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THE RELATIONSHIP BETWEEN SW-846, PBMS, AND INNOVATIVE ANALYTICAL TECHNOLOGIES

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Introduction

This summary explains EPA's position regarding testing methods used within waste programs, documentation of EPA's position, the reasoning behind EPA's position, and the relationship between analytical method regulatory flexibility and the use of on-site measurements (also termed "field analytical methods") to improve the cost-effectiveness of contaminated site cleanups.

Although the flow of site cleanup work can be accelerated and site cleanup can be more economical when on-site analytical methods are used, the adoption of field methods has been hindered by misunderstandings about regulatory requirements for data quality and a traditional reliance on fixed laboratory methods to provide nearly all of the data upon which site decisions are based. Contrary to widespread opinion [see Reference 1, Note 4], EPA policy does NOT "approve" (in a restrictive sense) which specific analytical methods may be used to generate most of the analytical chemistry data used within the "waste programs" (such as the RCRA, Superfund, or other contaminated site cleanup programs). However, to support the analytical needs of the RCRA program (and by extension, other waste/contaminated site management programs), EPA has created and maintains a methods compendium, entitled *Test Methods for Evaluating Solid Waste, Physical/ Chemical Methods* (also known as "SW-846"). [EPA's SW-846 Manual and supporting information are available on-line at: http://www.epa.gov/SW-846/sw846.htm.] SW-846 is currently in its Third Edition, and Draft Update IVB has just been issued [see Reference 9].

SW-846 is a guidance document meant to assist analytical chemists and other users by suggesting sampling and analytical procedures that have undergone thorough evaluation to identify the strengths and weaknesses of the methods, and the expected analytical performance for the range of sample types evaluated [see Reference 1, Notes 1 and 3]. It is EPA's position that for the majority of methods in SW-846 (which are not method-defined parameters, as discussed further below):

- SW-846 is NOT the ONLY source of methods that can be used.
- Methods in SW-846 do NOT need to be implemented exactly as written in SW-846.
- Performance data presented in SW-846 methods should NOT be used as regulatory default or absolute "QC requirements" [see Reference 2, page TWO-1 and -2].

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Causes of Confusion about "EPA-Approved Methods"

Policies in other programs

One source of confusion about requirements for "EPA-approved methods" within the waste programs stems from the fact that EPA's Water programs have regulatory requirements for "EPA-approved reference methods" which are specifically written into their regulations. If these reference methods are followed exactly, by definition in these programs, the data generated using these reference methods are automatically considered to be appropriate for regulatory compliance. These methods are mandatory and prescriptive. Because so many U.S. commercial laboratories are set up to comply with Water program requirements, and since discussions about "EPA methods" are rarely explicit about the specific regulatory program under discussion, many people assume that the same policy of prescriptive methods applies to <u>all</u> EPA programs. However, EPA's Office of Solid Waste and Emergency Response (OSWER) which includes the programs responsible for cleaning up contaminated sites operates under a very different analytical paradigm than the Water programs. There are a number of reasons for this. The most important reason is that the variety of matrices encountered in the waste management and cleanup programs, and the variety of decisions involving those matrices, are much too diverse to expect prescriptive, one-size-fits-all sampling and analytical methods to produce scientifically defensible data across this entire range of variables [see Reference 2, PREFACE-1].

Therefore, there are no "reference methods" (as defined by EPA's Water program) included in SW-846. Within the waste programs, all SW-846 methods or other appropriate methods must be demonstrated by the analyst to generate scientifically reliable data (i.e., data of known quality) for the analytes of concern, in the matrices of concern, at the concentrations of concern, within the context of the intended application. EPA policy in the waste programs is that analyses are required to "get the right answer" as demonstrated by quality assurance mechanisms. If an accepted method cannot "get the right answer" due to analytical difficulties with the matrix, etc., selection of a different method, or modification of a method is required. Having run a method "as written" is no excuse for reporting faulty data. These issues will be discussed in additional detail below.

