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Outcomes of the first comparative examination of the measuring instrument software

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BACKGROUND OF THE PROBLEM AND THE SOLUTION

Legal metrology: measurements necessary to be supervised by the state and regulated by law:

- **human and animal health,**
- **protection of environment,**
- **Transactions of goods and services,**
- **general technical safety and**
- **proceedings before jurisdictional institutions.**

Examples:

– **Utility meters (water meters, gas meters and volume conversion devices, active electrical energy meters, heat meters),**
– **measuring systems for continuous and dynamic measurement of quantities of liquids other then water,**
– **automatic weighing instruments,**
– **taximeters,**
– **exhaust gas analysers,**
– **breath analyzers,**
– **Road traffic enforcement measuring instruments**
– **…**

Legal metrology instruments are subject to conformity assessment

Several conformity assessment modules
(A**,** A1**,** ***B***,** C, C1**,** D, D1, E, E1**,** ***F***,** F1, G, H**,** ***H1***)**

Several conformity assessments instances and inspections during their lifecycle.

Initial conformity assessment procedure (type approval).
First verification, regular and extraordinary verifications and inspection examinations.

Institutions that perform these conformity assessment procedures are both governmental and private bodies.

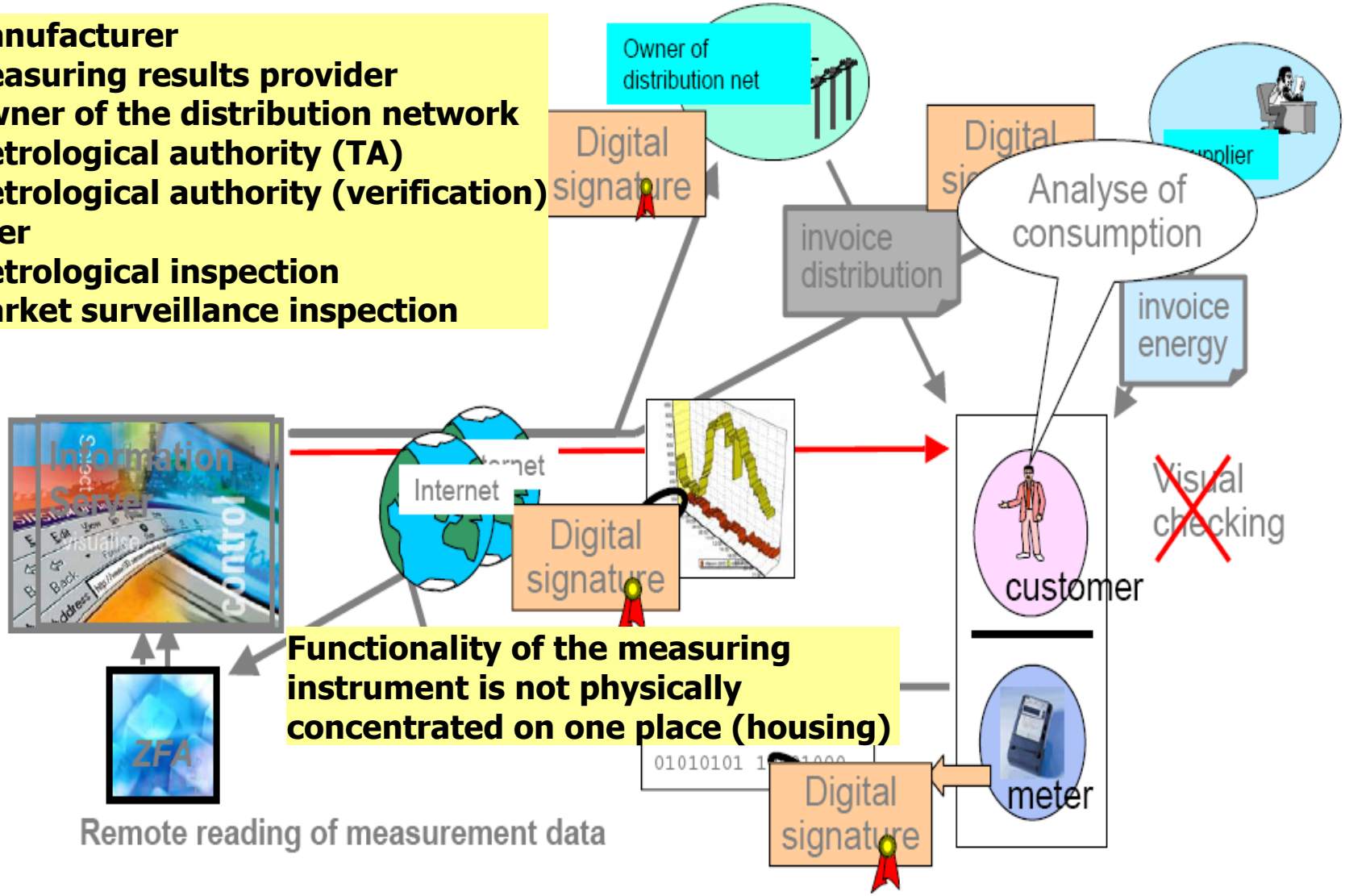
Confidence shifts from employees of state institutions to procedures of conformity assessment in private bodies.

