The *Daubert* Standard

As Applied to Exposure Assessment Modeling Using the Two-Zone (NF/FF) Model Estimation of Indoor Breathing Zone Concentration as an Example

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Background

The *Daubert* standard governs the admissibility of expert witness testimony during all U.S. federal legal proceedings and over half of state proceedings. It allows for the legal challenge of any expert witness testimony. In essence, the expert scientific witness has the burden of proof relative to the validity and acceptability of his or her scientific conclusions. An example of a potential Daubert challenge for exposure assessors or industrial hygienists exists in the use of first principle physical-chemical models of human exposure. We present the relevant details of *Daubert* in the context of an industrial hygienist providing testimony based on these types of models. As an example, we present the *Daubert* criteria to address a potential challenge for the Near Field/Far Field (two-zone) indoor air model of breathing zone concentration.

Introduction

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993),[1] the U.S. Supreme Court held that Federal Rule of Evidence 702 applies to the admissibility of expert testimony at trial. FRE 702 states:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The Supreme Court concluded that FRE 702 requires a trier of fact to serve as the "gatekeeper." As the gatekeeper, the trier of fact must, among other things, exclude expert testimony that is not reliable. To determine whether expert testimony is reliable, a trier of fact may consider (1) whether the theory or principle used can and has been tested, (2) whether the theory or principle used has been subjected to peer review and is generally accepted, (3) the known or expected rate of error of the theory or principle used, (4) the existence and maintenance of standards and controls concerning the operation of the theory or principle used, and (5) whether the theory or principle used is generally accepted in the relevant scientific community.

Given the gatekeeper role of the trier of fact under *Daubert*, accepted expert testimony is essentially an affirmation of the scientific and professional status

of the presenter, and there is thus a significant role for expert witnesses regarding the admissibility of their testimony. Litigation is an adversarial environment in which expert witnesses are typically compensated financially to provide scientific opinions and testimony in favor of either the plaintiff or the defendant. As a result, the other side is highly motivated to discredit these opinions. Thus, it is in the best interest of anyone considering providing expert testimony to understand and apply the relevant burden of proof criteria for their potential testimony.

In preparing the text of the affidavit for a case involving a toxic tort, legal counsel advised addressing four factors set forth in *Daubert* in an effort to show that the two-zone indoor air model (also called the near field/far field, or NF/FF, model) of breathing zone concentration was indeed reliable and met *Daubert* criteria. The case settled before the analysis of the factors and the model was accepted or rejected. However, the analysis of the NF/FF model as presented in this commentary is ready for use in future litigation or to guide analysis of other professional work in light of *Daubert* requirements. We present the model theory and discuss our methods, findings, and conclusions below following four key *Daubert* requirements:

1. Testing of the model
2. Status of peer review and acceptance
3. The technique's rate of error and standards for the model's application
4. Personal/professional experience and use of the model.

Methods

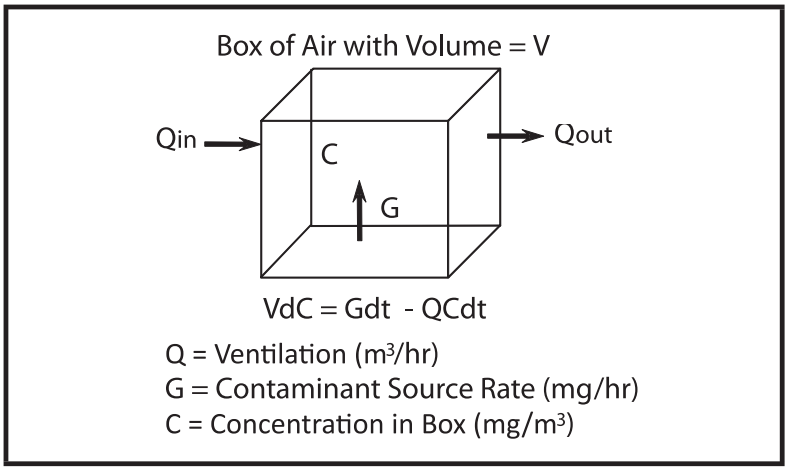
Evaluation of the Literature

Based on known publications about the two-zone model, literature searches (Scirus, Google Scholar, PubMed) and reference chaining, we identified references that will be cited and discussed in the remainder of this commentary to support our *Daubert* criteria analyses. The searches' main objective was to identify studies that used the NF/FF model to predict concentrations as well as providing measurement data under conditions suitable to evaluate the model's results.

