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Factors for Determining Validity of Evidence in Clean Air Act Litigation

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**Cover Page Footnote**
The author wishes to thank Professor Paul Giannelli and Professor Wendy Wagner of Case Western Reserve University School of Law for their suggestions and encouragement. Special thanks are due to Mr. Patrick Haines of the Ohio EPA; his kind assistance in providing detailed information on Method 9 is deeply appreciated. The author dedicates this paper to the memory of Gail S. Mueller; her courage and compassion are remembered by all who knew her.

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FACTORS FOR DETERMINING VALIDITY OF EVIDENCE IN CLEAN AIR ACT LITIGATION

SUSAN NORTON*

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I. INTRODUCTION

This article discusses the admissibility of scientific evidence proffered during environmental compliance litigation. Specifically, it addresses the question of how a federal district court handling such litigation can develop a rationale for evaluating that evidence for reliability under Federal Rule of Evidence 702. The major premise of this article is that the holding in Daubert v. Merrell Dow Pharmaceuticals, Inc.\(^1\) requires the court to use an expanded version of the four factors listed in that case for determining the scientific validity of evidence. Further, in order to determine the evidentiary reliability of environmental compliance data, the court must identify and apply factors that test the scientific validity of both the technology that generates the compliance data and the methods used to analyze the data.

This article proposes a set of factors that support this determination because they:

1. have a basis in the scientific method;
2. follow Daubert’s requirement that they focus on the expert’s reasoning rather than his conclusions\(^2\) and
3. require the court to make a clear distinction between what components of the evidence are based on science, and what are based on non-science policy.

The ideas presented in this article are developed within the context of the "Any Credible Evidence" Rule\(^3\) ("ACE Rule" or "Rule") of USEPA’s ("EPA" or "Agency") 1990 Clean Air Act Amendments ("CAAAA" or "Amendments").\(^4\) Both the Rule and its enabling statute\(^5\) fail to completely define "any credible evidence".

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2. See id. at 594-95.
However, when *Daubert* factors are thoughtfully devised and applied to air emissions data to determine their reliability, a sharper definition of "any credible evidence" emerges.

Part II briefly discusses the ACE Rule, states why it is of concern to industry, explores the current understanding of what evidence the EPA expects the Rule to include, and explains why the minimal guidance the EPA has given requires the use of *Daubert* factors in evaluating this evidence. Part III turns to the question of how scientific, engineering, and technical evidence should be evaluated for reliability according to *Daubert*. The discussion considers the two major cases since *Daubert* that address reliability: *General Electric Co. v. Joiner*\(^6\) and *Kumho Tire Co., Ltd., v. Carmichael*.\(^7\) Part IV then examines how the courts can develop *Daubert* factors appropriate to ACE Rule evidence. The process of developing these factors begins with "guidepost" criteria that have been identified as demonstrating scientific validity\(^8\) when applied to the most basic scientific endeavor: the development and testing of a hypothesis. Part V familiarizes the reader with Method 9, a standard emissions method. Part VI applies a representative selection of the new *Daubert* factors devised in Part IV to Method 9 to illustrate their use in determining validity and reliability.

In conclusion, the guidepost criteria are shown to be the logical source of appropriate *Daubert* factors, which the court can apply to assess the validity of data-generating technology and data-interpreting methods. In this specific instance, the factors are applied to an air emissions monitoring technology. However, they could be applied to technologies and methods used for monitoring and evaluating environmental compliance data from any source.

**II. THE ACE RULE AND THE NEED FOR *DAUBERT* FACTORS**

The Clean Air Act Amendments expand potential enforcement liability of major emissions sources, in part because the Act states that "any credible evidence" may be used in enforcement actions. Although the EPA does not define "any credible evidence", the Agency has indicated it must be based on scientific principles and is otherwise only limited by the Federal Rules of Evidence. "Any

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credible evidence” is therefore subject to an analysis for scientific validity under Daubert.

A. Major Stationary Sources and Expanded Compliance Under the CAAA

The enactment of the Clean Air Act Amendments in 1990 critically expanded the compliance obligations and enforcement exposure of major stationary sources ("major sources").

Prior to the Amendments, major sources were not required to obtain permits for their emissions or report their own violations. Although the EPA required them to maintain continuous compliance with emissions standards, the Agency monitoring was minimal and monitoring practices were extremely favorable to industry. Facilities were notified in advance of Agency inspections and could fine-tune their emissions control equipment beforehand. In essence, a facility could meet Agency requirements by showing it had the ability to be in compliance, rather than by actual demonstration of day-to-day compliance.

Lastly, citizen plaintiff groups, the regulated community, and the EPA were limited to using the EPA’s "reference test methods" to demonstrate compliance or noncompliance. The reference test methods are forty methods premised on well-established scientific principles and documented by a brief bibliography. These methods were adopted and published by the EPA over the twenty years prior to the CAAA and are still available for industry, Agency, or citizen use.

Major sources are now subjected to two significantly demanding programs: the Title V permitting program and the Compliance Assurance Monitoring Rule, or "CAM" Rule. Both programs

9. Major stationary sources are facilities that have the potential to release more than one hundred tons of regulated emissions annually. Examples include petroleum refineries, electric power plants, steel mills, and other large factories. See U.S. GENERAL ACCOUNTING OFFICE, AIR POLLUTION: IMPROVEMENTS NEEDED IN DETECTING AND PREVENTING VIOLATIONS 8-9 (GAO No. RCED-90-155) (Sept. 1990).
11. See U.S. GENERAL ACCOUNTING OFFICE, supra note 9, at 21.
12. See id.
14. Although it may not necessarily be true that these principles have been applied correctly in the design of a given test method itself.
16. The Title V operating permit program was codified at subchapter V of the CAA, 42 U.S.C. §§ 7661-7661f, and was added to the CAA as part of the Clean Air Act Amendments, Pub. L. No. 101-549, Title V, 104 Stat. 2399 (1990).
require major sources to generate, retain, and report massive quantities of monitoring data to demonstrate continuous compliance. These programs also create concern for major source operators that their enforcement liability has been enormously expanded, not only with respect to the EPA and its state designates, but also under the citizen suit provisions of the Clean Air Act.

Another feature of the 1990 Amendments, the Credible Evidence Revisions, amplifies these concerns. Generally referred to as the "Any Credible Evidence" Rule, it allows the use of both reference test method data and "comparable non-reference test data" in proving or disproving CAAA violations in enforcement actions. Furthermore, any data developed by facilities under the CAM Rule or Title V may be used in judicial enforcement actions pursuant to the ACE Rule. To date, industry efforts to challenge the rule have been unsuccessful, and the regulated community remains stymied by one of the rule's most frustrating features: its failure to define exactly what "any credible evidence" means in the context of Clean Air Act enforcement.

B. The ACE Rule and Why Daubert Has a Bearing on its Interpretation

The ACE Rule is of concern as much for what it does not say as for what it does say. It states that non-reference test data (as opposed to data from reference test methods) can be used for establishing the facility compliance certifications required by the CAM Rule and the Title V permitting program, as well as enforcement actions. The EPA has included a requirement that a given set of non-reference test data "relate" to the underlying air toxics standard it measures, and that it be "comparable" to the reference test methods contained in that standard. Clearly, the EPA intends to secure the status of the reference test methods as "benchmarks"

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23. See Clean Air Implementation Project v. EPA, 150 F.3d 1200, 1208 (D.C. Cir. 1998). (holding that the issues concerning the impact of the credible evidence rule were not ripe for review).
25. See id. at 8319.
for non-reference test methods. However, the Agency gives no guidance on what “comparable” means, how “comparability” or “benchmarking” will be determined, nor does the Rule identify any form of evidence as presumptively credible, stating, “[t]his regulation also does not designate any particular data as probative of a violation of an emissions standard.”

However, the Agency is fairly clear about two criteria for credible evidence. First, whether the data is derived from either reference test methods or non-reference test methods, the implication is that it must be based on scientific technology. With respect to reference test data, it has been noted that the methods are based on well-established scientific principles. As to non-reference test data, the EPA states that it can include “engineering calculations, indirect estimates of emissions, and direct measurement of emissions.” For example, the EPA identifies “continuous emissions monitoring (CEM) data . . . and air flow rate of a regenerative thermal oxidizer” as “generally” providing “accurate data” with respect to determining compliance. Further, because the data from the non-reference methods is derived from applied science (engineering), there is nothing novel about the scientific methodology that underlies the technology. Hence, underlying both reference and non-reference methods are well-established principles whose validity does not require examination.

What may be more open to question is: (1) whether the underlying science was correctly applied in designing the test method; and (2) even if the application was correct, whether the resulting data was correctly interpreted. These two questions bear on the evidentiary reliability of the data and are subject to the analysis proposed in Part IV.

