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IV.7

QA/QC in solid waste characterization, waste disposal monitoring and waste management practice*

Quality Assurance organizational–catalytic–technical

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IV.7.1. Introduction

According to recent national studies, over two-thirds of all participants in quality assurance (QA) and quality control (QC) systems are disappointed in the results. Quality is clearly a good thing, but quality systems are not dynamic when two out of three lead to disappointment. What's wrong? Is it possible that dynamic quality systems (Fig. IV.7.1) incorporate special additives (catalysts) that normal quality systems (Fig. IV.7.2) do not?

In a normal quality system for the monitoring and the remediation of solid wastes, two distinct levels of QA requirements are addressed: the organizational (or institutional) level and the technical (or project) level. Dynamic quality systems, on the other hand, not only include the normal components but also integrate catalytic components. These catalytic components are critical to the foundation supporting the quality system pyramid (QSP), however, they are often overlooked in the design stage of many quality systems. While this chapter does consider the characteristics of a normal quality system, an intentional focus is levied at the seldom-explored dimension – catalysts.

IV.7.2. Organization (or institutional) QA

The essential elements of QA management systems have been discussed widely in the literature. For instance, the 9000-series documents of the International Organization for Standardization (ISO, 2000) list 20 components of QA management systems, with

* *Foreword*: This chapter has been written by an author with many years' professional experience as a Quality Assurance Manager at US EPA National Risk Management Research Laboratory. It presents basic principles and mechanisms of the successful dynamic QA systems, equally applicable both to solid waste management issues as a part of the environmental field and to other relevant project-oriented endeavors, e.g. health sciences. This broader character of the QA system's philosophy is of particular value. The quality assurance and quality control in specific solid waste management activities are addressed in the references and web sites to this chapter that provide the details of the relevant procedures and case studies.

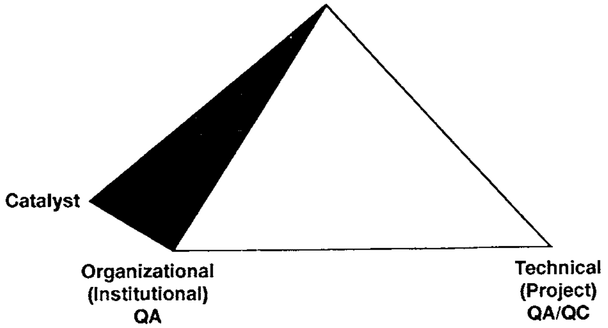

Figure IV.7.1. Dynamic quality system pyramid.

emphasis on production and engineering organizations. ISO/IEC 17025 (2000) (formerly ISO Guide 25) from the same organization adapts these guidelines to routine testing laboratories. Since early 1990s the US Environmental Protection Agency has been developing general QA management requirements intended for organizations generating environmental data (US EPA, 2001a). Other agencies have produced similar guidelines for their areas of concern (e.g. US DOE, 1991), and private authors have also presented their views on the essential elements of general QA management (Garfield, 1991).

These standards and guidelines, while differing in organization and emphasis, specify similar elements. In all cases, an organization's general QA practices must be documented in a QA management plan, which at a minimum describes the organization's policy and goals; the organizational structure of the QA effort and its relationship to the larger institute; the authorities and responsibilities of all parties, including both production and QA personnel; and the general activities and tools of the QA group. Depending on the nature of the organization, these documents also specify that the QA management plan addresses document control, flow-through provisions for subcontractors and vendors, product traceability, calibration requirements for instrumentation, training requirements, etc. Thus, the QA management plan provides the basic infrastructure that enables consistent quality procedures to be applied to similar projects.

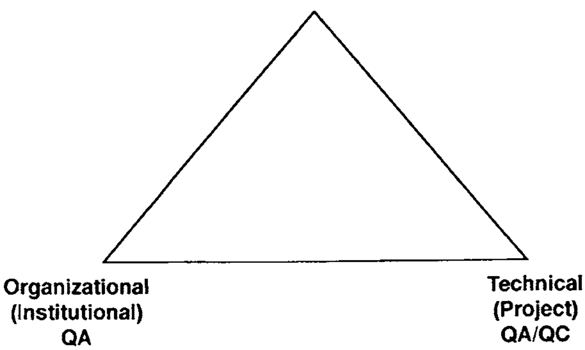

Figure IV.7.2. Normal quality system triangle.

Nevertheless, a quality system containing all the expected elements is no guarantee of success. Much like an Olympic athlete who possesses all the same body parts as the average person, so the quality systems of both mediocre and superior organizations possess the same QA elements. For both the athlete and the organization, it is how well these elements operate together that distinguishes the champion from the ordinary. It is not only the organizational elements, but also the sum of the attitudes and relationships – the culture of the organization – that lead to success or failure.