The CLP in the Superfund program

Another cause for confusion is that the Superfund program maintains the Contract Laboratory Program (CLP), which has had a history of highly prescribed methodologies, reporting limits, and QA/QC criteria. The reason for the prescriptiveness of the CLP results however, not from regulatory requirements, but from *contract* requirements. The Contract Laboratory Program is maintained by the Superfund program as a service to provide Regional offices with ready access to contract laboratory services. The CLP strives for consistency in data reporting formats and expected analytical data quality [see information on http://www.epa.gov/superfund/programs/clp/aboutsrv.htm], since CLP results are often relied upon for enforcement and other sensitive situations. This is done by having laboratories that participate in this program agree to the exact terms of the contract in order to win a place on the list of available CLP labs. Although many of the terms of past contract mechanisms were <u>planned</u> with the expectation that compliance with those terms would ensure consistency in analytical quality, the realities of waste sample types and difficult analytes have the potential to generate inaccurate or non-informative data if needed method modifications, such as changing extraction procedures or adding cleanup steps, were not permitted according to the terms of the contract. Fortunately, this situation has changed substantially in recent years as the CLP explores new ways to permit the analytical flexibility needed to ensure data quality on a sample-by-sample basis, while still accommodating the requirements of a government contract mechanism (for additional information, see www.epa.gov/superfund/programs/clp/methflex.htm).

It should also be noted that use of CLP services by EPA Regions is not required, but is one option open to site managers to simplify their workloads. Obviously then, compliance with CLP contract requirements is not incumbent upon entities not governed by those EPA contracts. Nonetheless, because of the discomfort of most environmental managers with selecting or evaluating analytical chemistry methods, any mechanism that seems to offer the ability to simply "check a box" when choosing laboratory services and abdicate responsibility for ensuring data quality to someone else (i.e., the "government") possesses an irresistible attraction. This has led many labs to market themselves to the private sector as CLP labs or equivalent in order to ride on the coat tails of the CLP mystique, has fueled the misconception that prescriptiveness in analytical methodologies can ensure consistently accurate data, and has furthered a misconception that CLP laboratories are certified or accredited by EPA (which they are not). On the other hand, where this has tended to promote consistency in reporting formats and enforcement expectations, there has no doubt been benefit.

Interpretation of the term "approved method"

Another reason for confusion has to do with the use of the word "approved," and understanding what that means. SW-846 methods are said to be "approved" for use under the RCRA regulatory program to "comply with the requirements of subtitle C of the Resource Conservation and Recovery Act (RCRA)" [see Reference 1, page 3089 and Reference 2, PREFACE-1]. To support application to RCRA programs, "SW-846 analytical methods are written [in their most rigorous form] as quantitative trace [<1000 ppm] analytical methods to demonstrate that a waste does not contain analytes of concern that cause it to be managed as a hazardous waste" [see Reference 2, page TWO-1 and section 2.1.1]. This form of "EPA-approval," however, not the same as that granted for methods in the Water programs, where methods must be used and followed as written. Approved methods for the RCRA program (i.e. SW-846 methods) are methods that have been validated for, and should be able to be used for, most RCRA applications, but they are not *required* to be used (except for the method-defined parameters–discussed below).

The application of "EPA-approved" methods is thus neither exclusive or restrictive [see Reference 2, Disclaimer-1 page]. SW-846 generally offers several alternative methods for the same class of analytes, any of which might be selected to measure target analytes in the context of a particular project or permit. Methods that are not in SW-846 may also be selected. No matter whether a waste generator uses an SW-846 method or alternative method, the user must still demonstrate that the method is applicable for its intended purpose. [see Reference 1, Note 2]. If a method not published in SW-846 is proposed, and there is also little or no performance data published in any peer-reviewed forum, then the amount of analytical documentation that will need to be submitted to the regulatory body for scientific evaluation will be greater than when an established method is used. But the regulatory body should not reject any scientifically valid method that is proposed by a regulated entity *simply* because it does not appear on the "SW-846 list." As long as a method can be demonstrated to achieve the needed sensitivity and accuracy for the target analytes in the matrix in question, then that method should be considered as a viable analytical option.

