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MAINTAINING DATA QUALITY IN AN ENVIRONMENTAL TESTING LABORATORY

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INTRODUCTION

In today's competitive and highly litigious world, it is critical that any laboratory generating data for the environmental and allied industries have a world-class Quality Assurance Program. This Plan must conform to the requirements of every agency and client with whom the lab does business. The goal of such a program is data defensibility; i.e., data validity. Data (usually qualitative analyte [compound or element] identifications and quantitative numerical results) are the end results of nearly all analytical laboratory processes, and the source of revenue. Clients pay for results. The clients expect the results to be accurate, precise, and repeatable. If their data has to go to court, the laboratory will be called upon to defend the accuracy and precision of their work. Without a strong QA program, this will be impossible. The potential implications and repercussions of non-defensible lab data are far-reaching and very costly in terms of loss of future revenues and in legal judgments.

There are many written quality assurance programs and guides, which originate from or are utilized by numerous federal agencies and departments. The following is a partial list of some of these programs and guides:

- ISO 9000 (International Standards Organization; Laboratory Quality System)
- ISO 14000 (Environmental Management System)
- 10 CFR 830.120 (DOE QA requirements)
- 40 CFR 160 (Good Laboratory Practice [GLP] standards)
- ISO 10011-1 (Auditing principles)
- ISO 10012-1 (Management of Measuring Equipment)
- FDA GALP (Good Automated Laboratory Practices [GALP])
- ISO Guide 25- (Laboratory accreditation)
- ASTM Standard D-3856 (Guide for Good Laboratory Practices in testing Laboratories)

The ISO standards are promulgated through the American National Standards Institute (ANSI) organization. The Code of Federal Regulations (CFR) is utilized by federal agencies. CFR is a compilation of all federal regulations. New

regulations are promulgated in the Federal Register via daily publication of the Register- both for comment and final implementation.

Usually, laboratory organizations prepare their own QA Plan, incorporating either by reference or by explanatory verbiage, the federal requirements. This paper is written in an attempt to present common elements that exist in all good QA programs- elements and concepts, that if incorporated into your laboratory, will provide your customers with data that are accurate, precise, complete, and possibly most of all, legally defensible. The content for this paper is substantially based on the quality assurance requirements found in 10 CFR 830.120, which are utilized at the Department of Energy's Fernald site in particular, and are also representative of the approach used throughout the DOE complex.

OVERVIEW OF A TYPICAL QA PLAN

A QA Plan that meets all applicable requirements will contain the following 10 elements, at a minimum:

1. Description of the QA Program, stating scope, requirements (drivers), how the QA plan is structured, responsibilities for implementing and fulfilling the Plan, and how the Plan will be implemented. This is the first section under the heading of *management*.

2. This section describes how personnel in the organization will be **trained and qualified** to perform work. The scope of this requirement and the personnel responsible for implementing and ensuring adherence to this requirement need to be discussed. (The Scope and Responsibilities subsections should be included in all 10 sections.) Training and qualification programs serve to ensure that all personnel know how to perform the tasks for which they are responsible (e.g., certain analytical procedures), and specifies how the training and qualification programs are accomplished (on-the-job-training, test samples, required reading, and so on).

3. The third section covers the processes by which **quality will be improved** throughout the laboratory. These processes include assessing the laboratory operations, identifying conditions that are adverse to quality, issuing written notifications of non-conforming items, and then correcting the process to prevent recurrence of the condition. Quality improvement can, and should be a grass roots effort. Personnel at all levels need to be part of the quality improvement process.

4. One of the most important aspects of any quality assurance program is **documentation and records**. All analytical work, from method development, analytical quality control, to result generation and reporting, must be well

documented. Laboratories must have systems in place to store data and related documentation for the long term.

5. This section begins the *performance* group of QA requirements. Specifically, section 5 deals with **work processes**. All analytical work must be performed to established standards and work practices using approved procedures or similar instructions. Equipment and instrumentation must be calibrated and maintained to ensure accurate readings. Procedures must be in place that completely describe how work is performed. Procedures and other documents that direct work must be controlled, to ensure everyone uses the same methods and/or processes to perform work. Processes must be in place for periodic and timely reviews and revisions of existing procedures. In addition, procedures must be in place that direct how automated and hard copy data are handled- how data are reviewed, checked, reported, and so on.

