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Technical Papers

Environmental Data Quality and Laboratory Systems

- J.Bennett, The Road to ISO 17025 - 1:00 PM
- J. Schofield, Take the Challenge, Initiating a New Laboratory into a Long-Term Monitoring Program - 1:30 PM
- J. Caprio, Data Quality Assurance: Asking Appropriate Questions - 2:00 PM

The Road to ISO 17025 – One Laboratory's Experience

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The State of Connecticut Department of Public Health Laboratory is regulated and accredited for programs ranging from Chemical/Bioterrorism response to environmental chemistry. Rather than attempting to maintain Quality Manuals for each of the programs, the laboratory decided to implement a unified QA Manual based on the ISO 17025 tenets. The CTDPH laboratory has not yet fully reached our goal, but this paper describes our experiences on the journey, and some lessons learned that might help others get there more quickly.

The State of Connecticut Department of Public Health Laboratory is composed of about 100 scientists analyzing clinical and environmental samples. The laboratory programs range from virology to biomonitoring to environmental microbiology to environmental chemistry. We also are part of the CDC Laboratory Response Network (LRN) for preparedness for a biological or chemical terrorism event or other Public Health emergency. The programs are regulated and accredited by CLIA, AIHA, FDA, Select agent, NVLAP and EPA.

Historically each program maintained separate QA manuals, which led to much confusion in the laboratory. The laboratory director realized that most programs were heading towards ISO, and made the decision that the default QA format for the laboratory would be ISO17025. The QA Manager created a bare bones QA manual in the ISO format that was to serve as the basis for a unified QA manual.

In early 2003 the State of Connecticut was facing a fiscal crisis, and in a prototypic fashion, decided to reduce staff by a combination of layoffs and early retirement incentives. The DPH laboratory was particularly hard hit and lost about one-third of its staff, including the QA manager. Thus the efforts to implement the ISO QA program languished for almost two years. It was only with the hiring of a new QA manager in late 2004 that the efforts were revitalized.

We were apprehensive about 2005 because it was "the year of the audit". Every agency that accredited the laboratory was coming on site for an audit. EPA started the parade in February and, every six to eight weeks thereafter another organization was coming in. Our goal remains to have one QA manual for the entire laboratory. We realized that we would not be able to accomplish this goal in the amount of time we had available so we decided to take a stepwise approach. The approach was that each program would develop a QA manual using the ISO format and addressing any specific requirements that a program might have. At the end of the process we would merge the manuals into one document and have appendixes to cover any program specific requirements.

Since EPA was the first agency scheduled to audit the laboratory, the Environmental Chemistry QA manual was given top priority because we only had a couple of months to get it in shape. The QA Manager and the Environmental Chemistry Manager agreed that the only opportunity to have a modicum of success was to work on the manual on a collaborative basis. The typical DPH laboratory staff chemist has worked at the laboratory for about 20 years, and this laboratory has been the totality of his or her experience. The chemists did not keep up with the evolving thought on quality systems but had kept the mindset that, if the chemistry was good, the result was correct. Since the hallmark of ISO is detailed recordkeeping, it was critical to introduce a paradigm shift in the laboratory.

The first step in the process was to start the revision of the QA manual. Our goal was to approximate the ISO format because EPA was not certifying us to ISO but rather to the Drinking Water Certification Manual requirements. The approach that we took was to "cut and paste" sections from the old QA manual into the ISO order for the various elements. We then went through the manual and made specific changes to the various sections to increase the level of detail, to reflect current procedures and to incorporate changes to increase the quality requirements. The revised QA manual was distributed to the staff prior to the audit so that staff would have a chance to review the changes. Because of the QA manager vacancy, the implementation of the quality system had taken a step backwards and there was resistance by the staff to the renewed emphasis on QA practices.

One of the requirements of the QA plan was to conduct yearly audits of the various areas of the laboratory. Since time was short and the QA officer was new in his role the internal audit focused on the deficiencies found in the last EPA audit. The analysts were interviewed and assured the audit team that the deficiencies were indeed corrected. Records were given a superficial examination and the internal audit was concluded. When EPA came in, we were surprised and dismayed to discover that some areas of the laboratory had not instituted the corrective actions that they had assured management were in place. This experience drove home the importance of independent verification of implementation of corrective actions. This is not to suggest that there was any intentional misrepresentation by the analysts of what they had done but to highlight the need for more than one perspective in examining a solution. The analysts may have thought that they had resolved the problem when in fact they had not. The independent verification is of particular importance when the solution involves a significant change to a process, and the person responsible for the change has only seen the process performed one way. It also highlights the need for analysts to keep up with the current state of the art in their field. I want to emphasize that the some areas of the laboratory came through the audit with "flying colors", and that my presentation today focuses on lessons learned from areas that needed improvement.

