You've Found The Cure For Cancer… But Can't Reproduce Your Results! Could Your Test Equipment Be The Weakest Link?

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ABSTRACT

To paraphrase from a compliance guide covering Good Manufacturing Practices (GMP): "*Manufacturers are responsible for ensuring the establishment of routine calibration on their test equipment so it will be suitable for its intended use*". The core requirements for establishing and maintaining an in-house metrology department can be found in various regulations and recommended practice guidelines. This paper explains how the Metrology Department at Promega Corporation meets all these requirements. Topics covered include identifying test equipment, writing procedures, training technicians, recording data, traceability of measurement and standards, uncertainty budgets, and scheduling practices. Also covered are some valuable lessons learned that might help you establish, improve, or maintain a metrology program that instills confidence in your measurements, and test equipment.

1 INTRODUCTION

1.1 Most in the Metrology community are familiar with calibration laboratories, and how they function and operate. What about companies that want to meet Good Manufacturing Practices (GMP) or the International Organization for Standardization (ISO) requirements, manufacture products worldwide, or are trying to find the cure for cancer? How can they guarantee their products and/or results are reproducible, at home or abroad, without sending all their test equipment off-site for calibration? Not only is this true for GMP, but also ISO, and any manufacturer or research facility requiring reproducible results or products.

1.2 Let's assume your R&D section thinks they have discovered the cure for cancer; but can only replicate their findings if they use one "special" set of pipettes. Or a research scientist believes she has found the answer to Alzheimer's disease, but gets various results depending on which spectrophotometer she uses. How about a problem your production facility has with cross contamination, unless they use the same autoclave each time for sterilization, holding up the production line, and leaving three other autoclaves idol in the process. Or even the possibility that foreign made parts won't align with American made parts on the assembly line, even though all are supposed to be made to the same tight specifications. Could the lack of calibrated test equipment possibly be the missing or weakest link in each scenario? Or worse yet, the use of improperly calibrated test equipment might be magnifying the problem, or masking the solution. A reputable metrology program that meets established guidelines could be the answer to some or all of these problems.

1.3 By incorporating a metrology program that encompasses a quality system used by trained technicians and supervisors, which follows established metrology principles, you will greatly reduce your risk, lower your overall cost in the calibration and maintenance of your test equipment, and be able to get accurate, repeatable, and traceable measurements anywhere in the world. It takes dedicated people, with the proper training, using traceable equipment, and a quality system that pays more than just lip service to its guidelines. All of these principles are tried and true, have been in use for decades, and allow companies, both large and small, to manufacture products all over the world, meeting the same specifications and achieving high quality, no matter their location, climate, or the nationality of the workforce.

1.4 Allow me to explain what I feel are the main differences between a calibration laboratory (commercial or private) and a Metrology Department. Most calibration laboratories are self-contained, located in their own facility, areas, or set of rooms. The customer usually delivers their test equipment to the scheduler or the cal lab's contact point. And the average calibration technician never sees or interacts with the equipment user/owner. In the Metrology Departments that I am familiar with, the vast majority of calibrations occur in the room, lab, or production area where the test equipment is located. Going "on-site" could mean stepping next door, or having to travel to another facility; taking your standards, calibration procedures, forms, and labels with you. Here at Promega, we are on a first name basis with each of our customers, and have a good idea how each piece of equipment is used on a daily basis. Each calibration technician is trained to do their own scheduling, using our software program, and is responsible for all the test equipment located in the building where they are assigned. This not only gives them a well-rounded background in the calibration and repair of a wide variety of equipment, but also builds self-confidence, initiative, and a pro-active attitude in addressing customer's problems and presenting solutions.

