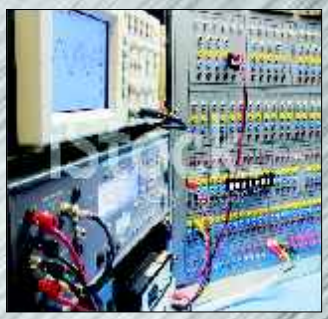


AOIL BULLETIN

Quarterly News Letter

Volume-1, Issue-3 **July – September 2016**

ASSOCIATION OF INDIAN LABORATORIES

INDEPENDENT 3RD PARTY TESTING

BUILDINGS, BRIDGES, HIGHWAYS RAILWAYS, AIRPORTS & PIPELINES

Polished Stone Value (PSV) of Aggregate	**BS 812: Part-114-1989**
Bridge Bearing-Elastomeric/POT/ POT-PTFE	IRC: 83-Part 2 & MOSRTH294
Highway SignageSheet Retroreflection Test	**ASTM E 810-03/ E 1709-08**
NDT-Concrete Structure-Reb. Hammer Test	IS: 13311 Part 2-1992
Thermoplastic Road Marking Materials	**BS 3262 & BS 6044**
CRMB, PMB, Paving Bitumen & Emulsion	IRC:SP:53/ IS:15462/ IS:8887
Curing Compounds for Concrete Curing	**BS 7542/ ASTM C 309-07**
Petrography of Rock, Stone & Aggregate	IS: 2386 Part 8/ ASTM C
Pre-Stressing LRPC Strands & Sheathing	**IS: 14268/ BS 5896: 1980**
Geogrid, Geotextile, & Geostrip for RE Wall	ISO 10319/ ASTM D6637

UP GOVT. MSME REGN No. 09015230925O/PART-II/2015

ANULAB®

INDUSTRIAL TESTING & ANALYTICAL LABORATORIES

ISO 17025, NABL Accredited Lab Cert. No.: T-0197 & T-0198

212 KM, Milestone, NH-2, Agra-Kanpur Road, Nagla Rambaksh
Post: Dhaurra, Tehsil: Etmadpur, Agra-283202, Uttar Pradesh
Cell: 91-9837052093, Ph:+91-562-252093, Fax: +91-562-2852826
Email: research@anulab.org Website: www.anulab.org

Watch complete test VIDEOS

www.youtube.com/user/anulabagra

YouTube Broadcast Yourself™

CENTRE FOR INSPECTION, TESTING & CERTIFICATION OF MATERIALS-CITCOM

NABL
ACCREDITATED LAB
C-100, C-158 & C-407

Accrediated as per
ISO/IEC :17025:2005
by NABL

BELZ
CAL LAB

Belz Instruments Pvt. Ltd.

Calibrate with Confidence

★ Providing quality calibration & testing services.
★ Provides Consultancy & Instruments for setting up new laboratory & its accreditation
★ Organizes training programs & workshops on calibration and quality aspects

Calibration Facility


Dimension


Dimension


Torque/Force


Mass/Volume


Electro-Technical


Thermal


High Current/Voltage


Energy/Power


Pressure

"BELZ" Calibration laboratory has strength of over 60 experienced & extensively trained engineers to provide competent & reliable calibration at laboratory or at customer's site.

Instruments


Coating Thickness Gauge


Radiation Pyrometer


Process Meter


Electronic Level


Flow Meter


Calibration Bath


Dead Weight Tester


Relative Humidity Generator/ Calibration System

The Company caters to different industries like Automobile, Pharmaceutical, Health care, Engineering, R&D, FMCG, Public Sector etc.

Belz Instruments Pvt. Ltd. (Since 1995)

Head Office : 5L-123, NIT Faridabad-121001 (Haryana) INDIA.
Ph. : 0129-2415646, 2414855, 09810087027 | Telefax : 0129-4055855
Branch Offices :
Zirakpur Ph. 01762-644352 Mob.: 09359053789, Baddi Mob.: 09250090197, Rudrapur Mob.: 09219524458, Haridwar Mob.:09219524458

E-mail:info@belzcallab.com | Website: www.belz.in

Celebrating 40 YEARS

An ISO/IEC 17025 Accredited Material Testing Lab

ELCA laboratories

ELCA LABORATORIES is one of India's leading ISO/IEC 17025 (NABL) Accredited Labs, specializing in Material Testing.

With over four decades of serving various industries, ELCA provides quality services in the field of Mechanical, Chemical, Metallurgical and Electrical Testing. The Labs also has state of art facilities for Corrossion, Plastic and Rubber testing as well.

The world class equipment at par with International Standards, ensure that the customer get accurate and reliable results everytime. This has led to ELCA being established as a trusted brand with its customers.

Mechanical Testing

Chemical Analysis

Microstructure Studies

Corrosion Testing

Electrical Testing

Rubber Testing

Plastic Testing

On Site Testing

Positive Material Identification

Asbestos Identification

Ingress Protection Testing

Surface Coating

Failure Analysis

Welder and Welding Electrode Qualification

RoHS Testing

ELCA takes pride in having a host of elite companies as its regular customers, who come from diversified fields like engineering, petrochemical, offshore, shipping, automotive, power, electrical and construction sectors.

ELCA has successfully met the stringent testing and analytical requirements of many a customers of India and abroad and continues to do so with its extended tailor made services. For more details, visit www.elcalabs.com

Contact us at:

Thane Lab

Plot No. A-444,
Road No. 37, (Off Road No. 28)
Near Rubber Products,
Wagle Estate, Thane 400 604,
INDIA.

Lab : 91 (22) 2582 44 99,
2047, 3142
E mail : info@elcalabs.com

Pune Lab

S. No.232/2,
Pune-Nasik Road,
Opp. Rupee Co Op. Bank Ltd.,
Bhosari, Pune 411 039,
INDIA.

Lab : 09822056975
09922960352
E mail : qc@elcalabs.com

Navi Mumbai Lab

Unit No: II,
W - 361, T.T.C. Industrial Estate,
MIDC, Rabale,
Navi Mumbai 400 701,
INDIA.

Lab : 91 (22) 27693483.
Fax : 91 (22) 27693492.
E-mail : rabale@elcalabs.com

Contents

Advertiser

ASSOCIATION OF INDIAN LABORATORIES

LIST OF GOVERNING COUNCIL MEMBERS AND OFFICE BEARERS FOR THE PERIOD 2015-2017.

1.	Sh. D. S. TEWARI	CHAIRMAN	9968151381	dstewari@aoilindia.org
2.	Sh. A. K. NEHRA	PRESIDENT	9810197068	aknehra@aoilindia.org
3.	Sh. RAJESH DESWAL	SECY. GENERAL	9811787807	rajeshdeswal@aoilindia.org
4.	Sh. PRAFUL YELVE	VICE PRESIDENT (CALIBRATION)	9821698504	prafful.yelve@aoilindia.org
5.	Dr. R. B. SINGH	VICE PRESIDENT (TESTING)	09837052O93	rbsingh@aoilindia.org
6.	Dr. S.Y. PANDEY	VICE PRESIDENT (GLP)	09909900919	sypandey@aoilindia.org
7.	Dr. NEERAJ JAIN	VICE PRESIDENT (MEDICAL)	9810492621	dr.njain@aoilindia.org
8.	Sh. LALIT PANERI	JT. SECRETARY	9829043949	lpaneri@aoilindia.org
9.	Sh. RAHUL GUPTA	TREASURER	9811565000	rahul.gupta@aoilindia.org
10	Sh. D. MATHUR	CHAIRMAN(N.R)	9312664533	dmathur@aoilindia.org
11	Sh. N. KALYAN	CHAIRMAN(W.R.)	09821056975	nkalyan@aoilindia.org
12.	Sh. SHASHI KUMAR	CHAIRMAN(S.R)	9972697755	shashikumar@aoilindia.org
13.	Sh. C.S. JOSHI	EDITOR	9313066685	csjoshi@aoilindia.org
14.	Sh. VIVEK BAGGA	MEMBER	9811672278	vivekbagga@aoilindia.org
15.	Dr. ALOK AHUJA	MEMBER	09837009700	alokahuja@aoilindia.org
16.	Sh. K. DHINGRA	JT. SECRETARY	9873001515	kdhingra@aoilindia.org
17.	Sh. KAPIL VASHIST	MEMBER	9810088217	kapilvashist@aoilindia.org
18.	Sh. GAURAV TEWARI	MEMBER	9811893191	gtewari@aoilindia.org
19.	Sh. ARUN R. FREDICK	MEMBER	9841085876	afredrick@aoilindia.org
20.	Sh. R.C. ARORA	MEMBER	9599056365	rcarora@aoilindia.org

Editor's desk

The role of testing laboratories in any economy is very important. This contribution becomes even more when goods and services are exported. The culture of accreditation lab is spreading fast in India also, though a lot more is required to accomplish. The accreditation is increasingly evolving into regularotary tool, which can ensure all-round development of the laboratory and service user alike.

Apart from performing regular testing the labs can be instrumental in developing new protocol and SOP's to reduce dependence of foreign players for their critical needs. The present testing area is largely restricted to conventional testing desired for regulatory requirement. While immense potential is awaiting in new fields such as forensic science, biometrics, human implant, health care and information system, energy efficient lighting, surface and fluid abrasion, electronics and telecommunication and security content automation protocol etc. This a challenge and opportunity both for Indian testing laboratories.

The other area of importance for labs are legal and statutory issues. With increasing global integration and awareness at local level, lab has to evolve and strengthen their systems to face these challenges in coming years. But one thing is sure that present scenario is conducive for growth and development of laboratory industries in India.

Yours truly

C S Joshi

Editor

Revision of ISO/IEC 17025 AND CD 2 ISO/IEC 17025

Devi Saran Tewari
AOIL Chairman, India
Former NABL Director

The following observations on CD 2 ISO/IEC 17025 were sent to Mr Jeff Gust, member WG 44 in required format for consideration of WG 44.

Please look for relevant clause in CD2 17025, to as you read.

Terms and definitions:

Comments:

3.9 Laboratory

The source of the definition of laboratory is not given in CD 2, to justify "Sampling" as a laboratory in itself.

The word Laboratory indicates that certain activities are performed from within the defined boundaries, and its product could be qualitative or quantitative.

Sampling is an act, which could also be performed by the laboratory, along with other mandatory acts needed to accomplish the task. Sampling is an important act, as results of testing or the output of the laboratory would be badly affected with improper sampling.

It is very important for WG 44 to consider all aspects/inputs, before defining the term "Laboratory" and may like to consider the following:

i. Laboratory has defined boundaries.
ii. Laboratory gives output which is/are used to take the decision.

As against this sampling can't be accomplished from within the defined boundaries and sampling itself does not give any output nor this itself is enough to arrive at decision.

Even if it is agreed to accord accreditation to those who do sampling, it would be impractical to do assessments, as samplers would not have defined boundaries. And the act of assessment can't be performed from unlimited boundaries and then the assessments would be confined to the premises for office activities, with or without the samples.

Under these circumstances, developing "Guidelines for Sample collecting agencies" and for its implementation would make us richer experience wise, to start accreditation for sample collecting agencies. Even ILAC can develop a document on it, under its G or P Series. G series would focus on how sampling is to be done and P series would bind laboratories to accept samples from sample collection agencies after a declaration from them has been obtained that in collecting the sample stated norms were followed.

5.6 e) identify management who, irrespective of other responsibilities, shall have the responsibility and authority that includes the following;

Comment: delete management and insert "a person"

6 Resource requirements

6.1 Except for "information system(s)" other items are required as resources in a laboratory, and by adding information system(s), there could be a situation when laboratories would be asked by assessors to adopt LIMS, which may involve an assessor's impartiality. Whereas without LIMS laboratories can be managed and are being managed.

If a laboratory can be managed without LIMS, why to impose, it may be left on laboratory to opt for it or not to opt.

Please ensure that new standard has no possibility for double interpretation.

Note of clause 7.12.3 says: In this international standard, "laboratory information management system" includes management of data and information contained in both computerized and non-computerised systems. ***Some of the requirements can be more applicable to computerised system than to non-computerised system.***

The portion in italics leaves a room for having the difference of opinion. This would put laboratories in disadvantageous position during the assessment.

6.2.8 It could be deleted as it is covered in Clause 4.1

6.4 Equipment

6.4.1 " access to" may be deleted

6.5 Externally provided products and services

6.5.1.1

Note: Products can include, …….. …… and assessment **"and auditing services.**" red portion needs be deleted.

Otherwise "Internal audit" would lose its meaning as assessors would advocate for externally provided services (second party audit compared to first party audit or internal audit), and could involve impartiality. Internal audit is an effective management tool for the management to know about the effective implementation of the management system, in their own organization.

Also this international standard needs to define what it considers as internal audit.

In 2005 version of ISO/IEC 17025 its Clause 4.5.1 i), focused on this aspect, and did not left, to laboratory to select competent auditors from outside laboratory staff. It gave a clear directive to the laboratory for having the quality manager and with defined responsibility and from within the staff.

The word/term “internal audit” implies that it has to be done by laboratory staff and without conflict of interest.

Clause 6.5.2.2

a) ensure that externally provided products and services remain within the control of its quality management system.

The word quality in red is required to be deleted.

And, Clause 6.5.2.2 (b) needs to be reworded as it is not giving clear message.

Clause 7.2.2.5 is a very good. It would help laboratory and customer.

Clause 7.2.2.6 Standard ISO/IEC 17025 is meant for those laboratories whose work is repetitive in nature, like testing and calibration laboratories. Such laboratories are not involved in research or developmental activities and therefore developing test methods on continual basis is not there need, in view of this retaining this clause in this standard would not serve any purpose.

Where development of test methods is an ongoing activity, it involves R & D or conduct of studies, and both these type of laboratories are not covered in the scope of ISO/IEC17025. However, WG 44 may gather the relevant information, through ILAC or on it’s own from accreditation bodies, to know about the number of laboratories, that have been accredited for their competence matching to Clause 7.2.2.6 or 5.4.3 of ISO/IEC 17025-2005.

Internal audit Clause 8.8

i. Internal Audit: In spite of the fact that this term gives a message that it is an internal activity and is to be accomplished by staff of the laboratory & Clause 4.1.5 i of ISO/IEC 17025, 2005 is very candid on it.

Whereas CD 2 in its Clause at 8.8.2 (c) states “select competent auditors and conduct audit to ensure objectivity and the impartiality of the audit process;” it could be amended to “select competent auditors from within the laboratory staff irrespective of other responsibilities and conduct audit to ensure objectivity and by complying to impartiality in the process of audit;

Comment: Portion in red to be added. This clarity would ensure in keeping internal audit as an internal activity and would forbid assessors in suggesting the laboratory to get the audit done by an out sider.

Even when clause 4.1.5 (i) of 2005 version standard, states that it has to be done by staff (QM) from with the lab, at times assessors insist that internal audit has to be done by an out sider.

Clause 8.6 (IMPROVEMENT)

Any standard is the means for improvement of the purpose for which the standard is written and ISO/IEC 17025 or CD 2 ISO/IEC 17025 is no exception.

Mathematically; Improvement is a function of all the clauses of the standard or CD2 ISO/IEC 17025.

Or

Improvement = f (all element/clauses of CD2 ISO/IEC 17025,) ,

The equation reaches a stage of imbalance with the inclusion of Improvement as an element/clause.

Improvement is an abstract noun and needs others to establish its existence. It can’t be measured on its own strength. Since it depends on other factors, this element/clause it is shown as the function of other elements, which are already there as the independent elements in CD2 17025, with intrinsic visible quantity.

Improvement = f (operational procedures, quality policy, overall objectives, audit results, corrective actions, management review, risk management, analysis of data, proficiency testing results)

If it is so, where is the need to include Improvement as an independent clause in ISO/IEC 17025.

With the same logic inclusion of Improvement as Clause in ISO/IEC 17025 (2005) is not justifiable.

The basic logic is that a clause/ element of set has to stand on its own strength, to justify its requirement, otherwise it is the duplication of the work already done.

When CD 2 has done away with term quality policy, then what is the need to include it as a function of Improvement as given above.

8.1 Options

Observations on Option A & Option B;

There would be operational problems in opting the system of option A and option B. The laboratory already having recognition for 9001, if given accreditation by an accreditation body would have two certificate, one on management system and the second for its competence to remaining clauses of ISO/IEC 17025. Both these certificate would have the recognition but for different periods.

