hardware and software environment that is suitable. Minimum resources and a suitable configuration necessary for correct functioning shall be declared by the manufacturer.	AD + VFTSw	AD + VFTSw + SMT	
5.2.5.9	Technical means shall be provided in the legally relevant software to prevent operation, if the minimal configuration requirements are not met.	AD + VFTSw	AD + VFTSw + SMT	
<b>Maintenance and re-configuration</b>				
5.2.7.2	Verified Update	AD	AD	
5.2.7.3	Traced Update	AD + VFTSw	AD + VFTSw + CIWT/SMT	Select "B" in case of high risk of fraud

**Commented [ME329]:** Related to CA-06, JP-12, UK-07, NL-15, JP-13

**Commented [ME330]:** Now dealt with in more detail below.

**Commented [ME331]:** Basic evaluation and verification methods (AD + VFTSw / AD + VFTSw + SMT) chosen as for all other clauses.

**Commented [ME332]:** Copied from evaluation and verification methods for software separation (shared indications) since field of application is similar. CIWT was omitted as source code of the operating system will normally not be available to the examiner.

**Commented [ME333]:** Copied from evaluation and verification methods for software separation (shared indications) since field of application is similar. CIWT was omitted as source code of the operating system will normally not be available to the examiner.

**Commented [ME334]:** Evaluation and verification methods copied from previous general clause 5.2.5.

**Commented [ME335]:** Evaluation and verification methods copied from previous general clause 5.2.5.

Table 2: Recommendations for combinations of [analysis and test](#) [evaluation and verification](#) methods for the various software requirements (acronyms defined in Table 1)

**Commented [ME336]:** Related to DE-07, AU-13, AU-19

## 6.5 Equipment under test (EUT)

Normally, tests are carried out on the complete measuring instrument (functional testing). If the size or configuration of the measuring instrument does not lend itself to testing as a whole unit or if only a separate component or software module of the measuring instrument is concerned, the relevant OIML Recommendation may indicate that the tests, or certain tests, shall be carried out on the components or software modules separately, provided that, in the case of tests with the components or software modules in operation, these are included in a simulated setup, sufficiently representative of its normal operation. The applicant is responsible for the provision of all the required equipment and specimens.

Commented [ME337]: Related to UK-08.

## 7 Verification of a measuring instrument

**7.1** If metrological control of measuring instruments is prescribed in a country, there shall be means to check in the field during operation the identity of the software, the validity of the adjustment and the conformity to the approved type.

Commented [ME338]: For consistency with definition 2.09 in V1

Commented [ME339]: Related to CZ-04

The relevant OIML Recommendation may require carrying out the verification of the software in one or more stages according to the nature of the considered measuring instrument.

Commented [ME340]: Related to UK-08.

The verification of the software shall include:

- an examination of the conformity of the software ~~with~~ to verify that it is the approved version (e.g. check of the software identification, check of securing means);
- an examination ~~of that~~ the configuration ~~is~~ to verify that it is compatible with the declared minimal configuration, if given in the ~~evaluation~~ certificate;
- an examination ~~that of~~ the inputs/outputs of the measuring instrument ~~to verify that they~~ are free of unwanted side effects;
- an examination ~~that of~~ the device specific parameters (especially the adjustment parameters) ~~to verify that they~~ are correctly set.

Commented [ME341]: Changed for correct usage of the term "examination"

Commented [ME342]: Changed for correct usage of the term "examination"

Commented [ME343]: Related to NL-02 and NL-29

Commented [ME344]: Changed for correct usage of the term "examination"

Commented [ME345]: Changed for correct usage of the term "examination"

PGs shall consider the following clause when writing instrument-specific verification procedures. The methods given in clause 7.2 are proposed as the standard procedure.

Commented [ME346]: Sentence and clause 7.2 were added to include SG1 results.

### 7.2 Verification methods, test items

The following methods comprise the verification steps which are needed to check the requirements of clauses 5.1 and 5.2: The following aspects shall be examined by the corresponding instructions listed below.

#### 7.2.1 Documents

The initial step of any software verification consists of checking the EUT for compliance with the certificate and its annexes.

- Check whether the certificate is valid
- Check whether the EUT complies with the pattern as described in the certificate and its annexes.
- Check whether the operating manual is available (if required).

