

CALIBRATION DATA MANAGEMENT: MEETING THE REPORTING REQUIREMENTS OF ISO/IEC FDIS 17025.

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Abstract - ISO Guide 25, General Requirements for the Competence of Testing and Calibration Laboratories requires the collection and reporting of various information about instruments calibrated by a metrology laboratory. Many Metrology Laboratories are using personal computers (PCs) connected to increase productivity and collect and report information required by the standards.

This paper discusses PC based tools to assist in the collection and reporting calibration information required by ISO17025 such as estimates of measurement uncertainty, calibration certificates, and calibration reports. Shown are examples using commercial Calibration and Asset Management software.

INTRODUCTION

This paper is about collecting and reporting quality information using computer software in the calibration lab. This task could be accomplished with paper and pencil, but the advantages of automating data collection and reporting have been previously documented [1].

It is based on examining the data collection and report requirements of ISO/IEC FDIS 17025: General Requirements for the Competence of Testing and Calibration Laboratories. Calibration laboratories that comply with ISO/IEC17025 also comply with ISO 9001:1994 or ISO 9002:1994[2].

SECTION 4.3.1 GENERAL DOCUMENT CONTROL

The first references to software we find are in section 4.3.1 Document Control.

4.3.1 General

*The laboratory shall establish and maintain procedures to control all documents that form part of its quality system (internally generated or from external sources) such as regulations, ... **software**, specifications, instructions, and manuals[2].*

From this section we see that the standard considers software a document to be controlled. Note 2 refers us to section 5.4.7 and 4.12 for additional information.

Continuing on, section 4.3.2.1 states:

4.3.2.1 All documents issued to personal in the laboratory as part of the quality system shall be reviewed and approved for use by authorized personnel prior to issue [2].

Since software is considered to be a document, this means that all software must go through a review and approval process before it can be used in a laboratory. This review process is straightforward for a primary software package such as Fluke Metrology Software or other packages. The laboratory compares features between different packages and examines sample software available from the manufacturer. The laboratory can also consult other users of the software packages or attend user group meetings to see what kinds of issues arise for users of each package. Laboratory personnel can then make a decision on the suitability of a particular software package.

However, "calibration" software typically allows the user to create calibration procedures or scripts, or uses external files, such as accuracy files, to provide information to the software. These procedures and external files are often written by the laboratory, or are provided "as is" by the manufacturer. For a lab to comply with ISO 17025, these procedures and files must be reviewed and approved before they can be used to for calibration. This topic is discussed in more detail in section 5.4.7, Control of Data.

The remainder of section 4.3 states that documents (software) should be periodically reviewed to make sure they are still suitable, that the lab has procedures in place to ensure that personnel are using the correct version, and that change control procedures are in place [2].

SECTION 4.9 CONTROL OF NONCONFORMING CALIBRATION WORK

Section 4.9.1 discusses the need to control nonconforming calibrations and states "where necessary, the client is notified and work is recalled [2]." Suppose a standard is found out-of-calibration? It would be nice to automatically print notices to all users whose calibration may have been affected. This requires a reverse traceability report to identify the affected equipment.

Reports can be performed on the PC using off-the-shelf software. If the database has an open architecture then a variety of tools can be used to query the database and print these reports. Fluke Metrology Software is Microsoft Open Database Connectivity (ODBC) compliant [3]. This means reports can be made using tools like Microsoft™ Word™, Excel™, Borland™ ReportSmith™, Crystal Reports™, or many other tools.

Fluke Metrology Software uses Crystal Reports™ as its reporting mechanism [3]. The report examples shown in this document are Crystal Reports and were printed by the Fluke Metrology Software Manual Entry application. An example of a reverse traceability report is shown in figure 1.

Figure 1 is the top of a simple reverse traceability report for instrument R4. Each level of instrumentation is indented to show the next level of calibration. For example, instrument R4 directly calibrated instrument 752, while 752 calibrated 5500-2. The calibration date is shown for each instrument. This allows for the retrieval of detailed information about an instrument.

