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VALIDATION OF A COMPLEX MEASURING SYSTEM

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Abstract: Applications of modern, computer (software) controlled measuring systems are various, from automation of testing and calibration laboratories to legal metrology measuring instruments and systems. Requirements to be met by such instruments or systems are usually defined by national or international legislation or international technical, safety, or laboratory competence standards [11]. Validation of fulfilment of these requirements is essential for the conformity assessment of these instruments and systems. The complexity of validation and resources needed in the validation process depend on the construction of the object of validation and may be very extensive, especially in the case of computer based measuring systems. Suggested approach for modular validation of complex measuring systems may reduce the validation efforts, as well as costs and time consumption.

Keywords: validation, measuring systems, modularity.

1. MEASURING SYSTEM

From the field of view of computer technology, a simple measuring system has at least two parts, although we can see it as one device. We may say that one part represents computer hardware with necessary sensors and interfaces, whether the other part comprises computer software. Software part includes operating system, drivers and measurement software, which is responsible for computation of measurement results, automation and control of complete measuring system and storage and transfer of measurement data. Complex measuring system could be build from several subunits (modules) that are functionally connected in different ways, exchange data via several possible communication means and are more or less dependent from each other.

With intention to decrease costs in development, manufacturing and maintenance as well as verification and validation of these particular phases, manufacturers very often use one type of module as a building block of several types of devices.

2. VALIDATION OF A MEASURING SYSTEM

Validation of a measuring system confirms that a complete measuring system fulfils particular requirements for a specific intended use, what is assured by examination and provision of objective evidence [12].

The validation procedure is easier in case of simple measuring system. In the case of complex measuring system the validation procedure could be very comprehensive, because it is necessary to validate all building parts taking into account their possible mutual influence. The part within the complex measuring system could be a standalone measuring instrument itself.

With aim to optimise resources needed for validation of a complex measuring system, it is necessary to analyse whether it makes sense to validate the system as a whole or by building subunits and to distinguish between parts of the system that may be validated separately and even parts that do not need to be validated at all (i.e. in case they are sub-units of a validated part).

Considering simplified hypothetical measuring system, built from sensor (A), computing unit (B) and a display (C), it is obvious that the system as a whole will fulfil particular requirements for a specific intended use only if all its' subunits fulfil the validation criteria. However, this is only the prerequisite but not necessary enough for drawing conclusion that the system as a whole fulfils validation criteria. On the other hand, it is obvious that the complete system will not meet validation criteria if the subunit (A) fails the validation.

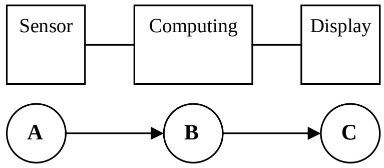

Fig. 1. Modelling of computer system

In case that we already know at the beginning of validation that subunits (A) and (B) fulfil the criteria (which may be proved i.e. by presenting credible test reports), we can focus validation only to the third part.

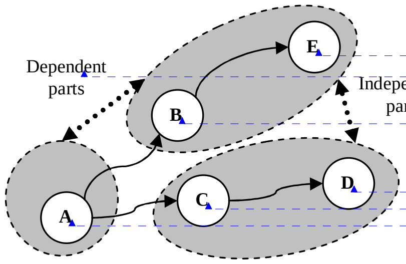

Fig. 2. Dependent and independent parts

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Useful tool for determination which modules may be validated separately is the graphical presentation of the measuring system. It is important to stress that separate validation may be performed only for independent modules.

During the conformity assessment of a modular structured measuring instrument it may be applicable that one type of such a building block (module) is validated only once. Once validated module may be lately implemented in several types of measuring instruments or systems without need for repeating the validation (or certification). However, for implementation of such a principle very clear rules have to be established and implemented.

3. MODULAR APPROACH IN VALIDATION OF COMPLEX MEASURING SYSTEMS

In many areas of metrology there are already established standards enabling testing of particular measuring instruments (like i.e. OIML recommendations in the fields of legal metrology [7], [8], [9]). In addition, there are also normative and guidance documents foreseen for conformity assessment of particular modules of measuring instruments, like OIML R 60: Metrological regulation for load cells [10], WELMEC 2.4: Guide for Load Cells [3] or WELMEC 2.5: Guide for modular approach and testing of PCs and other digital peripheral devices (Non-automatic Weighing Instruments).

