SmartCalibration and ISO17025

Introduction

With the increase in manpower cost and cost of maintaining records on paper, more and more laboratories are wishing to adopt Calibration LIMS software (other than Excel) so that they can get the benefit of IT revolution that has already started wide spectrum of other industry sectors. For these laboratories the benefits are many such as following:

1. Less reliance on Paper, thus reducing paper based operations, reduce cost of preserving paper records
2. Increase in efficiency
3. Reduction in clerical mistakes that creeps in to system during transfer of data from paper based forms to worksheets (in Excel)
4. Strengthening process of control and governance

While earlier, cost of software was prohibitively high, with the advent of Cloud computing, now a days laboratories can adopt a cloud hosted software without taking any cost of IT infrastructure other than availability of Internet thus reducing overall cost of adoption of Calibration Lab Management Software.

SmartCalibration is one such product that is available on internet hosted and serviced by SCC IT solution pvt. Ltd. SCC takes prides in the fact it aims is to propagate adoption of Software in small and very small business organization.

SmartCalibration: Calibration Lab Management Software

Functional coverage of Laboratory Operation by SmartCalibration Lab software

For the sake of this paper, summarizing SmartCalibration features coverage of any laboratory operations, we are assuming that all the features of SmartCalibration are used by the laboratories (although each of the modules can be switched off such as quotation, invoicing).

1. Quotation
2. Customer Order logging
3. Creating Project/Assignment from the customer order
4. Logging DUC/UUC details against each of the job
5. Publishing Service request form/order and Job card
6. Logging Calibration Results
7. Calculations of derived data including Uncertainty, and other environment correction
8. Publishing of Observation form and Certificate document
9. Invoicing the customer
10. Maintaining data related to standard references and its traceability.
11. Defining pre-defined uncertainty

Access to each of the module could be defined for each user based on the user group that he/she may belongs to or on exception by laboratory senior manager. Each of the document or module have two level of hierarchy, one who is drafting the data and other who approves the data and allows transaction or document produced by it to be sent to the client/customer.

Language and Platforms

Software Language: PHP

Web Server: Apache

Database Server : Mysql

Applicable Extent of Validation Process

As per guidelines of the EUROLAB paper, all the software system has been categories into five type, depending on the category, process of validation could be designed accordingly.

As per the paper, there are six different steps in validation process which are as follows

Validation Type	Validation Step	Relevance to SmartCalibration
V0	Manufacturer Documentation	Not Applicable
V1	Requirement Specification	Relevant, Functional Specification of SmartCalibration would be handed over to the laboratory
V2	Design and Implementation (coding)	To be maintained by SCC as code developer
V3	Inspection and structural	White Box testing conducted by software provider

	testing	
V4	Installation	Provided by software provider
V6	Acceptance testing (black box testing)	Laboratory must take a confidence test even when it is COTS version however if customization and configuration changes are made, then it is essential first step

- Table of Validation Types are taken from EUROLAB document (please see references section)

SmartCalibration is Commercial Off the shelf Software, thus the laboratories wishing to use the software as is with the supplied formats and templates, donot need to validate it as per 5.4.7.2 which states "Commercialoff-the-shelfsoftware (e.g. wordprocessing, databaseand statisticalprogrammes) in generaluse within their designed application range may be considered to be suflicienUy validl'ted. However. laboratory software configuration/modifications shouldbe validatedas in 5.4.7.2a), " thus it is essential that all changes in calibration results capturing formats, printing templates must be validated for input/output.

Breadth and depth of Validation Steps

Since SmartCalibration is COTS application, Laboratories must carry out following steps (correlating to T1 and T2 of EUROLAB document)

T1: Typical Input data set and operations (navigation thru the application) as guided by the user manual or training material, check for obvious errors and log these in the test pack.

T1b: Test of data transfer by direct observation, eg from database to Observation ODT document template

T2: Test of SW functionality, with respect to integrity, traceability, access rights, safety etc.

T2a: Validation of Calibration data by way of comparison method, we recommend that at least 5 separate data sets must be selected from existing paper based or currently used application data for each type of instrument using each of the standard reference.

1. Enter Sample input data from existing calibration results (sourced from raw data sheet)
2. Verify the calculations with Worksheet (Excel calculations) or existing calculation supporting tool (Internet based free to use website)
3. Compare the output published in ODT document by Smart Calibration with Certificate corresponding to source data.

Output : Evidences thus collected, screen shots and documents generated by application and a copy of existing source data must be filed diligently with uniquely test step identification number.

Clause wise analysis of SmartCalibration features that helps in conformity

ISO17025.4.1.5c: HAVE POLICIES AND PROCEDURES TO ENSURE THE PROTECTION OF ITS CUSTOMERS' CONFIDENTIAL INFORMATION AND PROPRIETARY RIGHTS, INCLUDING PROCEDURES FOR PROTECTING THE ELECTRONIC STORAGE AND TRANSMISSION OF RESULTS.