Scientific Basis of the NF/FF Model

The two-zone model is a derivative of the simpler, well-mixed box model (WMB), so an examination of the WMB scientific principles lays groundwork for understanding the scientific principles of the two-zone model. The WMB box model is depicted in Figure 1.

Figure 1. General Well-Mixed Box Model (WMB)



The WMB model is based on first principles of science. The first principles definitions are:

- Basic, foundational propositions or assumptions that cannot be deduced from any other proposition or assumption
- Principles from which other truths can be derived
- A core set of working assumptions, hypotheses, and key beliefs.

The fundamental propositions of this model are simple, with four main conditions:

1. Mass entering and leaving the box cannot be created or destroyed.
2. The air entering the box (Q) equals the air leaving the box (Q) in any reasonable time frame, else the box would pressurize and explode or become evacuated of air.
3. The source rate of mass entering the box (G) is either constant over the time frame of interest for constant rate sources or a predictable function of time.
4. Mass within the box is all airborne—that is, there is no adsorption or deposition of the substance on the interior surfaces of the box.

These are typically valid assumptions on their face; however, as is the case with all physical processes, they are not absolute. Specifically, chemicals of interest entering the box at Rate G may not come in at an absolutely constant or predictable time-dependent rate and might undergo reactions and transformations to another chemical form while in the box, for example, via chemical reaction with the usual molecular constituents of room air or with room surfaces. Similarly, depending on the nature of the airborne contaminant entering the box, there could be some sorption of the material to the surfaces within the box; however, it has been our experience that this effect is almost invariably insignificant, particularly in large rooms with relatively low surface area-to-air volume ratios.

This deviation from stated model conditions occurs to varying extent in all physical-chemical models and leads to an important point regarding model validity; specifically, all models are more or less generalized portrayals of reality and are not perfect renditions of the real world. Few would argue with the inherent utility and validity of using models to predict the near-term weather; however, for the reasons mentioned above, these prediction are always accompanied with an acknowledged level of uncertainty.

Thus, given the acceptance of the above set of assumptions, the WMB can, within reasonable limits, accurately predict the overall spatial *average* concentration of airborne contaminant in the well-mixed box at any point in time. The average concentration is simply the total amount of material in the box at any point in time divided by the volume of the box.

It is obvious to casual but technically informed observers that the airborne concentration near an emitting source within a room is most often considerably greater than it is at farther points within the same volume. If the worker is near the source, exposure will be higher than that predicted by the average for the room. Thus, when emission sources are localized and the room is relatively large, then the *average* concentration provided by the WMB represents a significant underestimation of the concentration inhaled by persons close to the source. As such, the assumption of perfect mixing is a serious limitation of the WMB for near-field (NF) sources. In fact, this deficiency led to the development of the NF/FF model.

As best as we can determine, the original concept for the NF/FF model was first put forth by W.C.L. Hemeon in the 1950s.[2] In a treatise on general ventilation and the limitations of the WMB model, Hemeon outlined the basic concepts of the NF/FF model. In 1996, both E. Furtaw[3] and M. Nicas[4] published papers in separate journals further developing the concept. Dr. Nicas derived the dynamic concentration equations for the model and has demonstrated and promoted its utility in industrial hygiene.

The NF/FF model as it currently exists today is a first principle attempt to address the fault of the WMB described above. It does so with a conceptual construct of a smaller virtual box or volume within the general box or total room volume. The assumption is again made that the air is well mixed within this smaller (NF) volume and the larger (FF) volume and that air exchanged between the two volumes is totally dependent on the linear airflow at the interface between the two volumes. As in the WMB model the determination of airborne concentration in the NF and FF represent a straightforward, if somewhat more complicated, accounting procedure based on the conservation of mass and the other assumptions mentioned above. Since the NF is now much smaller and close to the source, the *average* concentration in the NF is much more accurate and useful for estimating the exposure potential for a person breathing the air within the NF.