On the other hand, simply because a method from SW-846 is selected does NOT mean that it can be assumed that implementing the method as written will automatically produce reliable data for a particular application. Especially when unusual or complex matrices are involved, SW-846 methods must still undergo a "demonstration of applicability" to establish adequate analytical performance in the context of that application [see Reference 2, Section 2.1]. Modification of generalized methods is often required to improve method performance for certain target analytes in certain matrices. It should also be noted that SW-846 methods are NOT equivalent to Standard Operating Procedures (SOPs), and cannot be substituted for project-specific or laboratory-specific SOPs [see Reference 2, PREFACE-1].

Failure to distinguish the impact of sampling considerations

One-size-fits-all approaches assign accountability based on whether a certain procedure was followed, not on whether work was performed correctly and accurately. While comforting in the short-run because of their simplicity, one-size-fits-all approaches are truly useful only as stop gap measures until more reliable information or understanding becomes available. Reliance on them after that becomes counter-productive, error-prone, and wasteful in the long-run as evidence of decision errors (due to faulty underlying assumptions) accumulate. The expectation that simply regulating how analytical methods are used can guarantee sufficient data quality is seductive to regulators and practitioners alike because it avoids the much more difficult issues of project planning, sample representativeness, and the integration of professional/technical competence and scientific advancement into all levels of project implementation [see Reference 2, PREFACE-1]. It is also convenient to think that if project decisions are later shown to be "wrong," the blame can be assigned to the laboratory for generating the "wrong" results.

But the unavoidable truth is that even *if* the most highly accurate laboratory methods were used on each individual sample, the data will be meaningless or misleading if the sample collection procedures (procedures implemented by field personnel over which laboratories have no control) do not ensure the *representativeness of the samples in the context of the project decisions.* In other words, does the sample selection process ensure that data from those samples will represent the parameter of interest? A sampling design that is supposed to determine whether spills or leaks could have occurred at a site will be very different from a sampling design that is supposed to determine the average concentration of contaminants across some risk-based exposure unit. Sampling design must consider where specimens are collected, when samples are collected, and how samples are collected. "Where" is frequently determined by statistically-based sample designs when quantitative estimates of decision certainty are desired. "When" may also be governed by statistical considerations, as well as by seasonal effects or other time-sensitive factors. "How" involves a consideration of representative "sample support" (the dimensions and orientation of specimens as they are extracted from the parent material being tested), and the selection of the sampling tools that will be used to extract the specimen (spatulas, soil corers, drum samplers, etc.). [See EPA guidances for statistics and sampling design available on http://cluin.org/chartext_edu.htm#stats. A more thorough discussion of the issue of representativeness in regard to environmental data can be found in EPA QA/G-5, Appendix H. See Reference 8.]

Failure to distinguish between determinative and sample preparative methods

Non-chemists also show a strong tendency to focus solely on *determinative* analytical methods (the instrumentation used to actually generate the analytical result) to the exclusion of other very important aspects of sample analysis, such as sample preservation, subsampling in the laboratory, sample preparative, extraction, or digestion methods, and extract cleanup methods. Yet, as with representative sample collection, appropriate sample preparative methods can mean the difference between data that are effective for defensible decision-making and data that are completely unreliable, irrespective of how much quality control is imposed on the determinative method. Sadly, a great deal of time and money is spent to micromanage laboratory determinative methodologies, while these other factors are completely ignored. Huge gains in the reliability of analytical results could be attained by refocusing resources to ensure the representativeness of sample collection, and by supporting the "mixing and matching" of sample preparative, cleanup, and determinative methods for the purpose of generating the appropriate data needed to address specific project decisions [see Reference 2, PREFACE-1, and Reference 3, page 3].

