UTILITY WATER ACT GROUP

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VIA FAX AND U.S. MAIL

Ms. Brooke Dickson
Office of Information and Regulatory Affairs
Office of Management and Budget
Eisenhower Executive Office Building
17th Street and Pennsylvania Ave., NW
Washington, DC 20503

Comments of the Utility Water Act Group on Proposed Guidelines for Information Quality

Dear Ms. Dickson:

Enclosed are comments of the Utility Water Act Group ("UWAG") on the Proposed Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, which the Office of Management and Budget published in the Federal Register on June 28, 2001 (66 Fed. Reg. 34,489). The entire package consists of a set of narrative comments and a 1989 article on analytical variability from the Environmental Law Reporter. Please consider these comments as you finalize the proposed information quality guidelines.

Should you have any questions regarding our comments, please do not hesitate to contact me (205/257-5234) or UWAG's counsel, Jim Christman of Hunton & Williams (804/788-8368).

Yours very truly,

Donna B. Hill

Donna B. Hill
Chair, UWAG Analytical Procedures Committee

Enclosure

COMMENTS OF THE UTILITY WATER ACT GROUP ON OMB'S PROPOSED GUIDELINES FOR INFORMATION QUALITY

August 13, 2001

These are the comments of the Utility Water Act Group (UWAG)[1] on the proposed guidelines published June 28, 2001, by the Office of Management and Budget for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by federal agencies, 66 Fed. Reg. 34,489 (June 28, 2001). Required by § 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106-554), the guidelines are to "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." Within a year after OMB issues these guidelines, federal agencies must issue their own implementing guidelines These must include "administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency" that does not comply with the OMB guidelines. 66 Fed. Reg. 34,489 col. 2

UWAG is primarily interested in information disseminated by the Environmental Protection Agency, and it is especially interested in numeric data, especially measurements of water pollutant concentrations that may be used for purposes such as setting water quality standards, making § 303(d) listing decisions, developing TMDLs, and setting and enforcing

[1] UWAG is an association of 146 individual electric utilities and three national trade associations of electric utilities, the Edison Electric Institute, the National Rural Electric Cooperative Association, and the American Public Power Association. The individual utility companies operate power plants and other facilities that generate, transmit, and distribute electricity to residential, commercial, industrial, and institutional customers. The Edison Electric Institute is the association of U.S. shareholder-owned electric companies, international affiliates, and industry associates. The National Rural Electric Cooperative Association is the association of nonprofit electric cooperatives supplying central station service through generation, transmission, and distribution of electricity to rural areas of the United States. The American Public Power Association is the national trade association that represents publicly owned electric utilities in the United States. UWAG's purpose is to participate on behalf of its members in EPA's rulemakings under the CWA and in litigation arising from those rulemakings.

effluent limitations in permits under the NPDES (National Pollutant Discharge Elimination System) permit program established by § 402 of the Clean Water Act. UWAG's interest in this matter is exactly the same as that of OMB's guidelines: to ensure that such data meet a "high standard of quality." See 66 Fed. Reg. 34,491 col. 3. Using and disseminating only data of high quality are exquisitely important, because data are used to determine whether permittees have violated environmental laws and therefore must pay heavy civil penalties or even, in some cases, serve time in prison. Data also are used to decide the extent to which permittees must reduce pollutants in their wastewater, and thus the magnitude of their investment in pollution control technology and related operational costs.

The OMB guidelines as proposed are appropriate and sound, as far as they go, but they do not go far enough. For example, the first guideline in section III, which is that agencies should adopt a "high standard of quality" is desirable, but it is not particularly groundbreaking and, indeed, ought to have been followed all along, even without formal guidelines.

Thus, UWAG's recommendation is that the OMB guidelines be made more detailed and specific, stating requirements for data that go beyond the obvious and that tell agencies precisely what data they should deem acceptable and what data they should not rely on.

In particular, the guidelines should include at least the following five requirements, which we might call the "Fundamental Principles of Data Integrity":

1. When federal agencies report or disseminate "measured" data (that is, data obtained from a test instrument), they should report the extent of the analytical uncertainty (that is, the error band) associated with the data. This is especially important for data the agency uses to make regulatory decisions, such as decisions to set standards and

permit limits and decisions as to whether someone has violated a permit or an environmental law

2. Federal agencies should identify the specific test methods that were used to generate data they rely on and to confirm that those test methods are approved under 40 C.F.R. Part 136, at least for those measurements (of environmental pollutants, for example) to which Part 136 applies

3. Federal agencies should state, when disseminating data, whether the data were generated by laboratories that complied strictly with all mandatory test protocols and quality assurance/quality control (QA/QC) procedures.

4. Federal agencies should adopt as part of their implementing guidelines the new quality assurance guidance for data that EPA published in 1999 and 2000 These guidelines are the following:

   Guidance for Data Quality Assessment (July 2000);

   Guidance for the Data Quality Objectives Process (August 2000);

   Guidance for Preparing Standard Operating Procedures (SOPs) (March 2001);

   EPA Requirements for Quality Management Plans (March 2001); and

   - *EPA Requirements for Quality Assurance Project Plans* (March 2001

5 Federal agencies should not rely on data that are below the level of quantification or level of detection of the instrument used to measure them.

With respect to the first principle, no test method is capable of measuring the exact concentration (that is, the true value) of a pollutant in a sample. All test methods and sampling procedures introduce some degree of error in the test result. While that analytical variability is

unavoidable, it is predictable. Ensuring high quality data demands that the data be reported along with the associated error band so that users understand what the data actually mean.[2]

With respect to the third of these principles, it is, unfortunately, necessary to remind the agencies of the importance of informing the public about data from labs that fail to comply with test protocols and QA/QC procedures. For example, EPA recently conducted an interlaboratory validation study on whole effluent toxicity testing, a type of test that exposes test organisms (water fleas or minnows, for example) to a wastewater sample to see how many of the test organisms die. In this interlaboratory study, a large percentage of the participating laboratories failed to comply with mandatory QA/QC procedures. EPA currently is considering how, if at all, it will disclose those QA/QC deficiencies in the study report it is preparing for publication. OMB guidelines should clarify that agency guidelines must require the agencies to acknowledge openly the QA/QC deficiencies associated with any data they report, and to specify the manner in which such deficiencies compromise the quality and utility of the data.

The fifth principle, which is the need to respect the limits of quantification and detection of the analytical instrument, fails to inflame passions and yet is crucial to the integrity of any regulatory system that relies on measurements – and which regulatory system does not?

All scientific measuring instruments and laboratory methods have inherent limitations. All of them can measure just so low and no lower. The "limit (or level) of quantification" of an instrument is the level of measurement (the concentration of a pollutant in water, for example) below which the instrument cannot get a reliable number. A lab test may have a limit of quantification of 3 parts per billion, for instance; if the test is run and shows a concentration of 2

[2] For a fuller discussion on data measurement error and other laboratory uncertainties, see Koorse, S., "False Positives, Detection Limits, and Other Laboratory Imperfections: The Regulatory Implications," 19 ELR 10211 (May 1989).

ppb, then the analyst may be able to say for certain that the pollutant is present in some concentration, but he simply cannot say how much. At some lower level, different for each chemical, the "limit of detection" of the instrument is reached; assume it is 1 ppb in this example. If the instrument with a detection limit of produces a measurement of 0.5, then the analyst cannot even say the pollutant is present in the test sample at all, let alone how much of it may be there.

It seems self-evident that measurements below the levels of quantification and detection have limited uses except to show that a pollutant is *not* present above a certain level. Certainly they cannot show noncompliance with legal requirements set below the level of quantification or level of detection. Thus the D.C. Circuit Court of Appeals has said that "[a] standard with which compliance cannot be assessed – and it is agreed that compliance with an effluent limitation set below the level of a quantification simply cannot be assessed – is no standard at all for purposes of due process." *American Iron and Steel Institute v. Environmental Protection Agency*, F. 3d 979, 994 (D.C. Cir. 1997). This principle should be written into the OMB guidelines for data quality.

The proposed OMB guidelines raise other issues of great significance as well. example, the OMB proposal refers to dissemination of information by the Internet. As EPA puts more and more information on its Web pages and collects more and more information electronically (a trend that is certain to increase in the future), one problem that arises is how to protect confidential business information. The OMB guidelines should adjure agencies to establish procedures to protect the confidentiality of information stored on government computers, including encryption as necessary. When a regulated company provides proprietary

information to an agency, it needs assurance that the information will not be accessed by unauthorized outsiders (that is, "hackers").

The other side of the confidentiality coin is that agencies should not use secret data to make regulatory decisions affecting people who are not allowed to see the underlying data. The OMB guidelines should tell agencies that, for regulatory decisions, they should not rely on data that are not available to the public. Recently, for example, EPA refused to make available certain data on the human health effects of mercury, apparently because the underlying data involved medical records. Presumably, the data could have been made available without revealing the identity of the patients, but EPA refused nevertheless. It is fundamentally unfair to make regulatory decisions based on secret information, and the OMB guidelines should not allow it.

The OMB guidelines provide that agencies should establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated that does not comply with the OMB guidelines. 66 Fed. Reg. 34,492 col. 1. This provision should be strengthened. Agencies should be told that they "must" establish such administrative mechanisms as a matter of due process of law. Moreover, persons aggrieved by inaccurate or unreliable information should have a right to an agency hearing, followed by resort to judicial review, if necessary. Of course, if the OMB guidelines succeed in inducing the agencies to make strong procedures for ensuring the quality of their data in the first place, there will be little need to resort to the procedures for correcting errors.

