Establishing an ISO 17025 Compliant Laboratory at a University

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Abstract

The continuing need for industry to follow and use International Standards Organization (ISO) standards puts pressure on university organizations, which perform laboratory testing for outside organizations, to insure that their results satisfy the required standards of the requesting organizations. The amount of outside testing of many university facilities makes full ISO 17025 certification economically unfeasible; however, such labs can be compliant to this standard thus satisfying those that use the university's laboratory services. In this paper we discuss our experiences in bringing our laboratory up ISO 17025 compliance. The problems, time commitment and personnel requirements as well as the advantages, both internally to the organization and to outside users will be discussed. The contributions of our quality program to students as well as the students' contribution to the quality system are significant and benefit both parties. Finally, the need for continuous work on such a program will be discussed and put into perspective.

Introduction

There is a continuing and accelerating need for industries to demonstrate that their products or services meet a certain minimum standard. To minimize the number of different standards most companies that have standards conform to those of the International Organization for Standardization (ISO). University laboratories are increasingly performing testing for outside companies and as such they are under increasing scrutiny and may be encouraged to obtain ISO certification. In this paper we discuss some of the many aspects of establishing an ISO 17025 compliant laboratory in a university setting, with the goal of providing guidance to other university labs that may need to travel down the same road.

Our laboratory, the Middlefield Research and Testing Laboratory, (MRTL) is located roughly 40 minutes from the Kent Campus within the NEO Beam facility. This facility is a joint venture between The Kent State University and a local plastics company, Mercury Plastics, Inc. NEO Beam has a 150 kW, 5 MeV electron accelerator that is used for production and research. This joint venture gives both parties access to an instruments and a facility that neither could justify individually. This arrangement allows our laboratory to provide basic and applied research to outside companies as well as for university projects. In light of our relationship with a plastic company we focus our external lab work on dosimetry (determining the dose a product absorbs) and the physical, chemical and mechanical properties of polymers and plastics. Internally, we have active research in a number of areas

[1]. The number of scientists and engineers at this facility varies over the year. It swells during the summer when students are present and is smaller during the academic year. Typically we have 5-6 professional scientists during the academic year and of this number, three to four are affiliated with the laboratory on a part time basis. Thus, we are a rather small laboratory and as we will discuss size is a determining factor in a number of our operational decisions.

Why should a university laboratory have a quality system? The establishment of our quality system began when a company asked about our quality system. Our first response was of the nature, "We are competent scientists with advanced degrees from highly ranked programs. We work at a major university using state-of-the-art equipment; of course, we do quality work." From the perspective of the company this answer is of the nature: true, true, true, but irrelevant. They want to know how it can be demonstrated. What is systematically being done that would lead them to accept the statement(s) about the quality of work? If we say the value of a parameter is x±y can they stake their reputation on it? This exchange indicates the major reason for establishing a quality system—customers demand it.

We are certainly not the first university laboratory to establish and implement a quality system, nor is this the first report of such efforts. In 2005 Rodima *et al.* [2] summarized their experience in working under an ISO 17025 quality system at the University of Tartu in Estonia. Their particular laboratory acts as a gateway to other units of the university. They concluded that implementing such a system is possible and that it "gives significant added value to the university" by bringing industry and the university closer together and by introducing students to the real world reality of such issues. Two years later in 2007, Zapata-García *et al.* [3] at the University of Barcelona describe their experience. They observe that it is a difficult task but, it can be accomplished and that the system had a positive impact because it helped put university members in touch with the real world and it also impacted research and academic content. Earlier work by Pritzkow [4] and Halevy [5] discussed the practical benefits and experiences of implementing ISO 17025. This work focused on non-university settings.

Distinguishing features of our laboratory include its size, variable number of personnel and the opportunities and challenges that these bring to establishing an ISO 17025 compliant laboratory. The system that we will discuss in this paper is not our facility's first attempt at establishing a quality system. A few years ago a former quality control manager from a local company who had joined the Kent State University faculty started on such a system. Full implementation of this system never took place as the system was too cumbersome and required too many documents to work smoothly in a laboratory where the quality manager was not present 3 days per week. However, it did help us establish the role of management and the quality manager in quality systems and gave us the impetus for the present system. It also illustrates the important lesson that one needs to have the right-size quality system for the organization.

