Guidelines for Preparing SAPs Using Systematic Planning and PBMS

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The term "data quality" is one that we see used very frequently with regard to environmental issues with a wide variety of meanings. Historically, much environmental data has been generated using very prescriptive approaches to sample analysis. In many cases, this analytical data is also accompanied by voluminous stacks of quality control data to document the "high quality" of these data points. However, in too many cases, this "high quality" data is inappropriate to be used in making some of the decisions for which it was originally intended, because of a lack of proper project planning. In other words, the project planning failed to generate a data set of the type or quality that was needed to answer the questions required to support the decision.

In this article we will discuss some approaches that will be helpful for generating data sets that will be appropriate and usable for their intended purpose—making environmental decisions. Some of the concepts that we will describe include: systematic planning of projects; some basic concepts regarding the performance-based measurement system (PBMS) approach to environmental monitoring; use of the term "effective data" to acknowledge that data collection, generation and interpretation activities are meaningful only when solidly anchored *in the context of the intended use of the data*; and the basic elements that need to be considered when preparing a sampling and analysis plan (SAP) as an integral part of the overall project planning process.

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Systematic Planning

It is the U.S. Environmental Protection Agency's (EPA) official position that systematic planning always be done before collecting environmental data. EPA Order 5360.1 CHG 1 requires that work performed by, or on behalf of, EPA be governed by a quality system to ensure the technical validity of products or services. The *EPA Quality Manual for Environmental Programs* explains that "environmental data operations shall be planned using a systematic planning process that is based on the scientific method. The planning process shall be based on a commonsense, graded approach to ensure that the level of detail in planning is commensurate with the importance and intended use of the work and the available resources." Three basic questions derived from the scientific method need to be answered before a project should be started:

- What is the purpose of the project?
- How will the data generated ultimately be used?
- What quality of data is needed to accomplish the goals of the project?

Systematic planning is the scaffold upon which defensible site decisions are constructed. The essence of systematic planning is asking the right questions and strategizing how best to answer them. First and foremost, planning requires that key decisionmakers collaborate with stakeholders to resolve clear goals for a project. A team of *multidisciplinary, experienced technical staff* then works to translate those goals into realistic technical objectives. Access to appropriately educated, knowledgeable practitioners from *all* disciplines relevant to the site's needs (not just engineering specialties) is vital to cost-effective project success.

Environmental practitioners are slowly coming to the realization that modern characterization and cleanup technologies have the potential to save money and speed the cleanup of hazardous waste sites. Not only can resources be saved, but at the same time the reliability and protectiveness of cleanup decisions can be improved, thus increasing the confidence and satisfaction of the public and other stakeholders in the cleanup process. This seemingly impossible "best of all possible worlds" is achievable when real-time results (generated usually by on-site analysis) are used to guide real-time site decisionmaking (through the use of a dynamic work plan), so that the "right amount" of the "right kind" of data are collected at the "right time" to make the "right decisions." In the hands of a team of competent technical professionals and with sufficient up-front systematic planning, this approach increases the likelihood that the nature of contamination and the best cleanup options will be determined rapidly and accurately.

A key tool used by successful project managers is a conceptual site model (CSM). Using all available information, the technical team develops a CSM that crystallizes what is already known about the site and identifies what more must be known in order to achieve project goals. A project's CSM may take any (or several) of a number of formats that can effectively portray site concerns, such as exposure scenarios, contaminant distribution, fate and transport, or other issues. The team will then use the CSM to direct field work that focuses on the information needed to remove important unknowns from the model. Data that is not needed to influence specific site decisions will not be collected. All proposed site activities must be tied back to defined project goals. This will allow the CSM to evolve as site work progresses and data gaps are filled. The CSM thus serves several purposes: as a planning instrument, as a modeling and data interpretation tool, and as a communication device among the team, the decisionmakers, the stakeholders and the field personnel that keeps all parties focused and on track.

During the planning phase, the most resource-effective characterization tools for collecting data are identified by technically qualified staff who are familiar with both the established and innovative technology tools of their discipline. The hydrogeologist will be conversant not only with the performance and cost issues of well drilling techniques, but also with the more innovative and (generally) less costly direct push technologies entering common use. The team's analytical chemist will not only know the relative merits of various traditional sample collection, preservation, preparation and analytical methods, but also the strengths and limitations of innovative techniques, including on-site analytical options. The chemist's responsibilities include designing the quality control (QC) protocols that reconcile project-specific data needs with the capabilities of the selected analytical tools, and ensuring that the data generated will be of known quality.

Systematic planning should be integral to all stages of a project's lifetime, from characterization through remedial and monitoring activities. It provides the structure through which foresight and multidisciplinary technical expertise improves the scientific quality of the work and avoids the blunders that sacrifice time, money and the public trust. It guides careful, precise communication among participants and compels them to move beyond the ambiguities of vague, error-prone generalizations. Its use should be automatic for all environmental projects.

Systematic planning for data collection can be performed in a variety of ways, depending on project needs. As an example, we will use the EPA's Data Quality Objectives (DQO) process.[1] The DQO process involves the entire planning cycle for a project and encompasses all of the activities necessary for its completion including sampling, testing and data evaluation activities. The process involves seven steps (Table 1) and will yield qualitative and quantitative statements that: clarify the study objective; define the type, quantity and quality of required data; determine the most appropriate conditions under which to collect the samples; and specify how the data will be used. As an example, we will briefly describe how the DQO process was applied to an ongoing EPA Office of Solid Waste study involving industrial surface impoundments, which we will refer to as the Nonhazardous Waste Surface Impoundment Study (SIS).

