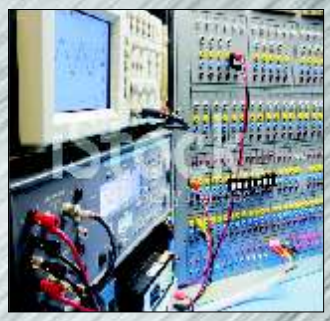

AOIL BULLETIN

Quarterly News Letter

Volume-1, Issue-4 **October – December 2016**

ASSOCIATION OF INDIAN LABORATORIES

INDEPENDENT 3RD PARTY TESTING

BUILDINGS, BRIDGES, HIGHWAYS RAILWAYS, AIRPORTS & PIPELINES

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

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Editor's desk

In a rapidly growing economy like India, quality testing labs have important role to play. Government thrust on "Make in India", "Zero Effect and Zero Defect", "Skill India" etc. have already paved way for future growth. In this environment Indian Laboratories have to equip themselves for a export oriented economy. A lot of integration with world standard, codex and other regulatory bodies is required to understand need and statutory requirement across the exporting countries. Understanding the global requirement and adoption of system, processes, instrument and protocol used in developing countries is the need of hour.

The recent joint annual meeting of IAF-ILAC, which was jointly hosted by NABCB and NABL in New Delhi, has provided such wonderful opportunity for Indian accreditation agency and laboratories to come across global accreditation agencies and associations working in the field of accreditation regime. Indian accreditation authorities such as NABCB, QCI, NABL deserve applaud for conducting this event with flawless perfection. This type of programme opens window for Indian laboratories and help them to understand the international accreditation needs and in course correction.

Indian regulatory & accreditation agencies along with Indian laboratories have capacity and capability to emerge as a global leader and the time is not far when the same will be realized.

Yours truly

C S Joshi

Editor

A new year is like a blank book,
and the pen is in your hands,
It is your chance to write
a beautiful story for yourself

Happy New Year
2017

ASSOCIATION OF INDIAN LABORATORIES

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ACCELERATED PAVEMENT TESTING-NDT METHODS FOR QUALITY, SAFETY & DURABILITY OF RIGID & FLEXIBLE PAVEMENTS

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Introduction

Construction of highways & expressways throughout the country has gained momentum during the last couple of years as BOT, PPP & DBFOT projects. The aim of NHAI is to construct 20 km/day highway in near future. Fast Construction needs fast testing of materials for suitability for highway construction & quick, speedy & reliable evaluation of construction quality of pavements with respect to design acceptance criteria & user expectations including safety & durability

To examine that the pavement construction has been carried out according to the design specifications, it is therefore, of utmost importance that the post construction and during construction, acceptance tests are performed employing popular NDT techniques & methods, which are rapid, reliable & economical with good repeatability & reproducibility

The paper deals with the latest, economical and widely used NDT tests on pavements at the site in general & structures in particular. The paper also has discussion on combined methods, when more than one non-destructive test methods are used for quality assessment, based on the data obtained from Rebound Hammer, UPV & Core tests. These NDT tools are economical basic, provide fast on site results.

There are few tests which can be performed in the lab and at site with same accuracy level, one such safety test is Skid Resistance Test of Pavement & Retroreflection Test of Highway Sign boards.

Although nondestructive tests are relatively simple to perform & instrument based, the analysis and interpretation of the test data is serious exercise, because the roads are made of complex materials, hence the engineers are cautioned that interpretation of the test data must always be carried out by trained specialists in NDT & results must be correlated with other conventional destructive tests & physical properties.

Popular NDT Tests for Concrete Pavements & Structures used in field are:

1. Rebound Hammer Test- RH Test
2. Ultrasonic Pulse Velocity- UPV Test
3. Core Extraction for Compressive Strength Test
4. Skid Resistance Test of Pavement Surface.
5. Permeability Test of Rigid Pavement.
6. Retroreflection Test of Highway Signboards

This paper, describes in detail Rebound Hammer (RH) test, Ultrasonic Pulse Velocity (UPV) test Core Test, Skid Resistance Test & Coefficient of Retroreflection test which are widely used, accepted by engineers at site and referred in MORTH Specs, for Inspection & testing of pavements. These are followed by a description of the combined methods approach in which more then one NDT method is used to estimate strength of concrete. The Ingredient Analysis, Cover Measurement, Permeability & Density methods are of specific application and briefly described in the concluding part of the paper.

1. Rebound Hammer (RH) Test

The determination of the Rebound Number is simple. Briefly, it consists of releasing the plunger from the locked position by pressing it gently against a hard surface. The hammer is then ready for use. To carry out the test, the plunger is pressed strongly against the concrete surface under test. This releases the spring-loaded weight from its locked position, thus causing an impact. While the hammer is still in its testing position, the sliding index is read to the nearest whole number. This reading is designated as the hammer rebound number. The number of the readings to be taken per test is the same as for calibrating the hammer.

Rebound Hammer with Calibration Anvil and UPV Test Instrument with Calibration Block

1. Rebound Hammer (RH) Test

There is a general correlation between compressive strength of concrete and the hammer rebound number. Coefficients of variation for compressive strength for a wide variety of specimens averaged 25 percent. The large deviations in strength can be narrowed down considerably by proper calibration of the hammer, which allows for various variables discussed earlier. By consensus, the accuracy of estimation of compressive strength of test specimens cast, cured, and tested under laboratory conditions by a properly calibrated hammer lies between ±15 and ±20%. However, the probable accuracy of prediction of concrete strength in a structure is ±25 percent.

2. Ultrasonic Pulse Velocity (UPV) Test.

The test instrument consists of a means of producing and introducing a wave pulse into the concrete and a means of sensing the arrival of the pulse and accurately measuring the time taken by the pulse to travel through the concrete.

Portable ultrasonic testing equipments are available. The equipment is portable, simple to operate, and includes rechargeable battery and charging unit. Typically, pulse times of up to 6500 ?s can be measured with 0.1-?s resolution. The measured travel time is prominently displayed. The instrument comes with a set of two transducers, one each for transmitting and receiving the ultrasonic pulse. Transducers with frequencies of 25 to 100 KHz are usually used for testing concrete. These transducers primarily generate compressional waves at predominantly one frequency, with most of the wave energy directed along the axis normal to the transducer face.

Although it is relatively easy to conduct a pulse velocity test, it is important that the test be conducted such that the pulse velocity readings are reproducible and that they are affected only by the properties of the concrete under test rather than by other factors.

The interpretation of the pulse velocity measurements in concrete is complicated by the heterogeneous nature of this material. The wave velocity is not determined directly, but is calculated from the time taken by a pulse to travel a measured distance. A piezoelectric transducer emitting vibration at its fundamental frequency is placed in contact with the concrete surface so that the vibrations travel through the concrete and are received by another transducer, which is in contact with the opposite face of the test object.

Application of Combined Test Methods

In evaluating the in site properties of concrete, one must take into account the potential differences between strengths in the lower and upper parts of structural member, and the extent to which this difference is affected by the size and the shape of a structural element.

Destructive tests can be influenced by a number of factors, and these should be taken into consideration when comparison is made or correlations are established with the nondestructive tests. For example, the cores drilled in a horizontal direction generally give lower results than vertical cores taken at the same location.

Subject to the above considerations, combined methods for which prior correlations were developed for the local concrete materials have been successfully used for nondestructive in site strength evaluation of concrete. The main advantage of a nondestructive test is the possibility of obtaining a very large number of spot readings at a relatively low cost and without affecting the integrity of a structure.

Use of the combined nondestructive technique became a routine method for evaluation the in site quality of suspect concrete in many parts of the country, and examples of its applications are in a variety of projects involving bridges, flyovers and precast plants.

3. Core Extraction for Compressive Strength Test

Portable Concrete Coring Machine (BOSCH) in Operation on PQC-SH-12, MP Shivpuri

Apparatus

Drill- A core drill shall be used for securing cylindrical core specimens. For specimens taken perpendicular to the horizontal surface, a short drill is satisfactory. For inclined holes, a diamond drill is satisfactory.

Test Specimens

Core Specimens- A core specimen for the determination of compressive strength shall have a diameter at least three times the maximum nominal size of the coarse aggregate used in the concrete, and in no case shall the diameter of the specimen be less than twice the maximum nominal size of the coarse aggregate. The length of the specimen, when capped, shall be as nearly as practicable twice its diameter.

Preparing Test Specimens from for Compression Test

Cores to be tested for compression strength shall have ends that are reasonably even, perpendicular to the axis and of the same diameter as the body of the specimen. A core which, before capping, has a maximum height of less than 95 percent of the diameter, or after capping, a height less than its diameter shall not be used.

5782

Capping - The ends of the specimen shall be capped before testing. The material used for the capping shall be such that its compressive strength is greater than that of the concrete in the core. Caps shall be made as thin as practicable and shall not flow or fracture before the concrete fails when the specimen is tested. The capped surfaces shall be at right angles to the axis of the specimen and shall not depart from a plane by more than 0.05 mm.