A critical parameter for the NF/FF model is the size of the NF. In general, it should be large enough to include both the breathing zone of the exposed person and the emitting source. In the case of hair spray (or similar spray applications) it has been estimated to be less than 1 m^3 in volume.[5] In recent work designed to estimate exposure from an evaporating spill in a laboratory or plant, it has been set at a volume of 25 m^3—the volume of a 2 m diameter, 2 m high hemisphere centered over the spill.[6]

Table I. Comparison of Measured and Modeled Concentrations

Chemical	Type of Measurement	Measured Value (ppm)	Predicted Value (ppm)	Ratio of Predicted to Measured Values	Reference No.
n-Pentane	10-min TWA Peak	89	126	1.42	36
		283	308	1.09	
Benzene	60-min TWA	0.55	0.33	0.60	37
	60-min TWA	0.29	0.29	1.0	
	60-min TWA	0.12	0.25	2.08	
Cyclohexane[A]	60-min TWA	68	71	1.04	38
	60-min TWA	40	40	1.0	
	60-min TWA	51	37	0.73	
Benzene[B]	240-min TWA	0.10	0.16	1.6	31
	240-min TWA	0.075	0.13	1.73	
	240-min TWA	0.11	0.11	1.0	
Methanol[B]	15-min TWA	57	67	1.18	39
	15-min TWA	115	136	1.18	
Benzene[A]	15-min TWA	0.063	0.12	1.90	16
	15-min TWA	0.25	0.35	1.40	
	15-min TWA	1.38	1.77	1.28	
	15-min TWA	3.1	3.44	1.11	
	15-min TWA	0.28	0.36	1.29	
	15-min TWA	1.13	0.55	0.49	
	15-min TWA	0.094	0.23	2.45	
	15-min TWA	2.75	2.38	0.87	
	15-min TWA	0.28	0.92	3.29	
	15-min TWA	0.28	0.6	2.14	

Note: To some extent, Cherrie[19] also evaluated the NF/FF model but via independent derivation and comparison of NF and FF concentration ratios.
[A]The reported values were in mg/m^3 and converted to ppm.
[B]The predicted values were read from a figure in the published article.

Results

Testing of the Model

From the literature search, we located multiple studies where the NF/FF technique has been appropriately used and tested. The testing of the model actually involves several stages:

1. **Correctness of the mathematical derivation:** The mathematical integrity of the model has been verified by others in the peer review process of Dr. Nicas' publications in journal articles and book chapters. Note an independent derivation of the principles was also completed and published by Furtaw et al.[3]
2. **Implementation of the computations and verification of the calculations:** The computational integrity of the equations and computations in MathLab (or other symbolic mathematical program) has been verified by independent setup in Excel[7] and by others as a result of the publication in articles and book chapters.[8, 9]
3. **Testing of the model against suitable real world air concentration data:** Verification of model predictions against real world data needs to include situations for which the model's assumptions are appropriate. There are multiple peer reviewed publications that fulfill this requirement. Table I shows the chemicals that were tested, the types of near field concentration measurements that were made, the corresponding near field concentrations predicted by the NF/FF model, the ratio of the predicted value to the measured value, and the study reference number. Among the 23 paired values of the predicted and measured near field concentrations, 21 out of 23 (91%) predicted values were within a factor of 0.49- to 2.14-fold the measured concentration value. In other words, the NF/FF model prediction was usually within the approximate range of 0.5- to 2-fold the measured concentration.

Another important study reports the results of stationary point and breathing zone monitoring in a process control room with point sources of emissions.[10] The stationary point monitoring data were input to a computer mapping procedure. The mapping program had the ability to interpolate concentration values in unsampled areas, thus creating contours of equal concentration levels within the horizontal plane of the room air. That is, it was able to draw lines of equal airborne concentration (i.e., isopleths) for the compound of interest (toluene) within the room, and visually display the concentration pattern within the area of the room. The technique was able to resolve and organize five daily time-weighted average (TWA) concentration areas or bins within the room. Table II presents those data. The room layout (reprinted from the original article)[10] is shown in Figure 2.

