Performance criteria and characteristics of field screening test methods

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Field screening test methods are often used in environmental and industrial hygiene applications for the on-site detection and/or measurement of toxic substances. On-site screening tests are carried out in the field in order to estimate the contents of toxic chemicals in environmental matrices, or to estimate human exposures to toxic species, so that overexposures to these substances can be prevented. The goal of screening analysis may not necessarily be to quantitatively determine the level of a particular toxic substance, but rather to assess whether the chemical species of concern is present above or below regulatory or recommended standard values or action levels. Field screening methods can provide a timely means for assessing exposures, but the validity of such methods is called into question if their performance has not been evaluated or verified.

Field screening tests can be classified into three method types: qualitative, semiquantitative, and quantitative. Qualitative techniques, such as chemical spot tests, give either positive or negative (i.e., yes/no) responses for target analytes;[1–3] in some cases, inconclusive results are also possible.[3,4] Semiquantitative methods are analyses that give estimated values for analyte concentration, but with less precision and/or greater bias than quantitative methods.[3,5–7] Quantitative methods are procedures meeting desired accuracy criteria for "definitive" tests, such as those described by the U.S. National Institute for Occupational Safety and Health (NIOSH) for industrial hygiene applications.[8] Quantitative and semiquantitative methods, when used for screening analysis, can be treated in a qualitative manner by converting measured values to positive or negative results via comparison with a specified threshold value.

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Herein, performance functions are described for qualitative, semiquantitative, and quantitative methods. Statistical protocols are outlined that provide the mathematical tools whereby performance criteria and characteristics for each type of screening analysis can be rigorously compared and contrasted. Through examination of the performance functions of the different types of methods, it becomes possible to unify the statistical treatment in a manner that enables direct comparisons of performance attributes to be made. If the performance criteria and characteristics of candidate screening tests have been closely estimated based on thorough testing and statistical evaluation, the potential uses of such tests for field screening analyses can be assessed.

Performance curves for qualitative screening methods

Before a given qualitative method is used in screening tests, its performance must be evaluated. For the method to be deemed acceptable, its performance must be found to meet desired performance criteria. A minimum requirement of a qualitative test method has to do with false-positive and false-negative rates. A test result is referred to as a false negative if a negative result is observed but the true value is above the exposure standard or action level. Conversely, an observation is called a false positive if a positive result is observed when the true value is below this level. For screening applications it is desired to minimize both false-positive and false-negative rates to acceptably low frequencies.

Qualitative test methods ordinarily demonstrate nonzero false-positive and/or false-negative response rates. Thus, a realistic requirement for qualitative screening methods should allow for limited false-negative and false-positive response rates, along with specified uncertainty regions about the applicable threshold values. It is expected that the positive response rate of a given qualitative test method will increase as the true concentration increases.[3,4] In order to statistically model the performance curve of a qualitative test method, it is necessary to define several variables and functions. In this paper, x will be the true analyte concentration, c the threshold value, $P(x)$ the positive response rate, and $N(x)$ the negative response rate of the method at x. A qualitative method can be statistically characterized by $P(x)$ and $N(x)$, referred to as performance functions. To handle inconclusive responses, let $I(x) = 1 - P(x) - N(x)$. Th s, $I(x)$ is the inconclusive rate of responses at x. For a method reporting only positive or negative responses, i.e., no "inconclusive" results, $I(x) = 0$.

For values of $x > c$, $P(x)$ is the correct positive e-

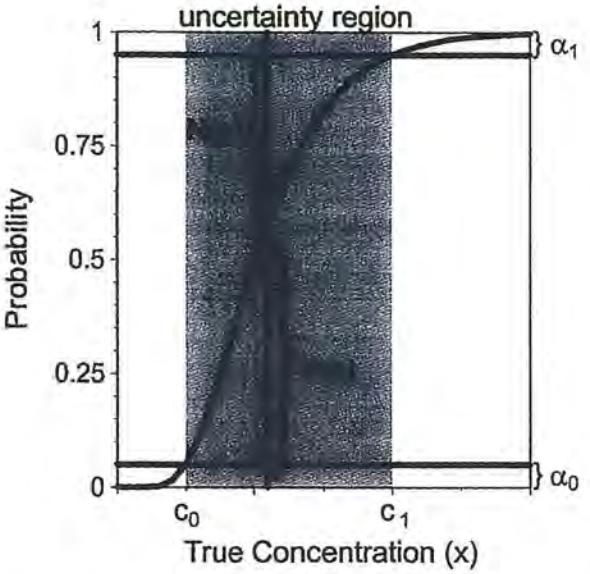

Figure 1 *Performance functions and performance parameters for a binary (yes/no) qualitative test method.*

