

Maintaining ISO 17025 Compliance in Automated Procedures

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Abstract

To meet the ISO 17025 requirements for accredited calibration procedures, almost all laboratories have created a myriad of documents and processes, especially if an automated procedure is involved. They usually comprise of an uncertainty analysis document, the automated accredited procedure, a calibration process document with the calibration requirements and applicable specifications, the validation process and respective data, the revision control document, etc. Their maintenance, management and control are one of the most difficult tasks of any laboratory.

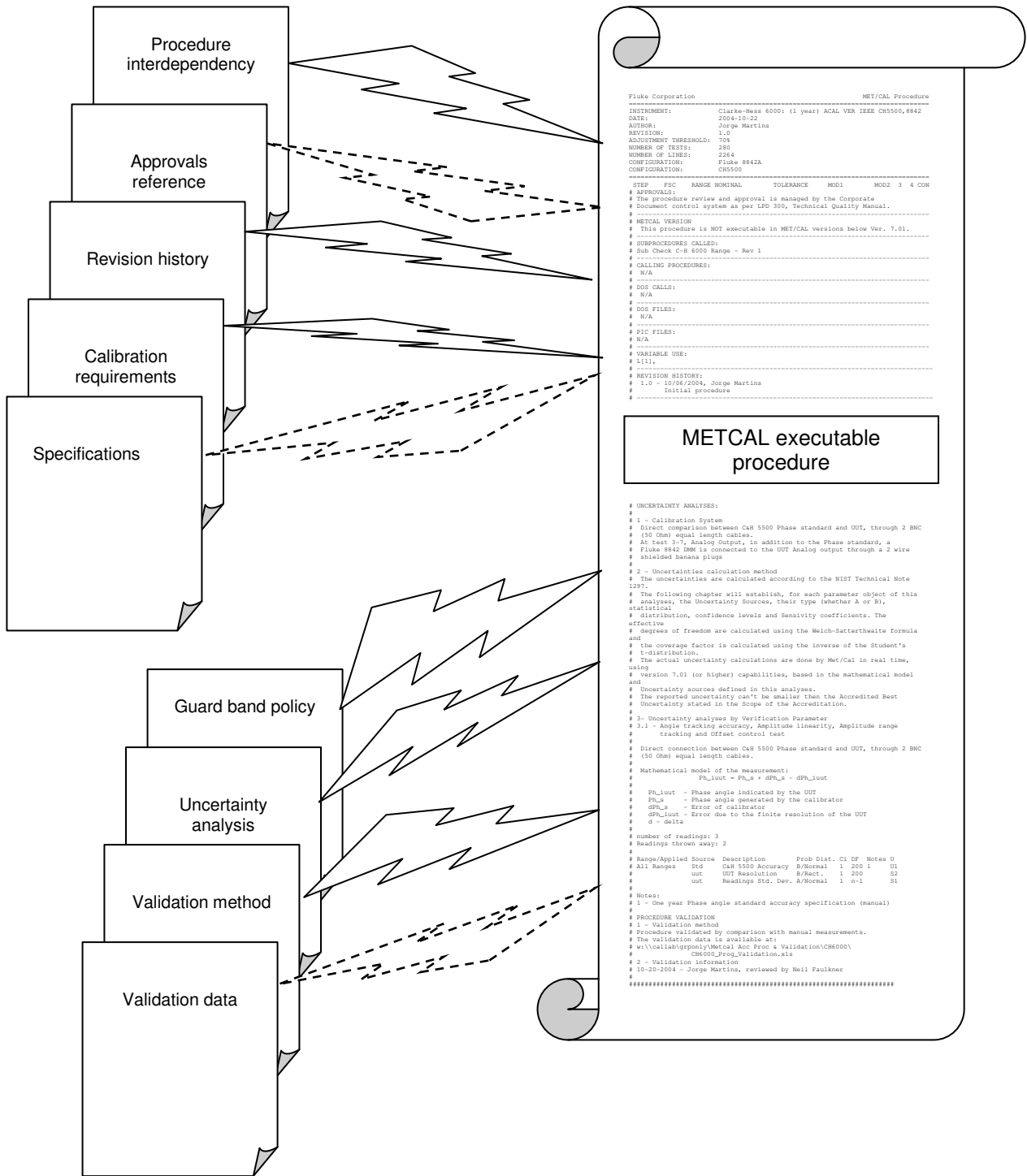
This paper describes how all these documents can be incorporated in a commercially available software product, greatly reducing the time spent on these essential tasks.

