Tests for an Upper Percentile of a Lognormal Distribution Based on Samples with Multiple Detection Limits and Sample-Size Calculation

KALIMUTHU KRISHNAMOORTHY1*, THOMAS MATHEW2 and ZHAO XU3

1Department of Mathematics, University of Louisiana at Lafayette, Lafayette, LA 70508-1010, USA; 2Department of Mathematics and Statistics, University of Maryland, Baltimore County, Baltimore, MD 21250, USA; 3Statacorp LP, College Station, TX 77845, USA

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The problem of determining sample size for testing an upper percentile of a lognormal distribution based on samples with multiple detection limits is considered. Two tests, the signed likelihood ratio test and another test based on a pivotal statistic, are outlined. These tests are very satisfactory in controlling type I error rates and comparable in terms of powers. Procedures and R codes for calculating sample sizes for these tests to attain a specified power are given. It is noted that for guaranteeing a given power, increased sample size is necessary due to the presence of detection limits, and the required sample size goes up as the proportion of non-detects goes up. It is also noted that in the multiple detection limit scenario, sample-size determination does not require knowledge of the proportions of non-detects that are expected to be below the individual detection limits; rather, what is required is a knowledge of the overall percentage of non-detects that is to be expected in the entire sample. Sample-size calculation is illustrated using a practical situation.

Keywords: maximum likelihood estimates; non-central t distribution; pivotal test; powers; signed likelihood ratio test

Abbreviations: \( z_p \), the 100\( p \) percentile of the standard normal distribution; \( \Phi \), distribution function of the standard normal random variable; \( \exp(\mu) \), the geometric mean of a lognormal distribution; \( \exp(\sigma) \), the geometric standard deviation of a lognormal distribution; \( \xi_p \), the 100\( p \) percentile of the \( N(\mu, \sigma^2) \) distribution, \( \xi_p = \mu + z_p \sigma \); \( \xi_p^0 \) is a specified value of \( \xi_p \), e.g., \( \xi_p^0 = \ln(OEL) \); \( DL_i \), the detection limit for the \( i \)th laboratory method or sampling device; \( i = 1, \ldots, k \); \( p_i \), probability of a non-detect for the \( i \)th device or method, \( i = 1, \ldots, k \); \( m_i \), the number of non-detects below \( DL_i \); \( i = 1, \ldots, k \); \( m = \sum_{i=1}^{k} m_i \), the total number of non-detects; \((\hat{\mu}, \hat{\sigma})\), the MLE of \((\mu, \sigma)\) based on a log-transformed random sample with log-transformed detection limits \( \ln(DL_1), \ldots, \ln(DL_k) \); \( \hat{\sigma}_p \), the MLE of \( \sigma \) under the constraint \( \xi_p = \mu + z_p \sigma \); \( t_{n-1, (1-\alpha)}(\delta) \), 100(1 - \( \alpha \)) percentile of the non-central \( t \) distribution with degrees of freedom \( m \) and the non-centrality parameter \( \delta \); \( \delta^* = \frac{\xi_p^0 - \xi_p}{\sigma} \), the scaled difference between the specified value and the true value of the 100\( p \) percentile of log-transformed exposure distribution \( \delta^* \) is independent of the unit of measurements.

INTRODUCTION

The detection limit (DL) problem has received considerable attention in the industrial hygiene literature due to its common occurrence among exposure data and due to the challenges it presents while performing the data analysis. It is now well recognized that replacing the values below a DL with a constant (such as one-half of the DL) can result in a test procedure with elevated type I error rates or a confidence interval with inaccurate confidence; the issue has recently been brought to...
focus by the commentary by Helsel (2010), the editorial by Ogden (2010), and by the discussions and examples in the second edition of the book by Helsel (2012). The DL problem has mostly been addressed in the case of a single DL, even though some researchers have also addressed the multiple DL scenario; see Krishnamoorthy and Xu (2011) and the references therein for some recent contributions. In the industrial hygiene context, most of the literature on DLs deals with the problem of estimating the relevant parameters, for example, the arithmetic mean, geometric mean, and the geometric standard deviation of the lognormal exposure distribution. The development of confidence intervals and hypotheses tests, as well as a exposure distribution. The development of confidence intervals and hypotheses tests, as well as a rigorous study of their accuracy, has been undertaken only recently; see Krishnamoorthy et al. (2009, 2011) and Krishnamoorthy and Xu (2011).