The major portion of this paper will discuss the specific issues, problems and solutions that we developed as we implemented our quality system. There are many issues and we have grouped them into five general areas: initial questions, problems and issues, early implementation issues, forms, financial aspects, and continuing issues. Our purpose in each

section is to describe issues we encountered, how we solved/avoided the issue, and finally why we opted for the process/answer that we used.

These sections will be followed by a series of conclusions and recommendations. This final section will discuss the benefits and costs of such implementation, the advantages to students and faculty, the continuing nature of such implementation and our view looking back after implementing our quality system.

Issues, problems and solutions

A. Initial questions

In this section we discuss some of the questions we encountered as we began to develop our quality system. These basic questions need to be answered before the initial development of the quality system takes place. In our case some of these issues were resolved in real time and there is no question that this caused bruised egos and lengthened the time needed to develop and initially start using our system.

The first step is to determine if a quality system is required by your customers. Here it is important to realize that there are two issues: Does the company need data from a laboratory with a quality system? And, are they willing to pay extra for it? There is no question that implementing and maintaining a quality system is costly to the testing laboratory. This cost is both a direct cost and in terms of the non-recoverable time people put into developing, testing and checking the system.

A particularly important question in a university laboratory is does the research at the lab require a quality system or some part of it? In most university labs older students teach newer students and there is little thought of what might get lost in translation until there is a problem. Is this the best way to teach students in the laboratory, or should there be instruction and standard operating procedures (SOPs) so the new student gets the official lab technique for performing an operation? Our experience is that SOPs greatly shortens the student and new faculty learning curves on many instruments. The related issue of calibration of instruments comes into play here. Many university research labs do next to no calibration of instruments, even those that require no more than making measurements on a reference sample.

This last question leads to related question; how do you handle internal research and external testing in the same laboratory? If these operations use different equipment what should the policy be? The easiest and most costly solution is to have all the equipment calibrated at periodic intervals. This is well beyond the financial means of a small university laboratory. In fact, since most university equipment is purchased without a service contract this either needs to be done internally or by an expensive technician from the manufacturer. If performed internally this may also require standards and related supplies. Our approach to this is to keep equipment that is used for outside testing in calibration through internal and external calibration. The equipment that is used only for internal research is designated as "for reference only" indicating that it has not been calibrated recently. For reference only

equipment includes most of our electronic meters, lock-in amplifiers and similar equipment. Those instruments used for dosimetry and external polymer testing are calibrated at regular intervals. Calibration will be discussed in greater detail later as a continuing issue.

Once the lab has decided that it wants to be ISO 17025 compliant or certified another issue immediately develops. Since our laboratory is small everyone was asked to be part of the initial development. We found that it was extremely helpful to bring in an outside facilitator with quality systems background (V. Fitzsimmons) to help with many of the remaining questions. For example, how large and complex of a system is necessary? The system needs to be simple enough to work yet complete enough to comply with the standard. The system must also accommodate the other hats the quality manager wears in the lab and the day to day time commitment a quality system requires in practice. A good facilitator knows what is necessary and the level of detail that is needed. Once the committee chair/facilitator is chosen the next question is will the lab be certified or only compliant? It is expensive to be certified and it must be renewed periodically. If the customers require it and they provide sufficient income to cover certification then go that route. If that is not the case and the university does not want to fund certification, then compliancy is the best the laboratory can achieve. In our case no customer needed certification and the university did not have the funds so we are compliant to ISO 17025, and ready to become certified if necessary.

Regardless of the result of the central decision of certification the decision to establish a quality system raises another set of issues. The first is who owns the system? In many cases when something is everyone's responsibility it ends up being no ones. To prevent this Fisch assigned K. Hullihen as quality manager, and set up a system where the three coauthors work together with consultation from the rest of the lab's members on various issues of particular interest to the specific lab member. The second question is who controls the system? In the present system the quality manager and lab director work together, with as many decisions as possible made by the quality manager. The system is controlled by the quality manager, but there is managerial oversight. This is in fact how ISO 17025 should work [6].

