Calibration DATA Management System Conforming to ISO17025

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Abstract

There has been much progress in powerful, generic software products for organizing work. However, in the calibration laboratory many tasks are still done by hand or not at all.

- Unable to down load the working standard data in graphical form.
- Visual trend analysis of calibration data is not available.
- Historical data (if available) is in various formats on individual test stations.
- Environmental data recorded manually (Humidity, temperature) or paper records from a chart recorder.
- Customer information recorded manually, even for returning customers.

Does this describe a laboratory environment for which you are responsible?
This paper will describe how the Measurement Standards Center of Agilent Technologies International Japan, Ltd. addressed these issues. By creating a user friendly custom application constructed on the MS Word, MS Excel and MS Access platforms, we have improved our systems to store and re-use consistent data about calibrations from a common data base. As a result, improved quality and efficiency have proven to be a bountiful return on this investment.

1. Introduction

The overarching goal for calibration laboratory automation is simplification of the total calibration processes from receiving a calibration item to shipping it. We did not have a system to address that need. There were many data entry and handwriting tasks. In some cases, we had to input the same data multiple times into different processes. We needed to look at the calibration laboratory as a whole, before we could make permanent efficiency improvements. Surprisingly, these improvements only required tools from the Microsoft Office® platform with simple programs written in Visual Basic® for Applications (VBA). As a result we have simplified our processes, supply a high quality certificate of the calibration and view the historical data graphically. This paper is a chronicle of that development by process.

2. Current situation analysis

While preparing a certificate of the calibration much data is generated from many different actions. Not just the measurement process creates information, but also the administrative process creates customer information and traceability information to be tracked. That was why we reviewed the entire customer transaction fulfillment process from receiving the item to shipping it. We will call this process the "Total Calibration". Figure 2-1 depicts the overview.

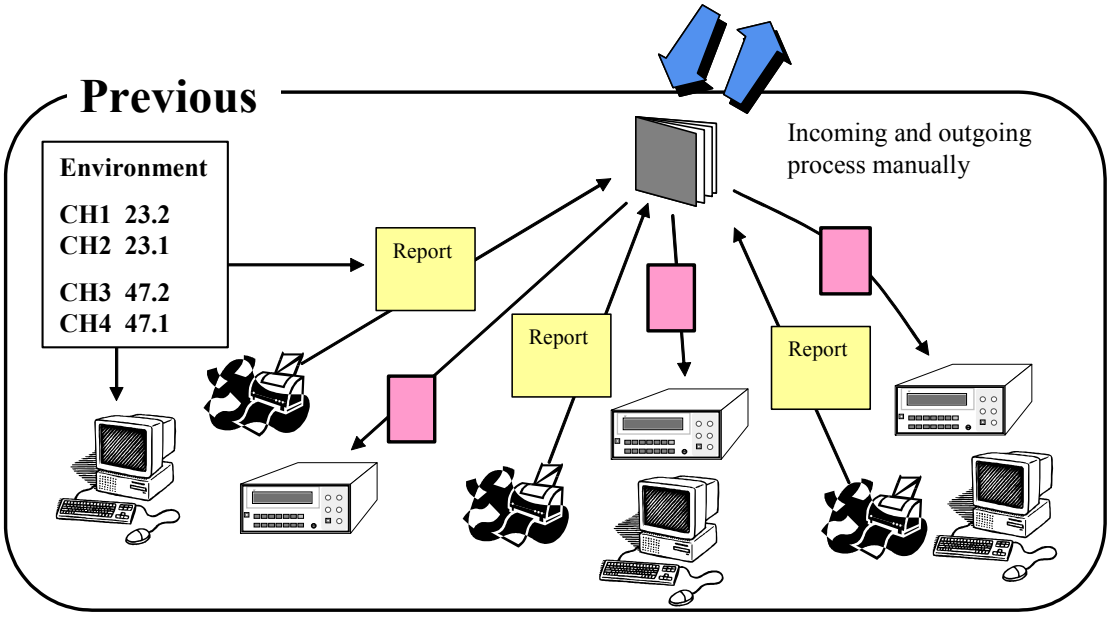

Figure 2-1. Overview of the obsolete Total Calibration process

Using this more comprehensive view, the current situation analysis leads us to define problems in a new way. The following is a description of those observations that are summarized in table 2-1.
[Tasks of the administrators]

- They had to put the user and calibration information into the calibration's performance schedule sheet at incoming and outgoing manually. (a-1, c-1)
- They had to put the user-model information into the small tag sheet which was attached calibration items manually. (a-2)
- They had to create the accounting and the shipping information manually. (c-2)

[Tasks of the technicians]