6. This section involves the **design** of work process-related items. A formal design process must be in place, which includes drawings, plans, design changes, related documents, system testing (validation and verification), and final readiness reviews.

7. **Procurement requirements** constitute the next section of the QA Plan. Vendors and suppliers must be evaluated and approved based on specific criteria. Processes must be in place to assure that the products provided by vendors and suppliers meet requirements for the life of the project.

8. **Equipment and materials must be inspected and then accepted** as satisfactory for the work to be performed. This section describes how the inspection and acceptance are to be performed, and what criteria are used for the inspection and acceptance of the items, processes, or services. The criteria may include hold points (points at which work can not continue until further inspections are completed). All inspection and acceptance procedures must be fully documented. These procedures are especially critical for measuring and test equipment (M&TE).

9. The third group of QA elements deals with ***assessments.*** The quality assurance organization (or function) bears primary responsibility for ensuring compliance with the first eight criteria. Assessments can take several forms, including self-assessments, internal assessments (surveillances and internal audits) or external audits. The purpose of an assessment is to observe the process and compare the process to the requirements for that process. In particular, the ninth criterion involves management assessments, where managers assess their own process against the requirements. This type of assessment can occur at any frequency, but should be done at least annually.

10. Independent assessments (from outside the group or organization) also compare actual processes against written requirements. The assessment group shall be independent of the group being assessed, and have authority to carry out such assessments. All persons conducting independent assessments must be qualified and certified to perform assessments.

An effective laboratory Quality Assurance program must comply with the requirements of all 10 criteria, as they apply to laboratory operations.

DEVELOPING THE PLAN

This section will discuss the specific questions that need to be addressed by the Laboratory Quality Organization and Lab Management before developing the QA Plan for the lab. The answers to these questions can provide direction regarding the way the QAP is written, as well as identify the most pressing needs requiring the most work to improve quality.

The first question is the most basic: Who are the Customers? From that general question flow the following considerations:

1. What analyses are required for each customer?
2. What particular methods do the customers need?
3. What will the customers do with the results? Are they required for government permits and programs, or are they for internal use only?
4. What level of documentation do the customers require? Just certificates of analyses (COAs)? Complete data packages? Do the customers need preliminary results by phone or facsimile (Fax)? Should the results be transmitted electronically (through e-mail or via a direct connection to the laboratory information management system [LIMS])?
5. Do our customers require certain education and experience levels for our analysts and management personnel? How does the lab train their analysts?
6. Will our customer require an audit before we begin performing work for them?
7. Does the lab require state or federal certification in any methods? (for example, coliform bacteria testing, trace metals in groundwater, PCBs)
8. Does the customer understand the laboratory requirements for sample size, turnaround times, and format of results? Are there points of contact established in case of questions or problems?

The second question deals with each analytical method:

1. What are the overall QA/QC requirements of each method?
2. What is the expected precision and accuracy of each method?
3. What particular QC tests are incorporated into each method (blanks, lab control standards, duplicates, matrix spikes, frequency of calibration...) and

what are the acceptance criteria for each parameter? (If a lab is using CLP or SW-846 analytical methods, most of this information is provided in each method.)
4. What happens if the results are not pleasing to the customer? Will we reanalyze the sample(s)? Will the customer provide another sample? Who will pay for the reanalyses?
5. What happens if the method does not work well?

The third main question deals with verification of results and the ability to produce valid results:
1. How many and in which interlaboratory performance evaluation programs should the lab participate?
2. How are the results from these PE programs handled, especially if some results are labeled as non-compliant or out of control?
3. How are actual sample results checked and verified? Is there a system for second-analyst review?
4. Will a customer or an independent group validate the data (i.e., determine data usability)?
5. How are the results stored (electronic, hard-copy) and for how long a period of time? How are paper records stored? (Secure location, fireproof cabinets)

Another area to be considered is procedures. An effective QA program requires controlled, current procedures covering all work processes. Items to be considered include the following:
1. Who is (are) the author(s) of procedures (analysts, managers)?
2. How are the procedures issued (paper copies or on electronic bulletin boards)?
3. How are procedures controlled, to ensure that analysts are using only the current revisions?
4. How often are the procedures reviewed to ensure that the processes described therein are still current?
5. If one-time changes (variances) need to be made to a procedure because of customer needs, how are these variances handled?
6. Is there an external/independent assessment group that verifies that work processes are being performed according to existing procedures?