1. State the problem.
2. Identify the decision.
3. Identify inputs to the decision.
4. Define the study boundaries.
5. Develop a decision rule.
6. Specify limits on decision errors.
7. Optimize the design for obtaining data.

Table 1. The seven steps in the data quality objective process.

Step 1. Concise Description of the Problem. Congress mandated that EPA study industrial wastes managed in surface impoundments, not classified as hazardous wastes under the Resource Conservation and Recovery Act (RCRA), to characterize the population of these nonhazardous waste surface impoundments in the U.S., and to estimate the potential health and ecological risks from chemical releases from these nonhazardous surface impoundments. These risk estimates will be used to determine whether EPA needs to develop regulations to address potential risks. In addition to the risk estimates, EPA will use the information to profile the attributes of nonhazardous waste surface impoundments and their physical

settings, such as their hydrogeologic settings, geographic distribution and surface impoundment use patterns across industries.

Step 2. Identify the Decision. The primary decision statement associated with the overall SIS is to determine whether releases from surface impoundments that are within the scope of the study pose unacceptable human and ecological risks and require further action, or to recommend that no further study or action is necessary. Several additional decision statements for the field sampling and analysis component of the SIS include the following:

- Determine, using actual field monitoring data (both submitted by facilities and generated by EPA), whether the multimedia models used provide accurate output.
- Determine, using EPA field monitoring data as a "spot-check" and process knowledge, whether facility-supplied data is within the range of expected values.
- Determine if there are gaps in the industry-supplied data, and whether these gaps should be filled by conducting field sampling and analysis or by requesting additional information/clarification from the facility.

Step 3. Identify Inputs to the Decision. In this section, for brevity, we will only mention a few of the key example inputs for the decision contained in the DQO document of the SIS quality assurance project plan (QAPP):

- *Risk goals to be achieved:* Cancer risk no greater than 10^{-5} and hazard index no greater than 1.
- *List of chemical constituents:* Will be facility or industry-category specific, based on analytes reasonably expected to be present.
- *Influent and effluent flow rates.*
- *Analytical methods:* Need to have sufficient sensitivity to determine the target analytes in the target matrices at the risk levels of concern.
- *Sampling procedures:* Must be representative of the wastestream sampled and of the decision and must take into account spatial or temporal considerations.

Step 4. Define the Study Boundaries. In this case, the study spatial boundary was the U.S., and the temporal boundary was the period of time allotted for collecting the samples (Summer 2000). The sample data will apply only to the time at which the samples were collected. Modeling will be used to predict future movements of the constituents.

Practical constraints may include limited physical access to a sampling location; unfavorable weather conditions; unexpected waste characteristics (may require special shipping containers or sampling devices); health and safety issues; unavailability of waste (no influent at time of sampling); and lack of cooperation from facility.

Step 5. Develop a Decision Rule. There are no concentration-based action levels defined for decisionmaking. The risk assessment process will generate estimates of risk based on the previously stated risk goals of cancer risk no greater than 10^{-5} and hazard index no greater than 1.

Step 6. Specify Limits on Decision Errors. To specify the decisionmaker's tolerable limits of decision error, it is necessary to determine the possible range on the parameter of interest; identify the decision errors and choose the null hypothesis; specify an acceptable margin of error; and specify an acceptable probability of making a decision error.

Step 7. Optimize the Design for Collecting the Data. Prepare a series of site-specific SAPs and delineate the analytical design and sampling design. Optimize the analytical design by analyzing only for those contaminants of concern reasonably expected to be present in the waste or only for those constituents for which data are missing and required by EPA. An initial list of constituents was used as a starting point for developing the site-specific SAPs. Sampling design options include simple random, stratified random, systematic or authoritative/judgmental sampling. By design, the population of interest will be stratified. Due to practical constraints, field sampling will be judgmental. Include the number of samples of each type to be collected and the appropriate QC samples in the individual SAPs.

The PBMS Approach

We will only briefly discuss PBMS in this article, since we have covered it in detail in previous articles. In a *Federal Register* notice, EPA defines PBMS as a set of processes wherein the data quality needs, mandates or limitations of a program or project are specified, and serve as criteria for selecting appropriate methods to meet those needs in a cost-effective manner.[2]

Using the PBMS approach, the operator must use some form of systematic planning to establish the goals and data quality needs for the particular project and be able to answer the following key questions that will help determine the appropriate methods to be used:

- What is the purpose of this analysis? (Why are we doing this?)
- How will the data be used? (What decisions will it support?)
- How good does the data have to be, or what quality of data do we need to support the decision?

The analyst has a great deal of flexibility in method selection. However, when a method is selected for a particular application, the analyst must be able to demonstrate and document that the method(s) performance meets the data quality requirements of the project. Two separate factors are involved in demonstrating method applicability: First, demonstrating that the operator can perform the method properly in a clean matrix with the analytical system under control, and second, demonstrating that the method selected generates "effective data" in the matrix of concern. The former is a lab or operator training/proficiency issue, while the latter involves demonstrating that the method selected performs with the appropriate selectivity, sensitivity, bias and precision, in the actual analytical matrix, to achieve project goals.

Effective Data

It is often unappreciated by the environmental community that the use of definitive analytical methods does not necessarily guarantee the generation of acceptable data. When these elements are overlooked, the ability of data to support defensible project decisions may be questionable, even if that data was generated by a definitive method. Conversely, the environmental community seldom appreciates that screening methods can be extremely powerful tools when demonstrations of proficiency and applicability are performed. It is helpful to review a few basic concepts about why this is so.