IV.7.3. Catalytic QA

The following text describes those catalytic aspects of QA management that are essential for an effective QA system. Much like a catalyst lowers the boundaries between reagents, the following "catalysts" make all of the organizational elements fit together to yield a product that is greater than the individual parts.

Communication is the glue that holds any organization together, and its importance to the QA system cannot be overemphasized. Like actual glue, communication must be applied consistently, must be accepted by all members, and must be allowed time to take hold.

What should the QA staff do to foster effective communication? First, the QA staff needs to take the initiative in identifying both internal and external customers of QA programs. (Here external customers are the end users of a company's product and internal customers are other groups within the institution who use QA services.) The QA staff must regularly contact these persons to establish effective communication. The *first* meeting should demonstrate the QA staff's sincere and serious commitment to a dynamic quality system. It is a confidence builder, plain and simple! *Second*, because the customer will likely spend several meetings venting past dissatisfaction or discussing both constraints and problems that affect their group, the QA staff needs to be good listeners. Listening is the least practiced form of communication. Effective listening will help the QA staff adjust their speaking and writing to get the QA message across. Active, attentive listening also communicates one's desire to understand and to engage in a mutual process. *Third*, the QA staff must be prepared to explain what QA can contribute and what QA requirements need to be satisfied. However, the QA staff should not plan to present everything at once. A more effective approach is to provide information when needed, when the user is likely to be most receptive. *Fourth*, the QA staff must be persistent. Developing effective working relationships requires time even when all parties are highly motivated. A major goal of the QA staff is to develop shared goals and effective mechanisms for achieving these goals.

Independence. The QA staff must report directly to top-level management to make independent judgments without concern for retribution and without the pressures of day-to-day production. This arrangement fosters independent thinking by the QA staff, for the benefit of all parties.

Management support. If the relationship with management is strained or not well established, a great deal of resistance to QA may result. For this reason, the QA manager should report regularly to management on QA activities, plans, and accomplishments.

The support of middle management is perhaps the most difficult to win, but the most important condition necessary for an effective QA program. Not only do middle managers strongly influence what resources will be directed towards QA efforts, but they also set the attitudes of much of the technical staff. Management must be approached on a basis of mutual trust and respect at the starting point. Comments by the QA staff regarding management or organizational performance must be non-threatening, lest critical information be obscured by a defensiveness that leads to attacks on the QA program. In the long run, relationships with project managers will become fruitful only when they realize that QA contributes to the quality of their projects and helps minimize rework/costs. The relationship with middle management should be a creative tension that is productive even if disagreements occasionally occur.

Employee involvement. Ideas for improvements can arise from any level within an organization. All employees should understand how their work product is used by others, and should be encouraged to contribute their ideas for product improvement. Incentive programs can assist in this area.

Full-time commitment. To benefit any organization, a QA program must be an empowered, intrinsic part of that organization, not an appendage. In establishing a QA program, the first step is committing full-time resources to QA, with no strings attached and no other assigned duties. Total commitment is paramount in reaching ultimate performance.

Substantial contributions. QA activities must make a difference. Otherwise, QA will be viewed as an irrelevant nuisance to be ignored while getting on with the "real work".

Customer awareness. The QA staff must be aware of the motivations and pressures on management and technical staff (the internal customer) in presenting its case. Resistance can be expected if QA procedures restrict the availability of traditional resources, add constraints, or require an excessive amount of documentation or labor. Sometimes changes recommended by QA simply meet institutional inertia, or challenge the egos of those who have labored long to establish the current procedures. Technical staff may also be concerned about additional labor requirements and delays, or may be facing imminent deadlines. If the project manager is packing for a sampling trip on Tuesday, then a lengthy QA review should not be planned for Monday!

Legitimate issues must be addressed in a forthright manner; after all, QA does require additional documentation, and sometimes QA reviews do unavoidably occur immediately before a sampling episode. The QA staff must strive to eliminate unnecessary cost and should avoid inopportune meetings, whenever possible. Discussions may need to be restricted to the most pressing issues with remaining topics postponed when deadlines are imminent. It is also helpful if the QA staff is able to provide convincing testimony regarding the long-term benefits of QA.

Since the QA staff can have an impact on the professional staff's decision to make a change, it is critical that credit and ownership go to the professional staff and not to the QA staff. Peak performance within an organization is the natural outgrowth of a partnership between management, the technical staff, and the QA staff. From persuasive presentations to painful prodding, the QA staff must help management and the technical staff to achieve their successes.

Lessons learned. The QA staff should be the corporate memory regarding lessons learned that might be helpful to future projects. Did some concerns that seemed critical during the planning stage turn out to be trivial? Were other important concerns overlooked? Were innovative procedures developed that might be useful for future projects? The QA staff should not only keep a log of such case studies as a benefit to future projects but also ensure dissemination of the information.