#### 7.2.2 Integrity of the software

- Indirectly: Check whether all seals required in the certificate are set at the right place and are intact.
- Directly: Check the software identifiers as required in the certificate.

Example:

Calculation of a checksum of the program code that is compared with the nominal value.

Commented [ME347]: Format of the example modified for consistency with the rest of the document

### 7.2.3 Parameters

#### 7.2.3.1 Correctness

- Indirect metrological verification of parameters: Perform a measurement and compare the results with a reference.
- Check whether all settable parameters are within the allowed range.

#### 7.2.3.2 Integrity

- Check whether the seals protecting the parameters are intact.
- Check the audit trail or log for entries concerning parameters.

#### 7.2.4 Identity of the software

- Check that the software identifier provided by the EUT is specified as valid for use in the certificate.
- Check the entries of the audit trail.

## 8 Risk assessment

**8.1** This clause is intended as a guide to determine a set of risk levels to be generally applied for tests carried out on ~~electronic software-controlled~~ measuring instruments. It is not intended as a classification with strict limits leading to special requirements, as in the case of an accuracy classification.

Moreover, this guide does not restrict the project groups from providing risk assessments that differ from those resulting from the guidelines set forth in this Document. Different risk levels may be used in accordance with special limits prescribed in the relevant ~~OIML~~ Recommendations.

Commented [ME348]: Related to JP-19

Commented [ME349]: Related to UK-08.

**8.2** When selecting risk levels for a particular category of instruments and area of application (trade, direct selling to the public, health, law enforcement, etc.), the following aspects can be taken into account:

- risk of fraud:
  - the consequence and the social and societal impact of malfunction;
  - the value of the goods to be measured;
  - platform used (~~built-for-purpose~~ or universal ~~computer devices~~);
  - exposure to sources of potential fraud (unattended self-service device).
- required conformity:
  - the practical possibilities for the industry to comply with the prescribed level.
- required reliability:
  - environmental conditions;
  - the consequence and the social and societal impact of errors.
- ~~interest-motivation~~ of the defrauder,
  - ~~simply being able to commit fraud can be a sufficient motivational factor.~~
- the possibility to repeat a measurement or to interrupt it.

Commented [ME350]: Related to FR-01

Commented [ME351]: Related to CECIP comment (at the Dordrecht meeting) and FR-04

~~PGs should consider risk assessment standards when deciding risk levels, e.g. ISO27005.~~

Commented [SR(M352)]: Related to FR-04

Throughout the requirements clauses (see 5) various examples for acceptable technical solutions are given



illustrating the basic level of protection against fraud, conformity, reliability, and type of measurement (marked with (I)). Where suitable, examples with enhanced counter measures are also presented that consider a raised risk level of the aspects described above (marked with (II)).

The ~~validation procedure~~examination level and risk level are linked. A deep analysis of the software shall be performed when a raised risk level is required in order to detect software deficiencies or security weaknesses. On the other hand, mechanical sealing (e.g. sealing of the communication port or the housing) should be considered when choosing the ~~validation procedure~~examination level.

Commented [ME353]: For consistency with clause 6.4

Commented [ME354]: For consistency with clause 6.4

## Annex A

### Bibliography

At the time of publication, the editions indicated were valid. All referred documents are subject to revision, and the users of this Document are encouraged to investigate the possibility of applying the most recent editions of the referred documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

The actual status of the Standards referred to can also be found on the Internet:

IEC Publications: [http://www.iec.ch/searchpub/cur\\_fut.htm](http://www.iec.ch/searchpub/cur_fut.htm)

ISO Publications: <http://www.iso.org>

OIML Publications: <https://www.oiml.org/en/publications/>  
(with free download of PDF files).

In order to avoid any misunderstanding, it is highly recommended that all references to Standards in [OIML International Recommendations](#) and International Documents be followed by the version referred to (generally the year or date).

