AUTOMATION-VALIDATION-VERIFICATION WITHIN AN ACCREDITED LABORATORY

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Abstract

This paper represents the interpretation of the standards for the Validation of Calibration Procedures and the Measurement Uncertainty Calculations and the Automated Calibration Processes in the Calibration Laboratory operated by Fluke Germany. It also shows how MetCal® - procedures are written and validated in our faculties throughout Europe.

Introduction

The DIN ISO 17025:1999 handles the subject of „Test and calibration methods and method validation“ in paragraph 5.4.ff. It says in paragraph 5.4.1: *„The laboratory shall use appropriate methods and procedures for all test and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.“*

Fluke Germany has been an accredited member of the Deutsche Kalibrierdienst since 1978 and has grown its capabilities ever since. Its accreditation includes such parameters as:
DC Voltage, AC/DC Voltage Transfer difference; AC Voltage, DC Resistance, DC Current, AC/DC Current Transfer difference, AC Current, Frequency and Oscilloscope parameters.

Most of them with very small measurement uncertainties. Validation of procedures as well as measurement uncertainties and the implementation of automated calibration processes have therefore become a very important issue in the past years for Fluke. This paper will try to show how these subjects co-operate in our Calibration Laboratory.

Validation of Calibration Software

The use of software that is usually part of an instrument is not easily done. We use instruments from Measurement International and Dataproof that come along with a software package without which they would not be operational. These instruments together with the software packages are mostly ready for use and a validation is almost impossible. The validation of such software packages is done by the manufacturer and since some of the equipment they produce is used by other calibration laboratories and the National Standards Institute you may take their experience as a validation. However, if a validation is really necessary, an Interlab-comparison between two laboratories could solve the validation problem.

Due to the complexity of MetCal® itself, a validation is not possible, but it is necessary to do a validation of the procedures that are written in MetCal®, which is the subject of the next chapter.

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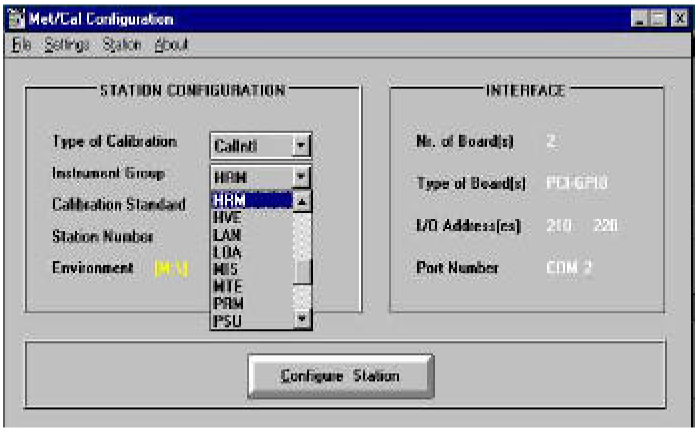
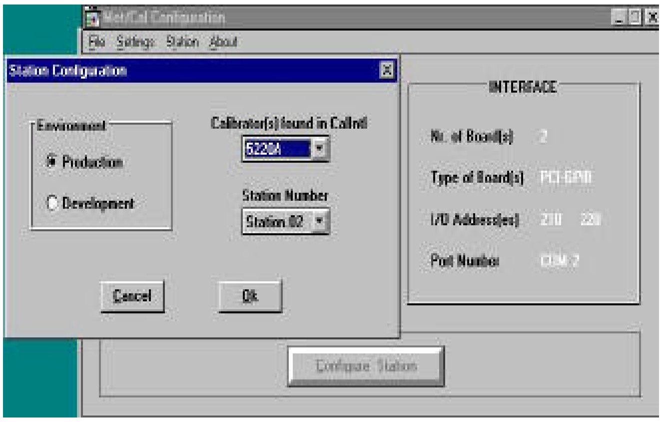
Validation of Procedure Writing in MetCal®

We have implemented a system in Europe, that allows every calibration technician and a metrologist in our calibration facilities to write calibration procedures in MetCal®. This system which is called „Framework for Calibration Procedures“ gives the general guidelines for writing procedures. The framework system divides the products into Product groups, which are shown in Table 1. MetCal® is set-up when installed, in a Server-based configuration. A small tool, called „MetCal®-Configurator“ allows the end-user to set-up MetCal® in different configurations. These configurations allow the use of two different virtual drives on the file-server, one holding all procedures for „Production“ and one for „Development“.