The EPA establishes its second criterion for credible evidence more explicitly: the Agency contends that only the Federal Rules of Evidence limit what can be used to prove a violation. In taking this position, the EPA confirms its intention to let in as much evidence as possible. The EPA’s position is also consistent with the “relaxed”

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26. See id. at 8320.
27. Id. at 8315.
30. A continuous emissions monitor (CEM) is an electromechanical device that measures emissions virtually continuously. See U.S. GENERAL ACCOUNTING OFFICE, supra note 9, at 19.
32. See id. at 8317.
standard for admissibility of expert opinion testimony under the Federal Rule of Evidence 702. But the EPA appears not to have noted a direct consequence. Because the data is subject to the Federal Rules of Evidence, it is subject to an analysis for scientific validity under Daubert. As will be subsequently shown, a thoughtful Daubert analysis is likely not only to make the standard for admissibility less relaxed, it may considerably sharpen the definition of credible evidence.

III. THE DAUBERT FACTORS FOR DETERMINING VALIDITY AND RELIABILITY

The Daubert Court invited subsequent courts to develop factors for evaluating scientific evidence, beyond the four it suggested. Nine criteria have since been identified that support development of such factors on the basis of objective scientific validity. Since Daubert, Supreme Court rulings have favored Daubert factors for engineering and technical testimony - hence, a Daubert analysis is applicable to environmental data. While the Court has not explicitly required that these factors be based on objective premises of scientific validity, these post-Daubert rulings implicitly require these premises. Further, objective criteria of scientific validity are necessary for a court to frime factors to assess environmental testimony in general and air emissions testimony in particular.

A. Daubert and Scientific Validity

In brief, Daubert holds that FRE 702 supercedes the Frye "general acceptance" rule. Daubert states that in evaluating expert testimony for admissibility under FRE 702, a court must first evaluate it for evidentiary reliability. The court is obliged to undertake its own analysis - it cannot merely use "surrogate" factors such as "general acceptance" by an outside community of experts, as Frye allowed.

Daubert suggested four factors for evaluating scientific evidence:

1. Whether the scientific knowledge upon which the evidence rests can be subjected to testing which may refute it;

33. See Daubert, 509 U.S. at 588 (citing Beech Aircraft Corp. v. Rainey, 488 U.S. 153, 169 (1988)).
34. See Daubert, 509 U.S. at 589.
35. See id. at 590.
36. Such analysis is typically done in a FED. R. EVID. § 104(a) hearing. See id. at 592-93.
2. Whether it has been subject to peer review and publication;
3. If it is a scientific technique, its "known or potential rate of
error;" and
4. "General acceptance" by the "relevant scientific
community."37 The Court allowed this factor in determining
if evidence is valid, but did not give it any special weight.

The Daubert Court only suggested the four factors as possible
guidelines for determining reliability of scientific evidence.38 The
Court regarded this list as non-exclusive and invited subsequent
courts to develop other factors as they deemed appropriate to the
evidence at hand.39 The Court's objective in developing factors to
assess the reliability of scientific evidence is to help assess the
scientific validity of the data.40 Standing alone, these four factors
lack sufficient detail or content to support this goal.

B. Efforts to Ground the Daubert Factors in Criteria for Scientific Validity

An attempt to provide a comprehensive framework for courts to
use in managing science-based litigation came with the publication
of the Federal Judicial Center's Reference Manual on Scientific Evidence
in 1994 (FJC Manual).41 However, the FJC Manual does not suggest
how courts can develop factors for assessing the validity of scientific
evidence.

The FJC Manual was followed in 1997 by Expert Evidence: A
Evidence).42 In its analysis of the law of expert testimony, Expert
Evidence identifies nine criteria for assessing scientific validity of
purportedly scientific expert testimony.43

The nine criteria at first appear limiting, largely because they are
defined abstractly and applied to assessing a scientific hypothesis.
However, as noted by their authors, the criteria are not to be used as

37. Daubert, 509 U.S. at 593-94.
38. See id.
39. See id. at 593.
40. See id. at 594-95.
41. FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE (Joe S. Cecil et al. eds., 1994) [hereinafter FJC Manual].
42. PRODUCT LIABILITY ADVISORY COUNCIL, FOUNDATION, EXPERT EVIDENCE: A
PRACTITIONER'S GUIDE TO LAW, SCIENCE, AND THE FJC MANUAL (Bert Black & Patrick W. Lee, eds., 1997) [hereinafter EXPERT EVIDENCE].
43. See id. at 44-46; see also Black, supra note 8, at 782 (citing identical criteria). The latter source will primarily be used for the criteria unless otherwise noted.
a checklist, but only as guideposts.44 Therefore, the criteria should be understood to be very de-limiting because they provide a framework that supports an objective examination of evidence, one that does not rely on "surrogate factors"45 that allows a court to evade its responsibility to make the analysis. By avoiding the use of surrogate factors, a court is forced to satisfy itself that every step of the expert's reasoning process is objectively sound.

In Part IV, this paper examines these guideposts in detail and discusses how they can be used to design useful factors specific to assessing environmental compliance data in general and air emissions data in particular. But before doing this, it is useful to consider several preliminary issues. The first is whether present law favors the aggressive development of Daubert factors, as suggested here. The second is whether present law favors subjecting engineering and other technical testimony (as opposed to purely scientific testimony) to Daubert analysis, as this paper also contends. The third is whether the Daubert analysis of engineering and technical testimony should be pinned exclusively to factors based on scientific validity. Lastly, with respect to engineering and technical testimony for environmental compliance, questions arise as to whether there has been any recognition of a need for Daubert factors in this context, and why such factors should be specially tailored for this type of evidence.

C. The Impact of G.E. v. Joiner and Kumho Tire on Daubert

In General Electric v. Joiner46 and Kumho Tire Co., Ltd. v. Carmichael47, the Supreme Court gave federal district courts freedom to develop Daubert factors as they see fit to determine evidentiary reliability. Kumho Tire's holding clearly states that a district court must subject engineering and technical testimony to a Daubert analysis. However, while Kumho Tire's holding expanded the factors for assessing such testimony to any which qualify as "reasonable reliability criteria", the Court's opinion failed to define this standard or to require that these criteria be grounded in an objective basis of scientific validity.

44. See Black, supra note 8, at 754.
45. A "surrogate factor" may be defined as any factor that does not directly address the expert's reasoning process. See id. at 732-33.

In General Electric Co. v. Joiner, the Supreme Court affirmed Daubert's holding that under FRE 702, the trial judge must ensure that any scientific testimony admitted is not only relevant, but reliable. Specifically, Joiner addressed the reliability of medical evidence that purported to show a connection between the plaintiff's lung cancer and his prior exposure to PCBs, dioxins and furans. The issue was whether the opinions of plaintiff Joiner's experts were sufficiently supported by the animal studies on which they purported to rely. The Supreme Court held that the studies used by the experts were so dissimilar to the facts of Joiner's case that it was not an abuse of discretion for the trial court to have excluded them.

The Joiner Court did not discuss what factors the trial court should use in determining reliability of scientific evidence, or what their relationship to scientific validity should be. However, in supporting abuse-of-discretion review, the Joiner Court endorsed giving the trial court great freedom in selecting Daubert factors to determine reliability. The Supreme Court subsequently spoke more clearly to this point in Kumho Tire Co., Ltd. v. Carmichael. Specifically citing Joiner, the Kumho Tire Court stated, "the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination." Further, "whether Daubert's specific factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge broad latitude to determine." First in Joiner, then more explicitly in Kumho Tire, the Court has given trial courts freedom to develop factors as it sees fit to determine reliability.

48. See Joiner, 522 U.S. at 142.
49. See id. at 139-40.
50. See id. at 144.
51. See id. at 144-45.
52. See id. at 141-43.
54. Id. at 142 (citing General Elec. Co. v. Joiner, 522 U.S. 136, 143 (1997)).
55. Id. at 153 (citing General Elec. Co. v. Joiner, 522 U.S. 136, 143 (1997)).
2. Engineering and Technical Testimony are Subject to Daubert Analysis.