- They had to input the user information into the calibration system manually. (b-1,6)
- They had to input environmental data into the calibration system manually. (b-2,6)
- They had to update the standard data in each calibration programs. (b-3)
- They had to compare the calibration results to the previous results manually. (b-4)
- They had to assign the calibration number just before issuing the certificate manually. (b-5)
- They had to put the information into the calibration re-call and re-trace system respectively. (c-3, c-4)

- They had to plot the standard data to a spread sheet to watch the stability and the trend at the individual test station. (c-5)

[Tasks of calibration systems (engineers)]

- It was a labor intensive task to take back up data by each local calibration system. (b-7)
- It was hard to re-issue the certificate of calibration because each system had its own electrical data saving format. (b-8,10)
- There was a need to update an obsolete PC and printer. (b-9)
- They had to maintain the software for issuing the certificate. (b-10)

[Task of manager]

- Manager signature on the certificate was hand written. (c-6)

Table 2-1. Problem analysis from the process

Process and Tasks	Admin.	Technician	Engineer (System)	Manager
a. Process at Incoming				
• Record administrator information	a-1, Manually			
• Make information tag	a-2, Manually			
b. Process at Calibration (Each system)				
• Input use information		b-1, Manually		
• Input environmental data		b-2, Manually		
• Input Using Equipment (Standard) data		b-3, Manually		
• Measure the item (Calibration)				
• Store data and issue the data sheet		b-4, Manually	b-7, Hardware b-8, Software	
• Assign the calibration number		b-5, Manually		
• Issue the certificate from LOCAL Printer		b-6, Manually	b-9, Hardware b-10, Software	
c. Process at Outgoing				
• Record administrator additional information	c-1, Manually			
• Sign to the certificate				c-6, Manually
- For External Item -				
• Ship the item				
• Make the accounting report	c-2, Manually			
- For Internal Item -				
• Put data to re-call system		c-3, Manually		
• Put data to re-trace system		c-4, Manually		
• Put data to historical graph		c-5, Manually		

Two projects were defined to be performed consecutively (as resources permitted)
Project #1: Improve the quality of the certificate (see chapters 3 and 4)
Project #2: The Historical Data Graph (see chapters 5)

3. Project #1: Improve the quality of the certificate

We defined the purpose of the first project to improve the quality of the certificate of the calibration. That includes an intent to standardize and simplify the certificate issuing system, to decrease manual job input and transcription errors and to make a stable system for editing and changes.

At the same time we had to consider time, cost and security constrains, maintain backward compatibility, and to conform to ISO 17025. Therefore Project #1 components should include:

- using common data disc which can be accessed from all individual calibration systems,
- using the most useful applications for the individual process,
- using the temporary text files for communication between the different applications,
- minimizing the change for the existing applications and
- declaring the purpose and the tasks in details for each of the 4 process improvements (3.2 through 3.5).

3.1 Base Improvement

We prepared the base infrastructure before proceeding with Project #1 as shown in Table 3-1.

Table 3-1. Total Calibration System Overview

	System	Hardware	Software (New/Re-making/Continuous)	necessary condition
3.1	**Data Hard Disc**	**Network Hard Disc**		**security** **LAN connection**
3.2	**External Calibration Tracking** **Internal Calibration Tracking**	**PC**	**MS Access (New)** **-**DB software-	**text output** **LAN connection**
3.3	**Environment Measurement**	**Room Env. Controller** **Env. Meas. Equipments** **PC**	**HP Basic (Continuous)** -Measurement software-	**Interface** **text output** **LAN connection**
3.4	**Calibration (Measurement)**	**Measurement Equipments** **PC**	**HP Basic (Continuous)** -Measurement software-	**Interface** **text output** **LAN connection**
3.5	**Certificate Issuing**	**PC**	**MS Word (New)** -word processor-	**LAN connection** **Get text data**
5.2	**Historical Data Watching**	**PC**	**MS Excel (Re-making)** -graphical application-	**LAN connection** **Get text data**

The first task was hardware, i.e. to connect the network hard disc and PC measurement controllers of each individual calibration system to LAN. And then, we selected the most useful software which is flexible and able to access text files from each process. To tie it all together, made a common data directory on the hard disc and defined the name and format of temporary data files which were to be used for the delivery the data between applications. Figure 3-1 depicts the overview.