Introduction

The process of developing an accredited automated calibration procedure includes several phases.

1. Collection of information about the unit under test (UUT).
2. Definition of the initial calibration strategy and guard band policy.
3. Perform the preliminary uncertainty analyses in accordance with NIST technical note 1297.
4. Automatic calibration procedure that implements the uncertainty analysis and performs all the necessary calculations.
5. Uncertainty analysis and procedure validation.
6. Calibration procedure approval and release.
7. Laboratory staff training that, in the case of a properly developed automated calibration procedure, can be minimal.

To document these phases, the laboratory ends up with a collection of several documents. Since most of them are considered quality or technical records, they need to comply with ISO 17025 paragraphs 4.3 Document Control and 4.12 Control of Records among others.



It is not proposed that all relevant information that is already written elsewhere should be included inside the procedure. Instead it is proposed that a template be used to keep most of the necessary information or data integrated, consistent, referenced, and protected in the procedure itself. Since the laboratory wants to have an automated procedure, why not keep all the important information in one place and readily available to whom ever may need it, both for internal laboratory use or external assessment.

The challenge

Develop a fully automated procedure to calibrate the clarke-hess model 6000 Phase Meter which also includes all the necessary uncertainty analysis and information to comply with ISO17025 requirements in a single document. The elected software to support this procedure is MET/CAL® calibration management software.

As standards, we are going to use the clarke-hess model 5500 Phase Standard and the Fluke 8842A DMM with IEEE-488 interfaces for automated control.

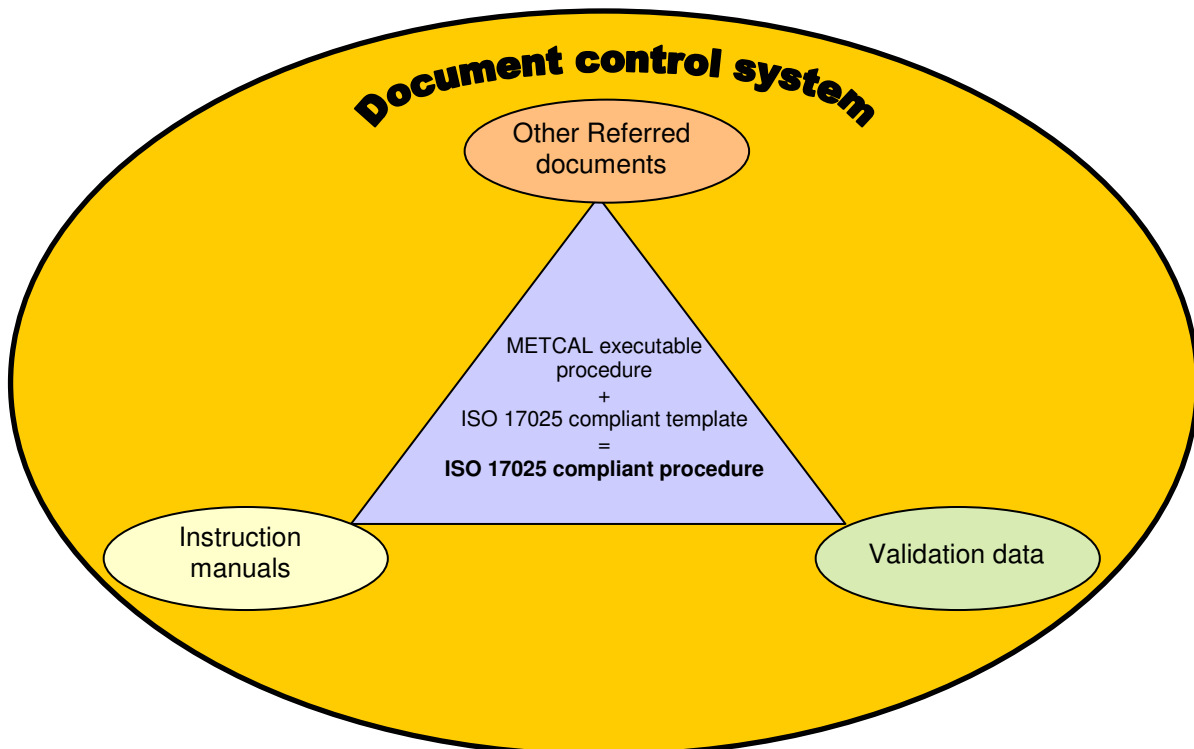
We are going to describe step by step how to achieve this goal. The automated calibration procedure used to exemplify the process is simple, although it offers some challenges that require the use of many features of the calibration software.