Reverse Trace Report

Date Printed 17-Nov-95

Data field presentation: Asset No, Mfg, Model, Desc, Serial No, Cal Date, Cal Time, Due Date,

Subject Asset: R4 FLUKE 742-10K 10K OHM RESISTANCE STANDARD TE:

2	_____	752	FLUKE 732A VOLTAGE STANDARD, DC TEST	3/15/95 00:00:00	4/14/95 00:00:00
3	_____	5500-2	FLUKE 5500A CALIBRATOR, MULTIPRODUCT TEST	4/12/95 00:00:00	5/12/95 00:00:00
4	_____	R2	FLUKE 742-1 1 OHM RESISTANCE STANDARD TEST	4/16/95 00:00:00	6/2/95 00:00:00
5	_____	8842A	FLUKE 8842A DMM: 5 1/2 DIGIT TEST	5/2/95 00:00:00	6/2/95 00:00:00

Figure 1. Reverse Traceability Report for Asset R4.

SECTION 4.12: CONTROL OF RECORDS

The next section of interest 4.12.1.4 states:

4.12.1.4 The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records [2].

In no uncertain terms, this means that the laboratory MUST have a documented procedure to back-up the data on their computer system. A very good backup system is described in chapter 2 of the Fluke Metrology Software Users Manual [3].

In addition, the software system must prevent access or modification of the data by unauthorized users. This is easily accomplished by using Fluke Metrology Software, because it uses an SQL Client/Server Database.

In the client server environment, only the data engine can read and write to the data file. The data file is typically placed on a computer that users do not have access to. The data engine controls all access to the data by requiring users to login using a username and password.

Security enforcement is compromised in a flat-file database by auxiliary programs that can be used to directly edit the data file and change calibration information.

SECTION 5.4.6 ESTIMATION OF UNCERTAINTY OF MEASUREMENT

We now move on to section 5, technical requirements. Section 5.4.6, Estimation of uncertainty of measurement requires that all laboratories analyze measurement uncertainty.

5.4.6.1 A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.

5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation, shall be taken into account using the appropriate methods of analysis [2].

Fluke Metrology Software version 6.0 product can provide this capability required by section 5.4.6. An overview of how Fluke Metrology Software handles measurement uncertainty is discussed here.

At the top level, the measurement uncertainty calculation is simply:

$$\text{Expanded Uncertainty} = EU = K * SU$$

where K is the coverage factor,
and SU is the Standard Uncertainty.

The Standard Uncertainty is:

$$SU = \sqrt{U1^2 + U2^2 + U3^2 + \dots + U10^2}$$

$U1$ is the Normalized System Accuracy, based on the accuracy of the calibration standard and is determined automatically by the software.

$U2$ is uncertainty of the UUT based on a sequence of actual measurements and the resolution of the UUT and is determined automatically by the software.

$U3$, $U4$, $U5$, $U6$, $U7$, $U8$, $U9$, and $U10$ are optional uncertainty components that may be specified by the laboratory. If not specified, they default to zero and do not affect the uncertainty calculation.

For a complete discussion of how Fluke Metrology Software provides measurement uncertainty capability, see "Implementing ISO 17025 Measurement Uncertainty Requirements in Software".⁴ Most parameters used in the measurement uncertainty calculation can be overridden at the procedure level.

SECTION 5.4.7 CONTROL OF DATA

Paragraph 5.4.7 Control of Data states:

5.4.7.2 Where computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

a) computer software developed by the user is documented in sufficient detail and suitably validated as being adequate for use;

b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission, and data processing;

c) computer and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data [2].

Subparagraph c is straightforward. Computer equipment must be in good working order and used within the environmental conditions to which it was designed.