The *Kumho Tire* Court clearly affirmed the use of *Daubert* factors for evaluating engineering and technical testimony. In *Kumho Tire*, the broad issue was "how *Daubert* applies to the testimony of engineers and other experts who are not scientists."56 The *Kumho Tire* Court held that *Daubert's* general holding, which requires the trial judge to act as a gatekeeper in evaluating expert testimony for admissibility, applies to testimony based on "technical" and "other specialized" knowledge.57 The *Kumho Tire* Court also concluded that in the case of engineering, technical, or other specialized knowledge, the "trial court may consider one or more of the specific factors that *Daubert* mentioned when doing so will help determine that testimony's reliability."58

*Kumho Tire's* holding makes it clear that a district court is legally required to subject engineering and technical testimony - hence environmental compliance testimony - to a *Daubert* analysis. However, the *Kumho Tire* Court stressed that "as . . . stated in *Daubert*, the test of reliability is 'flexible', and *Daubert's* list of specific factors neither necessarily nor exclusively applies to all experts or in every case."59 When the petitioners asked the *Kumho Tire* Court whether the trial judge might use the four factors cited in *Daubert* to determine the admissibility of an engineering expert's testimony, the Court replied that the trial court may use them, emphasizing that the Court's "emphasis on the word 'may' thus reflects *Daubert's* description of the Rule 702 inquiry as 'a flexible one.'"60

The narrow issue in *Kumho Tire* was the reasonableness (hence, reliability) of the expert witness's use of certain methods of obtaining and analyzing tire-wear data in order to draw an evidentiary conclusion.61 The *Kumho Tire* Court held that the District Court was within its lawful discretion in excluding the evidence on the basis of its failure to satisfy either *Daubert's* factors or any other set of reasonable reliability criteria.62 The *Kumho Tire* Court thus expands

56. *Id.* at 141.
57. See *id.*
58. *Id.*
59. *Id.*
60. *Id.* at 150.
61. See *id.* at 153-54.
62. See *id.* at 158.
Daubert factors to any which qualify as "reasonable reliability criteria."

The outcome of the *Joiner* and *Kumho Tire* rulings is that while a district court has great discretion to develop Daubert factors for determining reliability, it need only meet an as yet undefined standard of reasonableness. With respect to engineering and technical, and hence environmental, evidence, there is no requirement that the factors have a basis in scientific validity.

D. Daubert Factors for Engineering or Technical Testimony Should be Based on Scientific Validity

Even though neither *Joiner* nor *Kumho Tire* confirm that Daubert factors for engineering and technical testimony should adhere to principles of scientific validity, there are good reasons to maintain this adherence. As the *Kumho Tire* Court notes, "[e]ngineering testimony rests upon scientific foundations, the reliability of which will be at issue in some cases."63 This statement leads to two conclusions. First, the use of principles of scientific validity to devise Daubert factors for this engineering testimony is logically consistent with the relationship between engineering and applied science to pure science. This logical consistency justifies adherence to the use of principles of scientific validity. Second, it implicates Daubert's requirement that the court focus on the expert's reasoning rather than his conclusions.64 This, in turn, recalls the basic requirement the factors must address: objectivity. As will be shown in Part IV, the guideposts for scientific validity are the primary tools for maintaining objectivity in developing the factors. The *Kumho Tire* Court indirectly acknowledges this in its comment that the objective of Daubert's gatekeeping requirement is "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."65

This comment seems to clarify what reasonable reliability criteria are with respect to engineering and technical testimony. Such criteria are Daubert factors that hold the expert to "the same level of intellectual rigor that characterizes the practice of an expert in the

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63. *Id.* at 150.
64. See 509 U.S. at 594-95.
65. 526 U.S. at 152.
relevant field." Intellectual rigor necessarily demands objectivity; as a result, an engineering or technical expert is held to standards of scientific validity.

It is crucial to recognize the relationship of standards of validity to engineering and technical testimony in the wake of *Kumho Tire*. *Kumho Tire* appears to allow trial courts unlimited license to devise factors by giving them "discretion to choose among reasonable means." *Kumho Tire* also secures *Daubert* analysis for ""other specialized' knowledge", a term so open-ended that it may be used to justify virtually any kind of expert testimony. A court's recognition of the relationship between scientific validity and engineering and technical testimony thus becomes critical. Without it, a court risks losing the "'gold standard" for securing the reliability of the expanded range of expert testimony it now must assess.

E. *Daubert* Factors Tailored to Assessing Environmental Compliance Data

This paper now responds to the question of why environmental compliance data should require their own *Daubert* factors.

Of the articles this writer reviewed for an understanding of *Daubert* factors, none were found that addressed how to devise factors for assessing environmental compliance data. Superficially, there appears to be nothing distinctive about environmental compliance data insofar as they are generated by conventional applied science. However, it can be argued that environmental compliance data requires application of factors that reflect an especially stringent level of objectivity. This is because the underlying standards that condition the choice of technology, and possibly the choice of method of data evaluation, are based not solely on science, but in part on policy decisions that have no scientific basis. This is true in general and specifically with respect to CAAA emissions standards. Thus, a court assessing the scientific validity of such information should be alert to the policy component that may bias it. This is not to argue that the policy component has no legitimacy; it is simply to stress that a court's decisions about the validity of evidence need to account for it. Without this precaution,

66. *Id.*
67. *Id.* at 159 (Scalia, J., concurring).
68. *Id.* at 147-48.
70. *See id.* at 1691-93.
any effort to determine evidentiary reliability is compromised. A
court's goal should be to deal with the policy-based concerns of
environmental litigation in a conscious and well-informed way.
Designing and using Daubert factors that help identify policy based
concerns is part of that process.

F. Daubert Factors Tailored Specifically to Air Emissions Data

With respect to air emissions data in particular, neither the ACE
Rule nor its preamble recognizes that a Daubert analysis is a required
part of CAAA federal court litigation. The closest the Rule
approaches this is a brief comment in the preamble: "Of course, in
judicial enforcement proceedings, what evidence is credible and
admissible will be determined by the court taking into account how
the evidence was gathered and the specifics of the emissions
standard and any associated reference method."71 The terms in this
passage suggest reliability ("how the evidence was gathered"... "specifics of the... standard... or method"). However, earlier in
the preamble, the EPA notes, "It should be emphasized that the
determination that evidence or information is credible is merely a
threshold determination that the evidence or information in question
is technically relevant, and therefore, legally admissible in an
enforcement action."72 Certainly a determination of relevance is
required under FRE 702. However, as Daubert teaches,
determination of evidentiary reliability through an assessment of
scientific validity is a court's initial task.73

Of all the literature reviewed on the ACE Rule, only one article
recognizes this requirement,74 and even this article did not
acknowledge that the process of developing and applying Daubert
factors for application to CAAA evidence will necessarily help define
what "credible evidence" means. So although it appears to have
been unrecognized, the question of what factors the court devises
becomes quite crucial to the interpretation of the ACE Rule.

72. Id. at 8317-18.
73. See 509 U.S. at 592-93.
74. See Peter Hsiao, American Law Institute-American Bar Association Continuing Legal
Education, New Developments and Trends in Clean Air Act Litigation and Enforcement, SABA ALI-
ABA, 403, 422 (1996).
IV. Daubert Factors for ACE Rule Opinion Testimony

This paper now explores what these Daubert factors should be and attempts to keep the focus on how the data was reached, not the data itself. This article will try, by analogy, to adhere to Daubert’s requirement that the analysis be based on the expert’s reasoning process, not on his conclusions.\textsuperscript{75} It also attempts to maintain objectivity as stringently as possible.

A. Relating the “Guideposts” to Air Emissions Technology and Measurement

The premise of this effort is that the validity of the process, which produces the data, guarantees the validity of the result. Hence, the factors must be applied to both the technology used for producing the data (sampling, monitoring, testing, etc.) and the methods used to assess it (calculations, statistical analysis, etc.) - i.e., the methods used for drawing the expert’s conclusions or inferences. For convenience, throughout the rest of this paper the former category will be referred to as “technology” and the latter as “method.” The goal is to identify factors that will determine whether both technology and method are applied in an objective way.

The point of departure for devising factors for validation is the “guideposts” alluded to earlier,\textsuperscript{76} which Black, Ayala, and Saffran-Brinks suggest as indicators of the validity of a scientific hypothesis. It is reasonable to assume that these guideposts apply to the science that underlies emissions monitoring technologies and methods.\textsuperscript{77} This section attempts, by analogy, to move from the validation of a hypothesis to the validation of applied science: the monitoring technologies and assessment methods. By making a logical extension from each guidepost, we can devise factors that help determine if the underlying science has been applied correctly. Just as Daubert was an attempt to eliminate “junk science” from the courtroom, the discussion below is an effort to find tools to eliminate “junk technology” and “junk methodology.”

The nine guideposts are presented below; each is followed by a paraphrase of Black, Ayala, and Saffran-Brinks’s explanatory commentary. Beneath each, in italics, are suggested factors — the

\textsuperscript{75} See 509 U.S. at 595.
\textsuperscript{76} See supra text accompanying note 8.
\textsuperscript{77} Gas physics, electromechanical theory, and statistical analysis are the kind of long-established “underlying science” referred to here.
factors that guideposts suggest for validating monitoring technology or assessment methods. Just as Black cautions that their guideposts should not be used as a checklist,\textsuperscript{78} likewise the suggested factors developed here are non-exclusive and should not be taken as limiting. Doubtless more could be identified. But any suggested factor for evaluating CAA technologies and methods should meet three criteria: it should have a logical relationship to the validation process; it should relate to how the data is determined, not merely to the data itself; and it should be more than a mere surrogate (that is, it should not be a substitute for a court’s own analysis of the technology and method that produce the data).