Commented [ME355]: Related to UK-08

Ref.	Standards and reference documents	Description
[1]	OIML V 2-200:2012 International Vocabulary of Metrology - Basic and General Concepts and Associated Terms (VIM), 3rd Edition	Vocabulary, developed by the Joint Committee for Guides in Metrology (JCGM),
<del>[2]</del>	<del>OIML B 3:2011</del> <del>OIML Basic Certificate System for OIML Type Evaluation of Measuring Instruments</del>	<del>The OIML Certificate System for Measuring Instruments is a system for issuing, registering and using OIML Certificates of Conformity for types of measuring instruments based on the requirements of OIML Recommendations.</del>
<del>[3]</del> 21	OIML D 11:2013 General requirements for measuring instruments – Environmental conditions	Guidance for establishing appropriate metrological performance testing requirements for influence quantities that may affect the measuring instruments covered by OIML Recommendations. (EMC, climatic, mechanical influences)
<del>[4]</del> 31	ISO/IEC 9594-8:2014 Information technology -- Open Systems Interconnection -- The Directory: Part 8: Public- key and attribute certificate frameworks	ISO/IEC 9594-8:2014 specifies frameworks and a number of data objects that can be used to authenticate and secure the communication between two entities, e.g. between two directory service entities or between a web browser and a web server. The data objects can also be used to prove the source and integrity of data structures such as digitally signed documents.

Commented [ME356]: Deleted since it is not referenced anymore.

<del>[5]</del> 41	ISO 2382-9:1995 Information technology -- Vocabulary -- Part 9: Data communication	Intended to facilitate international communication in data communication. Presents terms and definitions of selected concepts relevant to the field of data communication and identifies relationships among the entries.
<del>[6]</del>	<del>IEC 61508-4:2010 Functional safety of electrical/electronic/programmable electronic safety-related systems - Part 4: Definitions and abbreviations</del>	<del>Contains the definitions and explanation of terms that are used in parts 1 to 7 of this Standard. Intended for use by Technical Committees in the preparation of Standards in accordance with the principles contained in IEC Guide 104 and ISO/IEC Guide 51. IEC 61508 is also intended as a stand-alone Standard.</del>
<del>[7]</del> 51	<del>ISO/IEC 25040:2011</del> <del>ISO/IEC 14598</del> series Information technology -- Software product evaluation	The <del>ISO/IEC 25040:2011</del> <del>ISO/IEC 14598</del> series of Standards gives methods for measurement, assessment and evaluation of software product quality. They describe neither methods for evaluating software production processes nor methods for cost prediction (software product quality measurements may, of course, be used for both these purposes).
<del>[8]</del> 61	OIML V 1:2013 International vocabulary of terms in legal metrology (VIML)	The VIML includes only the concepts used in the field of legal metrology. These concepts concern the activities of the legal metrology service, the relevant documents, as well as other problems linked with this activity. Also included in this Vocabulary are certain concepts of a general character which have been drawn from the VIM.
<del>[9]</del> 71	IEC 61508-5:2010 Functional safety of electrical/electronic/programmable electronic safety-related systems - Part 5: Examples of methods for the determination of safety integrity levels	Provides information on the underlying concepts of risk and the relationship of risk to safety integrity (see Annex A); a number of methods that will enable the safety integrity levels for the E/E/PE safety-related systems, other technology safety-related systems and external risk reduction facilities to be determined (see Annexes, B, C, D and E). Intended for use by Technical Committees in the preparation of Standards in accordance with the principles contained in IEC Guide 104 and ISO/IEC Guide 51.
<del>[8]</del> 91	WELMEC Guide 2.3, May 2005 Issue 3 Guide for Examining Software (Weighing Instruments)	
<del>[9]</del> 11	WELMEC Guide 7.2, Issue 2015 Software Guide (Measuring Instruments Directive 2014/32/EU)	This document provides guidance to all those concerned with the application of the Measuring Instruments Directive (European Directive 2014/32/EU; MID), especially for software-equipped measuring instruments. It addresses both manufacturers of measuring instruments and notified bodies which are responsible for conformity assessment of MID instruments. By following the Guide, compliance with the software-related requirements contained in the MID can be assumed.

Commented [ME357]: Deleted since it is not referenced anymore.

Commented [ME358]: Related to US-comments submitted at the Dordrecht meeting

Commented [ME359]: Related to JP-20, IR-05

Commented [ME360]: Related to JP-21, IR-06

Commented [ME361]: Related to JP-22, IR-06

## Annex B

### Example of a software ~~evaluation~~test report (Informative)

Commented [ME362]: Related to NL-30

*Note:* The Technical Committees and Subcommittees developing OIML Recommendations should decide which information shall be included in [Software Test Report](#), [Evaluation Report](#) and OIML Certificate of Conformity. E.g. the name, version and checksum of the executable ~~file code~~ from the following example should be included in the [Test Certificate](#).