B. Implementation Issues

Our basic system is available on-line [1]. The initial draft of this system was developed by Fitzsimmons and Fisch and then passed through several rounds of editing and meetings by all lab members. There was consensus on all aspects of this part of the plan. The SOPs were written by the faculty member most familiar with the equipment and edited by Hullihen and Fisch.

This section will discuss issues that occurred after the initial system was in place and when the initial steps of writing, editing and using our SOPs became important. Some of these issues are rather basic such as how is work divided, while others, such as who can perform a test for an outside customer are more complex.

A problem in a large project that has several participants with other commitments is how to divide the work so that the project is completed in a timely manner. We used a three step system with feedback. First a faculty associate who is very familiar with a given

test/equipment was assigned or volunteered to write a first draft of the SOP. The quality manager then forwarded a standard format for the SOPs for the assignee to complete. After the first version of the SOP was written the copy was edited by the quality manager to insure formatting was uniform. The quality manager or another person then ran the procedure exactly as written and noted inconsistencies, missing steps, and similar problems. These problems were resolved by the quality manager and the person who wrote the SOP. The SOP was then forwarded to the lab director for reading and commenting and then sent back to the quality manager. After this edit, the quality manager had the writer check the final version. It was then sent once more to the lab director for final acceptance. In almost all cases a student who was not familiar with the SOP was then asked to verify that the procedures were clear. This division of labor clearly requires significant time commitment on the part of the quality manager, and more reasonable amounts on the writers and the lab director. We had no complaints on this system and edited SOPs generally were returned in fairly short order. The time spent by the faculty associate was especially useful to them because it forced them to look at the process carefully and thus made them more proficient at performing the task and teaching others.

Training is another time issue that can be difficult to include in schedules that are already overfilled. Questions such as, who should train a new person, how many distinct aspects should they be trained on, and even if trained who is qualified to perform a test for customers all needed to be answered [7]. Our small size, limited personnel, and focus on very precise SOPs have allowed us to take a piecemeal approach to the training. If a person needs training on a particular instrument, a faculty associate or the quality manager teaches them during normal operation of the instrument. Since there is little need to train someone in something they do not use, we focus the training on just the processes that a particular person will use. When testing is performed for an outside customer, we allow trained students to perform the test provided they are supervised by senior personnel qualified to run the test. This supervision is close enough to prevent large errors, but sufficiently distant that students learn how to self-check and the other skills that go with being a professional doing quality work.

An important part of ISO 17025 is establishing a policy for estimating the uncertainty of a measurement. This puts us at variance with some of our customers. For example, when we test according to ASTM standards, the standard may specify make two distinct measurements, but the customer wants one measurement and wants to use the second measurement for a different sample. The customer is generally right, so we explain this is not the ASTM standard that we follow, and the best we can do on an uncertainty is the following estimate on a single sample. Other customers find uncertainty clouds rather than clarifies the issue and don't care nor want it. In other cases so long as the value is below a certain value there is no problem. Thus while we can give estimates of uncertainty to our measurements, we have minimal focus on this aspect of the standard. This is part of our still evolving system and as in all compliance to standards ultimately depends on the customer.

C. Forms

It was our experience and also that of another university lab [2] that adapted a quality system that in our first attempts we produced systems that required excess documentation. In practice these systems were too top heavy in administrative details to work well and were then dropped or reworked into more modest systems. This section will discuss the forms and formats that we use in our system. This is certainly not the last word, but rather an example that we hope will be modified and used by others. .