Celebrating success. How did QA benefit each project? Were some projects saved from failure by early intervention? Were some projects lost because QA advice was ignored? Were cost savings realized by a better focusing of effort? Success stories that embody the value of QA need to be shared with everyone, especially management.

Measuring quality. Quality should be measured over time to objectively assess quality improvement. For instance, a laboratory might track the percentage of reports delivered within schedule, or a research group might record the number of times their work is cited in the literature. These examples suggest that such measurements must be consumer oriented and must present data that allow the organization to take effective action.

Back-up support. A QA staff cannot possibly have all the technical expertise to cover every problem that may arise. It may be necessary to enhance the quality system by judiciously employing external QA support. This arrangement permits access to a wide range of practical experience and resources that are often unavailable within the organization.

Individual recognition. Undoubtedly the most important factor in achieving a quality product is the ability and dedication of the technical staff and management. Managers are acutely aware of this and spend great effort in recruiting and retaining talented scientists and engineers. To retain productive staff, the best performers should be awarded with improved salaries and increased professional challenges and opportunities. The QA staff can assist upper management in identifying the best performers by informing them of any outstanding achievements.

Education and training. The essence of an effective quality system is learning, not coercing or controlling. Learning takes time; it requires real problems to be solved; and it involves trial and error, experimentation, and tolerance for mistakes.

Training is an important component for any quality system. Training must be general and specific; appropriate and relevant; and timely. Quality training must target both specific audiences and specific skills.

Initial employee training should expose employees to QA concepts and philosophy. It should focus on general QA principles to make everyone cognizant of the "who, what, where, when, and why" of the QA process.

Awareness training, however, is of little benefit if specific skill training is not provided in a timely manner. Skill building must answer the "how to" question by introducing the customer to the tools and mechanisms for pursuing quality.

Finally, training benefits are best recognized when there are opportunities to apply the new knowledge. Consequently, "just-in-time" training – giving people the skills they need immediately before a project – is critically important. Unfortunately, "just-in-time" training requires a one-on-one training approach and is often neglected because of the short-term drain on resources. However, those organizations investing in this approach very quickly realize substantial returns.

Continuous improvement through "rapid inching". All quality systems must constantly evolve to remain relevant to the challenges of tomorrow. Take fast but small steps (rapid inching). Tweak your program and continually seek out small increments of optimization. Solicit constructive criticism and be prepared to change.

Vision. Envision the QA future in rich detail and then turn vision into action by practicing the nine E's:

1. *E*nvision the challenge.
2. *E*ntice others to become interested in the challenge.
3. *E*nable participants through education and understanding.
4. *E*ngage participants to create alliances.
5. *E*mbrace the cause of the team.
6. *E*mpower the team to action.
7. *E*mploy the team in action.
8. *E*njoy the rewards.
9. *E*nvision new challenges.

By envisioning the future, one embraces the belief that the future can be influenced. That belief helps create the fact.

IV.7.4. Technical (project) QA

The previous section discusses the attitudes and relationships, the QA catalysts, essential to an effective QA system. How are these general concepts applied to a specific project? Given the task of designing and verifying a cleanup action, or the task of assessing the effectiveness of a new test kit, or that of establishing the efficacy of a new vaccine; how does the QA staff apply the aforementioned concepts?

To illustrate some concepts applicable to projects in general, consider first a specific example, namely, an evaluation of a nearly mature, pilot-scale environmental control technology at a specific site. Figure IV.7.3 represents the general flow of activities for such a project from initial planning to release of the final report. Here, activities led by the QA group are shadowed to distinguish them from other project activities.

Project activities can be summarized as follows:

a. *Complete necessary preliminary studies.* For a project of this maturity, information from treatability studies and site characterization activities may be available to aid in experimental design. Further, any questionable measurement methods will be "debugged" before proceeding with the test. The extent of prior knowledge may vary significantly for other projects.
b. *Agree to project objectives.* Project objectives should be stated in the most quantitative form possible to aid in the subsequent design. An effective statement of project objectives must reflect the goals of all principal participants to the project, must be practical, and must define the scope of the investigation. Arriving at a clear statement of project objectives is perhaps more difficult but more important as the complexity of the project or the number of principal participants increases. Less explicit objectives may be needed for more exploratory projects.
c. *Prepare a written project plan.* Preparation of a written document relating project objectives to the individual measurements is central to any complex test. This document is important for the data producers in that it serves as the project "Standard Operating Procedure" for those groups involved in the sample collection,