B. The “Guideposts” and the Factors They Support

1. Falsifiability of the hypothesis:\textsuperscript{79}

A hypothesis is “falsifiable” if it can be subjected to a testing regime with the capacity to show the hypothesis is false, if that should be the case. Thus, the hypothesis must have a logical form that allows it to be subjected to empirical testing.\textsuperscript{80} Along with testing, the Daubert Court listed falsifiability as its first factor.\textsuperscript{81}

\textit{Suggested factors:}

\begin{itemize}
  \item[(a)] In the case of a technology, has it been subjected to rigorous testing by someone with the pertinent expertise to test it objectively?
  \item[(b)] In the case of a data assessment method, has it been demonstrated to be appropriate to the data by individuals with the pertinent expertise, who can recommend it objectively and independently?
\end{itemize}

2. Explanatory power of the hypothesis:\textsuperscript{82}

A valid hypothesis explains and clarifies relationships between phenomena, not merely describes them.

\textsuperscript{78} See Black, supra note 8, at 782.
\textsuperscript{79} Id. at 783.
\textsuperscript{80} See id.
\textsuperscript{81} See 509 U.S. at 593.
\textsuperscript{82} Black, supra note 8, at 783.
Suggested factor:

(a) Is there a logical relationship between the underlying theory and the technology or method that purportedly applies it? Valid scientific theory cannot be used to support invalid applications. A valid connection must be demonstrated between the theory and its application.

The hypothesis provides a plausible mechanism to explain the phenomenon in question.\(^{83}\)

Suggested factor:

(b) Is the technology's mechanism consistent with the theory it is based on? (Example: continuous emissions monitors measure opacity using reflected beams of light, consistent with laws of physics and optics).

The hypothesis is predictive as well as descriptive,\(^{84}\) this reflects the common sense observation that a simple and direct predictive explanation is the one most likely to be correct.\(^{85}\)

Suggested factor:

(c) Can the technology or method used for one type of emissions parameter be successfully applied (with only reasonable modification) to use with another? (Example: can a given method of sampling/analyzing one airborne chemical be applied (with only reasonable modification) for use in sampling/analyzing another?)

3. The hypothesis must have logical consistency.\(^{86}\)

The hypothesis cannot be self-contradictory; if so, it cannot be tested empirically.

Suggested factor:

(a) The technology or method has not been applied in such a way as to manipulate the data to demonstrate inconsistent or contradictory results.

\(^{83}\) See id.
\(^{84}\) See id.
\(^{85}\) See id.
\(^{86}\) Id.
4. Scope of testing of the hypothesis:  

A "good" test for a hypothesis is one that yields useful information about the hypothesis and its limits. The more "severe" and the more "diverse" the experiments are that fail to falsify the hypothesis, the more likely it is to be valid, and therefore reliable. The more varied and diverse the tests are, the more likely they are to shed new light on the hypothesis and its limits.

Suggested factors:

(a) In the case of a monitoring technology, has it been subjected to testing that will duplicate the full range, and even push the outside limits, of the conditions under which it will be used? If such testing has been done, to what degree of reliability have the results been determined, and within what range of conditions?

(b) In the case of a data assessment method, have limits beyond which the method does not apply been identified?

5. Consistency of the hypothesis with accepted theories:

Abandonment of a previously accepted theory "requires a clear alternative explanation and adequate empirical support." Black, Ayala, and Saffran-Brinks suggest that this evokes the Frye test, but note that the Daubert Court did retain "acceptance" as a factor to be considered in assessing science.

Suggested factor:

(a) If a facility abandons use of one technology or method for another, is its decision justifiable on grounds of improving accuracy in data generation and evaluation, or are other factors involved?

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87. Id.
88. See id. at 783-784.
89. "Severity refers to the likelihood that a test will have an outcome incompatible with a hypothesis if the hypothesis is false." Id. at 763.
90. "Diverse" refers to the variety of tests to which the hypothesis is subjected. See id. at 762.
91. See id.
92. Id. at 784.
93. Id.
94. See id.
6. Subsequent application and use of the hypothesis by the scientific community.\textsuperscript{95}

The more consistent a theory is with accepted theories, the more likely it is to be accepted by the scientific community. This is actually similar to the \textit{Frye} general acceptance test; and if misapplied, it would be a surrogate.

\textbf{Suggested factors:}

(a) Correctly applied, the notion of consistency supports healthy skepticism by a court. This suggests a corresponding factor for determining validity:

Does a record exist indicating why the EPA or the facility has adopted a given technology or method? Can adoption of the technology/method be justified solely on grounds of scientific accuracy and completeness of the data it will produce? If other factors were involved, what were they, and to what extent did they influence the decision?

7. Level of precision of the hypothetical statement.\textsuperscript{96}

Precise hypothetical statements are easier to correlate and have more predictive power than broad statements.\textsuperscript{97} They also are more amenable to severe and varied empirical testing.\textsuperscript{98}

\textbf{Suggested factors:}

(a) Are points identified in the data generation (technology) and data evaluation (method) processes where error may be introduced? Have they been addressed?

(b) Is the technology’s equipment maintained and calibrated with the appropriate procedures and frequency, and according to objective and independent standards?

(c) Is the sampling/measurement regime representative of the full range of operating conditions the facility experiences?

(d) If samples must undergo laboratory testing, are appropriate laboratory validation techniques in place?

\textsuperscript{95. Id.}\textsuperscript{96. Id.}\textsuperscript{97. See id.}\textsuperscript{98. See id.}
8. Post-hypothesis testing: 99

An untested hypothesis is no more than mere speculation, regardless of how many phenomena it accounts for. If the hypothesis has not been subjected to adequate experimental testing, it cannot be shown to have any level of validity.

**Suggested factors:**

(a) This guidepost suggests that a court apply skepticism when a party introduces a novel technology or method, and that a court demand a rigorous demonstration that it is based on valid underlying science, applied in a valid way. The case of novel technology or method only strengthens the need for a court to use both Black, Ayala, and Saffran-Brinks's guideposts and the suggested factors for technology- and method-validation given here.

9. Degree to which the hypothesis has been subjected to peer review and publication: 100

If a hypothesis and the experiments used to test it have not been subjected to peer review by individuals with appropriate expertise, the hypothesis should be viewed skeptically. 101

The *Daubert* Court listed peer review as one of its factors. 102 However, it could easily be used by a court as a surrogate for its own examination of validity, and as such it resembles the *Frye* general acceptance test. With respect to a hypothesis, peer review serves as a prompt for skepticism. However, it should be looked at more flexibly in the context of applied science. *Expert Evidence* notes that in some situations, internal review procedures may be used instead of submitting work to a journal, and that in areas of applied science, peer review may not be appropriate. 103 For example, a report on a facility's internal audit of the efficiency of its pollution control devices could be scientifically valid but would not be published in a scientific journal. *Expert Evidence* further suggests that a court that deals with applied science “should be particularly attentive to factors like general acceptance, potential sources of error, and the plausibility of any assumptions. The expert’s report should explain

99. *Id.* at 785.
100. *Id.*
101. *See id.*
102. *See Daubert,* 509 U.S. at 593.
the reasoning used to reach conclusions, and his reasoning should be appropriate.”

Suggested factors:

The suggestions given in the entry above are exactly what this paper attempts to identify, expand upon, and give content to in the context of environmental compliance. Two additional factors present themselves:

(a) In the context of environmental compliance, it is especially important for a court to examine the standard technologies or methods used, including any EPA standard technologies or methods.

(b) Whatever technology or method used, a court needs to determine if it has a purely scientific basis. As noted, the EPA’s underlying standards frequently incorporate non-scientific, policy-based elements. Industry may also have incorporated non-science rationales into its technology or methods. In either case, Daubert’s requirement that scientific validation be applied to scientific evidence to establish evidentiary reliability demands this separation of policy and science.

This paper adds a tenth guidepost to Black, Ayala, and Saffran-Brinks’s list:

10. The hypothesis must be handled (that is, discussed, analyzed, and empirically tested) objectively at all stages in its validation

Although this is implicit in the nine guideposts, it is worth stating expressly because the validation process that Daubert demands is so contrary to the conventional approach of litigation. Litigation is by nature biased; validation requires objectivity.

Suggested factors:

(a) A court must vigilantly focus its analysis on determining the scientific validity of the technology and method in question. This means that each link in the chain of reasoning used to support the application of the technology or method has to sustain the assessment for validity.

(b) A court must identify any components of the technology or method (or their underlying standards) that are based on non-science policy.

(c) A court must be alert to unsupported assertions or projections by the expert who testifies on the technology or the method.

104. Id. at 43.
105. See supra text accompanying notes 69-70.
(d) An expert testifying on the technology or method cannot deliberately ignore documents and figures that would properly deserve his attention and review.

(e) An expert cannot pick and choose selectively among purported facts, data or alternative technologies or methods without a valid reason.