1.5 The basic premise and foundation of a good quality system is to "Say what you do, do what you say, record what you did, check the results, and act on the difference". Simply stated: "***Say what you do***": write down in detail how to perform every job (have calibration procedures); "***Do what you say***": following those procedures every time you calibrate your test equipment; "***Record what you did***": accurately recording the results of your measurements and adjustments; "***Check the results***": ensuring the equipment meets all your specified tolerances; and finally, "***Act on the difference***": if the instrument is out of tolerance, you must inform the user because they may have to re-evaluate manufactured goods, change a process, or recall a product. This concept is not new. It has been around as long as companies have wanted to produce a quality product, no matter the location of the manufacturing facility, or skill level of the workers…follow established instructions, record the findings, and act on the results.

1.6 You should establish a quality management system to ensure that all operations throughout the metrology department occur in a stable manner. The effective operation of such a system will result in stable processes and, therefore, in a consistent output from those processes. Once stability and consistency are achieved, it is possible to initiate improvements. Technicians must follow the calibration procedures, collect the data, as it is found, and document the results accurately. Only then can trends be evaluated, intervals increased or decreased, and improvements to your processes and/or procedures implemented.

1.7 According to the small entity compliance guide, under calibration requirements: *The Quality System regulation requires in section 820.72(b) that equipment be calibrated according to written procedures that include specific directions and limits for accuracy and precision. GMP calibration requirements are:*

- *Routine calibration according to written procedures;*
- *Documentation of the calibration of each piece of equipment requiring calibration;*
- *Specification of accuracy and precision limits;*
- *Training of calibration personnel;*
- *Use of standards traceable to the National Institute of Standards and Technology (NIST), other recognizable standards, or when necessary, in-house standards; and*
- *Provisions for remedial action to evaluate whether there was any adverse effect on the device's quality.* [1]

1.8 Each of the areas identified above will be discussed in detail in section 2 through section 8. Section 9 contains some "lessons learned" from an ISO 9001 compliant metrology program that has been in place for five years. A short summary can be found in section 10.

1.9 Promega Corporation is a worldwide leader in applying biochemistry and molecular biology to the development of innovative, high-value products for the life sciences. The Metrology Department at Promega has a manager, an electronics engineer/repair technician, and two calibration technicians. We support 6500+ items, with more than 3700 items requiring calibration and/or preventive maintenance inspections. We have had no items overdue calibration since February 1999. The mention of any particular company's product or service in this paper does not imply an endorsement by Promega Corporation, or any of its employees.

2 METROLOGY MANAGEMENT

2.1 *Managers and administrators should understand the scope, significance, and complexity of a metrology program in order to effectively administer it. The selection and training of competent calibration personnel is an important consideration in establishing an effective metrology program. Personnel involved in calibration should ideally possess the following qualities:*

- *Technical education and experience in the area of job assignment;*
- *Basic knowledge of metrology and calibration concepts;*
- *An understanding of basic principles of measurement disciplines, data processing steps, and acceptance requirements;*
- *Knowledge of the overall calibration program;*
- *Ability to follow instructions regarding the maintenance and use of measurement equipment and standards; and*
- *Mental attitude which results in safe, careful, and exacting execution of their duties.* [1]

2.2 Training new calibration and/or repair technicians can be a daunting task. Hiring qualified, trained, and experienced personnel can be difficult, depending on the skill levels needed, geographical location of your facility, or economic status of your location and company. This should not keep you from having a training program in place. At Promega, we list all the required training, and update according to the changing environment of test equipment we

support. Integrity, traceability, documentation, computer skills, and a sense of humor are the foundation for our training program. No matter what new equipment is purchased, or old equipment repaired and placed back in service, the above disciplines have to be understood and met by each employee in the department.