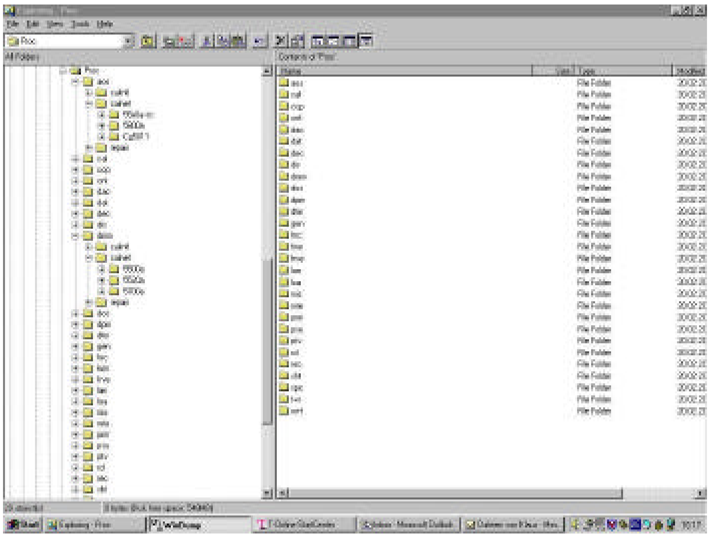




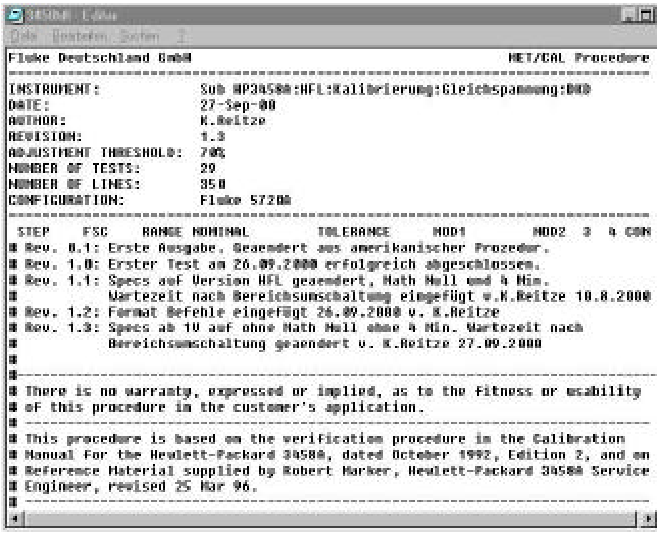
Picture 1 and 2: Sample screens of „MetCal®-Configurator“

The writing of procedures is of course limited to the skills, the ability and the area a technician or metrologist works in. Yet, the system allows you to write MetCal® procedures in a development area which limits the use of these procedures to testing and verification only.

Once a MetCal®-procedure is completed, the technician or metrologist who developed it must ask a colleague to double-check the contents, functionality and metrological correctness of it. Both, the developer and the person checking it, sign and date it on a so called „MetCal® Procedure Approval“ form. The form is then forwarded to the management of the calibration laboratory for final review and approval. The management of the calibration laboratory will transfer the MetCal® -procedure onto the production drive after final approval.



Picture 3: MetCal®-Procedure-Directory



Picture 4: Sample MetCal®-Procedure Head

Frameworks	Abbreviation
Analogue Oscilloscopes	AOS
Calibrators	CAL
Current Clamps	CCP
Counter / Timers	CNT
Data Acquisition	DAC
Decade Banks	DEC
Distortion Meters	DIS
Digital / Analogue Multimeters	DMM
Digital Oscilloscopes	DOS
Digital / Analogue Power Meters	DPM
Digital / Analogue Temperature Meters	DTM
Generators	GEN
High Resolution Calibrators	HRC
High Resolution Multimeters	HRM