(It is important to note that the previous 24 questions are **not all inclusive**; your organization may develop many more questions that relate specifically to the processes performed at your facility.)

Once these issues are completely addressed, and included in the QA plan, the Plan can (and should) be implemented. It will require a concerted effort on the part of management, the QA organization, and bench level personnel to successfully implement the QA plan. There may be a need for orientation or

training meetings to fully explain the QA plan, and how it is expected to be implemented, including the time frame. Implementation may not occur immediately; the QA plan may require a paradigm shift on the part of several staff members, especially those who may feel that there is no need to change from the "way it has always been done". However, it is evident that laboratory data are under intense scrutiny by many government agencies, and an effective operational QA plan is a major step in successfully defending laboratory results.

The last (and maybe most important) consideration in setting up a Quality Assurance plan is continuous process improvement. Once developed, the Plan must remain dynamic- changing as the needs of the customer expand and change, and as the laboratory capabilities change. After the QA Plan has been in effect for some time, it must be evaluated to determine if it is actually fulfilling the purpose for which it was developed. Asking all the questions above and evaluating the responses can accomplish that goal. If the results are generally affirmative, and there is documented evidence for the affirmative responses, then it may be concluded that the QA plan is successfully improving or maintaining the quality of the laboratory operations. If the responses are not clearly affirmative, the Plan may require revision, or the lab operations may need to be significantly changed to fulfill the requirements of the QA Plan. Several iterations of this process are often necessary to align the Plan with actual performance of work. Even after the plan is successfully implemented, evaluation continues.

IMPLEMENTATION OF A QA PROGRAM

To implement a quality assurance program in a laboratory environment (e.g., analytical testing lab), there are several prerequisites. First, and possibly most important, is management support. Management provides the internal drivers for a quality assurance program, and management also provides the financial support for the creation of such an initiative. Then personnel must be identified who will be responsible for the development and maintenance of an effective QA program. It is highly recommended that a department or section dedicated to quality be created. This QA group must be independent; the development and maintenance of the quality assurance function can not be the responsibility of analysts and other staff members who generate the data. The potential QA staff must be trained in aspects relevant to QA, such as statistical process control, data evaluation, assessment techniques (including root cause analysis of non-conforming items or processes), and, if needed, technical writing and presentation skills. The QA staff should already have a good working knowledge of the processes for which they will have QA oversight; in the case of an analytical laboratory, the QA staff should understand the basics of analytical chemistry (sample collection, sample preparation, instrumental analysis, QC parameters, data reduction, and so on). It is advantageous to utilize personnel who have actually performed chemical analyses for inclusion in

any new QA department or section. In general, one individual should be designated as the Quality Assurance Officer or Director; this person is responsible for the overall QA program. He or she may designate certain QA staff members to perform certain functions, or to be responsible for one particular analytical area (inorganic analysis, radiochemical analyses, and so on).

There are a number of functions the QA organization is responsible to perform, and must have the freedom to perform. They include the following:

- The QA organization, with the assistance of the analytical staff and management, must prepare a written Quality Assurance Plan (QAP). This Plan must address all ten elements described at the beginning of this paper. Roles and responsibilities must be identified, and actions taken in the event of deficiencies or deviations must be spelled out.
- QA staff must have unrestricted access to all analytical data and related information. As an independent oversight function, all aspects of the analytical process are within their purview. Therefore, ready access, even when unannounced, must be granted to the QA personnel. In general, QA staff will request permission to view certain items, however, unless the material is highly proprietary, there is no reason to deny permission.
- Inspection of all analytical instrumentation and ancillary equipment is a necessary activity of QA staff. These inspections are for the purpose of ensuring that instruments are calibrated and that preventative maintenance is performed at the required intervals. Instrument Logbooks are vital records of these processes, and should be evaluated as well. Lapses in the performance of regular and required calibrations and preventative maintenance are indicators of potentially erroneous data, and need to be documented as a nonconforming condition, then tracked to ensure corrective actions are initiated.
- QA staff members are responsible for the identification of all non-conforming conditions that are, or may be adverse to the generation of high quality data. These conditions may be identified by the analysts themselves, and reported to the QA personnel. (Nonconforming conditions identified by the analysts as soon as they occur often are more quickly corrected. In addition, in the likely event of future audits, self-identified deficiencies that have been corrected are viewed favorably by the auditing entity. Nonconforming items still being corrected at the time of an audit are unlikely to be "re-identified" by the auditors.)
- In order to ensure that the laboratory is adhering to their Quality Assurance plan, regularly scheduled internal audits and other assessments (such as surveillances) will be performed. In general, these assessments should not be unannounced. The analytical staff should be aware that an assessment is scheduled at least a few days in advance. (Unannounced assessments

can give the impression of distrust, where the assessors are just looking for problems.) Scheduled assessments do cause analytical staff to be more cognizant of the QA program and requirements, and they are more likely to follow the plan. Accountability is a good tool for maintaining a high-quality laboratory.

It should be noted here that a laboratory QAP should NOT be the highest-tier quality document in an organization. Every organization should have a comprehensive Quality Program in place that covers all aspects of the organization- including personnel, procurement, documents and records and other aspects that parallel the 10 criteria presented earlier. These criteria are discussed from a more general, corporate perspective in a higher-tier document; specifics are left for the more detailed department-level plans. The higher-tier plan requires that detailed QA plans be in place at the level of the day to day operations.

MAINTAINING A LABORATORY QA PLAN ONCE IT IS OPERATIONAL

Maintenance of the QA Plan is a daily activity. A QA Plan does not function on automatic pilot; it requires a deliberate effort to ensure all components of the Plan are being followed on a continuous basis. It is easy, when one is busy, to overlook a particular requirement (thinking it is not that important), or to say, "I'll take care of it later.". All too often, later never arrives, and an auditor finds the lapse in the program. Quality is a continuous process, and must become part of everyday life in the laboratory.

There are several evidences of a mature, functional QA plan. The first, and maybe most obvious evidence is that everyone is following the QA plan to the best of their ability. The Plan is being consulted frequently, and the visible aspects of the Plan exist in the laboratory, such as control charts, independent assessments, viable controlled procedures, and so on. Another evidence of an operational plan is frequent discussions about lab QA issues and QA Plan requirements. As personnel become accustomed to utilizing the QA plan, they will encounter situations that may not be well covered in the Plan, or where the information/guidance included in the Plan does not address the situation. A third evidence of a maturing QA plan and process is increased emphasis of continuous process improvement. The Plan and related procedures should always be open to improvement- improvement designed to increase the quality of the data produced by the lab, as well as improve efficiency of operations where that is possible (without sacrificing quality). These improvements may be driven by the identification of non-conforming conditions, which require corrective actions. Internal and external assessments will usually look at the QA Plan closely, and check to see if lab operations are adequately described in the Plan and that they are following the Plan.

Based on QA programs that exist and are successful, (specifically the program the author has been involved with for a number of years), there are a number of ongoing activities that can traced to the program (activities that may not exist without the impetus of a strong, active QA program).