Commented [ME363]: For consistency with 6.4 (JP-18)

Commented [ME364]: Related to NL-04, UK-02

Commented [ME365]: Related to NL-30

#### ~~Validation-Evaluation~~ [Software Test report](#) no XYZ122344 of Software of the flow meter Tournesol Metering model TT100

The software of the measuring instrument was ~~validated-verified~~ to show conformance with the requirements of the OIML Recommendation R-xyz.

The ~~validation-evaluation~~ was based on the report OIML International Document D 31:YYYY, where the essential requirements for software are interpreted and explained. This report describes the ~~examination~~ [evaluation](#) of software needed to state conformance with the R-xyz.

Manufacturer	Applicant
Tournesol Metering	New Company
P.O. Box 1120333	Nova Street 123
100 Klow	1000 Las Dopicos
Syldavie	San Theodorod
Reference: Mr. Tryphon Tournesol	Reference: Archibald Haddock

#### Test object

The Tournesol Metering meter TT100 is a measuring instrument intended to measure flow in liquids. The intended range is from 1 L/s up to 2000 L/s. The basic functions of the instrument are:

- measuring of flow in liquids,
- indication of measured volume,
- interface to transducer.

The flow meter is described as a built-for-purpose ~~measuring instrument device~~ (an embedded system) with a storage device containing legally relevant data.

Commented [ME366]: Related to FR-01, CZ-05

The flow meter TT100 is an independent instrument with a transducer connected. The transducer incorporates a temperature compensation. Adjustment of flow rates is possible by calibration parameters stored in a non-volatile memory of the transducer. It is fixed to the instrument and cannot be disconnected. The measured volume is indicated on a display. No communication with other devices is possible.

The embedded software of the measuring instrument was developed by

**Tournesol Metering, P.O. Box 1120333, 100 Klow, Syldavie.**

The ~~executable~~ file name of the executable code is “**tt100\_12.exe**”.

Commented [ME367]: Related to NL-04, UK-02

The ~~validated-verified~~ version of this software is **V1.2c**. The software version is presented on the display upon instrument start-up and by pressing the “level” button for 4 seconds.

The source code comprises the following legally relevant files:

- main.c 12301 byte 23 Nov 2003;
- int.c 6509 byte 23 Nov 2003;
- filter.c 10897 byte 20 Oct 2003;
- input.c 2004 byte 20 Oct 2003;
- display.c 32000 byte 23 Nov 2003;
- ethernet.c 23455 byte 15 June 2002;
- driver.c 11670 byte 15 June 2002;
- calculate.c 6788 byte 23 Nov 2003.

The executable ~~file-code~~ “**tt100\_12.exe**” is protected against modification by a checksum. The value of the checksum by algorithm XYZ is **1A2B3C**.

Commented [ME368]: Related to NL-04, UK-02

The ~~validation-evaluation~~ was supported by the following documents from the manufacturer:

- TT 100 User Manual Release 1.6;
- TT 100 Maintenance Manual Release 1.1;
- Software description TT100 (internal design document, dated 22 Nov 2003);
- Electronic circuit diagram TT100 (drawing no 222-31, dated 15 Oct 2003).

The final version of the test object was delivered to the National Testing & Measurement Laboratory on 25 November 2003.

#### Results of ~~validation-evaluation~~

The ~~validation-evaluation~~ was performed according to the OIML D 31:YYYY. The ~~validation-evaluation~~ was performed between 1 November and 23 December 2003. A design review was held on 3 December by Dr. K. Fehler at Tournesol Metering head office in Klow. Other ~~validation-evaluation~~ work was carried out at the National Testing & Measurement Laboratory by Dr. K. Fehler and Mr. S. Problème.

The following requirements were ~~validated-verified~~:

- software identification;
- correctness of algorithms and functions;
- software protection;
- prevention against accidental misuse;
- ~~fraud-protection~~ evidence of intervention;
- support of hardware features;
- storage of data, transmission via communication systems.