Our system consists of an introductory document that specifies five other documents and then a series of related documents that address specific issues of calibration and related issues. The introductory document is entitled "MRTL Quality Management System" and states:

> "The purpose of the Middlefield Research and Testing Laboratory (MRTL) Quality Management System (QS) is to implement quality management methodology throughout the laboratory and associated processes in order to:
>
> - Plan and perform Laboratory operations in a reliable and effective manner to minimize the impact on the environment, safety, and health of the staff and the public;
> - Standardize processes and support continuous improvement in all aspects of Laboratory operations; and
> - Enable the delivery of products and services that meet customers' requirements and expectations. "

This document goes on to define roles of the individuals involved in the quality system and very briefly describes the five documents that to a large measure, define the fundamentals of our quality system. These are described in Table I below:

Table I. Documents in our Quality System

Document number and title	Purpose
QP 10 Document Control	Describes document control, nomenclature, destroying documents, etc.
QP 20 Review of requests for work	Procedures in checklist form for reviewing requests for work
QP 30 Control of nonconforming testing and calibration at MRTL	Procedures in checklist form for nonconforming measurements and/or calibration
QP 40 Corrective and Preventative Actions	Procedures in checklist form for corrective and preventative actions
QP 50 Document and Record Retention	Procedures in checklist form for retaining and destroying records

QP 10 describes document control, and nomenclature. An important part of this document is the method we developed for labeling documents. In this part of the system we tried to produce the minimum number of different types of documents as necessary. Nevertheless, the shear number rapidly becomes rather large. The letters used to designate a particular

document were chosen because they were appropriate and made sense to our lab. They may not be appropriate to all labs. Moreover, in many cases we separated documents into separate categories that others may want to join. For example, a measurement procedure and a measurement procedure sheet could be combined. We separated them so that when needed only the measurement procedure sheet had to be printed. The measurement procedure could be left adjacent to the instrument at all times so that it could be referred to as necessary. The revision number is in the upper right of the header on all documents. When the revision number is less than one, the document is still under review, these documents may be used for reference only. Table II describes our nomenclature and generally indicates, through its title, the purpose of the document.

Table II: Nomenclature used in our quality system

Prefix	Meaning	Explanation/example
EO#a	**E**quipment **O**perating Procedure	EO006 Equipment operation procedure 6
PR#a	**Pr**eventative Maintenance Procedure	PR006
MP#a	**M**easurement **P**rocedure	MP006
MPS#a	**M**easurement **P**rocedure (check-off and record) **S**heet	MPS006 Note that many measurement procedures have a measurement procedure sheet with the same number and revision number. MP006 uses MPS006 Sheet
CE#a	**C**alibration procedure for **E**quipment	CE006
CS#a	**C**alibration procedure for **S**ystems	
QP#	**Q**uality **P**rocedure	QP10

We have associated with most measurement procedures (MP), or more colloquially SOPs, a measurement procedure sheet (MPS). The MP and the corresponding MPS have the same numbers. The MPS has checkboxes and fill-in spaces with the corresponding procedure step. This provides natural error checking for a person performing a test.

We have two calibration documents. CE documents are for an individual piece of equipment such as a differential scanning calorimeter (DSC) which describes the calibration of that piece of equipment. This generally requires specific procedures and reference standards or instruments. For example, in DSC calibration the melting temperature and transition enthalpy of a standard substance (near room temperature very pure indium) are determined. The instrument is said to be in calibration if the measured transition temperature and enthalpy are within specified deviations from those determined by national standards laboratories. Similarly thermometers may be calibrated by comparing the temperature of the thermometer being calibrated to a calibrated thermometer and adjusting the calibrated thermometer's values so there is minimum deviation from the calibrated thermometer.

CS documents describe dosimetry system calibration procedures. These are necessary in our dosimetry lab where we have several different dosimetry techniques that often require the use of more than one instrument and cross calibration against standards from national / international standards laboratories such as NIST. The ISO/ASTM standards on dosimetry define a dosimetry system as, "A system used for determining absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the systems use [8]." Calibration of a dosimetry system requires (i) irradiation of dosimeters to a number of known, different absorbances over the range of interest/validity. This is done at a standards laboratory. Then (ii), the dosimeters are analyzed using calibrated equipment. Finally, (iii) a "calibration curve" that relates the analytic equipment response to dose is made. This requires both calibrated standards and instruments.

We also separated out equipment operating procedures (EO) from measurement procedures (MP) so that as the tests evolve the basic operation of the instrument does not need to be explained in every procedure. If a person needs to review how to operate an instrument in general or wants to develop a new technique, they refer to the EO document. However, for a particular type of measurement for which we have already established a measurement procedure, they use the MP and MPS corresponding to the desired measurement.

