When Nothing Is Something: Understanding Detection Limits

David Elias and Robert C. Goodman

Jones makes an offer on Blackacre, a former gasoline service station in Anytown, U.S.A. Jones hires an environmental consultant who prepares a "Phase II" report. Jones reviews the text and tables in the Phase II report and sees that while the property has low levels of gasoline, it is "ND" or "nondetect" for several volatile organic compounds. Jones' environmental lawyer opines that the solvents are the big concern anyway and that the gasoline levels are manageable from an environmental standpoint. Jones decides to buy the property. Down the road from Blackacre, Acme Widgets receives an analysis of its effluent from its laboratory, showing that copper (one of the substances for which it has a permit discharge limit) is below the reporting limit of the lab. Acme Widgets then submits its discharge monitoring report (DMR) to EPA reporting nondetect for copper. Both Jones and Acme Widgets may have made a crucial error. Had Jones (and her lawyer) and Acme Widgets carefully reviewed the lab reports they would have seen that "ND" does not necessarily mean an absence of the contaminants of concern.

The analytical data on Blackacre and the data that Acme Widgets considered in preparing its DMR were generated by laboratories. While scientists like to differentiate themselves from lawyers, the laboratory reports were likely filled with enough caveats, footnotes, and limiting language to make any lawyer proud. However, in both of these examples, the parties accepted the information provided to them at face value and as facts. Indeed, while lawyers are presumably trained not to do this, they are more apt to do so when dealing with something as seemingly straight-forward as the reporting of analytical data. While lawyers need not become scientists—that is why lawyers hire consultants, after all—lawyers should have an appreciation of the analytical chemistry process, because analytical chemistry provides the foundation for all environmental investigations, remediation, and litigation.

Analytical data lie at the heart of any site investigation. And all analytical data are reported together with a reference to detection limits. However, the term "detection limit" does not have a single, fixed meaning. In fact, a single laboratory report may refer to a variety of detection limits. This underscores why the environmental lawyer must make sure that the terms are defined and understood properly, early in the decision-making process. Without this understanding with the analytic laboratory, the analytic data generated may be useless for the client.

As noted above, the term detection limit does not have a single meaning (for clarity's sake, we will sometimes use the term analytical threshold as a generic description of the wide range of detection limits). For example, one form of detection limit is a practical quantitation limit. This is the concentration at which analytical results can be calculated within an acceptable statistical range. The laboratory may be able to see lower concentrations (the method detection limit), but they won't be able to report a numerical concentration with acceptable accuracy. Understanding the difference between these detection limits may prove important if a client wishes to know if a compound exists on her property, but does not need to know an accurate concentration.

The reporting limit is the threshold at which a laboratory reports a concentration. Regulatory guidelines often require specific reporting limits, even though the instrumentation may be able to "see" smaller quantities of a substance. Thus, labs often report only concentrations above the reporting limit.

The most common analytical thresholds are summarized in Chart 1 on page 518.

Every time a lawyer or client requests an analysis, she should discuss the detection limits with the analytical laboratory. A lawyer must understand that by choosing an undesirable detection limit, he may create problems for both his client and the regulatory community by generating data that does not meet the regulatory guidelines. As an environmental professional, a lawyer should be prepared to discuss appropriate detection limits before the onset of a project. This is called establishing data quality objectives. If detection limits change during an investigation it may be difficult to compare the disparate analytical results. Also, if the detection limits are based solely on one purpose, for example, on cleanup objectives, the data may be use-

Mr. Elias is a California-registered geologist and a senior geologist with Cambria Environmental Technology, Inc., in Oakland, California. Mr. Goodman is a partner in the San Francisco law firm of Goodman/Kang LLP and an adjunct professor at the University of San Francisco School of Law. He is a former trial lawyer with the Environmental Enforcement Section of the U.S. Department of Justice.

less for a different purpose, such as a risk assessment.