Commented [ME369]: Related to US-comments submitted at the Dordrecht meeting

The following ~~validation-evaluation and verification~~ methods were applied:

- analysis of the documentation and ~~validation-evaluation~~ of the design;
- ~~verification-validation~~ by functional testing of metrological features;
- walkthrough, code inspection;
- software module testing of module calculate.c with SDK XXX.

#### Result

The following requirements of the OIML D 31:YYYY were ~~validated-verified~~ without any ~~non-~~

conformities/faults being found:  
5.1.1, 5.1.2, 5.1.3.2, 5.2.1, 5.2.2.1, 5.2.2.2, 5.2.2.3.

Commented [ME370]: Related to DE-11

The result applies to the tested item with Serial No. 1188093-B-2004 only.

Conclusion

The software of the **Tournesol Metering TT100 V1.2c** fulfils the requirements of OIML R-xyz.

National Testing & Measurement Lab.  
Software Department  
Dr. K.E.I.N. Fehler  
Technical manager

Mr. S.A.N.S. Problème  
Technical Officer

### Checklist

Clause	Requirement	Passed	Failed	Remarks
<b>5.1</b>	<b>General requirements</b>			
<b>5.1.1</b>	<b>Software identification</b> <del>Software of a measuring instrument/component shall be clearly identified. Legally relevant software shall be clearly identified.</del>			
<b>5.1.2</b>	<b>Correctness of algorithms and functions</b> <del>The measuring algorithms and functions of a measuring instrument shall be appropriate and functionally correct for the given application and device type. The measuring algorithms and functions of a measuring instrument shall be appropriate and functionally correct.</del>			
<b>5.1.3</b>	<b>Software protection</b>			
<b>5.1.3.1</b>	<b>Prevention of misuse</b> <del>A measuring instrument shall be constructed in such a way that possibilities for unintentional, accidental, or intentional misuse are minimal. A measuring instrument shall be constructed in such a way that possibilities for unintentional, accidental, or intentional</del>			
<b>5.1.3.2</b>	<b>Fraud protection</b>			
a)	Software shall be protected in such a way that evidence of any intervention (e.g. software updates, parameter changes) shall be available. Software shall be secured against unauthorized modification, loading, or changes by swapping the memory device.			
b)	Only clearly documented functions may be activated by the user interface, which do not influence the metrological characteristics of the instrument.			
c)	Parameters that fix the legally relevant characteristics of the measuring instrument shall be secured against unauthorized modification. If necessary for the purpose of verification of a <u>measuring instrument</u> , displaying or printing of the current parameter settings shall be possible.			
d)	Software protection comprises appropriate sealing by mechanical, electronic and/or cryptographic means, making an unauthorized intervention impossible or evident.			
<b>5.1.4</b>	<b>Support of hardware features</b>			
<b>5.1.4.1</b>	<del>Support of fault detection</del> <b>Detection of significant defects</b> The manufacturer of the instrument shall be required to design checking facilities into the software or hardware parts or provide means by which the hardware parts can be supported by the software parts of the instrument.			
<b>5.1.4.2</b>	<b>Support of durability protection</b> It is the manufacturer's choice to realize durability protection facilities in software or hardware, or to allow hardware facilities to be supported by software.			
<b>5.1.5</b>	<b>Time stamp</b> <del>The time stamp shall be read from the clock of the instrument. Appropriate protection means shall be taken according to the risk level to be applied.</del>			
<b>5.2</b>	<b>Requirements specific for configurations</b>			
<b>5.2.1</b>	<b>Specification and separation of legally relevant parts and specification of interfaces</b> Legally relevant parts of a measuring instrument shall not be inadmissibly influenced by other parts of the measuring instrument.			
<b>5.2.1.1</b>	<b>Separation of components</b>			
a)	Components of a measuring instrument that perform legally relevant functions shall be identified, clearly defined, and documented.			
b)	It shall be demonstrated that the functions and data of legally relevant components cannot be inadmissibly influenced by commands received via the interface to the other, legally non-relevant parts.			