A range of Daubert factors for ACE Rule opinion testimony now has been identified. The next step is to examine how effective the factors are for assessing the scientific validity of a technology or method. Part V of this paper examines a commonly used air emissions monitoring technology in detail. Part VI then illustrates the factors by applying a representative range of them to this monitoring technology.

V. AN EMISSIONS MONITORING TECHNOLOGY FOR DAUBERT ANALYSIS

This section describes the rationale for the selection of a specific air emissions monitoring technology for an analysis according to the factors discussed in Part IV.B. It then familiarizes the reader with the chosen technology’s underlying principles and application in practice.

A. Selection of A Monitoring Technology


Method 9 was chosen for several reasons. First, Method 9 is used specifically for determining compliance of major stationary


107. See id.

108. ENVIRONMENTAL MONITORING SYSTEMS LABORATORY, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, EPA-600/4-77-027b, QUALITY ASSURANCE HANDBOOK FOR AIR POLLUTION MEASUREMENT SYSTEMS: VOLUME III. STATIONARY SOURCE SPECIFIC METHODS, ADDITION § 3.12 (1984) [hereinafter QUALITY ASSURANCE HANDBOOK].
sources. Therefore, it is a potential source of evidence subject to the ACE Rule. Secondly, Method 9 is a designated reference method. As noted earlier, the ACE Rule requires that any non-reference test data be comparable to reference test method data. Method 9 provides typical reference test data. Third, it has been in continuous use by the Agency and its designated state implementing authorities since the 1970s. Decades of use indicate general acceptance of the method’s validity. Fourth, while it applies scientific principles, Method 9 is not technically elaborate. Its simplicity demonstrates the factors very concretely. Finally, certain elements of Method 9 prompt skepticism that it is truly “scientific.” This aspect of Method 9 makes it an excellent candidate for examining how the factors can be used to evaluate the purported scientific validity of a technology.

B. Method 9: Underlying Principles

Method 9 is based on two underlying principles. The first is that there is a direct correlation between the density, or opacity, of visible emissions and the presence of non-visible emissions. The second is that this correlation can be mathematically - and therefore objectively – quantified in the form of percent opacity.

1. Emissions Plume Opacity

Major stationary sources commonly release both visible and non-visible emissions into the atmosphere. Emissions may be released from one or a few tall chimneys, as at a utility, or from numerous smaller stacks, as at a manufacturing facility. A familiar example is the “plume” from a coal-fired power plant, which is the visible portion of the plant’s emissions due mainly to particulates that result from incomplete combustion. The less efficient the combustion process, and/or the less effective the plant’s emissions controls, the

109. See Method 9, supra note 106, § 1.2.
110. See supra text accompanying notes 20-27.
111. See Method 9, supra note 106, § 4 (citing MELVIN I. WEISBURD, FIELD OPERATIONS AND ENFORCEMENT MANUAL FOR AIR, 4.1-4.36 (1972) (U.S. Environmental Protection Agency, Research Triangle Park, N.C., APTD-1100)).
112. See infra text accompanying notes 159-65.
113. Telephone Interview with Patrick Haines, Environmental Specialist II, Ohio Environmental Protection Agency, Division of Air Pollution Control Emissions Monitoring and Testing Unit (March 12, 1999). Mr. Haines organizes Ohio EPA’s Method 9 training and certification program and is the person in Ohio EPA most familiar with the method.
more dense the plume appears. Because combustion inefficiency and emissions controls ineffectiveness directly correlate with non-visible emissions, such as nitrogen oxides (NOx) and sulfur dioxide (SO2), plume density may be used as a general indicator of non-visible emissions. This direct correlation has made plume density, or "opacity," a conventional measure of emissions compliance since the Clean Air Act's inception.

Despite this correlation, the EPA and its state designates consider opacity readings insufficient to indicate specific levels of particulate or non-visible emissions. This is because opacity readings are influenced by numerous factors, including particle color, particle density, particle refractive index, and particle size distribution. Hence, opacity readings are not used to determine violations of other emissions standards. Rather, percent opacity is an emissions standard in its own right, with which the facility must comply. For example, twenty percent opacity is a typical limit for emissions from an electric utility.

2. Percent Opacity

More formally, plume opacity is defined as "the degree to which the transmission of light is reduced or the degree to which visibility of a background as viewed through the diameter of a plume is reduced." In the context of optics physics, plume opacity may be reduced to mathematical terms: given that \( I_0 \) is the incident light flux and \( I \) is the light flux leaving the plume along the same light path, then "opacity is dependent upon transmittance \( (I/I_0) \) through the plume."

Opacity may then be defined in terms of "percent opacity":

\[
\text{Percent opacity} = (1-I/I_0) \times 100.
\]

Percent opacity is thus the percent reduction in transmission of light, or percent reduction of visibility of the background, as viewed

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114. See id.
115. See U.S. GENERAL ACCOUNTING OFFICE, supra note 9.
117. See id.
118. See Interview with Patrick Haines, supra note 113.
119. QUALITY ASSURANCE HANDBOOK, supra note 108, § 3.12.1.1.
120. Id.
121. Id.
through the diameter of the plume. Method 9 is a procedure for determining percent plume opacity from a stationary source, using direct observation by a trained observer.

C. Method 9: Application

The following discussion familiarizes the reader with how Method 9 is applied in the field. It describes the procedures for reading opacity, recording and reducing data, the EPA’s training and certification procedure, and specifications for the equipment used in training certified observers. It also summarizes variables and sources of error inherent in the method, as well as levels of accuracy that can be achieved with it.

1. Procedure

An observer stands at a sufficient distance from the stack or chimney to have a clear view of the plume. The recommended distance is between three stack heights, as though the height of the stack were laid end-to-end on the ground three times, and a quarter mile from the base of the stack. The observer must stand with the sun behind him, and the sun must be within a sector of 140 degrees to the center of the observer’s back. Insofar as possible, the observer maintains a position that keeps his line of vision perpendicular to the plume’s direction.

If the plume is from a rectangular outlet, the observer must, consistent with the above requirements, keep his line of vision “approximately perpendicular to the longer axis of the outlet.” When more than one stack is involved, the “line of sight should not include more than one plume at a time.”

The observer takes his observations “at the point of greatest opacity” in the plume; however, he must not take it from a portion of the plume where water vapor is present. Water vapor should be readily distinguishable to the trained observer. The observer is

122. See id.
123. See Method 9, supra note 106, Introduction.
124. See Method 9, supra note 106, § 2.1.
125. See QUALITY ASSURANCE HANDBOOK, supra note 108, § 3.12.4.3.
126. See Method 9, supra note 106, § 2.1.
127. See id.
128. Id.
129. Id.
130. See Method 9, supra note 106, § 2.3.
131. See QUALITY ASSURANCE HANDBOOK, supra note 108, § 3.12.4.4.8.
not permitted to look at the plume continuously, but instead must view it "momentarily at 15-second intervals."  

2. Recording and Reducing the Data

An observer is expected to be able to make opacity determinations to the nearest 5 percent and must note his observations at 15-second intervals on a record sheet. Each "momentary observation" is considered to represent the average opacity of the plume over a 15-second period.

An observer bases the record on "sets" of observations. The observer may base the record on any number of sets of observations, but each set must be composed of a minimum of twenty-four consecutive observations made at 15-second intervals. The sets may not overlap, but they do not need to be chronologically consecutive.

The observer averages each set of twenty-four observations by summing the percent opacities of the twenty-four observations and dividing the sum by twenty-four. The EPA provides a model record sheet that accommodates ten averages, but neither the model form nor the language of Method 9 give any indication of what number of "averaged sets" is desirable.

3. Training and Certification

Method 9 requires an observer to be trained and certified to make emissions opacity readings according to its procedures. To qualify for certification, a candidate views a run of fifty plumes emitted by a smoke generator. Although all the runs within a given set of twenty-five are either all black or all white, their opacity is randomized. The candidate is scored after a total run of fifty plumes. A candidate who does not qualify may retest, but must
view a complete run of fifty readings. A candidate may receive training and/or preliminary runs of the smoke generator to familiarize themselves with gradations of opacity.

A candidate is certified as a qualified observer when he is able to determine opacity readings in 5 percent increments for twenty-five different black plumes and twenty-five different white plumes. An observer’s level of error may not exceed 15 percent opacity on any one reading, and his average level of error may not exceed 7.5 percent opacity in each category. Certification is valid only for a period of six months; to retain certification, the observer must repeat the qualification procedure.

4. Equipment Specification and Calibration

The smoke generator used for training and certification of compliance observers is constructed according to design and performance specifications that allow its output opacity to be measured and the generator to be calibrated. Its basic components are generator units for black and white smoke, fan and stack chimneys, and a control panel and strip chart recorder. Output opacity is measured with a transmissometer, a device that reads transmission of light through the plume. The smoke generator must produce smoke of opacities ranging from 0 to 100 percent. The EPA recommends, but does not require, that the machine be able to achieve and hold opacities in 5 percent increments at plus/minus 2 percent for a minimum of 5 seconds. Detailed calibration instructions for the smoke generator and its ancillary equipment are provided in the Code of Federal Regulations and EPA’s Quality Assurance Handbook.

