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APPLYING THE CONCEPT OF EFFECTIVE DATA TO ENVIRONMENTAL ANALYSES FOR CONTAMINATED SITES

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Executive Summary

Analytical chemistry methods can be classified as "definitive methods" or "screening methods." Environmental decision-makers and practitioners frequently make a simplifying assumption that definitive analytical methods generate "definitive data," while screening methods generate "screening data." The pervasiveness of this incorrect assumption inhibits the development and application of more cost-effective strategies for environmental sampling and analysis at contaminated sites. Adopting the concept of "effective data" could promote the cost-saving advantages of modern measurement and monitoring options in the context of contaminated site cleanup, while ensuring the reliability of site cleanup decisions. This concept embodies the principle that the information value of data (i.e., data quality) depends heavily upon the interaction between sampling design, analytical design, and the intended use of the data. Considering site-specific conditions, sample support, quality control, and data documentation assure the scientific defensibility of effective data. When the interplay of these factors is understood, screening methods can play important roles in generating data that are effective for making defensible project decisions, while simultaneously improving the cost-effectiveness and efficiency of site restoration activities.

Introduction

This issue paper provides detailed discussion to supplement the article, *Managing Uncertainty in Environmental Decisions: Applying the Concept of Effective Data at Contaminated Sites Could Reduce Costs and Improve Cleanups*, that appeared in the October 1, 2001, issue of *Environmental Science & Technology (1)*.

This paper assumes that the regulatory action levels or threshold values used to establish acceptable/unacceptable levels of contamination have been developed in a defensible manner. Although evaluating the validity of the action level is a very important component of scientifically defensible decisions about whether a site poses unacceptable risk, the topic itself is beyond the scope of this paper.

Likewise, while the selection and implementation of specific cleanup activities are important, the topic of remedial technologies is also beyond this discussion. This paper addresses issues that revolve around the generation and use of contaminant data as produced by analytical chemistry methods. Uses for this data include determining the "nature and extent of site contamination," short- or long-term monitoring of remedial effectiveness, and demonstrating regulatory compliance. Contaminant data are used to decide whether remedial actions are required for a site, and if

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so, to guide the selection and design of remedial activities. The reliability of contaminant data (as well as other types of data) may be critical to the success and cost-effectiveness of remediation or monitoring activities.

Overview

It is important that regulators provide direction on how compliance with an action level is to be demonstrated. For example, is the action level intended to represent an average concentration that should not be exceeded over some exposure unit, or does it represent some other statistical benchmark? A clear mechanistic understanding of what an action level represents is needed in order to design a scientifically valid sampling and analysis plan. Without this understanding, project decision goals will remain vague, resulting in confusion and wasted effort. An important task of project-specific systematic planning is to establish how regulatory action levels will be applied to a particular site or project. Obviously, the regulatory agency must "participate" in the up-front planning process for efficient design and implementation of a project plan to be possible. This "participation" may range from written guidance that presents clear, unambiguous interpretation of the regulatory benchmark to regulatory staff representation on a project-specific planning team. Modernization of site characterization and cleanup activities requires that all parties bring the industry and regulatory experience gained over the past 25-30 years to the table when planning today's projects.

When gathering contaminant data, regulators, lawyers, and project managers dealing with contaminated sites have often insisted upon using "approved" analytical methods. There is a very common perception that prescriptively mandating *what* methods may be used (and *how* they may be used) can assure defensibility and data quality. In other words, it is assumed that if "approved" methods are used, the data can be trusted. If the methods used are not considered to be regulator-approved, the data may be considered suspect solely on those grounds and for that reason be rejected the regulator. A commonly expressed concern is that data produced by not-approved methods will not be legally defensible. This concern is unwarranted when courts operate from the basic common-sense principle that if data are scientifically defensible, they should be legally defensible. Federal standards (and at least some state standards) do operate from this principle, and for those courts, the admissibility of evidence does not require adherence to methods approved by EPA or any other standard-setting organizations *(2)*. A more thorough discussion of the regulatory and technology issues surrounding the question of "EPA-approved" methods within the context of the waste programs is found in another paper *(3)*.

This issue paper will argue that rigidity in the application of analytical methods to environmental samples can undermine the very data quality and defensibility that regulators seek to secure. Furthermore, this paper will argue that using more modern and innovative methods for sampling and analysis holds the promise of greatly improving the cost-effectiveness of scientifically defensible environmental decision-making. But taking advantage of these modern new tools will require that regulatory-driven conceptualizations of "data quality" be placed on a more scientifically defensible footing. In addition, realizing the benefits of analytical flexibility requires that practitioners take responsibility for instituting the multidisciplinary teaming and training needed to select and use analytical tools properly.

Transitioning to a more modern site restoration paradigm is facilitated when judgments about "data quality" are more closely linked to the project decisions actually driving the data collection efforts (i.e., the data's intended use), rather than tied solely to the analytical procedures used (which is the current paradigm). In other words, the data assessment question should not be, "Was an approved method used and followed exactly as written?" Rather, the primary questions should be, "Are the data effective for making the specified decisions, and are both the sampling and analytical documentation accompanying the data sufficient to establish that they are?" Answering this question is the foundation of scientific defensibility. We suggest that the terms "effective data" and "decision quality data" could intuitively reinforce scientific defensibility within environmental cleanup programs if the terms become part of the environmental lexicon, paving the way for more modern and more cost-effective work strategies. More cost-effective investigations and cleanups mean that more sites may be evaluated and brought to resolution for the same resource investment.

Terminology—Methods vs. Data

First, a distinction between *methods* and *data* is required. Although analytical methods are indeed used to generate data, the analytical method is one of the last links in a very long chain of events that forms the foundation of scientific data. Nonetheless, decision-makers at all levels of policy and practice assume that "definitive *data* of high quality" is automatically produced when traditional laboratories use definitive analytical *methods (4)*. It is further assumed that any decisions based on those data will be legally defensible as long as the laboratory strictly adhered to the "approved" method and to whatever quality assurance/ quality control (QA/QC) is assumed specified for that method (irrespective of the QC's relevance to the data's intended use). On the other hand, on-site analytical methods are usually categorized as "field screening methods" [despite the fact that some field methods are based on definitive method technologies *(5)*].