After checking for irregularities, the core shall be placed in water at a temperature of 24O to 30O for 48 hours testing. The overall height of the specimens, with capping shall be measured to the nearest millimetre.

Test for Compressive Strength of Concrete Specimen

This clause deals with the procedure for determining the compressive strength of concrete specimens.

Capped and Cured Concrete Core Specimen under Compressive Strength Test in CTM

Calculation - The measured compressive strength of the specimen shall be calculated by dividing the maximum load applied to the specimen during the test by the cross-sectional area, calculated from the mean dimensions of the section and shall be expressed to the nearest kg per sq cm. Average of three values shall be taken as the representative of the batch provided the individual variation is not more than ± 15 percent of the average. Otherwise repeat tests shall be made.

A correction factor according to the height/diameter ration of specimen after capping shall be obtained from the hardened curve. The product of this correction factor and the measured compressive strength shall be known as the corrected compressive strength, this being the equivalent strength of a cylinder having a height/diameter ratio of two. The equivalent cube strength of the concrete shall be determined by multiplying the corrected cylinder strength by 5/4.

4. Skid Resistance Test on Pavement Surface

Skid Resistance of the Pavement is required to be maintained in order to prevent vehicle skidding due to polished surface of pavements, particularly in rainly season, when hydropanning is common during rains.]

The skid resistance of the pavement is achieved by using the Polished Stone Value (PSV) index of road aggregate as min 55 for highways surface texturing, microsurfacing & hydrojetting are techniques for post construction upgradation of pavement surface & remedial measures to increase the skid resistance of the pavement surface.

The Portable Skid Resistance Tests (PSRT) developed by TRRL is handy equipment used for field & lab testing of skid resistance of the surface in test of Polished Stone

Value (PSV) in accordance with BS: 812 Part 114-1985. The test is very fast & required no surface preparation & min. obstruction to highway traffic.

The pavement surface to be tested is cleaned free of dust oil & grase (if any) & vetted by water. The reading are takes on field scale (main scale) by using the rubber slides touchy distancing of 120 mm. fire ready are takes, First two are discarded & the average of three reading are takes as PSV of the Surface. The test is repeated & the average to two set of tests is reported as Polished Stone Value (PSV) of the surface as skid Resistance.

5. Permeability Test of Rigid Pavements

The durability of Concrete is integral to the design requirements for the life of the pavement. Lack of durability could be caused by environmental agents or internal weakness of structure. Durability causes can be categorized as physical, mechanical & chemical.

Permeability of Concrete is one of the popular means to assess the durability of structure. The specimen can be drawn from the structures by Core extraction and test performed in a simple lab set up without much instrumentation. The permeability all containing concrete specimen under hydraulic pressure is tested for water permeability. The standard test method IS 3085 & MORTH Specs are available for comparison of results.

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ASSOCIATION OF INDIAN LABORATORIES

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Four days Training Programme on
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Seminar on

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team (AOIL)
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LEGAL LIABILITIES & POSSIBLE IMPROVEMENTS IN ACCREDITATION
SYSTEM FOR LABORATORIES
FLUKE

Visit of Mr. Peter Unger at Fare Labs, Gurgaon on 12.11.2016

Visit of UILI Team Members at FareLabs, Gurgaon on 27.10.2016

NEED FOR CALIBRATION PROCEDURES

Ms. Rachna Parekh
Quality Manager
Calitech, Vapi

In a Quality Management System procedure details the purpose and scope of an activity and will also identify how, When, where and by whom the activity is to be carried out. A well documented procedure ensures consistency in operations and the records so generated during the process of working with a procedure give objective evidence that the activity has been carried out in accordance with specified Procedure. That is why control of calibration Procedure is an important element of calibration system.

"The Laboratory shall use appropriate method and procedure for all calibration within its scope. The Procedure Shall include handling, transport, storage and preparation of item and where appropriate an estimation of Measurement uncertainty, as well as statistical techniques for analysis of calibration data."

Calibration procedure s provide the specified performance tolerances and other functional criteria information of Measuring equipment and measurement standards. They provide essential information and instruction to calibration Organization personnel to revise that information to local measurement standards equipment and conditions and Then determine whether the unit under calibration (UUC) is operating within those performance specifications.

A Calibration procedure shall be organized with the UUC performance capability in mind and will describe the technical process to evaluate and determine whether test and measuring equipment or measuring standard is Functional and performing to documented specified performance criteria. A Calibration procedure must provide the information required by a qualified and responsible test and measuring Equipment and measurement standard calibration testing organization ,to evaluate and modify the CP to their Existing measurement standard and perform the calibration process with a minimum amount of interpretation, effort, labour and time.

The Calibration process provides a logical and timely sequence of necessary facts to understand and verify the test And measuring equipment standard unit-being-calibrated to its intended performance capabilities and operating Quality Condition.

GENERAL RULES FOR WRITING PROCEDURES

Procedures play an important role in safeguarding against quality, environmental, health and safety problems. People often learn, or are reminded, how to perform a task through procedures. Since the human memory prone to play tricks on everyone, it is highly likely that most people will forget how to do a task that is not repeated with Great frequency, hence the need for procedures. Procedures often includes check lists that provide extra control to assure that work is performed properly. Procedures also provide detailed information about instrument settings, Safety precautions and special problems that are know to occur.

GROUND RULES FOR DEVELOPING PROCEDURES

Here are a few ground rules for developing effective procedures.

1. Make sentences short and to the point. Be specific.
   a. How to operate a piece of equipment.
   b. How to administer a treatment.
   c. How to run a test.
   d. How to maintenance on equipment
2. The Person who use the procedure is a customer. Write with the customer in mind, not the expert.
3. Develop procedures that can be read and used under stress.
4. Use a simple numbering and Identification system.
5. Place procedures where the users can get them.

THE PROCEDURE WRITING PROCESS

People can waster a great deal of time writing procedures if they do not have an effective process. Time is wasted in writing material that is technical in accurate because the writer did not get out and look at the job or interview the staff. If a person has poor organization

skills, he or she will not be effective in organizing Information in to procedure.

Here are the actions that make up an effective procedure writing process.

1. Look at the job.
2. Organize your information. use a flow diagram to establish the sequence of work and integrate your Firsthand observation with manuals and regulatory standards.
3. Write down the information
4. Walk it down and check it out. Make sure the procedure is usable, accurate has the right level of detail and fits your general guidelines for procedures
5. Roll it out, Get it in the users hand

GUIDELINE FOR WRITING PROCEDURES

Procedure writing is unlike other forms of writing. In school you were encouraged to use large words and fairly Long sentences. The opposite is true for writing good procedures.

Here are some guidelines for writing good procedure.

1. Use short sentences
2. Use active Voice ("Turn the switch" instead of "the switch should be turned")
3. Be direct .Tell the reader what to do.
4. Use short words.("Raise" instead of "Evaluate)
5. Do not use abbreviations or acronyms.
6. Be consist with Terminology.
7. Do not assume the reader knows something.
8. Put the steps in right sequence.
9. Use heading to help organize information. This helps people find information quickly and understand the Flow of the procedure.

The objective in writing a procedure is to give the reader crisp and clear information. Additional information is Usually not a good idea. When extra details may helpful, or when the reader might need some background Information, it should not be buried in the text. Action steps and notes should be laid out in separate columns so That the reader can move quickly through the action steps and be able to refer to notes on as-needed basis.

PROBLEMS TO WATCH OUT FOR

There are some common problems you can expect to meet when setting up a procedure program. Here are a few typical things that can go wrong in writing a good procedure:

1. Do not put the actions in the notes column
2. Clearly mark any warnings or cautions. It is a good idea to use bold print for these or to put them in a Highlighted area.
3. Put warnings before an action step, not after
4. Do not put multiple steps in paragraph, Separate step so they are visible.
5. Include emergency steps and highlight them. The emergency steps are what people are looking for when Under stress.
6. Use specified ranges, not plus or minus some value.
7. Do not required to calculations to use the procedure. Give them in notes, if useful.
8. Make sure you have included the flow down of any upper level requirements in to the procedure.

What does flow down of an upper-level requirement means? If your Laboratory has a policy that requires the control of chemical waste materials, then this need to be flow down in to procedures on the unit or department Procedures are the mechanism for assuring that upper-tier policy decisions become concrete actions in The Laboratory room.

USE FLOW CHARTS TO ORGANIZE

Flow charts are handy tools to get information organized for writing a procedure.

Procedure writers can sketch their own rough charts as they observe the performance of a task and interview

The people who are doing work to get everything in the correct order.

It is also good idea to put a flow diagram in to a procedure to give people a quick visual concept of the overall Work flow. Action items are placed inside of blocks and connected by arrows that indicate the sequence of steps.

Decision points are indicated by diamonds, which are also connected to actions by arrows.

PROCEDURE REVIEW PROCESS

Managers in organizations should establish teams to conduct periodic reviews of procedures on at least a three Year cycle .Each team should involve practitioners and trainers to ensure that the procedure remains current and Reflects what has become the best practice in the industry since the last review

Technical News

Pitt State Researchers Use Nanosensors to Detect E. coli in Water, Food

The chemistry department at Pittsburg State University (Pittsburg, KS) have come up with a new way to detect foodborne bacteria in food and water in less than an hour.