Blackacre is soon to be developed for residential use. The use of very low detection limits therefore would be appropriate to allow the reporting of the low concentrations of contaminants that may be acceptable at a residential site. However, the lawyer failed to communicate this information to the laboratory because "detection limits are all the same." The laboratory analyzes the samples using higher detection limits appropriate for an industrial site, and uses all of the sample material performing the analyses. Because Blackacre will be developed for residential uses, the analytic results are potentially useless to the client because the reporting limits are higher than the risk-based acceptable thresholds. This situation *may* be salvageable, if the laboratory can re-interpret the data. An initial clear understanding with the laboratory regarding the detection limits prior to analyzing the samples would have avoided this embarrassing and costly situation. The lawyer needs to anticipate the different uses of detection limits and be able to explain coherently these ideas and results to her client.

Technological Advances

Detection limits are constantly changing. Over the last twenty years, engineers and chemists have worked to design instruments that can detect and quantify smaller concentrations of compounds. They have successfully improved the instrumentation, thus increasing sensitivity and precision. The original 1979 EPA methods for the analysis of volatile and semivolatile compounds were called the 600 methods, and were promulgated for the analyses of water and wastewater. The latest methods were developed for the analysis of drinking water and are called the 500 methods. EPA completes a pilot study of its methods prior to publication using about eleven different laboratories. In the study, each laboratory determines its method detection limits for a specific method. The table below shows the improvements in sensitivity from the 600 methods to the 500 methods for detection limits generated in the preliminary studies. We have included a common volatile organic compound, polynuclear aromatic hydrocarbon (PNAs), and polycyclic biphenol (PCBs).

Chart 2 below, demonstrates how the latest analytical methods are able to detect smaller concentrations of the substances of concern.

Hewlett-Packard, a manufacturer of gas chromatography/mass spectrometry instruments, provided the following information about the sensitivity improvement of its instruments over the last thirteen years.

The comparisons presented in chart 3, below, relate to the concentration at which the instrument can detect the presence of a compound. The laboratory, using these instruments, is not measuring exact quantity of the compound.

Chart 1

Term	Definition
Instrument detection limit	The lowest concentration at which a compound can be detected. This limit is calculated when a compound produces an instrument output signal that is twice the root-mean-square of the electronic "background noise" that the instrument routinely produces, assuming ideal conditions.
Detection limit	The lowest concentration at which a compound can be detected in matrix, i.e., soil or water (does not assume ideal conditions).
Method detection limit	The concentration at which it can be stated with 99 percent confidence that a compound exists above zero in a given matrix containing analytes. Based on regulatory guidelines for specific methods involving sample preparation. A lab must conduct a study to determine the specific method detection limits for each instrument. These detection limits vary between labs and instruments, and must be verified annually for each method and each instrument, or if the lab has modified the instrument.
Practical quantitation limit	The measured value that is close to the true value, with low relative standard deviation. Usually within 5 to 10 times the method detection limit.
Limit of quantitation	Same as the practical quantitation limit.
Reporting limit	Usually 5 to 10 times the method detection limit, or identical to the practical quantitation limit. The reporting limit can never be less than the practical quantitation limit. The lab can also choose a reporting limit based on regulatory requirements, cleanup goals, or risk-based goals.
Reported detection limit	Takes into account sample size, matrix interference and dilution. This is the method detection limit for a particular run or sample.
Control limit	A range within which a specified measurement result must fall to be compliant. This is used in the laboratory quality assurance/quality control analyses.

Chart 2

Comparison of Method Detection Limits (µg/L or parts per billion)

Compound	Method 600s	MDL	Method 500s	MDL	Difference
Arochlor 1260 (PCB)	625	36	525	0.27	Factor of 133
Benzene (Volatile)	624	4.4	524	0.04	Factor of 110
Phenanthrene (PNA)	625	5.4	525	0.069	Factor of 78

Chart 3

Hewlett-Packard Gas Chromatography/Mass Spectrometry Improvements

HP Model	Year Introduced	Hexachlorobenzene Instrument Detection limit (µg/L)
5970	1983	100
5971	1989	50
5972	1993	10
5973	1996	2

These are only a few of the examples of improvements in technology that have lowered detection limits significantly over the past twenty years, and they by no means represent a comprehensive list. The examples demonstrate why it is important to maintain a current understanding of the technology, terminology, and the regulations. For example, over a period of only three years, 1993 to 1996, the instrument sensitivity improved five-fold. Without understanding these improvements, a lawyer could easily choose an outdated "detection limit."