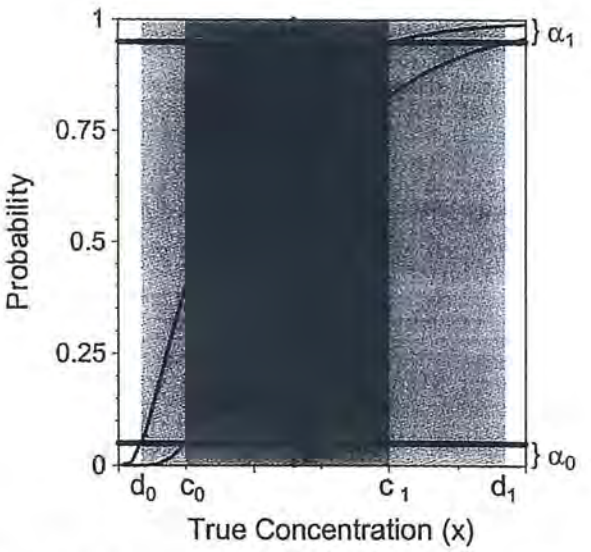

Figure 2 *Performance functions and performance parameters of a qualitative test method with inconclusive outcomes.*

sponse rate, and $N(x)$ is the false-negative rate at x. Conversely, for $x < c$, $P(x)$ is the false-positive rate, and $N(x)$ is the correct negative response rate at x. It may be specified to limit the false-positive and false-negative rates in terms of probabilities α_0 and α_1. This results in an interval (c_0, c_1) such that the region bounded by $P(c_0) = \alpha_0$ and $N(c_1) = \alpha_1$ is the uncertainty region corresponding to false response rates. When $I(x) = 0$ (i.e., no inconclusive results are possible) (c_0, c_1) is also the uncertainty region corresponding to correct response rates (*Figure 1*):

$$1 - N(c_0) = \alpha_0, \qquad 1 - P(c_1) = \alpha_1 \tag{1}$$

But, if $I(x) > 0$, the uncertainty region corresponding to correct response rate is different from that corresponding to false response rates. Here the uncertainty region corresponding to correct response rates is given by (d_0, d_1), where d_0 and d_1 are concentration levels (*Figure 2*):

$$1 - N(d_0) = \alpha_0, \qquad 1 - P(d_1) = \alpha_1 \tag{2}$$

Figures 1 and 2 illustrate generic sigmoidal performance curves for qualitative analyses in the absence (Figure 1) and presence (Figure 2) of inconclusive results. If inconclusive readings are possible, the uncertainty region is usually greater than in the corresponding case where only yes/no results are possible, i.e., $(c_0, c_1) \subset (d_0, d_1)$; compare Figures 1 and 2.

In order to ensure the quality of qualitative screening tests, the applicable performance criteria for a qualitative method must specify the uncertainty region (c_0, c_1) and the maximum false-positive and/or negative response rates allowed. Alternatively, the performance criteria for a qualitative method need to specify the uncertainty region (d_0, d_1), and the correct positive and/or negative response rates required. The former case applies when only yes or no results are possible, while the latter situation is operative if inconclusive readings are also possible. Stated in terms of false-positive and negative response rates, (I) the false-positive rate at or below c_0 is less than or equal to α_0, and the false-negative response rate at or above c_1 is less than or equal to α_1.

Stated in terms of correct positive and negative response rates (where inconclusive results are possible), (II) the correct negative response rate at or below d_0 is greater than or equal to $1 - \alpha_0$, and the correct positive response rate at or above d_1 is greater than or equal to $1 - \alpha_1$.

For qualitative screening tests in medically related applications, the correct positive response rate is referred to as sensitivity, while the correct negative response rate is called specificity.[9] Positive and negative response rates would be expressed with respect to the applicable action level(s) and a desired confidence level (usually at least 95% for analytical applications).