The OMB guidelines should caution agencies to be extremely careful about relying on data from one medium (for example, air pollution) to draw conclusions about the effect of the same chemical in other media (for example, water). Pollutants have different effects in different

NEWS & ANALYSIS

ARTICLES

False Positives, Detection Limits, and Other Laboratory Imperfections: The Regulatory Implications

by Steven J. Koorse

Editors' Summary: The major federal environmental regulatory schemes make frequent use of numerical standards. The consequences of exceeding these standards can be extremely serious—companies may be subjected to civil or even criminal liability, or required to undertake increased regulatory responsibilities. For example, liability under the Clean Water Act is based on exceedances of numerical limits in NPDES permits. The author of this Article asserts that the methods by which such numerical standards are developed and by which compliance with them is measured display intrinsic, irreducible imperfections, or variability. According to the author, these imperfections, unless they are accounted for, can result in false liability or excessive regulatory burdens. This Article explains what analytical variability is, and how it can affect the regulatory process. The author asserts that EPA is constitutionally required to account for analytical variability in its regulations, but that its attempts to do so thus far are inadequate. Finally, the author puts forward a series of recommendations to guide the regulated community in protecting itself from the adverse consequences of analytical variability.

"False positives," "detection limits," and "analytical variability" are terms that, until recently, were buried within the arcane vocabulary of the scientific community. Massive liability exposure threatened by the wave of environmental legislation evolving over the past two decades has thrust these terms out of the laboratory and into boardrooms and courtrooms across the nation. Indeed, these terms are bound to become commonplace, given the recent emphasis on blood testing for acquired immune deficiency syndrome, cholesterol, and anabolic steroids, and the profound implications of erroneous test results.

While environmental statutes differ from one another in terms of the media they protect and the regulatory schemes prescribed for doing so, they share a common feature. They generally contain numerical standards, the exceedance of which may result in civil or criminal sanctions, or in the imposition of burdensome regulatory requirements. Unfortunately, the laboratory test methods used to develop and assess compliance with such standards exhibit varying degrees of irreducible performance variability. This can significantly impair the reliability of test data,[1] and can cause uncertainty and unfairness in regulatory decisions based on these data.

Indeed, failure to consider analytical variability in assessing laboratory data collected for regulatory purposes can lead to "false" liability or excessive regulatory burdens.[2] To avoid such consequences, the regulated community[3] must develop a sound understanding of: (1) what analytical variability is, (2) how such variability can be quantified, (3) how analytical variability can manifest itself in the regulatory process, and (4) what the Environmental Protection Agency (EPA) is doing (or ought to be doing) in response. This Article discusses these issues and concludes with a section providing recommendations on how the regulated community can protect its interests.

Mr. Koorse is an associate with the law firm of Hunton & Williams in Richmond, Virginia. He is also a registered professional engineer who spent several years in the United States Environmental Protection Agency's enforcement and water programs. The author wishes to express special thanks to Turner T. Smith, Jr. of Hunton & Williams. This Article was adapted from a speech Mr. Koorse presented on behalf of the Utility Water Act Group at a seminar entitled, "Laboratory QA/QC and the Regulatory Environment," sponsored by the Electric Power Research Institute.

1. This analysis is limited to a discussion of "analytical" variability (i.e., that caused by the instrument, the analytical procedure, and the laboratory analyst). It does not address the other forms of variability that may influence compliance monitoring results (e.g., that caused by the method of sampling and process fluctuations).

2. It may also be the case that analytical variability can lead to false negatives (i.e., a determination that a sampling result meets applicable standards when in fact the standard has been exceeded).

3. For purposes of this analysis, references to "companies" or "industry" are intended to encompass regulated public entities as well.

What is Analytical Variability?

No matter how well-trained their analysts and how sophisticated their analytical equipment, laboratories can never eliminate imperfections in their performance capabilities. A host of human and mechanical factors prohibits even the best laboratories from performing flawlessly. The intrinsic imperfections associated with all analytical methods are generally referred to as "performance limitations."[4]

Even though performance limitations cannot be eliminated, they can be minimized through diligent quality assurance and quality control (QA/QC) practices. Moreover, performance limitations can be quantified, and the resulting performance data ("performance characteristics")[5] can be utilized to avoid unjust results in the regulatory process.

Performance limitations generally manifest themselves in the form of "analytical variability," which refers to the inability of test methods to measure reliably and consistently the actual concentration ("true value") of the substance being analyzed.[6] Due to the unique "precision"[7] and "bias"[8] characteristics of individual test methods, a single analyst performing replicate analyses on a water sample containing ("spiked with") a pollutant of known concentration will, as a practical matter, never be able to determine the true value of that pollutant. Each successive test result will differ to some degree from previous results and will collectively form a range or "error band" about the true value. The same limitation will be exhibited by several analysts measuring identical portions ("splits") of a prepared sample; however, greater variability is introduced when the number of analysts is increased, and the error band surrounding the true value will usually be broader.[9]

The degree of analytical variability exhibited by each test method will depend on several factors, including: (1) the type of chemical being analyzed,[10] (2) the concentration of that chemical,[11] (3) the interferences caused by the type of matrix[12] being measured, and (4) human, instrumental, and ambient influences. That variability has traditionally been expressed in terms of linear regression equations. Simply put, regression equations allow one to estimate the variability of a test method at all concentrations over the range of concentrations tested for a particular chemical. EPA has derived such equations for several test methods[13] based on data collected in a number of studies ("method studies")[14] designed to prove the acceptability of (to "validate") those methods.[15] Of course,

4. This analysis focuses predominantly on the performance limitations associated with test methods used to measure individual chemical constituents (e.g., volatile organic compounds measured by gas chromatography). Performance limitations also arise in the context of biological test methods (i.e., methods that measure the response of certain test organisms that have been exposed to a particular waste for a designated time period). Where appropriate, significant distinctions between the performance limitations of chemical and biological test methods are identified.

5. Performance characteristics are generally described with respect to a particular analytical method applied to a specified type of sample and can be expressed in any of three ways, depending on how they are derived. If derived on the basis of replicate data from a single laboratory, they would be referred to as single operator, or intralaboratory, performance characteristics. If derived on the basis of an averaging of the intralaboratory performance characteristics from several laboratories, they would be referred to as average, single operator performance characteristics. Finally, if derived on the basis of the collective data from several laboratories, they would be referred to as interlaboratory performance characteristics.

6. Performance limitations may also manifest themselves in the form of test failure (i.e., the inability of a laboratory to run a particular test protocol to completion). This form of performance limitation is particularly prevalent in biological testing, where the test organisms subjected to some "placebo" solution, for control purposes, may exhibit unacceptable mortality.

7. The "1986 Annual Book of ASTM [American Society of Testing and Materials] Standards" defines "precision" as:

> The degree of agreement of repeated measurements of the same property expressed in terms of dispersion of test results about the arithmetic mean result obtained by repetitive testing of a homogeneous sample under specified conditions. The precision of a method is expressed quantitatively as the standard deviation computed from the results of a series of controlled determinations.

Vol. 11.01, AMERICAN SOCIETY OF TESTING AND MATERIALS, STANDARD PRACTICE FOR DETERMINATION OF PRECISION AND BIAS OF APPLICABLE METHODS OF COMMITTEE D-19 ON WATER, 1986 ANNUAL BOOK OF ASTM STANDARDS, ASTM D2777-85 at 29 (1986). By analogy to a game of darts, the smaller the spread of darts on the dart board, the better the precision.

8. Bias is defined by ASTM as, "[t]he persistent positive or negative deviation of the method average value (x) from the assumed [i.e., true (c)] or accepted value" (i.e., bias = x − c). *Id.* By analogy to a dart game, the closer the darts are to the bull's eye, the smaller the bias. Because it is impossible to quantify the "true" toxic response of organisms exposed to a particular toxicant, the term "bias" is not used to express analytical variability in the context of biological tests.

9. Because the measurement data on which compliance determinations are made can often be produced in any one of several different laboratories (i.e., industry, government, commercial), interlaboratory performance characteristics are far more appropriate than intralaboratory characteristics in assessing the relevance of those compliance monitoring results. *See supra* note 5.

10. For example, the variability associated with measuring organic compounds is generally higher than it is for measuring metals. *Compare* 40 C.F.R. Part 136 App. A (1987) *with* 52 Fed. Reg. 33,553 (Sept. 3, 1987) (these references contain performance characteristics for organic compounds and metals respectively).

11. Test methods generally exhibit increasingly greater relative variability as the concentration of the substance being measured is decreased.

12. "Matrix" refers to the sample (especially its physical and chemical properties) in which the specific constituent being measured is present (e.g., water, soils, or sludges from various types of sources).

13. *See, e.g.*, 40 C.F.R. Part 136 App. A (1987) (the "600 series"), which contains regression equations describing the performance characteristics for the test methods prescribed for measuring organic chemicals under the Federal Water Pollution Control Act (FWPCA, also known as the Clean Water Act).

14. EPA's method studies essentially consist of sending to several laboratories vials of concentrated standards that each recipient dilutes in a specified manner to achieve water samples containing known concentrations of individual substances over a range of concentrations. These laboratories are asked to analyze the samples using specified test protocols and to send their test results back to EPA. Using regression techniques, EPA converts those data into equations that allow one to estimate the variability that could be expected at any concentration within a specified range.