Other considerations

Once the MET/CAL calibration procedure is approved, it must be saved in a written protected directory to avoid any non authorized changes. The ISO 17025 document control requirement is fundamental to maintain accreditation and the laboratory commitment to sustain high levels of standardization and quality of service to the customers.

The calibration laboratory must be able to determine without any doubt the procedure used to calibrate a particular piece of equipment at any particular time. Nevertheless, this fact is not enough if it can't identify all the other information, references and engineering knowledge put in the procedure development and maintenance. Even worse, is its inability to keep that information consistent through the life of the calibration procedure.

It would be almost impossible and not even desirable to incorporate all necessary documents in the actual calibration procedure. It is not our aim to copy the user's or service manuals, specifications and the validation data into the calibration procedure, but we must know exactly what reference documents were used and presumptions were made. Those documents that are readily available in the laboratory can be simply referred to in the procedure, keeping in mind that they have to be unequivocally identified.



The supporting template

The MET/CAL procedure language is composed of a number of FSC's (Function Selection Codes) that comprise the executable part of the automated procedure. Since this software offers the possibility of adding non-executable text in the form of comments, we are going to take advantage of that to attach the necessary information and achieve our goal of building a ISO17025 compliant automated procedure.

After the basic MET/CAL header the following information should be added as comments (line starting with the character "#"):

Sub procedures called:
List all the sub procedures called by this procedure and include their revision. Note: MET/CAL saves in the MET/TRACK data base calibration record the version of the main procedure executed. However the subprocedure can have impact in the measurements performed or its execution, so it must be controlled as strictly as the main. If a subprocedure is reviewed the main must updated to reflect the changes. Since MET/CAL allows the user to define the version field, each lab can implement his own revision policy. At the Fluke service centers we are using the xx.yy format. It was decided that major revisions are the ones that have impact in the measurements or in the procedure execution. This implies a new validation and approval (change the integer portion of the revision field, i.e. 03.05 to 04.00). Minor changes need to be approved but don't require a full validation, (only the decimal portion of the field is updated i.e. 04.00 to 04.01).
Calling Procedures:
List all external procedures calling this procedure. Note: If this is a subprocedure, this is the list of procedures that must be updated.
External DOS Files:
List all external DOS Files called by this procedure (i.e. Correction files (.cor), value files (.val)). Note: Exhaustive list of all the correction files, value files and others, used in the procedure.
PIC files:
List of all pictures used.
INTRODUCTION AND PURPOSE:
Brief explanation about the scope of the procedure and the compliance with standards. Note: Also reference the source process that this procedure is implementing (i.e. Manufacturer's recommendations, international standards, accreditation body's policies and recommendations or other).
Approvals:
Reference the document that defines the laboratory's calibration procedure approval process. Note: In most calibration laboratories the approval process and responsibilities are detailed in the Quality manual and implemented using commercial document management software.