Subparagraph b discusses how data is handled. Part of this paragraph is very similar to section 4.12.1.4 discussed earlier, and essentially means that you should have a good backup system. You should also have a computer system that allows you to control user access, who can change the data, and keep out unauthorized users.

According to subparagraph a, any software written by the lab needs to be validated that it is suited to the task. At a minimum, this requires user documentation, a test plan, and proof that the test plan was executed.

The note for section 5.4.7.2 is useful, stating that "Commercial off-the-shelf software ...in general use within its designed application range may be considered sufficiently validated" [2]. This means that programs like Fluke Metrology Software may be used with their default

configuration without any additional validation work.

It is important to read the rest of the note “However, laboratory software configuration/modifications should be validated as in 5.7.4.a” [2]. Many of the software packages today, including Fluke Metrology Software, are highly customizable. This means that if the laboratory changes the product from its default configuration, it needs to validate that the changes from the default configuration work as expected, and that the changes do not adversely affect the adequacy of the software.

One final comment on user developed software is the point previously discussed about calibration procedures and external files. Commercial calibration software allows the laboratory to write calibration procedures or scripts or to modify many of the input data sets for the software [3]. These procedures and modifications are considered to be software. Thus, for a lab to comply with ISO 17025, these procedures must also be documented and validated before they can be used for calibration.

SECTION 5.5 EQUIPMENT

Paragraphs 5.5.4 and 5.5.5 address data collection requirements. These paragraphs are:

5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:

a) identity of the item of equipment and its software;

b) manufacturer’s name, type identification, and serial number or other unique identification;

c) checks that equipment complies with the specification (see 5.5.2);

d) current location, where appropriate;

e) the manufacturer’s instructions, if available, or reference to their location;

f) dates, results, and copies of reports and certificates of all calibrations, adjustments, acceptance criteria; and due date of next calibration;

g) maintenance plan, where appropriate, and maintenance carried out to date;

h) damage, malfunction, modification or repair to the equipment [2].

These paragraphs list specific data elements the database must maintain. These elements are divided into 4 types of information: Inventory, calibration, location, and maintenance information.

Inventory information is information about an instrument or asset that does not change over time. These are listed in paragraph 5.5.4, 5.5.5.a, 5.5.5.b, 5.5.5.e, and part of 5.5.5.g. Information about where the asset is, or location information is called out in 5.5.5.d. 5.5.5.c, and 5.5.5.f requires calibration information. Repair and maintenance information is called out in 5.5.5.g and h.

Therefore, we need to gather inventory data, and calibration, location, and repair data over time to satisfy ISO 17025.

The Fluke Metrology Software product has been designed to gather these required data elements. It can also gather other information, since we may want information in addition to that required by the standard.

Figure 2 shows an example Inventory data entry form. The title bar on the form shows this is the inventory form, that the user is changing asset number SAMPLE-11. Note that the date is shown using decimals for separators, allowing customization for local configurations in different countries.

Linked validation is superior to having a validation list for each field. First, it reduces the amount of entry the user has to make, but more importantly it guarantees that the data makes sense. For example, 5700 may be a valid model, and GAGE BLOCK may be a valid description, but they do not make sense if these values both appear for the same instrument. The linking and validation values of fields are under user control.

The screenshot shows a software window titled 'Inventory 11 of 14'. The menu bar includes 'File', 'Search', 'Record', 'Form', 'Field', and 'Help'. Below the menu is a toolbar with navigation and action icons. The main form area contains several input fields and dropdown menus. The 'Manufacturer' dropdown is open, showing a list of manufacturers: AGILENT, FLUKE (highlighted), HART, and HOKE. Other fields include 'Asset Number' (SAMPLE-11), 'Model' (11), 'Serial Number' (1100110001), 'Description' (DIGITAL MULTIMETER), 'Interval' (D), 'Interval Units' (6), 'Trace Code' (6), 'Options' (NONE), 'Acquisition Date' (08.14.1994), 'Purchase Cost' (79.95), 'P.O. Number' (95485812), 'Default Calibration Procedure Name' (FLUKE 11: (1 YEAR) CAL VER /5500), 'Arrive Date' (11.09.1999), 'Status' (ACTIVE), 'Calibration Seal OK' (Y), and 'DB Subset' (MT).