15. The following paradigm illustrates how regression equations can be applied. If a company receives a draft NPDES permit with a daily maximum limit on cadmium equal to 50 ug/l (micrograms per liter), it can calculate the variability of test results that can reasonably be expected to occur at this level. EPA specifically endorses the use of its regression equations for this purpose. 52 Fed. Reg. 33547 (Sept. 3, 1987). EPA's proposed regression equations for the analysis of cadmium by atomic absorption are $X = 0.919(C) + 2.97$, where X is the measured concentration expressed as ug/l, and C is the true value (here 50 ug/l) expressed as ug/l; and $S = 0.108(X) + 5.08$, where S is the interlaboratory standard deviation. *Id.* at 33553. Applying these equations, $X = 48.92$, and $S = 10.36$. Assuming the company desires variability results expressed with 95 percent confidence, it would multiply S by a factor of 2 to arrive at the value that can be expected to represent the upper and lower bounds of variability that would occur. A factor of 2 is used because 95 per-

the confidence one can place on the predictive powers of EPA's regression equations is directly proportional to the confidence one has in the manner in which such equations were derived. EPA's practices to date in this regard have been the subject of much controversy.[16]

In some instances, EPA expresses analytical variability in terms of the percentage of laboratories that are capable of measuring to within a specified percentage of a certain concentration of a particular substance. For example, in a recent rulemaking under the Safe Drinking Water Act (SDWA),[17] EPA stated that 75 percent of the experienced government laboratories whose data were used could routinely measure to within plus or minus 40 percent of the maximum contaminant levels (MCLs) it set for several organic compounds.[18]

Analytical variability, on a relative basis, increases in inverse proportion to the concentration of the substance being measured. That is to say, the lower the concentration of the substance being measured, the greater the relative size of the error band about the true value. As analytical variability increases, testing results become progressively less reliable. Some test methods are more sensitive at lower levels than other test methods, but all lose their detection capability at some point.

Measurement data toward the lower margin of a test method's capability are usually assessed with respect to two reference levels of critical regulatory significance. The first arises at a concentration below which variability becomes too large to afford any confidence in the numerical value produced by the testing protocol. Depending on the regulatory context involved, and sometimes the regulatory authority's preferences, that value is generally referred to as the Practical Quantitation Level (PQL)[19] or the limit of quantitation (LOQ).[20] EPA defines PQL as "the lowest level achievable by good laboratories within specified limits during routine laboratory operating conditions."[21] While measured values below a properly derived PQL or LOQ cannot be relied on for numerical significance, such values can theoretically be relied on to establish whether or not a particular substance is present in the sample being analyzed.

The second reference level used to assess the significance of test data is the concentration below which a measured value cannot be relied on to establish whether or not a constituent is present in a sample—the so-called "detection limit." EPA uses the phrase "detection limit" in two ways. It sometimes refers to detection limits as the "signal to noise ratio" of an analytical instrument. Used as such, the phrase has meaning to the analytical chemist, but it does not provide a reasonable basis for characterizing a test method's detection capability for use in the regulatory process.[22]

Alternatively, EPA uses the term "method detection limit" (MDL)[23] to describe detection limits. While an MDL provides a more realistic basis than "signal to noise ratio" for estimating detection capability, it nonetheless has significant limitations when applied in a regulatory context. EPA has derived and published MDLs for a number of methods and substances,[24] but it acknowledges that those values will vary depending on both instrument sensitivity and matrix effects.[25] While EPA has published procedures by which an individual laboratory can derive its own MDL for a particular substance, test protocol, and matrix,[26] it acknowledges that "MDLs are not necessarily reproducible over time in a given laboratory, even when the same analytical procedures, instruments, and sample matrix are used."[27]

To sum up and contrast the concepts of MDL and PQL, EPA states:

> The Agency developed the PQL concept to define a measurement concentration that is time and laboratory independent for regulatory purposes. The . . . MDL, although useful to individual laboratories, [does] not provide a uniform measurement concentration that could be used to set standards.[28]

cent of all data that are normally distributed (i.e., exhibit a "bell-shaped" curve) can be expected to lie within plus or minus 2 standard deviation from the mean. Thus, in this example, laboratories measuring a water sample containing cadmium at a true value of 50 ug/l could be expected to measure 48.92 ± 20.72 ug/l (or between 28.20 and 69.64 ug/l) with 95 percent confidence.

16. For example, all of its proposed regression equations for the test methods for measuring metals were derived from data collected in virtually interference-free water, rather than in the more complex matrices that are representative of those occurring in the regulatory process. EPA's reliance on such "reagant water" data, in disregard of the matrix effects it acknowledges to exist, 52 Fed. Reg. 33548 (Sept. 3, 1987), can lead to an exaggerated level of confidence in the ability of the test methods to perform in the regulatory process. *See supra* note 12.

17. Safe Drinking Water Act, 42 U.S.C. §§300f-300j-11, ELR STAT. 41101-41122.

18. 52 Fed. Reg. 25705 (July 8, 1987).

19. EPA created the PQL concept in the context of its SDWA regulations. 50 Fed. Reg. 46906 (Nov. 13, 1985).

20. 52 Fed. Reg. 25699 (July 8, 1987).

21. 50 Fed. Reg. 46906 (Nov. 13, 1985). *See infra* notes 100-109 and accompanying text for an extensive discussion of PQLs.

22. The "signal to noise ratio" provides a basis for estimating the sensitivity of the instrument alone. It does not take into account the significant influence on detection capability caused by the analyst, the test protocol, and ambient interferences.

23. EPA has defined "detection limit" as "the minimum concentration of an analyte (substance) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero . . . ." 40 C.F.R. §136.2(f) (1987).

24. *See* 40 C.F.R. Part 136 App. A (1987). EPA has also published "detection limits" that have found their way into various Environmental Protection Agency regulatory documents. MANUAL OF METHODS FOR CHEMICAL ANALYSIS OF WATER AND WASTES, EPA 600/4-79-020 (revised Mar. 1983); TEST METHODS FOR EVALUATING SOLID WASTE, SW-846 (Nov. 1986) (currently being revised, 54 Fed. Reg. 3212 (Jan. 23, 1989)).

25. *See, e.g.*, 40 C.F.R. Part 136 App. A (1987).

26. 40 C.F.R. Part 136 App. B (1987).

27. 50 Fed. Reg. 46906 (Nov. 13, 1985).

28. 52 Fed. Reg. 25699 (July 8, 1987). Some regulatory authorities have been known to misuse the terms "MDL," "detection limit," and "PQL" in their regulatory activities. In some cases, this misuse may have been due to a lack of understanding about the precise meanings of those terms. In other cases, the misuse of those terms simply reflects the regulatory agencies' decision to use the most conservative convention available pending a policy decision on how they intend to deal with low-concentration standards in general. For example, a state agency interested in prohibiting the discharge of a particular contaminant might attempt to impose a permit limitation expressed as the MDL for that contaminant. Such a limitation could result in false positives since the MDL, by EPA's definition, is a theoretical limit that cannot be reliably measured by even the best laboratories. The appropriate way to accomplish the regulatory authority's objective without penalizing the discharger would be to determine a detection limit that is generally achievable by competent laboratories.

Impact of Analytical Variability in the Regulatory Process

In negotiating or litigating over appropriate numerical standards, be it in a rulemaking, a permit proceeding, or some other regulatory context, industry is faced with several concerns. Will analytical variability increase a company's exposure to liability or to increased compliance costs? Will analytical variability render a standard so ambiguous that a company will be unable to determine what action it must take to ensure routine compliance? At what point in the regulatory process will it be possible (or preferable) to seek clarity on how analytical variability will be taken into account? In what manner might the government be willing to deal with analytical variability? In seeking to resolve the above concerns, industry will presumably be faced with a government agency exhibiting a strong interest in fulfilling its statutory obligations and in maintaining efficiency in the regulatory processes it has established for doing so.

The concerns of industry are not necessarily irreconcilable with the interests of government. While the particular approach may vary depending on the applicable statutory scheme, analytical variability can be taken into proper account through the application of good science and effective communication within and between industry and government at both the legal and technical levels. The following discussion illustrates why industry has legitimate concerns about analytical variability in the regulatory process.

Analytical variability, if not adequately taken into account, can exacerbate the compliance obligations and other regulatory burdens to which a regulated entity may be subject. The type and extent of such impacts depend on the nature of the regulatory scheme involved. For example, under any regulatory scheme involving "not-to-exceed" numerical limits—for example, NPDES limits under the Federal Water Pollution Control Act (FWPCA, also known as the Clean Water Act),[29] MCLs under the SDWA,[30] and emission limits under the Clean Air Act[31]—analytical variability can cause harsh economic ramifications. That impact is capable of manifesting itself in two ways. First, it could appear in the form of penalties and legal transactional costs arising out of enforcement proceedings alleging violations that reflect the inherent variability of the test methods, rather than any actual excursion of a compliance standard. As a simple example, EPA may impose an NPDES permit limit of 10 ug/l (micrograms per liter) on a company and seek to bring an enforcement action in response to a monitoring result of 11 ug/l, even though the error band for the test method is ± 2 ug/l. With civil penalties of up to $25,000 per day for violations under many environmental statutes, regulated entities stand to be substantially affected by such "false violations."