An important feature of most of our documents is that they are in checklist form so that the document serves as both the quality procedure and the checklist for what to do. This double duty use reduces the number of forms, and makes it clear what aspects of the procedures are very important. An example is part of the procedure part of QP 40 shown in Fig. 1. These procedures are as simple as possible within the constraints of ISO 17025, and are written with the size of our laboratory in mind. This is important as larger laboratories may want and need more formal and longer procedures.

MRTL	Program on Electron Beam Technology Middlefield Research and Testing Laboratory **Corrective and Preventive Actions**	Document # QP40	Rev 1.0 August 2006 Page 1 of 1

III. Procedure:

A. Annual Audit

☐ The Quality Manager (QM) is in charge of the annual audit in part to identify situations where preventive and/or corrective action is necessary.

☐ All situations identified in the audit as needing preventive and/or corrective action will be addressed by the QM as discussed in section C below.

B. Discovery of a potential need for action

☐ When an associate identifies potential sources of nonconformities in need of preventive and/or corrective action, he (she) will inform the QM of their observation as soon as possible.

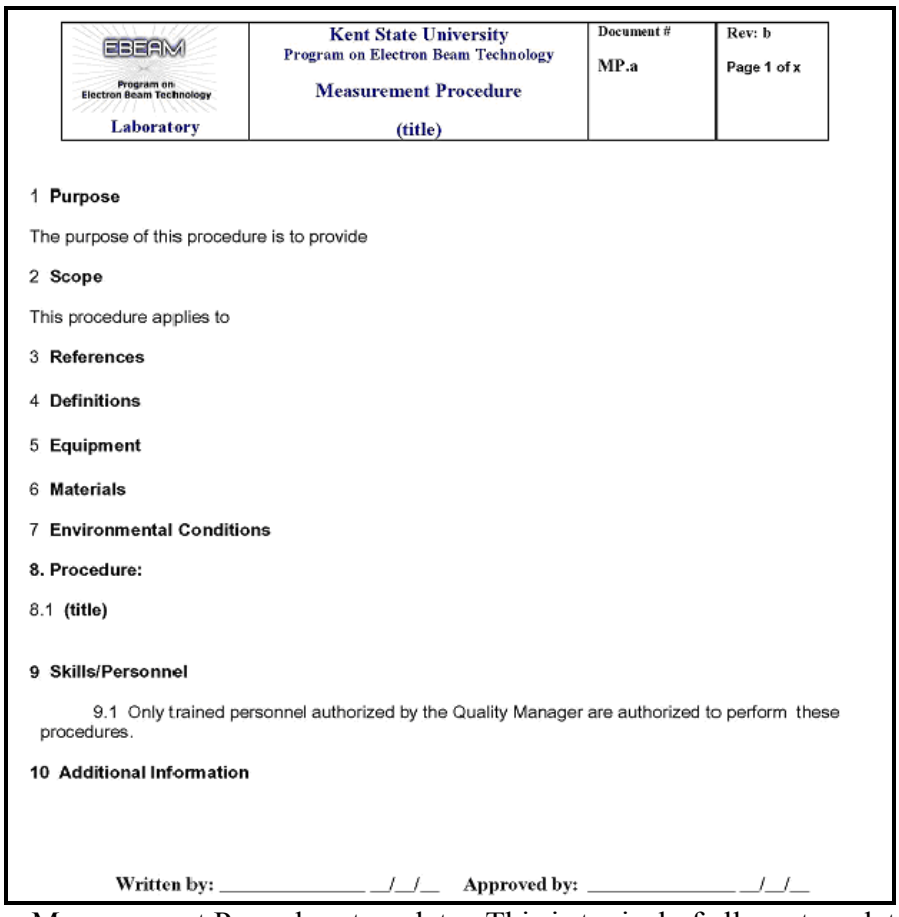
C. Addressing the need for action

Figure 1. Part of QP 40; the use of a check list in a quality procedure

There are a few documents that do not easily fit into this rubric. For example, the work order sheet is a two sided, one page document that includes a checklist to assure that the proper management procedures are followed. Similarly many of our templates have no number. These templates indicate the major headings and information that must be generically provided on forms of a given type. An example is shown in Fig 2, the measurement procedure template. We have item 9 on all relevant documents so that it is clear that one must be trained and qualified by the quality manager to perform a measurement. Item 10 includes calculations, error analysis and other relevant information.