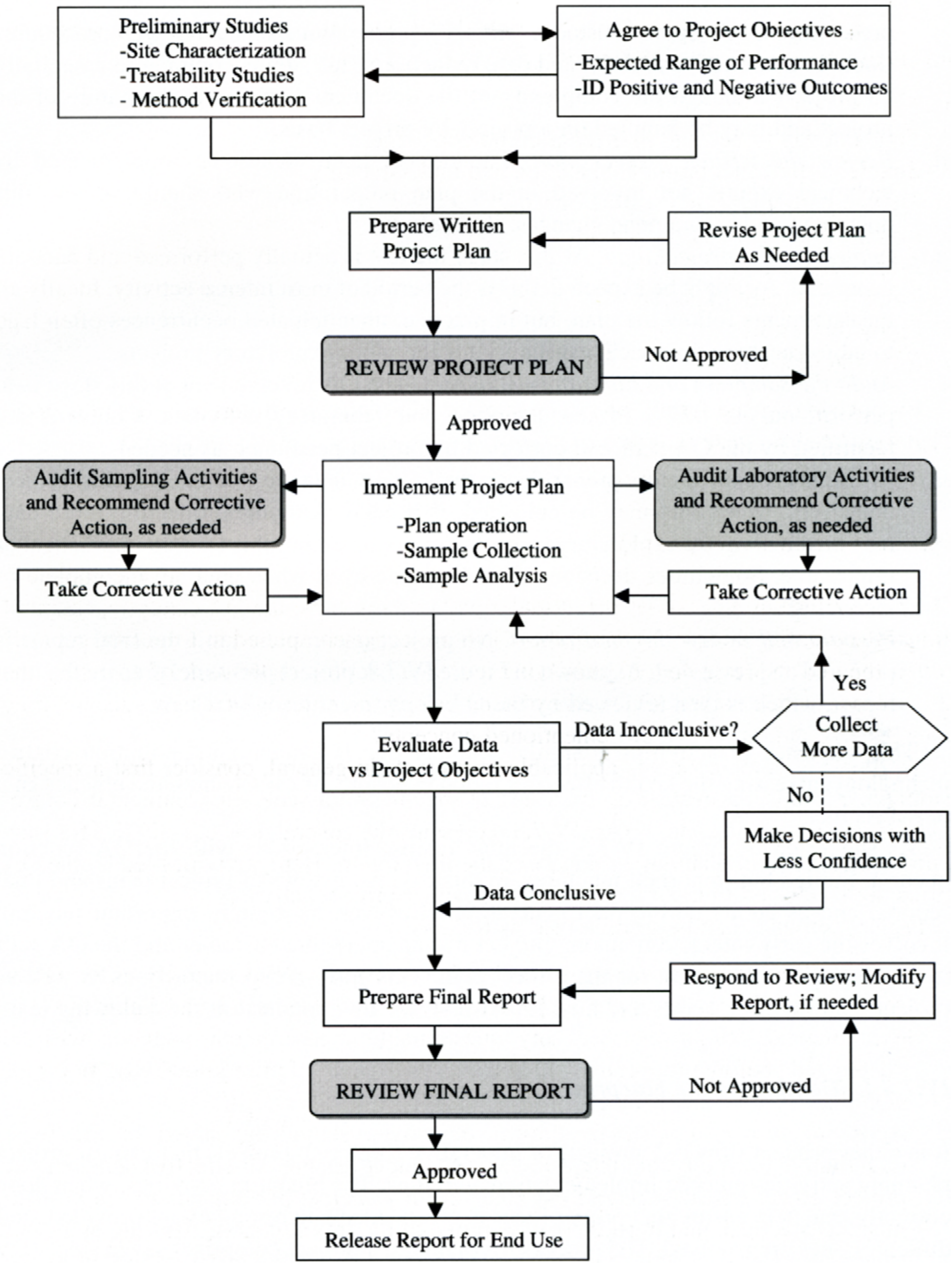

Figure IV.7.3. Typical flow of project activities.

preservation, transport, custody, storage, preparation, analysis, QC procedures (including corrective action), and data reduction. This step is common to essentially all projects although the complexity of the document varies with the nature of the project and may be handled on a project-by-project basis.

d. *Review the written project plan.* The project team should be supplemented by technical experts not involved in the plan preparation who should review this document and recommend changes, if necessary.
e. *Implement the project plan.* At this stage the test is actually performed and data are generated. As might be expected, this is the period of most intense activity. Ideally all measurements follow the plan, but in practice, unanticipated occurrences often lead to adjustments in approach, especially for the more exploratory projects.
f. *Audit the sampling and laboratory activities.* The QA involvement at this stage is to perform on-site audits of the sampling and laboratory activities. Concerns are identified by the QA staff and corrected by project personnel, as needed.
g. *Evaluate the data.* Before preparing the final report, data are evaluated against project objectives. More data may be collected, if needed. Although collecting more data may be the norm for exploratory projects, for major studies this is often impractical or impossible. Sometimes decisions must be made even when data are incomplete or inconclusive.
h. *Prepare and review the final report.* No project is complete until the final report is prepared and reviewed. As shown in Figure IV.7.3, project personnel prepare the final report, which is then reviewed by the QA department prior to release.