Prescriptive SW-846 methods for method-defined parameters

Yet another reason for confusion is that there are a few specific requirements in regulations to use SW-846 methods exactly as written. EPA regulations state [see Reference 1, Note 2] that "Several of the hazardous waste regulations under Subtitle C of RCRA require that specific testing methods in SW-846 be employed for certain applications." These requirements relate to testing used to determine a specific kind of property that is termed a "method-defined parameter." The regulation goes on to say that "**Any reliable method may be used** to meet **other** requirements in 40 CFR parts 260 through 270" [emphasis added].

"Method-defined parameters" are characteristics or properties of waste materials that are defined by the outcome of a particular testing procedure. The test must be performed exactly as written because the way the method is performed determines the results, and interpretation of the results has been standardized based on implementing the testing procedure in the same way every time. Where RCRA regulations are involved, a method-defined parameter is a method that defines the related regulation, and so it must be followed exactly as written. Examples of these method-defined parameters are the Toxicity Characteristic Leaching Procedure (TCLP, SW-846 Method 1311), and tests to determine the free liquid component of a waste (SW-846 Method 9095) or the corrosivity of a waste material (SW-846 Method 1110). If the method is not performed in the exact manner as written (for example, if the TCLP is performed with a different leaching solution or for a different time period), the result for the measured parameter cannot be used to interpret compliance with the corresponding regulation [see Reference 2, page TWO-1; and Reference 3, page 4].

There are only a few method-defined parameter methods in SW-846. The vast majority of SW-846 methods (and much, if not all, of the testing done during hazardous waste site characterization) are not method-defined parameters. That means the analytical method is measuring a parameter that is real physical matter, such as the total amount of arsenic (As) in a kilogram of soil. The amount of total arsenic is an independent, verifiable quantity that is at theoretically and conceptually possible to measure exactly, even if that measurement is a technological challenge. Such methods are proper candidates for method modifications or for selection of alternative methods that permit improvement of analytical performance for specific sample types, or to improve the cost-effectiveness of environmental monitoring programs while still ensuring that the "correct" regulatory decisions are being made. The goal of the RCRA methods program is not to arbitrarily require specific procedures (which is a command-and-control mechanism), but to allow members of the environmental community freedom to achieve their regulatory objectives in ways that make both scientific and economic sense within their particular context. This is called a performance-based, or results-oriented, approach.

The development of regulation-defined testing procedures should be considered carefully. Where there are regulatory requirements for certain testing procedures to be implemented as written in the regulation, the responsibility for the accuracy or realism of the results is assumed by the regulating entity. For example, the purpose of the TCLP is to estimate the likelihood that waste deposited in a landfill will leach toxic constituents into groundwater. If the TCLP test predicts that no leaching will occur, and the waste is placed in a landfill, but then leaching does occur in the real world, the blame for faulty real-world predictability does not lie with the regulated entity, but with the regulator/regulation for requiring a test that does not always yield reliable results. Yet developing a prescriptive test that will be reliable across multiple impacting variables is extremely difficult, if not impossible.

Writing regulations that require prescriptive methods for actual physical quantities (such as the amount of benzene in a liter of groundwater) turns these measurements into method-defined parameters from a regulatory perspective, and ceases to recognize benzene concentrations as real molecules whose accurate quantification is continually improved with experience and technology advancement. If a regulating entity relies on prescriptive methods, it is then under continual pressure to update its regulations to keep pace with improvements in analytical chemistry technology. This has proven to be an impossible task. A more technologically, economically, and scientifically feasible approach is the Performance-Based Measurement System approach (discussed below).

Performance-Based Measurement Systems (PBMS)

Why a performance-based approach to analytical methods is advantageous

As discussed above, prescriptive regulation of analytical methods is not wise for several reasons:

1. Eliminating analytical flexibility forces some testing to be done inappropriately because site- or sample-specific issues (such as matrix complexities, recovery issues, or interferences) cannot be addressed to ensure accurate analytical results.