Second, the economic impact could arise in the form of "margin of safety" treatment costs that companies incur to minimize the occurrence of "false violations." Companies may use method performance characteristics to calculate a self-imposed compliance limit that is low enough to ensure that analytical variability will not skew their sampling results beyond the actual compliance limit. Compliance planning decisions (e.g., whether treatment is necessary, and what treatment processes and operational regimes are appropriate) based on a self-imposed stricter limit can be costly. For example, after negotiating an appropriate permit limit equal to 10 ug/l, a company might conclude that, while it can achieve 10 ug/l in its effluent most of the time without an advanced treatment system, it will need to install such a system to avoid excursions caused by analytical variability.[32]

In addition to its impact on a company's ability to comply with "not-to-exceed" standards, analytical variability can cause adverse consequences under statutes relying on numerical standards as the basis for determining the nature and extent of a company's regulatory obligations. The following examples illustrate these potential impacts.

Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA),[33] the type and extent of a cleanup action, and thus its cost, will often depend on the presence and concentration of hazardous substances at a site. For example, if the selected cleanup remedy is soil excavation down to "background" levels of a particular substance, a decision will have to be made regarding an appropriate background level. Even though the natural background value of many substances is zero, a company subjected to a cleanup standard of zero, or any other value lower than the appropriate detection limit, will potentially be exposed to unjustified cleanup costs. Indeed, a measurement below an appropriate detection limit could spur additional excavation requirements, notwithstanding that such a measurement does not reliably establish whether or not the substance of concern is actually present.[34]

Also under CERCLA, liability for cleanup costs may turn on the ability to detect a particular hazardous substance at a disposal site. Take, for example, a company that sends to a disposal site several drums of waste that are later reshipped to another site. If the first site becomes the target of an enforcement action, the government's inability to establish the presence at that site of the "type" of substance[35] in the company's shipment could thwart a CERCLA cost recovery action. As another example, take a company that sends to a site a shipment of wastes that are segregated[36] in an environmentally sound manner from

29. 42 U.S.C. §§1251-1387, ELR STAT. FWPCA 001-065.

30. 42 U.S.C. §§300f-300j-11, ELR STAT. 41101-41122.

31. 42 U.S.C. §§7401-7626, ELR STAT. CAA 001-050.

32. It may, of course, be entirely appropriate for the company to argue for a limitation sufficiently above 10 ug/l such that the company can achieve 10 ug/l without an advance treatment system. This illustration is only a simplified example of the measures companies may pursue to avoid noncompliance. In practice, other factors, particularly process variability, also play a significant role in the compliance decisions companies must make. *See supra* note 1.

33. 42 U.S.C. §§9601-9675, ELR STAT. 44001-44081.

34. False negatives, in addition to false positives, may result at standards below the appropriate detection limit. *See supra* note 2. The use of such standards is therefore somewhat like a lottery, in that the result is largely unpredictable.

35. Several courts have held that, to establish liability, the government is merely required to show that a substance "like" that sent by the generator is contained at a site. These courts have not required the government to "fingerprint" the waste; thus a company might be exposed to liability even if its wastes were reshipped from the site at which a cost recovery action is targeted. *See, e.g.*, United States v. Wade, 577 F. Supp. 1326, 1332, 14 ELR 20096, 20098 (E.D. Pa. 1983).

36. For example, it is not uncommon for landfills to establish designated cells for certain wastes.

wastes shipped by other generators. In the event of a release that spurs an enforcement action, the extent of the company's liability may depend on the government's ability to establish the presence in the release of the substances contained in its shipment. Moveover, if the company's waste is detected in soils, but not in groundwater at the hazardous waste site, the company might be able to negotiate a favorable settlement with the government or a favorable allocation of costs among other potentially responsible parties. Indeed, while liability for cleanup costs at Superfund sites is generally joint and several, a company may limit its liability by establishing that the harm caused by its wastes is divisible from the rest.[37]

Unless appropriate detection limits are recognized, laboratory data may be misinterpreted to indicate the presence of a pollutant where none in fact exists.[38] Absent such recognition, the ability of a company to avoid or limit CERCLA liability may be compromised.

Under the Resource Conservation and Recovery Act (RCRA),[39] onerous regulatory requirements apply to generators whose wastes fail the Extraction Procedure (EP) toxicity test.[40] That test involves measuring the concentration of various constituents in a leachate that was extracted from the waste material in accordance with a designated protocol.[41] If the concentration of any of the measured constituents exceeds a certain standard, the waste is considered hazardous. Analytical variability can potentially elevate the test results such that a waste whose EP constituents are actually below the standard will fail the test.

Also under RCRA, owners or operators of land-based hazardous waste management units operating under a RCRA permit must set up a groundwater monitoring program and sample for a variety of specific constituents.[42] Where those constituents are detected in a company's monitoring program, remedial action may be required.[43] Failure to apply appropriate detection limits can subject owners and operators to unnecessary remedial action requirements.[44]

In addition, RCRA prohibits the land disposal of certain wastes (e.g., solvents) if they contain hazardous constituents above a specified concentration.[45] Companies whose wastes exceed those limits must either treat their wastes as a prerequisite to land disposal or find an alternative—and generally more expensive—disposal method (e.g., incineration). Analytical variability creates uncertainty as to whether or not a particular standard has been exceeded.

Finally, under the Toxic Substances Control Act,[46] the manner in which equipment and containers containing PCBs are regulated—and the attendant cost to industry—depends on the concentration of PCBs present.[47] Analytical variability can influence these regulatory consequences.

EPA Is Required to Account for Analytical Variability in the Regulatory Process

The United States Constitution, at least in theory, entitles individuals to be placed on notice of the type of conduct the government deems unlawful. This requires regulatory authorities not only to describe unambiguously the conduct they choose to prohibit, but also to provide an objective standard by which such conduct can be measured. Government regulatory activity that fails to conform to these fundamental protections is vulnerable to legal challenge. As the following discussion illustrates, companies have legitimate legal grounds for expecting EPA and state agencies to recognize and take account of analytical variability in their regulatory decisions.

In 1926, the Supreme Court in *Connally v. General Construction Co.* declared that "a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application violates the first essential of due process of law."[48] More recently, the Supreme Court examined the vagueness doctrine in *Grayned v. City of Rockford.*[49]

> It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined. Vague laws offend several important values. First, because we assume that man is free to steer between lawful and unlawful conduct, we insist that laws give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. Vague laws may trap the innocent by not providing fair warning. Second, if arbitrary and discriminatory enforcement is to be prevented, laws must provide explicit standards for those who apply them. A vague law impermissibly delegates basic policy matters to policemen, judges, and juries for resolution on an *ad hoc* and subjective basis, with the attendant dangers of arbitrary and discriminatory application.[50]

Courts have applied the vagueness doctrine to questions of environmental law on a number of occasions. For example, in 1975, a federal court of appeals remanded pretreatment standards for corn milling plants because they were "too vague to warn the industry of the scope of prohibited conduct."[51] The vagueness issue might conceivably arise in the context of an enforcement proceeding involving a numerical standard below a reasonable detection limit. Arguably, any standard below the detection limit, because it cannot be measured, should be deemed impermissibly vague.

37. United States v. Monsanto Co., 858 F.2d 160, 19 ELR 20085 (4th Cir. 1988); United States v. Stringfellow, 661 F. Supp. 1053, 1060, 17 ELR 21134, 21135 (C.D. Cal. 1987).

38. *See supra* note 34.

39. 42 U.S.C. §§6901-6992k, ELR STAT. RCRA 001-050.

40. 40 C.F.R. §261.24 (1988).

41. 40 C.F.R. Part 261 App. II (1988).

42. These constituents are identified at 40 C.F.R. §264.97 (1988).

43. *See* 40 C.F.R. §264.100(i)(2) (1988).

44. EPA has issued a rule in which it discusses the way in which it intends to take detection limits into account in groundwater monitoring programs. 53 Fed. Reg. 39720 (Oct. 11, 1988).

45. 53 Fed. Reg. 31138 (Aug. 17, 1988); 52 Fed. Reg. 25760 (July 8, 1987); 51 Fed. Reg. 40572 (Nov. 7, 1986).

46. 15 U.S.C. §§2601-2654, ELR STAT. TSCA 001-048.

47. 40 C.F.R. §761.60 (1987).

48. 269 U.S. 385, 391 (1926).

49. 408 U.S. 104 (1972).

50. *Id.* at 108-109.

51. CPC International Inc. v. Train, 515 F.2d 1032, 1052, 5 ELR 20392, 20401 (8th Cir. 1975), *cert. denied*, 430 U.S. 966 (1977). *Cf.* Maryland v. Environmental Protection Agency, 530 F.2d 215, 220-21, 5 ELR 20651, 20653 (4th Cir. 1975) *vacated and remanded on other grounds*, 431 U.S. 99, 7 ELR 20375 (1977) (EPA regulation requiring employers to develop a plan to encourage employees to use mass transit remanded due to lack of a standard defining what constitutes an acceptable plan).