"Screening analytical methods" are assumed to produce screening quality data that are considered inferior and not legally defensible. It is also assumed that adequate QA is not possible when screening methods are used, and particularly when analysis is performed in the field. Whatever utility these assumptions may have had in the past, the evolution of analytical technologies and of our experience in using them shows these generalizations to be false. Data produced by screening methods *can* be of known and documented quality; adequate quality control *can* be used in conjunction with data generated in the field. But to do so, common traps that compromise data quality and drive up costs must be avoided. Current engineering practice must be challenged to integrate analytical chemistry expertise into project planning when data collection efforts are designed. This challenge is especially critical to the use of on-site measurement technologies that are based on screening methodologies where potential analytical uncertainties must be balanced according to the data's intended use. As will be discussed in more detail later in this paper, there is no "bright line" that distinguishes screening analytical methods from definitive analytical methods. Rather there are gradations where screening methods tend to have more uncertainty in analyte identification and quantification than methods that are considered to be definitive. Yet definitive methods are far from foolproof. Even methods such as ICP-AES and ICP-MS are not free from interferences that can compromise data quality *(6)*.

When data quality issues are treated as if they were solely dependent on method requirements and independent of data use, a myopic focus on managing *analytical* error can actually trigger major *decision* errors *(7)*. Environmental decisions are especially susceptible to error in site cleanup situations because the major source of decision uncertainty (as much as 90% or more by some estimates) is due to sampling variability as a direct consequence of the heterogeneity of environmental matrices *(8-10)*. Figure 1 illustrates the paradox that highly accurate and QA-documented (i.e., "high quality") data *points* may actually form a *poor* quality data *set* that produces misleading conclusions and erroneous project decisions. Figure 1 depicts two different sampling and analysis scenarios for a cartooned site containing two hot spots (locations with significantly higher contamination concentrations than the surrounding area). Analyzing samples using a highly

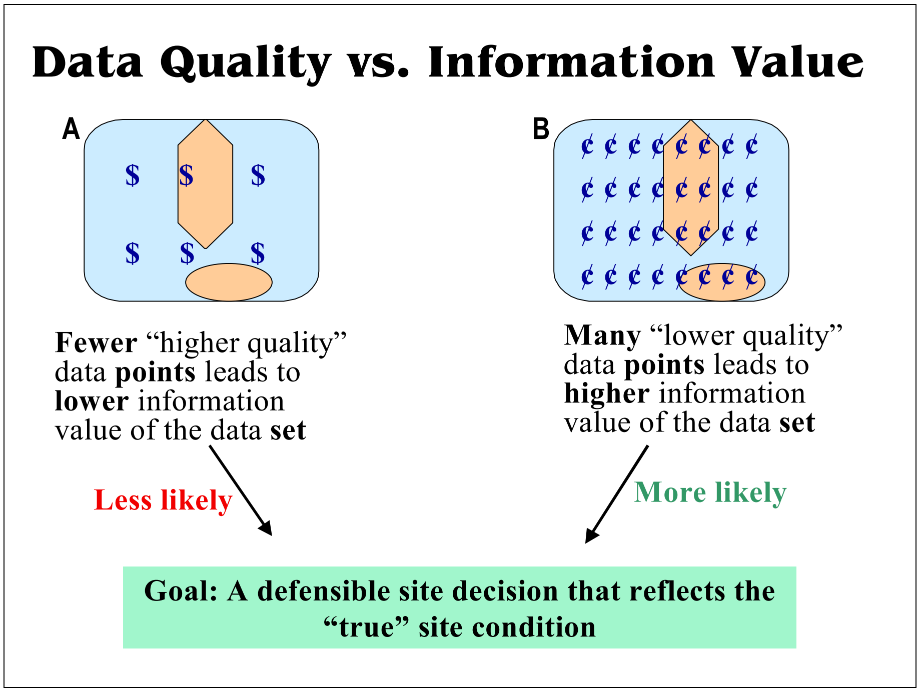

Figure 1.

accurate method is very expensive, so the hard truth is that budget constraints frequently limit the number of samples used to determine the presence and degree of contamination.

Even if the data points themselves are "perfect," an inaccurate assessment is likely when a few samples cannot accurately locate or represent site contamination (i.e., the samples are not "representative" of the site in the context of the intended decisions about the site). A much more accurate picture of the site is gained when many samples are analyzed, even if the analytical method itself is somewhat less accurate.

Thus, we must move beyond the pervasive assumption that the use of definitive *methods* will automatically produce definitive *data*. "Data" (as measurements produced on *samples* for the purpose of supporting decisions) are the end product of a long chain of activities. Selecting representative samples is one of the early activities that critically impacts the usefulness and reliability of data for decision-making purposes, but there are many other steps that contribute to the overall "quality" or validity of environmental measurements. Errors and problems can occur in the processes of collecting a sample; preserving it; transporting it to the laboratory; taking a subsample for actual analysis; extracting analytes from the sample matrix; introducing the analytes into an instrument; coping with any chemical and physical interferences that may arise; ensuring that analytical quality control criteria are met; and finally documenting and reporting the results to the data user. A problem in any single step can compromise or invalidate the accuracy of a data point generated from that sample, no matter how much attention is given to other steps. Therefore, project planning must carefully consider *each* step in the data generation chain in light of the project goals and the nature of the site conditions *(11-14)*. Yet, discussions about "methods" (especially references to SW-846 methods) almost always focus exclusively on instrumental determinative methods, completely ignoring the critical importance of methods for sample collection, sample preparation, and extract cleanup *(15)*. If quality assurance deliberations concentrate only on strengthening only one or two links in isolation from the rest of the data quality chain (for example, ensuring stringent laboratory QA/QC practices for the determinative method), the weaker links [for example, unevaluated variability in sampling and subsampling *(16)*] can still severely compromise the ability of data to support valid environmental decisions. This is one of the reasons why, despite heroic efforts to control variability in the delivery of laboratory services, data quality problems continue to plague environmental programs *(17)*.