Table II. Daily TWA Zones Found by Jones and Harris

Zone	Concentration Range
Zone 1	0.0–0.07 ppm
Zone 2	0.07–0.14 ppm
Zone 3	0.14–0.21 ppm
Zone 4	0.21–0.28 ppm
Zone 5	0.28–0.35 ppm

Note: Jones and Harris.[10]

The data were taken for 3 days, and the results for toluene are presented in Figures 2-4 of the referenced paper. Figures 3-5 (from Jones and Harris)[10] clearly show the effect of typical imperfectly mixed room air. They also show the quantitative magnitude of concentration enhancement near the source. All five of the above concentration bins were represented within the room. Thus, there were five concentration bins extant within the room, with averages between the lowest and highest varying by approximately 5-fold. Actual values reported and ranges in the figures show an even higher disparity.

The most concentrated zone/zones appears/appear to be essentially circular in cross-section around the source(s); also the diameter of this zone is relatively small within the room varying between six and 12 feet. This concentration effect is exactly what is portrayed within and described by the NF/FF model. Also, if the resolution of these experiments were better (i.e., more sampling stations zones within the room), the maximums would most likely reveal even higher exposures closer to the source. It is also interesting to note that the TWA personal breathing zone samples of the workers (who were not always stationary within the room) were statistically the same as TWA concentration calculated from the contour map values combined with the workers' work-time schedule.

Table III. Reference List from Sahmel et al.[5]

Armstrong, T.W., and C.N. Haas: Quantitative microbial risk assessment model for Legionnaires' disease: Assessment of human exposures for selected spa outbreaks. *J. Occup. Environ. Hyg. 4*:634–646 (2007).

Eickmann, U., A. Liesche, and W. Wegscheider: Harmonization and further development of models to calculate airborne contaminant concentrations at the workplace. Expositionsmodell, *Gefahrstoffe-Reinhaltung der Luft April 67(4)*:127–132 (2007).

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Nicas, M., M.J. Plisko, and J.W. Spencer: Estimating benzene exposure at a solvent parts washer. *J. Occup. Environ. Hyg. 3*:284–291 (2006).

Spencer, J.W., and M.J. Plisko: *A Comparison Study Using a Mathematical Model and Actual Exposure Monitoring for Estimating Solvent Exposures during the Disassembly of Metal Parts*. Annapolis, Md.: Environmental Profiles, 2007.

Vernez, D.S., P.O. Droz, C. Lazor-Blanchet, et al.: Characterizing emission and breathing-zone concentrations following exposure cases to fluororesin-based waterproofing spray mists. *J. Occup. Environ. Hyg. 1*:582–592 (2004).

Vernez, D., R. Bruzzi, H. Kupferschmidt, et al.: Acute respiratory syndrome after inhalation of waterproofing sprays: A posteriori exposure-response assessment in 102 cases. *J. Occup. Environ. Hyg. 3*:250–261 (2006).

Von Grote, J., C. Hurlimann, M. Scheringer, et al.: Reduction of occupational exposure to perchloroethylene and trichloroethylene in metal degreasing over the last 30 years: Influences of technology innovation and legislation. *J. Expo. Anal. Environ. Epidemiol. 13*:325–340 (2003).

Von Grote, J., C. Hurlimann, M. Scheringer, et al.: Assessing occupational exposure to perchloroethylene in dry cleaning. *J. Occup. Environ. Hyg. 3*:606–619 (2006).

Another test of the NF/FF model[5] used airborne monitoring data for hair spray propellant components that were collected in 1972[11] and were considered suitable for model evaluation. The modeled results compared with the monitoring results were within a factor 1.8, even though, as noted by the authors, the monitoring techniques chosen for that study could have contributed to the differences between measured and modeled results.