Revision history:
<p>x.z – mm/dd/yyyy – author Reason that triggered the revision and a succinct description.</p> <p>Note: the revision description must be enough to identify what was changed in the procedure and substantiate the attribution of a major or minor revision status.</p>
References:
<p>List the documentation that supports the development of the calibration procedure.</p> <p>i.e. UUT service manual number xxxx, revision yyyy Standard user's manual, dated mm/yy</p>
UUT Specifications:
<p>Reference the document that supports the stated specifications.</p> <p>i.e. According to UUT Service manual number xxxxxx revision yyyyyy</p>
Calibration Conditions:
<p>Reference to the calibration conditions that the laboratory must meet to perform this calibration in order to achieve the stated uncertainties. Minimum environmental requirements, accessories and other requisites.</p>

(The next elements can be inserted after the executable procedure)

Guard Band:
<p>Information about the guard band strategy implemented in this calibration procedure if any.</p> <p>Note: The guard band strategy doesn't have to be the same along the procedure; it can be different for diverse parameters or even within the same parameter. Use enough detail to make clear what strategy was implemented for each test.</p>

Uncertainty Analysis:

1 – Calibration System

Brief description of the calibration system implemented in this procedure.

Note: Enough detail should be provided about the model to support the subsequent uncertainty analysis

2 – Uncertainties calculation method.

The uncertainties are calculated according to the NIST Technical Note 1297.

The following section will establish, for each parameter object of this analysis:

- Uncertainty sources.
- Source type (whether A or B).
- Probability density functions.
- Confidence levels.
- Sensitivity coefficients.

The effective degrees of freedom are calculated using the Welch-Satterthwaite formula and the coverage factor is calculated using the inverse of the Student's t-distribution.

The actual uncertainty calculations are done by MET/CAL in real time, using version 7.1's capabilities, based on the mathematical model and uncertainty sources defined in this analysis.

3- Uncertainty analysis by calibration parameter

3.x – Parameter Y

Detailed description of the calibration system for this parameter.

Mathematical model of the measurement.

Number of readings: "Number of effective readings per measurement".

Readings thrown away: "Number of initial readings discarded".

(Budget header)

"Range" "Source" "Description" "Type/PDF" "Ci" "DF" "Notes" "U"

Note: Range – Applicable range.

Source – Source of uncertainty.

Description – identification of the uncertainty.

Type/PDF – type of uncertainty (A or B) and Probability distribution function associated with this uncertainty element.

Ci – Sensitivity coefficient.

DF – Degrees of freedom of this source.

Notes – Reference to complementary notes.

U – MET/CAL variable attributed to the uncertainty component (ex. U1, U4).

Procedure Validation

1 – Validation method

Brief description of the method used to validate the procedure. Validation data or reference to where it is available in the laboratory should also be included.

2 – Validation information

Provide information about: validation date, who did it, and who approved it.

Mathematical model

The calibration of the clarke-hess model 6000 Phase Meter is comprised of two parts with distinct mathematical models; one related with the phase calibration and the other with the calibration of the phase-to-voltage conversion performed inside the UUT.

1. Phase Uncertainty Evaluation



Measurement mathematical model:

$$\theta_{iuut} = \theta_s + \delta\theta_s - \delta\theta_{iuut}$$

θ_{iuut} - Phase angle indicated by the UUT.

θ_s - Phase angle generated by the calibrator.

$\delta\theta_s$ - Error of the calibrator.

$\delta\theta_{iuut}$ - Error due to the UUT.