Analytical Variability in the Courts

In *Amoco Oil Co. v. EPA*,[52] the court was asked to review regulations limiting the use of leaded gasoline. In responding to arguments about the adequacy of test methods available for measuring the lead limit, the court stated:

> The possibility of statistical measurement error, which is often unavoidable where regulations set quantitative standards, does not detract from an agency's power to set such standards. It merely deprives the agency of the power to find a *violation* of the standards, in enforcement proceedings, where the measured departure from them is within the boundaries of probable measurement error.[53]

Notwithstanding the foregoing precedent, the courts have tended to restrict companies from raising the analytical variability defense in enforcement actions. In a recent case before the District of Columbia Circuit,[54] the court rejected a mining company's argument that the alleged violations of a respirable dust standard were invalid due to the inaccuracy of the analytical technique prescribed by Congress for dust measurement. In doing so, however, the court did not dismiss entirely the significance of analytical variability. To the contrary, in deciding not to question Congress' willingness to tolerate "some error . . . in enforcement of the dust standard,"[55] the court made clear that there were boundaries beyond which analytical variability would not be tolerated in the regulatory process. Some of the factors that influenced the court to conclude that variability was tolerable under the facts in this case included: (1) the dust standard was developed to reflect the analytical variability anticipated from the testing procedure, (2) the compliance determination was based on an average of sample results rather than on a single sample, and (3) the regulatory program imposed rigorous operator certification and QA/QC requirements.[56]

Under the FWPCA, the courts have generally rejected analytical variability arguments raised in enforcement actions based on data reported to EPA in discharge monitoring reports (DMRs).[57] This precedent has been grounded largely on the FWPCA's legislative history, which emphasizes the need for expeditious enforcement action. Consequently, companies have routinely been held strictly liable for all violations that could be gleaned from the face of their DMRs.[58]

Despite the adverse case law, permittees involved in FWPCA enforcement actions should bear in mind the following factors. First, while the analytical variability defense has not had much success to date, the Supreme Court has never directly addressed the issue, and there is some precedent supporting a defendant's ability to challenge the content of its DMRs at the time of enforcement.[59]

Second, the cases alluded to above have been limited to a narrow set of facts—liability was based exclusively on DMRs whose accuracy had been certified to unconditionally by the permittee.[60] None involved a DMR in which the permittee had expressed its data along with the error band of the method used or with a disclaimer as to the inherent variability of test methods in general. Furthermore, none of those cases involved a challenge of monitoring data collected by a regulatory agency or a citizen group.[61] It is conceivable that a court faced with data collected by outside sources, rather than data collected by and "certified" by the permittee, would be amenable to considering analytical variability in its liability deliberations. In addition, in none of these cases had the defendant invoked EPA's "upset" provision, which allows permittees to establish an affirmative defense where there is "an exceptional incident in which there is unintentional and temporary noncompliance . . . because of factors beyond the reasonable control of the permittee."[62] EPA has intimated[63] that the upset defense could apply[64] where analytical variability is suspected of causing permit violations.[65] In short, depending on the particular facts involved, a permittee may be able to convince a court to depart from precedent and hold that evidence of analytical variability is admissible in an enforcement action.

Third, some of the courts holding that the analytical variability defense is not cognizable in an enforcement action have made clear that their holding applies exclusively to the liability phase of the case. As to the remedy phase of the case (i.e., the assessment of penalties), those courts have held that evidence of analytical variability may be ad-

52. 501 F.2d 722, 4 ELR 20397 (D.C. Cir. 1974).

53. *Id.* at 743, 4 ELR at 20407 (emphasis in original).

54. Consolidation Coal Co. v. Federal Mine Safety and Health Review Commission, 824 F.2d 1071 (D.C. Cir. 1987).

55. *Id.* at 1087.

56. *Id.*

57. *See, e.g.*, Sierra Club v. Union Oil Co. of California, 813 F.2d 1480, 17 ELR 20547 (9th Cir. 1987) *vacated and remanded on other grounds*, 108 S. Ct. 1102 (1988); Connecticut Fund For The Environment v. Upjohn Co., 660 F. Supp. 1397, 17 ELR 21137 (D. Conn. 1987).

58. It remains to be seen whether the courts' reluctance to consider analytical variability in FWPCA enforcement actions will carry over to enforcement actions under other statutes imposing "not-to-exceed" compliance obligations. For example, EPA has imposed extremely strict not-to-exceed limitations under the SDWA. EPA openly acknowledges that even the best laboratories measuring samples at such low concentration will be unable to measure consistently to within 40 percent of the true value. 52 Fed. Reg. 25705 (July 8, 1987). Because of the differences in the way not-to-exceed limits are set in the FWCPA and the SDWA, the adverse precedent developed under the FWPCA may well find little acceptance elsewhere. In particular, while EPA claims to take analytical variability into account in promulgating technology-based effluent guidelines under the FWPCA, it merely identifies, but fails to take account of, analytical variability when setting MCLs under the SDWA.

59. *See, e.g.*, United States v. City of Moore, No. CIV-84-618-E (W.D. Okla. 1985); Friends of the Earth v. Facet Enterprises, Inc., 618 F. Supp. 532, 536, 15 ELR 20106, 20107-08 (W.D.N.Y. 1984).

60. *See* 40 C.F.R. §122.22(d) (1987) (permittee must certify that the information provided in a DMR is "true, accurate, and complete").

61. *See infra* note 125.

62. 40 C.F.R. §122.41(n) (1987).

63. *See* 52 Fed. Reg. 42564 (Nov. 5, 1987); ENVIRONMENTAL PROTECTION AGENCY, RESPONSES TO PUBLIC COMMENTS ON THE PROPOSED ORGANIC CHEMICALS, PLASTICS AND SYNTHETIC FIBERS EFFLUENT LIMITATIONS, GUIDELINES AND STANDARDS, *cited at* 52 Fed. Reg. 42567 (Nov. 5, 1987).

64. Note that the upset defense currently does not apply to violations of water quality-based effluent limitations. *See* Natural Resources Defense Council, Inc. v. United States Environmental Protection Agency, 859 F.2d 156, 19 ELR 20016 (D.C. Cir. 1988) (EPA's upset provision remanded in response to industry's charge that its failure to apply to water quality-based limits was arbitrary and capricious).

65. As a procedural matter, issues relevant to the upset defense may involve genuine issues of material fact and therefore may not be amenable to resolution on summary judgment. To the contrary, issues relevant to the analytical variability defense per se may be amenable to resolution on summary judgment, since a court may well rule, as a matter of law, that evidence regarding the content of DMRs is inadmissible.

electric industry, EPA attempted to regulate certain cooling tower discharges by imposing a "no discharge" requirement on 129 priority pollutants.[96] In response to comments raising concerns over the inability to measure chemical constituents below their detection limit, EPA substituted "no detectable" for "no discharge" and concluded that the appropriate detection limit is 10 ug/l (i.e., 10 parts per billion).[97]

Under the Safe Drinking Water Act

☐ *Use of PQLs.* EPA attempts to take analytical variability into account in the process of setting MCLs under the SDWA. As a prerequisite to setting MCLs, the SDWA requires EPA to set maximum contaminant level goals (MCLGs), which represent the concentration of a contaminant at which "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."[98] EPA is then required to issue MCLs that are set at levels "as close to the maximum contaminant level goal[s] *as is feasible.*"[99] In those instances where it has set the MCLG at zero (e.g., for carcinogens), EPA has implicitly recognized that the detection limits for the substances it is regulating must be considered in determining what MCL is feasible.

Toward that end, EPA has developed an approach that makes allowances for the elevated variability exhibited by laboratories measuring levels close to the detection limit. For contaminants whose MCLG is zero, EPA has set MCLs at the so-called PQL, which, as discussed earlier,[100] is defined as, "the lowest level achievable by good laboratories within specified limits during routine laboratory operating conditions."[101]

While EPA's adoption of the PQL concept is laudable, its benefits are compromised by several factors. First, the manner in which PQLs are derived is questionable. Theoretically, a PQL is derived by collecting performance data over a range of concentrations from a number of laboratories and selecting the lowest concentration that an acceptable percentage of those laboratories was able to measure within some designated error band.[102] In practice, however, EPA develops PQLs by excluding data collected from commercial laboratories and relying exclusively on data collected from experienced government laboratories that "knew they were being tested with standard samples in distilled water and without matrix interferences."[103] EPA's PQLs therefore exaggerate the quality of laboratory performance that will actually occur in the regulatory process. Indeed, EPA has stated:

> Actual day to day operations in a wide variety of laboratories using "real" samples in natural water *would be expected to produce poorer results*, i.e., wider performance ranges especially at the lower concentration levels.[104]

Second, the PQLs EPA has derived to date have bee set at levels that exhibit too much variability and thus ar too low to be used as "not-to-exceed" standards. For e ample, in the MCLs published for organic compound EPA acknowledged that only 75 percent of the most e perienced laboratories would be able to measure to withi plus or minus 40 percent of the PQL.[105] EPA admitted tha the remaining 25 percent of the ideal laboratories woul be expected to perform with an error band in excess of 4 percent, and that commercial laboratories would perfor poorer yet. In response to an industry comment expres ing concern about the effect that such a high degree c variability will have in compliance determinations, EP conceded that it does not consider a single violation to b grounds for an enforcement action.[106] While EPA's e pressed willingness to exercise prosecuterial discretion worthy of praise, it does not suffice. As a practical ma ter, analytical variability might give rise to more than or false violation. After all, EPA would acknowledge tha even its best laboratories testing a sample known to cor tain a compound at the MCL concentration would measu in excess of the MCL approximately every other tes Moreover, state agencies and citizen groups may not en brace, and are not necessarily bound by, EPA's positio on enforcement matters.

Finally, where EPA has not collected the requisite inte laboratory data to calculate PQLs directly, it instea estimates PQLs by multiplying available MDLs, whic have been derived from "a few of the most experience laboratories under non-routine and very controlled cond tions,"[107] by a factor of between 5 and 10.[108] The validi of that "fudge" factor is questionable, and it may we underestimate the method variability exhibited by mo laboratories.[109]

96. 45 Fed. Reg. 68352 (Oct. 14, 1980).

97. 47 Fed. Reg. 52295 (Nov. 19, 1982).

98. SDWA §1412(b)(4), 42 U.S.C. §300g-1(b)(4), ELR STAT. 41103.

99. *Id.* (emphasis added).