1. Strong management support. Managers and supervisors are involved in the overall QA program, although not at the bench level. They receive regular reports regarding assessments, performance evaluation results, and provide input on quality issues in general. Managers keep current on the latest QA concepts, and if they merit discussion or implementation, pass them down to the QA organization. Even though management may not handle day-to-day QA operations, they are accountable for ensuring that a strong QA plan is in operation in their facilities.
2. A strong assessment program. Effective quality assurance programs are assessed frequently at several levels. Team Leaders and supervisors review analytical data continuously to check the performance of methods, instrumentation, and personnel. The independent QA group conducts more formal assessments (surveillances and/or audits) of all processes on a periodic basis. These assessments are scheduled in advance, and are formally documented as part of the organizations reporting and documentation system. External auditors (from state or federal agencies, for example) may conduct annual or biannual audits to ensure compliance with their regulatory requirements. GLP-C-01 ("Conducting a Field Studies GLP Compliance Inspection", June 7, 1999 revision) provides an excellent example of the kinds of processes that are reviewed in field agricultural or other environmental study locations, but which are also applicable to fixed laboratory-based operations. ISO/IEC 17025 ("General Requirements for the Competence of Testing and Calibration Laboratories", December 15,1999 edition) also provides a good template for a laboratory assessment. Frequent feedback from all these assessments is very helpful to laboratory personnel. Often, during audits, daily meetings are convened to review the day's activities and findings.
3. Effective tracking of QA/QC parameters. One important aspect of any QA program is the evidence that the data generated meets the needs of the customer. For the majority of programs, this evidence is in the form of quality control checks throughout the analysis. From initial calibration through final calibration verification, these QC parameters show that the analytical system is in control throughout the analysis. If a QC parameter fails specified criteria, the analysis is usually terminated, corrective action is performed, then the analysis is started again, or picked up at the point where the noncompliant QC affects the data (e.g., the previous 10 samples). These QC analyses are often plotted on control charts, which are regularly reviewed to determine if there are any trends that may lead to a decline in data quality. Internal and external assessments of the lab QA

program will almost always examine control charts- especially for evidence of trends. These assessments frequently evaluate the frequency of internal reviews, and actions taken when QC data are trending towards an unfavorable situation. Even if an auditor notes non-compliant QC data, if there is evidence of frequent internal review and corrective actions, the auditors may not view these non-compliances as unfavorably as those that appear to be ignored by the lab staff.

4. Participation in external Performance Evaluation (PE) Studies. Most state and federal laboratory programs require participation in these studies. PE studies consist of test samples generated by an independent organization (such as ERA®, APG®, or by a DOE or EPA regional laboratory). These samples are analyzed by the laboratory by a certain due date, then the results are forwarded to the organization for evaluation. The evaluation is sent back to the laboratory (and sometimes state or federal agencies) for their use. Any noncompliant (out of control) results are flagged. The laboratory should investigate the cause for the deviation, and initiate any corrective actions to prevent recurrence of the noncompliant situation. Laboratories are often granted "approved" status by state or federal agencies (or their agents/ contractors) on the basis of initial acceptable performance in such PE studies, and are required to demonstrate continued successful participation to remain approved to perform work for these agencies.
5. Frequent QA-related training. The world of QA theory and application is continually expanding. New concepts and practices are continually being developed and refined in the laboratory environment. Better and faster ways of tracking QA/QC issues are being developed - especially those that utilize information technology. Real-time control chart generation is possible now, which allows real-time identification of non-conforming items. In order to be useful, however, lab staff must be educated on these advances in electronic tracking. The QA organization itself must continually keep abreast of new methods of assessing quality, and help keep the lab in compliance with the latest state and federal QA requirements, such as ISO certification. (Some ISO guidelines are still in the development process, especially the ISO 14000 and 17000 series.) There are many courses covering ISO principles at QA conferences and seminars around the world.
6. A "Culture" of Quality. Probably the best evidence of an effective QA plan is the daily awareness of quality throughout the laboratory operations. All staff, from the highest level manager to administrative personnel, are always assessing the quality of their work, and looking for ways to improve the quality of all lab operations. Quality is not simply relegated to analytical processes, but includes all facets of the lab operations. Sample collection and associated paperwork and/or electronic sampling input accuracy and completeness are an integral part of the sample analysis process, and, therefore, contribute to the quality of the analysis. Equally as important,

after sample analyses are completed, data reduction, report generation, and transmission of results to the customer require care to ensure accuracy and completeness as well. There are many opportunities for error in the sample analysis flow, and a high level of quality is needed to minimize (hopefully eliminate) errors along the path. A culture of quality means that there are many checkpoints along the path to ensure that errors are identified and corrected before the final results are released. Nothing damages the credibility of a laboratory more quickly than frequent corrections to submitted results.