144. See id.
145. See id. § 3.2.
146. See id. § 3.1.
147. See id.
148. See id. § 3.3.
149. See QUALITY ASSURANCE HANDBOOK, supra note 108, § 3.12.1.2.4.
150. See id.
151. See id.
152. See id.
153. See Method 9, supra note 106, §§ 3.3.1-3.3.2.7.
154. See QUALITY ASSURANCE HANDBOOK, supra note 108 § 3.12.1.2.5.
5. Uncontrollable Variables and Sources of Error Recognized by the EPA

In addition to the emissions-specific variables cited in section B.1, the EPA has identified variables which are uncontrollable during field operations and which may significantly affect the appearance of the plume and the observer's ability to rate its opacity. These include how brightly the sun is shining on the plume, "luminescence", and the color contrast between the plume and the background against which it is viewed. According to the EPA, field studies show that a plume is most visible and also "presents the greatest apparent opacity" when it is "viewed against a contrasting background." The EPA's field trials have determined that observers rate plume opacity most accurately when a contrasting background is present.

a) Sources of Positive Observational Error

A bright cloudless afternoon therefore logically suggests itself as perfect for plume viewing. However, the EPA notes that when a plume is viewed under these seemingly ideal conditions, there is the greatest potential for "positive error." A positive error, or "positive bias", increases the likelihood that the observer will incorrectly cite a facility operator for an emissions violation as a result of an observational error.

b) Sources of Negative Observational Error

Likewise, the apparent opacity of a plume diminishes as color contrast and luminescence decrease. As color contrast and luminescence approach zero, apparent opacity approaches zero. A white or gray plume viewed on a gray November day will be difficult to assess, and as dusk approaches will become even more problematic. The EPA notes that as conditions become less contrasting, the observer tends to make negative errors.

\[ \text{References:} \]

155. See Method 9, supra note 106, Introduction.
156. See id.
157. Id.
158. See id.
159. See id.
160. See id.
161. See id.
162. See id.
163. See id.
negative bias decreases the likelihood that the facility will be cited for an opacity violation as a result of observer error.\textsuperscript{164}

6. \textit{Uncontrollable Variables and Sources of Error Not Discussed by the EPA}

The greatest unacknowledged variable and potential source of error in Method 9 is its most crucial piece of equipment - the human eye. It strains credulity to assert that scientifically valid evidence can be obtained from observations made by individuals with "calibrated eyes". The EPA barely acknowledges this, saying, "In practice, the evaluation of opacity by the human eye is a complex phenomenon and is not completely understood".\textsuperscript{165} Therefore, it is important to understand the level of accuracy obtainable with the method.

7. \textit{Obtainable Levels of Accuracy}

The EPA discusses unspecified studies evaluating the magnitude of positive errors that qualified observers may make under contrasting conditions.\textsuperscript{166} The studies were based on field trials in which 769 sets of twenty-five readings each were assessed.\textsuperscript{167} Black and white plumes were each observed.\textsuperscript{168}

Recall that "positive error" increases the likelihood that the observer will mistakenly note a violation.\textsuperscript{169} For any set, the positive error was determined as equal to:

\[
\text{positive error} = \text{(average opacity obtained from the observer's twenty-five observations) - (average opacity obtained from the twenty-five recordings made by the generator's transmissometer).}
\]

In the case of black plumes, sets produced by a smoke detector were observed while its output was measured by the generator's transmissometer.\textsuperscript{170} Of the 133 sets observed, 100 percent of the sets were read with a positive error of less than 7.5 percent opacity\textsuperscript{172} and

\begin{itemize}
  \item \textsuperscript{164} See id.
  \item \textsuperscript{165} QUALITY ASSURANCE HANDBOOK, supra note 108, § 3.12.1.1.
  \item \textsuperscript{166} See Method 9, supra note 106, Introduction.
  \item \textsuperscript{167} See id.
  \item \textsuperscript{168} See id.
  \item \textsuperscript{169} See id.; see also supra text accompanying notes 159-60.
  \item \textsuperscript{170} Method 9, supra note 106, Introduction.
  \item \textsuperscript{171} See id.
  \item \textsuperscript{172} See id.
\end{itemize}
99 percent were read with a positive error of less than 5 percent opacity.\textsuperscript{173}

In the case of white plumes, the sources varied: 168 sets were observed at a coal-fired power plant, 170 sets were observed at a smoke generator, and 298 sets were observed at a sulfuric acid plant.\textsuperscript{174} For white plumes, 99 percent of the sets were read with a positive error of less than 7.5 percent opacity, while 95 percent were read with a positive error of less than 5 percent.\textsuperscript{175}

The EPA cautions observers that valid observations can only be conducted when the sun is “positioned at the observer’s back.”\textsuperscript{176} The observer’s failure to do this can result in “significant positive bias,” a consequence of forward light scatter.\textsuperscript{177} The Agency stresses that its studies show that when “improper sun angle” is eliminated, “observation biases [instead] tend to be negative.”\textsuperscript{178}

Recall that “negative bias” results in a decrease in the likelihood that the facility will be cited for an opacity violation as a result of the observer’s error.\textsuperscript{179} Consequently, as long as the observer keeps himself correctly positioned to the sun and eliminates positive bias, a reading that indicates a violation can be regarded as the minimum opacity required to trigger a violation.\textsuperscript{180} The plume is at least dense enough to be in violation, and may be even more so. Thus, the documentation of the violation is valid.\textsuperscript{181} For example, if a power plant’s emissions are required not to exceed 20 percent opacity and the observer reads 30 percent, the reading is arguably at least 30 percent, and likely higher.

VI. A DAUBERT ANALYSIS OF METHOD 9

This section illustrates how the Daubert factors developed in Part IV can be applied to Method 9. Because Method 9 generates data rather than evaluates it, Method 9 falls into the category this paper refers to as technology.\textsuperscript{182} The factors proposed in Part IV. B. have been examined. Of these, fourteen have been identified as cogent to

\textsuperscript{173} See id.
\textsuperscript{174} See id.
\textsuperscript{175} See id.
\textsuperscript{176} QUALITY ASSURANCE HANDBOOK, supra note 108, § 3.12.4.4.1.
\textsuperscript{177} See id.
\textsuperscript{178} Id.
\textsuperscript{179} See Method 9, supra note 106, Introduction; see also supra text accompanying note 163.
\textsuperscript{180} See Quality Assurance Handbook, supra note 108, § 3.12.4.4.1.
\textsuperscript{181} See id.
\textsuperscript{182} See supra text accompanying notes 75-76.
technologies and to Method 9. The fourteen are drawn from eight of the nine guideposts suggested by Black, and from the suggested tenth factor. In theory, these factors should allow a well-rounded assessment of Method 9's scientific validity. As before, each factor is presented in italics. A brief discussion then illustrates how a court could apply it to Method 9. Because no specific data is available, a thorough assessment of Method 9 is not possible. The method is used simply to illustrate application of the proposed factors. A discussion of the results of this application concludes this section.

Factor (1)(a)

In the case of a technology, has it been subjected to rigorous testing by someone with the pertinent expertise to test it objectively?

It appears from the studies cited by the EPA that Method 9 has been subjected to testing sufficient to determine sources of error, whether the source of error leads to positive or negative bias, and the degrees of bias within which the method can be expected to give an acceptable result. A court's task would be to examine these studies to verify these claims. A court would also examine the citations as the end of Method 9, and the list of seventeen references provided in the EPA's Quality Assurance Handbook. In applying this factor, a court would select those studies and references that document testing of Method 9 and evaluate them for objectivity and sufficient expertise.

Factor (2)(a)

Is there a logical relationship between the underlying theory and the technology that purportedly applies it? Valid scientific theory cannot be used to support an invalid application. A valid connection must be demonstrated between the theory and its application.

Method 9 is based on two theories, and both require examination. The first is that the amount of particulate matter in a plume directly correlates with the amount of light the plume obscures. In essence, the theory says that the background to a plume is obscured in direct

183. The remaining factors addressed data evaluation methodology, or were otherwise inapplicable.
184. See supra Part V.C.5.-7.
185. See Method 9, supra note 106, § 4.
186. See QUALITY ASSURANCE HANDBOOK, supra note 108, § 3.12.9.
proportion to the amount of particulate in the plume. Support for
this is readily found in common observation and in optics physics.
Specifically, the EPA cites a basic physics textbook to support the
theory;\textsuperscript{187} thus, in this case, the connection between theory and
application can be readily demonstrated.