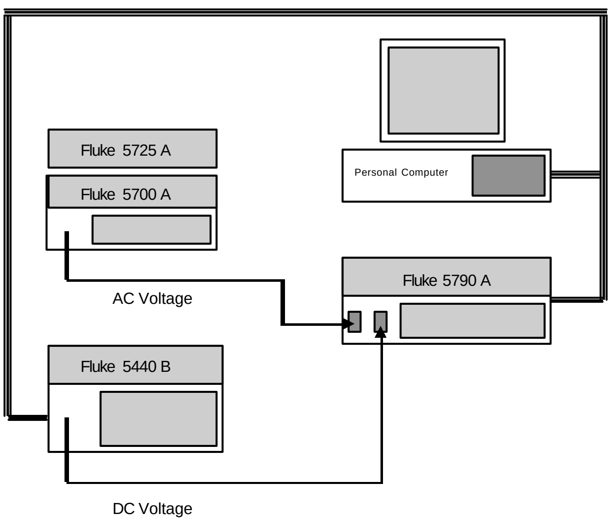
Frameworks	Abbreviation
High Voltage Equipment	HVE
Network Testers	LAN
Logic Analyzers	LOA
Miscellaneous	MIS
Meggers / Earth Testers	MTE
Pressure Modules	PRM
Power Supplies	PSU
Professional TV Test Equipment	PTV
RCL Meters	RCL
Recorders	REC
Shunt / Standard Resistors	SHT
Tachometers / Stroboscopes	T&S
Wow and Flutter Meters	W&F

Table 1: Framework Product groups

Automation of Calibration Processes

Turnaround times of an „Unit under test" in a calibration laboratory are an important issue in today's Test & Measurement World. It is an essential issue for customers and a challenge for a customer support service to keep downtime of an instrument to a minimum when it comes into the calibration laboratory for calibration.
What requirements are we looking at and what can be done to meet the limits of the requirements of turnaround times? If we look at a Multifunction calibrator like a Fluke 5700A, we can say that the customer has done a large investment to calibrate his instruments and could not afford to have this calibrator gone for a long time when it is due for calibration. A minimum of ten working days would be acceptable for him. Yet, the calibration laboratory which does the calibration for this customer may not just calibrate this calibrator. To meet the customer's expectations, the calibration laboratory has to automate the calibration process of this kind of product.

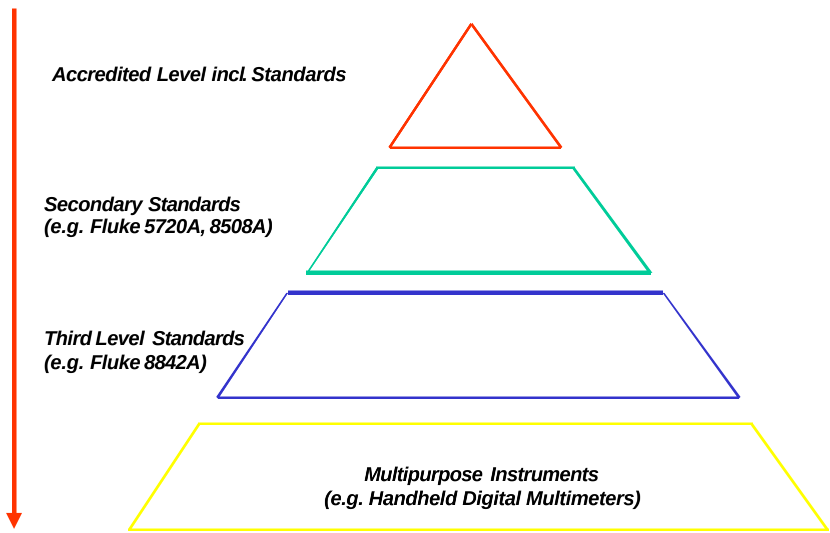
We have gone further and asked our customers to book an appointment for the calibration of their instruments and guarantee a turnaround time of five working days, only if the instrument is in good working condition. Meaning that an instrument arrives at our facility latest by Monday afternoon and will leave the same week Friday.
That is only possible if the complete calibration process is automated. We use MetCal® and appropriate MetCal®-procedures in the automation process of the calibration of almost any product that we calibrate.