Terminology—Effective Data

Public stakeholders do not care whether Method A or B was used to generate data at hazardous waste sites. They *do* care whether correct decisions are being made that protect their well-being. The key to defensible environmental decision-making is to openly acknowledge all underlying assumptions and to manage all sources of uncertainty that can significantly impact the correctness of a decision to the degree feasible. Often a "weight of evidence" approach is needed because no single piece of information can provide definitive evidence given the complexities present in environmental systems. Although it makes regulators' and practitioners' jobs much more difficult, the inescapable truth is that relying on one-size-fits-all approaches to gathering environmental data ultimately compromises the validity (or "quality") of environmental decisions. This is true whenever a wide variety of sampling and analytical conditions and a broad range of decisions are encountered in site restoration programs. A multitude of complex and interacting variables cannot be accommodated by preparing a simple checklist of prescriptive sampling or analytical methodologies, or by substituting laboratory certification for systematic project planning *(7)*. Flexibility (both in the choice of analytical method and in the specific operations of a method) and the professional expertise to apply it are vital if site data are to be generated reliably and economically.

Terminology that explicitly or implicitly judges *data* quality according to the definitive vs. screening nature of the determinative *method* is misleading, because (as argued above) the nature of the determinative method is inadequate to assess whether the data themselves are useful and reliable for their intended purpose. Some environmental practitioners report that they use the term "definitive data" to apply to *any* data that is of known quality and demonstrated useful and reliable for their intended purpose, even if generated by a screening method. This is a legitimate application of the term "definitive data." But it must be recognized that use of the term in this manner runs counter to the way it has been traditionally used in the environmental industry, and such usage could create additional confusion in an already ambiguous and conflicted environmental lexicon.

To foster clarity, this paper suggests that different terminology be introduced. This paper suggests the term "effective data" as a term that describes "data of known quality that can be logically shown to be effective for making defensible project decisions because both sampling and analytical uncertainties have been managed to the degree necessary to meet clearly defined project goals." The term "decision quality data" carries the same intuitive meaning, and is viewed as an equivalent term.

There are a number of implications of this definition that should be noted:

1) In contrast to evaluation protocols that evaluate "data quality" solely on adherence to analytical protocols, data judged to be of decision quality (alternatively, data judged to be effective for decision-making) must *explicitly* include evaluations of sample representativeness as a fundamental data quality indicator *(18,19)*. It is a matter of common sense that if the samples cannot be shown to be representative of the site conditions in the context of the decision to be made, evaluation of the measurement quality for the analysis on those samples is meaningless. *If evidence for representativeness is not presented, the data cannot be characterized as effective for project decision-making.* Demonstrating appropriate analytical quality is only part of the picture.

2) Data cannot be characterized as effective for decision-making (alternatively, data cannot be characterized as being of decision quality) unless the *decision(s)* that the data are to support has (have) been clearly articulated, along with an expression of the amount of uncertainty that can be tolerated in the decision. Thus, a systematic planning process based on the scientific method, such as EPA's Data Quality Objectives (DQO) process, is vital *(20)*. All pertinent project planning and reporting documents using the term "effective data" should contain clear statements that concisely describe:

   - what the primary project decisions are;
   - what level of confidence is desired in those decisions;
   - what sources of uncertainty could lead to making an incorrect decision;
   - what strategies are used to manage for each source of uncertainty so that making an incorrect decision is avoided;
   - what assumptions are used when knowledge gaps are encountered that are not feasible or practical to fill with more definitive information; and
   - how do these assumptions impact the decision outcome.

   A summary sheet concisely listing these items would have supporting discussion contained within the body of the planning or reporting document.

3) What are the types of "decisions" for which the term "effective data" should be used? Introduction of the term "effective data" seeks to address issues associated with the generation and use of analytical chemistry data for characterizing chemical contamination or demonstrating regulatory compliance with limits placed on the amount of contaminants present in environmental media. Therefore, the "decisions" to which the term "effective data" alludes are those that address questions about contamination: Is contamination present, and if it is, is it at a high enough concentration to exceed regulatory levels or to pose a threat to receptors? These might be called "primary project decisions" or some other term that denotes that these are decisions that must be made in order to resolve the status of a potentially contaminated site (or portion thereof). There are many other decisions that must be made during the course of site activities, but unless they directly involve decisions determining the presence/absence of contamination, the distinction of "effective data" probably is not necessary. Overuse of the term would be undesirable since it would undermine the meaning and impact of the term.

4) Managing uncertainty in environmental decision-making will often involve the collection and interpretation of environmental data, but this is not an absolute. Careful planning may indicate that the cost of a reliable sampling and analysis program is as, or more expensive, than simply assuming a worst case scenario and acting accordingly to manage the assumed risks. One case study showed that, although using immunassay methods to guide clean up of a small contaminated site saved the responsible party at least 50% over projected costs, relying solely on a traditional site characterization scenario to delineate contaminated hot spots would have cost as much as assuming the entire soil mass needed to be incinerated without attempting characterization *(21)*.

5) A data set that might not be effective for making a certain decision when considered alone may become

part of an effective data set when considered in conjunction with other relevant information, such as another data set that contains supporting or complementary information. An example of this is when the cost of a definitive analytical method may prohibit the sampling density needed to manage sampling uncertainty, whereas existing screening analytical methods cannot supply all the analytical quality needed. Intelligent sampling and analysis design may be able to select an inexpensive screening method to manage sampling uncertainties, while judicious confirmatory analysis of selected samples by the definitive method manages for residual analytical uncertainties in the data set produced by the screening method. In this way, the two data sets *collaborate* to produce data effective for supporting the final decision(s) *(21)*.

6) There is a key phrase in the definition of effective data that must not be overlooked: data must be of "known quality." This means that analytical quality assurance and quality control (QA/QC) protocols must be selected, implemented, and interpreted so that the analytical sensitivity, bias, precision, and the effect of potential interferences can be determined and reported. To achieve this at the project level, a demonstration of method applicability (wherein site-specific samples are evaluated for matrix-specific impacts on method performance) may be required to identify the sampling and analytical uncertainties requiring management, and permit the proper selection of the QA/QC parameters and acceptance criteria to be used during project implementation *(22)*. Estimating the contribution to data variability due to matrix heterogeneity and subsampling may also be important to establishing that data are of known quality *(19)*. No matter whether a method is considered to be a screening method or a definitive method, QA/QC procedures are required to produce data of known and documented quality from any analytical chemistry method.