Additional measuring instruments functionality:
collecting and analysis of reports (mostly implemented by software and IT)

Consumer protection v.s no barriers to trade

STATE OF THE ART LEGALLY CONTROLED MEASURING SYSTEMS: AN EXAMPLE

Manufacturer
Measuring results provider
Owner of the distribution network
Metrological authority (TA)
Metrological authority (verification)
User
Metrological inspection
Market surveillance inspection



Dr. Norbert Zisky, PTB

SW IS INEVITABLE, VITAL PART OF LEGAL MEASURING INSTRUMENTS

Specifics of software in legal metrology arise from following requirements and facts:

- **Support for high precision, accuracy, reliability and repeatability of measurements;**
- **Support for reliability, security and availability of measuring results;**
- **Variety of simultaneously applied engineering technologies;**
- **Facilitation of building measuring systems of components made by various vendors (which are not always compatible in functionality and communication);**
- **Minimisation of expenses of putting the instruments into use and their later maintenance (remote download for bug-fixed versions of software of measuring instruments in use);**
- **Support for suitable consumer protection;**
- **Support for new parties involved into operation of measurement systems (measurement data providers);**
- **Necessity of operation and validation support for software components developed by metrological domain experts (which are not software technology experts);**
- **Support to legal metrology verification procedures;**
- **Support to metrological surveillance procedures.**

REQUREMENTS: AN EXAMPLE (MID)

Suitability

7.6 **A measuring instrument shall be designed so as to allow the control of the measuring tasks after the instrument has been placed on the market and put into use. If necessary, special equipment or software for this control shall be part of the instrument. The test procedure shall be described in the operation manual. When a measuring instrument has associated software which provides other functions besides the measuring function, the software that is critical for the metrological characteristics shall be identifiable and shall not be inadmissibly influenced by the associated software.**

8.1 **Protection against corruption**

The metrological characteristics of a measuring instrument shall not be influenced in any inadmissible way by the connection to it of another device, by any feature of the connected device itself or by any remote device that communicates with the measuring instrument.