Accreditation body may take a stand, and would be right in doing so, that its accreditation stands terminated with the laps of certification on 9001, then its accreditation can’t be seamless.

Also for such a laboratory a situation is bound to come when it would prefer to relinquish its certification of 9001, and continue with accreditation based on ISO/IEC 17025.

For laboratories through option B, there would be two internal audits and management reviews to satisfy both the agencies giving 9001 certification and accreditation. If not, then why?

Keeping its operational problems in view, it is better keep it as primary activity rather than degrading it to secondary category which is not sustainable.

8.9.4 Its sub-clause (i.) on Customer feedback needs to retained but the intent of sub-clause (k.) on Improvement is being covered by element of which it is the function.

WORKSHOP ON CD2, ISO/IEC 17025 REVISION

held on

New Delhi (14.04.2016), Mumbai (15.04.2016), Bangalore (16.04.2016)


Mr. Mohammad Mohsin, I.A.S.


WORKSHOP ON ISO/IEC 17025:REVISIONS
CHIEF GUEST
Mr. Mohammad Mohsin, I.A.S.
EMINENT SPEAKERS
Mr. Peter Unger
Mr. Jeff Gust
Mr. D. S. Tewari
Mr. Anil Relia

AOIL Workshops on 17025 Revisions (Delhi, Mumbai and Bengaluru)

Mr. Peter Unger
Chair ILAC

Compilation from questions and comments submitted on Slips of Paper AOIL Workshops on 17025 Revisions

Clause	Locale	Questions/Comments from 3 Workshops (i.e. Delhi, Mumbai and Bengaluru)
General	Delhi	What are the prime objectives behind revising the existing ISO/IEC 17025:2005? Whose interests are being protected in the proposed revised 17025?
General	Mumbai	Are "Notes" suggestions, comments or requirements? Will there be any explanations for the requirements whose clauses need clarification?
General	Mumbai	Alignment with ISO 17043, ISO 17034 and ISO 17020 is required.
General	Bengaluru	Will the final document be aligned with ISO 9001:2015?
General	Bengaluru	A general consensus of laboratories is that the current ISO/IEC 17025:2005 leave a lot to the assessor's discretion. Do you think the revised document would solve this issue, which would enable the labs to implement the requirements more confidently.
Intro	Mumbai	Principles of quality management are contained in ISO 9000. ISO 9001 contains requirement for quality management systems. Meeting the requirements of ISO/IEC 17025 should be considered as least equivalent to meeting the ISO 9001 requirements.
1.3	Delhi	This clause allows one-person laboratories, but 7.10.6 requires another person to communicate the outcome from those involved in the complaint. "Where possible" is needed. Which ILAC policy document addresses this since it is possible ABs will not have a uniform position on this point? (ILAC has not addressed this)
3.	Delhi	What is the difference between "compliance" and "conformity"?
3.	Mumbai	Definitions for" accreditation" and "certification" should be added.
3.3	Bengaluru	Please clarify as estimates of Z-scores for two-lab inter-comparisons are meaningless.
3.3 – 3.5	Bengaluru	Please consider combining these three definitions into one.
3.9	Delhi	For sampling activities, as a lab, how is this standard applicable?
3.10	Delhi	Need some clarification of decision rules.
3.10	Delhi	There are various methodologies for calculating measurement uncertainty. Is there a specific methodology ILAC is recommending (ILAC P10 and P14 cited).
4.1	Delhi	How is impartiality applicable for in-house laboratories?
4.1	Bengaluru	How does impartiality apply to in-house labs?
4.1.1 – 4.1.4	Mumbai	Clauses 4.1.1 to 4.1.4 should be merged.
4.1 & 4.2	Bengaluru	How will labs demonstrate impartiality and confidentiality and how will assessors assess these clauses?
4.1 & 4.2	Bengaluru	What is the rationale for elements of the separate impartiality and confidentiality clauses also repeated later in other clauses (e.g., clause 6.2.8)?
4.2	Mumbai	With respect to confidentiality to their customers, government labs have difficulty when under the Right-to-Information Act, somebody asks for information . . . in the public interest. How does one address this and can 17025 add a sentence with respect to a country's laws that would supersede the requirements of the standard?
4.2.1 – 4.2.2	Mumbai	Clauses 4.2.1 to 4.2.2 should be merged.
4.2.3 – 4.2.5	Mumbai	Clauses 4.2.3 to 4.2.5 should be merged.
4.2.4	Mumbai	Please clarify the words "client" and "customer." What is the difference?
4.2.4	Mumbai	What is meant by "client" and "customer" in this clause?
5.4	Delhi	Does this clause intend to cover insurance of the employees, staff involved in doing hazardous testing activities, e.g., flammable liquids, dry chemical powders, electrical

		conductivities, bursting tests of empty extinguishers, etc? If not, could you please incorporate such provisions?
5.4	Mumbai	Please elaborate regarding the provision to ensure liabilities. How can AOIL help?
5.4	Mumbai	Does this mean adequate finances to run the lab?
5.4	Mumbai	What is the intent of this clause? How is this achieved for a government lab?
5.4	Bengaluru	Will the adequate provision of liabilities through insurance or resources be enforced for a government laboratory?
5.4	Bengaluru	What is the meaning of "adequate provisions for liabilities"?
5.4	Bengaluru	This clause is very difficult for government labs to meet as we cannot go for insurance or provide bank guarantee. In my opinion. the word "shall" should be replaced by "should".
5.4	Bengaluru	To what extent does a laboratory have to cover its liabilities arising from its activities?
5.4	Bengaluru	How can the liability coverage be evaluated and what are all the parameters to be considered for this evaluation?
5.4	Bengaluru	What should be the extent of liability provisions? Does the lab have to take insurance to cover damages to internal and particularly external effects?
5.5	Delhi	What is the purpose of this clause requiring the lab to define the range of activities covered by this standard? If a laboratory performs other services which do not use lab data then should that be informed or documented?
5.5	Mumbai	Does the range of laboratory activities also mean scope or type of services?
5.5	Mumbai	Can you elaborate on how "range" is different from "scope"?
5.5	Bengaluru	How is the "range of laboratory activities" defined?
5.6e	Mumbai	What is the difference between "management" and "laboratory management"?
5.6e	Bengaluru	This clause will be impractical for small labs.
6.2	Mumbai	Why isn't the safety of personnel addressed in 6.2 and 8.5?
6.2	Mumbai	For competency, do we need to identify educational qualifications?
6.2	Mumbai	In the context of safety requirements, does the standard insist on meeting statutory requirements and what is the acceptance level?
6.2	Mumbai	Can key management personnel and technical staff work at multiple locations in a chain of laboratories?
6.2.4	Mumbai	What should be the mechanism for the lab communicating to each person their duties, responsibilities and authorities?
6.2.8	Delhi	Please elaborate on the risk to impartiality arising from one's overfamiliarity. Isn't this highly subjective and how is it going to be assessed? Is it not equivalent or already addressed by clause 4.1.5?
6.2.8	Delhi	What is the meaning of overfamiliarity both personnel and customer? Please give an example.
6.2.8	Mumbai	How does one comply with this over-familiarity phrase and how is it going to be assessed?
6.2.8	Mumbai	Under this situation, what type/format of proof is required to be established by the accreditation body assessor?
6.2.8	Bengaluru	This clause I guess should address companies who have their own calibration facility. 'Like I manufacture and also certify its good'
6.3	Mumbai	Please elaborate on environmental conditions to be "periodically reviewed."
6.3	Delhi	Why is good housekeeping deleted?
6.3.2	Bengaluru	Can you give examples of what it means to use facilities outside of its permanent control?
6.3.2 & 6.4.2	Bengaluru	What is the difference between clause 6.3.2 and clause 6.4.2?
6.3.3	Delhi	Does the lab decide the effectiveness of the separation of incompatible activities? If the accreditation bodies decide, they have their own interpretation? None of the standard specifications include such standards. Normal operation of a lab would take sufficient precautions to minimize interference. It should accordingly be prefaced. "wherever practical."
6.3.3	Delhi	What is the time interval for periodically reviewing environmental conditions?

6.4	Mumbai	What is the meaning of software measurement? Is it calibration of software or validation of software?
6.4.1	Delhi	The definition of equipment as stated shall include software, measurement standards, reference materials, reagents, etc., but it does not mention measuring instrument, since JCGM 200:2012 has separate definitions of measurement standard and measuring instrument (JCGM clause 5.1 and 3.1).
6.4.4	Delhi	Can a lab be accredited for using equipment which is not under its control, i.e., outside direct control?
6.4.7	Bengaluru	Does software and electronic signatures need to be validated? Is it mandatory for software?
6.4.7f &g	Delhi	What is the difference between 6.4.7 (f) and (g)?
6.4.7g	Bengaluru	Considering the financial burden on small labs, can there be some via-media methods to validate expired CRMs so that they can continue to be used?
6.4.9	Bengaluru	Why is "when necessary" included? Aren't intermediate checks required in all cases?
6.5	Mumbai	Indicating-type instruments do not have to be calibrated.
6.5.1.1 Note	Delhi	What is the meaning of "assessment and auditing services"? Is this relevant for internal audits?
6.5.1.2b	Delhi	Wouldn't this situation be covered as a customer-supplied product since the customer is involved in the outcome of the measurement?
6.5.1.2	Delhi	Please explain about what "product" means in the statement "The lab shall control externally controlled product and services when these are intended for incorporation into the lab's own activities. ISO 9001 definition of product appears different as it includes services.
6.5.2	Mumbai	For subcontracting work, getting approval from customers will delay the testing. Just informing the customer about subcontracting should be sufficient. If the customer has any objection, he will inform the lab.
6.5.2.2a	Mumbai	Can a lab use any outside equipment held by another accredited lab?
6.6	Delhi	Is metrological traceability different from measurement traceability as per this CD2? However, as per GUM reporting of result includes any error by correcting the final values reported (may be additive or subtractive).
6.6	Delhi	If a laboratory is accredited for a certain scope with calibration reference standards, can the laboratory claim accreditation for the same scope with working standards other than reference standards? What about metrological traceability?
7.1	Delhi	How is impartiality applicable for labs doing only in-house testing, particularly review of requests?
7.1	Delhi	When a client claims the equipment complies with ASTM, DIN, ISO or any other standards, what does it mean? Does it mean that the specified ASTM, DIN, or ISO procedure can be adopted to perform analyses on the said equipment is then in compliance?
7.1.1.3		
7.6.3		
7.7.1a	Bengaluru	More clarity is required for decision-making management especially chemical testing labs, where there are a lot of unresolved issues and ambiguity in the proper calculation of uncertainties. The rationale and background behind these clauses is needed where decision rules are involved.
7.1.1.4	Mumbai	Please explain the last sentence: "Deviations requested by the customer shall not jeopardize the integrity of the laboratory or the results."
7.1.2.1		
Note b	Bengaluru	When the laboratory does not have the resources or competence to perform the activities and subcontracts them, how can the lab ensure the correct execution of the job and report before issuing the report to the customer?
7.2	Delhi	Is there any information or regulation related to development and validation of analytical methods for unidentified impurities?

7.2.2.2 7.2.2.4		
7.2.2.5		
7.2.2.6	Delhi	How are these four clauses relevant when there is a fixed-scope policy of the AB?
7.3	Bengaluru	Logically, no one can calibrate their instrument on a sampling basis at all. So why is there a clause for sampling?
7.6	Mumbai	What is a suggested timeframe or frequency for calculating one's uncertainty of measurement?
7.7	Delhi	In the analysis of results could one use correlation of results with properties, with performance, with durability and with failure/forensic?
7.7.1	Delhi	Please provide some guidance on decision rules?
7.7.1	Delhi	In acceptance criteria (decision rule) how is uncertainty of measurement accounted for?
7.7.1	Delhi	How is the measurement uncertainty quoted and interpreted for compliance?
7.7.1	Mumbai	Regarding the measurement uncertainty requirement what is the effect going to be on testing laboratories?
7.7.1	Mumbai	Many microbiology labs do not follow uncertainty of measurement. What standard should be followed for such microbiological tests?
7.7.1	Mumbai	Does a lab have to report measurement uncertainty with microbiological test results? If no, then why do we have to calculate uncertainty for microbiological analyses?
7.7.1	Mumbai	How does one handle decision rules for qualitative measurement?
7.8.1	Mumbai	What would be the acceptance criteria for QC checks such as intermediate checks, re-calibration of retained items, replicate calibration and in-service verification?
7.8.1j	Bengaluru	Can we expect to have more details about ILC/PT (e.g. test method, other lab criteria)?
7.8.1k	Delhi	Clarify what is a blind test?
7.8.1k	Mumbai	What is expected under "blind test"?
7.8.1k	Delhi	What is a "blind test"?
7.8.1k	Delhi	Clarify what is the meaning of "blind test"?
7.8.1k	Delhi	What is "blind test"?
7.8.2	Delhi	Apart from participating in PT/ILCs, can you please suggest other means for lab to monitor the quality of output comparing with the output of other labs?
7.8.2	Delhi	For quality assurance of measurement results two methods are in practice: 1) PT and 2) ILC. The easier way for labs is ILC. Is the standard going to specific periodicity for a laboratory to take part in PT instead of doing ILC all the time?
7.9.4.3	Delhi	Could you provide details on the purpose of prohibiting calibration interval statement on labels?
7.9.1	Delhi	Reports may have many test parameters. Would the date of analysis for each of the tests now be required to be mentioned?
7.9.3.1	Bengaluru	Is it mandatory to report uncertainty for all test results in test reports?
7.9.3.1	Bengaluru	Do labs have to mention uncertainty in each test report?
7.9.4	Mumbai	Can a calibration certificate state that it shall not be used for further calibration of other devices?
7.9.5.1	Bengaluru	Is it mandatory to issue a compliance statement in certificates?
7.9.5.2	Mumbai	Opinions and interpretations clause needs detailing.
7.10.6	Delhi	This clause allows one-person laboratories, but 7.10.6 requires another person to communicate the outcome from those involved in the complaint. "Where possible" is needed.
7.10.6	Delhi	How can a one person lab have an independent complaint management system desired under the proposed revision?
7.12.2	Delhi	There seems to be nothing being talked about re data integrity: How do you ensure this; what steps are essential and what is the verification to see it is in place
8	Delhi	What is the benefit of placing management requirements at the end when it was at the

		beginning on the 2005 version.
8	Bengaluru	Is a quality manual required to be prepared as per the revision when it is released?
8	Bengaluru	Does the quality manual have to be thoroughly revised once this revision goes into effect?
8	Bengaluru	When the lab is part of a larger organization with ISO 9001 or AS9100C certification, what is the laboratory's role in the audit process of the organization? Is it necessary to have separate quality manuals complying with both 17025 as well as 9001 or AS9100C?
8	Bengaluru	The new revisions of ISO 9001 or AS9100C do not focus much on the QMS clauses in the auditing process. It is based more on implementation and effectiveness of process (or process-based approach). In this context, where does the revision of 17025 stand?
8.1	Delhi	Since ISO 9001 is an acceptable option what is the relevance of Option A? Seems like CASCO has compromised the technical rigor and competence elements of 17025.
8.1	Mumbai	Isn't a quality manual necessary? What is the alternative to a quality manual?
8.1	Delhi	What is the meaning of Option A and Option B?
8.1	Mumbai	Options should not be allowed as labs will take advantage.
8.1	Bengaluru	Is it mandatory to write all the clauses of 17025 into the quality manual? If yes, the quality manual becomes voluminous.
8.5	Mumbai	Is risk assessment the same as "HIRA," i.e. Hazard Identification and Risk Assessment?
8.5	Mumbai	Is this clause equivalent to Failure Mode Effects Analysis as defined in ISO/TS 16949?
8.5.2	Delhi	What is risk management related to a laboratory? Please give an example.
8.5.2	Bengaluru	What should the extent of risk assessment cover? Should it include risk to external environment, people, etc.?
8.5.2	Delhi	Management of risk and opportunities: Should this be for all processes and activities? What is the reference for guidance? (ISO 31000 and Guide 73 cited); Our institute would need training on this.
8.7	Bengaluru	Why are corrective action procedures and records not made a requirement?
8.8	Mumbai	The frequency of internal audits should be specified.
8.8	Mumbai	Why is the frequency of internal auditing not defined in 8.8 as it was defined in the 2005 version as at least a year?
8.8	Mumbai	Is it required for internal audits to be conducted at a place of sampling if it is outside the testing laboratory?
	Delhi	Can there be a provision for "empaneled auditors" for conducting internal audits since the quality manager position is not required?
Annex	Delhi	Are you mapping the standard with ISO 9001:2015 similar to the Annex in 17025:2005?
Annex	Bengaluru	The 2005 version provided a nominal cross-reference to ISO 9001:2000. Will the revised 17025 have a similar Annex for cross-referncing to the clauses of ISO 9001:2015?
Annex A	Mumbai	Clause 1.3.1 suggests technical competency of a calibration service provider should be evaluated. Why? If the provides is NABL-accredited why is a separate check required?
ILAC	Bengaluru	Will the presentation material be available on the ILAC website? (No; AOIL will make them available on its website)
ILAC	Delhi	When ILAC aspires to get results of all accredited labs accepted across the globe how do you see the role of 21 CFR Part 11 when it comes to equipment such as LIMS software? (I was not familiar with this US regulation)
ILAC	Bengaluru	What will be the time frame give to accredited labs for implementation of these changes after the revision is published? (to be determined by ILAC and ISO, perhaps 3 years was projected)
ILAC	Bengaluru	With reference to Mr. P. Unger slide "Accredited once, accepted everywhere," it is not a current situation in India. For example, many regulators do not accept NABL accreditation. So labs are compelled to go for multiple accreditations. AOIL can be instrumental in getting many regulators under a single 17025 umbrella. (India is not alone. Many countries regulators do not accept 17025 accreditation)
Accreditation	Delhi	The accreditation cycles of accreditation bodies are different. Examples: IANZ: 3 years; NATA: 4 years: UKAS: 4 years; NABL: 2 years. Why? (17011 allows it)