Commented [ME371]: Inserted because of new requirement 5.1.5

<b>5.2.1.2</b>	<b>Specification and separation of software parts</b>			
<b>a)</b>	The conformity requirement applies to the legally relevant software part of a measuring instrument (see 5.2.6) and it shall be made identifiable as described in 5.1.1.			
<b>b)</b>	If the legally relevant software part communicates with other software parts, a software interface shall be defined. All communication shall be performed exclusively via this interface. The legally relevant software part and the interface shall be clearly documented. All legally relevant functions and data domains of the software shall be described to enable a type evaluation authority to decide on correct software separation.			

Clause	Requirement	Passed	Failed	Remarks
<b>c)</b>	<del>There shall be an unambiguous assignment of each command to all initiated functions or data changes in the legally relevant part of the software. Commands that communicate through the software interface shall be declared and documented. Only documented commands are allowed to be activated through the software interface.</del> <u>There shall be an unambiguous assignment of each command to all initiated functions or data changes in the legally relevant software part. Functions that are triggered through the software interface shall be declared and documented. Only documented functions are allowed to be activated through the software interface.</u>			
<b>d)</b>	<del>Where the legally relevant software part has been separated from the non-relevant software part, the legally relevant software part shall have priority using the resources over non-relevant software. The legally relevant process shall not be inadmissibly interrupted by legally non-relevant software.</del>			
<b>5.2.2</b>	<b>Shared indications</b> If a display or printout is used both for legally relevant and legally non-relevant outputs, the legally relevant information should always be readable, and clearly distinguishable from other information.			
<b>5.2.3</b>	<b>Storage of data</b>			
<b>5.2.3.1</b>	The measurement value stored shall be accompanied by all relevant information necessary for future legally relevant use.			
<b>5.2.3.2</b>	The stored data shall be protected by software means to guarantee authenticity, integrity and, if necessary correctness of the information concerning the time of measurement. <u>The software that displays or further processes the measurement values and accompanying data shall check the time of measurement, authenticity, and integrity of the data after having read them from the storage. If an irregularity is detected, the data shall be discarded or marked unusable.</u>			



<b>5.2.3.3 Automatic storing</b>			
a) When data storage is required, measurement data <del>shall</del> <b>must</b> be stored automatically when the measurement is concluded. The storage device <del>shall</del> <b>must</b> have sufficient permanency to ensure that the data are not corrupted under normal storage conditions. There shall be sufficient memory storage for <del>the intended</del> <b>a particular</b> application.			
b) Stored data may be deleted if either: <ul style="list-style-type: none"> <li>- the transaction is settled;</li> <li>- these data are printed by a printing device subject to legal control.</li> </ul>			
<b>5.2.3.4 Time stamp</b> <del>The time stamp shall be read from the clock of the instrument. Appropriate protection means shall be taken according to the risk level to be applied. If the information concerning the time of measurement is necessary, the reliability of the internal clock of the measuring instrument shall be enhanced by specific means.</del>			
<b>5.2.4 Transmission via communication lines</b>			
<b>5.2.4.1</b> The measurement value transmitted shall be accompanied by all relevant information necessary for future legally relevant use.			
<b>5.2.4.2</b> The transmitted data shall be protected by software means to guarantee the authenticity, integrity and, if necessary correctness of the information concerning the time of measurement. <del>The software that displays or further processes the measurement values and accompanying data shall check the time of measurement, authenticity, and integrity of the data received them from a transmission channel. If an irregularity is detected, the data shall be discarded or marked unusable.</del>			
<b>5.2.4.3</b> The measurement shall not be inadmissibly influenced by a transmission delay.			
<b>5.2.4.4</b> If network services become unavailable, no measurement data shall be lost.			
<b>5.2.4.5</b> <del>The time stamp shall be read from the clock of the instrument. Appropriate protection means shall be taken according to the risk level to be applied. If the information concerning the time of measurement is necessary, the reliability of the internal clock of the measuring instrument shall be enhanced by specific means.</del>			