PSU chemist Tuhina Banerjee, assistant professor Santimukul Santra, professor and biochemist James McAfee and six chemistry students were able to combine magnetic resonance imaging (MRI) and fluorescence to create a device that enables scientists to detect the presence of dangerous bacteria in food and water. The team's research was inspired by widespread news stories of food related E. coli outbreaks in the U.S. As a result, they began pondering way to use nanosensors to try to detect common pathogens, first in water.

The nanosensors are made up of iron oxide particles combined with an optical dye and antibodies that latch onto the E. coli cells. The nanosensors clump around the bacteria and this can be detected by MRI, for very small amounts, and fluorescence, for large amounts. The method was initially tested using water from PSU's University Lake, along with other water resources. The nanosensor was "very good" at picking up contamination, according to researchers.

The next step, in order to make a rapid detection system available in the field, is miniaturization.

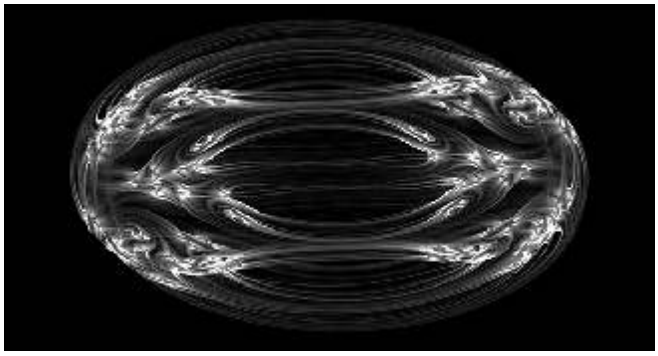
"The next step is to work with engineers to develop a chip that can take the process out of the lab and into the field," says Banerjee. In the meantime, the researchers are exploring ways the technique they've developed could be used for the rapid detection of other pathogens, such as influenza and Zika.

As a result of this work, one student--Tyler Shelby--was awarded with the Star Trainee Award from the Kansas IDeA Network of Biomedical Research Excellence and he is following up the research on E. coli with a paper that explores how nanosensors may be used for the rapid detection of the influenza virus.

PSU's research was recently published in the American Chemistry Society's journal Infectious Diseases. Since publishing their work, the team has been getting calls from researchers around the world.

Courtesy: Food Safety Magazine

Magnetic crystals hold drug delivery potential



Chinese researchers have discovered a way to control microscopic crystals using magnetism, leading to hopes that it could be used to apply cancer treatments directly to tumours.

When magnetised, these minute crystals are able to reverse their magnetic field as the temperature changes – known as superparamagnetism. The scientists have succeeded in creating crystals large enough to be manipulated using magnetism.

Kezheng Chan, from Quingdou University and co-author, said: "The largest superparamagnetic materials that we have been able to make before now were clusters of nanocrystals that were together about a thousand times smaller than these. These larger crystals are easier to control using external magnetic fields, and they will not aggregate when those fields are removed, which will make them much more useful in practical applications, including drug delivery."

During the creation of these magnetite crystals, high temperature and pressure cause tiny micro particles of magnetite to escape. This leads to an unusual pock-marked surface on the crystal, inducing a high degree of stress and strain into the growing crystals' lattice.

This method of creating large superparamagnetic crystals could lead to the development of bulk materials controllable by external magnetic forces. Forming irregularities are they are grown; it is these that are responsible for superparamagnetism. Similar crystals grown at a lower temperature and lesser pressure were only weakly magnetic.

Applications may not be linked to just biology, these crystals could be used in engineering projects that need 'smart fluids' which change their properties when a

magnetic field is applied. For example, vehicle suspension systems could adjust automatically as road terrain changes. It could also be used to build prosthetics that are both more comfortable and realistic.

Courtesy: Physics Letters A.

Gut's Microbial Community Shown to Influence Host Gene Expression

The upshot of the study is another indictment of the so-called Western diet

In our guts, and in the guts of all animals, resides a robust ecosystem of microbes known as the microbiome. Consisting of trillions of organisms—bacteria, fungi, and viruses—the microbiome is essential for host health, providing important services ranging from nutrient processing to immune system development and maintenance.

Now, in a study comparing mice raised in a "germ free" environment and mice raised under more typical lab conditions, scientists have identified yet another key role of the microbes that live within us: mediator of host gene expression through the epigenome, the chemical information that regulates which genes in cells are active.

Writing online Nov. 23 in the journal Molecular Cell, a team of researchers from the University of Wisconsin–Madison describes new research helping tease out the mechanics of how the gut microbiome communicates with the cells of its host to switch genes on and off. The upshot of the study, another indictment of the so-called Western diet (high in saturated fats, sugar, and red meat), reveals how the metabolites produced by the bacteria in the stomach chemically communicate with cells, including cells far beyond the colon, to dictate gene expression and health in its host.

"The bugs are somehow driving gene expression in the host through alteration of the epigenome," explains John Denu, a UW–Madison professor of biomolecular chemistry and a senior researcher at the Wisconsin Institute for Discovery, and a co-author of the new study. "We're starting to understand the mechanism of how and why diet and the microbiome matter."

The study, which was led by Kimberly Krautkramer, an MD/PhD student in the UW School of Medicine and Public Health, revealed key differences in gene regulation in conventionally raised mice and mice raised in a germ-free environment. The mice were provided with two distinct diets: one rich in plant carbohydrates similar to fruits and vegetables humans consume; the other mimicking a Western diet, high in simple sugars and fat.

A plant-based diet, according to Federico Rey, a UW–Madison professor of bacteriology and also a co-corresponding author of the new report, yields a richer microbiome: "A good diet translates to a beautifully complex microbiome," Rey says.

"And we see that the gut microbiome affects the host epigenome in a diet-dependent manner. A plant-based diet seems to favor host-microbe communication."

The new Wisconsin study shows that a small set of short-chain fatty acids produced as the gut bacteria consume, metabolize and ferment nutrients from plants are important chemical messengers, communicating with the cells of the host through the epigenome. "One of the findings here is that microbial metabolism or fermentation of plant fiber results in the production of short-chain fatty acids. These molecules, and potentially many others, are partially responsible for the communication" with the epigenome, says Denu.

In the study, the gut microbiota of the animals that were fed a diet rich in sugar and fat have a diminished capacity to communicate with host cells. According to the Wisconsin team, that may be a hint that the template for a healthy human microbiome was set in the distant past, when food from plants made up a larger portion of diet and sugar and fat were less available than in contemporary diets with more meat and processed foods.

"As we move away from plant-based diets, we may be losing some of that communication between microbes and host," notes Rey. "With a Western-type diet, it seems like the communication between microbes and host gets lost."

Foods rich in fat and sugar, especially processed foods, are more easily digested by the host, but are not necessarily a good source of food for the flora inhabiting the gut. The result is a less diverse microbiome and less communication to the host, according to the researchers.

A surprising finding in the study is that the chemical communication between the microbiome and host cells is far reaching. In addition to talking to cells in the colon, the microbiome also seems to be communicating with cells in the liver and in fatty tissue far removed from the gut. That, says Denu, is more evidence of the importance of the microbiome to the well-being of its host.

Courtesy: Lab manager

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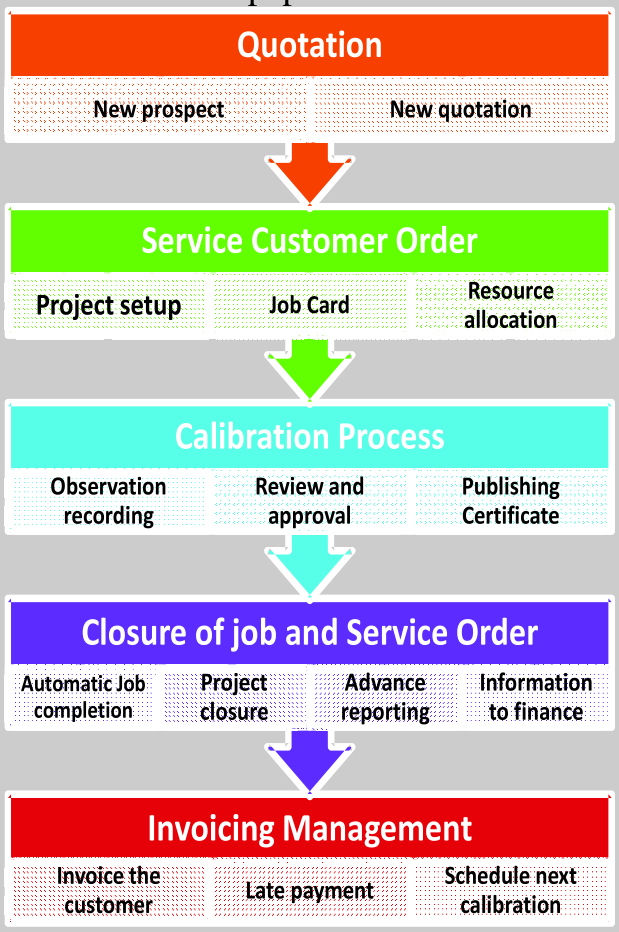

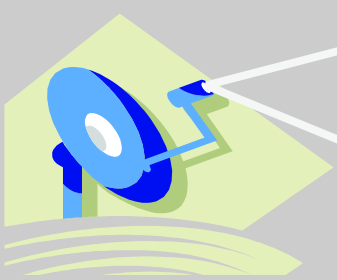

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HVAC VALIDATION SCOPE

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"

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COMPRESSED AIR VALIDATION

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A blood test for early detection of lung cancer

An immune response can reveal cancer. As a normal cell undergoes tumorigenesis, it expresses aberrant protein antigens, known as tumor-associated antigens (TAAs). They are recognized as non-self by the immune system, thereby triggering a B-cell response. The production of autoantibodies by B cells is not dependent on the size of a tumor and can occur throughout all stages of the disease. Most important, autoantibodies are produced early in tumorigenesis, when just a few antigens may stimulate a prolific immune response.1Autoantibodies, therefore, can serve as an early cancer marker.