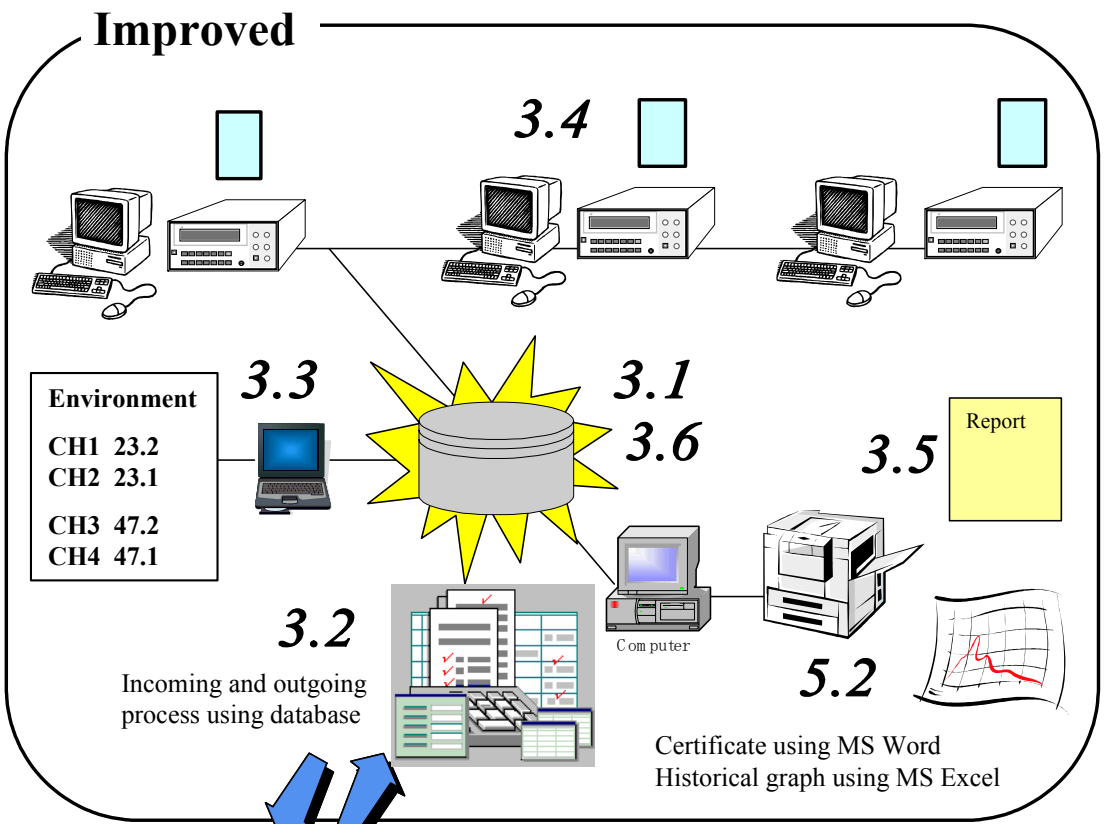

Figure 3-1. Overview of the new Total Calibration process

3.2 Process Improvement 1 (Calibration Tracking Application)

The mission of this process is to store the customer information and to control our internal standards, which includes the shipment and accounting information and equipment lists for re-call and re-trace. The main purpose for improvement in this process is to decrease the amount of manual data transfer at the incoming and outgoing process as shown in Table 2-1.

We selected Microsoft Access data base software because of availability and our data volume was not large. (Though there are many applications for calibration process management).

The tasks which are required for this data base application are

- to input customer information at receiving and store it by calibrating item ID,
- to input the information for internal standards and equipments,
- to output the customer information as the text file named “cust_data.txt”,
- to output the traceability information of used standards used during calibration and
- to output the shipment and the accounting information of the calibration items.

3.3 Process Improvement 2 (Environment Measurement System)

The mission of the process is to control and display the environmental data of the standards room.

The main purpose of this improvement is to eliminate manually logging during the calibration and issuing the certificate as shown b-2 and b-6 in Table 2-1.
Room environment controller of our standards room fortunately had an RS232 interface.
The tasks which are required for this application are
- to control and display room environment of temperature, humidity and atmosphere,
- to output the measurement data via any interfaces by using a suitable application and
- to store the measurement data to the text files temporarily and continuously by using a suitable application.

3.4 Process Improvement 3 (Each Calibration System)

The mission of the process is to do the calibration which is defined by the procedure based on the technical document. The main purpose of this improvement is to decrease manual data entry at the calibration and issuing the certificate as shown b-1, b-2, b-3, b-4, b-7 and b-8 in Table 2-1.
This process requires controlling the measurement equipment and making the new text type data file. We selected HP Basic for Windows because that was the existing measurement application.
The tasks which are required for this application are
- to input the measurement conditions (environment or customer information),
- to input the data of the using standards used,
- to do the calibration,
- to store the measurement data to the file which is usually binary type,
- to copy the data file from binary type to the new text type named “report_data.txt” and
- to compare the measurement data to the calibration limit and/or previous result.