Screening vs. Definitive. The term "screening" implies that the degree of uncertainty associated with the analytical results is high enough (relative to the project goals) so that the analytical information provided is *suggestive* of certain conclusions, but these conclusions are not "airtight." Stated another way, more than one interpretation of the results is possible if no other evidence is used to rule out alternative interpretations. On the other hand, the term "definitive" implies the opposite: that the degree of uncertainty in the analytical information is low enough (i.e., the confidence is high enough) that reliable conclusions may be safely drawn based on the analytical results alone. The chance that a significantly different interpretation could be used to explain the data is quite small.

There is no sharp demarcation between "screening" and "definitive." The concepts lie on a continuum and what constitutes "definitive" in the context of one project may be "screening" in another.

Methods vs. Data. Environmental practitioners have tended to assume that definitive methods will unfailingly provide them with "definitive data." This is an erroneous assumption. A "definitive analytical method" may be described as one that is based upon scientific principles that *theoretically* will permit the generation of data that has a sufficiently high degree of certainty for both the identity and the quantitation of the analyte(s) under ideal conditions. It is tempting to assume that "ideal conditions"can be ensured by prescriptively specifying the analytical methods to be used, or the details about how those methods will be performed. However, the unpredictable nature of many environmental matrices and the wide range of sample types encountered in the environmental field invalidates such one-size-fits-all assumptions (except in a few specific instances such as drinking water). Mandating the use of definitive methods does not, and cannot, guarantee that environmental data will automatically lead to the correct conclusions. It is ironic that the very prescriptiveness that many regulators trust to give them "high quality" data points can actually sabotage the ability of definitive environmental methods to produce it.

For example, many definitive determinative methods are used to generate data for a long list of compounds. *EPA Method 8260, Volatile Organic Compounds by GC/MS,* has been demonstrated to be applicable for the determination of at least 135 compounds using a variety of sample preparative methods. However, this does not mean that the exact same gas chromatography/mass spectrometry (GC/MS) operating conditions should be used for every compound on the list, nor are all of the listed compounds amenable to a single sample preparation method. It is not possible to optimize a single determinative method to cope with the range of properties (e.g., volatility, solubility, polarity, and so on) presented by a large number of compounds all at the same time. When a determinative method like Method 8260 is prescriptively "generalized" to try to cover all potential analytes on its list at the same time, some analyte results will *necessarily* be less accurate than others, and some will be impossible to obtain. The same principle applies to generalizing a single sample preparative method to simultaneously encompass a wide range of compounds. Some analytes will demonstrate good recoveries, others will have poor recoveries. It is not the fault of the lab–it is a fact of nature that becomes more pronounced as sample matrices become more complex. Accurate results are much more likely when a limited number of specific analytes of interest are requested, and the analyst is given the freedom to optimize the performance of both the determinative and preparative methods as necessary for those analytes.

Prescriptive methods jeopardize the quality of data produced by definitive methods in other ways. Overly rigid standard operating procedures (SOPs) obstruct the analytical flexibility needed to modify or substitute methods to accommodate complex environmental samples. Matrix interferences (due to its physical or chemical characteristics) can severely degrade recoveries or raise analyte detection limits relative to the regulatory action levels, so that a result of "non-detect" is misleading or meaningless. Moreover, even if the method provided completely accurate results for what is present in the sample at the time of analysis, the data may not be representative of the original matrix if the sample preservation was inadequate, the sample was collected from a nonrepresentative area of the matrix, or if too few samples were collected to evaluate the effect of heterogeneity on the reliability of the data set. Figure 1 shows a schematic of a site with two hot spots to illustrate how too few data points do not produce a reliable data set, even though the data points may themselves be highly accurate.

A method may be considered to be a "screening method" for two reasons: First, because it is known to be subject to a number of interferences or cross-reactivities, and thus the identity of the compound producing the analytical response may be somewhat uncertain; or second, because the assay is more imprecise than is generally seen as desirable, and thus the quantitation may be relatively uncertain. When considered in a vacuum, these characteristics may appear to limit a method's usefulness. However, when considered within the context of a particular project and particular project decisions, it may be possible to control for these uncertainties with other information provided by the site history. Additionally, in the hands of competent chemists data produced by screening methods will be of known and documented quality when an adequate QC protocol is followed.

As symbolized in Figure 1, the lower cost of many screening methods allows more samples to be collected from the site to address heterogeneity issues. As long as the analytical uncertainty is significantly less than the sampling uncertainty (created by the heterogeneity of the matrix), the denser data coverage supported by "screening methods" will produce a much more informative data set (i.e., a data set representative of actual site conditions). When few "high quality" data points are collected, it is often unknown whether they can be trusted to meaningfully represent the true condition of the site with respect to the site decision.