SmartCalibration is protected by Login and Password that is further protected with random string Captcha to prevent robots attacking. Laboratory should draft policy to ensure that each user keeps password difficult to guess and accesses to the users are assigned on role basis.

ISO17025.4.2.1: THE LABORATORY SHALL ESTABLISH, IMPLEMENT AND MAINTAIN A MANAGEMENT SYSTEM APPROPRIATE TO THE SCOPE OF ITS ACTIVITIES.

Software can be part of the management system, Laboratories have to modify their standard operating procedures to make it part of the process.

ISO17025.4.3.1: THE LABORATORY SHALL ESTABLISH AND MAINTAIN PROCEDURES TO CONTROL ALL DOCUMENTS THAT FORM PART OF ITS MANAGEMENT SYSTEM (INTERNALLY GENERATED OR FROM EXTERNAL SOURCES), SUCH AS REGULATIONS, STANDARDS, OTHER NORMATIVE DOCUMENTS, TEST AND/OR CALIBRATION METHODS, AS WELL AS DRAWINGS, SOFTWARE, SPECIFICATIONS, INSTRUCTIONS AND MANUALS.

Calibration Methods, and standard points of calibration could be specified in the format for capturing calibration results within the application. The access to these modules are part of the calibration setup functionality thus could be restricted only to senior and authorized laboratory resources.

ISO17025.4.3.1: MANAGEMENT SYSTEM DOCUMENTS GENERATED BY THE LABORATORY SHALL BE UNIQUELY IDENTIFIED. SUCH IDENTIFICATION SHALL INCLUDE THE DATE OF ISSUE AND/OR REVISION IDENTIFICATION, PAGE NUMBERING, THE TOTAL NUMBER OF PAGES OR A MARK TO SIGNIFY THE END OF THE DOCUMENT, AND THE ISSUING AUTHORITY (IES).

All the documents generated by the SmartCalibration modules are uniquely identified either by its entity for example quotation reference, job card number, SRF number or another unique sequence number accordingly. Certificate number sequence is separately maintained and its uniqueness is ensured by software as well as by database constraints. Laboratory can customize certificate number sequence pattern that would be generated for each of the certificate.

Everytime a calibration result format is changed to include a new column, change existing details or formula functions, a new version of the format is created that would be effective from the date of change.

ISO17025.4.3.4.PROCEDURES SHALL BE ESTABLISHED TO DESCRIBE HOW CHANGES IN DOCUMENTS MAINTAINED IN COMPUTERIZED SYSTEMS ARE MADE AND CONTROLLED.

This applies only to the documents that are published by the SmartApplication, File name generated by the application could be suffixed or prefixed with time stamp thus creating a different version every

time the document is regenerated. By default, versioning is switched off thus it would overwrite the document that was generated earlier.

ISO17025.4.4.1 THE LABORATORY SHALL ESTABLISH AND MAINTAIN PROCEDURES FOR THE REVIEW OF REQUESTS, TENDERS AND CONTRACTS. THE POLICIES AND PROCEDURES FOR THESE REVIEWS LEADING TO A CONTRACT FOR TESTING AND/OR CALIBRATION SHALL ENSURE THAT:

This is applicable only when laboratories wish to use quotation, and invoicing modules of Smart Calibration. Customer order registration is essentially part of calibration module thus is mandatory for all the laboratories that are wishing to use SmartCalibration module.

ISO17025.4.13.1.2. ALL RECORDS SHALL BE LEGIBLE AND SHALL BE STORED AND RETAINED IN SUCH A WAY THAT THEY ARE READILY RETRIEVABLE IN FACILITIES THAT PROVIDE A SUITABLE ENVIRONMENT TO PREVENT DAMAGE OR DETERIORATION AND TO PREVENT LOSS. RETENTION TIMES OF RECORDS SHALL BE ESTABLISHED.

All the modules and screens are not more than three clicks apart if using mouse for navigation thru SmartCalibration product interface. In addition to this, users can create bookmarks for the modules that they frequently visit.

SmartCalibration Module could be configured to purge or archives data related to customer and services provided after a laboratory specified retention period.