The most significant findings resulting from the EPA audit were in the areas of documentation, traceability and data review. EPA demanded a quick response from the laboratory. The Environmental Chemistry Manager and the QA Manager decided that the best solution would be extensive retraining of the personnel in the affected areas. We wanted the analysts to feel comfortable with the process, so we used a "roundtable" format. Representatives from the QA department, the section supervisor, the analysts involved, and the environmental chemistry

manager met and discussed the performance of the method, and the steps in the performance of the method that needed to be documented. We also discussed ways to do the documentation to ensure that the appropriate data was captured and would be available for review. We stressed the importance of linkages among the various components of the analytical process to ensure traceability. The roundtable was conducted in a manner that facilitated an open exchange among the participants to arrive at a consensus.

Prior to beginning the roundtables, we decided on some fundamental changes to the data flow. The existing data flow process had been decentralized. Calibration information was stored in one spot, sample results were kept in another spot, and supporting data was kept in a third spot. We implemented a system whereby all the data necessary to reconstruct an analytical sequence would be stored in one spot. The data package would include the raw data, copies of sample prep logs, copies of standard and reagent prep logs, and copies of any other relevant data. Additionally, we created data review checklists for each parameter to ensure that all critical QC parameters were reviewed prior to acceptance of the data. The data review checklist enforced and documented the multi-level review process necessary to validate the data for release.

The process changes required revisions to the SOP's. We looked at this as an opportunity to create some order out of chaos. The SOP's in use in the laboratory varied widely in both format and content. People with varying levels of writing skills had created them at different points in time. We had developed a standardized format prior to the last annual revision and gave the format and the SOP to the lab staff and asked them to implement the changes in the revision. The results that were returned to us were not encouraging. Therefore, the Environmental Chemistry Manager decided to take on the task of standardizing the SOP format. A series of ten testing SOP's were chosen to get the process started. The first round of revisions resulted in a significant step toward format standardization. Significant detail concerning QC acceptance criteria and documentation was added as well. The first round was sent out for comment and, based on suggestions from EPA and internal review a second round was done. Training on the newly developed standardized format will be done and it will be extended to all SOP's as they come up for review, with the ultimate goal being that the staff will update their own SOP's.

The next audit was from NVLAP for our bulk asbestos program. NVLAP audits to their Guide 150, which follows ISO17025. The next step on the road to a unified ISO 17025 manual was accomplished by taking the quality manual from the EPA program and making it very closely conform to the ISO outline. The QA manager spent a great deal of time comparing section by section to the Guide 150 checklist and making changes. In some cases it meant making the wording of the section more general so that it could be applied to multiple programs, and in some cases it meant becoming very specific for the NVLAP requirements. We formed a team that met daily for an extended period of time to discuss the changes and to come to a consensus on the interpretation of various provisions. Team members were assigned various sections to rewrite based on our discussions, and the team reviewed their work. NVLAP required only very minor changes to the QA manual after their review process.

We used the lessons learned from the EPA experience to restructure the internal audit process, and implemented it starting with the internal audit for NVLAP. The internal audit is now a two-part process. The first part consists of a roundtable with the members of the group. We stress at

the beginning of the meeting that this is meant to be a frank and open discussion and that the purpose is to build a sense of team among the analytical areas and the QA department. We have found this to be a very effective way to elicit information from the staff about the procedures followed in their area. Sitting around a table in a conference room counteracts the natural tendency of an analyst to view the internal auditor as an adversary. Of course, the auditor has to refrain from jumping down the analyst's throat when he hears something that sends up a "red flag". The QA auditor takes notes about areas that appear to need follow up. The second part of the audit is actually visiting the analytical area. The auditor does have a checklist, and does verify the items on the checklist but he already has a good idea of the areas that need to be probed deeply. This two-part process has been very successful in making the audit both effective and efficient. The audit report is provided to the supervisor and staff to use in preparing for the external audit. It is also given to the manager and laboratory director for their review.