Expanded uncertainty expression:

$$U = k \sqrt{\left(\frac{u_s}{2}\right)^2 + \left(\frac{u_{iuut}}{\sqrt{3}}\right)^2 + u_{rand}^2}$$

u_s - C&H 5500 Phase calibrator accuracy.

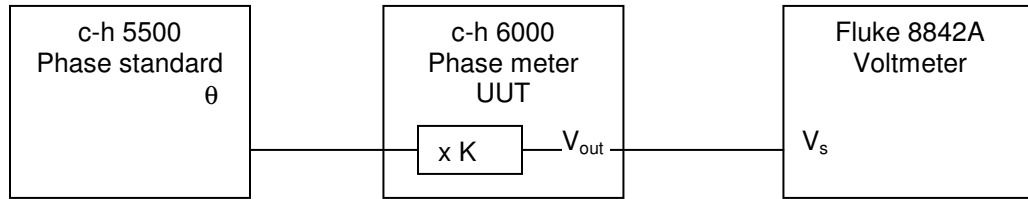
u_{iuut} - UUT resolution.

u_{rand} - Experimental Standard deviation of the readings.

k - Coverage factor.

Note: other sources of uncertainty were evaluated and found to be insignificant.

2. Analog Output Uncertainty Evaluation



Measurement mathematical model:

$$V_s = (\theta_s + \delta\theta_s) \cdot (K_{uut} + \delta K_{uut}) - \delta V_s$$

V_s - Voltage value indicated by the standard voltmeter.

δV_s - Error of the voltage indicated by the voltmeter.

θ_s - Phase angle generated by the calibrator.

$\delta\theta_s$ - Error of the calibrator.

K_{uut} - Phase-to-voltage conversion factor ($K = -10 \text{ mV/}^\circ$).

δK_{uut} - Error of the UUT phase-to-voltage output conversion.

$$\frac{\partial V_s}{\partial V_s} = 1 \quad \Rightarrow C_V = 1 \quad (\text{Voltage sensitivity coefficient}).$$

$$\frac{\partial V_s}{\partial \theta_s} = K_{uut} \quad \Rightarrow C_\theta = -0.01 \quad (\text{Phase sensitivity coefficient}).$$

Expanded Uncertainty expression:

$$U = k \sqrt{\left(\frac{u_s}{2} \cdot C_\theta\right)^2 + \left(\frac{u_{V_s}}{2} \cdot C_V\right)^2 + u_{rand}^2}$$

u_s - C&H 5500 Phase calibrator accuracy.

u_{V_s} - Voltmeter accuracy.

u_{rand} - Experimental standard deviation of the readings.

k - Coverage factor.

Note: other sources of uncertainty were evaluated and found to be insignificant.

Implementation

I'm going to present a possible implementation of the ISO 17025 compliant template in the original automated calibration procedure. This template can be implemented in any existent automated procedure provided that the software is able to be the complete uncertainty calculation engine and the user makes the necessary changes to enable it.

Some of the statements are closely tied with the calibration laboratory in which they were implemented. Every procedure must be evaluated and validated in the place where it is going to be used and with the resources and conditions available in the calibration laboratory.

Since we want to use the comment fields of MET/CAL to complete our documentation task, the uncertainty analysis must be documented without the benefit of an equation editor.

Proposed ISO 17025 compliant template to calibrate the clake-hess 6000 Phase Meter