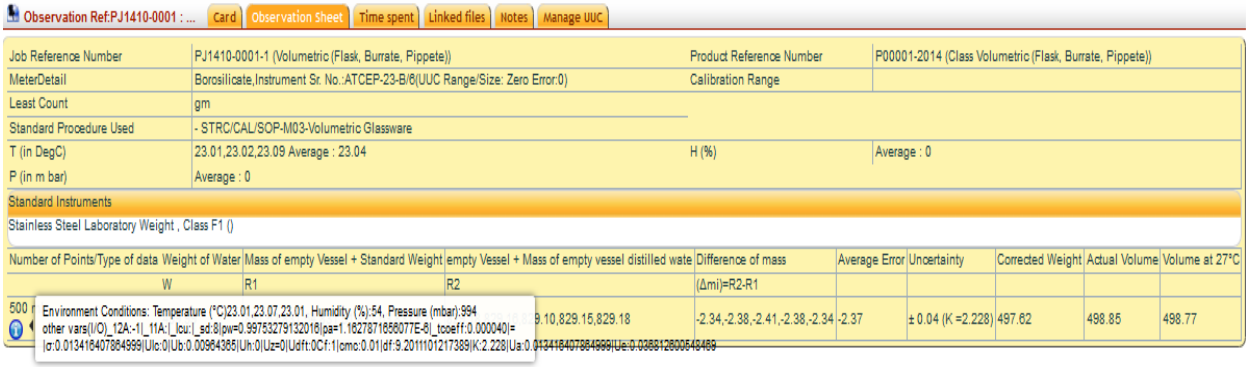
ISO17025.4.13.1.4 THE LABORATORY SHALL HAVE PROCEDURES TO PROTECT AND BACK-UP RECORDS STORED ELECTRONICALLY AND TO PREVENT UNAUTHORIZED ACCESS TO OR AMENDMENT OF THESE RECORDS.

SmartCalibration is open application and cloud hosted, SCC IT Solution its administrator ensure backup of database is taken on every day, every week and every month on recyclable basis (ie, today back up will overwrite yesterday backup). All the backups are stored away from the laboratory thus it would be save even in case of fire or any disaster at or around laboratory. Backups are stored at Hosted Server space contracted by SCC, while monthly backup is preserved in local server of SCC India office.

As the data is stored in 3GL database and in 3rd normal form, it is difficult for laboratory user to change the data by itself. The data in the database layer could be modified by people who not only understand how database works as a technology but also understand how database for SmartCalibration is organized.

ISO17025.4.13.2.1 THE LABORATORY SHALL RETAIN RECORDS OF ORIGINAL OBSERVATIONS, DERIVED DATA AND SUFFICIENT INFORMATION TO ESTABLISH AN AUDIT TRAIL, CALIBRATION RECORDS, STAFF RECORDS AND A COPY OF EACH TEST REPORT OR CALIBRATION CERTIFICATE ISSUED, FOR A DEFINED PERIOD. THE RECORDS FOR EACH TEST OR CALIBRATION SHALL CONTAIN SUFFICIENT INFORMATION TO FACILITATE, IF POSSIBLE, IDENTIFICATION OF FACTORS AFFECTING THE UNCERTAINTY AND TO ENABLE THE TEST OR CALIBRATION TO BE REPEATED UNDER CONDITIONS AS CLOSE AS POSSIBLE TO THE ORIGINAL. THE RECORDS SHALL INCLUDE THE IDENTITY OF PERSONNEL RESPONSIBLE FOR THE SAMPLING, PERFORMANCE OF EACH TEST AND/OR CALIBRATION AND CHECKING OF RESULTS

Smart Calibration preserve and save all raw data and calculated data in the database which could all be printed also in a report or document.



Observation Ref:PJ1410-0001 : ... | Card | Observation Sheet | Time spent | Linked files | Notes | Manage UUC

Job Reference Number	PJ1410-0001-1 (Volumetric (Flask, Burrate, Pippete))	Product Reference Number	P00001-2014 (Class Volumetric (Flask, Burrate, Pippete))
MeterDetail	Borosilicate,Instrument Sr. No.:ATCEP-23-B/6(UUC Range/Size: Zero Error:0)	Calibration Range	
Least Count	gm		
Standard Procedure Used	- STRC/CAL/SOP-M03-Volumetric Glassware		
T (in DegC)	23.01,23.02,23.09 Average : 23.04	H (%)	Average : 0
P (in m bar)	Average : 0		

Standard Instruments

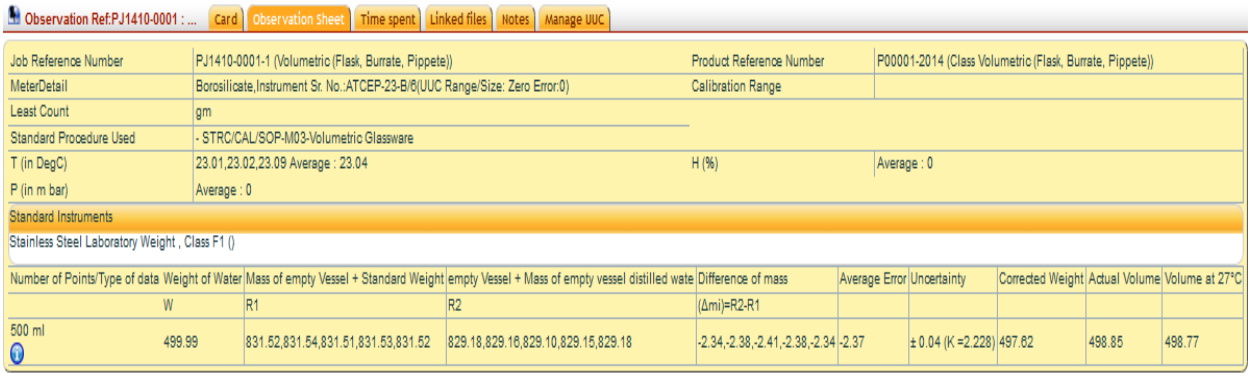
Stainless Steel Laboratory Weight , Class F1 ()