This sequence of activities is similar whether one is evaluating a pollution control technology, assessing the health effects of radon exposure, or establishing the efficacy of a new vaccine.

As suggested by Figure IV.7.3, the most intense interactions with the QA function occur at limited but important junctures, in this case as reviews of project plans and final reports, and as audits during data generation. However, an equally important juncture involves the early interaction among project management, the customer and the QA staff in developing the blueprint for the project plan. This early group interactions as well as project plan reviews, audits and final report reviews are explained in the following text.

IV.7.4.1. Developing the blueprint

It is either prudent (low risk project) or imperative (high risk project) that earnest project planning activities precede implementation activities. The blueprint activities, when done correctly, can help ensure that proper focus is given, adequate resources are provided, and difficult issues are resolved. The process for planning a project comprises seven steps (US EPA, 1994):

1. State the problem.
2. Identify the decision.
3. Identify the inputs to the decision.
4. Define the study boundaries.
5. Develop a decision rule.

6. Specify tolerable limits on decision errors.
7. Optimize the design.

Implementation of these seven steps results in qualitative and quantitative statements that pinpoint specific study objectives, define the types of data needed, define the statistical population the data are considered to represent, and specify the tolerable risks for false positive and false negative decision errors.

IV.7.4.2. Initial inputs (steps 1–3)

The initial inputs include a concise statement of the problem that is being addressed, the decision(s) that will be made based on the results of the study, and all of the critical parameters that are needed to make the decision(s). Parameter inputs may include decisions such as: list of analytes, sampling strategies, type of sample containers needed, sample preservation requirements, analytical methods that can be used, types of QC samples needed, approaches to statistical interpretations, etc.

IV.7.4.3. Define the study boundaries (step 4)

This step involves the defining of the physical boundaries of the site being investigated as well as the boundaries of the inference space (i.e. defining the conceptual population represented by the sample data). Defining the boundaries of the study, however, goes beyond defining the physical boundaries of the site. It also includes defining temporal boundaries (i.e. considering and addressing the potential impacts of seasonality or other time-related considerations and how these will be addressed in the data collection process).

One of the fundamental ideas that must be kept in mind when defining the boundaries of a study is that the decisions made, ultimately, rest on inference. Although one talks about measuring the concentration at a site and basing decisions on the data, what one actually does is make decisions on the basis of inferences that are, in turn, based on estimates. The analytical result on one sample is only one out of a theoretically infinite number of possible results for a theoretically infinite number of possible analyses of that sample.

IV.7.4.4. Develop a decision rule (step 5)

The decision rule is a summary statement that defines how a decision maker expects to use data to make the decision(s) identified in step 2. The same way that multiple decisions, for example, might pertain to multiple areas within a site, there may be (and often are) multiple decision rules for different areas of the site or for different pollutants. Development of a decision rule involves the following check steps:

- Specify the statistical parameter (e.g. mean, 90th percentile, upper tolerance limit, etc.) that characterizes the population of interest.
- Specify the action level of the study.
- Develop an "if…then" statement that describes the decision rule in terms of alternative actions.

IV.7.4.5. *Specify tolerable limits on decision errors (step 6)*

As noted in the discussion on defining study boundaries, decisions about a site ultimately rest on estimates of parameters of statistical populations. The true average concentration at a site is not known and is not knowable because it is a mean of an infinite population. Therefore, decisions based on average site concentration must be made using estimates of the true site average, developed on the basis of limited sampling data for an infinite population. This introduces sampling error into the estimate that is used as the basis for decision making. These estimates, which are based on measurement data, also have an inherent uncertainty associated with them because of random and systematic errors in the measurement process. These elements of uncertainty reflect measurement error. Because decisions are based on estimates that contain inherent uncertainties, there is always some risk of error in the final decision.

Decision errors are commonly divided into false positive errors and false negative errors. To reduce the risk of decision errors, the study design must include sufficient data collected in a statistically sound manner to adequately estimate the population parameter used as the basis for decision making. Uncertainty due to sampling error can be reduced by collecting large number of samples. Uncertainty due to measurement error can be reduced by using more precise and accurate analytical methods and by performing multiple analyses of each sample and averaging the results. However, reducing uncertainty and associated risk of decision errors increases the cost of collecting data. Therefore, one of the most important steps in the initial planning process is the sixth step, in which the acceptable risks of the two types of decision error are established.