2. For some site decisions, rigorous quantitative data may not be needed–only a semi-quantitative or "go or no-go" result is required to make the correct decision. It is wasteful to pay for high levels of analytical data quality that are not relevant to project needs; yet regulatory programs that prescribe specific methods seldom permit a graded approach to selecting methods or so that analytical performance can be tailored to match specific project needs. However, it is well established that as long as adequate planning and QA/QC protocols ensure that the data quality will be *known* and *appropriate to the intended data use*, it is frequently possible to use less expensive analytical methods for some or all of the data collection efforts, while achieving a *higher level of overall decision certainty* if a more representative number of samples can be tested [see Reference 7].

3. Regulatory analytical rigidity damages the ability of the environmental laboratory community to grow in expertise and advance technologically. Prescriptive methods prohibit the use of professional analytical chemistry skills that could otherwise select the most appropriate methods or modify and troubleshoot methods to ensure that the "right answer" is obtained. Discussions with experienced environmental chemists and skilled laboratory auditors reveal a common consensus that years of prescriptive methods has atrophied the competence of U.S. commercial environmental laboratories, and is a contributing factor to laboratory fraud. These observers have seen highly trained and experienced professional chemists replaced by technicians who mindlessly operate equipment while lacking the technical understanding and critical thinking abilities needed to guarantee the analytical quality needed to support environmental decisions (see WTQA references regarding laboratory and data quality issues).

4. In addition, prescriptive requirements inhibit the development of new and better analytical methods for the environmental laboratory because of the great time lag between the introduction of an innovative, improved technology and the regulatory acceptance that would allow it to be freely used in the marketplace. While analytical science is making great strides in other industries, application of improved, cost-effective analytical technologies in the environmental arena lags

behind. Statements from instrument makers and vendors reveal their reluctance to develop and market new equipment for environmental applications because a near-term return on their investment appears unlikely no matter how much promise the technology may offer in lower analytical costs or improved analytical quality.

PBMS within EPA's waste programs

Although the Methods Team responsible for maintaining SW-846 has worked under a performance-based approach since the inception of SW-846, this fact is seldom recognized. Despite the many efforts of the Methods Team to counteract disturbing trends toward analytical micromanagment, SW-846 has been misapplied in a prescriptive manner in the implementation of many federal and state programs [see Reference 3, page 2]. In another attempt to combat analytical prescriptiveness, EPA has formally adopted an agency-wide policy called the Performance-Based Measurement System (PBMS) approach, as announced in an October 6, 1997 Federal Register Notice [see Reference 4]. Although the policy addresses all agency programs, this discussion will only involve the application of PBMS to RCRA-related programs (and by extension, to all programs relying on SW-846 methods), as announced in a May 8, 1998 Federal Register Notice [see Reference 5].

As discussed in Section II.A, page 25431 of the May 8, 1998 Federal Register Notice, a PBMS approach "conveys 'what' needs to be accomplished, but not prescriptively 'how' to do it... [T]he regulating entity will specify questions to be answered by the monitoring process, the decisions to be supported by the data, the level of uncertainty acceptable for making the decisions, and the documentation to be generated to support the PBMS approach...Data producers will demonstrate that a proposed sampling and analytical approach meets the monitoring criteria specified in the Quality Assurance Project Plans or Sampling and Analysis Plans for the individual projects or applications."

This means that any analytical method may be used to generate data (whether or not it is currently published in SW-846) as long as it can be demonstrated to:

- measure the constituent of concern,
- in the matrix of concern,
- at the concentration level of concern,
- at the degree of accuracy as identified as necessary to address the site-decision.