Number of Points/Type of data	Weight of Water	Mass of empty Vessel + Standard Weight	empty Vessel + Mass of empty vessel distilled wate	Difference of mass	Average Error	Uncertainty	Corrected Weight	Actual Volume	Volume at 27°C
	W	R1	R2	(Δmi)=R2-R1					
500			9.10,829.15,829.18	-2.34,-2.38,-2.41,-2.38,-2.34	-2.37	± 0.04 (K =2.228)	497.62	498.85	498.77

Environment Conditions: Temperature (°C)23.01,23.07,23.01, Humidity (%):54, Pressure (mbar):994
other vars(I/O)_12A:-1|_11A:|_Icu:|_sd:8|pw=0.9975327913201 8|pa=1.1627871656077E-8|_tcoeff:0.000040|=
Ic/:0.013416407864999|Ulc:0|Ub:0.00964385|Uh:0|Uz=0|Udft:0Cf:1|cmc:0.01|df:9.2011101217389|K:2.228|Ua:0.013416407864999|Ue:0.038612600548469

*ISO*17025.4.13.2.2 OBSERVATIONS, DATA AND CALCULATIONS SHALL BE RECORDED AT THE TIME THEY ARE MADE AND SHALL BE IDENTIFIABLE TO THE SPECIFIC TASK.

As Smart Calibration is Web application, engineers can log the result even when they are on the site using laptop or tablet devices if these are connected to the Web. Observation forms can be accessed through the job module only and is uniquely to each job number. Pl see snapshot of application



Observation Ref:PJ1410-0001 : ... | Card | Observation Sheet | Time spent | Linked files | Notes | Manage UUC

Job Reference Number	PJ1410-0001-1 (Volumetric (Flask, Burrate, Pippete))	Product Reference Number	P00001-2014 (Class Volumetric (Flask, Burrate, Pippete))
MeterDetail	Borosilicate,Instrument Sr. No.:ATCEP-23-B/6(UUC Range/Size: Zero Error:0)	Calibration Range	
Least Count	gm		
Standard Procedure Used	- STRC/CAL/SOP-M03-Volumetric Glassware		
T (in DegC)	23.01,23.02,23.09 Average : 23.04	H (%)	Average : 0
P (in m bar)	Average : 0		

Standard Instruments

Stainless Steel Laboratory Weight , Class F1 ()

Number of Points/Type of data	Weight of Water	Mass of empty Vessel + Standard Weight	empty Vessel + Mass of empty vessel distilled wate	Difference of mass	Average Error	Uncertainty	Corrected Weight	Actual Volume	Volume at 27°C
	W	R1	R2	(Δmi)=R2-R1					
500 ml	499.99	831.52,831.54,831.51,831.53,831.52	829.18,829.16,829.10,829.15,829.18	-2.34,-2.38,-2.41,-2.38,-2.34	-2.37	± 0.04 (K =2.228)	497.62	498.85	498.77

*ISO*17025.*5.4.7.1 CALCULATIONS AND DATA TRANSFERS SHALL BE SUBJECT TO APPROPRIATE CHECKS IN A SYSTEMATIC MANNER.*

Since lot of calculations are dependent on data setup by the laboratories on application (such as defining uncertainty factors as per the process and of standards), formulas and functions that are used in data formats thus ***it is essential that calculations to be validated by the laboratories before putting it to regular use. Please refer to Observation Form published by SmartCalibration*** Annexure-3 Observation Form

SmartCalibration providing review and approval process within the application.

1. Laboratory Administrator can assign Authorised Approver and Calibration engineer on each of the job. Calibration Engineer will have access to calibration result capturing module and can send captured result for review by clicking on “Send for Review” button, this triggers a information mail to the assigned approver who should login onto the application and approve the results after his/her review.
2. User can publish certificate document only after authorized signatory approve it formally on the application by clicking on Approve Button with his review comments or statement wrt calibration results.

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

ISO17025.5.4.7.2a, 5.5.2: COMPUTER SOFTWARE DEVELOPED BY THE USER IS DOCUMENTED IN SUFFICIENT DETAIL AND IS SUITABLY VALIDATED AS BEING ADEQUATE FOR USE;

SmartCalibration training material and user guide are good enough to guide technical or commercial team to make best use of features. In addition to the documents, SCC also provides user support to the customer team.