100. *See supra* notes 19-21 and accompanying text.

101. 50 Fed. Reg. 46906 (Nov. 13, 1985).

102. *Id.* at 46906-07.

103. 50 Fed. Reg. 46907 (Nov. 13, 1985).

104. *Id.* (emphasis added).

105. 52 Fed. Reg. 25700 (July 8, 1987).

106. U.S. ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF DRINKI WATER, SUMMARY OF COMMENTS AND EPA RESPONSES ON THE PR POSED MCLS FOR THE VOLATILE SYNTHETIC ORGANIC CHEMICALS A REQUIREMENTS FOR MONITORING UNREGULATED CONTAMINANTS, 1- (June 1987).

107. 50 Fed. Reg. 46906 (Nov. 13, 1985).

108. For derivation of the 5-10 fudge factor, *see* ENVIRONMENTAL PR TECTION AGENCY, OFFICE OF DRINKING WATER, VOLATILE ORGA CHEMICALS: METHODS AND MONITORING DOCUMENT, App. C (Ju 1987).

109. Even if the fudge factor were properly derived, EPA's applicati of it has been arbitrary to date. In its proposal to publish MC for several volatile organic compounds, EPA generally used a f tor of 10 where interlaboratory data were insufficient. 50 Fed. R 46907 (Nov. 13, 1985). The one exception was vinyl chloride, which EPA applied a factor of 5. *Id.* In support of a more conser tive factor, EPA cited three reasons: "(1) A much smaller numb of systems would be required to monitor for vinly [sic] chloride opposed to other VOCs in [the] proposal, (2) vinyl chloride analy will be carried out on a sample which has already been characteri for a number of related VOC compounds, which would in eff improve a laboratory's measurement efficiency, and (3) vinly [s choloride [sic] analysis requires special handling resulting in wh can be more focused attention and careful analysis procedure *Id.* EPA's logic is somewhat curious, given the "analytical c ficulties" that, according to EPA, are more severe for vinyl chlor than they are for the other volatile compounds. *Id.* More recent EPA has stated that a factor of 5 times the MDL is justifiable wh "other considerations [e.g., higher human risk] suggest that the P should be lower." 53 Fed. Reg. 31551 (Aug. 18, 1988); *accord* Fed. Reg. 25700 (July 8, 1987). While human health risk is unqu tionably a key factor in setting MCLs, EPA must not disregard statutory duty to set MCLs as close to the MCLG "as is feasibl SDWA §1412(b)(4), 42 U.S.C. §300g-1(b)(4), ELR STAT. 41103. S ting MCLs at levels too low to allow water suppliers and enfor

☐ *Other attempts to account for variability.* EPA's final rule on organic compounds provides that "[s]tates have discretion to delete results of obvious sampling errors from [compliance determinations]."[110] How "sampling errors" will be interpreted by the various states remains to be seen.

To compensate for variability,[111] at least a part of which might be attributable to method performance limitations, EPA often bases compliance determinations on an average of sample results rather than on a single result.[112] In those cases where it has done so, however, EPA has provided no data either to quantify, or to establish that the averaging period is sufficiently long to offset, the expected analytical variability.

Under the Resource Conservation and Recovery Act

☐ *Use of PQLs.* EPA routinely uses PQLs rather than MDLs in various parts of its hazardous waste regulatory program (e.g., in evaluating delisting petitions,[113] and in applying its toxicity characteristic leaching procedure model to determine at what concentration land disposal of certain wastes is permissible).[114] Interestingly, the shortcomings of PQLs that arise under the SDWA may not arise or may not have as harsh a result under RCRA. In its final rule entitled "Statistical Methods For Evaluating Ground-Water Monitoring Data From Hazardous Waste Facilities,"[115] EPA acknowledges that PQLs "may be unattainable because they are based on general estimates for the specific substance."[116] To compensate for this deficiency, EPA allows owners and operators of regulated facilities to develop "facility-specific" PQLs.[117] This approach has the potential to yield PQLs that reflect the actual performance of the laboratories whose results will influence regulatory decisions.[118]

☐ *Groundwater monitoring.* Owners and operators are required to install groundwater monitoring wells around their hazardous waste management units.[119] They were originally required to measure for each of the hazardous constituents listed in 40 C.F.R. Part 261 Appendix VIII.[120] If any were detected, costly remediation might be required. EPA thereafter published a rule recognizing several gaps in the availability and validity of analytical methods to measure many of the Appendix VIII constituents. To compensate for those gaps, EPA developed a substantially reduced list—the Appendix IX list[121]—to be used in lieu of the Appendix VIII list. Unfortunately, EPA maintains that it has the authority to require monitoring for constituents outside Appendix IX, yet it does not specify on what basis it would determine whether a valid method exists for those constituents.[122]

How to Cope with Analytical Variability

To avoid, or at least minimize, the adverse effects that laboratory performance limitations might generate in the regulatory arena, regulated entities should consider the following precautionary measures.[123]

1. Develop an understanding of analytical variability as it may apply in the particular regulatory context to which you are or may be subject. This includes knowing how to collect or locate the necessary performance data (i.e., precision and bias equations, and detection limits) and how such data can properly be applied.[124]

2. After NPDES permittees have obtained effluent limitations that properly account for analytical variability, they should design and/or operate their treatment systems as necessary to achieve long-term average pollutant removals that account for interlaboratory precision and bias (i.e., removals that may be more stringent than the actual compliance limits).

3. Maintain a rigorous QA/QC program for both your in-house laboratory and any outside laboratory services you procure. This includes regularly sending "blind" samples of a known concentration (i.e., quality assurance "standards") to outside laboratories along with your regular samples. It may be advisable to notify your outside laboratory that you intend to engage in such a practice routinely without further notice.

4. Select with great care the analytical methods used for compliance monitoring. If you suspect your sample may contain constituents that are relatively close to the numerical compliance standards, you will want to use the most sensitive and most interference-free method available.[125] On the other hand, if your sample quality is safely below the compliance standards, you need not be as concerned about analytical variability creating a "false" violation or an unnecessary regulatory burden. If this is the case, you will have more flexibility in the test method you select.

5. Do not accept a "not-to-exceed" numerical limit expressed as "zero" or any other concentration below (what *you* believe to be) the detection limit for the regulated substance in your laboratory. If your regulatory authority proposes and you accept a limit at 5 ug/l, but your

ment officials to measure compliance within an acceptable degree of confidence arguably contradicts that statutory standard.

110. 52 Fed. Reg. 25713 (July 8, 1987) (to be codified at 40 C.F.R. §141.24(g)(5)).

111. *See* 40 Fed. Reg. 59575 (Dec. 24, 1975).

112. *See, e.g.*, 40 C.F.R. §141.24(c) (1987); 52 Fed. Reg. 25713 (July 8, 1987) (to be codified at 40 C.F.R. §141.24(g)(5)).

113. *See, e.g.*, 53 Fed. Reg. 26283 (July 12, 1988).

114. 51 Fed. Reg. 21652 n.1 (June 13, 1986).

115. 53 Fed. Reg. 39720 (Oct. 11, 1988).

116. *Id.* at 39721.

117. *Id.* EPA has not formally indicated how it expects facility-specific PQLs to be derived.

118. EPA has published PQLs in 40 C.F.R. Part 264, App. IX (1987) and in SW-846, *supra* note 70, for several compounds regulated under RCRA. Actually, SW-846 contains MDLs together with PQL conversion factors. Unlike the SDWA program, which prescribes a factor between 5 and 10, *see supra* note 97 and accompanying text, SW-846 prescribes several multipliers (sometimes ranging from 10 to 1250) whose use depends on the matrix (e.g., groundwater, sludge), and the expected concentration range of the contaminant (e.g., high level, low level) being analyzed. *See, e.g.*, Method 5030 in SW-846, *supra* note 70, at 8020-2.

119. 40 C.F.R. §§264.92, 265.91 (1988).

120. 52 Fed. Reg. 25942-43 (July 9, 1987).

121. 40 C.F.R. Part 264 Appendix IX (1988).

122. 52 Fed. Reg. at 25944 (July 9, 1987).

123. These suggestions are offered for illustrative purposes only, and should be pursued only under the advice of individual counsel.

124. Beware of published detection limits, such as those in EPA's *Methods for Chemical Analysis of Water and Wastes*, EPA-600/8-78-017 (1978), which are based on "signal to noise ratio." Such detection limits will generally overestimate the detection capability of many methods. *See supra* note 22.

missible and that such evidence may have a mitigating effect.[66] Given a permittee's potential exposure to $25,000 per day for each violation of a daily limit,[67] not to mention the possible exposure of up to $775,000 for violation of a monthly average limit,[68] the impact of analytical variability on a penalty assessment could be quite substantial.

How Does EPA Deal With Variability?

EPA has long recognized the inherent limitations in laboratory performance. The first edition of its guidance document *Methods for Chemical Analysis of Water and Wastes,* issued in 1974, presented each of several test methods along with their respective detection limits and numerical estimates of precision and bias.[69] More recently, EPA included MDLs and statements of both single operator and interlaboratory precision and bias along with the analytical methods it published at 40 C.F.R. Part 136 for measuring organic pollutants in wastewater.[70] And, in a recent rulemaking proposal regarding three methods for the analysis of metals, EPA stated:

> For any given parameter, the array of approved methods will not necessarily give the same precision, accuracy (recovery of spikes) or detection limits when repeated aliquots [portions] of samples are analyzed.[71]

Thus, the relevant question is not whether EPA *recognizes* laboratory performance limitations, but whether EPA adequately *compensates* for those limitations in the regulatory process.