For screening test methods that report either positive or negative results, the two criteria (I) and (II) above are identical. In this instance, if the performance function $P(x)$ is a monotonically increasing function of x, then the performance criterion is equivalent to:

$$P(c_0) \le \alpha_0 \tag{3}$$

and

$$1 - P(c_1) \le \alpha_1 \tag{4}$$

This case is illustrated in Figure 1. However, a qualitative test method could meet the first criterion, but not the second. This situation applies when using a test method that can report a result as either positive, negative, or inconclusive, as shown in Figure 2.

Performance curves for semiquantitative and quantitative screening methods

Methods yielding numerical values are often used for screening analysis in the field. Screening methods demonstrating poorer overall accuracy than definitive quantitative methods (used for fixed-site laboratory analysis) may nonetheless prove useful for on-site analyses. Such methods may be viewed as quantitative procedures that have low precision and/or high bias. Screening methods of this kind are commonly referred to as semiquantitative to indicate that these methods do not meet the same performance requirements for accuracy (precision and bias) as the more definitive quantitative methods. Certainly, quantitative procedures that meet more stringent performance requirements for overall method accuracy can also be used for screening purposes. Applications of semiquantitative and/or quantitative methods for screening may be manifested in the use of such procedures for making decisions on whether measured concentrations of analyte(s) is(are) above or below levels of concern.

Methods yielding numerical values are often used for screening analysis in the field.

In using a semiquantitative or quantitative method for screening tests, a threshold value may be established in order to convert each numerical measurement to a qualitative (yes/no) outcome. For a given measurement method yielding numerical values, the performance of the method is characterized by its bias and precision, or its measurement distribution. Assuming that measurements are distributed normally, the distribution of results is determined by the mean and standard deviation at each concentration level. As a qualitative test procedure, the performance function of the semiquantitative or quantitative method for screening applications depends on the threshold value and its distribution of numerical measurements (which are converted to positive or negative responses).

Let $m(x)$ and $s(x)$ be the estimated mean response function and the estimated standard deviation function, respectively, of a given semiquantitative or quantitative measurement method. The performance function of the derived qualitative method is then expressed by:

$$P(x) = \Phi\{[m(x) - t]/s(x)\} \quad (5)$$

where $\Phi(x)$ is the cumulative distribution function of a standard normal random variable x, and t is the threshold value. The threshold value can be defined as the expected response value at the standard or action level: $t = m(c)$.

The mean response function and the standard deviation function of a semiquantitative or quantitative method is now considered. The performance function and performance parameters of this method will depend on the threshold value of concern. With false-positive and false-negative rates α_0 and α_1 (expressed as probabilities), the $(1 - \alpha_0 - \alpha_1) \times 100\%$ confidence interval at x can be expressed by functions $L(x)$ and $U(x)$:

$$L(x) = m(x) - z(1 - \alpha_1)s(x),$$
$$U(x) = m(x) + z(1 - \alpha_0)s(x) \quad (6)$$

where $z(1 - \alpha_{1,0})$ is the $(1 - \alpha_{1,0}) \times 100\%$ percentile of the standard normal distribution. The associated uncertainty region (c_0, c_1) can be obtained by solving $U(c_0) = t$ and $L(c_1) = t$.

For a method with constant bias B and a constant precision (expressed in terms of relative standard deviation) R,

$$m(x) = (B + 1)x \quad (7)$$

and

$$s(x) = Rm(x) = R(B + 1)x \quad (8)$$

Here, the uncertainty region (in terms of concentrations) is given by:

$$c_0 = t/[(1 + B)[1 + Rz(1 - \alpha_0)]],$$
$$c_1 = t/[(1 + B)[1 - Rz(1 - \alpha_1)]] \quad (9)$$

The method bias can be corrected for if B is known and is small in magnitude.[8] If R is not constant but is concentration dependent, c_0 and c_1 can be computed using $R = R(x)$.