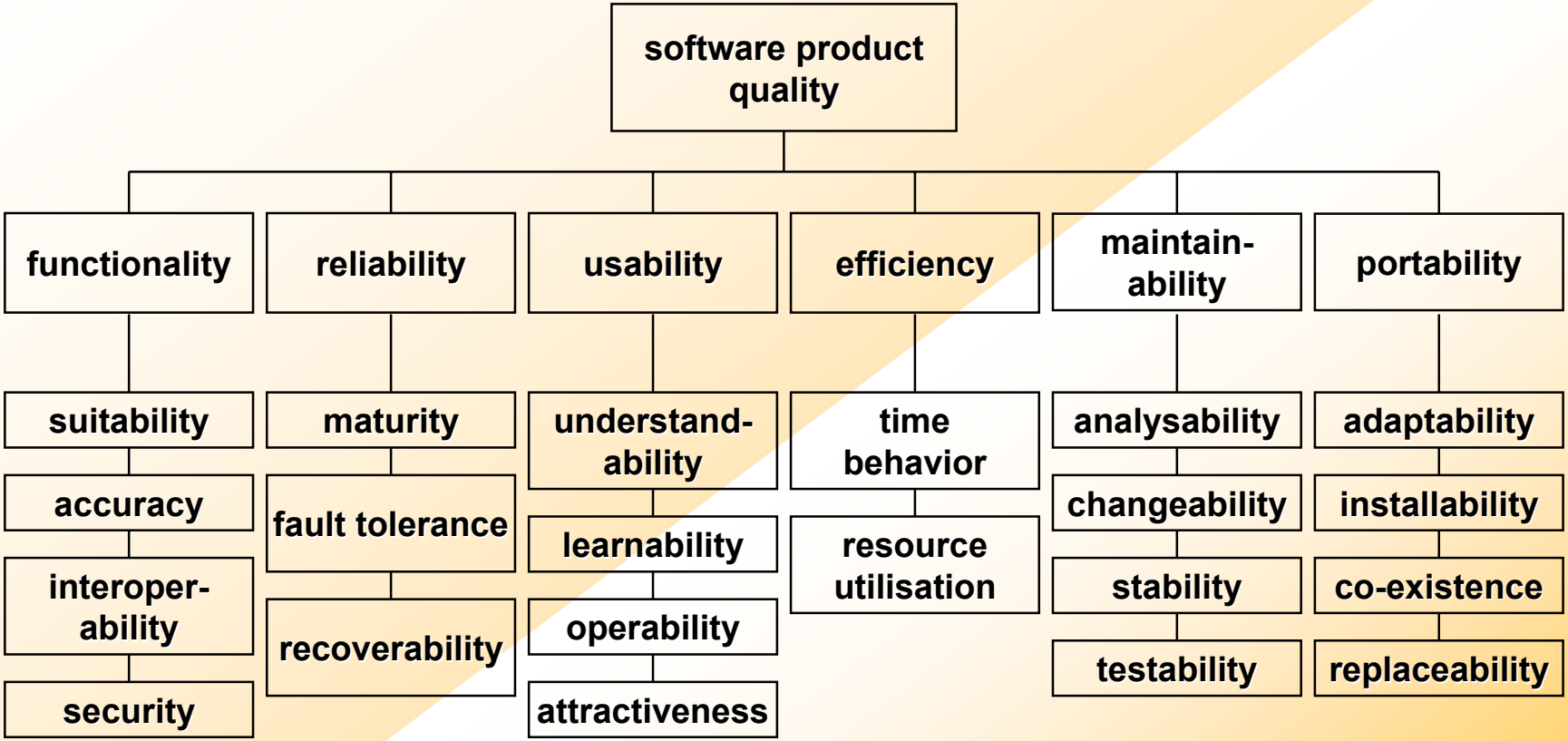
8.3 **Software that is critical for metrological characteristics shall be identified as such and shall be secured.**

Software identification shall be easily provided by the measuring instrument.

Evidence of an intervention shall be available for a reasonable period of time.

8.4 **Measurement data, software that is critical for measurement characteristics and metrologically important parameters stored or transmitted shall be adequately protected against accidental or intentional corruption.**

SOFTWARE PRODUCT QUALITY



ISO/IEC 9126-1:2001: Software engineering – Product quality – Quality model

Static testing techniques
- Inspection
- Walktrhrough
- Desk Checking

Dynamic testing technques/Test cases
- Logic-Coverage Testing
- Equivalence Partitioning
- Boundary Value Analysis
- Cause-Effect Graphing
- Error Guessing

Levels of testing
- Unit; module; component testing
  - Function testing
  - System testing
  - Acceptance testing
  - Installation Testing

Planning and control of testing

End of testing: Criteria

DILEMMAS FOR PEOPLE DOING EXAMINATION OF SW IN LEGAL METROLOGY

Conformity assessment supposed to be performed by metrologists
Metrologists know:
- Accuracy,
- Repeatability
- Uncertainty
- …

Metrologists do not know:
- Equivalence Partitioning
- Boundary Value Analysis)

Solution1:
IT experts take over testing of metrological software
IT expert do not know:
- Accuracy,
- Repeatability
- Uncertainty
- …

Solution2:
Prepare tools for domain experts (metrologists) to be able to test metrological software.