Deciding What Limit Is Appropriate

Often the regulatory requested reporting limit is different from the instrument's practical quantitation limit. Thus, there is room for professional judgment in possibly requesting a lower reporting limit before starting a project. The decision of what reporting limit to request will be greatly influenced by the type of project or transaction, as well as the client's specific needs or style. Because of the improvements in technology, we now have the ability to choose to look for extremely small concentrations. We can request reporting limits below the regulatory requirements, if that will serve our client's interests.

For example, Acme Widgets plans to continue operating at its site, and does not anticipate a future change in ownership or land use. Acme Widgets would want to use reporting limits that comply with regulations, but not lower reporting limits that may reveal new regulated compounds on its property that will need further investigation. In the case of the Blackacre property, the client is interested in knowing as much as possible about the condition of the property so she can assess her exposure and the true value of the property. Thus she may see value in a more rigorous investigation that may disclose contaminants not previously detected.

Detection limits and related issues come into play in virtually every area of environmental law, from the purchase of a piece of property, to its remediation, to compliance with permit limits.

In the purchase of Blackacre, for example, Jones thinks she is buying a piece of property not contaminated with volatile organic compounds (VOCs) when in fact that may not be the case. Remember that the Phase II report stated that the groundwater samples were "ND" for VOCs. Had Jones' lawyer reviewed the lab reports, he would have seen that the lab's reporting limit for tetrachloroethene was 100 μg/L. Thus, tetrachloroethene could be present at Blackacre in concentrations as high as 99 μg/L. And at those levels, it is likely that some remediation would be required. If Jones were to buy the property—blithely assuming that it is "clean"—she could very well be in for a rude surprise when she sells her property. A prospective buyer may sample for VOCs using more sensitive methods than she used, and discover the problem.

In evaluating the environmental condition of the property, Jones' lawyer should discuss with the consultant whether it is possible to determine the presence of the lower concentrations of solvents. If so, Jones must decide whether she wants that information. Most buyers of property (and their lenders) are interested in knowing as much as possible about the condition of the property, and determining whether it is in fact contaminated. Thus, they would presumably want to use the lowest detection limit possible.

Detection limits also play a critical role in the remediation of property. In the Blackacre example, an important consideration is whether a regulatory agency would consider "ND" (with a reporting limit of 100 (μg/L) to be non-detect or 100 μg/L. Currently, most regulatory agencies specify the reporting limit that will pass for a non-detect, meaning that the target compound does not exist in that sample. However, if new information (such as toxicity data) reveals that a compound deserves more attention, regulatory agencies may request additional sampling at lower reporting limits. Also, it is common practice when calculating health risk to include non-detect analytic results as one-half the reporting limit. A sample that shows non-detect at 1 ppm might be included in the calculations as 0.5 ppm.

Obviously, if a regulatory agency considers ND to mean 100 μg/L, it is possible that Jones could be required to "remediate" contamination that does not exist or at least, required to resample using lower reporting limits. She, therefore, has an interest in more precisely measuring the contamination.

Compliance with Discharge Permit Requirements

The issue of detection limits also often arises in the context of compliance with permit limits. National Pollutant Discharge Elimination System (NPDES) permits issued under the Federal Water Pollution Control Act, 33 U.S.C. §§ 1251 *et seq.*, for example, often set forth reporting limits for a variety of parameters. Courts have consistently ruled that a party that reports a violation in its DMR is virtually precluded from a later challenge of testing method or a claim that there actually was not a violation because of technological limitations. Two United States district court cases highlight the problem.