For analytical applications, at least 95% confidence is desired, hence $\alpha_0 = \alpha_1 = 0.05$ is chosen. For an unbiased method, $B = 0$, and with $\alpha_0 = \alpha_1 = 0.05$,

$$c_0 = t/(1 + 1.645R) \quad (10)$$

and

$$c_1 = t/(1 - 1.645R) \quad (11)$$

A semiquantitative or quantitative method can be characterized by its overall accuracy A. For measurements of airborne toxic substances in the occupational hygiene arena, a desired method accuracy criterion has been defined by the NIOSH.[8] This criterion states that at least 95% of measurements must fall within $\pm A\%$ of the "true" concentration level, where accuracy is defined as a function of precision and bias. An approximation of the relationship linking accuracy to precision and bias is expressed as:

$$A = 1.96 \times (B^2 + R^2)^{1/2}$$

$$\text{if } |B| < R/1.645, \text{ or} \qquad (12)$$

$$A = |B| + 1.645R$$

otherwise (i.e., with high bias B).[10] An analytical method meets the NIOSH accuracy criterion if $A \leq 0.25$; i.e., at least 95% of the measurements must fall within ±25% of the "true" value.[8]

But here, it was desired to use a quantitative or semiquantitative method for screening purposes. Consider first a situation in which the accuracy criterion is met for a method demonstrating no bias, $A = 0.25$ and $B = 0$. We thus have $c_0 = 0.827t$ and $c_1 = 1.267t$. So, if $B = 0$ and $t = m(c) = c$ at the threshold concentration, $c_0 = 0.827c$ and $c_1 = 1.267c$ (*Figure 3*). Figure 3 illustrates the situation in which a quantitative method satisfying the NIOSH accuracy criterion can be used for screening purposes through the conversion of numerical values to positive or negative outcomes.

To reiterate, a semiquantitative method can be described as a quantitative analysis that demonstrates poorer precision and/or greater bias than a method that meets the NIOSH accuracy criterion. But a semiquantitative method can meet the criterion (I) previously described for qualitative methods. This can be accomplished by reporting results near the threshold value as inconclusive, which may thereby reduce false-negative and false-positive rates. Such a method having a nonzero inconclusive rate can be characterized by its positive response rate function $P(x)$ and its negative response rate function $N(x)$. Recall that the inconclusive response rate is given by:

$$I(x) = 1 - P(x) - N(x) \qquad (13)$$

For methods with inconclusive possibilities, there are two classes of uncertainty intervals: (c_0, c_1) defined in terms of the false-positive and false-negative rates, and (d_0, d_1) defined in terms of the correct positive and correct negative response rates (recall Figure 2). But if $I(x) = 0$ for all x, then $c_0 = d_0$ and $c_1 = d_1$.

A semiquantitative method not meeting the performance criterion (II) could meet the performance criterion (I) in consideration of the threshold level t. The method could then meet criterion (I) by defining an inconclusive range (t_0, t_1) in terms of lower and upper limits that are concentration dependent:

$$t_0 = L(c_1) = L(\gamma c),$$
$$t_1 = U(c_0) = U(\delta c) \qquad (14)$$

where γ and δ are coefficients such that $\gamma > 1$; $\delta < 1$. *Figure 4* demonstrates an example of such a case, in which the inconclusive range is defined with $\gamma = 0.5$; $\delta = 2$ (i.e., $c_0 = 0.5c$; $c_1 = 2c$). For semiquantitative screening, $P(x)$ is the probability that a measurement at x is greater than t_1, $N(x)$ is the probability that a measurement at x is less than t_0, and $I(x)$ is the probability that a measurement at x falls within the interval (t_0, t_1); compare Figures 2 and 4. By defining an inconclusive range, we provide for a semiquantitative method to be used as a screening technique. The width of the inconclusive range will of course depend on the precision and bias characteristics of the semiquantitative procedure.