The third step on the road was the preparation for the AIHA audit of our environmental lead program. This was a "true" ISO 17025 auditing program. The QA manager took the NVLAP manual, and removed everything that was program-specific. He created an appendix with the program-specific requirements and referenced the appendix in the appropriate areas in the body of the main document. The process pointed out that there was still work to be done. There were two particular areas that stood out. The first was the distinction between analyst training and analyst authorization. Until this point in time our laboratory had never explicitly detailed procedures to ensure that an analyst was authorized to perform a procedure. Our philosophy had been that, if they were trained, they were authorized. The second was that we had the corrective action process split between two sections based on the severity of the problem. Solutions were easy to implement, but this serves to show that each time you review a document it is important to look at it as if it was the first time. At this point in time the QA manual appears to be in good shape and, from now on when the quality system of a program comes up for review, we will create a program-specific appendix to the manual.

Finally, the day of the AIHA audit arrived and because the team had put hard work preparing for it, it was a success story for our laboratory. The laboratory staff and QA had met on a weekly basis for several months to go over the ISO and AIHA requirements so that there would be no surprises. These meetings also served to familize the staff with the level of detail required in the implementation of a modern quality system, and gave them some insight that the QA department is a partner and not the enemy. The auditor found twelve deficiencies (all relatively minor), but we were able to correct six of them before the closing meeting.

There were several suggestions by the auditor, and we believe that the outcomes from two of the suggestions have the opportunity to significantly enhance our overall QA program. The auditor pointed out that the most important, and the one least often utilized properly, element of an ISO17025 quality system is the management review. Many labs just use it as a means to report to management on what was done over the prior year (i.e. no PT failures, corrective action reports trending similar to last year, etc). It should focus on effectiveness, on how we are doing, on are we going to where we need to be. The second suggestion was to re-examine our Corrective Action / Preventative Action process. Our auditor mentioned that the most poorly understood portion of the ISO standard is the Corrective Action / Preventative Action process. We agree that we need to re-examine this portion of our QA program, and at this point in time

the outcomes are not clear. We realize that much work needs to be done to further develop our understanding of the true intent of those sections. The analogy that we are using to help guide our thoughts is that the Corrective Action process is like a policeman. A policeman investigates to determine if laws are broken. If a law is broken, it is a Corrective Action. If the law is not broken but continuing on the present course could lead to a broken law, it is a Preventative Action. The challenge is deciding what the laws are. Some are obvious, and some are not.

Our laboratory still has a long way to travel on the road to ISO compliance, but we are making good progress. One area that still needs a lot of work is our documentation of problems and their resolution. We currently use a manual system and it is challenging to get compliance with the documentation requirements of our Quality System. The analysts complain that it takes longer to document the problem than it takes to fix it. We continually remind them that "if it is not documented, it is not done", and it is a continuing battle. The lab's IT infrastructure is behind the times, which hinders our efforts to automate some of the QA tracking and notification. We just transitioned "Outlook" and are investigating the possibility of using it to somewhat automate the process in an attempt to increase compliance. We are starting to educate our staff that there is a strong customer-centric component to the ISO Quality System, and that generating good data is not our only job. Our focus is on making one step at a time and each incremental step will further us towards our final goal.

There are some important lessons that we have learned from our first steps on the process that can help others. The first one is that the project needs at least one person who is totally committed to being an agent for change. That person (or persons) must be persuasive and consistent in their message. They must be able to clearly express their vision about where the process will lead, and must be resilient and tenacious enough so that they will be able to overcome the resistance that will be inevitable. They must not be afraid to repeatedly bring the same message to the staff because once is not enough. They must be willing to work with staff members (often on an individual basis) to get changes implemented. A method that I have found helpful is to express to the staff member what needs to be done, and ask them how to accomplish it. Review their suggestions, and do not be afraid to tell them that it is not quite what is needed. However, accept it if it works, even if it does not meet your vision of the best way of doing something. Finally, continuous oversight is particularly important, especially at the beginning. If the job is not done correctly, make them re-do the work. This will reinforce the message. In the end, the changes will be incorporated into the daily workflow and the analysts will be accustomed to them.