IV.7.4.6. *Optimize the design (step 7)*

The seventh and last step of the initial planning process is to develop and optimize the project design. This involves integrating the outputs of the previous steps into the most resource-effective data collection design that satisfies the data user (i.e. customer) needs. The outcome of this last step will provide the necessary information to decide on one of two plans of action: (1) given the available resources, the project objectives can be achieved and, therefore, the project can move forward or (2) given the available resources, the project objectives cannot be achieved and, therefore, the initial planning process (steps 1–7) must be repeated with an adjustment to resources, project objectives or both.

IV.7.4.7. *Reviewing the project plan*

Even if no formal QA review were planned, preparing a written project plan is an essential step in any formal investigation. Preparing such a plan has the virtues of

- clarifying the thinking of all involved parties;
- integrating the goals and efforts of disparate project participants into a single document that can be reviewed by all;
- permitting a review by independent experts;
- providing clear instructions to data generators; and finally,
- fostering agreement on how data will be interpreted.

To achieve these goals, the project plan must not merely list the methods to be used, but must demonstrate how the intended measurements will achieve the project goals. This plan must provide concrete steps for assuring that the data will be of known and adequate quality, and should provide means for documenting data quality. The project plan should also assign responsibilities and establish means for regular communication among project participants.

The QA staff reviews this document in detail using experts in the field of interest. The primary question asked by the reviewers is "Will the planned test achieve the project objectives?" Questions relating to this central issue include the following: "Are objectives clearly stated? Are sampling and analytical methods appropriate, and are the applicable QC methods clear and adequate? Will data reduction and statistical procedures permit unbiased statements of overall uncertainty?" In short, the QA reviewer "thinks through" the entire project to recognize any problems beforehand, and then writes up observations in a detailed report that delineates each concern and its potential implication. This report is then sent to project management.

It is noteworthy that the project plan is "repaired" not by the QA staff but by project staff. It is thus essential that the reviewer describes all concerns clearly, emphasizing the effect that the planned approach will have on the outcome of the project. Once the cause-and-effect relationships are clear, project staff normally is anxious to solve the concern before it can develop into an intractable and perhaps embarrassing problem. It is also important that the QA reviewer avoids "nit-picking" and concentrates on the most important issues. Consequently, QA reviewers must be aware of the general programmatic setting and must be experienced and knowledgeable in the technical field of interest. Often it is necessary to employ multiple reviewers with complementary expertise to address all aspects of a project. To maintain the necessary objectivity and to provide a fresh outlook, it is also best that the QA reviewer not be previously involved in the project.

Keeping with the philosophy that project management – not the QA office – is responsible for overall quality, project management may choose to address all or some of the QA review comments. However, in the vast majority of cases, all review comments are satisfied before the project proceeds.

IV.7.4.8. Auditing the project

The audit can be divided roughly into three parts – planning, the site visit, and reporting. The planning stage must begin by defining the goals and scope of the audit, i.e. by defining the standard against which the audit will be performed. The auditor must become familiar with the planned measurements and should attempt to anticipate likely areas of concern. The auditor must also contact the principal participants to identify their requirements and to set up schedules. The site visit is the central activity and consists largely of personal interviews with technicians and other data generators. During this stage the auditor must inspect relevant operations, samples, and documentation. Any apparent concern must be brought up promptly and discussed as needed. A closeout meeting must be conducted at the end of the review to inform management of any concerns and to discuss possible corrective action, if needed. While a formal written report must be prepared after completion of the review, project management should not be "surprised" by any major findings in the follow-up report.

To be useful, the audit must be conducted early in the project cycle to permit corrective action before irreversible harm has occurred. Identifying concerns late in a project cycle is usually not constructive and does little more than build resentment.

Perhaps more than other QA tasks, the audit requires verbal and interpersonal skills. The auditor must take the lead and set the tone but at the same time must foster the free exchange of ideas. During an audit, most information is obtained from personal interviews with the individual technicians who handle the samples, and in this situation the auditor must be patient, perceptive, and persistent. While the auditor likely arrives with certain routine questions in mind, it is often the unexpected finding that leads to the most significant concern. After all, the technicians have likely been audited before and have consequently corrected the most common problems. Thus, flexibility and inquisitiveness are very important during the audit process.

Sometimes the auditor meets resistance and must persist to fully uncover an adverse situation. In these cases, it is particularly important to explain the potentially deleterious effect on the project, and to consider the opinions of all parties. The auditor must convince project management that the concern truly matters if corrective action is to occur.

IV.7.4.9. Reviewing the final report

The review of the final report is the last "inspection" before the "product" is released. As in the case of the project plan, the final report is reviewed by technical experts who were not involved in the project. The principal goal here is to assure that the data support the conclusions, that the major areas of uncertainty are identified, and that data are developed in a logical and consistent manner. A written review is prepared identifying all concerns and providing recommendations, as needed.