2.3 I wrote the following in a paper published in *Cal Lab*: "Allow me to paraphrase RP-6 [2], paragraph 5.12.: *The selection and training of competent calibration personnel is an important consideration in establishing and maintaining an effective metrology program. Calibrations should be performed by personnel having the necessary education, training, and experience. They should have a basic knowledge of metrology and calibration concepts, and the ability to follow instructions.* There are different ways to get proper training and experience; attendance at vocation or trade schools, through the military's Precision Measurement Equipment Laboratory (PMEL) school, specialized classes given over a few days such as the Lighthouse Training Group [3] offers, or on-the-job-training under an experienced Metrologist. NCSLI can assist in locating various sources as your needs dictate. The training and knowledge gained by an experienced PMEL technician can be useful in filling these requirements. Most PMEL technicians understand traceability, authoring of calibration procedures, and the set-up and maintenance of an effective scheduling program. This has allowed them to develop the skills and patience to produce a quality product as a matter of course. You could consider this paper a blueprint for setting up a metrology program. Like any well designed program, you need the right person to read and understand those blueprints. You'll need to modify the design to fit the requirements and circumstances of your organization. A good place to start your program might be with an experienced Metrologist, who has a background in PMEL management, scheduling practices, writing procedures, and extensive experience calibrating a variety of test equipment. I'd like to stress one point here…Regardless of the quality of your standards or the best intentions in the world…**if your technicians do not understand *metrology concepts and disciplines*, and do not have the *highest integrity***; your program is doomed to fail! ***Integrity*** is the glue that will hold your program together." [4] This is as true today as it was when the Royal Egyptian Cubit was originally used more than 5000 years ago.

2.4 To help get started on a training program, here are some of the common areas that should be explained to new and, in some cases, experienced calibration technicians. Traceability and documentation are discussed from the start, and repeated often. Since our department is paperless in data collection and storage, competent use of computers, both PC and laptops is essential. Once the ability to properly document, save and store information is shown, we can move on to other topics. The proper use of our management software is critical in their ability to schedule their own workload, see what is coming up, overdue, or needs to be repaired. We use an in-house program that has been tailored for our specific needs. There are numerous off the shelf programs that can be adapted to fit your needs and requirements. As a starting point, LABMATE by Norfox [5], and CALIBRATION MANAGER by Blue Mountain Quality Resources [6] are used throughout the industry, and provide demo software for trial periods. We also explain how and why we sometimes limit the calibration of some equipment. If a particular function on an instrument is not working, but not used by the customer, and that function has no effect on other functions of the test instrument, it might be cost effective to delay or cancel repairing the unit and give it a limited calibration.

2.5 This is when you would use a limited calibration sticker to inform the customer that all functions of the test equipment were not calibrated. If a test instrument requires calibration at specific settings due to the needs of the customer or process, a limited calibration would also be appropriate. There are many other areas that we cover, but most are specific to the type of test equipment used throughout a biotechnology manufacturing company.

2.6 One area that of concern to most, no matter what you manufacture or produce, would be in determining the accuracy of each type of equipment. The main concern here is with instruments that have digital readouts. Keeping in mind that the least significant digit (LSD) can impact your readings and accuracy limits should be addressed when setting tolerances for these types of items. Also, explaining the difference between tolerances that specify percent of reading versus percent full scale can be difficult for new technicians to understand. Using examples of specific test equipment where they can see the difference it makes can help get them off on the right foot.

3 PROCEDURES

3.1 Allow me to give a partial quote form 21CFR820.72 Inspection, measuring and test equipment; "*(a) Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. These activities shall be documented. (b) Calibration procedures shall include specific directions and limits for accuracy and precision. These activities shall be documented. (1) Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. (2) The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented.*" [7] Can you see a trend developing here? Proper documentation is critical, not only to the process, but also for future statistical analysis, review of calibration intervals, and production trends and root cause analysis when problems are identified. By having the proper documentation in place, you do not have to "re-invent the wheel" every time a person in a critical position moves on, retires, or gets hit by a train. Continuity is an important ingredient of everybody's production and manufacturing processes and procedures.