3.5 Process Improvement 4 (Certificate Issuing Application)

The mission of the process is to print out the certificate of the calibration. The main purpose for improvement in this process is to decrease manual data entry when issuing the certificate and discontinue the use of local printers as shown b-6, b-9 and b-10 in Table 2-1.
We selected the Microsoft Word application (with embedded visual basic). Important was the Greek symbol character which is necessary to show the unit “Ω”, “μ” and etc. based on SI description.
The tasks which are required for this application are
- to down load the data from “cust_data.txt” which has the customer information data,
- to down load the data from “trace_no.txt” which has the traceability information,
- to down load the data from “report_data.txt” which has the calibration data,
- to paste above data at fixed locations, defined by using the book marks in the template files,
- to set the file security (Conforming to ISO17025 4.13.1.4),
- to print the file to the LAN printer and
- to paste the electrical signature.

3.6 Connection data file (Temporary text files)

This new function will deliver the data between the different applications. The main goal of this function is to make a stable system that can endure changes in circumstances.

Text file is the simplest file type and easy to access from any applications. We prepared some files which had the fixed names and they were updated every calibration at suitable timing in the total calibration process.

The defined text files delivering the data between the calibration process application and the certificate printing application are “cust_data.txt” file which has the customer information data and “trace_no.txt” file which has the traceability information.

The defined text files delivering the data between the environment measurement system and the each calibration system is “R-current.txt” file which has the system environmental data.

The defined text file delivering the data between the each calibration system and the certificate printing application is “report_data.txt” file which has the calibration data.

This file is key element in our improved system.

```
1, “Data Name A     ”, 10.00000
2, “Data Name B     ”, 10.00001
3, “--------------------”, *******
```

Figure 3-2. DATA File Sample

We define the storing directory to “(Home directory)/(model name)/(serial number)/report_data.txt”. We use the simplest format which is the data number, the data description and the raw data as showing in Figure 3-2.

These definitions for the file have some advantages.

The fixed file name: “report_data.txt”, temporally until next calibration, makes it easy to control the file in the software.

The fixed simple data arrangement makes it easy to store and load from different applications.

The data Number also makes it easy to write the software document as showing in Table 3-2, simplifying the software program. For example the start number is 4 and the end number is 15 in “FOR NEXT Loop” making it easy for other persons to trace the data. (Conforming to ISO17025 5.4.7)

We use the same format for that of reference standard, working standard and customer’s equipment. It enables common usage in the each calibration program. Each calibration program only has the information for the model number and the serial number of the standards currently being used. Now that the calibration program can read standards data in real time, the declaration on the certificate is always consistent.

Table 3-2. DATA Doc. Sample

I	D$(I)	Data (I)
1	Date (YYYYMMDD)	Data(1)
2	Temp	Data(2)
3	Hum	Data(3)
4	0.1 V DC	Data(4)
5	-0.1 V DC	Data(5)
6	1 V DC	Data(6)
7	-1 V DC	Data(7)
8	10 V DC	Data(8)
9	-10 V DC	Data(9)
10	100 V DC	Data(10)
11	-100 V DC	Data(11)
12	700 V DC	Data(12)
13	-700 V DC	Data(13)
14	1000 V DC	Data(14)
15	-1000 V DC	Data(15)

The change in each of the calibration programs was to add a sub routine for reading the using standard data and for outputting to the "report_data.txt" file. The originally existing data file which was owned by each calibration system dose not has to change.

4. Result of Project #1

As a result of the improvements in chapter 3, we are able to make the certificate accurately and automatically in accordance with MS Word template shown in Figure 4-1 and 4-2.