This also means that sampling considerations (the number and placement of specimen collections) interact with the analytical consideration and the decisions to be made in an integrated fashion to generate a specified level of overall certainty in a decision. For example, contrast two scenarios wherein a given waste stream contains constituents subject to regulatory monitoring to ensure to some specified degree of statistical certainty that the true constituent concentration is indeed less than a given regulatory threshold. In Scenario 1, the regulated analytes tend to occur at levels very *close* to the regulatory threshold. Statistical calculations determine that a certain number of samples and a certain level of analytical method accuracy (i.e., precision and bias) will be required to establish regulatory compliance. In contrast, for Scenario 2, the same regulated analytes in the same waste stream tend to occur at concentrations *significantly less* than the regulatory threshold, but all other conditions (such as the desired degree of statistical confidence) are the same. For Scenario 2, demonstrating that regulatory compliance is achieved would require *fewer* samples and *less* stringent analytical accuracy than those required in Scenario 1.

For this reason, regulations should serve only to set a bar for overall statistical certainty in environmental decisions, but should not attempt to prescribe sample numbers or to limit analytical technologies. When regulated entities are given clearly defined (and consistently enforced) compliance goals and the freedom to customize their processes and monitoring programs to match their particular circumstances, industry quickly discovers the most cost-effective means to achieve the goals of environmental regulation, including the creation of innovative technologies. Flexibility can also encourage regulated entities to *exceed* the environmental protection goals desired by regulatory requirements, if the cost of lowering the absolute concentration of discharged regulated analytes in the waste stream can be offset by savings in the monitoring costs (as exemplified in Scenario 2). If appropriate technical expertise is incorporated by the regulatory body, it is not difficult to develop oversight programs that discourage "cheating" while permitting this kind of flexibility.

When sampling and analytical considerations are allowed to be co-variables in an equation whose output is the overall confidence (statistical certainty) desired in a regulatory decision, a much more *cost-effective and protective* monitoring program can be developed than is possible under programs built on a foundation of prescriptive, one-size-fits-all assumptions.

A PBMS is consistent with Agency-wide EPA policies regarding quality management and the implementation of quality systems. EPA quality policies do not require that specific procedures or analytical technologies be required or designated. Rather, EPA's Agency-wide Quality Manual requires the use of "a systematic planning process based on the scientific method [and based on] a common-sense 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" [see section 3.3.8 of Reference 10]. Quality policies require that whatever methods are used, they must be adequately documented in order to demonstrate that the data quality will be known and be adequate to defensibly support achievement of the stated project objectives [see sections 5.3.1 and 5.3.3 of Reference 10].

Implications of PBMS for contaminated site cleanup

Integration of new analytical technologies for characterization and monitoring, and new remediation technologies for cleaning up sites, offer "smarter solutions" for managing the environmental issues related to hazardous waste. When hazardous waste practice clings tenaciously to the familiar habits developed during its infancy, everyone loses.

Performance-based approaches are the foundation of the paradigm shift away from command-and-control regulatory structures (which are very expensive and unsatisfactory in other ways) toward more results-driven, economical, market-based approaches to environmental protection. Adopting a PBMS policy is a first step toward accepting newly available analytical tools and the work strategies they support so that management of contaminated sites can be made more affordable and more defensible. The **triad approach to site cleanup** (i.e., the integration of systematic planning, dynamic work plans, and on-site analysis) is based on PBMS principles. It has consistently demonstrated savings up to 50% over the life of a project when compared to the costs of more traditional cleanups, *while maintaining or improving confidence in protective site decisions.* The dynamic work plan approach using on-site (i.e., field) analytical methods has been described in the informative video entitled, "Field Analytics: The Key to Cost Effective Site Cleanup" [Reference 6]. More information about the triad approach and its implications for the management of hazardous waste sites can be found in Reference 7.