3.2 *A typical equipment calibration procedure includes*:

- *Purpose and scope;*
- *Frequency of calibration;*
- *Equipment and standards required;*
- *Limits for accuracy and precision;*
- *Preliminary examinations and operations;*
- *Calibration process description;*
- *Remedial action for product; and*
- *Documentation requirements*. [1]

3.3 Please refer to ***Example 1*** and ***Example 2*** on the following pages. At Promega, we specify the calibration interval for each particular instrument on the matching calibration worksheet (shown in ***Example 3***). This is where the calibration dates are also recorded, and used in helping the calibration technician fill out the calibration labels.

Title: Balance and Scale Calibration Procedure		Procedure No. SOP169	Rev. No. 03
Submitted by: Anna Terese Public	Date: 2/29/00	Approved by: Ayumi Jane Deaux	

READ THE ENTIRE PROCEDURE BEFORE BEGINNING.

1 PURPOSE

This Standard Operating Procedure (SOP) describes the responsibilities of the Metrology Department as they relate to the calibration of all balances and scales. The intent of this SOP is to give the reader an example of how to format and structure a calibration procedure.

2 SCOPE

This SOP applies to all balances and scales that impact the quality of the goods supplied by Acme Widget Corporation, Eatmorecheese, Wisconsin.

3 RESPONSIBILITIES

3.1 It is the responsibility of all metrology technicians who calibrate balances and scales to comply with this SOP.

3.2 The person responsible for the repair and calibration of the balance or scale will wear rubber gloves and eye protection. The balance or scale must be cleaned and/or decontaminated by the user before work can be accomplished.

3.3 A calibration interval of 12 months will be used for all balances and scales, unless otherwise stated.

4 DEFINITIONS

4.1 **NIST** National Institute of Standards and Technology

4.2 **TI** Test Instrument.

TEST INSTRUMENT SPECIFICATIONS

Manuf.	P/N	Usable Range	Accuracy
Allied	7206A	500 mg ~ 500 g	± 30 mg (500 mg ~ 30 g) > 30 g ± 0.1% of Rdg
Denver	400	500 mg ~ 400 g	± 20 mg (500 mg ~ 20 g) > 20 g ± 0.1% of Rdg
Ohaus	V02130	50 mg ~ 210 g	± 3 mg (50 mg ~ 3 g) > 3 g ± 0.1% of Rdg

EQUIPMENT REQUIREMENTS (STANDARDS)

Weight Size	Accuracy (mg)	Class
25 Kilograms	± 2.5 grams	F
5 Kilograms	± 12.0	1
50 milligrams	± 0.01	1
1 milligrams	± 0.01	1

Example 1. Calibration procedure requirements.

5 PROCEDURE

5.1 General inspection

5.1.1 This gives the reader an idea of numbering and formatting of these procedures.

5.2 Leveling the TI

5.2.1 Be as specific as possible in your instructions.

5.3 Calibrating the "edges" of the weighing pan

5.3.1 Following the example in Figure 1, place a weight equal to approximately 1/2 the capacity of the TI, on "edge" 1 (place the ***single*** weight 1/2 the distance between the pan center and the usable edge). Record the reading on the calibration worksheet.

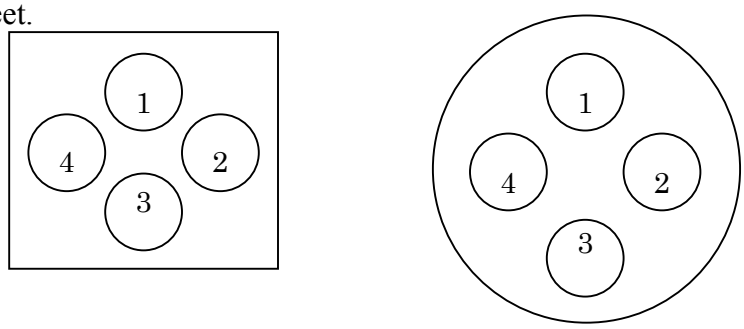

Figure 1

5.4 Calibrating the TI

5.4.1 Tare or zero the TI.

6 RELATED PROCEDURES

7 FORMS AND RECORDS

8 DOCUMENT HISTORY

Rev. #	Change Summary
00	New document
01	Added "edge" calibration.
02	Changed accuracies to be ± 0.1% of Reading, and instituted usable range at low and high end of all balances.