Biomarkers for lung cancer

A blood test that measures a panel of seven autoantibodies associated with lung cancer is available to clinicians to further assess a patient's risk of lung cancer being present.2-5 The test provides additional insight into the patient's lung cancer risk beyond self-reported risk factors, such as age, smoking history, exposure to carcinogens (e.g., radon, asbestos), etc. A tube of blood is drawn from the patient, and the isolated serum is sent to a CLIA-certified laboratory, where autoantibodies are measured utilizing a proprietary platform technology based on indirect enzyme-linked immunosorbent assay (ELISA) principles.

The test results

Results are reported for each autoantibody as well as an overall test result.2-5 Two clinically-derived cut-offs for each autoantibody are utilized to determine whether a patient's autoantibody levels are low, moderate, or high.3 A low level of autoantibodies does not rule out lung cancer; it simply means that the patient's lung cancer risk has not changed appreciably from what was estimated by his or her self-reported risk factors.3 Conversely, patients with moderate or high levels of any one or more autoantibodies are at increased risk of having lung cancer, which may warrant additional testing consistent with the patient's history and overall risk profile.3

Clinical validation

Clinical validation of the autoantibody test utilized serum from three cohorts of newly diagnosed lung cancer patients (n=655) and serum from risk-matched control patients. (Controls were not diagnosed with cancer and were risk-matched to lung cancer cases by gender, age, and smoking history.) The studies demonstrated that the autoantibody test detects all types and all stages of lung cancer equally.5 The panel of autoantibodies was subsequently changed from six to seven autoantibodies, which improved accuracy to 92 percent, PPV (positive predictive value) to one in eight (assumes lung cancer prevalence 2.4 percent) and specificity to 91 percent at 41 percent sensitivity.2 A second cut-off for each autoantibody was implemented to stratify the positive autoantibody results, with the primary advantage being the enhancement in specificity and PPV with a high level result to 98 percent and one in four (assumes lung cancer prevalence 2.7 percent), respectively.3 The performance characteristics demonstrated by these studies support the test's utility in helping physicians identify which patients are at highest risk of having a lung cancer. (Note: The test is a rule-in test and cannot be used to rule-out a patient having lung cancer.)

A clinical audit was performed on 1,613 U.S. patients whose physicians had ordered the autoantibody test due to their patient's high risk for lung cancer. Patients provided HIPAA authorization to release their medical records for the clinical audit. Records regarding cancer diagnosis were reviewed six months following testing for all patients with a positive or negative test result. Sixty-one patients (four percent) were identified with lung cancer, 25 of whom had a positive autoantibody test (sensitivity 41 percent). A positive autoantibody test was associated with a five-fold increase in risk of lung cancer versus a negative test. In the lung cancer patients with a positive autoantibody test, where stage was known, 8 of 14 (57 percent) were Stage I or II. The clinical audit also confirmed a highly statistically significant improvement in specificity of the seven-autoantibody panel and demonstrated that the autoantibody test performs the same in routine clinical practice as was shown in the case-control validation studies.4

In another clinical audit study, the autoantibody test was evaluated in 296 high-risk patients with non-calcified pulmonary nodules (lung cancer prevalence 25 percent). The patient's lung cancer risk was calculated using the Swensen/Mayo Clinic Nodule Calculator.6 A positive autoantibody test resulted in a greater than two-fold increased relative risk of lung cancer.7 Using a "both positive rule" of combining binary tests, adding the autoantibody test to the Swensen risk model improved the diagnostic performance with high specificity (> 92 percent) and positive predictive value (> 70 percent). Accordingly, a positive autoantibody test reflects a significant increased risk of lung cancer in non-calcified nodules 4-20mm in largest diameter.7

Prospective trials

Currently, there are two large prospective trials underway evaluating the autoantibody test. In Scotland, the National Health Service (NHS) is conducting a randomized prospective trial of 12,000 individuals at high-risk for lung cancer. Participants are randomized, with half getting the autoantibody test and half not. Those with a positive autoantibody test are followed-up with a chest x-ray and CT chest scan. (Low-dose CT chest scans are not approved for screening in Scotland.) The goal of the study is to determine if screening with the autoantibody test reduces the number of patients being diagnosed with Stage III or IV lung cancer. This trial completed accrual in June 2016 and follow-up is ongoing.8

The second prospective trial, at National Jewish Health in Denver, Colorado, combines screening with low-dose CT chest scan and the autoantibody test. The goal of the study is to determine if screening with both modalities results in a higher rate of detecting early stage lung cancer.9 To date, more than 1,300 high-risk participants have been enrolled. Encouraging preliminary results of both studies were presented at the World Conference on Lung Cancer in Denver in late 2015.8,9

Currently, only 25 percent to 30 percent of all patients with lung cancer in the United States meet the criteria for lung cancer screening with low-dose CT chest scans.10 Clearly there is a need for additional tests, such as the autoantibody test described here, to help identify the remaining 70 percent to 75 percent of lung cancers while they are asymptomatic and early stage. Additionally, as the number of patients with non-calcified pulmonary nodules is rapidly growing through CT screening, there is an urgent need for supplemental tests to assist physicians in determining which are malignant and which are benign.

Courtesy: Medical Laboratory Observer

SIX SIGMA AS QUALITY MEASUREMENT TOOL IN MEDICAL LABORATORIES

Dr. Neeraj Jain
Managing Director
Jain Diagnostics

Dr. Rohini Kalhan
Managing Director
Alaknanda Diagnostics

In medical school, the first concept expressed to students is a Latin phrase, primum non nocere, meaning "first, do no harm." This phrase is well known among health workers and dates back to Hipocrates. However, in reality, the situation is slightly different. According to the report of the Institute of Medicine, each year in the USA, approximately 98,000 people die from medical errors (Kohn et al., 2000). Unfortunately, more people have died each year during mid-1990s from medical errors than from AIDS or breast cancer (Kohn et al., 2000). Despite this situation, we cannot say that adequate attention has been paid to the application of high standards in the healthcare sector to effectively prevent medical errors. Yet in industry, for more than a century, modern quality control has been applied to prevent errors and produce high quality goods. The result of these long-term efforts is that in many companies, the rate of errors approaches a negligible level. Regrettably, we cannot say the same thing for medical services, because the components that produce errors or defects in medical services are many more than those involved in any industrial or business sector. Despite these facts, it is clear that the quality of medical services is more important than the quality of most other goods. Consequently, healthcare professionals must pay more attention to quality than any industrial professionals do.

Among healthcare services, clinical laboratories are particularly important because physicians make their decisions mostly in accordance with laboratory results. In this context, accurate test results are crucial for physicians and their patients. First,the laboratory must be able to produce an accurate test result before any other dimension of quality becomes important. From this point of view, the evaluation of laboratory performance is critical to maintaining accurate laboratory results .

Six Sigma methodology was developed by Motorola, Inc. to reduce the cost of products, eliminate defects, and decrease variability in processing. It consists of five steps: define, measure, analyze, improve, and control (DMAIC) These steps are universal and could be applied to all sectors of industry, business, and healthcare. The sigma value indicates how often errors are likely to occur; the higher the sigma value, the less likely it is that the laboratory reports defects or false test results. The best or "world class'' processes for industry or business have a six sigma level, which means that in such a process, fewer than 3.4 defects (or errors) occur per million products . However, in the healthcare sector, the six-sigma level may not be adequate for many situations. For example ,in blood banking or other critical medical services, an error may cause fatal or irreversible results. Thus, in medical services, the six-sigma level should not be accepted as the ultimate goal. We have to decrease the number of defects by as much as possible, and indeed, the sigma level should be higher than six. Our slogan should be 'zero defects.'

To calculate the sigma level of a laboratory, we have to determine the errors or defects and measure the performance of the unit or process in which we are interested. If you do not measure, you do not know, and if you do not know, you cannot manage. So Six Sigma shows us how to measure and, consequently, how to manage the laboratory.