Introducing the Term "Effective Data". The need for data generation designed to be matched to the intended use of the data can not be overstated. Yet the current

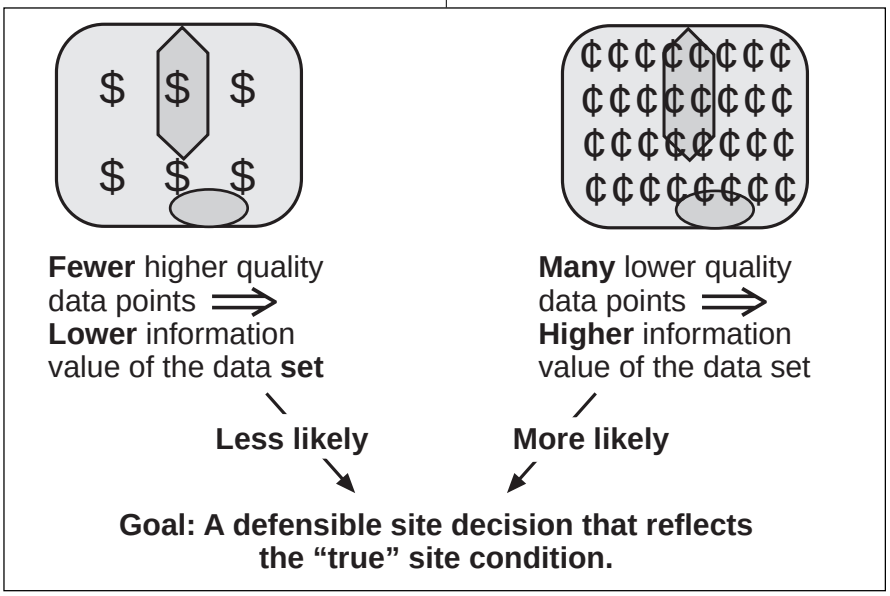

Figure 1. Data quality vs. information value.

language, especially the way the terms "screening" and "definitive" are used, tends to focus on data quality in a vacuum. As we have seen, this fosters erroneous assumptions and misdirects scarce data collection budgets. Therefore, a new term, "effective data," is proposed to acknowledge that the information value of data is not solely dependent on the nature of the analytical method, but also on how the data are to be used to make decisions and what context surrounds those decisions.[3]

"Effective data" are defined as analytical data of known quality that are effective for project decisionmaking. This means that effective data meet project requirements without requiring additional confirmation testing to back them up on an individual, point-by-point basis. The term effective data acknowledges that data generated by a "screening method" may still be adequate (i.e., effective) to meet project goals either because the degree of uncertainty is inconsequential with respect to the decision to be made, or because other project information (i.e., the context) controls for the uncertainty present in the screening method. Documented demonstrations of proficiency and applicability are vital to establish that data are indeed effective, and under PBMS this is as important for definitive methods as for screening methods.

We briefly present here a hypothetical example to illustrate application of the concept of effective data. Assume that a project is using an immunoassay kit for polychlorinated biphenyls (PCBs) in a quantitative screening mode to tests drums of PCB-contaminated soils for disposal purposes. In a "quantitative screening mode," numerical data are generated through an analytical design that maximizes the reliability as defined in the project DQOs of "yes" or "no" decisions around a predefined action level. In this illustration, the project decision is to decide whether individual drums are to be routed for treatment under the Toxic Substances Control Act (TSCA) regulations (if the mean concentration of PCBs in the drummed soil is equal to or greater than 50 ppm) or under RCRA regulations (if the mean concentration of PCBs in the drummed soil is less than 50 ppm). Treatment of the drummed waste under TSCA is more expensive than treatment under RCRA. A comparison of the list of non-PCB crossreacting compounds for the immunoassay (provided in the package insert) with evidence provided by site records found no likelihood of potential crossreactive interferences to affect the performance of the PCB immunoassay at the action levels. For the sake of this hypothetical example, assume the following: sufficient systematic planning and an optimization study (that also included demonstrations of proficiency and applicability) ensures that the sampling design will provide samples representative of the drum mean to the degree of certainty specified in the DQOs; that the immunoassay procedure accounts for the specific Aroclor in the drums and aging/weathering effects; and that the ongoing field quality assurance/quality control (QA/QC) protocol would be adequate to ensure that all field data would be of known quality.

Also assume that he selected immunoassay test kit is known to have a built-in positive bias that serves to minimize the likelihood of false-negative decision errors with respect to an action level. From the hypothetical optimization study, project/kit-specific decision levels should be established at kit results of 45 ppm and 65 ppm. A kit result at 45 ppm or below would demonstrate (to the degree of certainty specified in the project DQOs) that the drum contains less than 50 ppm of PCBs and could be treated under RCRA. A kit result of 65 ppm and above would indicate that the drum most likely (to the degree of certainty specified in the project DQOs) contains more than 50 ppm of PCBs and is a TSCA waste. Drums with immunoassay results between 45 ppm and 65 ppm would be reanalyzed by a more definitive fixed-lab method (gas chromatography/electron capture detection [GC/ECD] using pressurized fluid extraction for sample preparation, SW-846 Methods 8082 and 3545). The GC/ECD results would be effective to determine whether these drums were to be handled as RCRA or TSCA wastes. Confirmation testing of immunoassay results in the 45-65 ppm range would be cost-effective, because many of these drums would be classified as RCRA waste, thus saving the cost of TSCA disposal. When immunoassay results are higher than 65 ppm, the probability of classifying a drum as RCRA waste would not outweigh the cost of Methods 3545/8082 confirmation testing.

In this illustration, immunoassay results less than or equal to 45 ppm or greater than or equal to 65 ppm would be considered "effective data," since drum-by-drum decisions would be made on the basis of the immunoassay data without needing backup testing. Immunoassay data between 45 and 65 ppm are designated as "not effective for project decision-making" because of the high potential for false-positive decision errors with respect to the action level (i.e., erroneously classifying the drum as TSCA waste) because of the positive bias of the kit. Although the immunoassay kit would not provide effective data in a 20 ppm window around the regulatory action level, significant funds would be saved over the life of the project by identifying the borderline drums needing the more expensive definitive analysis, and by shortening the result turnaround time so that rapid on-site decisionmaking would be possible.