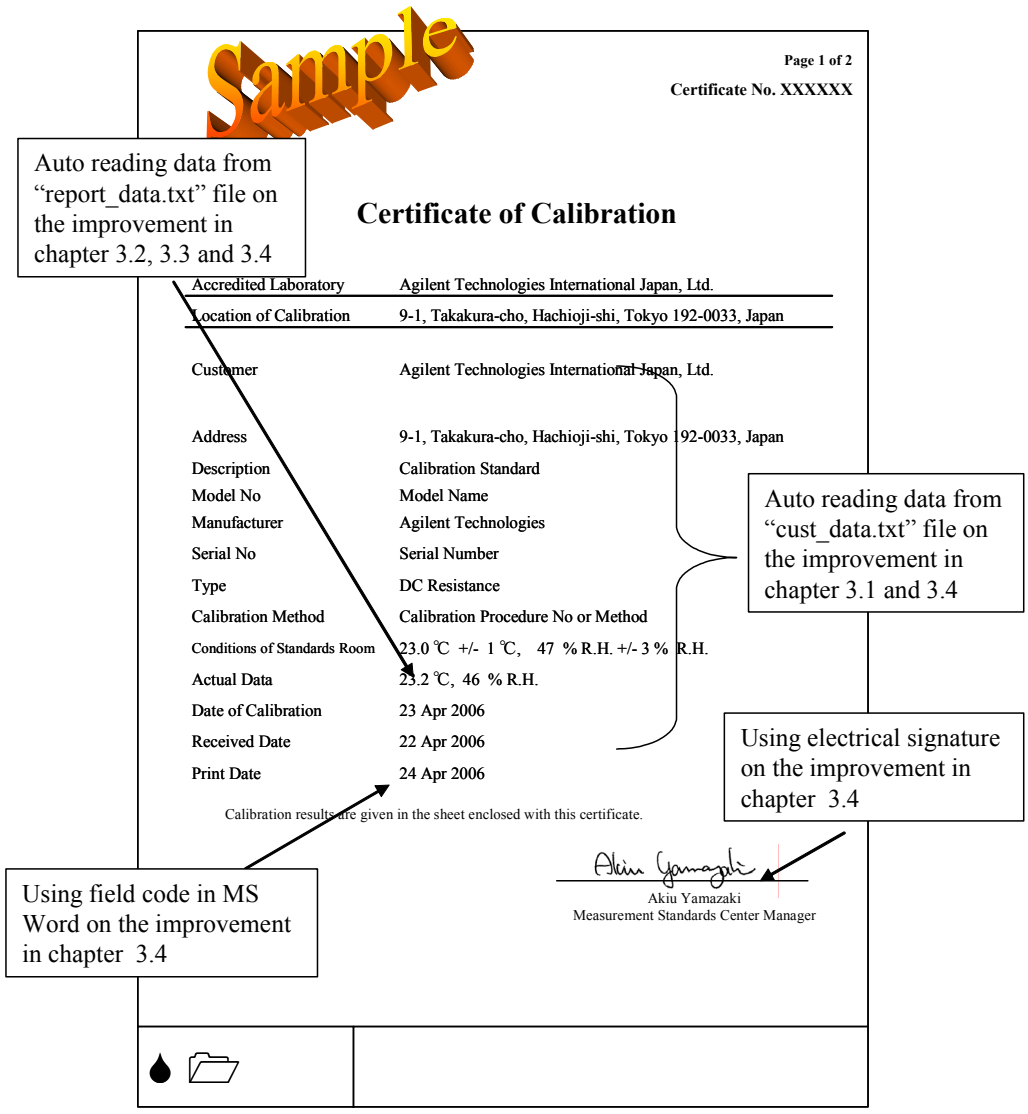

Figure 4-1. Certificate Sample 1

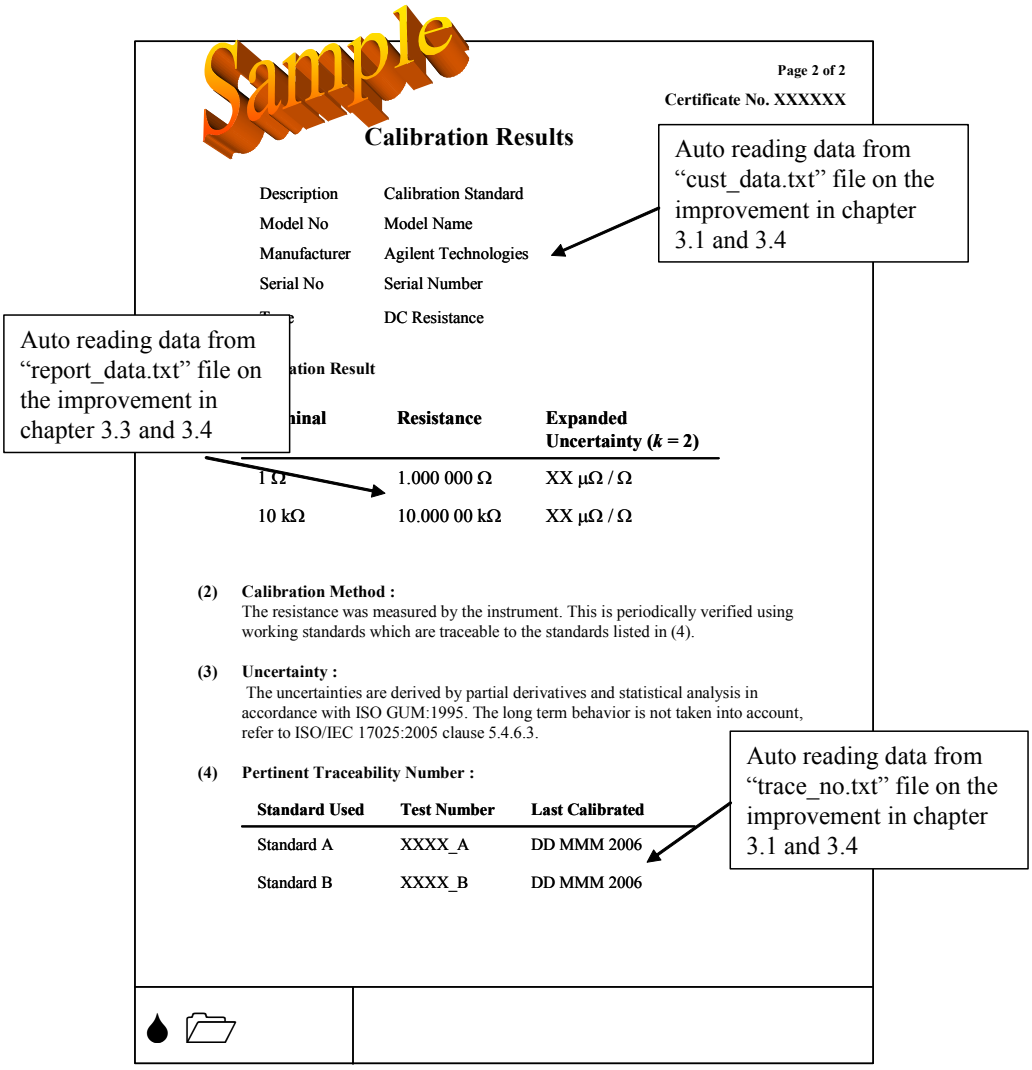

Figure 4-2. Certificate Sample 2

We were enabled to save the money for updating each printer used at each individual calibration system by centralizing to LAN printer.

We were enabled to stop getting the hard copy of the issued certificate manually for storing the record and instead of it we can store the electrical file as official record. (Conforming to ISO 17025 4.13.2.1)

We were enabled to copy the data files at each calibration system to another hard disc as back up via LAN automatically. (Conforming to ISO 17025 4.13.1.4)

We were enabled to reduce the manual data entry throughout the total process. Especially effected was the increased integrity of the standard data.

The calibration system is now more flexible due to the partitioning the individual measurement systems from the common certificate issuing system. We will also be better able to respond to updates of the OS and platform application in future.

5. The second action focused to Historical Data Graph

5.1 Purpose and Idea

We defined the purpose of the second action to create a historical data graph automatically. The benefit will increase the quality for the calibration result by watching the historical trend.
The idea was to copy the temporarily "report_data.txt" file to MJD.txt file after each calibration. MJD (modified Julius day) is the serial date number which is usually used in the frequency measurement field.

5.2 Process Improvement 5 (historical graph application)

The mission of this process is to transfer the calibration data to the graph application.
We selected the Microsoft Excel application (with embedded Visual Basic) because of availability.