Clinical Laboratories in the Healthcare Sector

One of the most important units of the healthcare sector, particularly in hospitals, is undoubtedly clinical laboratories. Obviously, without accurate test results, physicians cannot make diagnoses or provide effective treatment. This is true even for experienced physicians. Currently, clinical laboratories affect 60~70% of all critical decisions, such as the admission, discharge, and drug therapy of patients . Based on our experience, we believe that this rate is even higher. Despite these vital functions, in the healthcare sector, laboratory costs are a very low proportion (5~10%) of the total cost of patient care (Forsman, 1996).

Quality Control in Laboratory Medicine

It is easier to apply quality principles to clinical laboratories than to other clinical services, such as surgery and obstetrics and gynecology, because laboratory scientists use technology more intensively than do other medical services. However, even within clinical laboratories, we cannot apply quality principles to

all sub-disciplines equally. For example, we can apply quality principles to clinical biochemistry or hematology quite readily, but the same thing cannot be done for anatomical pathology. Consequently, the error rate in anatomical pathology is higher than that in clinical biochemistry.

Errors in analytical phases have two main components: random and systematic errors.

Using these two components, we can calculate the total error of a test as TE = Bias + 1.65CV (I) where TE is total error, bias and CV (coefficient of variation) are the indicator of systematic and random errors respectively.

For the pre- and post-analytical phases, we can prepare written guidelines and apply these principles to clinical laboratories. Then, we can count the number of errors within a given period or number of tests. For the pre-pre- and post-post-analytical phases, we do not have the experience to prepare guidelines or written principles. However, this does not mean that we can do nothing for these two phases. Laboratory consultation may be the right solution

Six Sigma in Laboratory Medicine

The sources of medical errors are different from those of industrial errors. To overcome the serious errors originating in clinical laboratories, a new perspective and approach seem to be essential. All laboratory procedures are prone to errors because in many tests, the rate of human intervention is higher than expected. It appears that the best solution for analyzing problems in clinical laboratories is the application of Six Sigma methodology.

The Six Sigma model is similar to TQM. The basic scientific model is “DMAIC”: define, measure, analyze, improve, and control. In comparison with TQM’s PDCA, we can say that define corresponds to the plan step, measure to the do step, analyze to the check step, and improve to the act step. The Six Sigma model has an extra step, control, which is important in modern quality management. With this step, we intend to prevent defects from returning to the process. That is, if we detect an error, we have to solve it and prevent it from affecting the process again. With this step, we continue to decrease the errors effectively until we obtain a desirable degree of quality.

Six Sigma provides principles and tools that can be applied to any process as a means to measure defects and/or error rates. That is, we can measure the quality of our process or of a laboratory. This is a powerful tool because we can plan more effectively, based on real data, and manage sources realistically.

Sigma Metrics

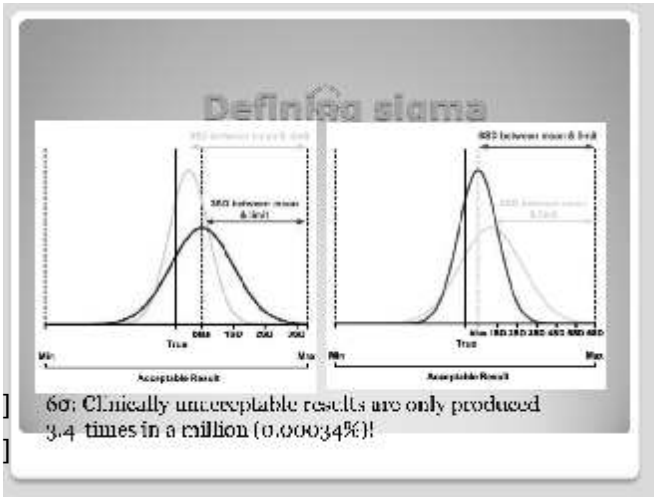
The number of errors or defects per million products or tests is a measure of the performance of a laboratory. Sigma metrics are being adopted as a universal measure of quality, and we can measure the performance of testing processes and service provision using sigma metrics

Usually, manufacturers or suppliers claim that their methods have excellent quality. They praise their instruments and methods, but the criteria for this judgment frequently remain vague.A simple technique that we can use in our laboratories is to translate the method validation results into sigma metrics . Performance is characterized on a sigma scale, just as evaluating defects per million; values range from 2 to 6, where “state of the art” quality is 6 or more. In terms of Six Sigma performance, if a method has a value less than three, that method is considered to be unreliable and should not be used for routine test purposes. A method with low sigma levels would likely cost a laboratory a lot of time, effort, and money to maintain the quality of test results. Sigma metrics involve simple and minimal calculations. All that is necessary is to decide the quality goals and calculate the method’s imprecision (CV,coefficient of variation) and bias levels as one would ordinarily do in method validation studies. Then, using the formula below, the sigma level of the method in question can readily be calculated:

Sigma = (TEa – bias)/CV (II)

where TEa is total error allowable (quality goal), bias and CV (coefficient of variation) are the indicator of systematic and random errors respectively.

For example, if a method has a bias of 2%, a CV of 2%, and TEa of 10%, the sigma value will be (10-2)/2 = 4. This calculation needs to be done for each analyte at least two different concentrations.



Evaluation of Laboratory Performance Using Sigma Metrics

Although the activities in laboratory medicine are precisely defined and therefore are more controllable than many other medical processes, the exact magnitude of the error rate in

laboratory medicine has been difficult to estimate. The main reason for this is the lack of a definite and universally accepted definition of error. Additionally, the bad habits of underreporting errors and insufficient error-detection contribute to the uncertainty in error rates. The direct correlation between the number of defects and the level of patient safety is well known. However, number of defects alone means little. It is important to classify the defects first, and then to count the number of defects and evaluate them in terms of Six Sigma.

There are two methodologies and both are quite useful in clinical laboratories to measure the quality on the sigma-scale . The first one involves the inspecting the outcome and counting the errors or defects. This methodology is useful in evaluation of all errors in total testing process, except analytical phase. In this method, you monitor the output of each phase, count the errors or defects and calculate the errors or defect per million and then convert the data obtained to sigma metric using a standard Six Sigma benchmarking chart (Table 1). The second approach is useful especially for analytical phase.

To calculate the sigma level of the process as described in equation (II) we have to measure and calculate some variables: bias (systematic errors), imprecision (CV, random errors) and total error allowable.

The error rate in each step is quite different. For example the average error rates for the preanalytical, analytical, and post-analytical phases were reported by Stroobants and Goldschmidt as 2.0% (Stroobants, 2003), 0.2% (Stroobants, 2003), and 3.2% (Goldschmidt, 2002) respectively. However the average error rates in pre-pre- and post-post-analytical phases are very high Stroobants and co-workers reported that, in the pre-pre- and post-post-analytical phases the average error rate are approximately 12% and 5% respectively (Stroobants, 2003). Among all the phases of a testing process, the analytical phase presents the lowest number of possible errors. Now if we calculate sigma level for only analytical phase we'll obtain 4.4 sigma for a 0.2% error rate which initially appear to be adequate. However this value does not reflect the reality and even mask it. Because analytical phase is not represent the total testing process and it is only a part of total testing process. However in many clinical laboratories, only analytical errors are taken into account and the laboratory performance are calculated usually based on only error rates in analytical phase. Consequently sigma is calculated for the analytical phase of a testing process.

In this situation the laboratory manager may assume that the performance of laboratory is acceptable and he/she may not take any preventive actions but the reality is quite different.

The total error frequency of each phase must be calculated separately, and then expressed as error per million (epm) .

TABLE I

Sigma Metric	Defects per million
1.0	698,000
2.0	308,000
2.5	159,000
3.0	66,800
3.5	22,750
4.0	6,210
4.5	1,350
5.0	233
5.5	32
6.5	3.4

Lean Concept

In recent years, special emphasis has been placed on enhancing patient safety in the healthcare system. Clinical laboratories must play their role by identifying and eliminating all preventable adverse events due to laboratory errors to offer better and safer laboratory services. All ISO standards and Six Sigma improvements are aimed at achieving the ultimate goal of zero errors. The main idea is to maximize "patient value" while reducing costs and minimizing waste. The "lean concept" means creating greater value for customers (i.e., patients, in the case of laboratories) with fewer resources. A lean organization focuses on creating processes that need less space, less capital, less time, and less human effort by reducing and eliminating waste. By "waste," we mean anything that adds no value to the process. Re-done tasks, transportation of samples, inventory, waiting, and underused knowledge are examples of waste. One of the slogans of the lean concept is that one must "do it right the first time." Lean consultants start by observing how things work currently, and they then think about how things can work faster. They inspect the entire process from start to finish and plan where improvements are needed and what innovations can be made in the future. Finally, they subject this to a second analysis to find ways to improve

the process. Lean projects can generate dramatic reductions in turnaround times as well as savings in staffing and costs. It is said that 'Time is money.' However, in laboratory medicine, time is not only money. Apart from correct test results, nothing in the laboratory is more valuable than rapid test results. The turnaround time of the tests is crucial to decision making, diagnoses, and the earlier discharge of patients. Although Six Sigma, and the lean concept look somewhat different, each approach offers different advantages, and they do complement each other. The combination of Lean with Six Sigma is critical to assure the desirable quality in laboratory medicine for patients benefit and safety. Taken together, Lean Six Sigma combines the two most important improvement trends in quality science: making work better (using Six Sigma principles) and making work faster (using Lean Principles)