DISCONNECT AND SECURE ALL TEST EQUIPMENT

TEST INSTRUMENT CALIBRATION POINTS

Manufacturer	Part Number	Calibration Test Points in Grams
Allied	7206A	.5, 1, 50, 100, 200, 500
Denver/Fisher	400	.5, 10, 50, 100, 200, 400
Ohaus	V02130	.05, .5, 5, 10, 100, 210

Example 2. Calibration procedure requirements.

3.4 We've developed an *Alert/Action* process for equipment that is found out of tolerance. Under this system, whenever test equipment is found out of tolerance by up to twice its specification, we call it an *Alert*. If it is out of tolerance by more than twice its specification, it falls into the *Action* category. Your needs and processes will determine where you draw the line between Alert and Action. We inform the equipment user of all the data collected, and if applicable, any history we have on the item. It is their responsibility to determine if the equipment had an affect on product or if a recall is needed. We aggressively track all our Alert/Action items. They have proven to be a good source of information for early detection of items that need their intervals changed, specifications reexamined, or combinations of both, but this must be done judiciously.

4 CALIBRATION RECORDS

4.1 *Calibration of each piece of equipment shall be documented to include:*

- *Equipment identification;*
- *The calibration date;*
- *The calibrator; and*
- *The date the next calibration is due.* [1]

4.2 An important part of your system will be your records. Whether you generate hard copy or electronic records, they need to be accurate, controlled and uniform. You'll also need to include the range and tolerances of the instrument being calibrated, identification of the standards used during the calibration, identification of the procedure used to perform the calibration, what your standard(s) read, and the "As Found" data of the test instrument being calibrated, and "As Left" if the unit was adjusted and/or repaired. We place all of the required information on the calibration label, in the calibration worksheet that is saved and stored in a secure location, and also in our Metrology Automated Management System (MAMS). When we are audited, we can show our paper trail of traceability through the calibration record and MAMS. Within MAMS, the date due calibration of the standard(s) used at the time the test instrument was calibrated is automatically recorded for future reference. It is also a way for the technician, and the person cosigning their paperwork, to check that the standards were not overdue at the time they were used to calibrate the test instrument (it is assumed that each and every time a standard is used, the calibration label is checked to ensure the standard is not overdue calibration; but the reality is most technicians take it for granted their standards are not overdue – management takes care of that, right?). Example 3 on the next page shows a calibration record used at Promega.

4.3 At Promega, we use a five digit bar code label attached to every piece of test equipment. It is the sole identifier we use on the calibration worksheet, and in MAMS. The part number and serial number were long used as an accurate system for identifying test instruments. We found this to have a couple of problems. The first was most instrument data plates were located on the back or bottom of the equipment. This made it difficult to easily identify the item without moving, lifting, or sliding it around bench tops. Also, many items do not have serial numbers assigned by their manufacturers, and scribing numbers, and making sure you don’t duplicate serial numbers can be time consuming and tedious. If we found an item without a serial number, we assign it the same five digit number we use as the ID number.

Title: Balance and Scale Calibration Worksheet		Procedure No. MCW169	Rev No. 13
Submitted by: Anna Terese Public	Date: 2/29/00	Approved by: Ayumi Jane Deaux	

ID #: _____ P/N: _____

Range/Capacity: _____ Accuracy: ± _____

Last Cal: _____ Today's Date: _____ Date Due Cal.: _____

Room No: _____ User Department: _____

Interval: ☐ 1 month ☐ 6 months ☐ 12 months ☐ 18 months

Edge	Std Weight	TI "As Found" Reading	TI "As Left" Reading
1			
2			
3			
4			
ID No.	**Std Weight**	**TI "As Found" Reading**	**TI "As Left" Reading**

This TI was tested against standard weights traceable to NIST (See the reverse side of this sheet for their accuracy and calibration due dates).