MID-SOFTWARE: 2002 ÷ 2004

Thematic network MID Software (supported by the 5 EU FP, contract no G7RT-CT-2001-05064).

PTB	**Germany**	**NMI**	**Project leader, WP1, WP3**
DELTA	**Denmark**	**NB**	
GUM	**Poland**	**NMI**	
HALE	**Austria**	**Man**	
Herbert Group	**UK**	**Man**	
JV	**Norway**	**NB**	
Gilbarco Veder Root	**Italy**	**Man**	
MT	**Switzerland**	**Man**	
NMi	**The Netherlands**	**NB**	
NWML	**UK**	**NB**	**WP1***
Sartorius	**Germany**	**Man**	
Landis & Gyr	**Switzerland**	**Man**	
MIRS	**Slovenia**	**NMI**	**WP4**
SP	**Sweden**	**NMI**	**WP2**
LNE	**France**	**NMI**	

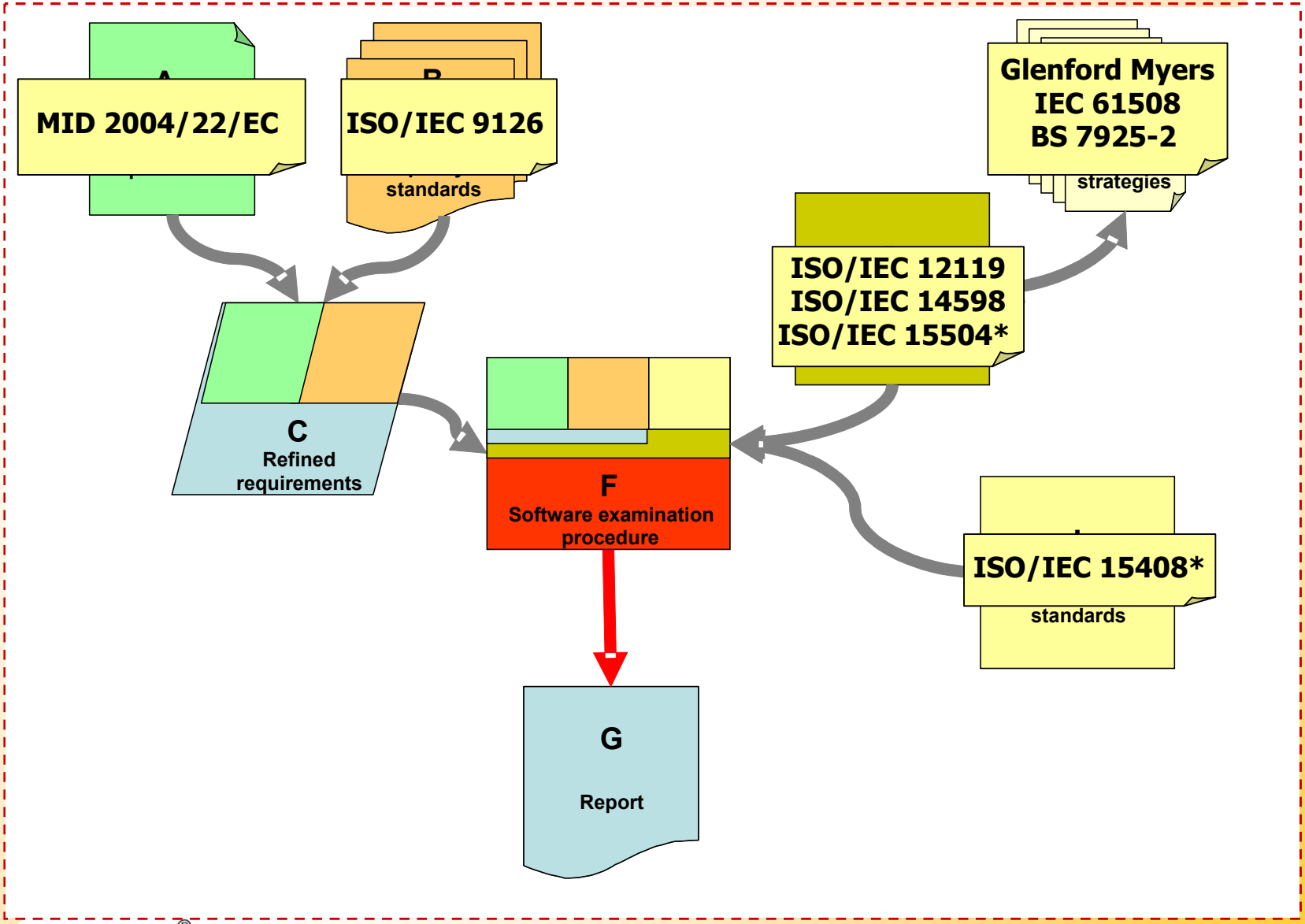
Result:
WELMEC 7.2: Software Guide (Measuring Instruments Directive 2004/22/EC) / May 2005