Terminology—Screening Data

Data that cannot be shown to be of decision quality may still provide some useful information. As such they might be characterized as "screening data." Screening quality data do not provide enough information to satisfactorily answer the question being asked with the desired degree of certainty. For example, consider data resulting from pesticide analysis by gas chromatography/mass spectrometry (GC/MS—considered to be a definitive determinative method) performed in the presence of high levels of hydrocarbon interferences without benefit of an appropriate extract cleanup method (assume that representative sampling was documented). Such interferences often raise the reporting limits of individual pesticide analytes *(14)*. If the reporting limits are higher then the project's decision levels, non-detect results are not sufficient to declare the samples "clean." Although a potentially definitive technique (GC/MS) was used, in this situation it provided screening data because other aspects of the analytical chain were insufficient to achieve the needed analytical data quality. The information provided by the compromised data is somewhat useful (there is indication that pesticide contamination is not present above the reporting limit for those samples), but that information does not meet the project manager's need to make the primary project decisions at the levels of concern. However, the screening data can also provide information that can guide the project chemist to modify any subsequent analyses (e.g., select an appropriate cleanup method) to address the analytical problems so that effective data can be generated.

Terminology—Sample Support

Because sample representativeness is a critical first link in the data quality chain, it is useful to discuss "sample support," a term not yet commonly used within the environmental industry, although it has been around for some years *(4)*. Sample representativeness can be divided into broad components of sample selection and sample handling. Sample selection must consider the "location" of samples (i.e., where or when the specimen is collected). The heterogeneity of most environmental matrices demands that sample selection be carefully considered so that the number, type, location, and timing of sample collection will be representative of spatial and temporal variability in relation to the study objectives. On the other hand, sample support impacts both sample selection and sample handling. The term "sample support" refers to the physical dimensions of the sample, which is determined by the interplay between a number of factors. Sample support is critical to sample representativeness. Evaluating sample support includes considering the size, shape, volume, and orientation of the specimen and of the components that comprise it, and the ability of the sampling tool (such as a coring device, spatula, or liquid sampler) to collect a representative specimen from the statistical population about which decisions are to be made *(19,20)*.

Even when analysis occurs *in situ*, the concept of sample support is very important to evaluate what "sample" the sensor or detector actually "sees." Understanding the sample support governs the comparability of *in situ* results to results obtained by the analysis of discrete samples, which, in turn, determines the ability to use *in situ* results to guide project decisions. In all sampling and analysis scenarios, sample support greatly influences the legitimate interpretation of analytical results. Yet under the current paradigm, analysts charged with the task of assessing the quality or usability of analytical data packages may not understand what the project goals are or what was done in the field well enough to evaluate whether the samples (and thus the analytical data package) were indeed representative and thus usable for their intended purpose *(7,23)*.

Whether samples are tree cores, fish tissue, soil borings, or industrial wastewater, the concept of sample support is critical to generating reliable environmental data. To illustrate, consider a hypothetical project where environmental decisions will hinge on ascertaining whether recent atmospheric deposition has contributed to lead contamination in surface soils. Contrast two possible sampling and analysis designs. In Design 1, an appropriately calibrated field portable X-ray fluorescence (XRF) instrument is operated in an *in situ* "point-and-shoot" fashion where each "shot" measures the total concentration of lead over a 2 cm^2 area to a depth of 1 to 2 mm, and a high sampling density across the site's surface soil is easily feasible. In Design 2, a small number of samples are collected because of the expense of sending samples to the laboratory for definitive analysis using atomic absorption spectroscopy (AAS). Design 2 samples are collected using a 4 inch diameter coring device that takes a 4 inch deep vertical core. The whole core is deposited in the sample container for transport to the laboratory. Once there, the lab technician thoroughly homogenizes the entire sample before a 1 gram portion is taken to undergo acid digestion. The digestate is then analyzed for lead content by the AAS instrumentation. *Which data generation approach would be expected to be more representative of the true site condition in relation to the stated project decisions?*

The XRF approach of Design 1 yields more representative data for two reasons. First, and most critically, the sample support (a thin surface layer of soil) analyzed by the XRF is more representative of soil contaminated through atmospheric deposition than a 4 inch deep core that is homogenized before analysis. Second, the higher number of samples possible with the XRF for a similar analytical budget permits a more thorough characterization of variability due to heterogeneity, improving confidence that anomalous readings (either high or low) will not distort interpretation of the results. If isolated high readings are found and if it is important to the project goals, the extent of hot spot areas could be quickly delineated during the same field mobilization if XRF were being used.

As part of a carefully designed XRF quality control program tailored to the needs of the project, a small number of split samples might be sent to an off-site laboratory to establish method comparability between the XRF data set and more traditional lead analysis results or to evaluate potential method interferences. Note that if samples are sent for off-site analysis, the sample support for the two sets of analyses must be the same or else there will be poor agreement. Typically, project managers assume that the field method is at fault if there is not close agreement with fixed laboratory "confirmatory samples." In actuality, both methods may be accurately reporting results *for the samples presented to them*. Differences in sample support (the physical nature of the sample, such as particle size) or matrix heterogeneity (a failure to achieve sufficient sample homogenization prior to splitting the sample) often accounts for differences between split sample results. Significant dissimilarities are also possible in the actual constituents being measured by each method, even though each method is working perfectly as designed. For example, the XRF measures *total* lead in the 2 cm^2 surface area it "sees," while the AAS method quantitates only the lead solubilized under the particular digestion conditions used *(24)*.

The Data Quality Conundrum—Finding a Better Way

Despite the fact that analytical rigidity in many environmental programs is counterproductive, prescribing how analytical methods are selected and applied has nearly universal appeal among regulators seeking simplicity and predictability in regulatory programs. This is a commendable goal, but past attempts at "standardizing" sampling and analysis procedures created a false sense of security *(7)*. The scientific need for *project-specific* sampling and analysis designs cannot be neglected in favor of convenient uniformity without jeopardizing the reliability of the environmental data and their ability to support sound decisions.