This TI was calibrated in accordance with SOP11C169.

This TI falls within specifications: ☐ Yes
☐ No (If no, an Alert/Action Procedures will be initiated)

Comments: _____

_____

_____

METROLOGIST: _____ Date: _____

MAMS Updated: ☐ Yes ☐ No ☐ N/A Cosigned/Approved By: _____

Example 3. Calibration record requirements.

4.4 We subscribe to the concept of using an actual day of the month when an item goes overdue calibration (as opposed to any time during a specific month). If you use a monthly schedule, an item can be calibrated on 1 February, and be due in March (if it has a 1 month calibration interval). If it is calibrated on 31 March, it has gone 58 days between calibrations. If it is calibrated on 27 February, and again on 3 March, it has met the system's criteria, but only gone 4 days between calibrations. This could be a waste of valuable resources (standards, the technician's time, and data collected on the test instrument). But the biggest draw back under GMP or ISO requirements would be when does the unit actually go out of calibration, or more importantly, when does the user have to stop using it? By having a specific date and time, midnight on the due date, there is never a question in anyone's mind.

5 SCHEDULING EQUIPMENT FOR CALIBRATION

5.1 *Measuring instruments should be calibrated at periodic intervals established on the basis of stability, purpose, and degree of usage of the equipment. A manufacturer should use a suitable method to remind employees that recalibration is due.* [1]

5.2 The use of metrology management software cannot be over emphasized. Without it, you probably will not be able to see what needs to be calibrated, what has gone overdue calibration, and not have the ability to collect data on trends, repairs, or calibration interval adjustments. As mentioned in paragraph 2.4, there are numerous off-the-shelf software packages available. Tailoring them for your individual needs will allow you to gather the required data with just a click of your mouse, or the press of a button. What you do with that data could be a different story.

5.3 When we generate a 30-day schedule, it is sorted by where it is located (facility and room) and type of equipment. Giving the calibration technician a look into the future, and the ability to understand what needs to be accomplished over a given period of time only enhances their productivity. By calibrating "like items", instead of each test instrument as their due date approaches, we can make better use of our resources. With limited standards available, the time to set-up and tear down equipment is critical in the overall picture. By looking at all the items coming due in a specific facility, conscientious time management, coupled with resource allocation, and reduced travel time have kept our overdues at zero, and eliminated the need for additional manpower during times of fiscal restraint and budget crunches. The majority of this came about because we use the tools (management software) that are at our disposal.

5.4 Most manufacturers recommend having their equipment calibrated at one (1) year intervals. In some cases, there are reasonable, historical data to support this time frame. However, in today's high tech world, where safe journeys into space and under the sea happen as every day occurrences; reliable test equipment has become the norm instead of the exception. By collecting data on how often items are found out of tolerance, and by how much, and how often they require unscheduled repair, calibration intervals can be realistically lengthened or shortened, and both time and money saved in the number of calibrations performed in a given year. There's a fine line between being "on the cutting edge" and being "on the ragged edge" when it comes to calibration intervals. Give any changes, especially lengthening of intervals, enough time to collect data to see if you've been a genius, or an idiot.

6 TRACEABILITY OF STANDARDS

6.1 *The QS regulation requires that standards used to calibrate equipment be traceable to the National Institute of Standards and Technology (NIST), or other recognized national or international standards. Traceability also can be achieved through a contract calibration laboratory which in turn uses NIST services.* [1]

6.2 If a company follows the guidance in ANSI/NCSL Z540-1-1994, paragraph 10.2(b) "*The laboratory shall ensure that the calibration uncertainties are sufficiently small so that the adequacy of the measurement is not affected. Well-defined and documented measurement assurance techniques or uncertainty analyses may be used to verify the adequacy of a measurement process. If such techniques or analyses are not used, then* ***the collective uncertainty of the measurement standards shall not exceed 25% of the acceptable tolerance*** *(e.g., manufacturer's specification) for each characteristic of the measuring and test equipment being calibrated or verified*" [8]; they will have traceable measurement. This 25% of the acceptable tolerance is where the 4:1 ratio is derived.