METROLOGICAL SW VALIDATION DOCUMENTS

	Field	Link to M	Life cycle	SW ID	Prot.	Risk	Upd	Dist.	IntF	Stor.	ValGuid
WELMEC 2.3	MI	+	-	+	+	-	+	-	+	-	+
WELMEC 2.5	MI	+	-	+	+	-	-	+	-	+	-
NORDTEST	Lab	+	+	+	+	+	+	-	-	-	+
Measurement Canada [1]	noMI	+	-	+	+	-	+	+	-	+	-
EEEE Guide [1]	Lab	-	+	+	+	+	+	+	-	-	+
FDA SW Validation	MedMI	-	+	+	-	+	+	-	+	-	+
FDA 21 CFR Part 11	MedMI	-	-	+	+	-	-	+	-	-	-
EN 61508 [2]	E/E/P	-	+	+	+	+	-	-	+	-	+
WELMEC 7.2	MI	+	-	+	+	+	+	+	+	+	+
OIML D-SW [1]	MI	+	-	+	+	+	+	+	+	+	+

1) Draft
2) Non-metrological

BUILDING OF DEDICATED GUIDANCE FOR VALIDATION OF METROLOGICAL SW



WELMEC 7.2: STRUCTURE

Basic Requirements	IT specific extensions	Instrument Specific Software Requirements
Basic Requirements for Embedded Software in a Built-for-purpose Measuring Instrument (Type P)	Extension L: Long-term Storage of Measurement Data	Water Meters
		Gas Meters and Volume Conversion Devices
	Extension T: Transmission of Measurement Data via Communication Networks	Active Electrical Energy Meters
		Heat Meters
		Quantities of Liquids Other than Water
Basic Requirements for Software of Measuring Instruments using a Universal Computer (Type U)	Extension S: Software Separation	Weighing Instruments
		Taximeters
	Extension D: Download of Legally Relevant Software	Material Measures
		Dimensional Measuring Instruments
		Exhaust Gas Analysers

Risk Classes

Although elaborated quite comprehensively (taking into account technological realization, implemented functionality and the specifics of intended use of a measuring instrument – "risk classes"), the software validation guidance in the document WELMEC 7.2 gives the performer of the testing significant freedom based on engineering knowledge, especially in selection of test methods and strategies to be applied. Consequently there is a latent danger of different interpretation between various performers of the software examination and furthermore obtaining different test results and conclusions on conformity for the same unit under test.