As was written earlier, the Connecticut DPH laboratory has a way to go, but we are committed to the process. Dr. Kati Kelley, our laboratory director, has said "the day we are able to hang a banner across our laboratory's entrance that says 'ISO 17025 Compliant' will be one of my proudest days." I agree.

Take the Challenge: Initiating a New Analytical Laboratory into a Long-Term Monitoring Program

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Coordinating a long-term monitoring program is a challenge in itself. Initiating a new analytical laboratory into the monitoring program raises a new set of unique challenges that must be addressed in order to maintain the rigor of the program and accuracy of the data. Ensuring data comparability is just one of these challenges and is not a straightforward task. What metrics should be used to assess data comparability? How can improvements in analytical techniques be incorporated into a monitoring program without jeopardizing data comparability? These were some of the questions facing the Great Lakes National Program Office (GLNPO) in implementing a long-term monitoring program.

The Great Lakes National Program Office is currently implementing the Great Lakes Fish Monitoring Program (GLFMP) in cooperation with the Great Lakes States, selected State agencies, and Native American Tribes. The program involves assessment of a variety of contaminants in sport and predatory fish collected from the five Great Lakes. GLNPO recently distributed a solicitation to obtain laboratory services to analyze fish tissue for the suite of target contaminants. In evaluating the analytical laboratories that submitted proposals, GLNPO identified a new laboratory that appeared to meet the requirements of the program for the best value. Because the data generated from the project will be used with data generated by other laboratories to assess time trends in fish contaminants, between-lab comparability is essential to the success of the project.

Therefore, GLNPO developed a strategy to evaluate the laboratory and the impact of this new lab on the quality and comparability of the data generated in support of this long-term monitoring program. Part of the strategy was to have the new laboratory participate in a performance evaluation (PE) study. The PE study included samples of fish tissue from three sources: NIST standard reference materials; a lake trout reference sample that had historically been used to evaluate data comparability; and actual field samples collected in 2003. Analytical results generated by the potential analytical laboratory, the current analytical laboratory, and a previous laboratory were evaluated to assess laboratory capability and comparability to historical data.

Data Quality Assurance – Asking Appropriate Questions In Order to Assure Data Quality

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Abstract

A principle role of a data quality assurance consultant is to assure the data collected will meet the requirements of the project data quality objectives, which are typically related to the appropriate characterization, remediation, and closure of a site. In order to do this, the data quality assurance consultant must maintain close communication with the client, the regulatory agency whose oversight the site(s) falls under, and the analytical laboratory. The consultant, client and regulator must define data quality objectives (DQOs) at the beginning of the process to ensure that the desired goals are achieved. Determination and documentation of the activities necessary to achieve the DQOs are initial project tasks.

Once DQOs have been established a quality assurance project plan (QAPP), field sampling plan (FSP) and work plan are developed. Of these three documents, the FSP and QAPP incorporate DQOs, project quality assurance measures, field quality controls, and laboratory measurement parameters, quality checks and quality assurance protocol. The FSP is crucial in that it specifies how and where samples will be collected, possible field screening processes, field quality assurance sample requirements and frequencies sample naming and field documentation requirements. Development and review of both of these documents can again be facilitated by the use of a simple decision tree which identifies questions pertinent to the project goals and requirements.

Throughout the process, the role of the data quality assurance consultant is to maintain communication between the analytical laboratory, the client, and the regulatory agency to ensure that the data collected will be analyzed in accordance with the methods specified by the QAPP and FSP. This entails assurance and documentation from the selected analytical laboratory(s) that the necessary level of analytical sensitivity (reporting levels) can be achieved for the full list of compounds of concern, the required level of quality assurance samples, and the necessary level of quality check samples are incorporated into the sample analysis. Beyond these basic requirements from the laboratory, time constraints, data deliverables specifications - including hard copy and electronic data deliverable requirements, must be discussed with the laboratory. Communication with the analytical laboratory through sharing work plan and QAPP documentation combined with verbal communication (i.e. asking knowledgeable questions regarding laboratory capabilities versus project requirements) greatly reduces the necessity of re-sampling and re-analysis caused by inadequate or poor quality analytical data results.