Finally, we have form MPS666 to describe variances from our normal procedures that the customer wants and for which there is an understanding between our laboratory and the customer. For example, the customer that wants only one measurement when two are suggested has explained this to us and we have agreed to just perform the measurement once.

In summary, even a simple system at a small lab has a remarkable amount of documentation; much of it, for example calibration reports are behind the scene. This section has illustrated our approach to keeping this collection as simple as possible. An important technique we found is to use checkboxes in procedures where possible so that a procedure can also serve as the template for what needs to be done.



Program on Electron Beam Technology Laboratory	Kent State University Program on Electron Beam Technology Measurement Procedure (title)	Document # MP.a	Rev: b Page 1 of x

1 **Purpose**

The purpose of this procedure is to provide

2 **Scope**

This procedure applies to

3 **References**

4 **Definitions**

5 **Equipment**

6 **Materials**

7 **Environmental Conditions**

8. Procedure:

8.1 **(title)**

9 Skills/Personnel

9.1 Only trained personnel authorized by the Quality Manager are authorized to perform these procedures.

10 Additional Information

Written by: _____ __/__/__ **Approved by:** _____ __/__/__

Figure 2. The Measurement Procedure template. This is typical of all our templates and is designed for ease of use.

D. A few Financial Aspects

The long term commitment of financial and personnel resources to a quality system is another issue that must be considered. While certification is too expensive to consider for most university organizations, our experience indicates that there is also a heavy financial burden to running a lab that is compliant, but not certified. This section will describe some of the costs associated with our ISO compliant lab. This will not be comprehensive, but should give the reader a sense of the relative expenses.

The first and relatively easy to quantify expense are the costs associated with equipment calibration. These expenses break into three parts: expenses for external calibration, expenses for standards, and time required by lab personnel to calibrate and track calibration of the instruments.

The expense of external calibration is generally unavoidable. Even if one calibrated their own equipment the standards used in the calibration must have known values. An example is the calibration of masses for calibrating balances. Calibrating a balance is not difficult, but requires calibrated masses. These masses need to be recertified at periodic intervals. The issue is how often. Our approach has been to follow the manufacturer's/ supplier's recommendation for yearly time intervals 2-3 times and then examine the calibrated values graphically to search for a systematic variation in the calibrated quantity. If a systematic variation is observed, then we continue to follow the recommendation. In those cases where there is no systematic variation, or small random variation, we then extend the calibration interval. We do not have enough data to judge how long we can extend the interval. However, we anticipate no more than a factor of two to three times the recommendation. Our dosimetry standards need to be verified and calibrated once per year. This area also includes the expense of updating computer software and hardware to take advantage of the newer developments in a particular instrument.

The second area is standards for calibrating equipment. An example of this would be samples to calibrate a differential scanning calorimeter or a thermogravitometric apparatus. These may be calibrated in our lab, but this is often costly. Once more, there is no easy way to avoid these expenses. If you want the equipment calibrated you need standards. One frustration here is that materials from the manufacturer are often much more expensive than those from other suppliers, but those from other suppliers is not certified. Here one has to use experience and knowledge to decide if the extra money is well spent or can the less expensive material be calibrated against the certified material to provide interim calibrations and hence reduce costs.

The final area is personnel. In the very large budget approximation, outside technicians can come in and calibrate equipment. In the real world the lab has to develop the competence to calibrate equipment to the extent possible. This requires time, skill, and training. We have our quality manager, in collaboration with associates doing as much of the calibration as possible. This makes keeping calibration records, and related quality issues all under the prevue of a single person.