Thus, the concept of effective data integrates the project-specific use of the data with the strengths and limitations of a particular analytical method to produce reliable information capable of supporting transparent, defensible project decisions. Since the use of a "definitive method" cannot guarantee "definitive data," sometimes it may be advisable to use a second method to confirm results of a primary method even when the primary method is considered to be a definitive method, e.g, second column confirmation of GC or high-performance liquid chromatography (HPLC) results. When screening methods are used, a certain level of confirmatory analysis will likely be part of the project-specific QA/QC protocol that establishes the ongoing reliability and comparability of the data set. (However, these confirmatory analyses cannot be the *sole* basis for establishing method reliability.) Depending on a number of factors (e.g., the project-specific performance of the method, how many sample results are actually found near the regulatory action level, how the QC protocol is designed) the number of samples actually sent for QC confirmatory analysis might be very low or very high. The rationale for the selection of QC confirmatory analysis should be explicitly described in the project's QA/QC protocol.

Basic Elements of SAPs

Sampling and analysis plans are an integral part of the systematic planning process. In many cases, SAPs are required in RCRA regulations, either as standalone documents in the groundwater regulations or as a part of a waste analysis plan (WAP) for a permit. They are also a key part of a QAPP for other RCRA regulated or information-gathering activities. While the PBMS approach allows a great deal of flexibility in methods selection for SAPs, once the document is prepared with detailed methods descriptions for all methods used, any deviations from the meth-

ods procedures must be documented with a rationale for the deviation.

The key elements that should be included in SAPs are detailed in the following section using the previous example as in the DQO section, the SIS. A generic QAPP was prepared for overall project activities, with provisions for developing site-specific SAPs based on information received from the affected facilities.

Step 1. SAP prepared based on available information prior to initiation of the project. A SAP is basically a "what to do" and "how to do it" document for a particular project. Therefore, it seems that logic would dictate that the SAP be completed and reviewed *prior to* initiating sampling and analysis for that project. In too many cases today, however, this is not done, and much too often data are generated that are not usable for their intended purpose. Therefore, it is imperative that whether the project planners use the DQO process or another form of systematic planning, a SAP must be prepared prior to starting up the project to increase the likelihood that "effective data" will be generated for that project. The SAP should be based on available information about the project. If one is preparing a SAP as part of a WAP for a RCRA permit, then the SAP would be designed around the available information about the waste-stream(s) involved.

Some of the basic questions that we need to address when preparing a site-specific SAP include:

1. Why are we doing this project?
2. What is the regulatory driver?
3. How will the data ultimately be used?
4. Will the ultimate decision be risk-based or technology-based?

The answer to the first question is the key point on which any project planning should be based. What is the goal of this project and what decisions need to be made to achieve it? Some RCRA examples include compliance with specific regulations, site cleanups for corrective action, delisting petitions, application for a RCRA permit, and groundwater monitoring around RCRA treatment-storage-disposal facilities (TSDFs).

As for Question 2, many sampling and analytical activities under RCRA are regulation driven. In preparing a viable SAP, one must be able to identify the relevant regulatory sections for the specific application and to address the specific sampling and analysis requirements. The most recent RCRA regulations, such as the Comparable Fuels Rule, MACT Rule, and Concentration-Based Listings, include DQOs for sampling and analysis and documentation requirements. The SIS is not regulation-driven, but is congressionally mandated.[4-6]

Questions 3 and 4 address the data quality issues. How analytical data will be used is the key factor in determining the quality of data needed for a particular application. The quality of data needed to determine whether a site is clean after corrective action is much more rigorous than that needed to determine the extent of contamination, or the determination of "hot spots." Data quality requirements are being included in the newer RCRA regulations. For example, regulatory language for an exemption under the Comparable Fuels Rule states: "The approach allows comparable/syngas fuel generators to use any reliable analytical method to demonstrate that no constituent of concern is present at concentrations above the exclusion levels. It is the responsibility of the generator to ensure that the sampling and analysis is unbiased, precise, and representative of the waste. For the waste to be eligible for exclusion, a generator must demonstrate that: 1) each constituent of concern is not present above the specified exclusion level at the 95% upper confidence limit around the mean; and 2) the analysis could have detected the presence of the constituent at or below the specified exclusion level at the 95% upper confidence limit around the mean."

With regard to Question 4, most RCRA regulations and monitoring activities are risk-based; i.e., regulatory or action limits are set based on values obtained from risk assessments. However, there are some situations, such as some land disposal restrictions, where the normal risk-based limits of 10^{-6} cancer risk for the regulated analytes cannot be achieved with available technology. In these cases, a technology-based regulatory or action limit will be used.

For the SIS, the action limits for the data generated were risk-based (cancer risk no greater than 10^{-5} and hazard index no greater than 1) and used to support a decision as to whether more protective regulation of nonhazardous surface impoundments was necessary.

Step 2. Have clearly defined purpose and project goals. We covered this element and the next one in some detail in the previous section. Once again, to reiterate, one must be able to answer the key questions "Why are we doing this project?" and "What are the decisions to be made?" For the SIS example, the key issue is whether the existing management scenario for surface impoundments is sufficiently protective of human health and the environment, or whether additional regulation needed.

3. Have clearly defined DQOs and MQOs. This element summarizes the project goals in a way that permits derivation of the needed data quality. In other words, clearly stated DQOs provide an indication of "What types of data are going to be needed?" and "How good do the data have to be to support the decision?" Where a quantitative expression of decision certainty is desirable, the project DQOs should answer the question, "What is the tolerable error of the decision?"