6.3 Here's an example: your standard has an accuracy of 0.25° C; the most accurate item you can calibrate could be no better than 1.0° C, or four times less accurate. You must ensure the combined uncertainty of the standard(s) being used is at least four (4) times more accurate than what is being calibrated. By calibrating test equipment in the environment where it is normally used, you can determine how well it works, and the repeatability of that instrument. This is also where traceability is derived. Traceability is defined as "an unbroken chain of comparisons" back to an international/national standard. During each calibration along that chain, a 4:1 ratio, or uncertainty analysis must be documented. Only then can you show your equipment is traceable back to a specific standard or level of accuracy.

6.4 NIST asserts that "providing support for a claim of traceability of the result of a measurement or value of a standard is the responsibility of the provider of that result or value, whether that provider is NIST or another organization; and that assessing the validity of such a claim is the responsibility of the user of that result or value. NIST also communicates, especially where claims expressing or implying the contrary are made, that NIST does not define, specify, assure, or certify traceability of the results of measurements or values of standards except those that NIST itself provides, either directly or through an official NIST program or collaboration." Service providers are responsible for showing their traceability, no matter to whom it is traceable.

6.5 Your documentation, rather it's your own calibration record, or a calibration certificate from an outside agency, needs to contain certain information. The items unique identification number and owner, when it was last calibrated, and its next due date are a given. There should be a stated uncertainty budget or ratio, and when applicable, a limit on the tolerances and specifications of the instrument that was calibrated. What standards were used to calibrate the instrument should be shown, as well as when those standards were calibrated or are next due calibration. There should be a signature of the person performing the calibration and the date the calibration was completed. As found and as left data should be included, or statements to the effect that adjustments were not made and that the instrument met tolerances as received.

7 CALIBRATION ENVIRONMENT

7.1 *As appropriate, environmental controls should be established and monitored to assure that measuring instruments are calibrated and used in an environment that will not adversely effect the accuracy required. Consideration should be given to the effects of temperature, humidity, vibration, and cleanliness when purchasing, using, calibrating, and storing instruments.* [1]

7.2 When a manufacturer produces test equipment, they specify certain parameters that must be met (e.g., an operating range of -10° C ~ 50° C). Why then does the unit need to be calibrated in an environmentally controlled laboratory when it is not used there? In most cases it doesn't! An environment that controls temperature, humidity, vibration, dust, etc., reduces the uncertainty of measurement, and allows for the calibration of state-of-the-art test equipment to high accuracies that could not be ascertained in an uncontrolled environment. I'm referring to tolerances of 3 parts per million, or ten thousands of an inch, as an example.

7.3 When calibrating in an area other than an environmentally controlled and monitored "calibration laboratory", the calibration environment need be controlled only to the extent required by the most environmentally sensitive measurement performed in the area. You need to consider not only the instrument being calibrated, but also the standards used to perform the calibration. Not all standards are created equal, so it is prudent to check the manufacturer's stated specifications for environmental conditions that the standard can be used in, both temperature and humidity, when applicable.

8 AUDITING OF THE CALIBRATION SYSTEM

8.1 *The calibration program shall be included in the quality system audits required by the QS regulation.* [1]

8.2 Are annual internal audits conducted? Are they documented and distributed to the appropriate personnel and managers? As a minimum, if there is no internal audit function, a self-inspection program could go a long ways in preparing you for audits and inspections. By setting up a self-inspection program, you're showing an effort to find problems and see where your not meeting the quality system you have in place; and demonstrating a desire to continuously improve your program through self initiative, and finding opportunities before there are found by others, makes you proactive instead of reactive to problems and solutions.