VALIDATION

It was necessary to determine the degree of equivalence of approaches to examination of software components in legal metrology between different national legal metrology authorities.
Selected method was the comparative examination of the same software component. Laboratories from six European national metrology institutes[1] took part in the intercomparison experiment. Selected unit under test was the software of an electrical energy meter, which is regulated under Directive on Measuring Instruments

Comparative software examination was performed never before in the area of validation of metrological software, so no systematic knowledge on this topic existed at the time of beginning of the experiment. The aim of the here explained performed experiment was not the proficiency testing, but rather validation the guidance document and gain knowledge in possibilities of harmonised implementation of existing software examination approaches in the specific field of validation metrological software.

[1] MIRS-Slovenia, BEV-Austria, CMI-Czech Republic, GUM-Poland, PTB-Germany, NMI-the Netherlands

THE EXPERIMENT: PERFORMANCE OF THE WORK

This plan is prepared according to WELMEC 7.2:2005 with some help from the ISO/IEC GUIDE 43-1:19972

Requirements

Every participant in exercise shall identify requirements from WELMEC 7.2 by himself.

Validation procedure

Validation is performed according to the validation guidance in the WELMEC 7.2. Selection of test methods and strategies (analysis of the documentation, functional checks, dynamic black-box testing…) is selected by each participant.

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

Identify all requirements

Prepare detailed test plan including selected test environment, test methods and test cases. Select methods for checking the requirements

Perform the tests

Prepare the results

Send results to MIRS

In case of detection of a bug during the testing:

The failure is recorded,

Software in EUT or EUT is not replaced with the new EUT

The testing is continued

Checklist for Requirements of Extension L						
Req	**Testing procedures**		**P**	**F**	**NA**	**Remarks**
L5	-	B&C) Are keys treated as legally relevant data and kept secret and protected against compromise by *simple software tools*?			x	
		D&E) Are keys and accompanying data treated as legally relevant data and kept secret and protected against compromise by sophisticated software tools? Are Appropriate methods equivalent to electronic payment used? Is user able to verify the authenticity of the public key?			x	
L6	D,F	Does the software used for verifying stored measurement data sets display or print the data, check the data for changes, and warn if a change has occurred? Are there means to prevent data detected as having been corrupted to be used?	x			*Continuous checking in the background ((E) Section 13).* Protection by a multistage security system. No direct access to stored data by the user.
L7	D	Are the measurement data stored automatically when the measurement is concluded?	x			*(E) Section 10.1.2*
L8	D	Does the long-term storage have a capacity which is sufficient for the intended purpose?	x			*(E) Section 10.2; circular buffer, adaptation of automatic storing intervals possible.*

THE EXPERIMENT: PHASES

Phase	Timeframe
MIRS prepares draft instructions for performance of the work (IPW).	Jun 6th 2006
WG7 colleagues comment IPW	
MIRS distributes improved instructions	Jun 23rd 2006
Landis+Gyr distributes EUT packages to evaluation performers (EP)	Jun 23rd 2006
Participants perform evaluation	
Participants send test results in agreed format (+ additional comments, test plan including test environment and test case description, …) to MIRS and Landis+Gyr	October 6th 2006
The group for analysis of results (GAR) meets in Ljubljana	October 23rd and 24th 2006
The group for discussion of results (GDR) meets in Ljubljana	October 25th 2006
GAR prepares the presentation of the results	

Participants:

- Bundesamt für Eich - und Vermessungswesen (BEV), Austria
- Physikalisch-Technische Bundesanstalt (PTB), Germany
- Laboratoire National d'Essais (LNE), France
- Czech Metrological Institute (CMI), Czech Republic
- Nederlands Meetinstituut (NMI), The Netherlands
- Landis+Gyr, Swiss
- Central Office of Measures (GUM), Poland
- Metrology Institute of the Republic of Slovenia (MIRS), Slovenia

Output of the testing process by each participant:

- Test plan
- Test report (as defined in chapter 12 of the WELMEC 7.2.)
- Text to be included in the type approval certificate (defined in WELMEC 7.2 chapter 12.4)
- Short evaluation report that contains a short description which of the applied parts of the Guide 7.2 are well applicable and which not and why including recommendations for enhancements, if any