Fluke Corporation
MET/CALProcedure

```
=====
INSTRUMENT:      Clarke-Hess 6000:(1 yr) ACAL VER IEEE CH5500,8842
DATE:            2004-10-22
AUTHOR:          Jorge Martins
REVISION:        1.0
ADJUSTMENT THRESHOLD: 70%
NUMBER OF TESTS: 280
NUMBER OF LINES: 2264
CONFIGURATION:   Fluke 8842A
CONFIGURATION:   CH5500
=====
```

```
=====
STEP   FSC   RANGE NOMINAL      TOLERANCE      MOD1      MOD2   3   4   CON
# SUBPROCEDURES CALLED:
# Sub Check C-H 6000 Range - Rev 1
# -----
# CALLING PROCEDURES:  N/A
# -----
# External DOS files:  N/A
# -----
# PIC FILES:
# PhaseConnections.jpg (ch5500 to ch6000 phase connections)
# PhaseVoltCon.jpg (Analog phase-to-voltage conversion connections)
# -----
# INTRODUCTION AND PURPOSE:
# The purpose of this procedure is to calibrate the clarke-hess 6000
# Phase Meter, according to the manufacturer's recommendations,
# published in Reference 1, Performance Tests.
#
# This procedure complies with the ISO 17025 requirements and the
# accreditation body policies.
# -----
=====
```

This section can be more or less detailed, depending on your quality manual and document control system.

APPROVALS:
The procedure review and approval is managed by the Corporate
Document control system as per LPD 300, Technical Quality Manual.

REVISION HISTORY:
1.0 - 10/06/2004, Jorge Martins
Initial release

References:
1. clarke-hess 6000 Phase Meter Instruction manual - Rev. 1996
2. clarke-hess 5500 Phase Standard Instruction manual - Rev. 1996
3. clarke-hess 5500 Errata sheet for 200 kHz modification of
model 5500 - Rev. 1996
4. Fax from clarke-hess providing official notification of 5500 new
specifications - dated 10 July 1996.
5. Fluke 8842A Digital Multimeter Instruction manual - Rev. 3, 7/96

UUT SPECIFICATIONS: According to Reference 1

CALIBRATION CONDITIONS:
Minimum warm-up period:
UUT - half-hour.
Standards - one hour
This procedure can be performed with an ambient temperature of 23 °C
±5 °C and a relative humidity equal or less than 80%.

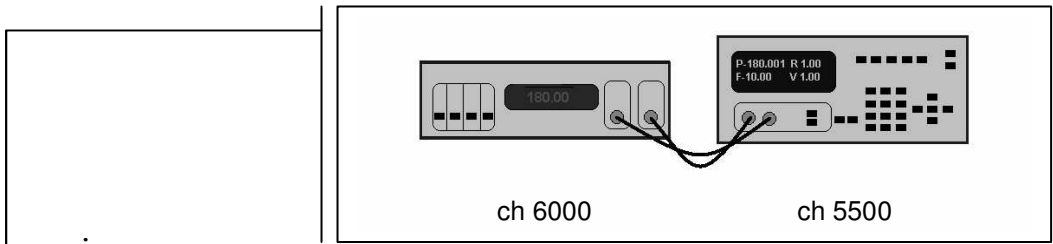
Cables: 2x Tektronix 012-0482-00, BNC (50 Ohm) cable or equivalent
with equal length.

GUARD BAND: N/A

UNCERTAINTY ANALYSES:

1 - Calibration System
Direct comparison between C&H 5500 Phase standard and UUT, through 2
BNC (50 Ohm) equal length cables.
At test 3-7, Analog Output, in addition to the Phase standard, a
Fluke 8842 DMM is connected to the UUT analog output through a 2
wire shielded banana plug.

2 - Uncertainties calculation method
The uncertainties are calculated according to the NIST Technical
Note 1297.
The following section will establish, for each parameter
object of this analysis, the Uncertainty Sources, their type
(whether A or B), the statistical distribution, confidence levels
and Sensivity coefficients.
The effective degrees of freedom are calculated using the Welch-
Satterthwaite formula and the coverage factor is calculated using
the inverse of the Student's t-distribution.
The actual uncertainty calculations are done by MET/CAL in real
time, using version 7.01 (or higher) capabilities, based on the
mathematical model and Uncertainty sources defined in this analysis.



```

.
.
# The reported uncertainty can't be smaller than the accredited best
# uncertainty stated in the scope of accreditation.
#
# 3- Uncertainty analyses by verification parameter
# 3.1 - Angle tracking accuracy, Amplitude linearity, Amplitude range
# tracking and Offset control test
#