References

Reference 1: Federal Register, Vol. 60, No. 9, Friday, January 13, 1995, Rules and Regulations, pages 3089-3095. Item is retrievable at http://www.access.gpo.gov/su_docs/aces/aces140.html. Search using the following entries: 1995 Federal Register; Final Rules and Regulations; On 01/13/1995; Search Term = "Hazardous Waste Management System"

Reference 2: Pages from the body of SW-846. These pages can be viewed or downloaded from the following websites:
page "DISCLAIMER-1" from http://www.epa.gov/SW-846/disclaim.pdf
pages "TWO-1 and TWO-2" from http://www.epa.gov/SW-846/chap2.pdf
pages PREFACE-1 and PREFACE-2 from http://www.epa.gov/SW-846/preface.pdf

Reference 3: Article entitled "An Update of the Current Status of the RCRA Methods Development Program," available from http://www.epa.gov/SW-846/rcra.pdf

Reference 4: Federal Register, Vol. 62, No. 193, Monday, October 6, 1997, Notices, pages 52098-52100. Item is retrievable at http://www.access.gpo.gov/su_docs/aces/aces140.html. Search using the following entries: 1997 Federal Register; Notices; On 10/06/1997; Search Term = "Performance Based Measurement System"

Reference 5: Federal Register, Vol. 63, No. 89, Friday, May 8, 1998, Notices, pages 25430-25438. Item is retrievable at http://www.access.gpo.gov/su_docs/aces/aces140.html. Search using the following entries: 1998 Federal Register; Proposed Rules; On 05/08/1998; Search Term = "RCRA-Related Methods"

Reference 6: Tufts University video, *Field Analytics: The Key to Cost Effective Site Cleanup*. 18 minutes in length. The video is available for viewing or ordering through the following website: http://cluin.org/video/Hanscom.htm

Reference 7: Access the issue paper, *Current Perspectives in Site Remediation and Monitoring: Using the Triad Approach to Improve the Cost-Effectiveness of Hazardous Waste Cleanups* (EPA 542-R-01-016) from http://cluin.org/tiopersp/

Reference 8: Access the document, *EPA Guidance for Quality Assurance Project Plans (EPA QA/G-5),* at http://www.epa.gov/quality/qs-docs/g5-final.pdf

Reference 9: Federal Register, Vol. 65, No. 228, Monday, November 27, 2000, Proposed Rules, pages 70679-70681. Item is retrievable at http://www.access.gpo.gov/su_docs/aces/aces140.html. Search using the following entries: 2000 Federal Register; "Proposed Rules"; On 11/27/2000; Search Term = "IVB"

Reference 10: Access *EPA Quality Manual for Environmental Programs* (5360 A1), at http://www.epa.gov/quality1/qs-docs/5360.pdf

Additional information regarding laboratory and data quality issues can be found in the following Waste Testing and Quality Assurance Symposium papers, available at http://cluin.org/products/dataquality

Selected papers from WTQA '97 - *13th Annual Waste Testing and Quality Assurance Symposium Proceedings*:
- "Options in Data Validation: Principle for Checking Analytical Data Quality" by Shawna Kennedy (pp. 169-172)
- "Laboratory Analyst Training in the 1990's and Beyond" by Roy-Keith Smith (pp. 172-182)
- "Investigation versus Remediation: Perception and Reality" by Emma P. Popek (pp. 183-188)
- "Performance-Based Evaluation of Laboratory Quality Systems: An Objective Tool to Identify QA Program Elements that Actually Impact Data Quality" by Sevda K. Aleckson and Garabet H. Kassakhian (pp. 195-199)
- "The Method Detection Limit: Fact or Fantasy?" by Richard Burrows (pp. 200-203)

Selected papers from WTQA '98 - *14th Annual Waste Testing and Quality Assurance Symposium Proceedings*:
- "Techniques for Improving the Accuracy of Calibration in the Environmental Laboratory" by Dennis A. Edgerley (pp. 181-187)
- "Interpretation of Ground Water Chemical Quality Data" by G. M. Zemansky (pp. 192-201)

Selected papers from WTQA '99 - *15th Annual Waste Testing and Quality Assurance Symposium Proceedings*:
- "Lessons Learned from Performance Evaluation Studies" by Ruth L. Forman (pp. 38-46)
- "Questionable Practices in the Organic Laboratory: Part II" by Joseph Solsky (pp. 121-125)
- "The Role of a Compliance Program and Data Quality Review Procedure under PBMS" by Ann Rosecrance (pp. 231- 235)