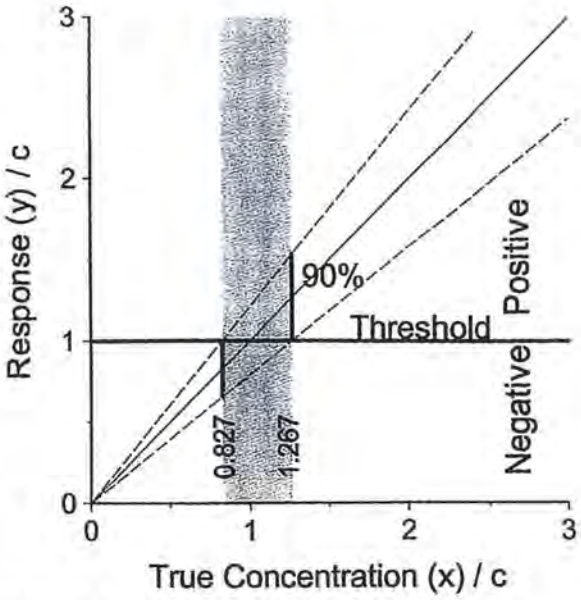

Figure 3 *A quantitative method with A = 0.25 and converted to qualitative outcomes (positive or negative with respect to a threshold level) by use of a threshold value.*

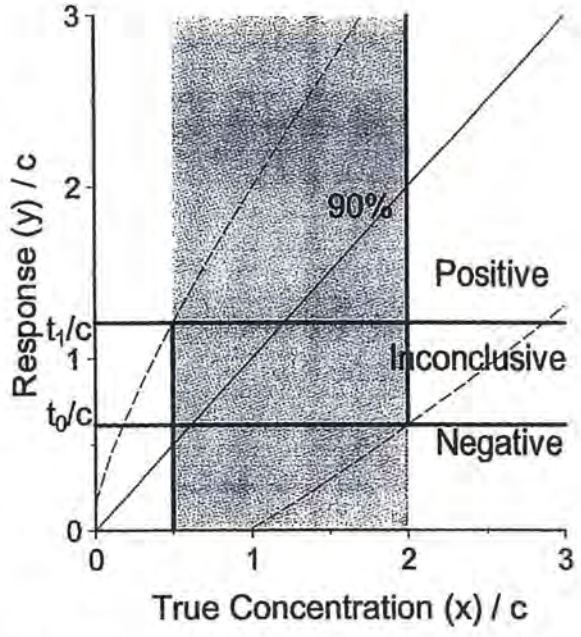

Figure 4 *A semiquantitative method converted to qualitative results (positive or negative) with inconclusive outcomes.*

The approach presented here applies to situations in which the action level or threshold value is significantly above the detection limit, and a concentration-independent estimate of method uncertainty, which is constant, is assumed. But in cases where the action level is close to the detection limit (and method uncertainty is therefore much greater than at higher concentrations), error rates may increase to such an extent that the desired confidence levels cannot be achieved. For these reasons, as a general rule it is desired that the detection limit of an analytical method be at least an order of magnitude below the action level or threshold value.[8] Hence, the use of screening methods may be limited to those instances in which the method detection limits are sufficiently low.

Examples

A few example cases of screening analysis concerning samples of interest in occupational and environmental health are presented. The use of qualitative, semiquantitative, and quantitative methods for screening purposes is demonstrated in light of the previous development. While the examples illustrated are specific for lead measurement in dust or air samples, it is emphasized that similar treatments may apply to virtually any analyte/matrix/method combination.

The statistical treatment outlined can be applied to virtually any method that yields a numerical value for any analyte of interest.

Spot test for lead in air samples

A statistical model was used to describe the performance characteristics of a qualitative spot test for lead in workplace air samples.[1] The following distribution function was used to fit observed yes/no spot test data.

$$P(x; a, b) = 1 - \exp[-(x/a)^b] \text{ (for } x \geq 0) \quad (15)$$

Here, P is the probability of observing a positive response and is a function of the lead mass x and parameters a and b, which are location and scale parameters, respectively. An increase in the value of a shifts the performance curve to higher concentration values, while increasing the value of b serves to increase the slope of the curve.

Spot test performance parameters of interest are at lead levels giving 5, 50, and 95% chances of a positive response (i.e., $p = 0.05$, 0.50, and 0.95). These performance parameters can be expressed as functions of the primary parameters a and b:

$$x_p = a[-\ln(1 - P)]^{1/b} \text{ (for } P = 0.05; 0.50; 0.95) \quad (16)$$

where x_p is the lead level at a given probability of positive test response. The 50% response point, $x_{0.50}$, is defined as the identification limit of the spot test method. This value is of interest in that it is equivalent to the detection limit of a quantitative analytical method in the following sense: Both the identification limit of a qualitative test procedure[11] and the detection limit of a quantitative method[12] correspond to analyte levels at which there is a 50% chance of a negative result. The 5% and 95% response points ($x_{0.05}$ and $x_{0.95}$, respectively) provide information such that when a test response is observed, one may be at least 95% confident that the lead level is either above $x_{0.05}$ in the case of a positive result, or below $x_{0.95}$ in the event of a negative reading. Thus $x_{0.05}$, $x_{0.50}$, and $x_{0.95}$ are parameters that may be used to characterize the performance of the spot test procedure.