The second theory is that the human eye can be trained to read
opacity in increments and with reasonable accuracy. As noted, this
seems improbable, and the EPA acknowledges that the process is not
completely understood.\textsuperscript{188} However, the EPA’s field studies
document that opacity can be read in 5 percent increments and with
reasonable accuracy, given that the observations are made within a
recognized range of conditions.\textsuperscript{189} Given the underlying theory that
the eye can be calibrated, a logical relationship exists between the
theory and the visual observation technology of Method 9 in the
sense that the eye is trained to function as a transmissometer or
CEM. However, because the mechanics of this process are not
understood, the question remains unanswered - it is merely
descriptive, not explanatory. Until the mechanism is better
understood, it will not be possible to posit a truly logical relationship
between the theory and its application and thus, this factor’s
application is the weakest one in this analysis.

\textbf{Factor (2)(b)}

Is the technology’s mechanism consistent with the theory it is based on?

To a certain extent, Factor (2)(b) mirrors Factor (2)(a). But as an
illustration of “consistency of mechanism with theory”, Method 9
successfully applies principles of optics and physics to measure
opacity by exploiting the behavior of light and the reflective,
refractive, and optically absorptive qualities of particulates.

\textbf{Factor (2)(c)}

Can the technology used for one type of emissions parameter be successfully
applied (with only reasonable modification) to use with another?

While Method 9 is generally limited to emissions from major
stationary sources, the EPA states it is possible to adapt Method 9

\textsuperscript{187} See Method 9, supra note 106, § 4 (citing E.U. CONDON & H. ODISHAW,
HANDBOOK OF PHYSICS (1958)).

\textsuperscript{188} See supra text accompanying note 165.

\textsuperscript{189} See supra Part V.C.7.
with minor modifications to measure "fugitive emissions."¹⁹⁰ Fugitive emissions arise from sources other than conventional stacks or vents.¹⁹¹ For the court to apply Factor (2)(c) in this case, it would have to make an objective assessment of this application's effectiveness in practice, ideally evaluating available studies. Lacking the availability of such studies, a court would have to undertake extensive data collection and evaluation.

**Factor (3)(a)**

*The technology has not been applied in such a way as to manipulate the data to demonstrate inconsistent or contradictory results.*

With respect to this factor, a court would be obliged to review the specific data for the case at hand. It is theoretically possible for an observer to intentionally bias the data. However, certain features of Method 9 deter such bias. First, the instructions in the *Quality Assurance Handbook* for on-site field observations are mandatory.¹⁹² These include detailed administrative and technical procedural instructions designed to lay a proper evidentiary foundation in the event of a subsequent enforcement action.¹⁹³ Second, while the observer is under no obligation to take the measurements from a point on the facility property, other required measurements necessitate plant entry. The EPA's instructions on plant entry are mandatory and include the requirement that the observer supply the company official with a copy of the opacity readings whether they were taken on or off the site.¹⁹⁴ Third, the data recording sheet provided by the EPA makes it difficult to manipulate observation data because the sheet requires a detailed account of site conditions.¹⁹⁵ These points, along with the fact that on-site readings will almost certainly be made in the company of a facility official, act to deter an observer from "fudging" data.

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¹⁹¹ Fugitive emissions are usually produced from outdoor industrial activities such as open burning, demolition, mineral crushing and sorting, and moving raw materials under windy conditions. See *id.*
¹⁹² See *Quality Assurance Handbook*, *supra* note 108, § 3.12.0 (citing § 3.12.4).
¹⁹³ See *id.*, § 3.12.0.
¹⁹⁴ See *id.*, § 3.12.4.2.3.
¹⁹⁵ See *id.*, § 3.12.4 fig. 4.2.
Factor (4)(a)

In the case of a monitoring technology, has it been subjected to testing that will duplicate the full range (and even push the outside limits) of the conditions under which it will be used? If such testing has been done, to what degree of reliability have the results been determined, and within what ranges of conditions?

As discussed earlier, the EPA has conducted field trials which have established the conditions within which Method 9 can reliably be used, and the degree of reliability which can be expected when they are met. The edition of Method 9 in the Code of Federal Regulations addresses the major limiting conditions succinctly. However, the mandatory section of the Agency’s Quality Assurance Handbook identifies additional conditions, addresses them in much greater detail, and whenever possible provides instructions to correct for any associated error. The EPA has clearly established the range of conditions under which Method 9 can be reliably used, and a court would take this into account in evaluating the data.

Factor (5)(a)

If a facility abandons use of one technology for another, is its decision justifiable on grounds of improving accuracy in data generation, or are other factors involved?

A court may use this factor when an allegedly violating facility attempts to introduce competing evidence obtained with an alternative technology. This is unlikely to be an issue with respect to Method 9, but may occur with respect to CEMs. Prior to the CAAA, the General Accounting Office (GAO) was charged with determining whether the EPA had used the most appropriate methods for detecting violations at major sources. The GAO’s report identified CEMs as providing data continuously, directly, and of an accuracy superior to that from inspections. The GAO report resulted in the CAAA’s requirement that major sources install CEMs or comparable devices as part of their compliance with Title V.

196. See supra Part V.C.7.
197. See Method 9, supra note 105, § 2.
198. See QUALITY ASSURANCE HANDBOOK, supra note 107, § 3.12.4.4.
199. See U.S. GENERAL ACCOUNTING OFFICE, supra note 9, at 1.
200. See id. at 2.
201. See Compliance Assurance Monitoring, 40 C.F.R. § 64.3(a) (1999).
The CAAA allows major sources to adopt alternative monitoring technologies and the ACE Rule allows a major source to introduce evidence other than CEM data. In applying Factor (5)(a), a court would require that the technology producing the data be at least as accurate as the one it displaced. A showing that improved accuracy was obtained with the alternative technology would enhance reliability and admissibility. Other factors, such as cost effectiveness, would not figure into the analysis.

**Factor (6)(a)**

*Does a record exist indicating why the EPA has adopted a given technology? Can adoption of the technology be justified solely on grounds of scientific accuracy and completeness of the data it will produce? If other factors were involved, what are they, and to what extent did they influence the decision?*

This factor is very much like Factor (9)(b), which directs a court to examine whether the technology is purely based on science, or whether the EPA has incorporated non-science based policies. However, Factor (6)(a) bears examination because non-policy considerations can easily play into Agency decisions. Sometimes adoption of one technology may actually be a failure to adopt a competing technology. This may result from non-policy reasons, such as intra-agency failures of communication. For example, the GAO report documents inconsistent guidance and direction by the EPA’s headquarters to its regional offices with respect to implementing use of CEMs by industries. Although the EPA had authority prior to 1990 to require industries to use CEMs, headquarters’ failure to consistently support the program undermined its implementation in Regions III and IV. This resulted in Method 9’s continued adoption by default. Given these circumstances, and that CEMs produce an essentially continuous stream of data and Method 9 is highly limited in its use, a court should fault Method 9 for reliability under this factor.

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202. See id. § 64.3.
203. See Source Surveillances, 40 C.F.R. § 52.12(c) (1999).
204. See U.S. GENERAL ACCOUNTING OFFICE, supra note 9, at 28-29.
205. See id. at 13 (citing § 114 of the CAA).
206. See id. at 28-29.
Factor (7)(a)

Are points identified in the data generation process (i.e., the technology) where error may be introduced? Have they been addressed?

In the case of Method 9, this factor turns out to be very similar to Factor (4)(a), which queries whether the technology has been tested to determine the limits under which it can be reliably used.\textsuperscript{207} As noted, the EPA’s Quality Assurance Handbook identifies points in the method where error may be introduced, and addresses them wherever possible with instructions to correct for them.\textsuperscript{208} A court should note this feature of the method in weighing the reliability of the data it generates.

Factor (7)(b)

Is the technology’s equipment maintained and calibrated with the appropriate procedures and frequency, and according to objective and independent standards?

Method 9’s equipment is the observer’s trained eyes. The observer may also use non-mandatory equipment – a rangefinder, clinometer for determining the vertical viewing angle, and binoculars - to improve the quality of his observations.\textsuperscript{209} A court should apply this factor to the specific observer and the equipment he used in the case at hand. The Quality Assurance Handbook provides instructions for maintenance and calibration of the non-mandatory equipment.\textsuperscript{210} With respect to applying this factor to the observer’s eyes, a court should look at the observer’s certification. Certification or six-month renewal is documented by a letter of certification and a copy of the qualification form.\textsuperscript{211} The training facility retains the original of the qualification form for at least three years, in the event of any subsequent legal proceeding.\textsuperscript{212} The Agency recommends, but does not require, that the training facility maintain a bound logbook of training sessions for at least three years as evidence that the observer has been certified by a recognized smoke training and certification group.\textsuperscript{213} A court should certainly

\textsuperscript{207} See supra text accompanying notes 87-91.
\textsuperscript{208} See QUALITY ASSURANCE HANDBOOK, supra note 108, § 3.12.4.4.
\textsuperscript{209} See id. § 3.12.2.
\textsuperscript{210} See id.
\textsuperscript{211} See id. § 3.12.1.3.
\textsuperscript{212} See id.
\textsuperscript{213} See id.
review these materials in applying this factor to determine the validity of the observations.