IV.7.5. Rules of engagement

The previous section briefly describes the tools available to the QA staff operating in a project environment. The following discussion presents guidelines to the QA staff regarding how they can apply these tools effectively.

Do your chores. QA staff in a project environment typically find themselves dealing with a variety of subject matter and personnel. Indeed, it is this feature that primarily distinguishes a project management environment from routine production setting. Nevertheless, the QA staff is expected to carry out certain routine tasks for nearly every project. For environmental projects, these tasks include reviews of test plans and final reports, on-site inspections during testing, and occasionally assistance to project management. Regardless of the setting, though, these operations constitute the most tangible and immediate contribution to project execution, and it is in this context that interaction with project management most often occurs. Consequently, such operations must be given first priority as the mechanism for making significant contributions and for building rapport with project management.

Require a written project plan. A written plan describing how project objectives will be achieved and how the needed quality will be assured is considered central to any investigation. For this reason, groups as diverse as the US Environmental Protection

Agency (US EPA, 1998, 2001b), the Japanese Ministry of Trade and Industry (1984), and the Organization for Economic Cooperation and Development (OECD, 1992) have for many years required that projects begin with a written plan. Subsequent experience has shown that preparation and review of a written plan clarifies issues and helps avoid errors. The various benefits of preparing a written plan were discussed previously.

Document your needs. The agencies cited previously provide only general guidelines for QA compliance. Unless the QA staff translates these into specific requirements for the projects typical of their work place, project managers will not know what is expected. In this situation QA requirements may simply be ignored, or efforts may be extensive but misguided. It is thus essential that the QA staff develop written guidelines translating the general organizational goals into specific, local requirements.

Be flexible. Diversity and variety are one hallmark of a project management setting. It is not unusual for the QA staff to deal with projects as disparate as basic research, demonstrations of mature technology, legal investigations, or even epidemiological studies. Professionals involved may include engineers, scientists, legal staff, economists, or medical personnel. In a university research setting, speed of response and flexibility are of utmost importance, and experiments can simply be repeated if results are inconclusive. In contrast, a demonstration of pilot-scale technology or a major epidemiological study may waste millions of dollars if results are inconclusive. In such situations the QA staff must adapt to the nature of the work and the potential risks, allowing the basic researcher maximum freedom while minimizing the risk of costly errors. This means providing different QA guidelines for different types of projects.

Set priorities. To make the most significant contribution, QA efforts must be weighed against the potential benefit. This means that QA involvement should be focused where the cost of wrong decisions is greatest, or in those areas most prone to problems. From this perspective, natural areas of focus are large programs requiring the participation of multiple parties.

Don't dilute responsibility. As is suggested by Figure IV.7.3, QA is only a small (but very important) part of the overall project effort. Here the QA manager may be likened to a visiting uncle who provides child-rearing advice to the parents. No matter how insightful the advice may be, the uncle's understanding of the situation is always less than complete, and consequentially the final authority and responsibility must rest with the parents. Further, unless such advice is offered with tact, it will be ignored and perhaps even resented. Similarly, the project management martials the resources, selects the personnel, makes the day-to-day decisions, and is fully involved over the entire duration of the project. The project manager must have the final authority and responsibility for the quality of the project. This means that the project manager may reject the advice of the QA staff, although in practice this is not likely to occur very often.

It has been said that "quality is everyone's responsibility." This is true in the sense that everyone needs to look beyond his/her limited assignment and take initiative to improve the final product. This statement means that the QA staff must perform their tasks competently and always be alert for additional methods of improving the final product. Nevertheless, the project manager has special responsibility for directing the effort and for acting as the "gatekeeper" of the product, not allowing the release of any product of inadequate quality.

Be on time, be prepared, and be an expert. There is a saying among project managers, "On time, on budget, on spec. – choose two!" In contrast, the QA staff must deliver in all three regards to gain the cooperation of project managers. The most insightful review, delivered when the subject activity is complete, is worthless. This means that on-site reviews must be completed early in the project to permit effective corrective action, if needed. Similarly, efforts must be completed within budgetary constraints and with minimum disruption to the project. Finally, it is not enough to be merely an expert in QA; the QA reviewers must also be technical experts in the subject area. If the QA team does not have the appropriate technical background, then it becomes necessary to find someone who does.

Be clear, but not confrontational. The QA staff should neither equivocate nor be unnecessarily confrontational. State the potential concern in terms of its possible impact on the project. Listen respectfully to possible explanations and suggested corrective action. Remember, what originally appears to be a serious shortcoming frequently becomes reasonable once further explanation is provided. If need be, contact upper management to resolve the problem. However, almost without exception, concerns can be resolved by the mutual effort of project participants.