8.3 One way to audit yourself is to follow the "Say what you do, do what you say, record what you did, check the results, and act on the difference" theme. Check if you are actually following the procedures, or are they simply there for fluff? Do all your records contain the required information, and do they show a paper trail for traceability purposes? If an item was found to be out of tolerance during calibration, was action taken? Was the customer informed, and do you have data to show that it occurred? The more specific you are, the easier it is to answer your questions. Self-inspections can be an important continuous process improvement, but it takes time, effort, and honesty at all levels.

9 LESSONS LEARNED

9.1 Of all the things **you must remember**: identifying your test equipment, writing procedures, recording data, ensuring traceability of measurements and standards, uncertainty budgets and scheduling practices; here's the one thing **you should never forget**…continually train, train, train! You cannot provide enough training in today's ever evolving world of metrology. While everyone around you is updating their computer systems, going paperless, using automated data processors and purchasing the latest and greatest in new technology; don't forget to provide the critical training on each and every one of these new systems or ideas. Having the latest technology does not mean everyone knows how to use it. Continuous training is the only way to ensure all your technicians are using the standards, systems, and data collection devices you have correctly. And documenting that training is the most reliable form of ensuring every one is singing from the same page, at the same time.

9.2 Telling your customers what is expected of them can solve problems before they get started. During our newcomer orientation briefing that is given to all new scientists, we not only get them started on the right foot with their test equipment, but we start a partnership between them and us in support of Promega's goals through the use of calibrated test equipment. We let them know what they are responsible for:

- Informing Metrology of their requirements and needs;
- Getting the proper training in the correct and safe usage of test equipment;
- Maintaining their test equipment without abusing, contaminating or damaging it under normal operating conditions;
- Using Metrology's work order system for requesting service when equipment is broken, malfunctioning, or in need of calibration.

9.3 The same theory also applies to our Metrology Department staff. TEAM METROLOGY is responsible for:

- Listening to our customers to understand their requirements and needs;
- Translating those requirements to the accuracy and specifications of the test equipment and support services that meet or exceed their quality expectations;
- Delivering test equipment that consistently meets requirements for reliable performance;
- Providing knowledgeable and comprehensive test equipment support;
- Continuously reviewing and improving our services and processes.

9.4 There are many times when you can use your test equipment in a limited capacity. If a particular function on an instrument is not working, but not used by the customer, and that function has no effect on other functions of the test instrument, it might be cost effective to delay or cancel repairing the unit and give it a limited calibration.

9.5 It is important in any quality system to have change control procedures in place, but it is critical in a metrology program. Whenever you make improvements or changes to your calibration procedures and/or calibration records, you must have a system in place to ensure old copies are removed and destroyed, as well as maintaining history in case you need to revert back to the original. You must also make sure everyone in the department is trained on those changes.

9.6 A comprehensive training record will help make sure this occurs. We all know how repetitive and boring it can be to calibrate the same widget 69 times in the same week, while following the same old boring procedure. When someone's life, or the lives of many, or the cure for deadly diseases is on the line, you better be doing it right the first time, and following your procedures is the only way to ensure that is going to happen. And the only way to keep track of your changes and improvements is to document them within your quality system.

10 SUMMARY

10.1 Have you figured out the answers to paragraph 1.2? At Promega, we calibrate all pipettes against traceable standards after performing preventive maintenance inspections and any needed repairs. The result – *all our pipettes are special*! We have more than thirty spectrophotometers, made by seven different manufacturers; each one receives a preventive maintenance inspection, alignment, and calibration at a regular interval. How do we solve the autoclave problem? Simple…we calibrate every one of them with traceable standards to ensure they meet specified tolerances. At Promega we follow an established program, using calibrated test equipment traceable to NIST. By doing so, test equipment will not be the weakest link in quality production.

References

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