The first two parts of equipment calibration costs can be easily quantified by review of budget. In our lab the cost varies from year to year, but averages about $8000/year. The cost of personnel to calibrate equipment and follow the calibration of standards and related issues can be quantified via detailed time cards. Our university laboratory's policy is to not require such detail in the accounting of time. Thus we can only present an estimate which is roughly $1/6^{th}$ of the time of a fulltime BS level laboratory coordinator. In our lab the quality manager not only calibrates the equipment but also manages the quality system. This person spends roughly $1/3^{rd}$ of her time on the quality system. Thus, at present we have the equivalent to ½ a person totally involved in our quality system.

We discussed earlier that many of our customers do not need the full benefit of an ISO 17025 certified system, so part of this expense is not being born by customers. At present this is lab overhead and illustrates a largely hidden cost of having a quality system. The benefits of a quality system go beyond the work for our outside customers and the tangible benefits to students who have worked on and under our system. These benefits will be discussed in the last section on conclusions and recommendations, but include greater confidence and better understanding of uncertainty in all our measurements.

E. Continuing Issues

Implementing a quality system and then using it in a laboratory requires continuous attention. The system is never complete and never runs on its own. A byproduct of this living nature is that the users of the system continually improve the system and yesterday's problem is today's opportunity. At the same time there are some issues that have no correct answer and continue to be a source of discussion. This section will discuss several of these issues and try to present several sides of our discussion of the issue. There is no particular order of importance within this section. We will discuss personnel issues, calibration and service issues, and some financial issues.

There are a number of personnel related issues that have arisen that are of a continuing nature. One aspect of routine laboratory testing is that it is routine and repetitive. This means that when the testing is performed by highly educated people with advanced degrees they tend to get bored. With boredom comes the potential of errors. In the long term we would like for most of our lab tests to be run by advanced undergraduate students or an AS/BS level employee. The difficulty with the former is that students come and go and our early experience indicates that the learning curve and training time make this inefficient. The latter option works if there is sufficient work to justify hiring such a person. In a small laboratory such as ours we are in the in between state. Some tests are run by faculty members, some by our lab coordinator/quality manager and some by students. Nevertheless, we are on constant watch through cross-checking to avoid errors due to lack of interest.

Different people will require different amounts of time for a given task. Is the slower person doing a better job than the faster person? Does the extra time, which is not charged in a flat fee test, provide benefits to the customer, so should the fee be raised? Since the individuals of both speeds are similarly trained and nominally following the same measurement

procedure we presume there is no difference in the final product; but this is difficult to ascertain except in side-by-side tests. Finally, in our laboratory every non-student qualified on a particular measurement may take orders from customers to perform a given test. This is largely out of necessity, in a larger company there would be an order entry person. However, it has had the advantage that customers develop a one-to-one relationship with a given person that promotes the laboratory.

The second area has been touched on before; that is calibration and the costs of calibration. As stated earlier we do not generally have service contracts because of their rather high price. This is simply an economic decision that at the present time makes good sense. But this needs to be examined continuously and for each instrument. The second issue is what is calibrated on a continuous basis? The secondary issues of why and how often comes into play. To a certain extent this depends on the test. In one test we put 25.6 kg on a sample that is heated to 190^{o}C and pushed through a small orifice. Other than a go-no go test of the orifice size we have done no calibration on this instrument. Clearly in a laboratory with greater resources this instrument would be calibrated on a periodic basis.

Two procedural issues have not been tackled. The first concerns accessibility of the various forms. Our approach has been to have printouts of the procedures near the equipment and procedure forms available with the procedure and from the quality manager. Ideally these should be in a data base and accessible to everyone regardless of the form needed. We do not have sufficient IT support to use this approach and intend to follow this approach in the future. The other procedural issue is where one stops writing procedures. For example does the procedure for measuring volume with a graduated cylinder need to be written, or the techniques needed to make solutions of a given concentration? We assume that procedures that are part of the standard associate/ bachelor degree program in chemistry, physics, or technology need not be covered. When problems do arise we write procedures to insure the problem does not reoccur. For example, one instrument requires the use of a crimping tool to hold samples. In spite of reading the instructions and being shown several times a particular student continually jammed the crimper. This was alleviated by further training and the production of a procedure to use the crimper.