OUTCOMES:1

Meeting of the Group for the Analysis of the Results

Harmonised software testing betwen diferen institution is possible:

With appropriate requirements

With appropriate validation guidance

With appropriate prepared documentation

CONCLUSIONS

The validation by comparative examination proved suitability of the WELEMC 7.2 guide for its' intended purpose – to enable comparable, harmonised approach to conformity assessment in the field of software in measuring instruments covered by the EU Measuring Instruments Directive. In addition, method of validation by comparative software examination was found as very useful tool in several aspects. The first is validation of a new guidance document. Next one is determination of the degree of equivalence of the implementation of the guide. The third aspect is that it may be an useful tool for maintaining once achieved degree of equivalence.

CONCLUSIONS

Some findings appeared that may be used for improvement of the guide and are significant to the common understanding of the legal metrology in generally. Performance of similar experiments in the future will be of great advantage for improvement of the software validation procedures. Presented intercomparison is related to the simplest software configuration of the instrument and to the conformity assessment module B ("type examination"). It will be of great benefit to validate parts of the guide related to more complex IT configuration of measuring instruments (i.e. based on universal computer, instrument with transmission of data via IT networks or with foreseen remote software update). Future development will very probably be expansion of the guide to other conformity assessment modules (especially H1: "declaration of conformity based on full quality assurance plus design examination", which is of great interest for manufacturers of measuring instruments). Intercomparison of approaches to H1 conformity assessment module will be very important for legal metrology community. Nevertheless, comparative examination may be very effective tool for the improvement or maintenance of once achieved level of equivalence in many other domains, not only in software examination in legal metrology.

	A			B			C			D			E			F		
Requirement	IDE	MET[1]	PAS	IDE	MET	PAS	IDE	MET	PAS	IDE	MET	PAS	IDE	MET	PAS	IDE	MET	PAS
P1 - Documentation	+	D	+	+	D	-[2]	+		+	+	D	+	+	D	+	+		+
P2 - Software identification	+	D,F	+	+	D,F	-[3]d	+		+[4]	+	D,F	-	+	D,F	+	+		+
P3 - Influence via user interface	+	D,F	+	+	D,F	-[5]	+		+	+	D,F	+	+	D,F	+	+		+
P4 - Influence via communication interface	+	D,F	+	+	D,F	-[6]	+		+	+	D,F	+	+	D,F	+	+		+
P5 - Protection against accidental or unintentional changes	+	*D,F*	+	+	*D*	+	+		+	+	*D,F*	+	+	*D,F*	+	+		+
P6 - Protection against intent. changes	+	*D,F*	+	+	*D*	+	+		+	+	*D,F*	+	+	*D,F*	+	+		+
P7 - Parameter protection	+	D	+	+	D,F	-[7]	+		+	+	D,F	+	+	D	+	+		+
L1 - Completeness of measurement data stored	+	*D*	+	+	*D,F*	+	+		+	+	*D*	+	+	*D*	+	+		+
L2 - Protection against accidental or unintentional changes	+	D	+	+	D	+	+		+	+	D,F	-	+	D,F	+	+		+
L3 - Integrity of data	+	D	+	+	D,F	+	+		+	+	D,F	+	N.A.		N.A.	+		+
L4 - Authenticity of meas. data stored	+	*D*	+	+	*D,F*	+	+		+	+	*D*	+	+	*D*	+[8]	+		+
L5 - Confidentiality of keys	-	D		N.A.		N.A.	N.A.		N.A.	N.A.		N.A.	N.A.		N.A.			N.A.
L6 - Retrieval of stored data	-	D		+	D,F	+	+		+	+	D,F	-	+	D,F	+	-		N.A.
L7 - Automatic storing	+	*D*	+	+	*D*	+	+		+	+	*F*	+	+	*D,F*	+	+		+
L8 – Storage capacity and continuity	+	*D*	+	+	*D*	+	+		+	+	*D,F*	+	+	*D*	+	+		+
I3-1 - Fault Recovery	+	D,F	+	+	D	?[9]	+		+	+	D,F	+	+	D	+	+		+
I3-2 - Back-up Facilities	+	*D,F*	+	+	*D,F*	+	+		+	+	*D,F*	+	+	*D*	+	+		+
I3-3 wake-up facilities and restoring ???	+	D	+															
I3-3 - (indication suitability)	+	*D*	+	+	*D,F*	+	+		+	+	*D*	+	+	*D*	+	+		+
I3-4 - (Inhibit resetting of cumulative measurement values)	+	*D,F*	+	+	*D,F*	+	+		+	+	*D,F*	+	+	*D,F*	+	+		+
I3-5 Dynamic behaviour	N.A.		N.A.	N.A.		N.A.	+		+	N.A.		N.A.	-					N.A.