```

```

# Direct connection between ch 5500 Phase standard and UUT, through 2
# BNC (50 Ohm) equal length cables.
#

```

```

# Mathematical model of the measurement:
# Ph_iuut = Ph_s + dPh_s - dPh_iuut
#

```

$$\theta_{iuut} = \theta_s + \delta\theta_s - \delta\theta_{iuut}$$

```

# Ph_iuut - Phase angle indicated by the UUT
# Ph_s - Phase angle generated by the calibrator
# dPh_s - Error of calibrator
# dPh_iuut - Error due to the UUT
# d - delta
#

```

$$U = k \sqrt{\left(\frac{u_s}{2}\right)^2 + \left(\frac{u_{iuut}}{\sqrt{3}}\right)^2 + u_{rand}^2}$$

```

# number of readings: 3
# Readings thrown away: 2
#

```

Range/Applied Source	Description	Prob Dist.	Ci	DF	Notes	U	
All Ranges	Std	C&H 5500 Accuracy	B/Normal	1	200	1	U1
	uut	UUT Resolution	B/Rect.	1	200		S2
	uut	Readings Std. Dev.	A/Normal	1	n-1		S1

```

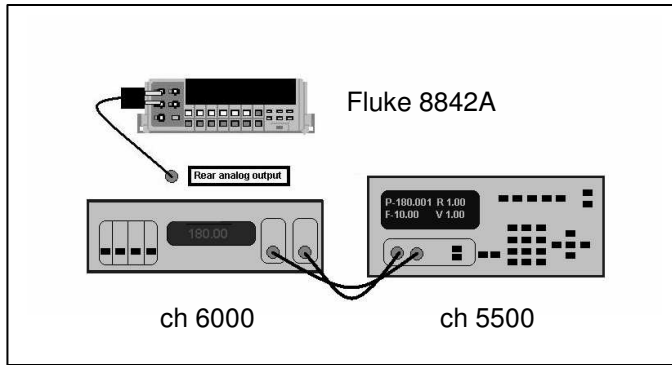
# Ci - Sensitivity coefficient
# DF - Effective degrees of freedom
# U - MET/CAL uncertainty components
#

```

```

# Notes:
# 1 - One year Phase angle standard accuracy specification (manual)
#
#
#

```



3.2 - Analog output test

Direct connection between C&H 5500 Phase standard and UUT, through 2 BNC (50 Ohm) equal length cables.
 # In addition to the Phase standard, a Fluke 8842A DMM is connected to the UUT analog output through 2-wire shielded banana plugs.

Mathematical model of the measurement:

$$V_s = (\theta_s + \delta\theta_s) \cdot (K_{uut} + \delta K_{uut}) - \delta V_s$$

$$V_s = (Ph_s + dPh_s) \cdot (K_{uut} + dk_{uut}) - dV_s$$

V_s - Voltage value indicated by the Standard voltmeter
 # Ph_s - Phase angle generated by the calibrator
 # dPh_s - Error of the phase standard
 # K_uut - Phase meter conversion factor (- 0.01 V/°)
 # dk_uut - Error of the analog output conversion
 # dV_s - Error of the voltage indicated by the Standard voltmeter
 # d - delta

number of readings: 3
 # Readings thrown away: 2

$$U = k \sqrt{\left(\frac{u_s \cdot C_\theta}{2}\right)^2 + \left(\frac{u_{V_s} \cdot C_V}{2}\right)^2 + u_{rand}^2}$$

Range/Applied Source	Description	Prob Dist.	Ci	DF	Notes	U	
All Ranges	PhStd	C&H 5500 Accuracy	B/Normal	-0.01	200	1, 2	U3
	VStd	voltmeter Accuracy	B/Normal	1	200	3	U1
	VStd	Readings Std. Dev.	A/Normal	1	n-1		S1