Figure 2. Inventory Manual Data Entry Form.

The data elements required by ISO/IEC 17025 are present. Of special interest is the "validation" box that is open on the model field where only models listed in the box are allowed as valid entries in the field. In addition, there can be "linked" fields. For example, we could link the model to the manufacturer and description fields. This would mean that if the operator enters 3458, the manufacturer field will be automatically filled in with AGILENT and the description field will be automatically filled in with DIGITAL MULTIMETER.

Figure 3 shows an example of Calibration data entry form. The form contains the date and time of calibration, its pass/fail status, when it is due, the standards used, and many other pieces of information.

Calibration SAMPLE-11 7 of 7

File Search Record Form Field Help

Cal-date: 06/04/1999 Cal-Time: 18:11:00 Pass: Y Due-Date: 06/02/2000 Due-Time: 18:11:00 Marginal Test: 0

Work Order: 087987 Temp: 23.5 Humidity: 24 Interval: 365 Interval Units: D Failed Tests: 0

Calibration Procedure Used
FLUKE 11: (1 YEAR) CAL VER /5700

Comment

Standards Used
SAMPLE-5500 FLUKE 5500A CAL

Figure 3. Calibration Data Entry Forms.

Similar forms are available for calibration results, location, repair and customer information. This covers data collecting but what does the standard say about data reporting? There are several sections that discuss reporting.

SECTION 5.6 MEASUREMENT TRACEABILITY

Section 5.6.1 requires the lab to “have an established programme and procedure for the calibration of its equipment” [2]. The note for this section indicates that the

program should include a system for selecting and maintaining standards and equipment used to perform calibrations. One aspect of such a program is the periodic recall of instruments when they are due for calibration. It would be useful if a software system could print some kind of recall for calibration report.

Figure 4 is a partial example “Due for Calibration Report.” This report identifies everything due and overdue for calibration. Overdue items are shown with a * character in the left column.

Calibration Due By Asset For 5 Days

Active assets due for calibration through: 22-Nov-95

Past Due					
Asset Number	Mfg.	Model	Description	Dept.	Location
* 123456789X123	STATIC				
* 0123456789123	FLUKE				
* R4	FLUKE	742-10K	10K OHM RESISTANCE STANDARD		
* 5500-2	FLUKE	5500A	CALIBRATOR, MULTIPRODUCT		
* R1	FLUKE	742-1	1 OHM RESISTANCE STANDARD		
* 102	FLUKE	8842A	DIGITAL MULTIMETER		
* 752	FLUKE	732A	VOLTAGE STANDARD, DC		
* 5700	FLUKE	5700A	CALIBRATOR, MULTIFUNCTION		
* 732	FLUKE	732A	VOLTAGE STANDARD, DC		
* 5500-1	FLUKE	5500A	CALIBRATOR, MULTIPRODUCT		
* R5	FLUKE	742-10K	10K OHM RESISTANCE STANDARD		
* R2	FLUKE	742-1	1 OHM RESISTANCE STANDARD		
* 8842A	FLUKE	8842A	DMM: 5 1/2 DIGIT		
* 901	HOKE	36	GAGE BLOCK SET, 0.05 TO 4.0 IN		
* 900	HOKE	36	GAGE BLOCK SET, 0.05 TO 4.0 IN		
* 555	FLUKE	77	DMM		

Figure 4. Calibration Due and Overdue Report.

Section 5.6.2.1.1 states that calibration laboratories shall ensure that measurements are traceable by an “unbroken chain of calibrations or comparisons linking them to relevant primary standards [2]”. One way to ensure this traceability is a forward traceability report.