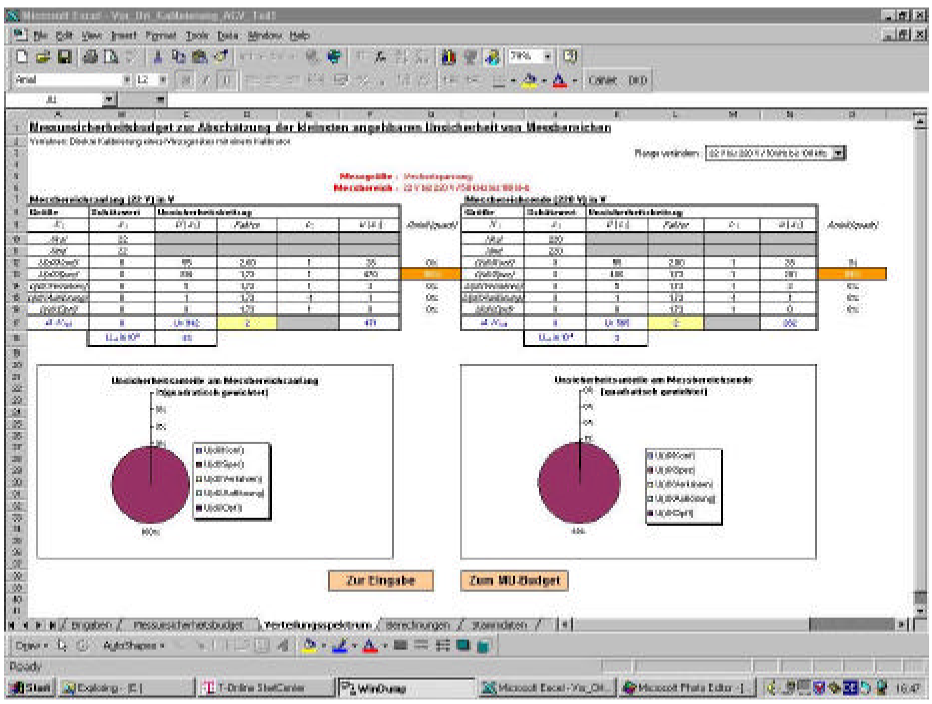
Picture 5: Example of an automated process to calibrate ac-voltage on a Fluke 5700A

Validation of Measurement Uncertainties Calculation for Calibration Set-ups

The end result of a calibration process is normally the issue of a „Certificate of Calibration“ that documents the measurement results in regards to the “Expanded Measurement Uncertainty“. The „Expanded Measurement Uncertainty“ expressed in such a Certificate of Calibration“ needs to be validated, as it may not directly show the „Best Measurement Capability“ (BMC) of the accreditation of the calibration laboratory. The „Best Measurement Capability“ is normally used in calibration of standards only, but calibration of any other instrument is usually derived from the *BMC*. In accordance with ISO 17025, a validation and maybe documentation of this derivation of an „Expanded Measurement Uncertainty“ of a measurement or instrument in a calibration process is necessary.
We decided to use Microsoft® Excel to help resolve this problem for us. One of the worksheets we created contains the accredited *BMC* with which we combine other worksheets that contain the errors and uncertainties of a calibration process (e.g. Fluke 5700A) and calculate the „Expanded Measurement Uncertainty“ in regard to the local regulations as well as to GUM[ii].



Picture 6: Combination of the *BMC* to Calibration



Picture 7: Example of a validation of “Expanded Measurement Uncertainties“

Conclusion

Validation and the verification of calibration procedures and processes as well as the validation and documentation of „Expanded Measurement Uncertainties“ can not be handled separately, they go hand in hand. The automation of calibration processes and the use of procedures requires such a validation, although today’s world is fast and things may change on daily basis any effort put into validation is being rapidly repaid. I may only urge everybody to find a process which is appropriate for the organisation he or she works in.

Allow me at the end of this paper to rephrase what John Fluke Sr. once said:

“We recognize that our Customer is our boss; we exist to serve his needs and he has a right to get a little more than he thinks he paid for.”

Also meaning that we should always do this in the best interests of our customers.

References

DIN ISO/IEC 17025:2000

DIN EN ISO 9001:2000

Calibration: Philosophy in Practice (Second edition) published by Fluke Corporation Everett/WA/USA

EAL-G12; Tracebility of Measuring and Test Equipment to National Standards

DKD-3; Expression of the Uncertainty of Measurement in Calibration

EAL-R2; Expression of the Uncertainty of Measurement in Calibration

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[i] MetCal® is a registered trademark by Fluke Corporation
[ii] GUM, Guide of the expression of the uncertainty of measurements in calibration