Accreditation	Mumbai	If a lab is certified as per ISO 9001, can management system requirements be waived off during an accreditation assessment?
Accreditation	Bengaluru	If a lab gets its management system ISO 9001 certified, can the management clause 8 be omitted from 17025 assessment?
Accreditation	Bengaluru	If an organization has an existing ISO 9001 certification, do the additional management system requirements of Option A have to be assessed?
Accreditation	Mumbai	Accredited labs undertaking testing of samples which have a direct impact on the public like drinking water, environment, food samples, drugs, etc. should be made mandatory to be available in the public domain.
Accreditation	Mumbai	Can the whole process of accreditation and documentation be made paperless to protect the environment? Is there any clause mentioning paperless processes?
Accreditation	Bengaluru	The standard makes it necessary to document the requirements. I request that ILAC check the possibility of reducing hard-copy documents wherever it can be avoided. We should strive hard not to cut more trees and let us save the environment (17025 document and records requirements do not demand paper media; they can be met by electronic means)
Accreditation	Bengaluru	For some equipment only the manufacturer does the calibration. If the manufacturer's calibration lab is not accredited, can they do the calibration and have it be acceptable or do we have to go to another third-party lab?
Accreditation	Mumbai	NABL has stopped publication of its newsletter long ago. Is NABL going to start it again? It is very useful for labs.
Accreditation	Mumbai	NABL has discontinued display of the status of accreditation for all applicant labs. Is NABL going to start it again?
Accreditation	Mumbai	When NABL accreditation is given by the Department of Food Science and Technology under the aegis of the Ministry of Science and Technology, why are other accreditations like FSSAI, BIS, Export Inspection Council, etc., operating. Can we not have one accreditation body preferably NABL which also has international recognition with APLAC and ILAC?
Accreditation	Bengaluru	If there are no NABL-accredited labs for stress analysis by XRD method, how can a lab perform ILC? How can we perform ILC when there are not a sufficient number of labs for certain tests? Why is 17025 silent about this?
Accreditation	Bengaluru	Is it mandatory for labs to follow the same test method as other labs for the same tests, even though for some tests, e.g., pH has more than one method?
Accreditation	Bengaluru	Some assessors insist that you have a separate license or certification from machine manufacturers even for machine software, e.g. universal/tensile testing machine software. Your comment.
Accreditation	Bengaluru	As the individual assessors have their own perception, is it possible to bring out a common audit checklist so that both auditors and auditees speak the same language?
Accreditation	Bengaluru	A manufacturer provided a '0' value and maximum value, but the assessor did not accept '0' value and asked for a minimum value.

I am solely responsible for any errors or misrepresentations of the questions or comments provided on paper slips by the attendees.

Peter Unger

Acknowledgment :

AOIL expresses its gratitude to Mr Peter Unger and Mr Jeff Gust for the time, support and guidance given by both of them. It is a matter of satisfaction for AOIL that all the three workshops were a great success, in terms of number of participants (850), and also for their active participation, as more than 155 questions were asked.

Chairman AOIL.

AOIL
SCHOOL OF LABORATORIES, INDIA

Four days Training Programme on

'Quality System Management and Internal Audit'

based on ISO / IEC 17025:2005

held at FARE Labs - Gurgaon from 27th to 30th June 2016

ISO Guide 80-2014

Preparation of In House Quality Control Material for Testing Laboratories at affordable Cost

Dr.K.Balasubramanian
Head Technical
Chennai Mettex Lab Pvt Ltd.

Introduction:

Ensuring the analytical accuracy within the defined control level is a great task for laboratories. Everyday there are many samples and various analytical parameters are being analyzed by different analysts. ISO 17025: 2005 is more emphasize the "Assuring the quality of tests" under Clause 5.9, which says "The laboratory shall have quality control procedure for monitoring the validity of tests". The laboratory must use Certified Standard Reference Materials (SRMs) or Certified Quality control materials (QCM) specific to the matrix. But considering the cost and quantity of Certified SRM or QCM, it is not possible to use those SRM or QCM in the lab very often.

ISO Guide 80 which was published in late 2014, helping us to prepare in house Quality control Materials which helps the laboratories to control the analytical process at affordable cost, comparing to those Certified SRM or QCM

There are many ways In house Quality Control Materials (IQCM) are being referred in the analytical communities i.e. "In house reference material", "Quality control samples", "Check samples", "Set up samples", etc...

The preparation of IQCM should involve homogeneity and stability assessments and a limited characterization of the material provide an indication of its relevant property values and their validation prior to use.

IQCM provides quality criteria that a material should fulfill to be considered fit for purpose for demonstrating a measurement system is under statistical quality control.

Importance of In house Quality Contorl Material (IQCM):

The main use of IQCM is to provide laboratories to check their routine test procedures for precision on a regular basis.

IQCM's are specific, limited purpose in the measurement process. There is no requirement for IQCM to have metro logically traceable assigned values.

Uses of IQCM include but are limited to:

- Preparation of QC charts- to demonstrate control of a measurement process within a laboratory or to confirm the effectiveness of a Laboratory's quality control process or to demonstrate control of a measurement process over a period of time.
- Comparison of results between methods and analysts.
- Method development- to establish the consistency.
- Instrument performance checks.
- Repeatability and reproducibility studies.
- Operator variability.
- As Check sample.
- To evaluate the competence of lab staff
- Impact of any changes to environmental conditions.

Preparation of IQCM:

IQCM should always comply with the basic requirements of any reference material. They should be sufficiently homogeneous and stable with respect to the properties of interest / Analyte of interest

The level of heterogeneity should be less than the expected standard deviation of the measurement process or an established criterion value against which the assessment of laboratory performance or the "Normalization" of results is acceptable.

The IQCM should be stable for a period of time that is at least as long as that during which it is intended to be used. It is recognized that the aim of many laboratories requiring is to minimize the time and effort needed to prepare the materials.

The fundamental purpose of IQCM is to detect the change. IQCM will be prepared by technically competent staff that is knowledgeable about the material and processes being used.

1. Matrix Specification& Sourcing :

- QCM are prepared for specific purpose and the material properties can be closely matched to the samples under analysis.
- The preparation of a sample comprising digestion,

extraction, cleanup, etc...

- Size of the individual unit of QCM should be based on the use of the material required for the measurement concerned. (Single or multiple measurements).
- Total bulk amount of material is procured based on the number of units required per year, unit size, preparation yield, stability and type and size of the required storage facility.

2. Material Processing:

- **Drying:** Drying of QCM is carried out at ambient or elevated temperature to remove the water and provide improvement in short and long time stability. Freeze drying is useful technique for temperature sensitive materials.
- **Milling and Grinding:** It is performed to improve the uniformity in particle size and material homogeneity.
- **Sieving:** It is performed to make the material more homogenous. Sieving may changes the matrix composition based on the composition of material.
- **Mixing and Blending:** Blending of two or more materials with sufficiently similar compositions and differing property values may enable the QCM with a desired property value. It is performed after milling, grinding and sieving. This process is required to get uniform homogeneous mixtures and uniform particle size distribution of QCM.
- **Filtration:** Generally, Liquid QCM is filtered through 0.45 µm filter prior to bottling.
- **Stabilization:** Addition of antioxidants, preservatives, texture stabilizers, etc. is added generally to make the QCM stable.
- **Sterilization:** Before stabilizing any candidate QCM , it is important to consider the impact of the proposed sterilization process on the material, particularly those which degrade at elevated level.

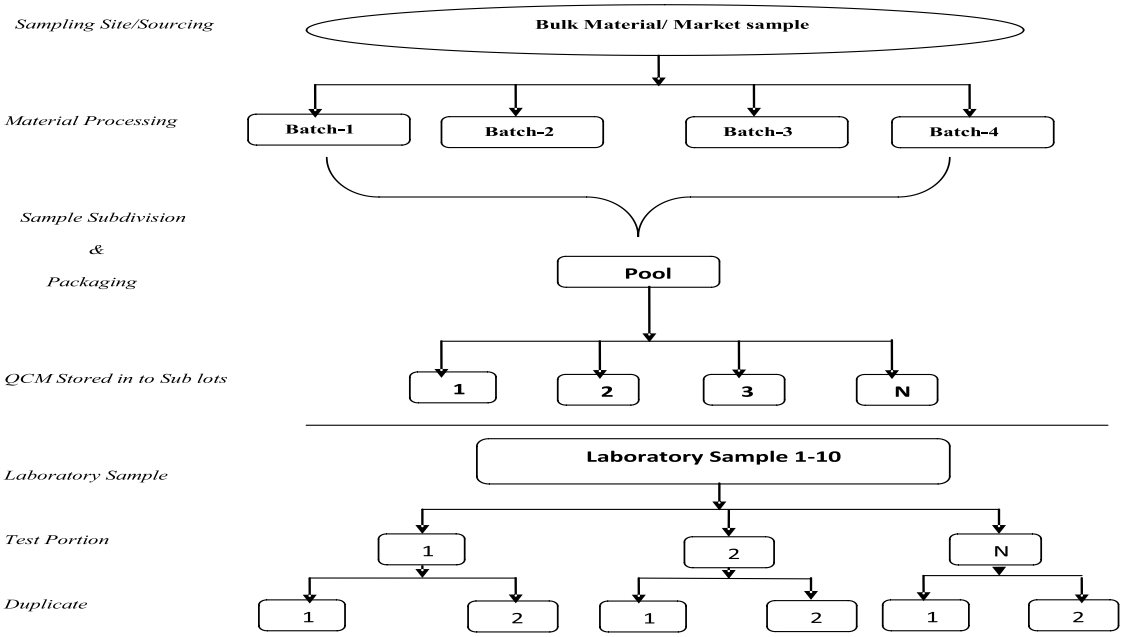
3. Sub division & Packaging:

- The choice of the container for the packaging is critical.
- QCM material should be sub divided according to its intended use to avoid moisture and other contamination.
- Oxygen sensitive materials are prepared using inert gas atmosphere.
- The effect of repeated opening and closing of the sample containers may also be assessed if repeated use of the material is anticipated.
- Sub division has to done as quickly as possible to avoid the QCM become heterogeneous.

4. Homogeneity assessment:

- It is important to establish that any variation is there in IQCM, a formal experimental investigation is required.
- A statistical evaluation of the data and a test for sufficient homogeneity are carried out which can be achieved using Spreadsheet software.
- A validated analytical method having a sufficient degree of repeatability should be selected for evaluation of the homogeneity. The selected unit should be representative of the entire batch and the number of unit is dictated by the total number of units produced.

The schematic representation of Homogeneity Study layout is shown below.



An example is given of a check for homogeneity of a Milk Powder control sample of 5 kg which was split into ten equal laboratory control samples of which the Zinc was determined in duplicate.

The Zinc can be determined as follows:

- Weigh approx. 0.5 g sample into a microwave vessel
- Then 10 mL of Nitric acid and 2 mL Hydrogen Peroxide is added and the sample is kept for pre digestion
- The sample completed Digested using Microwave Digestion and made up to 25 mL with Milli-q-Water.
- The sample is analyzed in ICP-OES against Zinc standards.
- Results are tabulated and Statistical data analysis is carried out.

Batch	Run	Result (mg/Kg)
Batch-1	1	32.8
	2	32.8
Batch-2	1	33.5
	2	34.4
Batch-3	1	34.7
	2	36.2
Batch-4	1	34.9
	2	37.4
Batch-5	1	38.2
	2	36.8

Statistical Parameter	Value
Count	10
Average	35.17
Standard Deviation	1.908
Relative Standard Deviation	5.426
Range	5.4
Lower Control Limit	29.445
Lower Warning Limit	31.353
Upper Control Limit	38.987
Upper Warning Limit	40.895

Note: Statistical Control Chart is prepared using the above Data and ANOVA can be calculated as per the procedure in the ISO Guide 80:2014.

5. Characterization and Value assignment:

- An effective way of determining an indicative property value is to use the overall mean derived from the homogeneity study.
- The range within which the property values may reasonably be expected to lie can be estimated by the deviation from this overall mean value.
- This deviation from the mean can be used to\ establish control chart warning limits.

6. Stability:

- It should be pointed out that as some IQCMs are made for repeated use, investigation of the stability of opened units may be particularly useful.
- Failures in preparation or unexpected contamination or impurities may impair the stability significantly.
- QCM is assessed based on the comparison with fresh calibration standards and precision/sensitivity checks to confirm any deviation.
- Any stated expiry date for a QCM should be based upon previous experience of the stability of the types of matrix and property values and any background information.

7. Documentation for IQCM:

- The following Information such as name and Description, reference number, date of preparation, intended use of material, unit size, storage information and safety precautions.
- Each IQCM's are clearly labeled that enables it to be unambiguously linked to the information for the material.
- Useful information relating to the preparation of the QCM will be required if query arises regarding the material during use.

8. Storage:

- Completed batches of IQCMs should be stored that will ensure they remain unchanged.
- Storage condition will vary with matrix. It has to clearly define the storage conditions for each IQCM.
- The relevant storage conditions should be monitored at regular intervals to ensure that the appropriate temperature is being maintained.

Significance of an In house QCM:

The major issue with the certified SRM and certified QCM are very expensive and it is not specific to the matrix or process.

- Cost Effective
- Stability and availability
- More Quantity
- Storage
- Specific to all matrix and process
- Transportation

Conclusion:

The demand of In house QCM is increasing and an important tool for laboratory management. This article has given overview to prepare IQCM with respect to ISO guide 80:2014 for testing Laboratories. More details can be referred in ISO Guide 84-2014.

A2LA Pursuing FCC Recognition to Accredit Test Firms in Non-MRA Countries

The U.S. Federal Communications Commission (FCC) recently published FCC 16-74 "Memorandum Opinion and Order on Reconsideration" (released June 15, 2016), which extends the deadline for all laboratories who perform Certification and Declaration of Conformity (DoC) testing per the FCC rules to be accredited to ISO/IEC 17025. The previous deadline to become accredited was set at July 13, 2016, but the FCC has now extended this for an additional one-year period – until July 13, 2017. As directed within publication 16-74, the FCC's Office of Engineering and Technology (OET) has now also released a revised version of its Knowledge Database (KDB) publication "974614 D01 - Accredited Testing Laboratory Program Roles and Responsibilities" (v04).

For the first time in history, this KDB now provides a procedure for laboratories that are located in countries that do not have a government-to-government MRA with the United States (i.e. APEC TEL MRA) to become designated as accredited (recognized) test firms with the FCC. The revised KDB indicates that labs in non-MRA countries "may use an accrediting body that the FCC has recognized for performing accreditation assessments within that specific country".