Calculation should be validated by the user laboratories the best way to validate the calculation is by cross verifying the results and calculations with the existing tools or applications (Excel based calculations vs SmartCalibration)

ISO17025.5.4.7.2b 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;

Responsibility lies with the laboratory; application allows laboratory organization to define user accesses as per roles and responsibilities. Other responsibilities that should be mentioned in the procedure manuals includes followings

- To ensure user passwords are complex enough for any guess making.
- To ensure, user is disabled promptly in case user leaves the organization
- To ensure, access to the application and jobs assigned stays only with the genuine resource working on it (for eg. Calibration engineer should not have access to customer module)
- Person on Sales and Engineer roles should be separate and should not have access

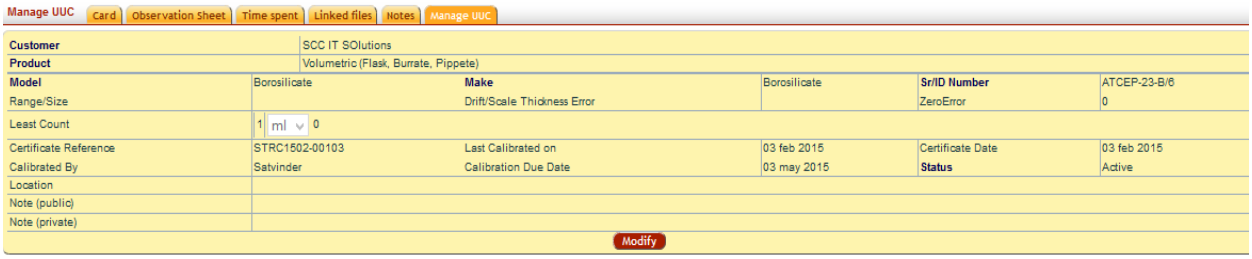
ISO17025.5.4.7.2c. COMPUTERS AND AUTOMATED EQUIPMENT ARE MAINTAINED TO ENSURE PROPER FUNCTIONING AND ARE PROVIDED WITH THE ENVIRONMENTAL AND OPERATING CONDITIONS NECESSARY TO MAINTAIN THE INTEGRITY OF TEST AND CALIBRATION DATA.

SmartCalibration hosted database and web server are maintained in environment meant for effective and efficient working environment (temperature controlled environment)

ISO17025.5.5.5. RECORDS SHALL BE MAINTAINED OF EACH ITEM OF EQUIPMENT AND ITS SOFTWARE SIGNIFICANT TO THE TESTS AND/OR CALIBRATIONS PERFORMED.

SmartCalibration allows each job to be uniquely associated with a (unit under calibration) UUC/(Device under Calibration) DUC. UUC/DUC received by the laboratory is uniquely identified with its model+make+serial number/ID number.

Smartcalibration also enables users to see all previous calibration data/certificate and observation results on screens or the documents relating to the previous assignment.



ISO17025.5.5.12 TEST AND CALIBRATION EQUIPMENT, INCLUDING BOTH HARDWARE AND SOFTWARE, SHALL BE SAFEGUARDED FROM ADJUSTMENTS WHICH WOULD INVALIDATE THE TEST AND/OR CALIBRATION RESULTS.

All the upgrades/enhancement, fixes to the deployed application should be fairly assessed and validated before accepting into practice. SCC is maintaining test site for the users to test the enhancement before accepting and acknowledging deploying new change or fixing. Acceptance testing should be done after the deployment by the laboratory.

ISO17025.5.10.2 EACH TEST REPORT OR CALIBRATION CERTIFICATE SHALL INCLUDE AT LEAST FOLLOWING, TITLE, NAME AND ADDRESS OF THE LABORATORY AND LOCATION WHERE THE CALIBRATION WAS CARRIED OUT, UNIQUE IDENTIFICATION OF CERTIFICATE NUMBER, IDENTIFICATION OF METHOD, NAME AND ADDRESS OF CUSTOMER, DATE OF RECEIPT OF DUC, VALIDITY, CALIBRATION RESULTS, DATE OF CALIBRATION, CALIBRATION RESULTS WHERE APPROPRIATE WITH UNIT OF MEASUREMENT, NAME, FUNCTION AND SIGNATURE OR IDENTIFICATION OF PERSON AUTHORIZING THE CERTIFICATE, A STATEMENT TO THE EFFECT THAT THE RESULTS RELATE ONLY TO THE ITEMS TESTED OR CALIBRATED, PAGE NUMBER AND TOTAL PAGES IN CERTIFICATE, NOTE 2, REFERENCE TO ENVIRONMENT CONDITIONS, A TRACEABILITY OF REFERENCES USED THE UNCERTAINTY OF MEASUREMENT

ISO17025.5.10.4 CALIBRATION CERTIFICATES

ISO17025.5.10.4.1 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 NOTE 2 IN 5.6.2.1.1).