A principle role of a data quality assurance consultant is to assure the data collected will meet the requirements of the project data quality objectives, which are typically related to the appropriate characterization, remediation, and closure of a site. In order to do this, the data quality assurance consultant must maintain close communication with the client, the regulatory agency whose oversight the site(s) falls under, and the analytical laboratory. The consultant, client and regulator must define data quality objectives (DQOs) at the beginning of the process to ensure that the desired goals are achieved. Determination and documentation of the activities necessary to achieve the DQOs are initial project tasks; however, identifying appropriate DQOs and appropriate FSP elements for a project is often a confusing part of project planning. Effective DQOs derive from (1) a clear understanding of the end use of each type of datum collected and (2) finding an appropriate balance between failing to collect information with

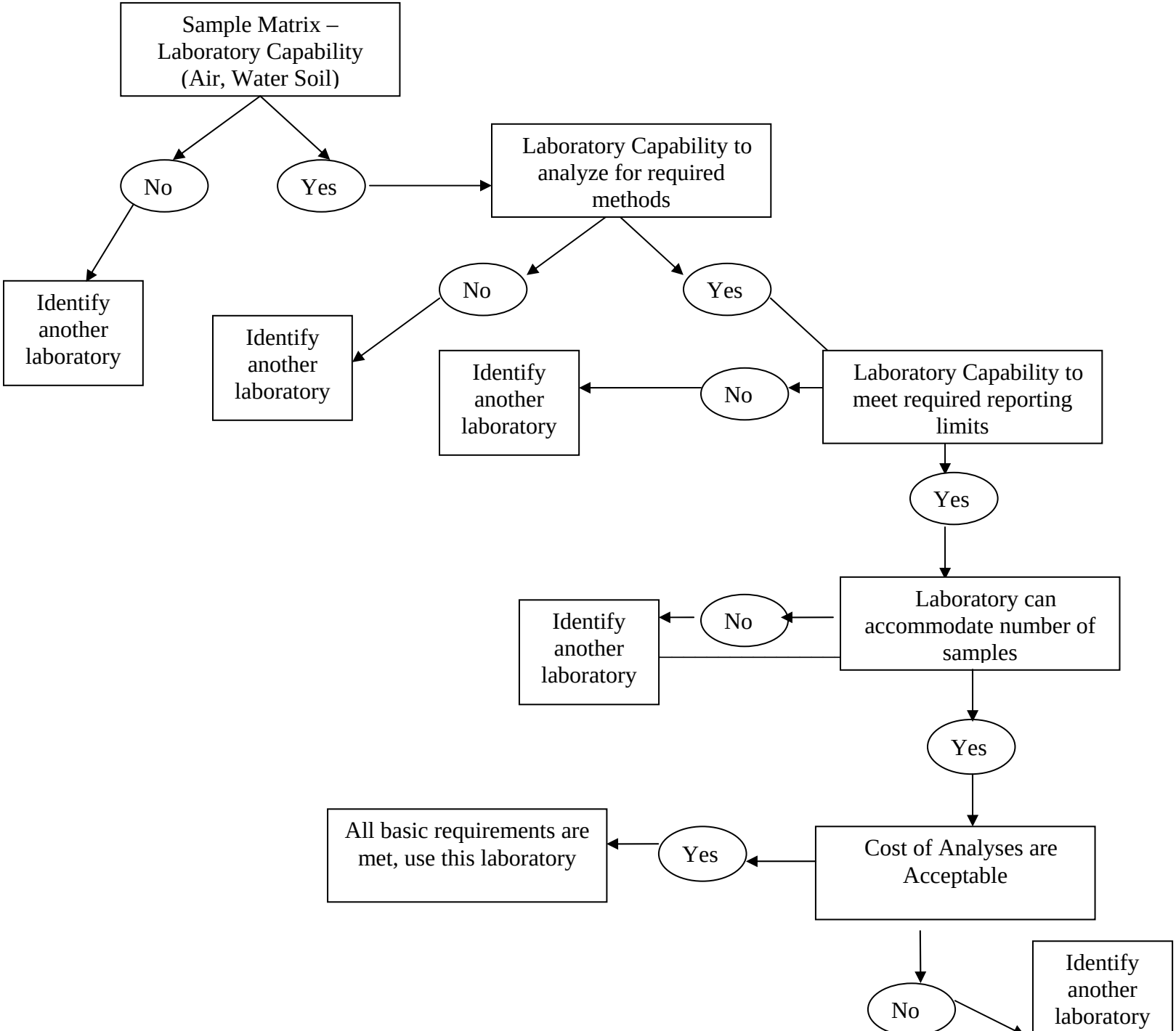
enough thoroughness to support its end use and overachieving such that, while the data are usable, the cost to collect exceeds the value of the information gained. Asking appropriate questions at the beginning of the project, during the planning stage, is crucial to assure data quality throughout that will achieve a best-value relationship between data usability and cost to collect.