The tasks which are required for this application are
- to download and put the data to the defined cell in the Excel sheet from the MJD.txt file,
- to make the graph template by using the defined cell and
- to analyze the long term stability or the trend for reference and working standards.

The tasks required for each calibration systems were
- to make the sub program to copy from report_data.txt to MJD.txt,
- to add the a few program lines to call the sub program in each calibration program and
- to make the translation utility to change the old historical binary file to MJD.txt file.

The MJD file name has the advantage of getting the data easily into the Excel sheet because MJD is ordered by date. Figure 5-1 is a sample of the macro.

A Example of data reading by using Excel macro

```
For d = 50000 To Mjd                          ‘ Date Serial Value 50000（995/10/10）to Now
      On Error Resume Next                     ' Error trap
      Open File_Name$ For Input As #1
      If Err.Number = 53 Then GoTo NextFile  ' Error number 53 means that the file dose not exist.
      i = i + 1                                 '  Count the number of Data file
      For j = 1 To 200                          ' Data line maximum is 200 in report_data.txt
         On Error Resume Next                   ‘ Error trap
         Input #1, NomNumber(i, j), NomDescript(i, j), ValueData(i, j) ' Data number、Data name、Value
         If NomNumber(i, j) = "" Then GoTo NextFile ‘ Skip where no data
         Jmax = j
NextData:
      Next j
NextFile: Close #1
   Err.Clear                                    ' Clear Error Resistor
   On Error GoTo 0                              ' disable error trap
 Next d
 Imax = i                                      ' The file number for historical data
```