Find the principles. In a large organization it may be difficult to identify what projects are underway and who is working on them. This means that some projects may evade QA oversight entirely, or that QA documentation may be prepared without the needed guidance. The QA staff may discover such projects only when a poorly prepared project plan is delivered for review. To provide uniform QA oversight in the most cost-effective manner, the QA staff must implement a mechanism for identifying active projects and the accountable project managers.

Take the initiative. The QA staff, because of their exposure to a wide range of projects, is uniquely situated to identify frequently occurring problems. For instance, the QA staff may become aware that several investigators need help in selecting appropriate statistical procedures in certain recurring situations, or that an important QA procedure is frequently overlooked. The QA staff should take the initiative and recommend solutions. The QA personnel should also be alert to possible cost savings that might be realized without degrading quality. Some project planners provide for an excessive number of expensive measurements, and such situations should be brought to the attention of project management for cost reasons, even when there is no adverse effect on quality.

IV.7.6. Summary

As depicted in the QSP (Fig. IV.7.1), a dynamic quality system consists of three interdependent parts:

- *Organizational (institutional) QA*: The management structure that provides the needed organization, tools, and resources.
- *Catalytic QA*: The attitudes and relationships among staff needed to make all of the organizational elements fit together to yield a product that is greater than the individual parts.
- *Technical (project) QA*: The application of concepts to a specific project.

None of the parts can be successful without the other parts. While the principles previously described are taken from the perspective of one working in the environmental field, it seems likely that they would apply equally well (with some adjustments) to other project-oriented endeavors such as the health or forensic sciences.

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References

Garfield, F.M., 1991. Quality Assurance Principles for Analytical Laboratories, 2nd edn. Association of Official Analytical Chemists (AOAC), ISBN: 0-935584-46-3.

ISO Central Secretariat, 2000. ISO 9000: 2000 Series International Standards for Quality Management, 3rd edn. International Organization for Standardization, Geneva, Switzerland, December 15, 2000.

ISO/IEC 17025 International Standard, 2000. General Requirements for the Competence of Calibration and Testing Laboratories. International Organization for Standardization, Geneva, Switzerland.

Japanese Ministry of International Trade and Industry, 1984. GLP Standards Applied to Industrial Chemicals and Annexes. Notification Number 85, March 31, 1984.

OECD, 1992. The OECD Principles of Good Laboratory Practice. Environmental Monograph Number 45, Paris, France, OECD/GD(92)32.

US DOE – Department of Energy, 1991. Good Laboratory Practices. Code of Federal Regulations, Title 21, Part 58; Current Good Manufacturing Practice, Order DOE 5700.6C, United States Pharmacopeia, Part 210, August 21, 1991.

US EPA – Office of Research and Development, 1994. Guidance for the Data Quality Objective Process. EPA QA/G-4, EPA/600/R-96/055, September 1994.

US EPA – Office of Research and Development, 1998. Guideline for Quality Assurance Project Plans. EPA QA/G-5, EPA/600/R-98/018, February 1998.

US EPA – Office of Environmental Information, 2001a. EPA Requirements for Quality Management Plans. EPA QA-R2, EPA/240/B-01/002, March 2001.

US EPA – Office of Environmental Information, 2001b. EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations. EPA QA/R-5, EPA/240/B-017003, March 2001.

For further information

ASTM: D5283-92 (1997) Standard practice for generation of environmental data related to waste management activities: quality assurance and quality control planning and implementation Book of Standards Vol. 11.04 ASTM Int.West Conshohocken, PA, 2002 p. 18. Web site: http://enterprise.astm.org/PAGES/D5283.htm.

US EPA 2001 – Region 9 Quality Assurance References and Guidances Region 9 Office San Francisco, CA Web site: http://www.epa.gov/region09/qa/r9-qadocs.html.

US EPA, 2002. Quality control, Chap. 1SW-846. Test Methods for Evaluating Solid Wastes. Physical/Chemical Methods 3rd edn Washington, DC, July 2002. Web site http://www.epa.gov/epaoswer/hazwaste/test/main.htm.

US EPA, 2001. Quality Manual for Environmental Programs (5360 A1), update May 2001. Web site: http://www.epa.gov/quality1/qs-docs/5360.pdf.

US EPA, 2002 – Technology Innovation Office. Quality Assurance Guidance for Conducting Brownfields Site Assessments. EPA 540-R-98-03.

WTQA, 2000. QA – then, now and next. Technical Session Proceedings of 16th Annual Waste Testing and Quality Assurance Symposium: "Environmental Sampling and Analysis in the 21st Century"American Chemical SocietyWashington, DC August 2000, pp. 63–96. Web site: http://www.epa.gov/epaoswer/hazwaste/test/proceedongsdoclist.htm.