Conclusions

To solve analytical or managerial problems in laboratory medicine and to decrease errors to a negligible level, Six Sigma methodology is the right choice. Some may find this assertion too optimistic. They claim that Six Sigma methodology is suitable for industry, but not for medical purposes. Unfortunately, such claims typically come from people who never practiced Six Sigma methodology in the healthcare sector. As mentioned previously, if we do not measure, we do not know, and if we do not know, we cannot manage. The quality of many commercial products and services is very high because it is quite easy to apply quality principles in the industrial sector. Regrettably, currently, the same is not true in medicine. Unfortunately, people make more errors than machines do, and consequently, if human intervention in a process is high, the number of errors would also be expected to be high. To decrease the error rate, we should decrease human intervention by using high-quality technology whenever possible. However, it may not currently be possible to apply sophisticated technology to all medical disciplines equally; however, for laboratory medicine, we certainly have the opportunity to apply technology. If we continue to apply technology to all branches of medicine, we may ultimately decrease the error rate to a negligible level.

Six Sigma is the microscope of quality scientists. It shows the reality and does not mask problems. The errors that we are interest are primarily analytical errors, which represent only the tip of the iceberg. However, the reality is quite different. When we see the whole iceberg and control it all, then it will be possible to reach Six Sigma level and even higher quality in clinical laboratories.

Strengthening GLP Study Audits through Effective Quality Assurance

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Abstract

An effective Quality Assurance (QA) function is an essential component of any compliance program. The Quality Assurance Unit (QAU) of every facility has the responsibility to assure compliance to non-clinical safety studies. This paper describes key activities that QAU need to carryout to fulfill the above responsibility.

Key Words: GLP, QA, SOPs

I. Introduction

An effective Quality Assurance (QA) function is an essential component of any compliance program. The objective of a Good Laboratory Practice QA Unit (GLP QAU) is to assure test facility management and eventually regulatory agencies that the compliant non-clinical (i.e. pre-clinical) safety studies meet quality, data integrity and regulatory requirements.

The roles & responsibilities of a GLP QAU are outlined in Organisation for Economic Development and Cooperation (OECD) Consensus Documents. As per these guidelines, the primary responsibility of GLP QAU is to monitor each compliant non-clinical safety study and assure test facility management that the facilities, equipment's, personnel, methods, practices, records and controls are in conformance with the OECD Principles of GLP, facility Standard Operating Procedures (SOPs) and approved study plan [1].

To carry out the above responsibility QAU shall perform the following key activities;

1) Access to an up-to-date copy of the master schedule.
2) Maintain copies of all approved study plans and facility's Standard Operating Procedures (SOPs).
3) Verify that the study plan is in compliance with the OECD Principles of GLP.
4) Monitor each nonclinical study at pre-defined intervals to assure the quality and integrity of the studies.
5) Maintain signed records of each inspection, including study plan verification.
6) Review the final report to confirm that the methods, procedures are accurately and completely described and reported results reflect pertinent raw data.

In addition, all regulations including US FDA emphasize on two critical QA functions: (1) effective monitoring during conduct of studies, and (2) prompt and timely reporting of audit observations to Study Directors and management.

The aim of this article is to understand the effective use of QA for study based audits.

II. STUDY SPECIFIC AUDITS

A non-clinical health and environmental safety study, henceforth referred to as "study", means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities. These study-specific audits are conducted at different stages of a study, starting from study plan review to finalization of the study report [2].

TABLE I
STUDY SPECIFIC QA ACTIVITIES

#	Sequence of Events		Activity
1	Study Initiation	-	Study Plan Review
2	Study Conduct	-	Identification of Critical Phases
		-	Inspection of in-life phases
3	Study Report Audit	-	Raw Data to Final Report Audit
4	QA Statement	-	Issue of QA statement

A. Study Initiation

Study plan shall be reviewed by QAU for clarity, internal consistency and compliance with facility SOPs, OECD Principles of GLP and applicable regulations.

There are many documents that provide important scientific and technical information including regulatory guidelines such as OECD test guidelines and ICH guidelines. The QAU auditors should have a working knowledge of these requirements to perform review of study plans. At study plan review stage QAU should play a pro-active role to assure that a scientifically sound and compliant plan is put forward. If required, QAU can also request for expert scientific opinions and regulatory inputs to accomplish the same. A general industry practice is to have signature of QA personnel on the study plan to indicate the involvement.

B. Study Conduct

Critical phases shall be identified by the QAU in conjunction with the Study Director (SD). These audits are conducted to observe specific activities within the actual conduct of the study in order to verify whether experiments are executed according to the approved study plan and applicable SOPs. The 'Critical Phases' which QA is required to inspect, are much more restricted parts of a study, down to single, but highly important activities, on which the quality of a study is 'critically' dependent.

An example of identifying critical phases is provided in the table below (repeated dose toxicity study);

TABLE II
IDENTIFICATION OF CRITICAL PHASES [2] [3]

#	Phase		Activity
1	In Life	-	Animal weighing
		-	Grouping of animals
		-	Food Consumption
		-	Formulation preparation and Sampling
		-	Test Item Administration
		-	Clinical Signs Observations/ Functional Observation Battery Test
		-	Blood Collection
		-	Urine Collection
		-	TK Analysis
			Formulation Analysis
			Necropsy
2	Terminal/ Completion	-	Histopathology
		-	Clinical Pathology
		-	Microscopy

In a GLP study, the In-Life phase is also commonly referred to as the 'In-process phase'. An in-life audit generally includes several routine procedures, for example, formulation preparation, test item administration, clinical signs observation, and animal weight and feed measurement. However some studies may call for sophisticated tests, for example, Electrocardiograph.

The number of critical phases varies depending on the length and nature of the study. For example, in a study with a single dose administration, the administration of test item is highly important and should be identified as a critical phase for inspection. However, in long term studies with multiple dose administration, each occasion of dose administration would not warrant to be identified as a critical phase.

It's a good practice to define the minimum number of in-life inspections for each type of study. This will help to standardize procedures across test facility and will reduce QA personnel to personnel variation.

Additionally, verification of critical equipment intended to be used in the study is recommended. QAU shall assure that all data points and observations are accounted for and any error is pointed out immediately to Study Director for appropriate corrective action. Verify deviations from study plan and applicable SOPs to be documented and communicated.

C. Study Report Audit

The data generated in a study are intended for inclusion in submissions to regulatory agencies in support of Investigational New Drug (IND) or Investigational Medicinal Product Application (IMPD) applications and/or product licensure. QAU shall assure the raw data and report accurately describes the methods and procedures followed, report is internally consistent and reflects the raw data [1].

QAU auditors shall ensure report is internally consistent which means raw data to compiled data, compiled to summarized data and statistical report and interpretations are consistent.

It should be emphasized that in addition to understanding of GLP guidelines, the QAU auditors shall have a thorough understanding of the science underlying each study in order to be effective.

Depending on the type and nature of the study QA auditors shall emphasize on certain data points during the report audit, which have a critical impact on the study outcome. Listed below are some of the examples which can be referred [4].

1) Qualifications/training of the technical staff performing critical data gathering.
2) Criteria for a valid test (i.e., positive and solvent controls within the historical ranges stated in the study plan/SOPs).
3) Correct temperature ranges for the incubators, refrigerators, or freezers used in the study.
4) Changes in the study methods not addressed in study plan.
5) Changing the system of randomizing of the animals after start of study.
6) Correct mathematics in the dose preparation calculations.
7) Using out of range formulations to dose the test systems without proper documentation of the deviation and action taken.
8) Proper documentation of all test item usage, including multiple repeat experiments (especially in genotoxicity studies).
9) Continuing the experiment in spite of a noticed mix-up between the test systems or test item administration.
10) Excessive mortality without proper documentation leaving insufficient number of animals to draw a valid conclusion of study results.
11) Reporting clinical signs of moribund sacrificed or accidentally killed animals after the incident.
12) Fluctuations or outliers in the body weight data.
13) Gaps in the data trail or missing a study document or data entries for a significant interval.
14) Proper adherence to the study plan in reference to cell exposure and incubation times – genotoxicity studies.
15) Presence of drug in control samples during toxicokinetic investigations.

QAU review large portions of the data in a relatively short period of time. QA audit reports shall clearly describe the actual data points considered for audit, sample size and method of sampling. QAU auditors shall also use historical understandings from previous studies while considering the sample size to be determined for audit.

D. QA Statement

QA statement should be a part of each final report signed and dated by an authorized QA representative. The statement should clearly indicate the types of inspections carried out and their corresponding dates. It must have the dates at which inspection reports have been sent to Test Facility Management (TFM) and Study Director. In case of multi-site studies, in addition to the above dates at which inspection reports have been sent to the Test Site Management (TSM) and Principal Investigator and Lead QA also needs to be captured. QA statement should also state exceptions if any.