*Factor (7)(c)*

*Is the sampling/measurement regime representative of the full range of operating conditions the facility experiences?*

Method 9 can only be used under a restricted set of conditions. Due to these limitations, it cannot be used to obtain data throughout the range of variation a major source may experience through the course of a 24-hour day or four seasons. However, Factor (7)(c) may not be applicable, depending on the government’s case.

If the Agency is simply trying to prove one or more violations of the facility’s opacity standard, then this factor is not relevant. The Agency’s case is that the facility violated its opacity standard for the requisite amount of time, for whatever number of times it was observed. All the Agency needs to do is to demonstrate that Method 9 was applied within the limits of its reliability over the periods in which the government asserts the source violated. Method 9 is insufficient if the government’s case is that the facility was in continuous noncompliance for a given period. While observations are not limited by the conditions the facility experiences, the observations are restricted by the conditions in which Method 9 is reliable.

*Factor (9)(a)*

*In the context of environmental compliance, it is especially important for a court to examine the standard methods used, including any EPA standard methods.*

Recall that Factor (9)(a) is derived from Black, Ayala, and Saffran-Brinks’s ninth principle of scientific validity - the degree to which the hypothesis has been subjected to peer review and publication.²¹⁴ While this principle should not be used as a surrogate by a court, *Expert Evidence* suggests that when a court deals with applied science, a court should give special attention to “general acceptance, potential sources of error, and the plausibility of any assump-

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²¹⁴. See *supra* text accompanying notes 100-101.
tions."^{215} Likewise, the expert’s report should explain his reasoning, and this reasoning should make sense.^{216}

This principle of validity supports Factor (9)(a). Factor (9)(a) is important in the context of the CAA because Method 9 is a reference method^{217} and the EPA expects reference methods to function as "benchmarks" for non-reference methods.^{218}

In applying Factor (9)(a) to a reference method, a court will be examining its general acceptance, the potential sources of error, and the plausibility of its assumptions. In examining Method 9, a court will find general acceptance documented by the reference materials in the Code of Federal Regulations^{219} and the EPA’s Quality Assurance Handbook.^{220} A court will identify the potential sources of error, which have been discussed previously,^{221} and it will accept as underlying assumptions the principles of physics and optics that support the concept of percent opacity.^{222} A court may struggle with the "not completely understood" mechanism of visual observation,^{223} but the observer’s expert testimony will likely be considered valid, hence reliable, if the observer’s field report thoroughly documents the observations and shows they were made under conditions within limits set by the sources of positive and negative error. The report will adequately explain the observer’s conclusion of a violation.

Further, the observer’s testimony would be considered reliable under Kumho Tire. Kumho Tire affirms Daubert’s position that the court’s "gatekeeping" function is not limited to "scientific" knowledge,^{224} and that the court may admit expert testimony on the "assumption that the expert’s opinion will have a reliable basis in the knowledge and experience of his discipline."^{225} Kumho Tire will support the admission of expert testimony, given a showing by the observer of sufficient training and expertise.^{226}

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215. Black, supra note 8, at 785.
216. See id.
217. See Method 9, supra note 106, Introduction.
218. See supra text accompanying note 26.
220. See QUALITY ASSURANCE HANDBOOK, supra note 108, § 3.12.9.0.
221. See supra Part V.C.5.
222. See supra Part V.B.2.
223. See QUALITY ASSURANCE HANDBOOK, supra note 108, § 3.12.1.1.
224. See Kumho Tire, 526 U.S. at 147-49.
225. Id. at 148 (citing Daubert, 509 U.S. at 592).
226. See id.
Factor (9)(b)

Does the technology have a purely scientific basis, or does it incorporate non-scientific, policy-based rationales?

The EPA’s adoption of CEM technology illustrates this factor. As noted in the discussion under Factor (5)(a), the CAAA requires major sources to install CEMs or comparable equipment as part of their Title V compliance.227 Here, the Agency forced facilities to adopt another technology partly on the basis of superior reliability.228 The change also resulted from a change in Agency policy to a more aggressive enforcement position - a non-science based reason. In this instance, the EPA’s change in policy did not compromise the reliability of the new technology. Instead, the policy change supports enhanced, uncompromised reliability.

From this it can be seen that Factor (9)(b) is really a two-pronged test for reliability. A court must ask:

1. Does the technology have a scientific basis? This is a threshold question. If it does not, then the technology’s reliability is immediately questionable under Factor (2)(a).

2. Even if the technology has a scientific basis, does it incorporate non-scientific, policy-based rationales? Here a court would need to examine Agency records, if any, which indicate why the EPA adopted the method.

As illustrated above, adoption of CEMs would readily pass scrutiny under both questions. The science of CEMs is sound and the policy behind their adoption encourages reliability.

Had a court examined the use of Method 9 under this factor prior to 1990, it would likely have come to another conclusion. While Method 9 might have passed the first prong, especially given the limited state of emissions monitoring technology at the time of the first CAA’s passage, the court would certainly have questioned the validity of the results based on the policies underlying its application. Recall that prior to 1990, the EPA notified facilities in advance of inspections, giving sources the opportunity to fine-tune control equipment beforehand.229 The EPA’s policy rationales for this were resource limitations and the press of higher priority


228. See id.

229. See supra text accompanying note 11.
activities, both non-science reasons. Had a citizens' suit been brought under the CAA for a source's chronic violations, a court applying Factor (9)(b) would have found the EPA or state data from Method 9 to fail for reliability given these policies.

*Factor (10)(a)*

*Does each link in the chain of reasoning used to support the application of the technology sustain the assessment for validity?*

Factor (10)(a) reminds a court that objectivity is the measure of validity, hence reliability. In applying Factor (10)(a) to Method 9, a court's assessment might look like this:

<table>
<thead>
<tr>
<th>&quot;Link&quot;</th>
<th>Applied Objectively?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Underlying scientific principles of Method 9.</td>
<td>Yes – the underlying principles are well-understood tenets of light and optics physics.</td>
</tr>
<tr>
<td>2. Application of principles of Method 9 in the visual observation technique.</td>
<td>Yes – although the mechanism by which the human eye measures the data is not completely understood, there is a known range of accuracy within specific conditions.</td>
</tr>
<tr>
<td>3. Application of Method 9 in the case at hand.</td>
<td>Yes – if the observer can testify that he is adequately trained, currently certified, and conducted the test within acceptable conditions. No – if the observer cannot testify that he meets these requirements.</td>
</tr>
</tbody>
</table>

4. Element of law to be proved.

| Yes - if the Method 9 observations are used to prove violations of a facility's opacity standards. |
| No - if the Method 9 observations are used to prove an emissions violation other than an opacity standard. |

In reviewing the results of this application of suggested factors to Method 9, some redundancy is apparent. Factors (2)(a) and (2)(b) conflate to a question of whether a logical link exists between an underlying theory and its application. Factors (1)(a), (4)(a), and (7)(a) and (7)(c) reach the issue of data reliability. And Factors (6)(a) and (9)(b) both attempt to identify any non-science components in the technology.

This possibility of redundancy is not necessarily a disadvantage. What may result in redundancy in the Daubert analysis of one technology or method may lead to a very different outcome in the analysis of another. Depending on the technology or method, some approaches may be more illuminating than others. A multitude of approaches gives a court more angles from which to inspect the evidence. Most importantly, the availability of many approaches may prompt a court to identify even more appropriate factors for the evidence at hand.

VII. CONCLUSION

The Clean Air Act Amendments of 1990 have expanded the enforcement exposure of major stationary sources to a level that is still not completely understood. The Any Credible Evidence Rule will figure prominently in this expansion. While the ACE Rule gives little guidance as to what constitutes credible evidence for purposes of litigation, it is clear that the EPA intends to take an expansive view. However, neither the EPA nor any of the CAAA's stakeholders - industry, environmental policy-setters, and the portion of the public that articulates its concern for clean air via citizens suits - have recognized that Daubert requires the threshold test for any proffered evidence to be a demonstration of its scientific validity.

This paper shows that Daubert factors can be specifically designed to assess environmental compliance technologies and
methods. Further, this paper illustrates the successful application of these factors to an emissions monitoring technology, illuminating the technology's strengths and limitations. The factors achieve this by focusing on how the data is obtained and how sources of error and non-science considerations may influence the data. In keeping this focus, the factors remain true to Daubert's charge that a court must determine the reliability of the expert's reasoning before it can admit the expert's result.

Counsel for major stationary sources can take the first step to protect their clients by mastering the concepts of scientific validity. Counsel can use this understanding to develop Daubert factors to assess facility compliance and identify areas that can be corrected well in advance of the threat of enforcement. By working though this process proactively, counsel will be prepared to control the definition of issues early in any litigation that does occur.