As illustrated in Figure 1, a one-size-fits-all quest for ill-defined "high quality data" easily adds to program costs without commensurate benefits. The effectiveness of subsequent remedial actions is put at risk when project managers respond to high per-sample costs by decreasing the number of samples, an action that increases the likelihood of faulty conclusions *(23)*. In contrast, EPA policies explicitly require project-specific data collection designs to be matched to the nature of the samples and to the intended use of the data *(25)*. EPA's SW-846 methods manual (used in the waste programs) warns that its procedures are "meant to be…coupled with the realization that the problems encountered in sampling and analysis situations require a certain amount of flexibility…[that] puts an extra burden on the user, [but] is unavoidable because of the variety of sampling and analytical conditions found with hazardous waste" *(15)*.

The way out of the data quality dilemma is to focus on the bottom line, which is ensuring the *overall quality of the decision* driving the data collection effort. Because uncertainty in environmental decisions is dominated by sampling variability, increasing the sampling density increases the certainty that decisions will be correct (as long as the data generated on those samples is of known quality commensurate with the decision). Recent advances in electronics, photonics, and biological reporter systems have supported the development of innovative characterization technologies that economically facilitate higher sampling densities. Better management of sampling uncertainty and increased statistical power (the ability to find a statistical difference when one actually exists) is possible when more samples are collected. Public interests would be well served by integrating these technologies into routine practice because better overall decision certainty is achieved through a combination of lower per-sample analytical costs and (most importantly) the ability of innovative measurement technologies to support smarter and faster work strategies by providing real-time analytical results.

Smarter work strategies have been articulated by various authors and practitioners over the years, and they go by names such as expedited site characterization, dynamic work plans, rapid adaptive site characterization, adaptive sampling and analysis plans, and similar terms *(26-29)*. The concept common to all is using real-time data results to guide real-time project decision-making and integrate characterization efforts with cleanup activities to the greatest extent feasible. Project managers that successfully use this strategy demonstrate significant cost-savings, dramatically shortened timeframes, and increased confidence in the protectiveness of project decisions. Successful implementation of a dynamic work plan approach requires considerable investment in funding and effort to perform thorough, up-front, systematic planning with a core team possessing the full range of technical skills relevant to project goals. Work plans are designed to be dynamic, so that subsequent site activities can rapidly adapt as new information is gained. Flexibility in the work plans is guided by transparent, regulator-approved, decision logic that is focused on achieving clearly defined project goals. Highly experienced staff must be present in the field to generate and interpret data, communicate with regulators, and implement the decision logic *(28,30)*. Yet, the investment in planning and qualified technical specialists is returned handsomely because lifetime project costs are as much as 50% lower than under traditional scenarios *and* project decisions are more reliable, often with statistically quantifiable certainty. Also, client and stakeholder satisfaction is much higher when work is done quickly and correctly the first time *(21,29,31)*.

There are a number of options by which real-time results may be produced. Paying for 24-hour turnaround from a traditional laboratory is an option that may be logistically and economically feasible under some circumstances. Under other circumstances, establishing on-site laboratory facilities in vans or trailers may be viable options. Field-portable or *in situ* instrumentation is increasingly an option of choice as technology development extends the capabilities of these technologies into a growing number of project situations. Selection of analytical platform should be made only after careful systematic planning has considered the pros and cons of each option in the context of the project's decision goals, contaminants of concern, site logistics, budget, contractor capabilities, etc.

Field-portable technologies used to generate on-site measurements encompass a growing number of both definitive and screening methodologies. However, since some of these technologies do not fit the "approved method" paradigm, regulatory acceptance has lagged, although there are signs that this is changing. Regulators should be cautious when field analytical technologies are proposed, ensuring that the use of these technologies has been carefully considered on a project-specific level. The regulator would want to feel confident that analytical and sampling uncertainties are managed and balanced to meet the desired decision certainty, as described in a project-specific quality assurance plan. It is to be expected that there would be a learning curve. The generation of data of known and documented quality using on-site measurement technologies requires that analytical chemistry expertise be part of the project planning process from the start. The selection of an appropriate field technology and the design of a field QA/QC protocol that will demonstrate that all relevant analytical uncertainties are managed to the degree needed to assure scientific defensibility requires a merger of project management expertise, statistical and geostatistical sampling design knowledge, and analytical chemistry sophistication. To achieve this multidisciplinary skill mix, the consulting engineering community might partner with analytical service providers, statisticians, and other disciplines. A shift to such extensive partnering will no doubt be new to many consulting firms and regulatory agencies.

Regulators can play an important role to foster this transition if their oversight shifts from controlling analytical methods to managing the overall uncertainty in project decisions. This can be done by ensuring that project planning documents 1) clearly explain what a project's goals really are, and what decisions have to be made in order to achieve those goals; 2) identify the major factors expected to contribute to uncertainty in the project decisions; and 3) ensure there is a technically valid strategy in place to manage each of those factors. As the project proceeds, quality assurance staff could assure the *overall* quality of project decisions by evaluating whether the relative contributions to overall uncertainty from the various components of sampling and analytical error have indeed been considered *(18,20,25)*. Planning documents must clearly distinguish between uncertainties that operate at the analytical level (i.e., analytical quality or performance at the laboratory level that is not affected by sample-specific constraints), at the data level (i.e., evaluation of data quality that includes sample-specific analytical performance and consideration about sample representativeness), and at the project level (i.e., expressions of decision confidence).

Data Set Information Value vs. Data Point Quality in the Use of Screening Methods

As discussed previously, accurate partitioning of sampling and analytical errors reveals that the ability of many environmental data sets to provide reliable information has less to do with analytical data quality than with sampling density. The advantage of many screening methods is that they are less expensive than most definitive methods (so more data points can be obtained) and they can be operated to provide real-time results. Contrary to popular belief, screening methods *can* be selected and operated in ways that produce data sets that contain meaningful information at a high degree of confidence, *but* appropriate analytical chemistry expertise and sufficient quality control mechanisms are required to do so. The cost advantages of using screening methods are not sacrificed by this investment in analytical proficiency.