The short answer is that EPA appears to recognize its legal obligation to factor analytical variability into the regulatory process, but that it approaches the issue with considerable caution. For example, in the context of the FWPCA, EPA has intimated that consideration of analytical variability is appropriate, but that it should be considered up front in the regulatory process, rather than during enforcement proceedings. Indeed, in a recent proposal to amend 40 C.F.R. Part 136,[72] EPA stated:

> EPA does not intend that . . . [the method performance information] be used in enforcement actions to avoid liability based on Discharge Monitoring Reports. Variability factors *are already taken into account* when effluent guidelines are established or when permit limitations are set.[73]

Were variability taken into account *properly* up front, there might be merit to EPA's position. Yet, whatever practice EPA follows in the future, it is clear that EPA has not consistently factored analytical variability into it past decisions (i.e., during effluent guideline rulemaking and permit proceedings). Thus, to the extent that prope up-front consideration has not already been provided, evi dence of analytical variability ought to be admissible dur ing enforcement proceedings.

EPA has attempted, in several instances, to compensat for the inherent variability of the test methods that are use in the various regulatory programs it administers. Whil EPA's efforts are laudable in principle, they seldom hav gone far enough. Nonetheless, EPA appears to be awar of its shortcomings and has shown signs of interest in im proving the situation. In a draft of a report[74] EPA wa required to submit to Congress in accordance with §51 of the Water Quality Act of 1987,[75] EPA discusses th sources of analytical variability and candidly highlight several areas in need of improvement within the nationa program to develop and validate test methods. Unfortu nately, the statutory provision requiring the Section 51 Report did not explicitly require EPA, and EPA has no otherwise attempted, to address how analytical variabilit should be accounted for in the regulatory process. As th following examples illustrate, EPA deals with analytica variability somewhat inconsistently under the variou regulatory programs it administers.

Under the Clean Water Act

☐ *Metals methods.* In 1984, EPA amended 40 C.F.R Part 136[76] by adding the inductively coupled plasma spec trophotometry (ICP) method to the two methods alread available for measuring trace metals in wastewater.[77] Whil industry was generally pleased with the added flexibilit that a supplemental test method would offer, EPA's rule making was fundamentally flawed. The ICP method ha not been validated[78] on the basis of interlaboratory data For that matter, the other two metals methods had neve been properly validated either. This was of major concer to industry, because the variability exhibited by differen laboratories is generally several times greater than that ex hibited by a single operator. Thus, a regulatory agency at tempting to take analytical variability into account on th basis of a method's single operator performance charac teristics would underestimate the variability that would ac tually arise.

66. *See, e.g.*, Connecticut Fund For The Environment v. Upjohn Co., 660 F. Supp. 1397, 17 ELR 21137 (D. Conn. 1987).

67. FWPCA §309, 33 U.S.C. §1319, ELR STAT. FWPCA 035.

68. Chesapeake Bay Foundation v. Gwaltney, 108 S. Ct. 376, 18 ELR 20142 (1987).

69. EPA-625/6-74-003. *See supra* notes 5-8 and accompanying text.

70. 40 C.F.R. Part 136, App. A (1987) (the "600 series"). The Part 136 regulations set forth the methods used under the FWPCA. EPA has also published performance characteristics along with the test methods prescribed for use in the RCRA and Superfund programs. *See* ENVIRONMENTAL PROTECTION AGENCY, TEST METHODS FOR EVALUATING SOLID WASTE, PHYSICAL/CHEMICAL METHODS, SW-846 (3d ed.) (currently being revised, 54 Fed. Reg. 3212 (Jan. 23, 1989)) (hereinafter SW-846).

71. 52 Fed. Reg. 33550 (Sept. 3, 1987).

72. *See supra* note 70 and accompanying text.

73. 52 Fed. Reg. at 33547 (Sept. 3, 1987) (emphasis added).

74. ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF RESEARCH AN DEVELOPMENT, AVAILABILITY, ADEQUACY, AND COMPARABILITY C TESTING PROCEDURES FOR THE ANALYSIS OF POLLUTANTS ESTAI LISHED UNDER SECTION 304(H) OF THE FEDERAL WATER POLLUTIO CONTROL ACT EPA/600/9-87/030 (Sept. 1988) (a report to the Con mittee on Public Works and Transportation of the House c Representatives and the Committee on Environment and Publ Works of the Senate (hereinafter SECTION 518 REPORT).

75. Pub. L. 100-4, tit. V, §518, 101 Stat. 86 (1987) (codified at 33 U.S.C §1315 note).

76. *See supra* note 70 and accompanying text.

77. 49 Fed. Reg. 43234 (Oct. 26, 1984). The other two metals metho are flame atomic absorption and graphite furnace atomic absor tion, which were published in 40 C.F.R Part 136 in 1973. 38 Fe Reg. 28758 (Oct. 16, 1973).

78. Method validation, in simple terms, is the process in which perfo mance characteristics of a particular test method are derived fro data collected both within a single laboratory (intralaboratory) ar from a "round robin" of several laboratories (interlaboratory). S *supra* note 5. EPA's SECTION 518 REPORT describes the validatic process in some detail. SECTION 518 REPORT, *supra* note 74, 3-1 3-12.

To prevent this unfairness, several electric utilities filed suit in the Fourth Circuit Court of Appeals.[79] After a period of negotiation, a settlement agreement was reached in which, among other things, EPA agreed to conduct interlaboratory method validation studies on all three metals methods and to publish the results in Part 136.[80] EPA has since completed those studies and has published the results in a proposal to amend Part 136.[81]

☐ *Effluent limitations for industrial categories.* In setting national effluent guidelines limitations for industrial categories, EPA typically analyzes performance data collected from a number of plants that employ a certain level of technology for a particular industry (e.g., best available technology economically achievable or BAT).[82] It then derives limitations that are supposed to represent the level of performance that can be achieved throughout that industry, within certain confidence intervals.

EPA takes the position that the process of integrating performance data produced in different laboratories, using the entire range of test methods that will be used for compliance determinations by industry, government, and citizen groups, will produce effluent limitations[83] that inherently make allowances for analytical variability.[84] In practice, however, EPA's approach may be flawed as a result of the data it collects, not to mention the data it rejects.[85] For example, if EPA does not use a representative cross-section of companies, or if it unjustifiably eliminates "outliers,"[86] the derived effluent limitations will not properly compensate for analytical variability. This result could also arise if EPA were to use data either generated in too few laboratories or measured with test methods whose performance characteristics were unrepresentative of the methods that will be used in compliance determinations.[87]

☐ *Biological test methods.* EPA has been inconsistent in the way it addresses analytical variability in the context of biological test methods. In a 1985 document providing guidance to regulatory authorities on controlling toxic discharges,[88] EPA recommended the use of biological test methods without adequately identifying their individual performance limitations or discussing how such limitations should bear on their use in the regulatory process. EPA's Section 518 Report, on the other hand, is quite candid about the inadequacy of certain biological test methods and points out the need for further validation efforts.[89] Indeed, EPA states that, "in all cases for methods that will have extensive regulatory use, a method should be fully validated and standardized,"[90] and notes that many of its biological test methods have never been properly validated.[91] Moreover, EPA also states, "more importantly, [biological testing] variability must also be accounted for when permit limits, criteria, or standards are set."[92]

EPA's inconsistent position can best be illustrated by a recent permitting action, in which it inexplicably failed to consider analytical variability in the effluent limitations it proposed. In a draft general permit covering the State of Florida, EPA Region IV proposed to subject permittees to a biological testing requirement whereby they must show that mortality will not occur in more than 50 percent of the specified test organisms exposed to their effluent for a 48-hour period.[93] If greater than 50 percent mortality occurs in any one test, the permittee would be subject to an enforcement action. Yet, notwithstanding the substantial analytical variability that the prescribed test method is expected to exhibit,[94] the draft permit is silent about how such variability should bear on compliance determinations. This and similar concerns were raised in comments filed by industry,[95] and it remains to be seen how EPA will respond when it issues the final permit.

☐ *Effluent limitations for the steam electric industry.* In the proposed effluent guidelines limitations for the steam

79. Virginia Electric Power Co. v. U.S. Environmental Protection Agency, No. 84-2227 (4th Cir., petition for review filed Nov. 9, 1984).

80. The settlement agreement was executed on July 12, 1985.

81. 52 Fed. Reg. 33547 (Sept. 3, 1987).

82. *See* Marathon Oil Co. v. Environmental Protection Agency, 564 F.2d 1253, 1266 (9th Cir. 1977) (court provides a detailed description of EPA's effluent guidelines derivation process).

83. EPA has made little progress thus far in addressing variability in the context of water quality-based effluent limitations. A scientifically defensible approach for dealing with variability in the water quality context is set out in Rice, *Managing Water Quality*, ELECTRICAL WORLD, Dec. 1988, at 49.

84. In its general NPDES regulations, EPA concedes that a "variability factor" may be appropriate in establishing effluent limitations. 49 Fed. Reg. 38003 (Sept. 26, 1984).

85. *See, e.g.*, 52 Fed. Reg. 42556 (Nov. 5, 1987).

86. "Outliers" consist of sampling results that are substantially outside the range of the bulk of the data collected. Eliminating outliers, other than those caused by documented spills or similar circumstances, has the effect of creating an unrealistic picture of the variability that can actually be expected to arise.