Figure 5 is an example Forward Traceability Report. It shows an unbroken chain from asset 8842A to the local standards that were sent to the vendor for calibration. As with the reverse traceability report, each level of instrumentation is indented. Note that this report has identified two circular

calibrations for this asset, a serious problem. One of the circular calibrations is an endless calibration, meaning one instrument in the chain points to a calibration event already in the chain. This is shown by asset 5500-1 calibrating itself using the calibration event of 5/1/95 both times. The other circular calibration is not quite as serious, as two different calibration events are in this chain. Asset 5700 (cal-date 4/30/95) is calibrating itself using a different calibration event on 4/10/95.

Forward Trace Report

Date Printed 17-Nov-95

Trace depth limit: 25

Data field presentation: Asset No, Mfg, Model, Desc, Serial No, Cal Date, Cal Time, Due

Subject Asset: 8842A FLUKE 8842A DMM: 5 1/2 DIGIT TEST 5/ 2/95

2	_____5500-1 FLUKE 5500A CALIBRATOR, MULTIPRODUCT TEST 5/ 1/95 00:00:00 6/ 1/95 00:00:00
3	_____732 FLUKE 732A VOLTAGE STANDARD, DC TEST 5/ 1/95 00:00:00 6/ 1/95 00:00:00
4	_____R5 FLUKE 742-10K 10K OHM RESISTANCE STANDARD TEST 5/ 1/95 00:00:00 6/ 1/95
5	_____5500-1 FLUKE 5500A CALIBRATOR, MULTIPRODUCT TEST 5/ 1/95 00:00:00 6/
	Endless circular calibration detected, see line 2
6	_____5500-2 FLUKE 5500A CALIBRATOR, MULTIPRODUCT TEST 4/ 12/95 00:00:00 5/ 12/95 00:00:00
7	_____752 FLUKE 732A VOLTAGE STANDARD, DC TEST 3/ 15/95 00:00:00 4/ 14/95 00:00:00
8	_____R4 FLUKE 742-10K 10K OHM RESISTANCE STANDARD TEST 3/ 1/95 00:00:00 3/ 31/95
9	_____VENDOR
10	_____5700 FLUKE 5700A CALIBRATOR, MULTIFUNCTION TEST 4/ 30/95 00:00:00 5/ 30/95 00:00:00
11	_____752 FLUKE 732A VOLTAGE STANDARD, DC TEST 4/ 20/95 00:00:00 5/ 19/95 00:00:00
12	_____R1 FLUKE 742-1 1 OHM RESISTANCE STANDARD TEST 4/ 15/95 00:00:00 5/ 15/95 00:00:00
13	_____5700 FLUKE 5700A CALIBRATOR, MULTIFUNCTION TEST 4/ 10/95 00:00:00 5/ 11
	Circular calibration detected, see line 10
14	_____VENDOR

Figure 5 Forward Traceability Report

SECTION 5.10 REPORTING THE RESULTS

Paragraph 5.10.2 Test reports and calibration certificates, lists 11 (a through k) items that should be found on a calibration certificate.

Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:

a) a title, (e.g. "Test Report" or "Calibration Certificate);"

b) name and address of the laboratory, and location where the tests and/or calibrations were carried out if different from the address of the laboratory;

c) unique identification of the test report or calibration certificate (such as serial number) and on each page an identification in order to ensure that the page is

recognized as part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;

d) name and address of the client;

e) identification of the method used;

f) description, condition, and unambiguous identification of the item(s) tested or calibrated;

g) date of receipt of test or calibration item(s) where critical to the validity and application of the results and date(s) of performance of the test or calibration;

h) reference to sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;

i) test or calibration results with, where appropriate, the units of measurement;

j) the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;

k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated.

5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:

a) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;

b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;

c) evidence that the measurements are traceable (see 5.6.2.1.1 note 1) [2].