Figure 5-1. Macro Sample

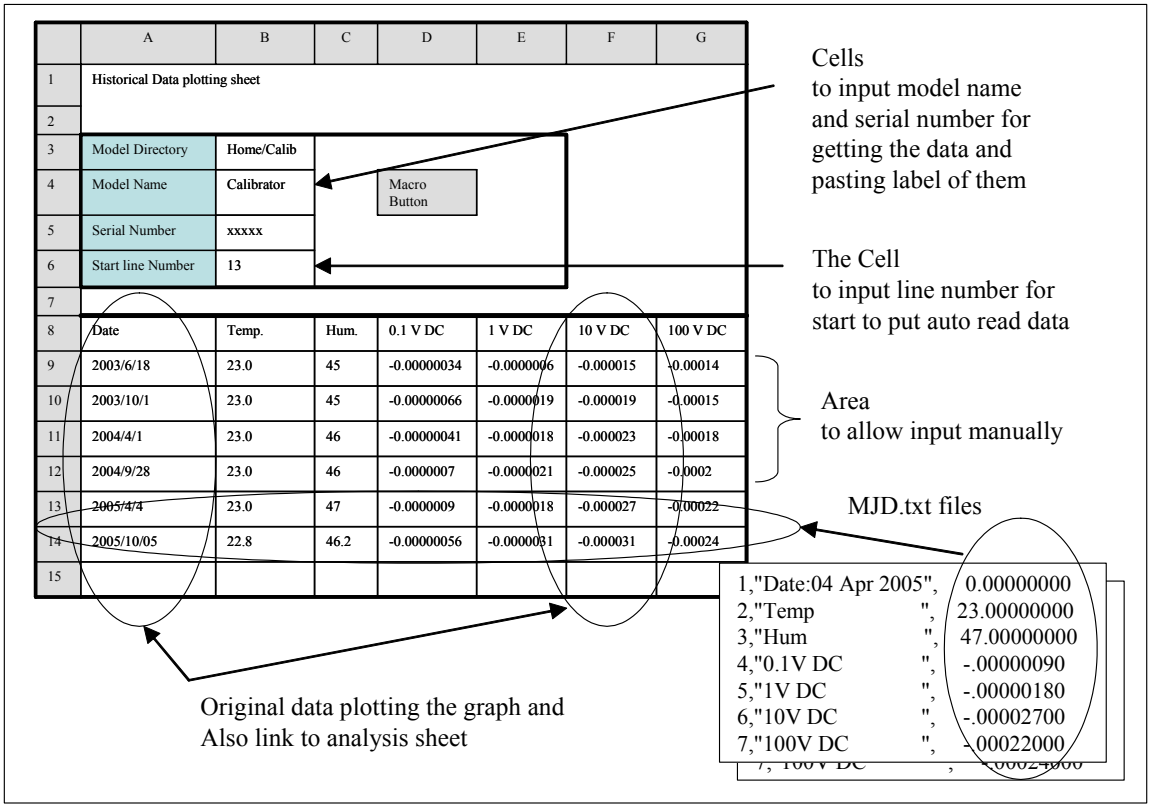

Figure 5-2. Input Sheet Sample

Figure 5-2 is a sample of the data input sheet for a historical data graph. Cell B3 contains the model name. Cell B3 is also used by the software to determine where the data is stored on the common hard disc. Although the report start date format is intended to be on line 9, the fetching macro can begin at any line indicated by Cell B6, and then input data from MJD.txt file. This is done when older legacy data exists that need to be input by hand.

The ranges containing the Date (Column A) and the DATA (Column F) link to the graph and the other DATA analysis sheet. The graph sample is in Figure 5-3. We can re-confirm the long term stability and know the newest trend (used by equations in the other data analysis sheet) because the linked data is automatically updated.

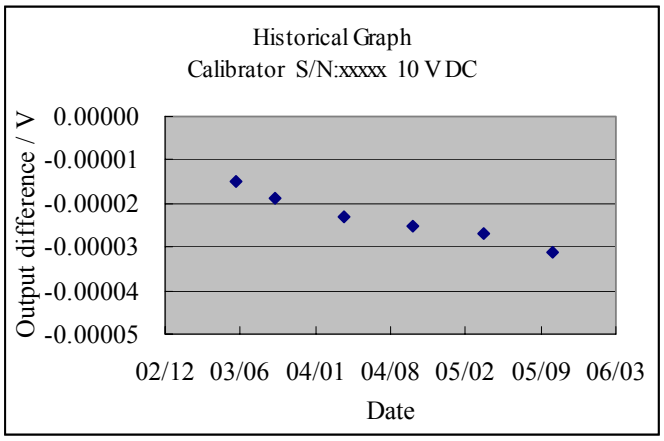

Figure 5-3. Graph Sample

The project is currently in the trial and standardization phase.

6. Conclusion

Table 6-1 shows the improved total calibration flow on the task. Comparing to Table 2-1, manual data entry decrease from 14 to 3 and the number of the task also decrease from 17 to 13. Other hardware and software problems were fixed. As the result, the time for the total calibration task decreased dramatically.

Table 6-1. Improved Calibration Tasks

Process and Tasks	Admin.	Technician	Engineer (System)	Manager
a. Process at Incoming				
• Assign the calibration number Input administrative information to database	Auto number! Input to Form			
• Print information tag	Auto print!			
b. Process at Calibration (Each system)				
• Download use information (in trail)		Auto read!		
• Download environmental data		Auto read!		
• Download Using Equipment (Standard) data		Auto read!		
• Measure the item (Calibration) and store the data		Auto comparing!	Fixed!	
c. Process at Outgoing				
• Record administrator additional information	Input to Form			
• Issue the certificate from LAN Printer			Fixed!	
• Sign to the certificate				Electrically!
- For External Item -				
• Ship the item				
• Output the accounting report from database	Auto print!			
- For Internal Item -				
• Put data to re-call and re-trace system		Input to Form		
• Put data to historical graph		Auto make!		