Calibration certificate includes all of the minimum information that has been mentioned in 5.10.2, Please refer to sample certificate in Annexure-4 Certificate

ISO17025.5.10.4.2 THE CALIBRATION CERTIFICATE SHALL RELATE ONLY TO QUANTITIES AND THE RESULTS OF FUNCTIONAL TESTS. IF A STATEMENT OF COMPLIANCE WITH A SPECIFICATION IS MADE, THIS SHALL IDENTIFY WHICH CLAUSES OF THE SPECIFICATION ARE MET OR NOT MET.

SmartCalibration provides facility to make a conclusion statement to the approver (authorized signatory) that could get published in the certificate template. The field can be left blank if not asked by the customer.

ISO17025.5.10.4.4 CALIBRATION CERTIFICATE (OR CALIBRATION LABEL) SHALL NOT CONTAIN ANY RECOMMENDATION ON THE CALIBRATION INTERVAL EXCEPT WHERE THIS HAS BEEN AGREED WITH THE CUSTOMER. THIS REQUIREMENT MAY BE SUPERSEDED BY LEGAL REGULATIONS.

SmartCalibration allows laboratory to record validity period in the Job card which is also used for automatic calculation of next calibration date however it is laboratory discretion whether to print it in the certificate document or not.

ISO17025.5.10.7 ELECTRONIC TRANSMISSION OF RESULTS IN THE CASE OF TRANSMISSION OF TEST OR CALIBRATION RESULTS BY TELEPHONE, TELEX, FACSIMILE OR OTHER ELECTRONIC OR ELECTROMAGNETIC MEANS, THE REQUIREMENTS OF THIS INTERNATIONAL STANDARD SHALL BE MET (SEE ALSO ISO17025.5.4.7).

While SmartCalibration allows email to be sent thru application for quotation, srf and invoice as these are published in PDF format but it does not offer to email certificate or observation document as these are published in ODT (Open Document Text), we expect laboratory to convert these documents into PDF using MS Word or any ODT document editor available (such as Libre Office) and mail the scanned and signed copy or converted read only version.

Annexure-1 Service Request form or order

SmallcapCRM Pvt. Ltd.
Service Request Form

Format No. : 4.4F-01

Customer Name & Address :

Contact Person :

S.R.F. No. : SIGPJ2014-000101
S.R.F Date : 03/11/2014
Customer Ref. : SIGCO1410-00001
Customer Ref. Dt : 10/10/2014

Description & Identification of Items

Lab Code	Nomenclature Accuracy/Acceptance Criteria Calibration Method	Make/Model Expected Delivery Calibration Points	Srl/ID No. Accessories Special Instruction	Location Physical Condition	Calibration Interval
SIGPJ2014-000101-1	Pressure Gauge (1 kg/cm2 --40 kg cm2) Lab Standard Procedure	JVG Engineers 2 Weeks	K-06-14770 Manuals	Okay	3 months
SIGPJ2014-000101-2	RTD Simulator Lab Standard Procedure	NA 2 Weeks	STRC -5059 Manuals	Okay	3 months
SIGPJ2014-000101-3	Thermocouple (5 Point in Range) Lab Standard Procedure	Fluke 2 Weeks	5650 Manuals	Okay	3 months
SIGPJ2014-000101-4	Digital Multi meter 3½ Digit Lab Standard Procedure	2 Weeks	Manuals	Okay	1 Year

Signature of Customer

Received By
(In-charge Customer Support)

Annexure-2 Job Card

SmallcapCRM Pvt. Ltd.
Job Card

Project SIGPJ2014-000101
Date start : 03/11/2014
Date end : 03/11/2014

Job Sheet Issued By : Satvinder SuperAdmin

Job Sheet Issue date : 03/02/2015

Description & Identification of Items

Lab Code Instruction	Instrument Details -->> Special Instruction	Make Delivery period	Sr/ID No. Accessories	Calibration Points Condition	Acceptance Location	Validity	Engineer Approver Method
SIGPJ2014-000101-1 Return	Pressure Gauge (1 kg/cm2 --40 kg cm2)	JVG Engineers 2 Weeks	K-06-14770 Manuals	Okay		3 months	Satvinder Satvinder Lab Standard Procedure
SIGPJ2014-000101-2 Return	RTD Simulator	NA 2 Weeks	STRC -5059 Manuals	Okay		3 months	, Rajan Satvinder Lab Standard Procedure
SIGPJ2014-000101-3 Return	Thermocouple (5 Point in Range)	Fluke 2 Weeks	5650 Manuals	Okay		3 months	Satvinder Satvinder Lab Standard Procedure
SIGPJ2014-000101-4 Return	Digital Multi meter 3½ Digit	 2 Weeks	 Manuals	Okay		1 Year	Satvinder Satvinder Lab Standard Procedure

Signature by Dept. Head

Received By
(In-charge Customer Support)

Annexure-3 Observation Form

SmallcapCRM Pvt. Ltd.