An issue that has been overlooked is that of sample-size determination. To simply say, does the presence of DLs require increased sample size to guarantee a specified power for a test, compared with the case of a sample with no non-detects? How does the presence of multiple DLs affect the power of a test and the sample size required to guarantee a given power? These are the issues investigated in this study.

Although we focus on exposure data following a lognormal distribution, the sample-size calculation described in the sequel is applicable for any distribution that has one-to-one relation with the normal distribution. For instance, if exposure data follow a gamma distribution, then cube root transformation can be used to determine the sample size (see Krishnamoorthy and Xu, 2011). Furthermore, the problem that we have addressed is that of testing an upper percentile of the exposure profile. This is one of the basic strategies recommended in the consensus standard published by the American Industrial Hygiene Association (see Mulhausen and Damiano, 1998; Ignacio and Bullock, 2006). Specifically, we have considered the problem of testing if an upper percentile is below an occupational exposure limit (OEL) and have rigorously investigated the computation of the sample size required to guarantee a given power (say, 80 or 90%). This is done in the multiple DL scenario. Note that the sample-size calculation has to be based on a test that performs well in terms of type I error probability. Such a test is developed by Krishnamoorthy and Xu (2011) based on a suitable pivotal quantity and the test is explained later in this study. In addition, we have also proposed the likelihood ratio test by K. Krishnamoorthy, T. Mathew and Z. Xu (unpublished data), implemented using simulations rather than using large sample approximations. Both the tests exhibit accurate performance regardless of the sample size and number of DLs. We have also included the algorithms necessary to carry out the tests. The sample-size problem is then investigated in the multiple DL scenario. The only other work that we have seen, where the sample-size issue is addressed under DLs, is the study by Chu et al. (2006). The authors have addressed the problem of comparing the geometric means of two lognormal distributions when the samples were below DL values and have investigated the sample-size issue.

Typically, sample-size determination does require some knowledge about the population parameters. In our investigation, what is necessary is a value of the percentile (under the alternative hypothesis) at which the power is required to be 80 or 90%, along with a knowledge of the geometric mean or geometric standard deviation of the exposure population. In addition, some idea about the overall percentage of the data below all the DLs is all that is required and it is not necessary to have information on the proportion of the data below each individual DL. This is a practically useful observation. On the basis of this observation, we provided tables of sample sizes required to attain a power of 0.80 or 0.90 when the proportion of non-detects is known a priori. We also posted an R program (www.ucs.louisiana.edu/~kxk4695) that calculates the power of the proposed test for a given sample size and DLs. Our conclusion is that the presence of DLs does result in increased sample size to guarantee a given power. DLs being a commonly occurring phenomenon in exposure data analysis, we hope our work will be of interest to industrial hygienists who want to determine the required sample size while planning their data collection.

**MAXIMUM LIKELIHOOD ESTIMATORS**

The starting point of the procedures that we shall develop is the computation of the maximum likelihood estimators (MLEs). Here, we consider only lognormally distributed exposure data. The lognormal distribution is known to be a very good approximation to model the distribution
of exposure samples in many practical scenarios. We recall that exposure measurements follow a lognormal distribution if the log-transformed measurements follow a normal distribution. We shall denote by \( \mu \) and \( \sigma^2 \) the mean and variance of the log-transformed data; the corresponding normal distribution will be denoted by \( N(\mu, \sigma^2) \). Thus, \( \exp(\mu) \) and \( \exp(\sigma) \), are, respectively, the geometric mean and geometric standard deviation of the exposure data.