Under these revised procedures, A2LA is excited to announce that it has now submitted its application to the FCC in order to seek recognition to accredit laboratories in the following non-MRA countries:

People's Republic of China, India, Malaysia, Philippines, Thailand, and Mexico

As A2LA is already an FCC-recognized accreditation body for testing laboratories located within the United States, and also supports various government-to-government MRAs around the world, we anticipate that our application for recognition to accredit laboratories in these non-MRA countries will be straightforward and efficient.

A2LA urges all interested laboratories to begin the accreditation process as soon as possible in order to avoid delays and the risk of missing the FCC's new deadline. We stand ready with full-time staff and technical assessor resources to assist in the accreditation of these laboratories on a global scale.

For additional information or to request a free estimate of costs associated with A2LA's accreditation program, please contact Mr. Adam Gouker (301-644-3217 oragouker@A2LA.org) or visit the A2LA Electrical Testing Accreditation Program page.

Courtesy: A2LA

Optical Metrology Solutions: The Future of Metrology

Global manufacturing has advanced into a highly competitive market, with narrowing margins and competitive pressures from factors not previously considered.

As a result, manufacturing efficiency has taken on new meaning with the role of automation. There are several initiatives undertaken by manufacturers across the globe to achieve 100 percent manufacturing efficiency, thus, ensuring productivity and profitability in the global manufacturing industry.

Quality control is an integral aspect of the manufacturing process. To effectively enable the evolution from traditional factories to smart factories, it is critical to substitute incumbent manufacturing and quality inspection technologies with emerging approaches.

Dimensional metrology is one of the key technologies used in the quality control process to inspect accuracy of produced components. This industry is also undergoing major technological developments to empower smart factory automation concepts.

Traditionally, dimensional metrology technologies such as coordinate measuring machines (CMMs) have been used in quality control rooms to inspect geometric features of a manufactured component. CMMs are considered to be the best solution to exhibit high precision results. The main disadvantage of traditional CMMs is that it takes a longer time to measure each point because of the process of approaching the surface and withdrawing has to be repeated for each point. For several decades, precise length measurements were dedicated to fixed, structured systems, such as CMMs. There was a strong acceptance that to be accurate, precise and repeatable, a rigid structure like a CMM was the solution for obtaining high-precision measurement results. That perception has slowly changed in the past 10 years after optical scanners were engineered for dimensional metrology inspection. As a result, the conventional CMMs such as bridge-type CMM, horizontal arm machine, gantry-type CMM and articulated arm machines are facing fluctuated growth rates across the globe.

Even today, CMM technology continues to dominate the dimensional metrology market. However, over the past 10 years, 3D laser scanners, white-light scanners and laser trackers have become widely implemented as dimensional metrology solution by end users. Apart from exhibiting faster and high-precision results, newer optical scanner products continue to capitalize on end user confidence by showcasing flexibility and portability. The need to complete inspection within production cycle is gradually demanding faster technology, as a result traditional CMMs are being replaced with faster optical metrology products. Optical scanners are faster and cheaper in comparison to the traditional CMMs. As a result, optical scanner products are more widely implemented for smart factories.

Market Snapshot

Recent Frost & Sullivan analysis indicates the global optical scanners market generated revenue of $430 million in 2014, and predicts the market will grow at a compound annual growth rate (CAGR) of 5.4 percent to approximately $520.0 million in 2019. This includes products such as 3D laser scanners, white-light scanners and laser trackers. With the proliferation of low-cost scanners, improving technology and superior features being incorporated into scanners each year, the optical scanner market is expected to continue expanding.

Quasi-Monopoly Structure Defines the Laser Tracker Market

Laser tracker equipment has been in existence for three decades and used widely in the automotive, aerospace and machine shops sectors for larger volume and high accuracy measurements. For example, key applications in the automotive sector include alignment, profiling, dimensional measurement and control. The small size of laser trackers, combined with their large volume measurement capabilities, drive their need in the automotive sector. In the aerospace, military and defense sector, laser trackers are used for inspecting curved surfaces of aircraft wings, part inspection, reverse engineering, and dynamic measurement. Laser trackers are preferred over other metrology solutions because of their portability and speed, along with the need in the aerospace, military and defense sector for accurate measurement of critical components.

In comparison to other technologies such as coordinate measuring machines, white-light scanners and vision based products, prices of laser trackers are relatively higher. Typically, mid-sized end users with limited inspection and maintenance budgets may not be able to justify expenses of $110,000 for a laser tracker solution. As a result, customers tend to opt for cost-effective metrology solutions, which further challenges market growth.

Hexagon Metrology, FARO Technologies and API Sensors together capture about 90 percent of the laser tracker market. Besides these tier-one companies, only a handful of others, such as Shenzen Chenguang Xinyuan Electronio Co.Ltd and Northern Digital Inc, are actively involved in this industry. The quasi-monopoly structure is expected to intensify the competition and challenge the tier-two companies to remain relevant in this industry. In the future, competitive pressures are expected to increase the trend toward acquisition of tier-two market participants for enhancing market share in the laser tracker market.

White-light Scanners—Fastest Growing Market Segment

Operating on the basis of white light interferometry, a white light scanner captures a series of data points across the vertical axis. Both the shape and phase of the interferogram are used to determine the object's physical geometrical features. Applying Fourier analysis to the data converts it into the spatial frequency domain, making it possible to create an accurate representation. Unlike CMMs, a main advantage of white light scanners is that the information generated can be used without the need for data handling by experts.

For almost 10 years, white-light scanners have been used in several application areas in the dimensional metrology market. They include measuring of dies and molds, casts and forged parts. White-light scanners are also used in comparing actual data with nominal data, scanning of design models for further processing of CAD data, documentation and acquisition of data for rapid prototyping. With ever-increasing market awareness and penetration, demand for white-light scanners is significant. Having gained a reputation as one of the most accurate technologies, a period of positive growth is expected. Frost & Sullivan research indicates that Gom gmbH, Steinbichler optotechnik gmbH, Hexagon Metrology and Aicon 3D have together captured about 82% of the global white-light scanners market in 2014. With the proliferation of low-cost white-light scanners, other noteworthy companies such as Phase Vision Ltd, 3D3 Solutions, and Miic America Inc are gaining increased market visibility.

Increased Price Point Competition Strains 3D Scanners Market

Frost & Sullivan research indicates that the 3D scanners segment generates highest revenue in the global optical scanners market. The basic function of laser scanners is

the complete imaging of an object to obtain many coordinate points that are used in the reconstruction of the image in 3 dimensions. The main components include a scan head and a platform for movement along directions that are integrated together by manufacturers. With the required software, the inspection is performed after mounting the object on a rotary table. Laser scanners can be used alone or in conjunction with fixed CMMs or portable arms.

3D scanners for fixed CMMs and portable arms are quite similar as the key contributors to revenue are industries such as automotive and machine shops. Since the introduction of scanners, customers were keen to have these fast and accurate measuring probes attached to traditional CMMs that were being widely used.

The stand-alone 3D scanners continue to account for a major portion of revenue, but significantly less than the share held by scanners that are attached to CMMs and arms. Research indicates that heritage preservation, medicine, animation, and education are expected to be key end-user industries for standalone 3D scanners that drive growth.

Conclusion

It is evident that optical scanners have made steady penetration in the dimensional metrology market. Leading companies in the optical scanners market such as Hexagon Metrology, Faro Technologies, Gom gmbh, Steinbichler Optotechnik gmbH, Nikon Metrology and API Sensors, have raised the bar in terms of technology and product development for optical metrology products. Their global presence and technology innovation has helped these companies consistently stay ahead of the competition. Furthermore, the competition amongst the leaders enunciates the need for high-accuracy optical scanners that increase measurement flexibility thereby exhibiting reliable and faster measurement results.

Frost & Sullivan finds that attaining absolute measurement results through optical scanners is the utopian ambition of several dimensional metrology manufacturers. If absolute measurement can be achieved using optical scanners, several industry experts believe that it could be an end to CMM era in the quality inspection process.

Courtesy: Qualitymag.com

SCC's SMARTCALIBRATION (LIMS for Calibration Laboratories)

An essential step to make Calibration lab processes efficient and paperless

Manage smartly with SmartCalibration

Reduce Turnaround time, deliver work faster

Reduce Clerical and Calculation mistakes

Reduce Paper wastage

Reduce probability of non-compliance

Manage workload and resources productively

SCC assurance and benefits:

Online and 24x7 availability, use anywhere*

On cloud thus reduced operational cost

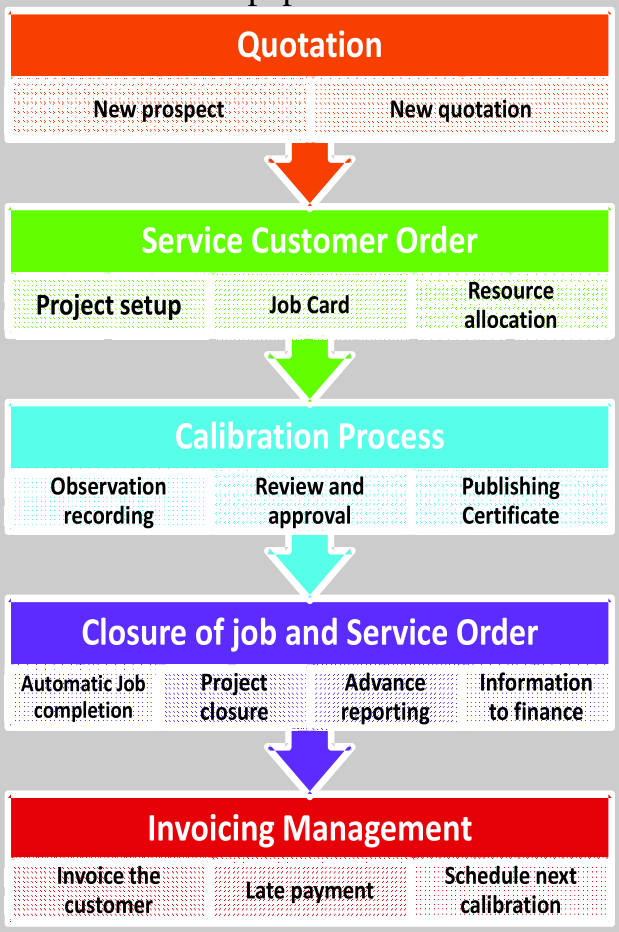
Assured Service, on software as service basis

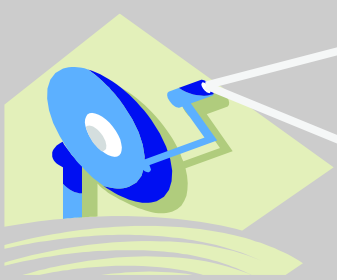
Regularly maintained and free upgrades*

Low capital investment, high return on investment

Grow your business faster and at less cost

- Access and speed to access the application is dependent on availability of Internet and its bandwidth
- SCC reserve right to offer some upgrades on chargeable basis
- Cover most of the instrument covering all streams of calibration (mechanical, thermal and electro-technical)





SCC IT Solutions Pvt. Ltd

C-50, Sector 2, Noida, U.P.201301
Redg off.: D68, Retreat, Plot#20, IP Extension, New Delhi, 110092
Phone: **09958091815**
E-mail: Sales@smallcapcrm.com
Web: smallcapcrm.com/SmartCalibration

Calitech

Total Quality Assurance Solution

NABL
Accredited Laboratory

ISO/IEC 17025:2005 NABL Accredited Laboratory

We undertake all types of Industrial & Healthcare Calibration/Temperature Mapping/Thermal Validation/ HVAC & AHU Validation/Steam Quality Test/Compressed Air Validation & PLC Validation

CALIBRATION

- Pressure/Vacuum/Magnehelic Gauges
- Temp. Controller / Sensors / Thermocouple / Transmitters
- Thermometers / Hygrometer & other measuring and process control equipments
- Lab Equipments / Electrical Equipments
- Vernier/Micrometer/Dail Gauges

THERMAL MAPPING / TEMPERATURE MAPPING / TEMP. & %Rh MAPPING

- Incubator, Muffle Furnace, Lab Oven, HPLC, G.C
- Ware Houses (Control Sample Room, F.G.Store. Etc...)
- Stability Chamber/Refrigerator/Cold Chamber/Deep Freezer

THERMAL VALIDATIOM OF EQUIPMENT

- Validation Of Autoclave / Bung Processor Dry Heat Sterilizer / Sterilizer tunnel
- Validation of SIP,CIP,& MFG. Tank, Lypholizer Etc...
- Validation Will Be Carried Out With 16 Channel Software Based PC Interface Data Logger
- Reports Will Include Drawings, Graphs, Lethality, and F0 Calculation.

HVAC VALIDATION SCOPE

Scope of Work

- Velocity Measurement
- Air Changes Per Hour Calculation
- HEPA Filters Integrity Leakage Test
- Air Borne Particle Count Test
- Recovery Time Test & Air Flow Pattern Test

Details of Instruments Used for HVAC Validation

- Airborne Particle Counter, Aerosol Photometer, Accubalance Capture Hood
- Standard Fogger and Handy Cam For Air Flow Pattern Test

"Test will be performed as per ISO 14644 & EU Guidelines"

STEAM QUALITY TEST

- Dryness Value Test
- Superheat Value Test
- Condensable Gases Test

Note:
SVMS USA Make Steam Quality Test Kit which is indigenously accurate and reliable in steam quality Validation done as per HTM 2010/EN 285 Guidelines.

PLC VALIDATION

- Computer System Validation
- Control System Validation(PLC/SCADA/Data Acquisition System -DAS/BMS/DCS
- Laboratory System Software Validation (HPLC/GC/SAS/Chem Station/WINnonLin Software
- Database Software,LCMS Software Validation, Spreadsheets (Excel Sheet) Validation

COMPRESSED AIR VALIDATION

- Non-Viable Particle Count Test
- Oil Mist
- Dew Point Temp. Test
- Water Vapour
- Carbon dioxide
- Oxygen
- Nitrogen
- Carbon Monoxide
- Sulphur Dioxide, and all other test specified by ISO 8573 Guidelines.

Our Prestigious Clients

Glenmark, Zydus dedicated to life, Dabur Celebrate Life!, Aristo, Intas Expressions for a Healthy Life, Ranbaxy Laboratories Limited, Rusan A Technology Driven Enterprise, Wockhardt, ipca, Parle Agro, Dr. Reddy's, Cipla, Unichem Laboratories Ltd.

CEO : Premal Patel, Tel. : +91 260 2423309 Cell : 09825041619
Website : www.calitech.in Email : calitech_vapi@yahoo.com, sales@calitech.in, contact@calitech.in
Head Office & Laboratory : 103, 108 Patil Chamber, New Telephone Exchange Road, GIDC, Char Rasta, Vapi; 396 195.
Branches: Ahmedabad / Gandhidham (Kandla) / Baddi (Himachal Pradesh) / Dehradun / Ankleshwar

Measurement Uncertainty in Medical Laboratories

Dr. Neeraj Jain
Managing Director
Jain Diagnostics

Dr. Rohini Kalhan
Managing Director
Alaknanda Diagnostics

Introduction

"A measurement result is complete only when accompanied by a quantitative statement of its uncertainty. The uncertainty is required in order to decide if the result is adequate for its intended purpose and to ascertain if it is consistent with other similar results."

In medical testing there are many potential "uncertainties" that can significantly affect test results (for example; poor specimen collection or transport, patient related factors such as biological variation and the presence of drugs, clerical and reporting errors, etc). Although it is important to identify and minimise such factors (for example, ISO 15189, 5.8.5; "The report shall indicate if the quality of the primary sample received was unsuitable for examination or could have compromised the result"), pre- and post-analytical influences do not affect the inherent uncertainty of the testing procedure itself, and therefore such factors are excluded from the estimation of uncertainty of measurement.

What is uncertainty of measurement?

ISO 15189 (3.17): The uncertainty of measurement is a parameter associated with the result of a measurement, that characterises the dispersion of the values that could be reasonably attributed to the measurand.

What is uncertainty of measurement in Medical Testing?

There are two major sources of uncertainty which contribute to the total uncertainty of measurement of a routine quantitative diagnostic method. Firstly, there is uncertainty associated with the numerical value assigned to the measurand present in the calibrator material used in the routine method. This uncertainty should be estimated by the commercial supplier of the calibrator, or by the laboratory if the calibrator has been prepared in-house.