The contrast between the *information value of data sets* and the *quality of individual data points* was illustrated in Figure 1. Assume that the data points of Scenario B were generated using a screening method with a higher detection limit, less precision, more interferences, and a tendency to be biased high compared to the more expensive definitive method depicted in Scenario A. However, the screening method is less expensive, and it can be used on-site to generate results within hours of sample collection. If the goal of the project is to detect the presence of hot spots above a certain contaminant concentration and greater than a given size, not only can the analytical method in Scenario B produce a more accurate representation of the site's contamination (producing site decisions that are more protective and defensible), the real-time results can be used to discover, delineate, and remove hot spots in a single field mobilization. This dynamic approach can save considerable time and money over a hot spot delineation approach phased over months or years while waiting for each round of laboratory results to be returned and interpreted. Instead, the screening method could produce data of known quality that are effective for site characterization and cleanup as long as project planning establishes that the following conditions are met:

- The quantitation limit of the screening method is well below the decision level(s) used to define unacceptable concentrations of the targeted contaminant(s).

- The analytical variability is minor compared to the precision needed to support hot spot detection and delineation.

- Adequate QC procedures (which may include, but *by no means* are limited to, split sample analysis by traditional laboratory methods) are used to monitor the amount of bias in the field results, and to control for any impact from interferences. Data quality is judged acceptable as long as the amount of bias or the effect of interferences is documented, and can be shown to not cause unacceptable errors in project decision-making.

Depending on the nature of the contaminants and the field methods used, confirmation that a site is "clean" for purposes of regulatory closure often will require the analyte-specific, highly quantitative results that only definitive laboratory methods can provide. But if prior site characterization using the field method was thorough, the representativeness of these expensive samples will be assured, even if they are relatively few in number. There will be no surprise "hits" or unexpected analytical problems with the closure samples, allowing statistical estimation of confidence in the closure decision to be determined cost-effectively *(21)*.

Screening Methods Can Produce Data of Known Quality

Results from screening methods are often viewed with suspicion. This view is justified if the QA/QC needed to establish validity of the data has not been performed, or if critical uncertainties in the analytical method have not been managed. Screening methods may be described as analytical methods for which significant uncertainties exist in the method's ability to positively identify individual compounds (within a class or of a certain type) and/or to quantitate analyte concentrations. For example, an immunoassay method for DDT will produce a response not just for the two DDT isomers, but also for degradation products of DDT and possibly other compounds with similar chemical structures. Most immunoassay kits for environmental applications are also designed to have a significant positive bias to minimize the chance of false negative results. Obviously, it would be foolish to expect that a result from a "DDT" immunoassay kit would be directly comparable to a DDT result from a definitive method *(21)*.

Although similar kinds of uncertainties exist for definitive methods as well, the magnitude of these uncertainties is expected to be much less for definitive methods than for screening methods. Yet, data users should be aware that the same definitive method that produces excellent recovery and precision for some analytes on the list of potential target analytes may well produce poor recovery and precision for other analytes on the list. That is because optimizing the operating conditions of an analytical technique for certain analytes necessarily degrades the performance of other analytes that have different chemical properties. This shortcoming is particularly true for generalized methods that have very long and diverse target analyte lists, such as SW-846 Methods 8260 (GC/MS for volatile organic compounds, VOCs) and 8270 (GC/MS for semi-volatile organic compounds, SVOCs). Even if only analytical quality is assessed, the data for some analytes from a sample might be considered "definitive" while other analyte results for the same sample and analytical run should be considered "screening." This is not a fault of environmental laboratories; this is the consequence of demanding that a diverse list of analytes be reported from a single instrument run to cut analytical costs. This is an acceptable approach as long as it is quite clear to the data user that some results should be considered "screening" (i.e., highly uncertain) despite the fact that they were generated from a definitive method.

The phrase "data of known quality" means that data quality characteristics such as representativeness, degree of bias and precision, selectivity, detection/quantitation limits, and impact by interferences are documented. The goal of project planning is to match an analytical method and its ability to produce data of a certain quality with the needs of the project. This principle is true whether definitive or screening techniques are being considered. With an appropriate project-specific QA/QC protocol, estimates for a screening method's quantitation limit, bias, and any other data quality indicators relevant to project decision-making can be determined. Together with evidence of sample representativeness, these parameters establish data of known quality. When the actual data quality generated through the use of project-specific QC samples is compared against the data quality needed for making defensible project decision, and the actual data quality is found inadequate for decision-making purposes, the data may still serve useful purposes as screening quality data. Screening data may be defined as data that provide some information (such as indications of matrix variability or analytical interferences) useful to furthering understanding of contaminant distribution or behavior. But the data contain too much uncertainty to be used for making solid project decisions that can bring the site to final resolution. Deliberately producing screening data (using either a screening or definitive technique) can be a highly cost-effective strategy, as long as the difference between decision quality data and screening data (and how they individually will be used in the context of project) remains clear.

Data that are of *unknown* quality (because of inadequate QC or sampling density) may possibly serve as screening data if interpreted very carefully and conservatively. But the production of data of unknown quality is an undesirable situation that generally means there was a breakdown in the project planning process. Data of unknown quality cannot be used to make project decisions (i.e., data of unknown quality cannot be treated as decision quality data) since, by definition, critical analytical uncertainties were not controlled and the possibility that the data may cause a decision error is too great.

Under the traditional paradigm, it may be weeks or months before project personnel get data packages returned from a laboratory and discover whether the actual data quality is of decision quality, screening quality, or unknown quality. Current procurement practices mean that laboratories are seldom aware of a project's actual data needs, and laboratories are seldom authorized to explore method modifications to improve data quality when sample interferences compromise analytical performance. By the time a project managers realizes that the data are inadequate, they are faced with a difficult decision. They must choose either to significantly delay subsequent site work and incur additional costs while samples are recollected or reanalyzed, or to significantly weaken the defensibility of their decisions by "taking their best guess" based on the data available.

On-site analysis offer substantial advantages in this area, as long as adequate systematic planning has clearly defined the data requirements. On-site measurement methods can easily be operated with a project-specific QA/QC protocol tailored specifically to meet the project's data quality requirements. During project implementation, real-time results provide immediate feedback to project personnel about actual data quality as it is being generated. Contingency plans (which are an integral feature of dynamic strategies) are activated if analytical or matrix problems are encountered, minimizing wasted analyses and delays. Analytical results that seem out of line can be immediately investigated to rule out clerical errors and other blunders, or to reevaluate the representativeness of the current sampling design *(32)*.