Commented [ME372]: Deleted because of new requirement 5.1.5

Commented [ME373]: Deleted because of new requirement 5.1.5

Clause	Requirement	Passed	Failed	Remarks
<b>5.2.5 Compatibility of operating systems and hardware</b>				
<b>5.2.5.2</b> <del>Each of the following operating system requirements shall be met by measures on application level, operating system level or a combination of both.</del>				
<b>5.2.5.3</b> <del>Hardware interfaces not equipped with a protective software interface shall not be able to inadmissibly influence the legally relevant software part.</del>				
a) <del>In order to ensure integrity and authenticity of the legally relevant software part, a chain of trust shall be established over the individual components of the boot process.</del>				

b)	The processing of the chain of trust can be interrupted, as long as its integrity is preserved.			
c)	The boot configuration shall be protected against unauthorized modifications.			
d)	Bootling via open interfaces shall be protected.			
5.2.5.4	The combination of legally relevant software part and operating system shall ensure that there are enough resources for the operation of the legally relevant application.			
5.2.5.5	<b>Protection during use</b>			
a)	The operation of software that is not legally relevant shall not inadmissibly influence the legally relevant application.			
b)	The combination of legally relevant software part and operating system shall ensure that the legally relevant display is distinguishable.			
c)	The access control shall be configured in such way that the intended use cannot be inadmissibly influenced.			
d)	The administration tasks of the legally relevant software part shall be protected.			
5.2.5.6	Communication with legally relevant software part shall be made via protective interfaces.			
5.2.5.7	<b>Testability and traceability</b>			
a)	The configuration of the operating system shall be identifiable.			
b)	If changes to the configuration of the operating system are possible, they shall be traceable.			
5.2.5.1	The manufacturer shall state the legally relevant components of the operating system. The configuration of the operating system shall be identifiable. Changes to the configuration of the operating system shall be traceable.			
5.2.5.8	The manufacturer shall identify the hardware and software environment that is suitable. Minimum resources and a suitable configuration necessary for correct functioning shall be declared by the manufacturer.			
5.2.5.9	Technical means shall be provided to prevent operation, if the minimal configuration requirements are not met.			
5.2.7	<b>Maintenance and reconfiguration</b>			
5.2.7.1	Only versions of the legally relevant software part that conform to the approved type are allowed for use.			
5.2.7.2	<b>Verified Update</b> After the update of the legally relevant software of a measuring instrument (exchange with another approved version or re-installation) the measuring instrument <del>is not allowed to be employed</del> should not be employed for legal purposes before a verification of the <del>measuring</del> instrument has been performed and the securing means have been renewed.			

Commented [HS374]: Related to CZ-04

Clause	Requirement	Passed	Failed	Remarks
5.2.7.3	<b>Traced Update</b>			
a)	Traced Update of software shall be automatic. If some of the securing measures of the instrument are turned off to enable updating, they <del>must</del> <u>shall</u> be turned on again immediately after update, independent of the result of the update process.			
b)	Software shall be protected in such a way that evidence of any intervention shall be available. During an update, any existing audit trail information <u>and event counter value</u> shall be retained.			
c)	Technical means shall be employed to guarantee the authenticity of the loaded software.			
d)	Technical means shall be employed to ensure the integrity of the loaded software, i.e. that it has not been inadmissibly changed before loading.			
e)	<del>Appropriate technical means</del> <u>An audit trail</u> shall be employed to ensure that Traced Updates <u>of the legally relevant software part</u> are adequately traceable within the instrument.			
f)	Depending on <u>the needs and</u> national <u>legal</u> legislation it may be necessary for the user or owner of the measuring instrument <del>to have</del> to give his consent.			Commented [ME375]: Related to UK-09
	<del>If the requirements 5.2.7.3.a through 5.2.7.3.f cannot be fulfilled, it is still possible to update the legally non-relevant software part. In this case the following requirements shall be met:</del>			Commented [HS376]: Related to NL-27
	<del>there is a distinct separation between the legally relevant and non-relevant software according to 5.2.1;</del>			
	<del>the whole legally relevant software part cannot be updated without breaking a seal;</del>			
g)	<del>it is stated in the type evaluation certificate that updating of the legally non-relevant part is acceptable.</del>			Commented [HS377]: Related to NL-30
	If the loaded software fails integrity test or authenticity test, the instrument shall discard the new version and use the previous version of the software or switch to an inoperable mode.			
5.2.7.4	The measuring instrument shall be fitted with a facility to automatically and non-erasably record any adjustment of the device specific parameter, e.g. an audit trail. The instrument shall be capable of presenting the recorded data.			
5.2.7.5	The audit trails are part of the legally relevant software <u>part</u> and should be protected as such.			

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## Annex C

## Index

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