Figure 6-2 shows an overview of the improved data flow in detail. As shown in the figure we still have some tasks to do under the plan and we are committed to continuous improvement. (Conforming to ISO 17025 4.10)

We will increase the quality for the calibration result and will not only issue the certificate of the calibration but also supply the historical graph to the customer in near future. (Conforming to ISO17025 5.9)

7. Acknowledgement

The authors would like to thank Robert L. Brown (Agilent Technologies) for a review of the manuscript.

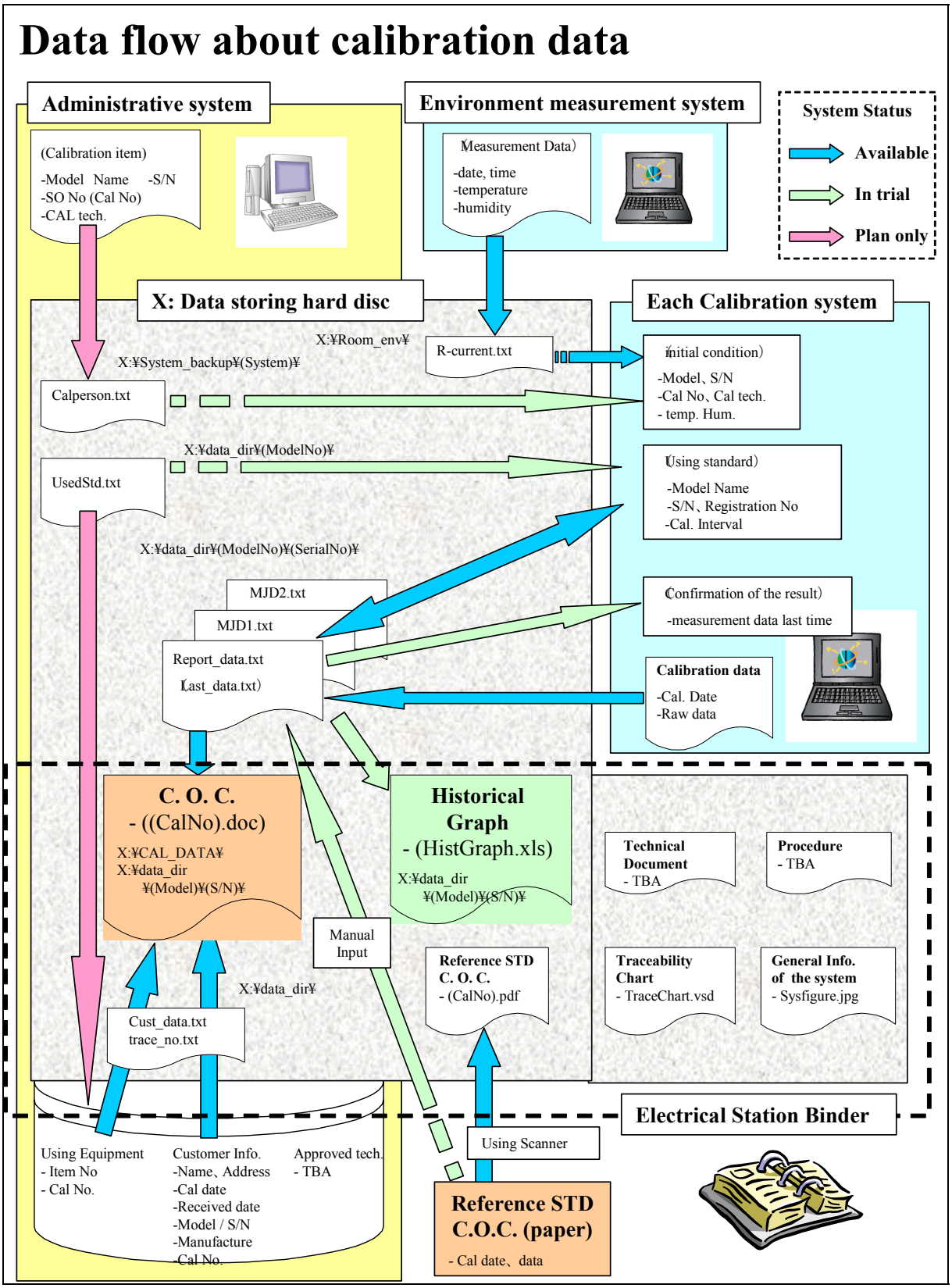

Figure 6-2. Data Flow Overview