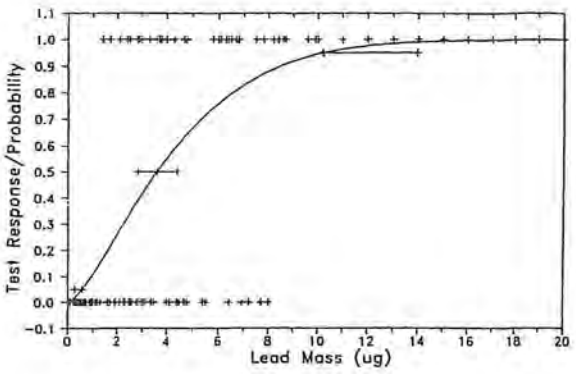

Figure 5 *Data fitted by statistical modeling: lead spot test applied on workplace air filter samples.[1] Plot of spot test response/probability versus mass of lead per filter (determined by GFAAS). +: individual data points; —: modeled performance curve.*

For the lead-in-air spot test data, the maximum likelihood method[13] was used to estimate the primary performance parameters a and b, enabling estimation of the 5, 50, and 95% response points. The performance curve of the spot test data was modeled semiempirically, and the best estimates of a and b were discovered to be ~4.7 and ~1.4, respectively (dimensionless quantities). Calculated estimates for $x_{0.05}$, $x_{0.50}$, and $x_{0.95}$ from experimental data were approx. 0.57, 3.6, and 10.2 µg Pb, respectively.[1] The performance curve of this lead spot test method is shown in *Figure 5*. A NIOSH spot test screening method for lead in air filter samples has been promulgated based on this work.[14]

The implications for using the lead-in-air spot test are as follows. If a negative result is observed, one may be at least 95% confident that the amount of lead in the sample is less than 10.2 µg. Conversely, if a positive response is seen, one may be at least 95% confident that the amount of lead in the sample is greater than 0.57 µg. With knowledge of sampling times and flow rates, these values can be used by the industrial hygienist to predict compliance or noncompliance with applicable action levels, e.g., Occu-

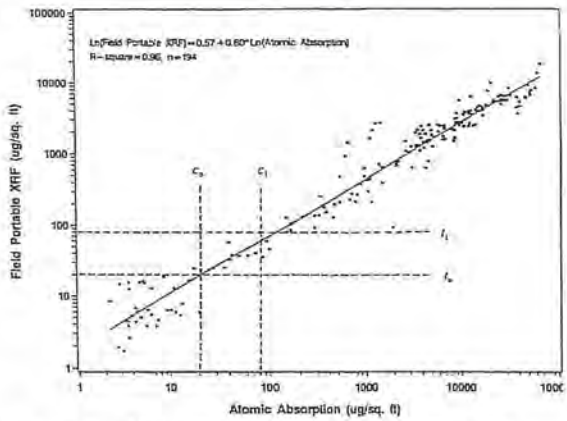

Figure 6 *Plot of field-portable XRF data versus GFAAS results for lead in dust wipe samples.[17] (Courtesy of D.T. Woody and Prof. C.S. Clark, University of Cincinnati.)*

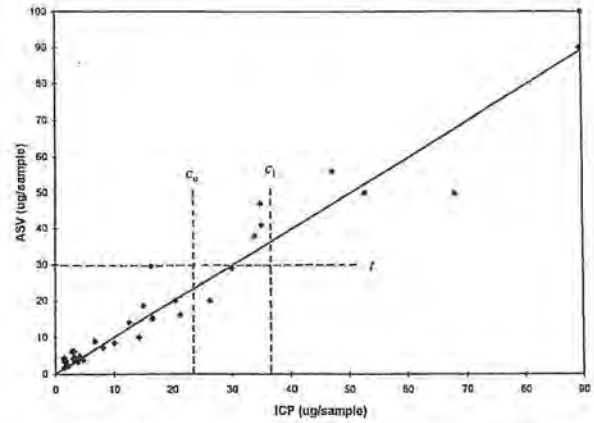

Figure 7 *Plot of data obtained by portable UE/ASV versus ICP-AES results for lead in workplace air samples.[23]*

pational Safety and Health (OSHA) Permissible Exposure Limits (PELs).[15,16]