Secondly, there is uncertainty associated with the value of a test result due to the random errors that normally occur when conducting the testing procedure. This uncertainty component is demonstrated by the dispersion of values observed when a measurand in the same specimen is repeatedly measured by a properly conducted test method. In the medical testing laboratory this dispersion is termed imprecision, and has long been used as the basic quantitative estimate of the confidence that can be placed in a result.

For practical purposes, imprecision data obtained from the routine application of internal quality control is recommended as the quantitative estimate of the uncertainty of measurement. For laboratory clients (clinicians), the dispersion of test results around a clinical decision value is the major uncertainty that has the potential to affect interpretation and clinical management. The Working Group also recognises that the implementation of the uncertainty of measurement requirement offers opportunities for pathology laboratories to value-add to their diagnostic services, particularly in educating users to better understand the limitations of tests, and in recognising when clinically significant changes in patient results have or have not occurred.

Where the estimate of uncertainty is known for both the calibrator and the routine analytical imprecision of a test procedure, the total estimate of uncertainty of measurement of the test results can be calculated by summing the two estimates (as squares of the variances).

As a laboratory generally employs a measurement procedure for long periods of time, the uncertainty of measurement information most relevant to interpreting its test results against fixed reference values is the imprecision of the test results across as many routine operating conditions as possible (intermediate precision control) (for example; multiple calibrator and reagent batches, multiple operators, equipment maintenance, summer/winter etc). With the caveat that quality control materials may not totally reflect the analytical behaviour of patient specimens, this imprecision is most easily derived from long-term internal quality control (QC) data, calculated as standard deviation (SD) or coefficient of variation (CV%). For the purpose of recording estimates of uncertainty of measurement the imprecision should be documented as the 95% confidence interval (± 1.96 SD; or ± 1.96 CV%). It should be noted that imprecision derived from the performance of a laboratory in an external quality assurance programme is not recommended for estimating uncertainty of measurement, because generally far fewer data points are available on which to base the uncertainty estimate relative to the number available from internal QC.

As part of the initial and ongoing review process, a laboratory should determine whether the uncertainty of measurement estimate for each method is fit for the clinical purpose for which the test results will be used (see below; Uncertainty of measurement and fitness for purpose). Reasons for not proceeding for a given method should be documented.

Step 1: Estimating uncertainty of measurement

Quantitative test results are usually interpreted by comparing the reported value against a reference or clinical decision value, or against a previous test value. For most methods the reference values used for interpretation have been determined or verified using the same method, and therefore uncertainty of measurement is most usefully estimated by the long-term imprecision obtained from in-house routine quality control data, expressed with 95% confidence limits as ± 1.96 SD or ± 1.96 CV%. The term 'long-term' is arbitrarily defined as the mean of QC values accumulated over a six month period, but should ensure accumulation of sufficient data points across most working conditions to satisfactorily reflect the routine uncertainty of measurement of the method. For newly introduced methods, the imprecision determined during the initial evaluation provides an interim estimate of uncertainty of measurement (a minimum of 30 data points across two or more different batches of reagents and calibrator). Uncertainty of measurement information should be updated at least annually.

For methods that require several levels of quality control material, the laboratory should determine whether the imprecision at the different levels is sufficiently different as to require separate quotation for clinical purposes. If not, a mean ± 1.96 SD (± 1.96 CV%) can be recorded as the uncertainty of measurement estimate.

For some methods, test results are interpreted against reference or clinical decision values that have been determined by a different method. In this situation, the uncertainty of the result includes not only the analytical imprecision of the method, but also any systematic error (method bias). For such methods the long-term bias should be recorded, ideally as full calibrator traceability and uncertainty data from the commercial supplier, or in its absence, from proficiency testing (external quality assurance) reports.

Step 2: Assessing uncertainty of measurement for fitness for clinical purpose

Having estimated the uncertainty of measurement of a method in routine use (as long-term imprecision), its fitness for purpose with respect to method imprecision should be assessed by comparing it to an appropriate clinical goal. For some measurands, an analytical goal may not be clinically or physiologically relevant. The goal for comparison should be relevant to the clinical application of the test result. An internationally recognised approach for such goal-setting is based on the intra-individual biological variation of the measurand.

There are three levels of analytical goal for imprecision based on intra-individual biological variation:

$$\textit{Optimum:} \quad CV_A = < 0.25 \times CV_I$$
$$\textit{Desirable:} \quad CV_A = < 0.50 \times CV_I$$
$$\textit{Minimum:} \quad CV_A = < 0.75 \times CV_I$$

where: CVA = Coefficient of variation (analytical), derived from long-term imprecision. The level(s) selected should be close to clinical decision points wherever possible. If CVAdiffers markedly at different levels, it may be important that separate CVA estimates are used at each level.

CVI = Coefficient of variation (intra-individual), derived from the intra-individual biological variation of the specified measurand (analyte).

The most clinically and technically appropriate goal should be set as the minimum for imprecision. If the goal selected compares unfavourably with the imprecision recorded by other methods and laboratories as indicated in external proficiency testing programmes, a more realistic goal or an alternative method should be considered. For analytes where CVIdata is unavailable or the goal is beyond current technology, other criteria may be used (for example, relative performance in external proficiency testing programmes, proportion of reference interval, clinical opinion etc.). For some applications an analytical imprecision goal based on intra-individual biological variation may not be appropriate (for example, serum hCG).

If: CVA = > (factor selected) x CVI

- The method steps/processes contributing = 30% to CVA should be identified and assessed for opportunities to reduce imprecision. This may not be feasible for fully automated commercial analytical systems.
- If CVA reduction is unsuccessful or not feasible, it may be appropriate to consider a change of method.

If test results are interpreted using reference or clinical decision values determined by a different method, bias should be considered as part of the estimate of

uncertainty of measurement and an appropriate analytical goal set.

There are three levels of analytical goal for bias based on biological variation:

$$\text{Optimum: } B_A = < 0.125\ (CV_I^2 + CV_G^2)^{1/2}$$
$$\text{Desirable: } B_A = < 0.250\ (CV_I^2 + CV_G^2)^{1/2}$$
$$\text{Minimum: } B_A = < 0.375\ (CV_I^2 + CV_G^2)^{1/2}$$

where:

BA = Bias (accuracy, systematic variation)

CVI = Coefficient of variation (intra-individual), derived from the intra-individual biological variation of the specified measurand (analyte).

CVG = CV of between - subject (inter-individual) biological variation.

The most clinically and technically appropriate goal should be set as the minimum for bias. If the goal selected compares unfavourably with the bias recorded by other methods and laboratories in external proficiency testing programmes, a more realistic goal or an alternative method should be considered. For analytes where CVI/CVG data is unavailable or the goal is beyond current technology, other criteria may be considered.

For methods where an analytical goal has been recommended by a recognised international authority, this goal should be adopted as the minimum requirement.

For methods where bias and imprecision must both meet performance criteria for clinical applications, the two parameters are conveniently combined as Total Error Allowable (Tea), for which various levels of analytical goal may be set:

$$\text{Optimum: } Te_a = < 1.65\ (0.25\ CV_I) + 0.125\ (CV_I^2 + CV_G^2)^{1/2}$$
$$\text{Desirable: } Te_a = < 1.65\ (0.50\ CV_I) + 0.250\ (CV_I^2 + CV_G^2)^{1/2}$$
$$\text{Minimum: } Te_a = < 1.65\ (0.75\ CV_I) + 0.375\ (CV_I^2 + CV_G^2)^{1/2}$$

THE CLINICAL USE OF UNCERTAINTY INFORMATION

Providing uncertainty of measurement data for clinical use

A summary of the key uncertainty of measurement information for all quantitative routine methods, in a “user friendly” and understandable format, should be available within the laboratory and available to clients of the laboratory service as required. Examples of this availability and the manner in which this information could be distributed may include; display on selected hard copy reports, included in electronic reports, form part of the information available in a departmental or electronic handbook.

For some specific methods or clinical applications, the provision of uncertainty data together with the test result may reduce the potential for significant clinical misinterpretation (for example, immunological-based methods, where antibody specificity, cross-reactivity with closely related species or clinically significant interfering substances are probably unknown to the requester).

It is understandable that for a quantitative pathology test both the clinician and the laboratorian focus on the actual numerical value of the result, neglecting the potential implication of the uncertainty surrounding the value.

In addition to the clinical application of a test result, there are two important aspects which also need to be considered. The most important of these is the in vivo biological variabilityof the measurand, as this is the signal that may differentiate health from disease. The second is the imperfection in the analytical method that may lead to different results on different occasions. It is vitally important that variation due to imperfect analysis (the analytical uncertainty) is less than the measurement signal we are trying to discriminate.

As a general principle, it has been widely suggested that the analytical goal for imprecision of a test method remain below half the intra-individual biological variation (CVA < 0.5 CVI). If this condition is satisfied and the analytical variability is appropriately less than the biological variability, the test can be confidently used for clinical diagnosis and monitoring. The impact of uncertainty does not end here however, as diagnostic decisions may be made by comparison to a reference population (reference interval or limit) or compared to a diagnostic cut-off. The methods used to establish these diagnostic decision points have their own imperfections, but once established they become set values without variation. Analytical uncertainty will change the “distance” between the test result and the particular cut-off used for comparison. If the “distance” between the test result and the diagnostic cut-off point is less than 1.96 SD, then it cannot be stated (at the usual 95% confidence level) that a repeat analysis would not produce an analytically valid result on the other side of that diagnostic cut-off. This analytical uncertainty should be conveyed to the clinician who might otherwise see the result in more absolute terms.

Clinical monitoring of a patient using quantitative results is different to diagnosis. Firstly, constant analytical bias (systematic error) is cancelled out in monitoring. It does not matter if the initial result is artificially high, when the follow up result will also be higher by the same amount. Secondly, both the initial and final result has an uncertainty, thereby increasing the overall uncertainty

when comparing these two values. Statistically, two results need to be more than 2.77 analytical CVA's apart (that is, v2 x 1.96) before there can be 95% confidence that they are significantly different from an analytical perspective.

If we wish to know if two results on a patient are significantly different also from a biological point of view, we need to additionally allow for the biological variation of the two results. To do this, the analytical variation and the biological variation of one of the results for the measurand are first summed . The two results being compared need to be more than 2.77 analytical and biological CV's apart (that is, 2.77 x v(CVA2 + CVI2)) before there can be 95% confidence that the patient's condition may have changed. (It should be noted that such calculations are based on the assumption that measurands show the same biological variation in healthy and ill individuals, for which currently there is little evidence).

Comments in patient reports on significant changes in test results can cause confusion as to what is meant. Is an analytical change of any clinical significance? Once again it is important to be mindful of biological variability before claiming that there has been a clinically significant change in a patient's result. When such commenting is used it should be clear and helpful.

Finally, for laboratories to acquire and retain the highest confidence of clinicians and patients, it is vital that they detect quality control violations, monitor and appropriately report the uncertainty of their assays with equal confidence.

Understanding ISO/IEC 17025:2005 and Calibration & Measurement Capabilities in Mass Measurements

Tripurari Lal
Ex Scientist G & Head Mass Standards
National Physical Laboratory, New Delhi-110012

Abstract

The International Standard ISO/IEC 17025 is one of the most importance components of the infrastructure of a country necessary to overcome the Technical Trade Barrier of the World Trade Organization in order to globalize its trade and to exploit its competitive advantages of indigenous raw materials and low labor costs. The importance of this standard in, capacity building of a country, conformity assessment, and principles behind it, have been summarized in this paper. Based on these principles, the concepts of CMCs for the parameter of mass measurements have been also highlighted.

1. Introduction

The Liberalization of Economies and the Globalization of Markets have intensified international competition. This has brought particular challenges to companies in developing countries. At the same time, it offers them opportunities to exploit their competitive advantages of indigenous raw materials and low labor costs. To make the most of these advantages, developing countries need to have a credible conformity assessment infrastructure to certify that their products conform to international standards. Testing and Calibration laboratories are an essential component of this infrastructure.

Testing & Calibration Laboratories in developing countries face major problems, however, in that their measurements and product certificates are often not accepted in other countries. The World Trade Organization (WTO) has recognized this as a Technical Barrier to Trade (TBT) and has established the TBT Agreement, binding on all member countries to counter the Practice. The WTO recognizes, however, that test results can only be mutually acceptable, if there is a mechanism whereby the user has confidence in the technical competence of the laboratories and soundness of their measurements. To achieve this, a global conformity assessment system for testing and calibration laboratories has been developed by the International Laboratory Accreditation Cooperation (ILAC) .

2. Conformity Assessment System & ISO/IEC 17025

The Conformity Assessment system is based on testing & calibration laboratories operating in conformity with the requirements of ISO/IEC 17025 which is an International Standards for testing and Calibration Laboratories quality systems.

The ISO/IEC 17025:2005 standard against which laboratories are accredited is entitled – General Requirements for the Competence of Testing and Calibration Laboratories. Thus this standard is about one thing only that is the "Competence" of Laboratories.

The "Competence" means that:

- the Persons in a laboratory have Specific Knowledge and Skills directly related to the SCIENCE underlying their Testing Procedures.
- the Persons in a laboratory can Demonstrate this Specific Knowledge.
- the Procedures conform to the requirements of the SCIENCE.

Only SOMEONE else who has the same level of knowledge and skills within that SCIENCE can determine "COMPETENCE". Demonstrated conformance to ISO/IEC 17025:2005 is a demonstration of competence.

Anyone hired to work in the laboratory could simply follow procedures without understanding the science behind a measurement or test, and this would allow them to conform to a stated specification- but they would not necessarily be "competent."

3 The Principles Behind ISO/IEC 17025

There are eight basic principles behind ISO/IEC 17025 which may not cover all aspect of every requirement in the standard, but they are broad enough to allow persons working in laboratories to appreciate the reasons behind most of the individual requirements. They may also allow

assessors to use their professional judgment in assessing the conformance of a laboratory to each of the requirements within the standard. These Principles are as follows:

(i) The Capacity of the Laboratory

Concept of Capacity is that a laboratory has the resources (PEOPLE with the required skills and knowledge, the ENVIRONMENT with the required facilities and equipment, the QUALITY CONTROL, and the PROCEDURES) in order to undertake the work and produce COMPETENT results.

(ii) Exercise of Responsibility

Concept that persons in the organization, have the authority to execute specific functions within the overall scope of work, and that the organization can demonstrate accountability for the results of the work.

(iii) Scientific Method

Concept that the work carried out by the organization is based on accepted scientific approaches, preferably consensus-based, and that any deviations from accepted scientific approaches can be substantiated in a manner considered generally acceptable by experts in that field.

(iv) Objectivity of Results

Concept that the results produced within the scope of work of the organization, are mainly based on measurable or derived quantities.

Concept that subjective test results are produced only by persons deemed qualified to do so and that such results are noted as being subjective, or are known by experts in that field of testing to be mainly subjective.

(v) Impartiality of Conduct

Concept that the pursuit of competent results through the use of generally accepted scientific approaches is the primary and overriding influence on the work of persons executing tests -all other influences being considered secondary and not permitted to take precedence.

(vi) Traceability of Measurement

Concept that the results produced, within the scope of work of the laboratory, are based on a recognized system of measurement that derives from accepted, known quantities (SI system) or other intrinsic or well-characterized devices or quantities.

Concept that the chain of comparison of measurement between these accepted, known quantities or intrinsic devices or quantities, and the device providing the objective result, is unbroken for the transfer of measurement characteristics, including uncertainty, for the whole of the measurement chain.

(vii) Repeatability of Test

Concept that the test that produced the objective results will produce the same results, within accepted deviations during subsequent testing, and within the constraints of using the same procedures, equipment and persons used during a previous execution of the test.

(viii) Transparency of Process

Concept that the processes existent within the laboratory producing the objective results, are open to internal and external scrutiny, so that factors which may adversely affect the laboratory's pursuit of objective results based on scientific method, can be readily identified and mitigated.

There are many ways to implement practices that help us do our jobs better in laboratories. The only difference between them is “why” the improvement is needed. If it is needed to help to enforce a very stringent law, then constant inspection may be the best approach. If being able to implement demonstrable competence is what is needed, a laboratory quality system that conforms to ISO/IEC 17025:2005 may be the best approach. The approach selected depends entirely on the reason for the needed improvement. Laboratory quality systems that conform to ISO/IEC 17025:2005 are to help the laboratory to produce valid results, and show to others that it is capable of doing so. This is the concept of “competence.”