Figure 2. Process Control Room Layout with Sample Locations and Work Areas from Jones and Harris.[10] Figure 1

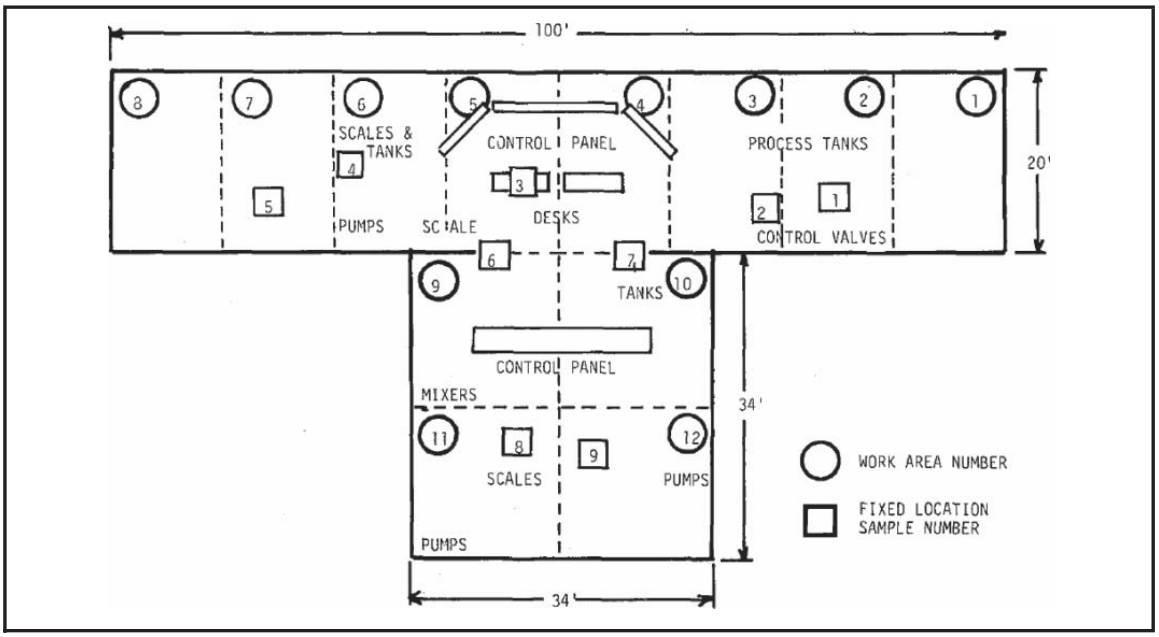


Figure 3. Day One Mapping of Toluene Concentration Isopleths from Jones and Harris,[10] Figure 2