In our laboratory, billing is handled by the lab director. This insures that there is a central location which invoices customers. Once more in larger/different laboratory this could be handled in a different way. However, by having completed test results go from the tester through the quality manager to the lab director there is constant administrative review and oversight of the whole process. Another issue that arose was the extent to which a university should do pro bono on projects. The arguments for it include the university should help companies and share their expertise. A counter argument acknowledges that there are real costs associated with a faculty member helping a company. We do not have a policy; both sides make excellent arguments.

III. Comments

This section will discuss our experiences and address question such as: Would you do it again? What are the benefits of your quality system? Does it make a difference? If so how?

How long will it take? Are there issues that can not be resolved except by compromise? The purpose of this section is to try to anticipate some of the readers' questions and provide our answers. Some of these answers are tentative, and may evolve with time. The important point that we reemphasize is that our quality system is simply an example, and our problems are representative, but certainly not all inclusive. Establishing a quality system in a university laboratory is an adventure.

There must be benefits to establishing a quality system in our laboratory or we would have stopped several years ago. Quality systems are not just academic exercises. As we mentioned earlier to date we have had few customers that actually require ISO 17025 compliance. It is our hope and belief that in the longer term this will become more important to our customers and help the testing side of our laboratory expand. In the mean time, there is a continuing need to justify the time and expense of our quality system. One of the primary benefits is that by documenting procedures we are much more isolated from a knowledge discontinuity if a faculty member leaves the lab. We also know that, to the best of our ability, everyone is doing the same measurement in the same way and has been taught by a person who knows the measurement. We are confident when we compare and combine measurements by multiple experimenters. Thinking about quality and performing measurements in a systematic and identical way every time has permeated our lab. Students that work in our lab learn very quickly that quality is not a meaningless adjective, but something that can be quantified and practiced. This appears to become part of some of the students' thought processes. We have had students work on the quality system and the experience of working in a lab with an ISO 17025 program is very different than course work in a quality course [9]. In fact, the non-financial benefits to the laboratory are so significant that even if the hoped for economic growth does not occur the quality system will be worth the time and effort. Students need to see how the "real world" has metrics for quality and the common undergraduate perception of quality being out there away from the university is outmoded. Fisch has run research labs in past and after this process it is difficult for him to imagine a lab without a basic quality system—too much is left to happenstance in most academic research labs that can be systematically controlled. Thus our answer to the question, "Would you do it again?" is a very positive yes.

While the time on a continuing basis has been discussed the total time was not. The process described in this paper has been occurring continuously for two years, and we expect it to continue into the future. A quality system is never complete, continuous improvement is a goal of our system and that of all other labs. Through internal reviews and continuous monitoring changes have been made and continue to be made. However, it is our expectation that after the initial large body of documentation and paperwork the time necessary to devote to the system with be reduced. There is an issue that we discussed earlier that continues to be the source of discussion and disagreement. The university embraces discussion and academic freedom. In practice this makes establishing a policy and saying this is the way it is difficult. We have accepted some ambiguity in non-procedural parts of our system, not because we like them, but the solutions are considered worse than the problems.

Finally, how do you know your quality system is successful, i.e. that it works? A successful quality system is one that seems natural to the user. The system has been set up so that while

there are procedures, paperwork and calibrations they are seen simply part of the measurement and are not overwhelming or too numerous. The procedures make sense because the operator knows why every step is necessary. The forms make it straightforward and he/she understands the importance and significance of the results to the customer or their research. The importance of calibration and preventative maintenance is also understood and appreciated by the operators and because they have assisted or performed these operations they know the instrument is within specifications. Under a successful quality system the operator does not ask why something is done a specific way, or why something is recorded, but rather they ask how can this be made better, easier or faster. In short success is measured by the extent to which quality is a part of every operator's interaction with customers, the equipment and themselves.

This paper has summarized our experiences in establishing an ISO 17025 compliant laboratory at a university. We have tried to address questions the interested reader might ask and defined a successful quality system. In spite of the time and cost establishing a quality system at a university laboratory has many advantages and we suggest that other university labs, even those not yet considering a quality system develop at a system. We have referenced our basic forms and will provide copies of specific documents to interested parties.

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Biographies

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