In *Connecticut Fund for the Environment, Inc. v. The Upjohn Co.*, 660 F. Supp. 1397 (D. Conn. 1987), the discharger analyzed its effluent using an acceptable method and periodically reported permit exceedances. At some point, EPA took samples of the discharger's effluent, and used a more sophisticated analysis called Gas Chromatography/Mass Spectrometry. In general, the discharger's sampling method reported concentrations 6.6 times higher than the more sophisticated analysis. The discharger then asserted that violations

(Continued on page 573)

the article with a discussion of the tax benefits associated with postmortem easement donations.

Nancy McLaughlin's principal objective in writing the article was to assist practitioners in understanding the complex provisions of the applicable tax statutes, particularly the recent additions. In this goal, she succeeds quite well. For an article dealing with complex tax issues, it is surprisingly readable.

Courting Science

(Continued from page 512)

dictable, and compliance hard to achieve.

Second, if courts conflate the evidentiary standard with the sufficiency standard, criminal environmental cases involving expert testimony will be exceptionally hard to prove. While it is often possible to demonstrate that a study underlying expert testimony shows that it is "more likely than not" that one event caused another, it is only in exceptional cases that an individual piece of evidence could meet the "beyond a reasonable doubt" criminal sufficiency standard. *See* Edward J. Imwinkelried, Daubert *Revisited: Disturbing Implications*, 22-May CHAMPION 18, 24 (1998). If the sufficiency standard is required for admission of scientific evidence in the criminal law context (and it has not yet been so applied) then many types of evidence critical to criminal environmental enforcement cases would be precluded from evidence. Exclusion of evidence relating to generation of waste streams, or identification of trace hazardous materials would "have a devastating impact on the prosecution's ability to marshall scientific evidence against an accused." *Id.*

Congress could also choose to modify the APA or specific statutes in a manner that would require the application of the Federal Rules of Evidence and hence *Daubert* to administrative decisions. The American Bar Association, for example, has recommended this kind of modification with respect to agency tribunals. In addition, some in Congress have advocated that CERCLA's Natural Resources Damage Assessment (NRDA) provisions be subject to de novo review by federal courts, instead of record review, which would make the Federal Rules of Evidence and *Daubert* applicable. While this application of *Daubert* may have only slight impact on NRDA determinations as compared with the loss of deference that would follow de novo review, subjecting agency decisions to *Daubert* would most likely increase federal agencies' burden.

As confirmed by *Carmichael, Daubert* provides broad guidelines as to how courts should fit what science has to offer with what our justice system demands. In doing so, it leaves much to the ingenuity of trial court judges and the circuits.

Detection Limits

(Continued from page 521)

reported based on the older analytical process may not have been violations at all because of the risk of "over reporting." The court rejected the argument:

> [A]lthough a basis for defendants challenge of the accuracy of its reports may exist as a matter of fact, that defense has no basis as a matter of law. If an entity reports a pollution level in excess of the Permit limits, it is strictly liable[.]

Id. at 1417.

In *United States v. Aluminum Company of America*, 824 F. Supp. 640 (E.D. Tex. 1992), the defendant's DMR reported a slight exceedance of a 5 ppb discharge limit. When sued for this violation (among others) the defendant presented expert testimony that there is a "95% confidence interval surrounding measurements at or near the permit daily maximum limitations." *Id.* at 648. Thus, the defendant argued that an exceedance reported as 7.78 ppb was not proof of a violation of 5 ppb permit limit. The court rejected this argument outright, stating that

> [w]hile the technology utilized may not have been fool proof, [defendant] cannot defeat the government's motion for summary judgment as to the five violations . . . based on imprecise measurements.

Id. at 649.

The lesson of these two cases: Deal with laboratory reporting limits before data are submitted to the government, rather than after.

There are other potential pitfalls relating to permit compliance. NPDES permits, for instance, sometimes include language relating to water quality limits that requires a permit holder to analyze to the lowest practical quantitation limit of a certified laboratory in its state. If the analytical capabilities improve, the new practical quantitation limit must be met (unless the quantitation limit is lower than the permit limit, in which case the permit limit governs). Thus, the limit established by the permit may change over time. Moreover, a source that believes it is in compliance based on its current form of analysis may learn that it is *not* in compliance as practical quantitation limits drop.