Figure 6 shows a calibration certificate generated by Fluke Metrology Software for asset sample-11. The items called out in paragraph 5.10 are visible, such as the title, identification of the instrument, name and address of the client and laboratory, calibration results with measurement uncertainty, and evidence that the measurements are traceable.

Calibration Certificate

My Calibration Company
1234 Cal Lane
Somewhere ST, 98199

UNIT UNDER TEST:	FLUKE 11 DIGITAL MULTIMETER	TEST RESULT:	PASS
SERIAL NUMBER:	1100110001	PERFORMED ON:	10 Nov 1999
ASSET NUMBER:	SAMPLE-11	DATA TYPE:	FOUND-LEFT
PROCEDURE NAME:	voltage tests w/ uncertainty	TEMPERATURE:	23.5°C
PROCEDURE REV.:		HUMIDITY:	25 %
CALIBRATED BY:	User Fluke5		
P.O. NUMBER:			
CUSTOMER:	MY CUSTOMER Wong Way Somewhere ST 50001		

My Calibration Company certifies that the above listed instrument meets or exceeds all specifications as stated in the referenced procedure (unless otherwise noted). It has been calibrated using measurement standards traceable to the National Institute of Standards and Technology (NIST), or to NIST accepted intrinsic standards of measurement, or derived by the ratio type of self-calibration techniques.

This report may not be reproduced, except in full, unless permission for the publication of an approved abstract is obtained in writing from the calibration organization issuing this report.

Standards Used

Asset	Description	CAL DATE	CAL DUE DAT
SAMPLE-5500	FLUKE 5500A CALIBRATOR	1 Jan 1999	19 Jun 2001

Test Data

PARAMETER	ASSIGNED	NOMINAL	UNCERTAINTY
1.000V	1V	1.00633V	0.00735611
10.00V	10V	10.0133V	0.00882607
100.0V	100V	100.06V	0.0987338
1000V	1kV	1000.33V	1.45341
1.000V @ 60Hz	1V	1.00633V	0.00735879
10.00V @ 60Hz	10V	10.0333V	0.133487
100.0V @ 60Hz	100V	100.033V	0.14972
1000V @ 60Hz	1kV	1000V	0.686867

End of Test Data

Signed: _____

REPORT OF CALIBRATION for

SERIAL NUMBER: 1100110001

ASSET NUMBER: SAMPLE-11

PRINTED ON: 10 Nov 1999

1 of 1

Figure 6. Calibration Results Report.

CONCLUSIONS

This paper has examined the requirements for data collection and reporting as described by ISO 17025. Inventory, Customer, calibration history, location history, and maintenance history data need to be collected about instruments calibrated and used for calibration. In addition, the calibration results must report measurement uncertainty.

Four different types of reports are necessary to satisfy the standard. We may need more reports for other purposes. These reports are:

Report	Section	notes
Calibration certificate	5.10	Need all data.
Due for calibration	5.6.1	Determine instruments that have exceeded calibration interval.
reverse traceability report	4.9.1	Identify all the instruments that are affected.
Forward traceability report	5.6.2	Show unbroken chain of traceability from an instrument to national standards.

These data collection and reporting requirements can be performed by the Fluke Metrology Software package. This package will assist your lab in meeting the requirements of ISO/IEC FDIS 17025.

References.

[1] Mason, Nicholas, "Software Strategies for On-Site Calibration." Measurement Science Conference: 1999 Workshop and Symposium, MSC, Anaheim, CA, 1999.

[2] ISO/IEC FDIS 17025 – General Requirements for the Competence of Testing and Calibration Laboratories", ISO/IEC, April 10, 1999.

[3] Metrology Software Users Manual, Fluke Corporation, Everett, WA, July 1999.

[4] Nicholas, Matt, "Implementing ISO 17025 Measurement Uncertainty Requirements in Software." NCSL Conference, Charlotte, SC, 1999.