Unlike a manufacturing facility, where the needs of the customer are balanced against the ability of the organization to meet them, a laboratory has only one master – that the science that underlies its test results. While a manufacturing facility can be registered to the world’s best “model-for-excellence” standard (ISO 9000:2008) in order to instill stakeholder confidence in its work, a laboratory gains the trust of its stakeholders (including regulators) through demonstrated competence only.

4 CMC as a Measure of Competence of a Laboratory

The competence of the Testing or Calibration Laboratories, is assessed by an Accreditation Body against all the requirements of ISO/IEC 17025. The Clause 4 of ISO/IEC 17025 specifies the managerial requirements and Clause 5 the technical requirements for the competence of the type of tests and/or calibrations the laboratory undertakes. The Calibration and Measurement Capability (CMC) as claimed by the Laboratory is the measure of its competence and is defined in ILAC-P14:01/2013 [3] and NABL 143 [4]. On successfully demonstration of the claimed CMCs, by the Laboratory, in compliance with the requirement of ISO/IEC 17025, defines that the laboratory is competent to implemented a quality system that conforms to ISO/IEC 17025:2005 and is able to produce valid results to the degree, or level that it has declared in its claimed CMCs.

5 Evaluation of Best CMC

st Measurement Capability (BMC), also known as Calibration and Measurement Capability (CMC), is defined as, “the smallest uncertainty of measurement that a laboratory can achieve within scope of accreditation, when performing more or less routine calibrations of nearly ideal measurement standards intended to define, realize, conserve of reproduce a unit of that quantity of one or more of its values, or when performing more or less routine calibration of nearly ideal measuring instruments designed for the measurement of that quantity.”

Therefore, in practice, CMC is the uncertainty values, which can, normally, be achieved by the laboratory in carrying out routine calibration services. The best CMCs consist of some components which depend on the factors for which the laboratory has to demonstrate its competence. Those factors may include:

- Education, training and technical knowledge & skills of personnel doing the calibration.
- Environmental condition of the laboratory under which the calibration is being carried out.
- The equipment their maintenance, including calibration intervals and verifications.
- The method and procedure being used for the calibration.

For producing adequate evidence of the claimed CMCs, observations to the laboratory condition must be done by considering the following:

5.1 Calibration Method

Calibration method affects CMC of the laboratory, because it usually states specification of unit under calibration, necessary environmental conditions, calibration and observation schemes, etc. The method used in the calibration processes yields the different CMC values for the same reference standards or measuring equipments.

In mass metrology, according to OIML R-111, there are two approaches for measurement of mass depending on the desired accuracy of the measurement results. The first approach is the direct comparison of the weights to be calibrated against a similar reference weight of known mass, using suitable balance. The second approach is the subdivision method involving various mathematical and statistical techniques. The Direct Comparison may be carried out using substitution method, double substitution method or transposition method of weighing and ABBA or ABA or cyclic weighing sequences. The subdivision method involves various weighing designs with varying efficiency depending upon the series of weights to be calibrated and available standards providing suitable restraint relations in the appropriate weighing designs. This approach leads to higher measurement uncertainty and hence higher CMCs.

5.2 Reference standard and measuring equipment

Reference standards and measuring equipments used in the calibration processes are the major uncertainty sources in the evaluation of CMC. The uncertainties of these standards define the type of unit under calibration, which can be calibrated by the respective laboratory. In particular cases, laboratories having the same reference standard will have different CMC if they are using difference measuring equipment. For two mass calibration laboratories each with mass standards of E2 classes, will have different CMC if one laboratory used mass comparator of 0.1 mg resolution and the other uses a mass comparator of resolution 0.01 mg.

Beside the uncertainty stated in the calibration certificate, one important uncertainty source is drift in mass values of those reference standard and measuring equipments. It must be remembered that the mass value stated in the certificates are only valid in the time of calibration. For the routine condition, the drift may occur,

and it can be estimated based on the historical data.

5.3 Support equipments

In the calibration processes, type and accuracy of support equipment used to monitor influence quantities for the respective calibration will affect CMC values, as well as the data processing system for the data analysis. In the process of calibration of weights, support equipments used to monitor the air density during calibration will give smaller CMC than the laboratory, which carry out weight calibration without air density monitoring system, and the uncertainty due to this factor estimated based on the worst condition of air density variation. The support instruments for measurement of air density are thermometer to measure air temperature, barometer to measure atmospheric pressure of air in side the laboratory hygrometer to measure relative humidity of air. The calibration status and measurement uncertainty of these instruments will also affect the CMC of the laboratory.

5.4 Measurement techniques

Different measurement techniques may cause the different CMC values, for example CMC for calibration based on direct comparison method Standard-Test-Test-Standard carried once will give larger CMC than that carried out in three or more series. If measurement carried out once, uncertainty due to repeatability will be (standard deviation of balance / v2), and for three series of measurement will be (standard deviation of balance / v6).

5.5 Influence quantities

Influence quantity is the quantity, which is not included in the definition of the measurand but affect the result of measurement. These quantities often cannot be eliminated perfectly so that the contribution must be taken into account in the uncertainty evaluation. For examples: for the calibration of mass standards based on the conventional weighing in which air density is assumed as 1.2 kg/m3, the deviation of the laboratory condition from this assumed value of air density shall be taken into account.

5.6 Personnel

Personnel carry out calibration processes will also contribute significant effect for the CMC evaluation. For example, calibration of a weight carried out by different personnel using the same mass standards and balance may give different measurement results, because repeatability of balance obtained by two persons may be different. The capability of personnel in observing the standard deviation of the balance or that of the weighing process will affect the routine calibration results of the same laboratory.

5.7 Specification of nearly ideal DUC

The Definition of CMC stated that CMC assigned for the routine calibration of nearly ideal measurement standards or measuring instruments which can be calibrated by the respective laboratory. Based on this definition, contribution of the weight under calibration cannot be neglected in the CMC evaluation. For example, in calibration of weights, a laboratory, which has mass standard of E2 class will has best capability to calibrate weight of F1 class, specification of mass standards give the specified densities range for each class of mass standards, in the CMC evaluation, it may be taken into account.

6. References

[1]. T-27 CALA:17025:2005 Handbook : November 2010

[2]. ISO/IEC17025 General Requirements for the Competence of Testing and Calibration laboratories, first edition, 2005.

[3] Complying with ISO 17025:A practical guidebook for meeting the requirements of laboratory accreditation schemes based on ISO 17025:2005 or equivalent national standards : Vienna, 2009.

[4] OIML R 111-1: 2004, Weights of classes E1, E2, F1, F2, M1, M1-2, M2, M2-3 and M3, Part 1: Metrological and technical requirements.

[5] JCGM 100:2008 :Guide to The Expression of Uncertainty in Measurement, Document jointly by the organizations (BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML).

[6] JCGM 200:2012 :International Vocabulary of Basic and General Terms in Metrology (VIM), Document jointly by the organizations (BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML).

FDA Looks to Clamp Down on Laboratory-Developed Tests and Put an End to 'Wild West of Medicine':

National news coverage over the deficiencies uncovered by Clinical Laboratory Improvement Amendments (CLIA) inspections of the clinical laboratory operated by Theranos in Newark, Calif., may have an interesting consequence that affects all medical laboratories and pathology groups.

Over the past 30 months, Theranos has regularly asserted that its laboratory-developed tests (LDTs) were under review by the Food and Drug Administration (FDA). For example, in an interview published in the December 14, 2014, issue of The New Yorker, Theranos Founder and CEO Elizabeth Holmes stated, "We believe that to realize our vision we must operate at the highest levels of excellence… And the FDA's stamp of approval is seen as an indicator of the quality of a product."

Thus, it would be ironic if the problems in the quality of clinical laboratory tests uncovered by federal CLIA inspectors at the Theranos lab facility in Newark was used by the FDA to justify their intent to regulate LDTs. The FDA has already released a report to the public that identified instances where laboratories running LDTs were alleged to have reported inaccurate lab test results to patients and their physicians.

In fact, this FDA report was one factor used by a Wall Street Journal (WSJ) story to label LDTs the "Wild West of Medicine." That story intensified the spotlight on clinical laboratory testing services and was seen as strengthening the FDA's hand as it looks to expand its regulatory reach.

Media Scrutinizes Mayo Medical Laboratory's Million-Dollar LDT Business : In its report, the WSJ expanded the investigative focus to include the multibillion-dollar-a-year business of LDTs, zeroing in on Mayo Medical Laboratories, which generates as much as half of its annual revenue of $600 million from LDTs. The WSJ stated that half of the roughly 3,500 medical tests done each year by Mayo Medical Laboratories are LDTs—a business supported by FedEx deliveries from hospitals and doctors worldwide.

Increased Regulation of LDTs Would Negatively Impact the LDT Business: While Mayo Clinic's total patients reached roughly 1.3 million, and its annual revenue nearly $9 billion in 2014, laboratory officials stated that increased FDA regulation would hurt their bottom line. Curtis A. Hanson, MD, of Mayo Medical Laboratories, told the WSJ that closer regulation by the FDA would result in "a serious and negative impact on our ability to provide high quality and accessible patient care."

Irving Nachamkin, DrPH, MPH, D(ABMM), FAAM, FIDSA, Director of the William Pepper Laboratory and the Division of Laboratory Medicine at Penn Medicine, takes issue with the WSJ's implication that clinical laboratories operate in a largely unregulated environment.

In a Penn Medicine blog, Nachamkin pointed out that the WSJ failed to mention the Clinical Laboratory Improvement Act (CLIA) regulations cover all lab tests, including LDTs.

"What is really needed is congressional action to modernize CLIA regulations to fill in the gaps to ensure LDT quality, rather than having the FDA impose new and unrealistic regulations on top of CLIA requirements," Nachamkin wrote. "To point: the majority of commercial test kits cleared by the FDA for sale to clinical labs go through a 510(k) review, and many provide neither sensitive nor specific results, nor are they required to do so.

"FDA clearance of LDTs, therefore, will not necessarily have the desired effect and only add significant cost to an already expensive and overburdened healthcare system, and impose additional regulations on laboratories that are already covered by existing, although not perfect, government regulations," Nachamkin added.

FDA Report Concludes Harm Has Been Committed: Increased Regulations Needed: The FDA bolstered its case for increased regulation of LDTs with the November 2015 release of a report titled, "The Public Health Evidence for FDA Oversight of Laboratory Developed Tests." The FDA reviewed 20 case studies of LDTs for Lyme disease, ovarian cancer, whooping cough, fibromyalgia, prostate cancer, autism, breast cancer, melanoma, Vitamin D, and other conditions. The agency concluded that in many instances "patients have been demonstrably harmed or may have been harmed by tests that did not meet FDA requirements."

The Association for Molecular Pathology (AMP) has been sharply critical of the FDA's report, challenging its

conclusion that FDA oversight would prevent the potential harm to patients outlined in the case studies.

The FDA report, however, contends additional oversight is needed because CLIA does not:

- Ensure the safety and effectiveness of LDTs prior to marketing;
- Assess the quality of the design and manufacture of devices;
- Ensure test labeling provides adequate directions for use;
- Require truth in marketing materials and other labeling;
- Require adverse event reporting;
- Permit removal of unsafe devices from the market;
- Require informed consent for patients participating in clinical studies of LTDs;
- Establish procedures for the conduct of such studies.

“While certain LDTs have undoubtedly brought benefits to many patients, the increase in complexity and patient volume brings [an associated] risk that patients will be harmed—and, in fact, have been harmed—and highlights the need for appropriate oversight,” the report states.

The WSJ article continues the growing trend of the national news media investigating medical laboratory failures or systemic problems in medical laboratory regulation and inspection. Given this ongoing public scrutiny, it is essential pathologists and clinical laboratory executives act now to improve the quality of their laboratory testing and associated services.

Courtesy: Dark Daily

Why scientists are freaking out about Brexit

In laboratories across the United Kingdom, scientists were shaking their heads about the unprecedented vote to leave the European Union, with worries about what the split will mean about the future of research funding and the possibility of a "brain exit."

Scientists were among the most opposed to Brexit. A survey by the journal Nature found that among 907 active U.K. scientists, 83 percent were in favor of staying. According to the journal, U.K. researchers have received 1.4 billion euro to support research since 2014.

Physicist Stephen Hawking and 150 other fellows of the prestigious Royal Society who in March wrote a letter arguing that a departure would be a "disaster for UK science," warning that it would imperil Britain's ability to attract the best scientists from across Europe.

In an interview with Scientific American, Lord Paul Drayson, a former British Minister of Science, said that there were a variety of reasons for scientists' opposition, ranging from philosophical ideas about the benefits of collaboration to more practical competitive reasons.

"I’m on the board of the council of Oxford University, and Oxford is very clear that its ability to maintain its position as a world-class university would be negatively affected by Brexit, because it would not be able to attract the very best talent in the way in which it has been able to do up till now," Drayson told the magazine.

In the wake of the vote, responses began to trickle in: "In the past, U.K. science has been well supported by E.U. funding. This has been an essential supplement," Venki Ramakrishnan, president of the Royal Society said in a statement.

“One of the great strengths of UK research has always been its international nature, and we need to continue to welcome researchers and students from abroad," Ramakrishnan added. "Any failure to maintain the free exchange of people and ideas between the UK and the international community including Europe could seriously harm UK science."

Helga Nowotny, former president of the European Research Council, summed up the sentiment for Science magazine: "It's a bad day for Europe, the U.K., and European science."

And in the U.S., academics on Twitter made wry comments about a new opportunity:

Well, back to work, I guess. Time to start putting job requisitions together for the flood of scientific talent about to flee the UK…

Courtesy: The Washington Post

The Effect of the FCC’s New Rules on Testing Laboratories

The Federal Communication Commission (FCC) ended 2014 with an overhaul of its Rules for device testing and certification. While everyone was getting ready to pop the champagne, the Commission released its long-anticipated “Rule Making 11652” on December 30, 2014. It was an uncorking that echoed around the world, most notably in the ears of our testing laboratory friends overseas.

In short, it may spell the end of testing for FCC compliance for hundreds of laboratories.

The stated reason for the new Rules is to update certain procedures for device certification and to "facilitate the continued rapid introduction of new and innovative products to the market while ensuring that these products do not cause harmful interference to each other or to other communications devices and services."1However, these changes will potentially affect billions of dollars of global trade in electronics in a very big way.

By implementing certain specific goals outlined in the preceding Notice of Proposed Rulemaking (NPRM) issued in 2013, the Rule changes that have been enacted jeopardize the recognition of testing laboratories in countries that do not have a mutual recognition arrangement (MRA) with the U.S., notably China, Malaysia, Brazil, India, Mexico and Thailand. Beginning sometime in 2016, data submitted by testing laboratories based in those countries will no longer be recognized by the FCC. As it now stands, electronic device manufacturers in those countries may have to find other ways to obtain the testing required for FCC approval.

Background

The FCC partly privatized its Certification process in the year 2000 at the dawn of what would be an explosion of wireless device innovation and development. As of the writing of this piece, approximately 233,000 entries2 have been made in the past 15 years or so in the FCC's Certification database, reflecting an astonishing array and diversity of products used for communications, entertainment, health, safety, energy and other critical areas of our modern lives. The pace is accelerating.

The globalization of research and development as well as manufacturing occurred during this same period. Taiwan, Korea and Japan were already largely invested in electronics development at the time of the FCC's original action. But, in the year 2000, China was just getting started on its high-technology race to the top.

Since the inception of its Equipment Authorization program, the FCC has historically accepted test data from any laboratory that complied with the minimum facility reporting requirements under Part 2.948 of the FCC's Rules. Reporting requirements included a description of the laboratory, information on its site attenuation characteristics, photos and a list of equipment. Testing laboratories from all over the globe that submit this information to the FCC are referred to as "Listed" laboratories, and their names are published on the FCC's website. This was a practical approach before the days of accreditation when the industry was evolving, and quite liberal when compared to some other regulatory regimens. However, several forces have changed the Commission's view of this process, making the Listing of testing laboratories become a thing of the past.