87. Even if EPA used the appropriate data base, its effluent guidelines development approach is inherently flawed, since it subjects companies to a virtually impossible compliance standard. EPA usually sets limitations at the level that can be achieved 99 percent of the time, for daily maximum values, and 95 percent of the time, for monthly average values. Yet, permittees must achieve compliance 100 percent of the time or face civil or criminal sanctions. Thus, EPA imposes standards that even the well-operated plant will be unable to achieve without a few days of noncompliance.

88. ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF WATER, TECHNICAL SUPPORT DOCUMENT FOR WATER QUALITY-BASED TOXICS CONTROL, EPA-440/48/4-85-032 (Sept. 1985).

89. SECTION 518 REPORT, *supra* note 74, at 4-49. Unlike the chemical test methods prescribed for use under the FWPCA, none of the biological test methods and their performance characteristics has been published in 40 C.F.R. Part 136. *See supra* note 70 and accompanying text. EPA's SECTION 518 REPORT recommends such publication, and, at the time this Article was being prepared, such a proposal was undergoing Red Border review at EPA.

90. SECTION 518 REPORT, *supra* note 74, at 3-6.

91. *Id.* at 4-51.

92. *Id.* at 3-11.

93. 53 Fed. Reg. 32442-43 (Aug. 25, 1988).

94. The literature is replete with authoritative materials on the variability inherent in biological test methods. *See, e.g.*, Rue, Fava & Grothe, *A Review of Inter- and Intralaboratory Effluent Toxicity Test Method Variability*, AQUATIC TOXICOLOGY AND HAZARD ASSESSMENT, Vol. 10, ASTM 971 at 190-203 (1988) (compilation of annual proceedings of American Society of Testing and Materials); EA Engineering, Science and Technology, Inc., A Review of Inter- and Intra- laboratory Effluent Toxicity Test Method Variability (July 1985) (unpublished report for the Chemical Manufacturers Association); Grothe and Kimerle, *Inter- and Intra- laboratory Variability in* Daphnia Magnia *Effluent Toxicity Test Results*, 4 ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY 189-192 (1985).

95. *See, e.g.*, Comments of the Utility Water Act Group in Response to Notice of Proposed Issuance of an NPDES Permit to the State of Florida (53 Fed. Reg. 32442 (Aug. 25, 1988)) (filed Sept. 24, 1988).

laboratory's detection limit is 10 ug/l, you may be forced to report all measurements between 5 ug/l and 10 ug/l. This could result in liability, even though measurements below your detection limit are incapable of reliably showing whether or not the substance is present in the sample, let alone at what concentration.

6. Do not accept a "not-to-exceed" limit expressed qualitatively as "detection limit" or some similar term. Such a limit creates two problems. First, it fails to identify *whose* detection limit will apply in compliance determinations (i.e., without a numerical detection limit in your permit, the regulatory authority may hold your company to a detection limit that is below the capability of the laboratories used for compliance monitoring). Second, it makes your limit a "moving target." That is, as technological advances improve instrument sensitivity, your permit limit may become more stringent, but without affording you the procedural protection that might otherwise be available (e.g., the NPDES permit modification process).[126] To avoid these problems, insist on a reasonable numerical limit.

7. For permitted entities, be prepared to negotiate with your permit writer about how analytical variability should be accounted for in the permit. If you are dealing with technology-based limitations, make sure the limits have been properly adjusted to reflect analytical variability.[127] If the limit has not been so adjusted, you may wish to argue for a higher limit in your permit. Alternatively, if you are dealing with a water quality-based limitation, you can refer to EPA's Technical Support Document (TSD) for guidance.[128] Bear in mind, however, that the TSD approach will require further development before it can be relied on to account adequately for variability.[129]

8. If you experience excursions from your permit limitation that are inexplicable, notwithstanding a comprehensive evaluation of your operations, consider invoking the upset provision in your permit. Beware of the strict notification procedures.[130]

9. In NPDES permit proceedings, as well as in other regulatory contexts, it may be desirable to specify the test methods that can be used in compliance determinations. This could eliminate enforcement actions based on data derived from methods that exhibit more variability than the one you use. This is particularly significant if threatened with biological monitoring requirements. Biological test methods exhibit substantial variability, the magnitude of which depends largely on the test protocol, the test species used, and the relative health of the species in each laboratory performing the test.

10. Report data to the appropriate number of significant figures. Because of the "strict liability" nature of enforcement actions under the FWPCA, a court may not offer you an opportunity to explain why, from a basic scientific perspective, a measurement reported in a DMR as 10.001 mg/l should not be considered a violation of a 10 mg/l limit. If you can legitimately report such a measurement as 10 mg/l, you should do so.

11. Express all reported data below the *appropriate* detection limits with a designation such as "not detectable," or "ND." You may also want to include the specific detection limits on which your reporting protocol is based.

12. Express reported data greater than the *appropriate* LOQ or PQL in terms of the measured value plus or minus the appropriate error band,[131] particularly where analytical variability has not already been taken into proper account at some earlier point in the regulatory process (i.e., at the effluent guidelines or permitting stages). You may also want to raise the analytical variability issue in a disclaimer statement attached to the DMRs sent to your regulatory authority. In that statement, you could explain that—despite best efforts—your ability to report data that is "true, accurate, and complete"[132] was impaired by irreducible analytical variability, and that your company therefore reserves the right to challenge its regulatory significance in any enforcement action.[133]

13. Where significant regulatory implications may arise from analytical testing at your facility, ensure that the available data base is of adequate size. In addition to anticipated analytical variability, spurious sample results are always possible.[134] Indeed, EPA recently stated, "even a superior analytical laboratory occasionally produces data that are outside the acceptable limits for statistical reasons rather than any actual analytic problem."[135]

14. If your facilities become the target of a compliance audit or other investigation involving sample collection, ask your regulatory authority to provide split samples for you to analyze. This will provide you a means to check the validity of the authority's test results.

15. Participate in the federal and state lawmaking and rulemaking processes in which numerical standards are set

125. In Connecticut Fund for the Environment v. Upjohn Co., 660 F. Supp. 1397, 17 ELR 21137 (D. Conn. 1987), the court found a company liable based on violations reported in its DMRs, even though samples collected during the same period by EPA—and analyzed using a more sensitive detection system—showed compliance.

126. 40 C.F.R. §122.62 (1987).

127. Bear in mind that for permit limitations arising out of national categorical guidelines, EPA may claim that FWPCA §509, 33 U.S.C. §1369, ELR STAT. FWPCA 060, precludes judicial challenge to such limitations more than 120 days after they have gone into effect. In light of changing analytical techniques and other considerations, EPA's position may not succeed, since challenges can be brought at any time if based on events arising after the 120th day. *Id.* In any event, EPA could not raise the §509 argument during a challenge to a federally issued permit involving technology-based limitations based on best professional judgment under FWPCA §402(a)(1)(B), 33 U.S.C. §1342(a)(1)(B), ELR STAT. FWPCA 051.

128. ENVIRONMENTAL PROTECTION AGENCY, TECHNICAL SUPPORT DOCUMENT FOR WATER QUALITY-BASED TOXICS CONTROL App. E (Sept. 1985). The TSD presents EPA's recommendations regarding when water quality-based effluent limitations are necessary and how such limitations should be derived.

129. *See supra* note 83.

130. 40 C.F.R. §122.41(*l*)(6) (1987).

131. Recognize that analytical variability can be a double-edged sword and conceivably could be used by an adversary in an attempt to argue that measured values slightly below the compliance limit are violations.

132. 40 C.F.R. §122.22(d) (1987).

133. Bear in mind that a disclaimer statement, while clearly legitimate, may generate an adverse reaction from your regulatory authority.

134. The U.S. Fish and Wildlife Service recently fell victim to the imperfections of analytical procedures. After assuming for over a year that a 19,000-acre wildlife refuge it was interested in purchasing was heavily contaminated with mercury, it determined that the data on which its assumption was based were spurious. A repeat sampling program established that mercury concentrations at the refuge were negligible. DEPARTMENT OF THE INTERIOR, FISH AND WILDLIFE SERVICE, CONTAMINANT SURVEY OF BIOTA AND SEDIMENT FROM THE PROPOSED BAYOU SAUVAGE NATIONAL WILDLIFE REFUGE NEW ORLEANS, LOUISIANA (Dec. 15, 1988).

135. 53 Fed. Reg. 31552 (Aug. 18, 1988).

Not only is it more efficient to raise the analytical variability issue at that time, but your company may be precluded from doing so later in the regulatory process. Indeed, most federal environmental statutes authorize courts to review disputed issues arising out of a rulemaking only if suit is filed within a set time period after the final rule is issued.[136]

16. Review EPA's Section 518 Report and make your views known if you support or disagree with its findings.[137]

Conclusion

Industry must contend with an ever-expanding number of quantitative regulatory standards arising under a myriad of federal and state laws. Those standards serve as the basis for determining both the regulatory burdens with which a company must comply and the liability for failing to do so. Unfortunately, the laboratory test methods used to develop and apply those numerical standards exhibit varying degrees of irreducible performance variability. EPA has demonstrated a willingness to compensate for such analytical variability, yet its practices thus far have failed to provide the relief to which the regulated community is entitled. Companies must therefore be vigilant about determining where in the regulatory process analytical variability can adversely affect their interests, and must vigorously pursue the various technical and legal means available to prevent those impacts from arising.

136. *See, e.g.*, FWPCA §509, 33 U.S.C. §1369, ELR STAT. FWPCA 060.

137. *See supra* notes 74-75 and accompanying text.