3.1. Validation of the measuring instrument software as an independent module

Considering software in legal metrology instruments, modules to be evaluated separately may be grouped either by measuring instruments' metrological functionality or by its software/IT functionality. According to the first grouping, examples for representative modules from the legal metrology world are the volume conversion devices and calculation units in gas meters, heat meters or measuring systems for the continuous and dynamic measurement of quantities of liquids other than water. On the other hand, according to the IT functionality as proposed in the guide WELMEC 7.2 [4], such modules may be the data storage devices or software, software modules handling transmission of measurement data via communication networks, software update module and indicating device or software.

WELMEC 7.2 is an example of guidance document that states quite clear and unambiguous requirements for software in measuring instruments covered by the EU Directive 2004/22/EC on measuring instruments (MID). Furthermore, some validation guidance is also included. The guide is modular itself – with chapters linked to technological realisation of the instrument and implemented functionality (whether it is PC-based or built for purpose, including long term storage of measuring results, data transfer via communication lines, separation of software under metrological control form other parts, remote update of measuring instrument software).

3.2. Comparability of results of the validation of the measuring instrument software as an independent module between different laboratories

The question that arose recently regards equal interpretation of WELMEC 7.2 between conformity assessment bodies. Both manufacturers of measuring instruments and legal metrology bodies that participate in WELMEC WG7 "Software" are concerned whether all conformity assessment bodies will implement the guide in the same way (i.e. understanding and identification of the requirements, selection of the risk class, selection the test methods and strategies). Therefore some kind of validation of understanding of the guide seems to be very useful for successful application of the guide. A small project of simultaneous examination of the software of the same type of measuring instrument between several laboratories has been initiated.

This is the first time such an exercise is performed regarding software of a measuring instrument. Very useful instructions have been found in the ISO/IEC Guide 43:1997 [5], [6]. Certain things are so specific that are agreed ad-hoc for this particular exercise, i.e. that every participant in exercise shall identify requirements from WELMEC 7.2 by himself and that the selection of test methods and strategies (analysis of the documentation, functional checks, dynamic testing, black-box testing…) is selected by each participant.

The justification for this is in the fact that the main objective for this intercomparison is not the proficiency testing of the participants but rather the validation of the common understanding and applicability of the guide.

Suggested procedure for performance of the work in the laboratory is:

1. Identify all requirements
2. Select methods for checking the requirements
3. Prepare test plan
4. Perform the tests
5. Prepare the results
6. Send the results to the coordinator

In case of detection of a bug during the testing:

- the failure is recorded,
- software in equipment under test (EUT) or EUT is not replaced with the new EUT,
- the testing is continued.

It is not the classical proficiency testing by interlaboratory comparisons [5], [6] because of several reasons:

- testing procedures and reports (checklists) are not defined in sufficient detail like in typical proficiency testing,
- validation of software in metrological applications is not a mature discipline and not many institutions are qualified for such a testing.

After the analysis of the results achieved by different laboratories important information will be available:

- is the guide understandable enough to participating laboratories,
- is the guide understandable enough to manufacturers,
- are the requirements reasonable,
- is the validation guidance sufficient,
- is it necessary to define more in detail test methods and strategies [13],
- is there a necessity to refer more in detail to software domain specific standards.

In addition, laboratories will be able to improve their testing procedures.

4. CONCLUSION

From the proposed approach may benefit both manufacturers of measuring instruments and conformity assessment bodies and laboratories, since the repetition of testing of the same instrument between different countries or between different types of instrument containing the same building subunits may be reduced.

Validation of the software in metrological applications is not a mature discipline and not many institutions perform it at a time. On the other hand the procedures for testing the software and related methods and strategies are not so well established and standardised as in other testing areas (i.e. chemical: ISO 13756-1997: "Determination of silver in silver jewellery alloys – Volumetric (potentiometric) method using sodium chloride or potassium chloride", hardness, …).

However, for wide international acceptance of intercomparison of software examination (V&V) lot of efforts have to be invested in definition of procedures, which may later evolute in a new international standard.

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