Ci - Sensitivity coefficient
 # DF - Effective degrees of freedom
 # U - MET/CAL uncertainty components

Notes:

1 - Sensivity coefficient due to the UUT Conversion factor (K=-10 mV/°)

pd(V_s)/pd(Ph_s)= K => Ci(Ph)=-0.01
 # pd(V_s)/pd(V_s)= 1 => Ci(V)=1
 # pd-partial derivative

2 - One year Phase angle standard accuracy specification (manual)
 # 3 - Fluke 8842A 90day spec, when offset control is not used (manual)

The MET/CAL "mfile" capabilities can be used to analyze and preserve the validation data. All the original readings and calculations are available in this file that can be exported to a spreadsheet for posterior analysis. The "mfile" file can also be used to debug the program and evaluate the uncertainty analysis with the actual readings.

```
.
.
#
# \PROCEDURE VALIDATION
# 1 - Validation method
#   Procedure validated by comparison with manual measurements.
#   The validation data is available at:
#   w:\callab\ MET/CAL Validation\CH6000\CH6000_Prog_Validation.xls
#
# 2 - Validation information
#   10-20-2004 - Jorge Martins, reviewed by Neil Faulkner.
#
#####
```

Although the template shown here is an uninterrupted list of statements, it can be broken into two or more segments to improve readability or to comply with particular laboratory requirements. In our application we have broken it in two parts, one at the beginning of the MET/CAL procedure contains the more generic information and requirements. The second, because it is more technical it can be inserted at the end of the executable procedure.

Anyhow, this is just a cosmetic decision and not a technical requirement as long as all the necessary information is readily available or referenced in the procedure.

```
# SUBPROCEDURES CALLED:
...
# CALIBRATION CONDITIONS: } First part of the template

MET/CAL Automated procedure

# GUARD BAND
# UNCERTAINTY ANALYSES
#PROCEDURE VALIDATION } Second part of the template
```

Conclusion

It is possible to build an automated calibration procedure that keeps all the necessary information and data integrated, consistent, referenced, protected and readily available.

It is out of the scope of this paper to provide detailed information on how to implement the automated measurement portion of this template with the MET/CAL FSC's. It can be implemented with any automated calibration software that is able to perform the necessary uncertainty calculations at run time, according with the NIST technical note 1297.

The basic steps to implement this process are:

1. Establish the calibration process.
2. Invest the necessary resources and know-how to develop a complete uncertainty analysis (with the mathematical model and the expanded uncertainty expression).
3. Fill the ISO/IEC 17025 compliant template to preserve the available information.

4. Develop the automated calibration procedure that is also the whole uncertainty calculation engine. In this step it is essential that what you have established in the uncertainty analysis is meticulously implemented. Say what to do and do what you say.
5. Define a comprehensive validation process.
6. Use the "mfile" or other form of results to document the validation process.
7. Perform the review and approval process.
8. Update the ISO 17025 compliant template with the last data.
9. Release the procedure.

Although the development of this ISO 17025 template is fairly new in our laboratory, we have already implemented it in several calibration procedures with success. I'm certain that it is a useful tool to improve the laboratory's quality of service.

This template is a live document that can be improved through the laboratory's experience and meet other requirements.

References:

- [1] ISO/IEC 17025:1999(E), "General requirements for the competence of testing and calibration laboratories".
- [2] NIST technical note 1297: 1994 edition, Guidelines for Evaluation and Expressing the Uncertainty of NIST Measurement Results.
- [3] clarke-hess model 5500 phase standard instruction manual
- [4] clarke-hess model 6000 phase meter instruction manual
- [5] Fluke 8842A digital multimeter instruction manual, Rev. 3 7/96
- [6] Nicholas, Matthew,
Guardbanding Using Automated Calibration Software,
NCSLI 2004
- [7] Nicholas, Matthew,
Implementing ISO 17025 Measurement Uncertainty Requirements in Software
NCSL 1999