The data quality parameters that need to be included here, which can be generated using the DQO process or another form of systematic planning, are the list of appropriate target analytes and the appropriate confidence level, including a determination that the tolerable error from all sources in the measurement process does not exceed the tolerable error for the decision. For most RCRA applications, we use a DQO of a 90% upper confidence limit around the mean, but this can vary depending on the application.

Measurement quality objectives (MQOs) that meet the project-specific DQO requirements need to be delineated in the SAP. An appropriate target analyte list should be prepared, based on constituents "reasonably expected to be present" from available site information. However, if site information is incomplete, a larger target analyte list may be needed to adequately characterize the site. The key MQOs for the analytical measurements include method sensitivity at the regulatory or action limit, bias, precision, and selectivity. In addition, samples collected must be representative of the waste(s) tested.

For the SIS, the target analyte lists were tailored to the individual sites based on information supplied by the facilities via questionnaires. Analytical parameters were set to meet the project DQO of cancer risk no greater than 10^{-5} and hazard index no greater than 1.

Step 4. Have built-in flexibility, allowing for changes in SAP at various in-process stages, based on evaluation of analytical results. Flexibility in the planning process and the concept of "dynamic work plans" is an important factor in the preparation of QAPPs and SAPs. One of the existing problems with current practices is that in many cases an approved QAPP becomes "cast in stone," i.e., there are no provisions for change if the data or analytical performance indicates a need to do so.

Therefore, it is imperative that SAPs be prepared in such a way that allows for frequent data review and a change in scope or analytical approach if the data indicate that MQOs are not being met or if there are surprises. Some examples of these potential changes include a revision of the target analyte list, i.e, compounds originally expected to be present were not found and some unexpected analytes were found; compound concentration ranges were either higher or lower than expected, requiring changes in methodology to optimize the analysis; or changing the sampling locations due to problems with getting appropriate samples from those locations originally included in the SAP. Any changes made to the SAP must be documented with an appropriate explanation as to why the change was made.

Dynamic work plans were primarily developed for site remediation activities involving on-site analyses. Flexibility must be built into the QAPPs and SAPs so that the results of the on-site analyses can change the focus of the remediation activity, if the actual data indicates a need to do so. Once again, the focus is on how a SAP or QAPP can be adapted during project implementation so that effective data are consistently generated to support project decision making. Dynamic work plans are essential elements for optimizing remediation projects by minimizing costs and speeding up the process.

For the SIS, there is built-in flexibility to both the generic QAPP and the site-specific SAPs to allow for changes that become necessary to generate "effective data" for the project. For example, changes in sampling locations were made at some facilities in order to be able to obtain appropriate samples.

Step 5. Define the number and type of samples required, based on the established DQOs. The sampling plan must include the number and types of samples that are needed to generate effective data to meet the project-specific DQOs for a particular RCRA application. One of the important regulatory DQO requirements is that the samples taken must be representative of the waste and of the decision. Other factors that must be considered in the sample plan having to do with the "representativeness" of the samples include the determination as to whether the use of composite or grab samples is appropriate, and when and where to take the samples to account for the potential spatial and/or temporal variability of the wastestream. When the analytes of concern in a wastestream are present at concentrations close to the regulatory limit, it is usually necessary to analyze a greater number of samples to demonstrate compliance than when these concentrations are well below the regulatory limits.

These sampling requirements are being included as DQOs in new RCRA regulations. Here are two examples of regulatory language involving sampling DQOs from the Comparable Fuels and Chlorinated Solvents Rules: "It is the responsibility of the generator to ensure that the sampling and analysis is unbiased, precise, and representative of the waste…At a minimum, the plan must include: (A) a detailed description of the test method(s) used to test for dioxin TEQ; (B) the sampling method used to obtain representative samples of each wastewater tank influent; and (C) how the design of the sampling program accounts for any expected fluctuations in concentrations over time, while ensuring that all samples are collected within a time frame that will allow for the analyses to account for potential variabilities in the waste stream."

An alternative MQO option was also proposed in the Chlorinated Solvents Rule with a minimum of four grab samples to be taken at the tank influent during a 24-hour period.

For the SIS, sampling requirements were included in the site-specific SAPs. Elements included were to make sure that an appropriate number of samples were taken to allow for statistical analysis, determination as to whether grab or composite samples were appropriate, location for sampling and times of sampling. These elements needed to be considered to make sure that the samples being collected were representative of the wastestreams being tested, and took into account potential heterogeneity resulting from spatial and temporal variability.

Step 6. Develop a cost-effective analytical plan utilizing appropriate sample preparation, cleanup and determinative procedures, based on the established DQOs. Using the PBMS approach provides a great deal of flexibility in selecting cost-effective methods that will provide the maximum amount of effective data for a project. The project-specific DQOs are the basis on which the performance requirements of the selected methods should be based in establishing method MQOs for the analytical parameters of selectivity, sensitivity, bias and precision in the matrices of concern. However, the methods selected for a particular project must be demonstrated to be suitable for use for that project; in other words, to demonstrate performance that meets the project DQOs.

In selecting appropriate target analytes, OSW only requires the analysis of target analytes "that are reasonably expected to be present" for a project, and allows for the elimination of many analytes on a long list through process knowledge. If the application is for a site survey, a wider range of target analytes may be necessary than for a monitoring application for a well characterized site, e.g., groundwater monitoring wells around a landfill. It is frequently appropriate for monitoring activities to use less expensive methods utilizing nonspecific detectors, e.g., a gas chromatography/photoionization detector (GC/PID), for a few target analytes, and treating all positives as hits, thus eliminating the need for confirmatory analyses. In some cases, appropriate quantitative screening methods, such as immunoassays, may be used for very selective monitoring at appropriate action levels for cleanup activities.