Permit holders also must be aware that the government or a citizens' group can always take them to task for failing to comply with the lowest practical quantitation limit available. The Acme Widgets example discussed at the beginning of this article illustrates this problem. Let us assume that Acme Widgets' permit had a provision similar to the permit language discussed above: a limit of 5 ppb for copper. The reporting limit of Acme Widgets' lab is 10 ppb, and its lab analysis shows no violation of this standard. However, an independent analysis of the effluent (by the government or a citizens' group), using a lower reporting limit might well detect a permit violation. Thus, Acme may be subject to penalties for violating its permit limits although it believes that it is in compliance.

The ability of scientists to detect ever smaller concentrations of substances is an issue that lawyers cannot ignore. In any instance where materials are analyzed—be it in the purchase of property, the remediation of a contaminated site, or the reporting of permit limits—it is important to be mindful of what the lab results mean to say and whether there are better tools available that should be used.

Bioprospecting

(Continued from page 532)

While NPS continues to support its interpretation of its own regulations and the FTTA, this framework may not be appropriate for other agencies. Some agencies may not have a facility that can be considered a laboratory. Other agencies may not have a regulatory permit process that works with a CRADA sufficiently to control access. An interagency work group, comprised of representatives from DOI, USDA, the Department of State, NIH and other interested agencies, is currently assessing and comparing the level of regulatory control available and the possibility of developing a uniform policy for land-managing agencies.

In the event a uniform policy and set of laws and regulations to govern bioprospecting on the public lands cannot be ascertained, congressional direction and legislation may be necessary. If the U.S. becomes a party to the CBD, the CBD carries the obligation to take legislative, administrative, or policy measures to implement the access to genetic resources provisions and sharing of benefits with source countries arising from the commercialization and other utilization of such resources. Present development of legislation to uniformly govern domestic access and benefit-sharing would meet our current needs and perhaps obviate the need for legislation implementing the CBD when the time comes.

While bioprospecting legislation can be drafted either broadly for further refinement by the regulatory agencies, or narrowly according to specifications designed by Congress, any legislation will necessarily be shaped by the following concepts: clarification of the legal property status of genetic resources, the valuation of genetic resources, the extent of bioprospecting activities already occurring, and the technical, administrative and financial resources available to develop a regulatory framework. Legislation should also consider control of genetic resources in ex situ collections, such as the clearinghouse where Dr. Brock deposited *T. aquaticus*.

Existing and draft templates for such legislation have been developed in countries party to the CBD. Thus far, five general patterns have emerged. The first comprises general environmental framework laws which direct a competent national authority to provide specific guidance. The second type includes framework laws governing sustainable development, nature conservation, or biodiversity more detailed than the previous category. The third template uses stand-alone national laws specifically controlling access. A fourth category is legislation that modifies existing laws and regulations and tailors them to extend to access and benefit-sharing arrangements. Finally, the fifth pattern involves agreements entered into between countries on a regional basis. *See* Lyle Glowka, *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources*, Environmental Policy and Law Paper No. 34, IUCN—The World Conservation Union, 1998.

In developing and implementing its own legislation, the United States should follow the third category, stand-alone specific legislation, to provide the best foundation for a uniform framework for the various federal agencies to follow. Whichever form it takes, comprehensive legislation will share certain similarities, such as specific principles, objectives and definitions; applicable scope; clarification of the legal status of genetic resources; procedures to provide access; enforcement and penalty provisions; and monitoring controls.

While uniform legislation addressing bioprospecting issues would be optimal, land managers other than NPS can use existing authorities to regulate bioprospecting. Discoveries, such as Dr. Brock's *T. aquaticus*, are beneficial to mankind and bioprospecting should be permitted to continue, subject to regulation and benefit-sharing. Private industry is beginning to acknowledge the concept of compensating the government and taxpayers for the past and future use of public land resources. In this current climate, where technology is rapidly outpacing bioprospecting policy, the United States cannot responsibly manage public lands without addressing and resolving these important issues.