When using a screening method to generate decision quality data, the key is to openly acknowledge the strengths and limitations of the method. In principle, this is true whether using a definitive method or a screening method, but there is more opportunity for error when selecting a screening method, which is why it is especially important that the person making the selection have the appropriate analytical chemistry experience. Method selection requires that the project chemist:

1) Demonstrate that the uncertainty in the data produced by the selected method will be insignificant in relation to the nature of the decision. For example, uncertainty about whether the actual result is 10 ppm vs. 20 ppm may be unimportant if the decision hinges only on whether the contaminant concentration is greater or less than 50 ppm (compare Figure 2);

2) Use various strategies to cost-effectively control potential analytical uncertainties, such as evaluating historical information to assess what contaminants likely may or may not be present, performing a demonstration of applicability (i.e., an analytical pilot study) to verify anticipated site-specific performance *(15)*, and tailoring a confirmation testing protocol to establish project-specific method comparability and detect any interferences; and

3) Use less specific methods to a project's advantage. For example, a method that detects a wide range of chlorinated organic compounds could be used to assess site locations for a large number of such contaminants simultaneously. Negative results at an appropriate level of quantitation could economically rule out the presence of contaminants such as polychlorinated biphenyls (PCBs), organochlorine pesticides, chlorobenzenes, chlorophenols, etc. Expensive traditional analyses could be reserved for selected samples with positive results higher than a concentration of potential concern that is kit- or project-specific; and serve to unequivocally identify the contaminant(s) and their actual concentration(s).

A prudent project chemist can use information about interferences and contaminant concentrations provided by screening method results to improve the quality and cost-effectiveness of any follow-up definitive analyses. Further, by collaborating with statistical expertise, the planning team can use screening methods in conjunction with limited definitive analysis to produce highly cost-effective data sets based on statistically rigorous sampling designs such as ranked set sampling and adaptive cluster sampling *(33)*.

When data are of known quality, it is possible to designate which data results are effective for making decisions, and which data results would not be effective. For example, when a screening method is used, results that fall well above or well below an action level are often effective for making decisions about "clean" versus "dirty" areas. However, when the uncertainty in the method's results overlaps the action level, results that fall within the range of overlap might not be effective for making decisions about that action level. Because further analysis would be required to make a defensible decision, data within that range of uncertainty would constitute screening data. Of course, those results are still highly valuable since they guide sample selection for more expensive analysis. In this way, the value of confirmation testing dollars is maximized since samples are selected for confirmatory analysis with a specific goal in mind, that of filling the data gaps most relevant to decreasing decision uncertainty and establishing regulatory compliance. Figure 2 illustrates how the data ranges that would comprise effective data in the context of a hypothetical project might be clearly specified in the project's sampling and analysis plan, along with the action that will be taken when data fall into a range that is not effective for making the project decision.

Benefits of More Descriptive Terminology

Adopting the concept of "effective data" would reinforce a more productive conceptual framework for data generation within the context of site restoration. The foundation of that framework is an appreciation for the importance of a systematic planning process (such as EPA's DQO process) *(20,34)*. Both terms, "effective data" and "decision quality data," equivalently serve to support systematic planning by encouraging critical thinking about the anticipated role of data. Both terms intuitively demand that these questions be addressed:

- What is it that the data are to be effective for? In other words, what is the intended use of the data? What are the decisions to be supported? And how "good" should those decisions be (i.e., what level of decision confidence or certainty is desired)?

- When planning to generate effective data, what are the strengths and limitations of the proposed methods (costs, labor requirements, quantitation limits, precision, expected rates for false positive and false negative analytical results, bias, turnaround time, complexity of the procedure, equipment reliability, etc.)?

- What are the site-specific considerations that could adversely impact analytical performance (e.g., physical and chemical matrix effects, and operating conditions for onsite analysis like temperature and humidity), and how will those things be controlled?

- What are the site-specific considerations that will influence representative sampling (e.g., contaminant variability in time and space, and the physical makeup of the matrix)?

- What are the site-specific considerations that will govern what statistical measure(s) should be determined (e.g., the mean concentration across some exposure unit vs. an estimate of some maximum value)?

Conclusion

When data needs are clearly articulated, and where a number of modern sampling and analytical options exist, it is possible to optimize data collection so that the information produced is sufficiently accurate for its intended purpose, yet at a much lower cost than previously thought possible. A judicious blending of screening *and* definitive methods, used both in the traditional laboratory setting *and* in the field, contribute to generating both effective *and* screening data sets that each play valuable roles in defensible, yet highly cost-

Effective Data Range Illustration

A project plans to classify drums of PCB waste as **greater** or **less** than a 50 ppm action level. An immunoassay (IA) kit is demonstrated to be effective for such decision-making if the kit result is < 45 ppm or > 65 ppm. **Between these 2 values**, IA kit accuracy does not achieve the level needed to meet the decision goal confidence as set in the project DQOs. Therefore, samples with kit results in the 45-65 range will be tested by another method that can provide the needed accuracy.

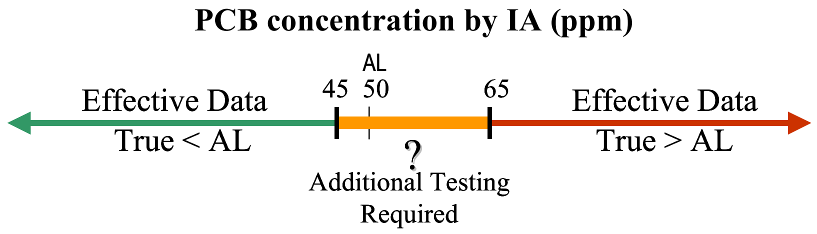

FIGURE 2.

effective decision-making, as long as the distinctions between them are understood by decision-makers. Emerging site characterization and monitoring tools promise to bring down the costs of environmental restoration and long-term monitoring, but only if regulators and practitioners incorporate them appropriately into modern, efficient work strategies, such as dynamic work plans.

Terminology that reinforces systematic planning and acknowledges the capabilities of new tools to assist environmental decision-making could cultivate a more productive attitude about data quality issues where assessment of "data quality" is solidly anchored in the data's intended use. Language is the instrument of thought, and unfortunately, terms like "definitive data" or "high quality data" have become ingrained with misconceptions arising from the idea that prescriptive method requirements can somehow guarantee that data point quality will equate to decision quality. A culture has emerged that rigidly scrutinizes data points, while the very foundations of information quality and scientific defensibility are neglected. The authors propose adoption of the equivalent terms, "effective data" and "decision quality data," as the foundation of a framework that can refocus the environmental community and data quality assessment on ensuring better decisions through more defensible, protective, cost-effective, and innovation-friendly approaches to environmental decision-making.