Portable XRF screening for lead in surface dust

A portable X-ray fluorescence (XRF) device was evaluated for its potential use in semiquantitative field screening for lead in dust wipe samples.[17] Nearly 200 surface dust samples were collected onto wipes from field sites during lead hazard mitigation activities.[18,19] The lead content in each wipe was then measured using portable XRF. This was followed by confirmatory analysis with graphite furnace atomic absorption spectrometry (GFAAS)[20] after hotplate digestion of the wipes in nitric acid and hydrogen peroxide.[21] *Figure 6* shows a log-log plot of portable XRF readings versus analytical results from GFAAS. The XRF method accuracy was computed to be approx. 34%,[17] which does not meet the NIOSH accuracy criterion.[8] Hence, portable XRF measurement of lead in dust wipe samples may be considered a semiquantitative analytical technique.

These semiquantitative XRF results can be examined in terms of a screening analysis application, considering, for instance, an applicable action level $c = 40$ µg/ft^2 for lead in floor dust.[22] For this example an operative inconclusive range for portable XRF of 0.5× to 2× the action level is chosen; i.e., $t_0 = 20$ µg/ft^2 and $t_1 = 80$ µg/ft^2 (Figure 6). Regarding GFAAS results as reference values, no XRF readings were found to be false positives or false negatives. For this data set, 14 XRF results, or 7.2%, fell within the inconclusive region. All XRF data below t_0 were less than c as measured by GFAAS, and all XRF results above t_1 were greater than c as measured by the reference method. This example amply demonstrates the utility of portable XRF as a screening technique for lead in dust wipe samples.

On-site measurement of lead in air by field-portable electroanalysis

A field-portable method for the determination of lead in workplace air samples, based on the use of ultrasonic extraction (UE) and anodic stripping voltammetry (ASV), was evaluated.[23] Workplace air samples were collected onto filters using personal sampling pumps. The filters were then subjected to UE in diluted nitric acid, and the lead concentration in the extracts was measured by ASV. Afterwards, the extracts and filters were subject to hotplate digestion prior to lead measurement by inductively coupled plasma–atomic emission spectrometry (ICP-AES),[24] which served as a reference analytical method. *Figure 7* shows a plot of lead-in-air data obtained using the field electroanalytical method versus results from ICP-AES.[23] The portable UE/ASV method was found to satisfy NIOSH accuracy criteria, indicating that this method can be regarded as a quantitative analytical technique.

The use of UE/ASV as a screening method is illustrated in Figure 7, where the OSHA action level of 30 µg/m^3 has been chosen as an operative threshold level t. (For a full 8-hr workday, this figure is close to 30 µg/sample; thus, $c_0 = 0.827t = 24.8$ µg, $c_1 = 1.267t = 38.0$ µg.) With $n = 36$, there is one false positive (at exactly the threshold) and there are no false negatives. While UE-ASV data can be employed for definitive lead-in-air measurements,[25] this example illustrates the application of a quantitative field method for screening analysis.

Summary

A statistical formalism has been presented that enables the estimation of performance criteria and characteristics of field screening test methods. By implementing appropriate statistical treatments on measurement data with subsequent confirmatory analysis, it becomes possible to evaluate qualitative, semiquantitative, and quantitative field methods for their potential use in screening analysis for given analytes of interest. It should therefore be possible to

use the results from screening analysis to make defensible decisions concerning potential human exposures to toxic substances.

The use of various methods for screening purposes may depend on the intended applications or purposes of the measurements. The discussion here has focused on the use of such measurements for making decisions concerning analyte concentrations above or below a given standard or action level (threshold). The statistical treatment outlined can be applied to virtually any method that yields a numerical value for any analyte of interest, and therefore has general applicability to field screening analysis.

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Forensic Science Meeting

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