LESSONS LEARNED

Developing a QA Plan, then implementing the Plan does not occur in a few days or weeks. The more services offered by your laboratory, the more processes the QA Plan must address. The Plan is not required to discuss every analytical method, or every SOP that exists (or should exist) in the laboratory. However, every method and SOP must meet all the criteria enumerated in the QA Plan. Other common errors to avoid include the following:

a. *Insufficient training of QA and analytical staff*- People cannot follow a plan for which they have not been trained. Training should be offered on such aspects as control chart preparation and maintenance, basic statistics, an overview of the organizations procedure system, safety in the lab, procurement and control of chemicals and analytical equipment, lab sample custody procedures, and format of reported results.

b. *Lack of follow-up of identified deficiencies*- It is often easy to identify non-conforming conditions, but corrective actions are not always generated or implemented. The lack of corrective action implementation can have a "snowball" effect; nonconforming conditions can create major problems with data defensibility and usability. If corrective actions are not devised and implemented within a short period of time, data quality deteriorates. Non-conforming conditions rarely correct themselves (recall the Second law of Thermodynamics...left to themselves, conditions deteriorate or tend to more disorder). Any QA plan must require timely corrective actions in the event of a nonconforming condition that is adverse to quality.

c. The *"We've always done it that way" syndrome*- In so many organizations, change is difficult. However, change is the norm in organizations that have a high commitment to quality. High quality operations require frequent course corrections, and the staff must be willing to make changes that are sensible and that will improve the quality of the final product (results). Many of the changes will be minor, and not affect the overall flow of work; some changes require a paradigm shift, and take more effort to implement.

d. *Leaving quality just to the quality organization*- Like a good safety culture, where everyone is responsible for their own personal safety as well as the safety of those around them, quality is no different. Quality work is a process of <u>ownership</u>; each staff member is keenly aware that his or her

piece of the work (process) must be of high quality before it is passed on to the next step. Deficiencies accumulate (propagate), and corrections can not be left to the end of the process. It is far less expensive to correct, or prevent problems than to correct them later.

e. *Lack of evidentiary documentation*- The key to having verifiable, legally defensible data is complete, accurate, and timely documentation. The late or incomplete generation and maintenance of records is a weakness found in many laboratories. Even in this information age, there is a large volume of information that still has to be recorded manually (instrument logbooks, standards preparation logbooks, for example). After preventative maintenance is performed, the details must be recorded in the appropriate location. If time elapses between an event and the recording of that event, details become faded and less trustworthy. Just as vital as timely record keeping is trustworthy record keeping. Recent investigations of laboratories have uncovered numerous instances of data falsification, in terms of analysis dates and actual results. Data integrity questions lead to investigations, and severe civil or criminal penalties. A strong QA program emphasizes accurate and timely recording of all pertinent information, even if non-compliant data are generated (QC failures, e.g.). Good record keeping will document problems and the subsequent corrective actions.

SUMMARY AND CONCLUSIONS

The goals of an organization as they relate to quality can be summarized in six statements:

1. Develop, then increase personnel awareness of the importance of quality.
2. Encourage personnel to identify then suggest improvements in processes that will enhance quality of operations.
3. Ensure that items that do not conform to specified requirements are controlled to prevent their installation and use. Vendors of such items shall be approved prior to using that vendor.
4. Ensure that any condition adverse to quality be detected, identified, reported, and processed (dispositioned) to correct that condition.
5. Focus upon problem prevention and performance improvement, rather than reacting to problems that are detected after they occur. Avoid blaming people: fix the system.
6. Evaluate and measure processes and performance to identify possible problem areas, identify trends in productivity and quality, apply lessons learned, and strive for continuous improvement of the process.

Quality must not be just an idea or an ideal; it must be a daily working reality. The creation of a viable QA Plan is an important effort in attaining the goals listed above. The plan should not be rushed- time spent at the front end will yield substantial dividends down the road. Quality must be a mindset, and if

the goals are presented to all personnel, and inculcated into their daily work processes, the organization will be successful.

REFERENCES/ FOR MORE INFORMATION

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