3/20, Nehru Nagar, New Delhi 110065

Phone: 9958091815

Email: sales@smallcapcrm.com

Form ID:

Observation Sheet

Job Order No: **SIGPJ2014-000103-5** Date of Calibration: **30/11/2014**

DUC Details

Name of Instrument: **Muffle Furnace/ Auto Clave (Calibration)** Range:

Instrument Location: Resolution/ least count: **1 °C**

Make: **Thermotech** Sr/ID Number: **STH-2004-**

Environmental Condition: **Temperature:** 0.0 **Humidity :** 0.0

Reference Standards

1. S-Type Thermocouple	2.	3.

Equipment Used:

S.No.	Calibration Points	Standard Value	DUC Value(°C)	Average Standard Reading	Average Measured Reading	Predefined TypeB Ub	Uncertainty at 95 % CL
		(B=1,2,3,4,5)	(C(1))				
1	400.000	398.71,398.815,398.71,398.919,398.815	400	398.794	400.000	1.42009	2.840
2	600.000	598.954,598.856,598.954,598.856,598.954	600	598.915	600.000	1.42009	2.798
3	800.000	801.746,801.838,801.93,801.93,801.746	800	801.838	800.000	1.42009	2.840
4	1000.000	1001.456,1001.543,1001.629,1001.543,1001.456	1000	1001.525	1000.000	1.42009	2.840

Predefined Budget contribution to uncertainity (in addition to factors based on observed readings and least count)

S.No	Range	NABL CMC	TypeB Factor Name	Error Estimate	Type B Factors	Distribution	Confidence	Resultant TypeB
1	0 to 1000 deg c	0.01 (°C)	UM due to S-type thermocouple (uB1)	1 (°C)	2	Normal	95	0.5
2	0 to 1000 deg c	0.01 (°C)	UM due to Stability of Temperature Source (uB4)	0.1 (°C)	1.73205	Rectangular	95	0.057735053837938
3	0 to 1000 deg c	0.01 (°C)	UM due to Uniformity of Temperature Source (u	2.3 (°C)	1.73205	Rectangular	95	1.3279062382726

Calibrated By : Satvinder SuperAdmin Checked By: **Satvinder SuperAdmin**

Annexure-4 Certificate

CALIBRATION CERTIFICATE OF: Volumetric (Flask, Burrate, Pippete) **Issued Date:** 03/02/2015

Calibration Certificate No. :	**STRC/STRC1502-00103**	**Calibration Date :**	03/02/2015	**Page 1 of 1**
Recommended Date of Next Calibration: (As Requested By Customer)	03/05/2015	**Date of Receipt :**		

Calibrated For:	**M/s** SCC IT SOlutions D68, Plot # 20, The Retreat , Patparganj, New Delhi-110092,Delhi 11092,India Phone: Email: Web:	**Reference:**

Item Description

Name of the Item	Condition of Instruments	Make/Model	Sr. No. / ID.	Range	Least Count	Location Lab/Site
Volumetric (Flask, Burrate, Pippete)	Visual Inspection: Okay Zero Error: N.A	Borosilicate / Borosilicate	ATCEP-23-B/6-		N.A	

Environmental Condition

Temperature (°C)	22±2 °C	**Humidity (%) RH**	50±4%

STANDARD REFERENCE DETAILS

Standard used	Make/Model	Serial No.	Certificate No.	Calibration Agency/ Traceability	Calibration Validity Period	Uncertainty at 95% CL Coverage factor K=2
Stainless Steel Laboratory Weight , Class F1	Maruti/Maruti	5011	WI/Sep/14/021	Weigh India/	20/09/2014 to 20/09/2017	

USED EQUIPMENT DETAILS:

METHODOLOGY OF CALIBRATION: As per Calibration Procedure No.: STRC/CAL/SOP-M03

RESULTS: All readings are "ml" at 27.0 °C

#	Sample Reading (Up to the Mark)	Actual Volume (Measured)	Uncertainty	Accuracy Class
1	500 ml	498.77	± 0.04 (K =2.228)	A

The reported expanded uncertainty of the measurement was evaluated at confidence level approximately 95% with coverage factor k=2 for a normal distribution.