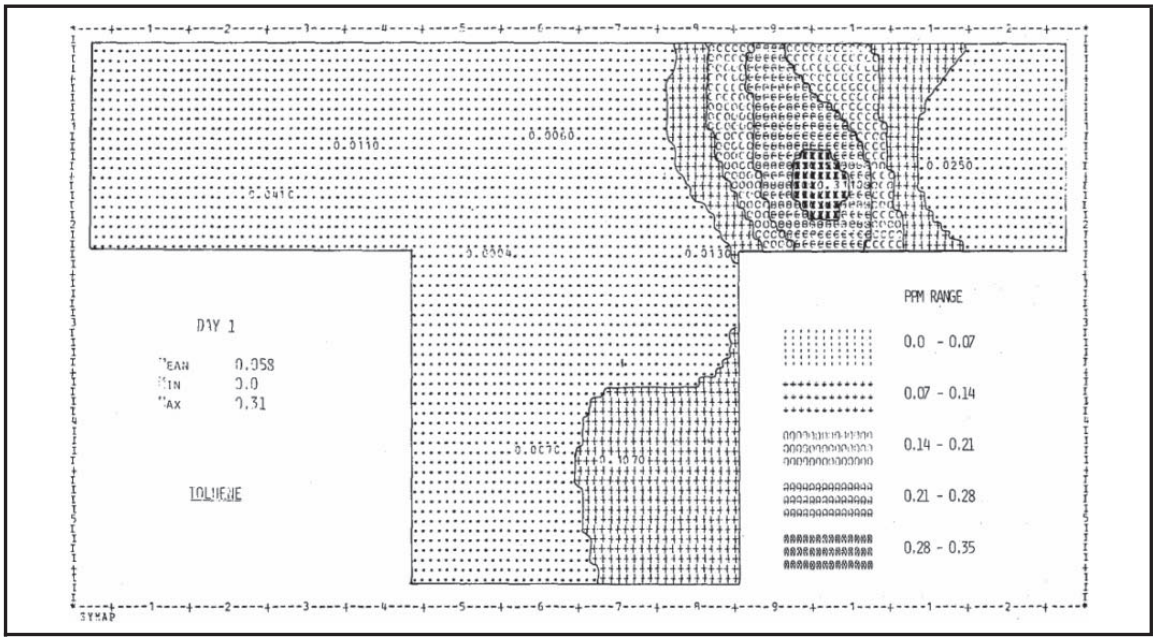


Figure 4. Day Two Mapping of Toluene Concentration Isopleths from Jones and Harris,[10] Figure 3

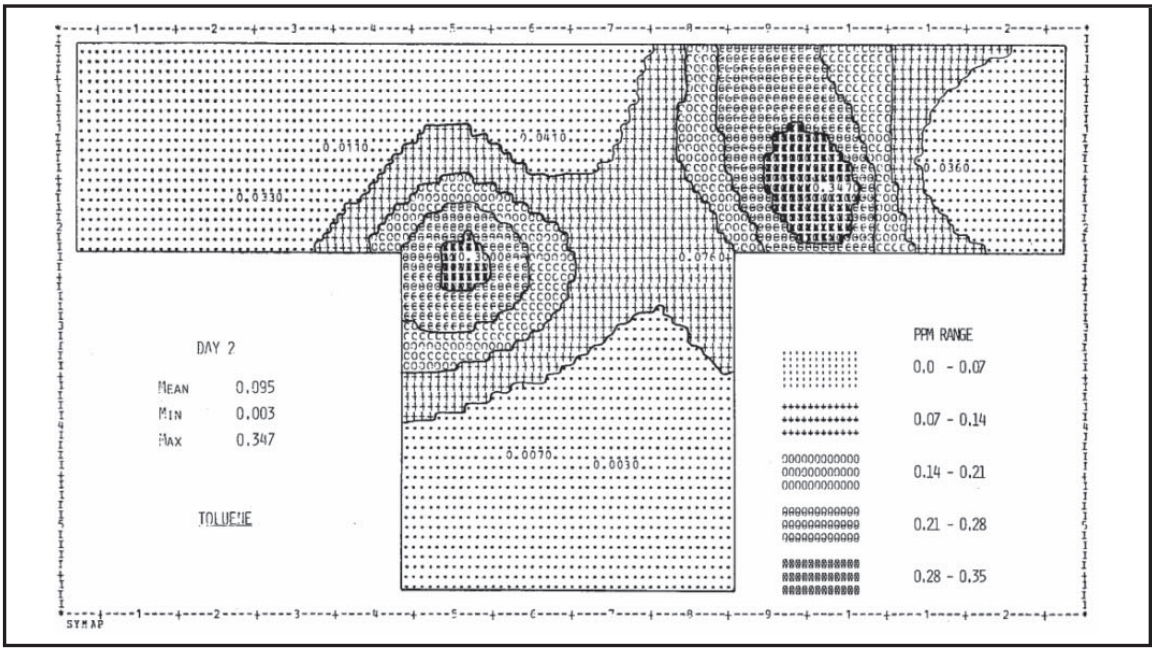
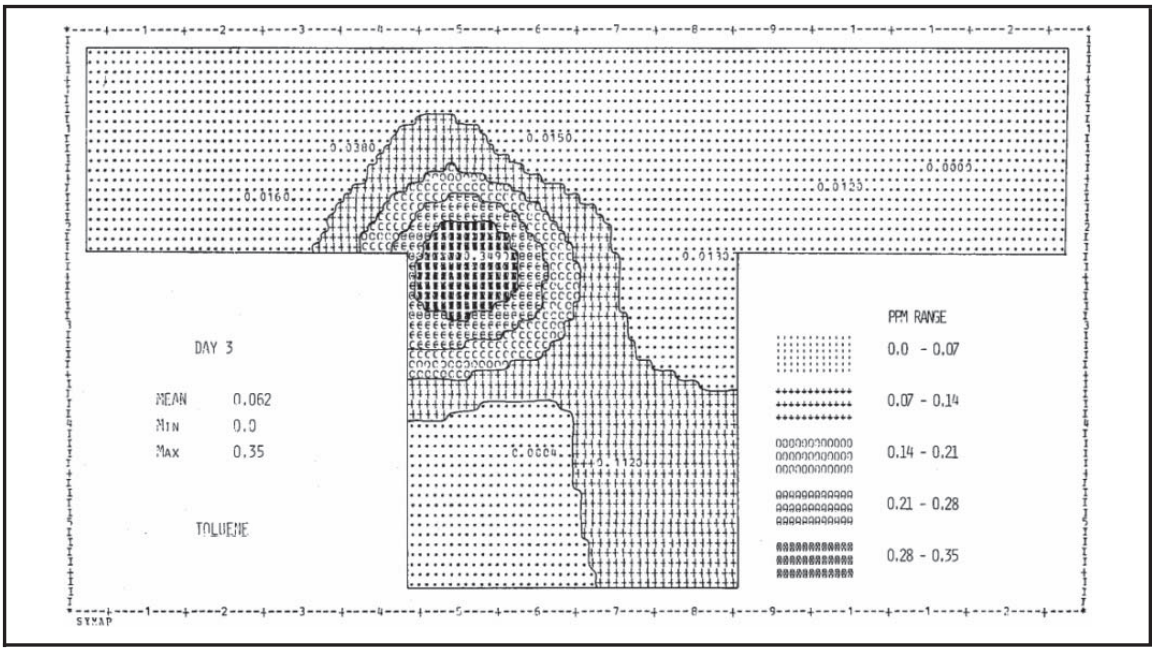