Glossary

Term	Description of term as used in this paper
field-based measurement technologies	Equivalent to "on-site analytical methods" and a host of similar terms that are used to denote that the instrumentation and methods used to perform real-time analyses is in close proximity to the actual location of sample collection. Implementation ranges from hand-held instruments used outdoors to full-scale mobile laboratories.
field screening	This term is highly ambiguous and misleading. Its use is discouraged unless additional descriptors are provided to clarify whether the speaker intends to refer to screening methods (i.e., non-specific, interference prone, imprecise analytical techniques), screening data (i.e., some useful information is provided, but not enough to defensibly support project decisions), or screening decisions (i.e., decisions that are not fully defensible because of insufficient evidence).
decision quality	Ideally, the degree to which an *actual* decision coincides with the decision that *would have been made* if complete and fully accurate information (i.e., the true state) were known (or knowable). Because the "true state" might not be known at the time of decision-making (i.e., it may not be feasible to know for certain whether the decision was correct in an absolute sense), decision quality is commensurate with the degree of *confidence* in the correctness of a decision. That confidence is a function of the extent to which information is weighed fairly while acknowledging the assumptions, conditions, and uncertainties that could impact the correctness of the decision. Hence, decision quality is also related to its ability to be defended in a reasonable, honest and logical discussion of issues.
data quality	Although usage of this term has tended to be vague, the EPA has recently defined data quality as "the totality of features and characteristics of data that bear on its ability to meet the stated or implied needs and expectations of the customer " (i.e., data user) *(35)*. In the same vein, recent EPA guidance states that "…data quality, as a concept, is meaningful only when it relates to the intended use of the data. Data quality does not exist in a vacuum; one must know in what context a data set is to be used in order to establish a relevant yardstick for judging whether or not the data set is adequate" *(36).* Since analytical data are generated from samples, pre-analytical considerations (such as sample representativeness and sample integrity) are crucial when determining whether the data are of sufficient quality to meet the user's need to make correct decisions.
analytical quality	An expression of the bias, precision, and other characteristics of the measurement process that reflect the ability of the analytical method to produce results that represent the true concentration of the target analyte in the sample that was presented to the analytical process. Pre-analytical considerations are not a factor in determining analytical quality.
defensible	Derived logically with all underlying assumptions and uncertainties openly acknowledged. To the degree feasible, uncertainties are controlled or documented so that the impact on the likelihood of decisions errors is understood. Conclusions are thus able to withstand reasonable challenge.

Term	Description of term as used in this paper
definitive analytical method	As the term is used in the environmental field: An analytical method for which the degree of uncertainty in the identification and quantification of target analytes is documented, normally using ideal or well characterized matrices. The specificity associated with an analytical measurement and the potential for influences from interferences can be identified. Example: GC-MS. Definitive methods are not free of uncertainties, but the degree of uncertainty is less than that considered to be characteristic of screening methods.
screening analytical method	Analytical methods for which higher levels of uncertainty are expected in the data produced because the method is limited in its ability to quantify the presence of specific analytes. The resulting data are expected to have higher quantitation limits, be more biased, be less precise, be less selective, and/or be more susceptible to interferences than data produced by definitive methods. Example: immunoassay kit for DDT.
data point	Analytical results for a single sample, specimen, or target analyte.
data set	Analytical results for a group of samples that are expected to be representative of the characteristic(s) of the environmental matrix under investigation.
definitive data	Although a legitimate term in science, this term is not recommended in the environmental field because the current convention for using the term has focused solely on analytical quality, and sampling uncertainty (or total measurement uncertainty) has not addressed in practice. The term has thus not been conducive to ensuring decision quality. Current usage of the term in the environmental field seems to stem from selective reading of an EPA definition says, in part: "Definitive data are generated using rigorous analytical methods…are analyte-specific, with confirmation of analyte identity and concentration." *(4).*
screening data	Data (points or set) that may provide some useful information, but that information by itself may not be sufficient to support project decision-making because the amount of uncertainty (due to sampling, analytical, or other considerations) is greater than what is tolerable. When data that would be considered screening quality (if considered in isolation) are combined with other information or additional data that manages the relevant uncertainties, the combined data/information package becomes effective for decision-making (see collaborative data sets).
effective data	Data (points or set) of known quality that can be logically shown to be effective for making scientifically defensible primary project decisions without requiring additional data or information to back them up, because both the sampling and analytical uncertainties in the data have been controlled to the degree necessary to meet clearly defined decision goals. Equivalent to "decision quality" data.
decision quality data	Term is equivalent to "effective" data.
data of known quality	Data for which the contributions to its uncertainty from both sampling and analytical variability can be estimated (either qualitatively or quantitatively) with respect to the intended use of the data, and the documentation to that effect is verifiable and recognized by the scientific community as defensible.
collaborative data sets	Data sets that might not be effective for making project decisions when considered alone, but combined together they manage all relevant uncertainties to the degree necessary to support defensible decision-making. This may sometimes be considered a type of "weight of evidence" approach.
ancillary data	Project data used to manage project activities other than those directly engaged in supporting primary project decisions. Examples of ancillary data include health & safety monitoring data, meteorological data, stratigraphic data, etc.
sample support	The size, shape (length, width and height dimensions), and orientation of a sample in relation to the parent matrix or contaminant population it is desired to emulate.
sample representativeness	An expression of the degree to which a sample can be used to estimate the characteristics of a population under investigation with respect to the decision to be made.
analytical representativeness	An expression of the degree to which a sample analysis represents the characteristic of a population under investigation with respect to the decision to be made.
primary project decision	For projects involving the cleanup and closeout of contaminated sites, these are decisions that drive resolution of that project. Generally these decisions are based on demonstrating the presence/absence of pollutants above/below certain thresholds. Therefore, contaminant data generated on environmental matrices by analytical chemistry methods usually drive primary project decisions.

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