III. CONTINUOUS IMPROVEMENT

Analysing and trending patterns of noncompliance is a

key approach to maintain continuous improvement of quality systems. Plan-Do-Check-Act' (PDCA) quality cycle used by Deming can be used to attain conformance standards. This approach facilitates (1) identification of the deficiencies (2) investigation of the root causes of noncompliance; and (3) corrective and preventive action plans and verification of CAPA.

IV. CONCLUSION

With changing regulatory scenario; management and QAU auditors shall be well trained to adapt to new advances in science and use of technology from the days of initial implementation. As organization expands its foothold it also tends to be a difficult time to revisit established procedures and policies. It is at that gesture QA audits shall serve as an essential tool to trend and analyse non-compliances with changing regulatory requirements. As an organization matures GLP principles shall be incorporated into an organization's quality systems to help a company 'live GLP' rather than just 'comply with GLP'.

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Trade News

Walmart Pledges $25M to Food Safety Research in China

Walmart Stores Inc., along with the Walmart Foundation, will invest $25 million to aid with food safety research in China. The retailer is placing more focus on this market to combat recent challenges brought about by various food safety scandals, the prominence of online shopping, and unfamiliarity with what Chinese consumers want.

The investment will be spread over 5 years and will support food safety research in the areas of applied science, education and communications.

"By bringing together the best food safety thinkers from across the food ecosystem, from farmers to suppliers, retailers to policy regulators, we'll accelerate food safety awareness and help make Chinese families safer and healthier," says Walmart CEO Doug McMillon.

Walmart made the announcement at a briefing held in Beijing where the company also launched the Walmart Food Safety Collaboration Center, a hub aimed at utilizing both local and international food safety research. Specifically, the center researches foodborne illness and new solutions for China's food supply chain.

Courtesy: Food Safety Magazine

Endocrine Disruptors Cost U.S. More Than $340 Billion in Health and Other Costs

Exposure to endocrine-disrupting chemicals (EDC)—environmental contaminants that interfere with hormonal systems, including reproduction—cost the U.S. up to $340 billion a year, nearly twice the cost in the European Union, according to a study published in TheLancet Diabetes and Endocrinology.

EDCs include industrial solvents or lubricants and their byproducts (polychlorinated biphenyls, polybrominated biphenyls [PBDE], and dioxins), plastics (bisphenol A), plasticizers (phthalates), pesticides (methoxychlor, chlorpyrifos, dichlorodiphenyltrichloroethane), and pharmaceutical agents (diethylstilbestrol).

Studies find a plethora of adverse effects from exposure to these chemicals, including prostate and breast cancer, infertility, male and female reproductive dysfunction, birth defects, obesity, diabetes, cardiopulmonary disease, and neurobehavioral and learning dysfunctions such as autism.

Researchers from New York University School of Medicine reviewed blood sample and urine analyses from the 2007-2008 National Health and Nutrition Examination Survey (NHANES). They then evaluated the economic impact of 15 exposure-response relations between seven chemicals or combinations and 11 disorders, including lost IQ points leading to intellectual disability, childhood and adult obesity, adult diabetes, testicular cancer, cryptorchidism, male factor infertility, attention deficit hyperactivity disorder (ADHD), autism, fibroids, endometriosis, and early cardiovascular mortality due to reduced testosterone.

They found median annual costs of $340 billion in medical and lost wages related to EDC exposure. This represents 2.3% of the 2010 gross domestic product (GDP). The total costs in Europe, which has far stricter policies on the use of such chemicals, was $217 billion, or 1.28% of the GDP.

The majority of the costs ($266 billion) stemmed from intellectual disability related to the flame retardant PDBE, which is applied to furniture to make it less flammable. It was responsible for 43,000 cases of intellectual disability and 11 million lost IQ points. The chemical has been banned in Europe since 2006, where PDBE-related costs were only $12.6 billion. This chemical also is banned in California and is being voluntarily phased out throughout the industry.

Di-2-ethylhexphthalate, which is commonly added to plastics to make them more flexible, was responsible for 86,000 cases of endometriosis at a cost of $47 billion, while organophosphate pesticides, which have been restricted in the U.S. since 1996 but never banned in Europe, were associated with 1.8 million lost IQ points and 7,500 cases of intellectual disability in the U.S. at an estimated cost of $44.7 billion.

In Europe, where these pesticides are not strictly regulated, organophosphates are linked to 13 million lost IQ points and 59,300 cases of intellectual disability each year, costing a projected $194 billion. Other key findings include 243,900 cases of adult diabetes resulting from exposure to dichlorodiphenyltrichloroethane; 240,100

cases of male infertility requiring assisted reproductive technology resulting from exposure to benzylphthalates and butylphthalates; and 10,700 early deaths related to low testosterone as a result of phthalates.

There is currently no requirement in the U.S. that chemicals be studied for endocrine effects before their widespread use. However, the Environmental Protection Agency (EPA) created the Endocrine Disruptor Screening Program to check for EDCs. To date, however, the agency has only screened 52 chemicals, with the bulk of the data based on animal studies.

Efforts to accelerate screening with EPA's ToxCast and Tox 21 High Throughput Screening programs have been stymied by flaws in the ability of ToxCast to detect synthetic chemical obesogens. Plus, it is unclear which chemicals fall into "high priority" and "low priority" groups for testing before approval.

Given the known transgenerational effects of EDCs, the study authors warned, "Continuing not to regulate EDCs adequately could have consequences for subsequent generations of U.S. children."

The study, wrote Michele A La Merrill of the Department of Environmental Toxicology and Comprehensive Cancer Center at the University of California, Davis in an accompanying editorial, "provides a lesson on the lasting economic effects of harmful chemicals: whether banned long term, currently restricted, or being voluntarily phased out, the precautionary principle of proving chemicals are safe rather than proving their harm might be more financially beneficial."

Courtesy: Clinical Laboratory News

BGAPMEA testing lab now open

The much-awaited testing lab of the Bangladesh Garments Accessories & Packaging Manufacturers & Exporters Association (BGAPMEA) was recently inaugurated by Senior Industry Secretary of Bangladesh, Md. Mosharraf Hossain Bhuiyan, who underlined that the newly-launched testing lab will help improve product quality and attract global buyers.

Located in Tongi Industrial Area, the BGAPMEA testing lab built under the Integrated Support to Poverty and Inequality Reduction through Enterprise Development (INSPIRED) project funded by the European Union (EU) and the Ministry of Industry Bangladesh, is established to provide internationally acceptable testing facilities for various types of RMG accessories and products to ensure quality as per the requirement of the global buyers.

"Bangladesh is the second largest exporter of RMG products in the globe, and since the country is entering into higher end products, the laboratory will help improve product quality as per the demands of global buyers," reportedly said Mosharraf, while calling upon the EU to provide more financial and technical support for the sector people so that they can produce best quality accessories products.

Speaking on the occasion, BGAPMEA President Abdul Kader Khan said, "For the first time in Bangladesh, with the help of EU and Industry Ministry, BGAPMEA has set-up the lab which will help attract buyers through fulfilment of their requirement," adding, "We have the testing lab to help the sector people contribute more as it would draw buyers to source accessories from Bangladesh due to its quality."

The BGAPMEA President also reportedly called upon the Government to provide cash incentives against the deemed export of accessories to make the sector self-reliant.

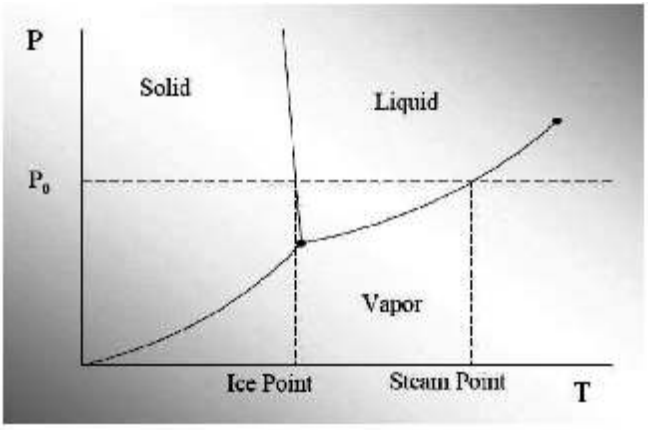
Courtesy: news.apparelresources.com

Triple Point of Water Cell

Introduction: The triple point of water is the most important defining thermometric fixed point used in the calibration of thermometers to the International Temperature Scale of 1990 (ITS-90). The triple point of water is state where 3-phase equilibrium between solid, liquid and vapor phases, it is assigned value on ITS-90 Scales is 273.16 K (0.01 °C). The triple point of water is one of the most accurately realizable of the defining fixed points. The triple point of water temperature can be realized with an accuracy of +0.0 °C, -0.00015 °C. The triple point of water is the temperature to which the resistance-ratios (W = R(t2)/R(t1)) given in Standard Platinum Resistance Thermometer calibrations are referred. In the ITS- 90, t1 is 0.01 ° C. The triple point of water provides a useful check point in verifying the condition of resistance thermometers. Water Triple Point cells from Tempsens Instrument are filled with high purity water. They are maintenance free and mainly used for calibration of platinum resistance thermometer.