Figure 5. Day Three Mapping of Toluene Concentration Isopleths from Jones and Harris,[10] Figure 4



Sampling and other practical issues typically limit the precision with which one can take and use monitoring data for comparison to NF/FF modeling predictions; however, the above examples clearly show the utility of the NF/FF model and also provide some information on its precision or the magnitude of difference or error in these comparisons.

Status of Peer Review and Acceptance

There are multiple peer reviewed publications on the model,[4, 12-16] coverage in two editions of the AIHA® book *Mathematical Models for Estimating Occupational Exposure to Chemicals*,[8, 9] and coverage in chapters in two other texts.[17, 18] In addition, Table III lists the studies in a review of the NF/FF model included in a report by Sahmel et al.[5] in 2009. At least 10 others, including European industrial hygienists, have published peer reviewed journal articles in which they used the model for predictions of exposures to various contaminants.[19-31] As noted above, at least six peer reviewed articles included comparisons of two-zone model predictions to real world measured data. Spencer and Plisko concluded "Application of the NF-FF model under the conditions described suggests there is a reasonable degree of reliability in forecasting airborne contaminant levels in the workplace environment."[26, p.253]

Zheng et al.[32,p. 409] concluded, "The predictions of near-field concentration for both the simulated and real data show nice concordance with the true values, indicating that the two-zone model assumptions agree with the reality to a large extent and the model is suitable for predicting the contaminant concentration." For more than a decade, the two-zone model has been taught in a mathematical modeling professional development course presented by members of AIHA's Exposure Assessment Strategies Committee. In summary, the two-zone model has been peer reviewed and is an accepted exposure assessment tool in the industrial hygiene profession.