Globalization

MRAs allow the free exchange of test data between countries ("economies" in MRA parlance). MRAs also form as a basis for Certification Bodies to be designated outside the U.S. They are also a key element in the acceptance of a Declaration of Conformity under

Part 15 of the FCC's Rules. For the most part, the MRA process has worked well and allows product developers to test locally and sell internationally.

However, because the FCC's process allows acceptance of test data from anywhere, the benefits of this liberal system can be enjoyed even by testing laboratories based in countries that do not have an MRA with the U.S. As a result, it has created an uneven playing field for testing laboratories and, by extension, their customers.

Along with the FCC, various U.S. government agencies have actively worked to establish working MRAs with numerous economies, some with great success and progress and, in other cases, not so much. Frankly, this has been the source of some frustration in and around the industry and with regulatory bodies as well.

So the changes promulgated in the FCC's new Rules will affect several hundred testing laboratories based outside the U.S. in non-MRA partner economies. The specifics are embodied in the summary of the Commission's Report and Order implementing the new Rules, wherein the FCC will "…require accreditation of all laboratories that test equipment subject to any of the certification procedures under Part 2 of the Commission's rules…"

The real issue is what accreditations will the FCC accept. This is a crucial issue for those testing laboratories that will lose their status as FCC Listed laboratories. The answer to this question is found in Section 48 of the Report and Order, which states that "the current rules allow for the recognition of accredited testing laboratories in countries with which there is no operational MRA with the United States," but (and it's a big "but"), "the Rules do not provide a process for such recognition." And there are no current plans to address this issue.

A couple of other nuances are also being massaged in the FCC's Report and Order. Notably, accreditation is being applied very broadly, not just on testing laboratories directly, but for subcontracted testing as well. That is, if a laboratory subcontracts testing work to

another laboratory, the subcontracting laboratory needs to be accredited for the work. Further, FCC-authorized telecommunication certification bodies (TCBs) will be obligated to accept work only from accredited and recognized testing laboratories.

Tick-Tock

The FCC's rulemaking raises several time-critical issues. At present, the new rules have not yet been published in the Federal Register, which is the first step in the implementation of the new requirements. Once the rules are published, a one-year countdown begins on the dissolution of the Listing program. This short timeframe could leave many busy testing laboratories high and dry. The way around this issue would be for the FCC to develop a formal process for officially recognizing testing laboratories, but the Commission has indicated that they are not currently working to develop such a recognition program.

So, how will this coil unwind? Well, for starters, non-MRA countries could get back to serious negotiations and execute MRAs with the U.S. This is a good idea, but probably not realistic given the limited amount of time. Another scenario is that the FCC allows existing testing laboratory listings to expire without further action, resulting in testing being redirected to countries with an MRA. This would this be a windfall for testing laboratories in those countries but devastating for incumbent testing laboratories in non-MRA economies. A more likely scenario is that the electronics industry will apply political pressure to exact a more reasonable solution, one that doesn't increase the time and cost for product testing and approval.

Courtesy: incompliance.com

Good Laboratory Practices in Field Trials

K. Madasamy
Manager- Instrumentation
Chennai Mettex Lab Private Limited, Chennai - 600032

1. Introduction

Crop field trials (also referred to as supervised field trials) are conducted to determine the magnitude of the pesticide residue in on raw agricultural commodities and should be designed to reflect pesticide use patterns that lead to the highest possible residues.

- Crop field trials are used to quantify the expected range of residue(s) in crop commodities.
- Crop field trials are used to determine, when appropriate, the rate of decline of the residue(s) of plant protection product(s) on commodities of interest;
- Crop field trials are used to determine residue values such as the Supervised Trial Median Residue (STMR) and Highest Residue (HR) for conducting dietary risk assessment and calculation of the dietary burden of livestock; and derive maximum residue limits (MRLs).

2. Crop Grouping

National authorities use targeted data sets and data extrapolation to provide sufficient data for exposure assessment for setting MRLs for major and minor crop commodity groups. Data extrapolation provides the mechanism for extending field trial data from several representative crop commodities to related crop commodities in the same crop group. Crop grouping and the identification of representative crop commodities are also critical for maximizing the ability to use a targeted data set determined for representative crop commodities to support minor uses.

3. Extrapolations

Extrapolation means that a residue data set from one or more crop commodities is extrapolated to establish a crop group MRL if the Good Agricultural Practice for the members within the crop group is the same. Extrapolation is closely connected to crop grouping.

4. Proportionality

Proportionality means that when increasing or decreasing the application rate the residue level increases or decreases in the same ratio. In an ideal situation it means that doubling the application rate results in doubling the residue. Proportionality implies that the relationship between application rates and residues is linear. A proposal to predict the level of residues in plant matrices on the basis of the assumption that residues will increase linearly with the application rate was considered by experts. The quantity of a pesticide initially deposited and retained on a crop surface depends upon many factors, including the physical-chemical properties of the active substance and especially the spray liquid, the nature of the (leaf) surface, growth stage and the application method used. The crop canopy is also important for determining spray deposits. Therefore, the extrapolation of residues usually was not accepted as a waiver for residue trials in the past. However, in a small number of cases, the approved label application rate may ultimately be different from the field trial study rate due to various reasons. Residue studies in plants are usually not conducted as parallel trials using different application rates under otherwise identical conditions. A proposal on predicting residues was recently considered which may save time, money and resources while avoiding significant uncertainty.

5. MRL Enforcement and Risk Assessment – Conversion Factors

In some countries authorities responsible for enforcement have to fulfil two objectives:

? Enforcing compliance with MRL legislation.

? Assessing consumer risk.

The laboratories must analyse as many active substances as possible. This is only possible by using up-to-date multi-residue methods. Analysing for complex residue definitions which are sometimes set for enforcement often requires more sophisticated work-up steps and a single residue method. This is not always feasible for the laboratories.

When conducting consumer risk assessments, several factors must be taken into account:

? Conversion from the residue definition for enforcement to the residue definition for risk

assessment.

? Residue in the edible part of the commodity.

? Processing factors.

? Formulations

Most types of formulations can be divided into two groups – those which are diluted with water prior to application and those which are applied intact. Emulsifiable concentrates (EC) and wettable powders (WP) are examples of the first type whereas granules (GR) and dusts (DP) are the most common examples of the latter.

6. Geographical Distribution of Residue Trials

The OECD Working Group on Pesticides and the FAO Pesticide Management Group invited a small group of residue experts from OECD and FAO Member countries to develop the concept of a global zoning scheme to define areas in the world where pesticide trials data could be considered comparable, and therefore where such trials could be used within each zone for MRL-setting purposes, irrespective of national boundaries.

7. Number of Trials National/Regional Approach to Number of Trials

To a certain extent the total number of trials required by a regulatory authority may include trials conducted in another region provided that these trials correspond to the critical GAP and the production conditions

8. Codex Approach to Number of Trials

JMPR performs the evaluation of the submitted information and estimates maximum residue levels if the database is considered sufficient, regardless of whether it represents worldwide use or is limited to a region. The number of trials and samples is dependent on the variability of use conditions, the consequent variation of the residue data, and the importance of the commodity in terms of production, trade and dietary consumption.

9. Results from Residue Trials to be used in MRL Estimations

In principle all data from residue trials conducted according to Good Agricultural Practice and considered valid should be taken into account for MRL setting.

The post-harvest use of a persistent, non-volatile active substance in stored products will lead to residues that can be calculated on the basis of the amount used to treat the stored commodity for short waiting periods. The MRL should not be set at a higher level than the application rate equivalent, but higher maximum residue levels may need to be considered on a case by case basis to account for inhomogeneous distribution of the pesticide during application or sampling difficulties. Any variation in residues depends on the precision of the application especially concerning the deposition of the active substance on the surface of the treated commodity. Environmental and commodity related factors will only have limited influence. Residue trials are necessary to reflect storage locations with variable conditions regarding temperature, humidity, aeration, etc. Once the relationship between application rate and residue level has been shown, additional trials with other application rates are not necessary. This relationship is based on special environmental and commodity factors independent from the conditions of the proportionality principle.

The OECD MRL calculator may not be a suitable tool to propose MRL for post-harvest application. In such a case, the estimate calculated as "CF X3 mean" should normally be disregarded and the MRL proposal based on the estimates calculated as "Mean + 4 SD" or "Highest residue" and considering the nominal application rate.

10. Reference

OECD, 2009. OECD Guidelines for the Testing of Chemicals – Crop Field Trial. No. 509, OECD, Paris.

Workshops On CD 2 of ISO/IEC 17025 Revisions

AOIL Organized Three Workshops at Delhi, Mumbai & Bangaluru On CD 2 of ISO/IEC 17025 Revisions

World Trade Organization (WTO) has identified non acceptance of test reports from one economy to other economy as a barrier to the trade. International Laboratory Accreditation Cooperation (ILAC), is an organization of laboratory accreditation bodies and inspection accreditation bodies. One of aims of ILAC is to establish a mechanism through which results from accredited laboratories and inspection bodies of one economy are accepted in other economies. ILAC through its cooperative approach has already established the norms and achieved harmonization in the functioning of the laboratories and in their recognition mechanism. ILAC is striving to establish global equivalence amongst the laboratories. Mr Peter Unger is the Chairperson of ILAC.

The Association of Indian Laboratories (AOIL) is non-profit making organization, created to provide a platform to the laboratories. Its objectives include promotion of professional practices, undertake educational program / training for laboratory personnel, to protect laboratories interest & interact with national and international authorities / establishments.

Amongst the objectives of AOIL, it aims to create an awareness amongst Indian laboratories with the global practices. Such awareness helps laboratories to achieve and maintain global equivalence which in turn helps in capacity building of the nation. Keeping this in mind AOIL joined ILAC as stakeholder organization from India and has started participating in its committees as the member. AOIL has already participated in two ILAC international annual meetings at Milan (2015) & mid-term meetings at Frankfurt in 2016.

As the International Standard ISO/IEC 17025: 2005, used to determine the competence of laboratories, is being revised, by working group WG 44 of ISO-CASCO, and in the process of revision, worldwide inputs are being sought from stakeholder- laboratories. To involve Indian laboratories in the process of revision AOIL sought the support International experts, Mr Peter Unger, Chair ILAC and Mr Jeff Gust member WG 44, for organising three workshops, from Delhi, Mumbai and Bengaluru on 14th, 15th, and 16th April 2016. Three venues were choosen to facilitate participation for the laboratories from all over the country.

As soon as the commitment was secured from Mr Peter Unger Chairperson ILAC, consent to involve National Accreditation Board for Testing and Calibration Laboratories (NABL) was taken from its director Mr Anil Relia, to make ita joint program of AOIL & NABL.

On 14th, 15th & 16th, of April 2016, the three workshops have been conducted, involving about eight hundred laboratories from India and neighboring countries, where the experts could participate and contribute in the development of international standard.

This is the first activity of its kind, and created a history where more than eight hundred experts from laboratories availed the chance to have first hand interaction with the international experts and were able to contribute towards development of the international standard ISO/IEC 17025. There are recorded one hundred and fifty-five questions and suggestions from more than this number of participants as there are many repeat questions from different participants and places. The number of questions/suggestions received and debated is a potential signal of the magnitude of the interest and involvement from the participating labs in the workshops on the subject, and in our country. AOIL understands and appreciate this spirit and is committed to continue its efforts to involve more and more laboratory personnel in the areas of their interest.

Besides this, these workshops also served the purpose of educating the laboratory personnel and NABL assessors and its officers to update their understanding and work accordingly, after new version of ISO/IEC

17025 is adopted by ILAC.

The three workshops were inaugurated by the Chief Guest(s) Dr. R. P. Singh, Secretary General QCI, at Delhi, Dr. M. R. Khambate President, Chamber of Small Industry Associations at Mumbai and Mr Mohammad Mohsin, MD Karnataka State Small Industries Development Corporation at Bengalururu. The participation included national institutions like NPL, BIS, Export Inspection Council, QCI, MSME & CMTI.

The three workshops were conducted by Mr Jeff Gust, Member WG 44 of ISO-CASCO, Mr Peter Unger, Chair ILAC , the moderator and also Mr Anil Relia Director NABL and Mr Devi Saran Tewari Chairman, AOIL.

The workshops were supplemented by the exhibition stalls from the sponsorers and supporters of the AOIL. The guests & invitees were felicitated with unique mementos, the sponsorers contribution was recognised-acknowledged & they were allotted time slot to present their PPT & product profiles. There were more than 800 participant in the three workshops and each one from them was given a certificate of participation, after the event for having participated in the workshop on CD-2 ISO/IEC 17025.

R. B. Singh,
ANULAB, Agra
email:- research@anulab.org

ASSOCIATION OF INDIAN LABORATORIES

B-203, Vigyan Vihar, GH-19, Sector-56, Gurgaon-122011. Haryana (INDIA)
Email: aoilsecretariat@gmail.com Website: www.aoilindia.org

MEMBERSHIP FORM (MF-01) **(For Laboratories)**

1. Name & address of Laboratory : .....
   .....
2. Name of Laboratory representative : .....
3. Alternate representative : .....
4. Field of Lab.: Medical / Testing / Calibration / GLP Laboratory .....
   (Tick & write the applicable)
5. Legal status of Laboratory: Proprietorship / Partnership / Private Limited / Public limited /
   Govt. sectors firm .....
   (Tick & write the applicable)
6. Recognition : NABL / GLP Authority / other / None .....
7. Email & URL address : .....
8. Contact Number : (Office) ..... Mobile: .....
9. Type of membership applied for : (Tick anyone)
   a) Regular member : Registration fee - Rs. 5000/- + service tax (as applicable)
      Annual Subscription - Rs. 10000/- + service tax (as applicable)
   b) Life member : Registration fee- Rs. 150000/- + service tax (as applicable) one time payment &
      Annual Subscription- Nil
10. D.D. / Cheque number ..... for Rs. .....
    drawn on ..... Bank : ..... Branch : .....
    is attached here with as the membership fee.

I, as the competent authority, affirm that that I am willing to join the Association of Indian Laboratories.

Date: _____ Name / Signature of Representative : _____

(Please enclose the documents for legal identity of the laboratory, two passport size photographs of representative and brief company profile)

(For office use only)

Payment Received by : ..... Signature of Treasurer :.....
Membership Approved by :..... Signature of Gen. Secretary :.....
Membership Number :..... Date of approval :.....

Account Details of AOIL

Account Name	: Association of Indian Laboratories
Banker Name	: ICICI Bank Ltd.
Branch	: Sector 21C, Faridabad.
Account No.	: 630301036487
IFSC Code	: ICIC0006303

ASSOCIATION OF INDIAN LABORATORIES

B-203, Vigyan Vihar, GH-19, Sector-56, Gurgaon-122011. Haryana (INDIA)
Email: aoilsecretariat@gmail.com Website: www.aoilindia.org

MEMBERSHIP FORM (MF-02) (For Individuals)

1. Name & address of Applicant :.....
   .....
2. Type of membership applied for : Individual / Student .....
3. Name & address of Organization/Laboratory (If associated/employed) : .....
   .....
4. Please mention expertise details : .....
   (If required attach annexure)
5. Contact number :..... Mobile :.....
6. Email address : .....
6. Membership applied for Associate member :.....
   Registration fee - Rs. 2000/- & Annual Subscription - Rs. 2000/- + Service Tax (as applicable)

I am willing to join the Association of Indian Laboratories.

Date: _____ Signature: _____

(Please enclose the documents for personal identity and address proof, two passport size photographs)

7. D.D. / Cheque number ..... for Rs. .....
   drawn on ..... Bank : ..... Branch : .....
   is attached here with as the membership fee.

I, as the competent authority, affirm that that I am willing to join the Association of Indian Laboratories.

Date: _____ Name / Signature of Applicant : _____

(Please enclose the documents for legal identity of the laboratory, two passport size photographs of representative and brief company profile)

(For office use only)

Payment Received by : ..... Signature of Treasurer :.....
Membership Approved by :..... Signature of Gen. Secretary :.....
Membership Number :..... Date of approval :.....

Account Details of AOIL

Account Name	: Association of Indian Laboratories
Banker Name	: ICICI Bank Ltd.
Branch	: Sector 21C, Faridabad.
Account No.	: 630301036487
IFSC Code	: ICIC0006303

Feed Back Form :

Aim - To Serve Laboratories

Laboratories are required to seek second party and third party recognition from govt., and non -governmental agencies by demonstrating their competence. At times laboratories are subjected to unethical and non-called for situations from visiting or fact finding teams. Also bodies providing recognition fail to identify issues relating impartiality within their own system.