IDE: requirement identified, MET: methods used, PAS: pass(+)/fail(-)

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[1] not always clear whether the functional test was performed through user interface or communication interface
[2] Documentation of the watchdog is missing
[3] The software ID could be read-out by the submitted software tools (F), however, it could not be indicated on the display.
[4] Partially ok, software identification performed by Firmware ID, no information about the procedure for the calculation of this ID was found.
[5] If the tools are used, the utility seal is broken, the verification seal is not broken, then
the security level 3 is reached (see (E) section 16). In this level it is possible for the user to write to some registers that are crucial, eg. the energy registers can be reset. This access that doesn't require to destroy the verification seal, is not allowed according to MID annex I paragraph 8.5. This is a reason for having failed the software validation.
[6] Write access to crucial registers is possible by communication via any of the interfaces of the instrument. Therefore deficiencies described in P3.3 and P7 also lead to failing requirement P4.
[7] Security level 3 gives too many permissions to the utility
[8] Functional check not possible
[9] Additional documentation is necessary.

PROPOSED PARAMETER PROTECTION CLASIFICATION

Functionality	Examples	covered by MID	settable (not protected by verification seal)	protected (under verification seal)	Remark
Basic characteristics of the instrument	Accuracy class, nominal voltage and current, frequency, I/O configuration	x		x	usually also strongly influenced by hardware
Energy registers (basic measurement)	Total and rated energy registers including their representation and identification on the display, meter constant	x		x	
Error register		x		x	
Security system	Access rights to data and parameters	x		x	if available
Calendar clock	Time/date, DST settings, clock base		x [1)]		not used for energy measurement
Demand registers	Average demand, maximum demand, cumulated maximum demand, integration period		x [1)]		
Stored values profile or other profiles	Capture period, buffer size, captured registers	x [2)]	x		
Rate control facilities	TOU and other control functions used for rate control		x		
Communication settings	Transmission speed, protocol settings, passwords		x		

[1)] These functions are not covered by MID. Anyway it is proposed to protect them under the verification seal if they are used for billing.

[2)] Extension L is only to be applied if the profiles are used for billing. Therefore the same rule as for [1)] is proposed.
All other functions of the instrument are not covered by MID and can therefore be changed after verification. The protection usually consists of a utility seal or a password. In the further discussion, it should be considered how to handle the question: If it is known to the manufacturer that functions or parameters of the instrument are used for billing under a any national law, how to secure these parameters and functions?

SUMMARY

Measuring instruments legal under control are subject to conformity assessment.
Conformity assessment should be based on clear requirements and test methods.

Metrological software is very specific.
Conformity assessment of metrological software demanding and comprehensive task. The main reason for this is absence of straightforwardly-defined procedures, i.e. in dedicated technical standards that address validation of metrological software.
Generic software validation approach is not suitable.

Therefore it was necessary to prepare guidance for validation of metrological SW
WELMEC 7.2 (pre-standard?)

Suitability of such a guidance document??? Validation!!!!

Lessons learned & Further activities

Intercomparison: good tool
Process assessment (H1)
Other measuring instruments
Other fields

Thanks for your kind attention

Questions?

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