The process of developing DQOs is comprised of seven steps. During the first step a project team is identified. This team can consist of representatives of the regulatory agency, the site primary responsible party (PRP), possibly the manager of an analytical lab, stakeholders, consultants, engineers, the site manager and a quality assurance expert. It is important to include expertise from as many of the involved parties, as possible, in order to have discussions and communication on the front end of the remedial process that will completely define the problem. (DQO teams do not have to be large, for instance smaller sites with familiar contaminants often develop DQOs using smaller teams comprised perhaps of the site manager, an engineer and a laboratory manager.) The first step then of the DQO process represents communication between the involved parties, asking the appropriate questions in order to define the problem, whether on a large site or a relatively small site. Although the next six steps of the DQO process will not be discussed in this paper, they all entail asking appropriate questions initiated through team discussion.

Once DQOs have been established a quality assurance project plan (QAPP), field sampling plan (FSP) and work plan are developed. Of these three documents, the FSP and QAPP incorporate DQOs, project quality assurance measures, field quality controls, and laboratory measurement parameters, quality checks and quality assurance protocol. The FSP is crucial in that it specifies how and where samples will be collected, possible field screening processes, field quality assurance sample requirements and frequencies sample naming and field documentation requirements. Here the role of the quality assurance consultant, in order to collect and determine representative and usable data from the site, is crucial. Many of the problems that arise on site after these plans have been finalized occur due to issues such as not identifying appropriate sampling methods, sampling frequencies, analytical methods or laboratory capabilities during plan development. For example, perhaps site logistics preclude immediate sample shipment to ensure that short analytical holding times are met therefore a laboratory within close proximity to the site is chosen only later to find out that after receiving the samples the laboratory does not have the capabilities of meeting the required reporting limit for the site constituents of concern (COCs). Another example is many times methods will be listed in the QAPP and FSP for COCs, samples collected and sent to the laboratory and the laboratory substitutes a similar but different method without notification to the site manager because no one thought to provide the information to the laboratory and/or asked the appropriate questions. The Site owner or site manager depends on the expertise and communication skills of their QA consultant to determine this information prior to execution of the project. Development and review of both of these documents can be facilitated by the use of a simple decision tree which identifies questions pertinent to the project goals and requirements . Decision trees are excellent tools for helping to choose between several courses of action. They can provide a highly effective structure within which options can be laid out and the possible outcomes of different decisions can be investigated. Decision trees can also help form a balanced picture of the risks associated with each possible decision. A simple illustration of some of the questions

regarding choosing an analytical laboratory for sample analysis is illustrated in Figure 1. The level of detailed questions required to select a laboratory should be commensurate with the size and complexity of the project..

Throughout the entire project, the role of the data quality assurance consultant is to maintain communication between the analytical laboratory, the client, and the regulatory agency to ensure that the data collected will be analyzed in accordance with the methods specified by the QAPP and FSP. This entails assurance and documentation from the selected analytical laboratory(s) that the necessary level of analytical sensitivity (reporting levels) can be achieved for the full list of compounds of concern, the required level of quality assurance samples, and the necessary level of quality check samples are incorporated into the sample analysis. Beyond these basic requirements from the laboratory, time constraints, data deliverables specifications - including hard copy and electronic data deliverable requirements, must be discussed with the laboratory. Communication with the analytical laboratory through sharing work plan and QAPP documentation combined with verbal communication (i.e. asking knowledgeable questions regarding laboratory capabilities versus project requirements) greatly reduces the necessity and out of scope expense of re-sampling and re-analysis caused by inadequate or poor quality analytical data results.


Sample Matrix – Laboratory Capability (Air, Water Soil)
No
Yes
Identify another laboratory
Laboratory Capability to analyze for required methods
No
Yes
Identify another laboratory
Laboratory Capability to meet required reporting limits
No
Identify another laboratory
Yes
Laboratory can accommodate number of samples
No
Identify another laboratory
Yes
Cost of Analyses are Acceptable
Yes
All basic requirements are met, use this laboratory
No
Identify another laboratory