AOIL considers all those acts as unethical that are not communicated in written form, which is a means of being transparent.

AOIL seeks laboratory's cooperation in compiling such incidents/ problems faced by laboratories, which in turn would be analysed and brought to the notice of the highest authority in the country along with the suggestions on how to eliminate/ minimise such happenings/incidents, which in turn reduce the hardships of the laboratories.

In order to connect with the non-member laboratories, AOIL intends to create and maintain the data base of all kind/ type of laboratories, be these government, private, in-house industry laboratory, and from any field of science and technology. This would facilitate compilation of relevant information from the laboratories, member or none members.

The kind of laboratories which formed AOIL are:

i. Medical Testing laboratories.
ii. Calibration laboratories
iii. Testing laboratories.
iv. GLP Facilities.

If any other group of laboratories remains to be included, please inform AOIL. All kind of laboratories, irrespective of ownership are requested to register with AOIL so that information exchange mechanism could be established. Also, AOIL intends to develop a consolidated list of laboratories.

Laboratories are requested to share their experience without any fear in the feedback form attached herewith. AOIL is committed to maintain confidentiality for the information it receives and also the laboratory has the option to not to declare it's name, if it wants secrecy.

To improve the Indian system, please mail filled feedback form at AOIL office address.

i. Becoming Laboratory Member of AOIL implies, that you have say in the management of AOIL.
ii. Getting registered means your lab is interested in exchange on information and flow of communication to your lab, irrespective of your accreditation status.

Your cooperation with AOIL is your strength.

ASSOCIATION OF INDIAN LABORATORIES

113, First floor, Sushant Tower, Sector 56, Gurgaon - 122011
Website: www.aoilindia.org

Feed Back Form :

Objective :
To determine the extent of prevalence of unethical practice.

Identify your lab by ticking:

i. Medical Lab
ii. Test Lab
iii. Calibration Lab
iv. GLP Lab

1. Name of Laboratory (optional) : _____

2. Location of laboratory (State) : _____

3. Was your lab subjected to (tick appropriately) : _____

i. Provide stay in 5-star hotel ? ◯
ii. Stopped from sending air ticket and charged in cash ? ◯
iii. Pay without getting travel details (air/train/car) ? ◯
iv. Asked for monetary favours ◯
v. Subjected to indirect favours ◯
- stay for extra days ◯
- Travel to nearby places ◯
- Paid for family during audit ◯
- Paid for more than one ticket ◯
- Air tickets for other purpose ◯

4. Please identify the years when you faced such situations.
2016 2015, 2014, 2013, 2012, 2011, 2010, 2009, 2008, 2007, 2006, 2005, 2004, 2003, 2002, 2001, 2000, 1999, 1998, 1997, 1996, 1995, 1994, 1993

5. Please identify Body _____ AB _____Others
(AB = Accreditation Body)

6. Any other point you may like to report.

ASSOCIATION OF INDIAN LABORATORIES

113, First floor, Sushant Tower, Sector 56, Gurgaon - 122011
Website: www.aoilindia.org

Feed Back Form :

Objective:
To determine the prevalence of impartiality / confidentiality / unethical practice.

1. Was your lab asked for: (tick appropriately):

i.	Photo copies of procedure/standards/ customer's details etc. (As it is against your business interest.) Were you bold enough to deny giving information ?	Yes / No Yes / No
ii.	Training in specified training centre / lab ?	Yes / No
iii.	Internal audit done by lab not accepted	Yes / No
iv.	Advised consultant or specific person to do audit.	Yes / No
v.	Asked for NPL Calibration without raising NC.	Yes / No
vi.	Calibration from a specified laboratory.	Yes / No
vii.	Calibration certificates from MRA member not accepted	Yes / No
viii.	In surveillance, contents of approved accreditation altered	Yes/No
ix.	Subjected to unrelated questions. (give example.)	Yes / No
x.	Was assessment/inspection abruptly stopped ? (Please give details)	Yes / No
xi.	If accessors were present during entire period of assessment	Yes / No

Note:
There are individuals who run their own training centres/school and are also assessors. It is a breach of impartiality and integrity and needs to be shared with concerned body to minimise mal-practice.

Any other reporting matter:

ASSOCIATION OF INDIAN LABORATORIES
113, First floor, Sushant Tower, Sector 56, Gurgaon - 122011
Website: www.aoilindia.org

Feed Back Form :

Objective:
To find if laboratories interests are protected on:

1. Identify the situation like: (tick appropriately):

i.	Was the date assessment fixed with your consent ?	Yes / No
ii.	Was Lab's consent sought on acceptability of assessor(s) ?	Yes / No
iii.	Was given consent honoured ?	Yes / No
iv.	Delay in accreditation (reassessment case).	Yes / No
v.	Break in continuity of accreditation.	Yes / No
vi.	Was assessment team competent (give details) ?	Yes / No
vii.	Did NABL observer behave like assessor?	Yes / No
viii.	Assessors recommendations not honoured & scope reduced. (Give details)	Yes / No
ix.	Test/calibration method of OIML/standard writing institution/ other reputed institution not accepted.	Yes / No
x.	Surveillance was an assessment.	Yes / No
xi.	Were queries to NABL officers were replied in time ?	Yes / No
xii.	Was complaint handled in time ?	Yes/No

Any other reporting matter:

AOIL BULLETIN

Quarterly News Letter of "Association of Indian Laboratories"

Advertisement Tariff

Back Cover (Colour)	Rs. 40000.00 per 4 insertions
Front inside cover (Colour)	Rs. 30000.00 per 4 insertions
Back inside cover (Colour)	Rs. 30000.00 per 4 insertions
Full page (Colour)	Rs. 25000.00 per 4 insertions
	(Service tax extra as applicable)

Mechanical data

Frequency of publication	:	Quarterly
Finish size	:	21cm x 28cm
Print area	:	18cm x 25cm
No. of columns	:	Two
Paper	:	Art paper

All Correspondence to:
C. S. Joshi, Editor, AOIL BULLETIN
L-17/3, DLF Phase-II,
IFFCO Ckowk, M. G. Road, Gurgaon-122002, Haryana, INDIA
Phone : +91-124-4034205
Telefax : +91-124-4036038
E-mail : aoilbulletin@gmail.com

Payment is to be made in advance by crossed cheque or demand draft in favour of "Association of Indian Laboratories" payable at Faridabad or
Transfer to A/c No. 630301036487
ICICI Bank Ltd., Sector-21C, Faridabad
IFSC No. : ICIC0006303
All material to be send to the Editor, AOIL BULLETIN

Subscription Form

Yes, I/We want to avail the special offers and would like to receive "**AOIL BULLETIN**" regularly from..... issue. Accept my/our subscription for one/two years and mail it to the address mentioned below :-

NAME : ..... DESIGNATION.....

ORGANIZATION..... .....

ADDRESS ....

....

DISTRICT..... CITY .....

STATE ..... PIN CODE .....

PHONE..... E-MAIL.....

I/We,am/are enclosing a Cheque / DD No ..... for Rs.....

drawn on ..... in favour of **"Association of Indian Laboratories"**
Add Rs.25.00 for cheques not drawn at New Delhi. Add Rs.250.00 per year for Courier / Registered Post delivery (optional).

Subscription Tariff

1 year : Rs. 800.00
2 years : Rs. 1500.00

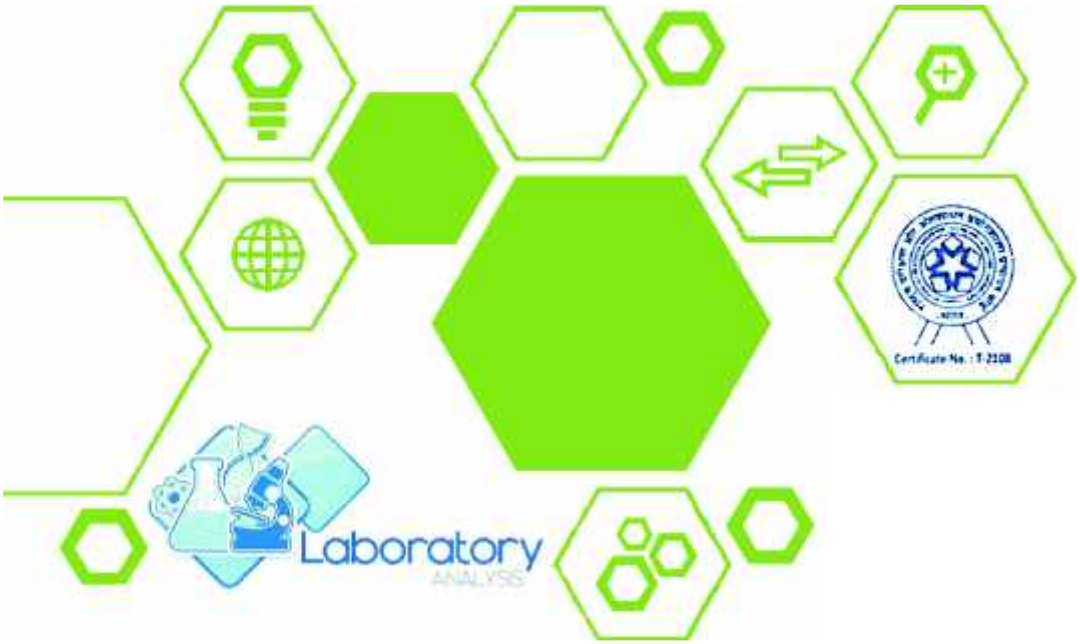
Mail the Subscription Form to :
AOIL BULLETIN
L-17/3, DLF Phase-II, IFFCO Chowk, M. G. Road,
Gurgaon - 122002, Haryana, INDIA
Phone : +91-124-4034205
Telefax : +91-124-4036038
E-mail : aoilbulletin@gmail.com

MEMBERSHIP

For Membership Form & other Information Please visit our website "www.aoilindia.org"

The quarterly periodical is published by Mr. A. K. Nehra, on behalf of Association of Indian Laboratories, B-203, Vigyan Vihar, GH-19, Sector 56, Gurgaon - 122011, Haryana India and printed by him at SANSOM ENTERPRISES, 194, Bhim Nagar, Gurgaon (9810262689) (sansom31@gmail.com)
Editor - C.S. Joshi

(for circulation among AOIL members only)



PERFACT RESEARCHERS PVT. LTD

- Incorporated in 2009 by Mr Praveen Bhargava and Mrs Rachna Bhargava as a Private Limited company with an aim to provide world class testing facilities for the improvement of environment and to innovate, research and develop new processes for environment.
- NABL ACCREDITED laboratory as PER ISO/IEC 17025:2005 for Environmental testing such as Air, Stack, Water, Soil, Waste Water and the testing facility of the lab is engaged in commercial testing for EIA consultants, Industries, Hotels etc.
- ISO 14001:2004 and ISO 9001:2008 Certified Organisation.
- Experts in waste recycling technologies, led by experienced and highly qualified people.
- World Leading Facilities for Trace Organics Analysis, Metal Testing & VOC Analysis.
- R & D Facility for Electronic Waste Recycling & other Innovations.

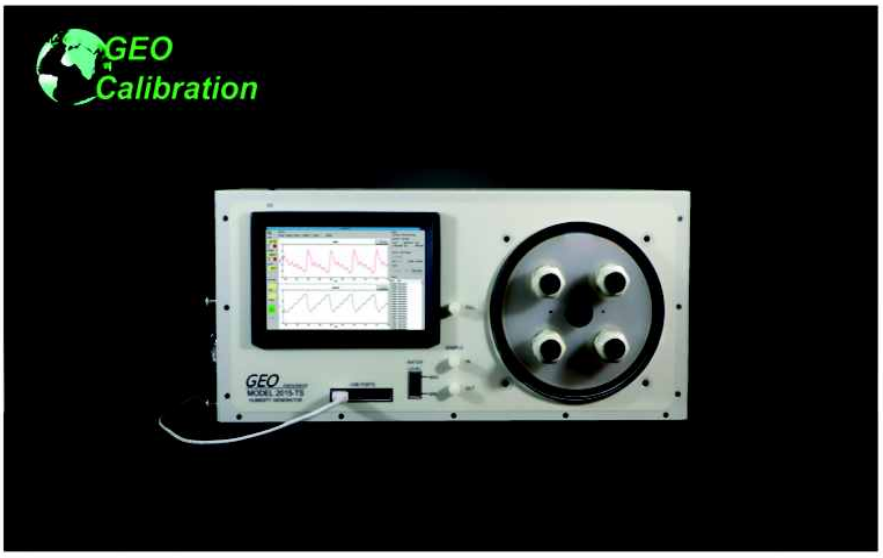
Perfact Group

Perfact Researchers Pvt. Ltd.	Perfact Services	Perfact Enviro Solutions Pvt.Ltd	Perfact Waste Management	Perfact Solutions

★ Environmental Impact Assessment ★ Environmental Management Plan
★ Risk Assessment & Management Plan ★ Disaster Management Plan
★ Electronic Waste Management & Hazardous Waste Management ★ Bio-Medical Waste Management
★ Designing & installation of Pollution Control System for Air Emissions, Water, rain water harvesting &Noise Pollution
★ Operation & Maintenance of Effluent Treatment Plant [ETP] & Sewage Treatment Plant [STP].
★ Environmental Monitoring including Sampling & Testing of ★ Environmental Parameters
★ Environmental Audit ★ Energy Audit ★ ISO: 9001 -2008 ★ ISO: 14001-2004

Contact : Ph. : 011-47528467
5th Floor, NN Mall, Mangalam Palace, Sector- 3, Rohini, Delhi-110085 (India)
Nipun Bhargava (Dy. Director) : 9818424364
Email : research@perfactgroup.com, info@perfactgroup.com, Website : www.perfactgroup.com

HUMIDITY GENERATOR MODEL 2015-TS



SPECIFICATIONS-:

HUMIDITY RANGE @ 23 °C	7% RH to 95 % RH
HUMIDITY RANGE @ 50 °C	7 % RH to 60% RH
TEMPERATURE RANGE	10°C to 55 °C

Stability @ 23 °C

Humidity	0.3% RH or better
Temperature	0.1°C

Features:-

i) User Friendly
ii) Probe feedback
iii) Remote Control & Monitoring
iv) Probe information database
v) Automatic Report Generation
vi) Leasing Programs are Available

Please visit **www.geocalibration.com** for: More Chamber Models, Video Demos, Further details

DVG LABORATORIES & CONSULTANTS PVT LTD

(Authorised distributors for Geo Calibration, NY, USA)

CALIBRATION, TESTING, CONSULTANCY, TRAINING

Geo Calibration
2190, Smithtown Avenue
Ronkonkoma, NY 11779,
USA

Send your enquiries too-:
DVG Laboratories & Consultants Pvt Ltd
dvglabs@dvglabs.com
Ph: +91-9811893191, 9818254877
www.dvglabs.com

FARELABS

FOOD ANALYSIS & RESEARCH LABORATORY

A commitment for a better tomorrow

Research and Development

Excellence

Creative industry oriented solutions

Analytical Testing

Accuracy

Attention to detail

Credentials

Trustworthiness

Successful business relationships

Consultancy and Training

Reliability

Abundant & diverse experience

Founded in 1999, FARE Labs Private Limited is a leading NABL accredited, FSSAI authorised & MOEF recognised laboratory institution of India. It is based in Gurgaon, and is promoted by Dwijendra Mathur and Chandra Shekar Joshi, a team of chemical engineers with a combined industry work experience of over 51 years.

FARE Labs possesses world-class competencies in Analytical Testing and Research & Development. In addition, it also has a strong Consultancy and Training division to provide holistic solutions to its clients.

Water, Fuels & bio-fuels
Food & Agriculture
Fats, Oils & Allied products
Pollution & Environment
Essential Oils, Herbs & Cosmetics
Soaps, Detergents & Toiletries
Packing material, Petrolium & Lubricants
Industrial & Fine Chemicals
Wood Testing & Soil Strength

FARE LABS Private Limited
L-17/3, DLF Phase-II, IFFCO Chowk, M. G. Road, Gurgaon-122002, Haryana, INDIA.
Phone : +91-124-4223207-08, 4034205, Fax : +91-124-4036038, Cell : +91-93126 64533
Email : farelabs@farelabs.com, Website : www.farelabs.com