Notes:	Calibrated By	Issued By
1. The calibration results reported in this certificate are valid at the time of and under the stated conditions. 2. This certificate cannot be reproduced except in full without our prior permission in writing. 3. This certificate refers only to the Particular items submitted for calibration. 4. DUC Stands for Device Under Calibration. 5. Temperature Scale: International Temperature Scale ITS:90	**Satvinder SuperAdmin (Calibration Engineer)**	**Satvinder SuperAdmin (Authorised Signatory)**

Annexure-5 Assessment worksheet - SmartCalibration features in the context as ISO17025 compliance supporting tool

Clause #	Clause Narrative as per ISO	Relevance to Software
4.1.5.c	have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;	Customer Information protection and protection of electronic storage and transmission of results
4.2.1	The laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities.	Software can be part of the management system
4.3.1	The laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, **test and/or calibration methods,** as well as drawings, **software, specifications,** instructions and manuals.	Test and or Calibration Methods, software specifications
4.3.2.3	Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).	Documents that are published by the software such as Job Card, SRF Sheet, observation form and certificate
4.3.3.4	Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.	Versioning of documents published by the software
4.4.1	The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:	In case, software is used for quotation and order booking
4.13.1.2, 4.13.1.3	All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.	Data retention policy and access to documents and data
4.13.1.4	The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.	Relevant Back and restore strategy
4.13.2.1	The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as	Software should preserve all raw data as well as derived data from various formulas

	possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results	
4.13.2.2	Observations, data and calculations shall be recorded at the time they are made and shall be Identifiable to the specific task.	Observation form need to be associated with job card
5.4.7.1	Calculations and data transfers shall be subject to appropriate checks in a systematic manner.	Automated calculations should be verified during validation
5.4.7.2a 5.5.2	computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;	Proper record of acceptance testing should be maintained (such as Excel vs SmartCalibration)
5.4.7.2b	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;	Data should be access controlled, a action log to be maintained for all user action on technical data
5.4.7.2c	computers 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.	Servers are maintained in adequate to use environment condition
5.5.5	Records shall be maintained of each item of equipment and its software significant to the tests and/or Calibrations performed.	UUC or DUC information should be uniquely identified in the software
5.5.12	Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.	All the changes to the software should be configuration controlled and revalidated before accepting it into practice
5.10.2	Each test report or calibration certificate shall include at least, i. Title ii. Name and address of the laboratory and location where the calibration was carried out iii. Unique identification of certificate number iv. Identification of method v. Name and address of customer vi. Date of receipt of DUC, validity, calibration results, date of calibration vii. Calibration results where appropriate with unit of measurement viii. Name, function and signature or identification of person authorizing the certificate ix. a statement to the effect that the results relate only to the items tested or calibrated x. Page number and total pages in certificate xi. Note 2, xii. Reference to environment conditions xiii. A traceability of references used xiv. the uncertainty of measurement	Published calibration certificates can be customized to actually look like the one that are being used by the laboratory. Software has all this information on the database and all the data can be published in Laboratory provided format or layout.

Author Disclaimer and Statuary Statement

SCC IT have tried to put facts and interpretations derived from various published information over the internet, it was our best attempt to put things in correct perspective thus any mistake or incorrect statement is inadvertent, however we will be happy to correct any anomaly or inconsistency if notified by email or through query forms after taking view from our consultants.

SCC IT solution is not making statement that laboratory adopting the SmartCalibration product will be compliant to ISO17025 regulation, as we believe that no software or application can make any laboratory compliant to ISO17025 automatically, or alternatively, No laboratory shall be certified conforming to ISO17025 by just adopting a software (that has all or some features that support conformance) in its working practices.

The above statement is fair as well, since it depends on laboratory how they use the software as a tool or application in its day to day processes and question. SmartCalibration is modular application that has flexibility to switch off modules not required by the laboratory, even within modules, features of modules can be switched off or made active based on lab requirements.

Appendix 6: Terms and Dictionary

Terms and Abbreviations	Explaination or description
DUC	Device Under Calibration (device received by the laboratory for calibration)
UUC	Unit under Calibration (instrument received by the laboratory for calibration)
NABL	Accreditation Board for Testing and Calibration
ISO	International Standards Organisation, responsible for drafting standards and guidelines
SRF	Service Request Form (generated by calibration labs after receiving instruments for calibration, it contains list of all work in scope of calibration from the customer)
Job Card	Lab Administrator entrust each of the job received in the scope of work to Lab engineers
IT	an abbreviation of Information Technology, technology commonly known and linked with computer, networking and software
PHP	Hypertext Preprocessor
Apache	is the world's most widely used web server software.
MySQL	A relational database management system most commonly used open source database
SW	Software
ODT	Open Document text
PDF	Portable Document Format
3GL	3rd Generation programming language normally used for scripting language used within RDBMS
WEB	An acronym used to say Internet
EUROLAB	European federation of national associations of Measurement, Testing and Analytical laboratories
COTS	Commercial Off-the-shelf software
MOTS	Modified Off-the-Shelf software

Appendix 7:References

Guidance for the Management of Computers - eurolab

Complying with ISO 17025 A Practical Guidebook - UNIDO

ISO/IEC 17025:2005 - General requirements for the competence of testing and calibration laboratories