Demonstration of appropriate method sensitivity in the matrix of concern is a critical element for the applicability demonstration. The RCRA Program does not require the formal method detection limit (MDL) studies required by other EPA program oiffices, since many applications operate at several orders of magnitude above the quantitation or detection limits of the methods used. It is necessary that the low calibration standard be selected to demonstrate that the method can unequivocally determine whether the analytes of concern are present at the action level. For analyses in the ppm range, we consider a low standard of about 50% of the action limit to be appropriate, while for analyses in the ppb range, we recommend a factor of 0.1 times the action level for the low standard. The analyst should select an appropriate calibration range to address the specific data quality needs of the project. It need not be more than one or two orders of magnitude in many cases. The last calibration issue that we will mention is that for most RCRA applications, it is only necessary to meet calibration requirements for the analytes of concern to the project, and not for all of the analytes in the "Table of Analytes" list for a particular method. Another suggestion for demonstrating appropriate method sensitivity is to spike the target analytes of concern into an appropriate sample matrix free of target analytes at 70-80% of the action level. Run the spiked sample through the analytical sequence and if recoveries of the target analytes are sufficient for quantita-

tion above the low standard, then method performance should be sufficiently sensitive for its intended application.

Bias and precision are also important project-specific parameters. Bias is measured using spike recovery of target analytes from the matrices of concern and precision from the analysis of either duplicate or matrix spike duplicate (if no target analytes are present) samples. Poor recoveries of target analytes generally indicate inappropriate sample preparatory conditions or method selection, interferences, or interaction with the matrix. The analyst should identify the problem and take steps to eliminate it. Poor precision at this point, since operator error has been eliminated, generally indicates sample heterogeneity and needs to be addressed as a sampling or sample handling issue. For projects involving highly contaminated sites, optimizing analyte recoveries is much less important than for projects where the objective is a site cleanup to a low action level. Sample reproducibility between operators and on repeated analyses of the same sample should be within the specific limits of the project plan.

The number of samples necessary for the demonstration of applicability will vary with sample type and proximity of the samples to the action level. Demonstrations for samples that have concentrations of target analytes that are well below action levels can be completed with relatively few samples. A demonstration for highly heterogeneous samples and samples with target analytes very close to the action level will need many more analyses to complete the demonstration and should be statistically calculated.

The sample preparation method(s) should be selected on the basis of the sample matrix, the intended target analytes (since these methods are matrix-specific and in some cases analyte-specific), and the ultimate use of the data generated to meet project goals. For example, if the analyst is evaluating a highly contaminated site with the intent of determining "hot spots" of contamination in the soil which need more extensive remediation, then a faster, less rigorous extraction procedure, like ultrasonic extraction is appropriate. However, if a project involves demonstrating that a site has been cleaned up through removal of contaminated soil, it is necessary to use a more rigorous extraction method, i.e., Soxhlet-type methods.

In some cases, there may be analytical interferences on a site or in a wastestream that prevent appropriate quantitation of the target analytes. In these cases, the use of cleanup procedures may be necessary to remove the interferences. A variety of cleanup methods exist, to be used either singly, or sequentially, to remove these interferences. Cleanup methods are not usually matrix-specific.

Determinative methods are not matrix-specific. Depending on the application, it may be possible to use less expensive techniques, e.g., GC with structurally nonspecific detectors such as ECD or flame ionization detectors (FID), in the monitoring mode for only a few well-characterized analytes. It may be more useful when doing a site characterization to use a survey method, e.g., GC/MS, which involves a structurally-specific detector, when the project involves a wide range of target analytes.

For the SIS, individual site-specific SAPs were prepared for each facility sampled. Site-specific target analyte lists were prepared and appropriate sample preparation, cleanup and determinative methods were selected based on the target analytes "reasonably expected to be present" at each site. MQOs were established based on the overall project DQOs of being able to detect and quantitate the target analytes at concentrations corresponding to cancer risk no greater than 10^{-5} and hazard index no greater than 1. Details of the operating conditions for sample preparative (solvents, extraction conditions, etc.) and determinative (calibration range, chromatographic conditions, etc.) were included in the site-specific SAPs.

Step 7. Make effective use of screening techniques. In many cases, screening methods can be used to generate effective data, as described in the previous "PCBs in drums" example. Data from reliable quantitative screening methods, e.g., immunoassays, colorimetric test kits, and X-ray fluorescence (XRF), may be used as effective data to directly support a decision about whether a site cleanup has been achieved. Other potential applications of screening methods to yield effective data include demonstration of the absence of specific classes of contaminants, such as PCBs and polynuclear aromatic hydrocarbons (PAHs) by immunoassay or TNT or RDX by immunoassay or colorimetry, on a site. These applications are key elements of the project, and as such, are an integral part of the SAP.

The traditional use of screening methods has been to demonstrate the presence of contaminants and to select those samples which need to be further analyzed using a more definitive analytical method. This application should be included in the SAP, but since the data derived from this activity are not directly used for decisionmaking, it is not absolutely critical that it be included. Screening methods were used in some of the site-specific SAPs for the SIS. However, the site-specific data for evaluation of the target analytes was generated using definitive methods.