The Technique's Rate of Error, and Standards for the Model's Application

This particular rate of error aspect of the *Daubert* criteria is difficult, in most respects, to differentiate from the aspects discussed in the Testing of the Model section. The famous statistician (G.E.P. Box) once said, "Essentially, all models are wrong, but some are useful."[33, p. 424] This statement is widely cited, but it is somewhat misleading. When used within the stated use conditions, a given model is completely correct. The issue is that all mathematical models to estimate air concentrations make use of simplifying assumptions because fully simulating the physical and chemical variables in the real world environment is, and may always be, beyond the realm of what is possible in modeling and computation. Even complex computational fluid dynamics models incorporate assumptions and bounding conditions. In fact, a number of the relevant variables for a given exposure scenario may be ultimately unknowable. Thus, in mathematical modeling to estimate exposures, the real question is `Does the chosen model, with its simplifying assumptions, adequately simulate conditions to give reasonable estimates and useful insights?" With respect to the NF/FF model, the answer is yes, it does, when used within its stated limits. This is accepted and has been demonstrated for the NF/FF model in many peer reviewed publications as noted previously.

The standards for the model's application have been stated as the principle "bounding conditions" for the model's use and can be summarized from the various publications and book chapters as follows:

- The contaminant is instantaneously mixed throughout the near-field and far-field work space. That is, the air concentration is uniform within each of the two spaces.
- There is limited airflow between the two zones.
- The random air velocity between the two zones is uniformly distributed across the NF/FF interface surface.
- There are no significant cross drafts.

Personal and Professional Experience and Use of the Model

In our work as risk assessors, the NF/FF model is currently considered to be the primary model of airborne concentration that we use when there are relatively few and concentrated sources within rooms. One of us (Jayjock) has used it extensively in consultations with industrial and government clients, including the European Commission and U.S. Fortune 500 companies, and is the first author on a recent study of the exposure potential from spills of electronic chemical solvents within laboratory and plant settings.[6] This study relies primarily on the use of the NF/FF model combined with experimental emission rate data to predict worker exposure potential. In addition, the model has been used to predict airborne concentrations of *Legionella*, in a Legionnaires' disease (LD) outbreak, as part of the development and evaluation of an LD quantitative microbial risk assessment model.[21, 22, 34]

Recently, a collaborative international initiative led to the development of a "freeware" spreadsheet[35] that includes the NF/FF model in the suite of models in an effort to simplify the computational burden of this important model for industrial hygienists. This effort is a general recognition of the value and utility of this important tool. Professional development courses (PDCs) at the American Industrial Hygiene Conference and Exhibition (Toronto, Ontario, 2009; Denver, Colorado, 2010; Portland, Oregon, 2011) have included coverage of the NF/FF model in the current[35] spreadsheet and had been covered in earlier versions of the PDC.

Conclusions

In light of the four Daubert criteria examined, the NF/FF model has:

1. **Extensive Peer Reviewed Publications and Scientific Acceptance of the NF/FF Model**. For example, Boelter et al.[20, p.298] concluded, in part, "This study emphasizes the need for field-derived welding fume generation rates and showed that personal breathing zone and area sample concentrations can be described by the two-zone model in a way that may help the industrial hygienist estimate exposures."

2. **Provided Valid Test Results Against Suitable Measurement Data.** As previously noted, Zhang et al.[32, p. 409] concluded, "The predictions of near-field concentration for both the simulated and real data show nice concordance with the true values, indicating that the two-zone model assumptions agree with the reality to a large extent and the model is suitable for predicting the contaminant concentration."

3. **Satisfied Suitable Criteria for an Acceptable Rate of Error and Standards of Use.** The *Daubert* decisions and analyses of them, that we are aware of, did not adequately define the meaning of the phrases "acceptable rate of error" or fully cover "standards of use." We interpret the rate of error as meaning how well the NF/FF model performs when used appropriately and compared with suitable measurements. In this case, its "error rate" is arguably equivalent to the error rate of measurement surveys conducted to evaluate the model.

   For the standards of use, our view is that the extensive guidance on the model's application—in peer reviewed publications, texts, and coverage in professional development courses offered for many years—adequately define the professional standards for the NF/FF model's use.

4. **The NF/FF Model Has Been Extensively Used in Professional Industrial Hygiene Practice and Exposure Assessment Studies.** The NF/FF model has clearly been accepted within the scientific community. The previously mentioned reference[5] lists 16 peer reviewed publications in the scientific literature in which the NF/FF model has been used to predict airborne exposure for a diverse range of inhalation exposure scenarios. It is expected that the use of and evaluation of this model will expand as its computational implementation[35] has become widely available.

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