International Temperature Scale 1990 (ITS-90): It is the current definition of temperature. A set of defined temperature point and equations is suggested by ITS-90. Those points include freezing point of tin, zinc and aluminium and Triple point of water and mercury etc. Temperature points of ITS-90 when measured with platinum resistance thermometry have range from -189 to -961.78°C. Triple point of water occurs at 0.01°C and this makes it a important temperature point because it is common to ITS-90 and Kelvin temperature scale.

Triple Point of Water: Water triple point is a state of water at which water exists in three states viz. solid, liquid and gas. For pure water this point occurs at 0.010°C but a small fraction of impurity can change the triple point of water significantly. The triple point of water provides a useful check point in verifying the condition of resistance thermometers. A measurement at the triple point of water made immediately upon the thermometer's return from calibration will reveal a shift which has occurred in transportation. Valuable history of the thermometer's stability is obtained if a record of the measurement results is placed on a control chart each time the thermometer is measured at the triple point of water.



Primary Calibration: It is a kind of calibration in which defined temperature points are used as a reference in place of a reference thermometer as in case of secondary calibration. Primary calibration is used where very high accuracy and uncertainty in calibration is required. All the SPRT are also calibrated with primary calibration and then they serve as a secondary reference thermometer.

Tempsens TPW cell: Being the key player in thermometry industry, Tempsens is 1st in India to launch water triple point cells at very reasonable price. Tempsens has made two types of cell one is FP-TPW-M & FP-TPW-B.

Key features of these cells are:

- High accuracy
- Low Cost
- 10 times better Uncertainty
- High reproducibility

Specifications:

	FP-TPW-M	FP-TPW-B
Uncertainty	3mK	2mK
Reproducibility	<1mK	<1mK
Dimensions	50 mm OD 12 mm ID 450 mm Long	32 mm OD 8 mm ID 180 mm Long
Material	Borosilicate Glass	Borosilicate Glass
Immersion Depth	118 mm	265 mm
Traceability	Conformity Certificate	

Maintenance Apparatus :

Tempsens made maintenance liquid bath is best fitted for TPW cells. They are carefully designed to give the required stability and uniformity and provide sufficient immersion depth for TPW cells. Tempsens made Liquid Bath provide 90mm x 105mm opening and up to 415 mm of immersion depth as stated by ITS-90.

Specification:

Specification:

Apparatus name	CalSYS -20/50
Calibration Vol.	90 x 105 x 415 mm
Temp Range	-20 to 50°C
Stability	±0.05°C
Working Fluid	Methanol

Realization procedure:

Following steps are to be followed when realizing Tempsens TPW cells:

1. Clean the TPW Cell with Isopropyl Alcohol/Methanol/Ethyl Alcohol.
2. Fill the reentrant well with Methanol for better thermal contact.
3. Insert the TPW Cell in the Maintenance Apparatus
4. Clean the UUC (Unit Under Calibration) with Isopropyl alcohol/Methanol/Ethyl Alcohol so that it should not contaminate the TPW Cell. .
6. Set the Maintenance Apparatus to -4.7 Deg C
7. After getting the Set point stable, take out the cell and shake it.
8. Shaking the cell will result the formation of Ice inside the TPW Cell.
9. Insert the quartz/metal rod in the reentrant well and immediately remove it.

   The ice mantle will now be free to revolve close to the reentrant well.

   If it is revolving, it is interpreted that correct plateau is made otherwise step 1 to 9 is to be repeated after setting the Maintenance Apparatus in the melt mode and stabilizing it around 5 Deg C.
10. If the ice mantle is revolving correctly immediately insert the TPW Cell inside the Maintenance Apparatus and set the Maintenance Apparatus to 0.01 Deg C.
11. Wait till the Maintenance Apparatus Display stabilizes on 0.01 Deg C.
12. Insert the UUC in the reentrant well of the TPW Cell.
13. Wait for at least 30 minutes to get the stabilized UUC readings.
14. After 30 minutes/or stabilization measurements can be started.
15. The resistance of the UUC in the readout is to be recorded for at least 1 hour in 5 min. interval.

Mean value of recorded resistance of this will be RTPW.

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ASSOCIATION OF INDIAN LABORATORIES

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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

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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 :.....

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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.

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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.

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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:

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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:

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	(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:
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IFFCO Ckowk, M. G. Road, Gurgaon-122002, Haryana, INDIA
Phone : +91-124-4034205
Telefax : +91-124-4036038
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Payment is to be made in advance by crossed cheque or demand draft in favour of "Association of Indian Laboratories" payable at Faridabad or
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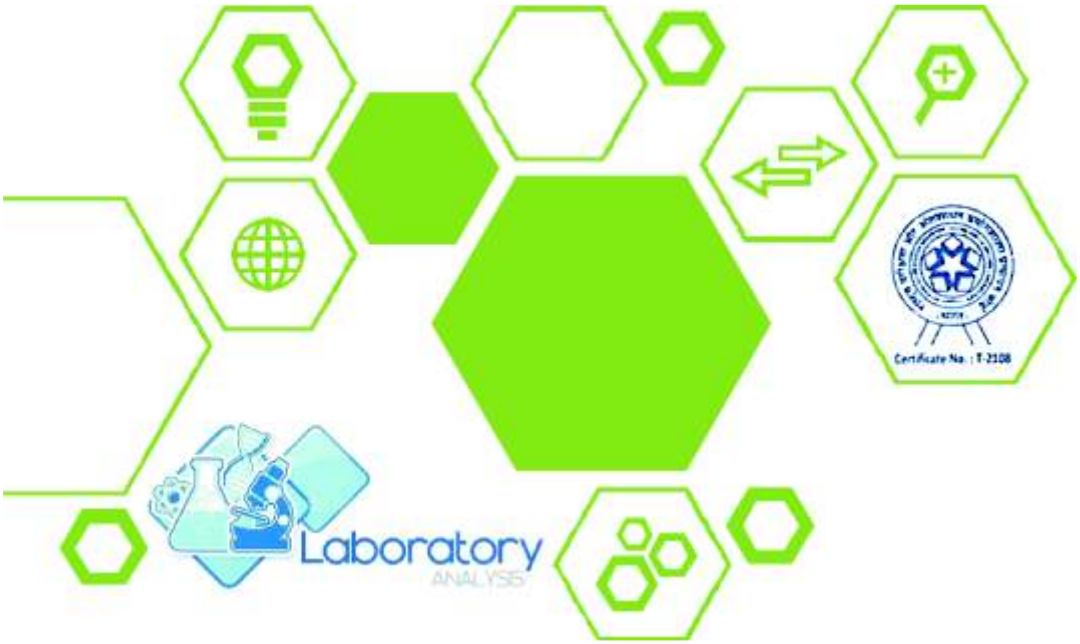
The quarterly periodical is published by Mr. A. K. Nehra, on behalf of Association of Indian Laboratories, B-203, Vigyan Vihar, GH-19, Sector 56, Gurgaon - 122011, Haryana India and printed by him at SANSOM ENTERPRISES, 194, Bhim Nagar, Gurgaon (9810262689) (sansom31@gmail.com)
Editor - C.S. Joshi

(for circulation among AOIL members only)



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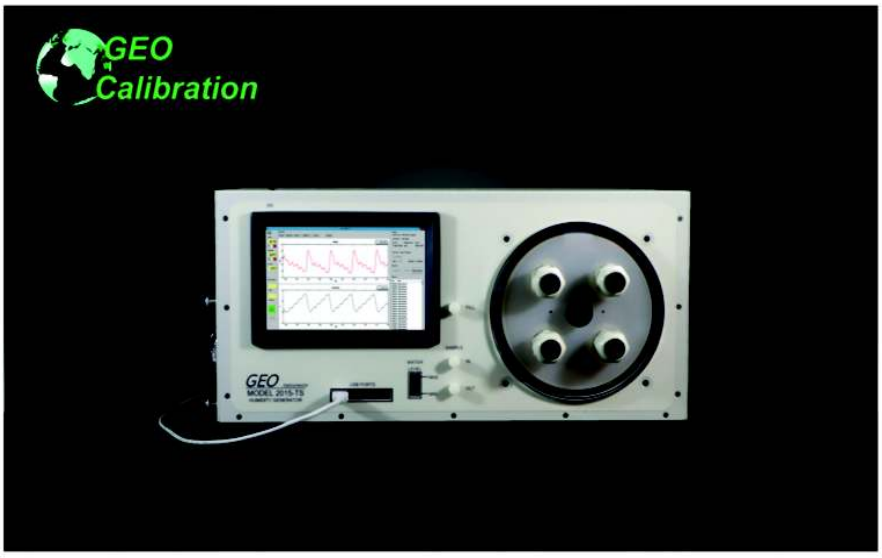

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