Step 8. Include clearly defined QC procedures to verify the effectiveness of the sampling and analytical procedures. We will not go into a great deal of detail on QC procedures in this article, nor will we describe the distinction between quality assurance and quality control, since QA/QC has already been covered in great detail in many other readily available documents. Appropriate QC procedures must be incorporated into the SAP to make sure that the methods selected continue to meet the project-specific DQOs and MQOs. Two types of QC information should be included: project-specific QC and method-specific QC. This distinction causes a great deal of confusion among practitioners. Simply put, project-specific QC involves the necessary procedures to demonstrate that the laboratory's quality systems are in control so that the data generated statistically meets the DQOs/MQOs of the project. These procedures include blanks, MS/MSDs, field duplicates, laboratory control samples, etc.

Method-specific QC, on the other hand, involves procedures that an analyst must perform in order to make sure that the selected method is being run properly. These generally include sensitive steps in an analytical method that must be performed without variation. Some examples of these types of operator-critical steps include running an immunosensor method at the specified pH to make sure that proper buffering takes place, specifying a maximum number of colorimetric tests that can be run simultaneously or a specified development time in a time-critical color development step. An absurd, but valid, example of method QC would be "the GC column must be connected to the detector." Method QC procedures are usually noted as operator-sensitive steps in the method itself. Both project-specific and method-specific QC procedures should be included as SAPs.

The SAPs for the SIS contained all of the appropriate site-specific, project-specific and method-specific QA/QC procedures needed to evaluate the quality of the data generated.

Step 9. Carefully document all of the sampling and analytical methods and QC proce-

dures used. Detailed documentation of the sampling procedures and analytical methods used are critical elements of a SAP. There is an old cliche in science that states, "If you didn't write it down, you didn't do it." Just quoting a published method number from SW-846 is not documentation. Too many times we hear that someone did semivolatile organics by Method 8270. All that we know from that statement was that a GC/MS was used. There is no way to determine whether the appropriate target analytes and calibration ranges were used, or whether appropriate sample preparation and cleanup methods were used. The reporting requirements for an exemption under the Chlorinated Solvents Rule reflect some of the key elements that should be documented in the SAP.[6] For example, in Section 3, Records, the rule states that the generator must maintain on-site records such as all information required to be submitted to the implementing authority as part of the notification of the claim; the certification signed by the person claiming the exclusion or his authorized representative; a brief description of the tanks covered by the claimed exemption, including dimensions and service in the wastewater treatment system; a description and process flow diagram of the wastewater treatment system, clearly identifying the exempt tanks and sampling points; the results of all analyses and all detection/quantitation limits achieved as required; and the waste sampling and analysis plan. The CSR also requires onsite records for all laboratory documentation that support the analytical results, among many other data. These records must be maintained for a period of three years, and a generator must maintain a current waste sampling and analysis plan during that three year period.

Demonstration of operator proficiency should be an integral part of the lab's quality system. If operator proficiency and analytical system control data are on file in the lab, then they need not be included directly in the SAP. The documentation in the SAP only needs to be a reference as to where the detailed information can be found. However, the data generated for the "demonstration of method applicability" of the methods selected for the project to meet project DQOs/MQOs should be included in the SAP.

Documentation of the sampling plan should include the number and types (grab or composite) of samples to be taken, spatial and temporal considerations, and the detailed sampling procedures used.

Documentation of analytical methods should include detailed SOPs of all sample preparation, cleanup (if necessary) and determinative methods used. It is not necessary to include the boilerplate details of an entire SW-846 method in the SAP SOPs. However, all of the key analytical parameters must be described in detail. Sufficient information should be included in the SAP so that a competent chemist is able to follow the entire analytical process, in detail, from start to finish.

For the sample preparation methods, details should include solvent systems and extraction conditions, such as time and temperature for extraction methods in the SOP. Purge-trap-desorb parameters should be included in the SOP for purgeable volatiles and the details of any other sample preparative method for volatiles used including sample storage and preservation. Acid leaching conditions should be included in the SOPs for sample preparation methods for metals and inorganic analytes.

Documentation for removal of interferences, if necessary, from the analytical approach should be included. Cleanup procedures are usually only necessary for organic analytes because the inorganic sample preparative methods generally remove organic interferences. These could include simple physical procedures such as removal of oil or water from samples which could potentially prevent some screening methods from working. If formal cleanup procedures for organic analytes are performed, details of solvent systems, stationary phase(s), elution times, elution temperatures and fraction collection should be documented.

For determinative methods, all calibration criteria including type of calibration, number and concentrations of individual calibration points, calibration range and acceptance criteria, and so on, should be included in the SOPs. Chromatographic or spectroscopic operating parameters used should be described in detail, including columns, detectors, temperature programs, flow rate, tuning criteria, wavelength and band width. Other parameters that should be included in the SAP SOPs are the surrogates used (if any).

Some of the project-specific QC elements that should be included in a SAP are types and number of QC samples, (e.g., blanks, matrix spikes, etc.), concentration levels of target analytes spiked into MS samples. Performance acceptance criteria (e.g., % recovery, precision, etc.), derived ultimately from the project DQOs, should also be included. Comparison of the laboratory data with expected performance will determine whether the quality of the data being generated is acceptable for its intended use (i.e., effective data), or whether modifications to the SAP need to be made. If, for a valid reason during the course of the sampling and analysis process, deviations are made from the procedures documented in the SAP, a written explanation detailing the rationale for these changes must be included in the analytical report.

SUMMARY

Before any environmental project can be initiated, some form of systematic planning must be used to delineate the goals of the project. The PBMS paradigm provides sufficient flexibility to allow the focused generation of data of appropriate quality to support environmental decisions. The concept of generating "effective data," or data points/sets of known quality that can be used for their intended purpose–to support a decision or are effective for decisionmaking–is the primary emphasis for environmental monitoring activities. SAPs are very important documents to guide project planning.

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