Consider a random sample of \( n \) exposure measurements, assumed to follow a lognormal distribution, subject to \( k \) DLs. Here, \( k \) represents, for example, different instruments or methods used for obtaining the exposure data. Let \( m_i \) denote the number of non-detects below the \( i \)th DL so that
\[
m = \sum_{i=1}^{k} m_i
\]
is the total number of non-detects. Let \( X_1, X_2, \ldots, X_{n-m} \) be the log-transformed data corresponding to the \( n-m \) observations that are above the log-transformed DLs. Thus, on the lognormal scale, we have a random sample of \( n \) measurements from a normal distribution, say \( N(\mu, \sigma^2) \), with \( m_i \) observations below \( \ln \text{DL}_i \) \( (i = 1, \ldots, k) \), \( X_1, X_2, \ldots, X_{n-m} \) being the observations that are greater than the log-transformed DLs (where \( m = \sum_{i=1}^{k} m_i \)). Define
\[
\bar{X}_d = \frac{1}{n-m} \sum_{i=1}^{n-m} X_i \quad \text{and} \quad S_d^2 = \frac{1}{n-m} \sum_{i=1}^{n-m} (X_i - \bar{X}_d)^2,
\]
so that \( \bar{X}_d \) and \( S_d^2 \) are, respectively, the sample mean and sample variance of the \( n-m \) observations \( X_1, X_2, \ldots, X_{n-m} \). The log-likelihood function, after omitting a constant term, can be written as
\[
l(\mu, \sigma) = \sum_{i=1}^{k} m_i \ln \Phi(z_i^*) - (n-m) \ln \sigma - \frac{(n-m)(S_d^2 + (\bar{X}_d - \mu)^2)}{2\sigma^2},
\]
where \( z_i^* = \frac{\ln \text{DL}_i - \mu}{\sigma}, \quad i = 1, \ldots, k \), and \( \Phi(\cdot) \) denotes the standard normal cumulative distribution function. The maximum likelihood estimates of \( \mu \) and \( \sigma \), say \( \hat{\mu} \) and \( \hat{\sigma} \), respectively, can be obtained by maximizing the above log-likelihood function. These can be numerically obtained using the bivariate Newton–Raphson iterative method; for details, see Krishnamoorthy and Xu (2011).

Remark 1. All the statistical methods proposed in the literature for the problems involving multiple DLs are based on the assumption that the measurements obtained using different instruments or methods have the same mean and variance. It is possible that the measurements obtained using different methods or instruments have different means and variances, and in that case we are dealing multiple exposure distributions each with a single DL. The problem of exposure assessment in such a set-up is theoretically complex and it is not possible to come up with a single upper percentile of several exposure distributions. Therefore, we shall proceed with the assumption that the measurements obtained by different instruments have the same mean and variance and keep in mind that the results in the sequel are valid only under such assumption.

**TESTS AND POWER CALCULATION**

Let \( \xi_p \) denote the 100th percentile of the normal distribution \( N(\mu, \sigma^2) \). Clearly, \( \xi_p = \mu + z_p \sigma \), where \( z_p \) is the 100th percentile of the standard normal distribution. Then, the \( p \)th percentile of the original lognormally distributed exposure data is \( \exp(\xi_p) \). Suppose we wish to test the hypothesis that the 100th percentile of the exposure distribution is below an OEL. Formulating this as the alternative hypothesis, we, thus, have the following null hypothesis \( H_0 \) and alternative hypothesis \( H_a \):
\[
H_0 : \xi_p \geq \xi^0 \quad \text{versus} \quad H_a : \xi_p < \xi^0,
\]
where \( \xi^0 = \ln(\text{OEL}) \). The rejection of \( H_0 \), based on an appropriate statistical test, leads us to the conclusion that the \( p \)th percentile of the exposure distribution is below the OEL. We shall now discuss tests for the above hypothesis, first based on an exposure sample that does not include any non-detects and then on samples subject to \( k \) DLs.

* A test procedure in the absence of non-detects

Let \( \bar{X} \) and \( S^2 \), respectively, denote the mean and variance based on a sample of size \( m \) from a \( N(\mu, \sigma^2) \) distribution. Clearly, the null hypothesis in equation \( (3) \) is rejected at a significance level of \( \alpha \) if a 100(1 - \( \alpha \))% upper confidence limit for \( \xi_p \) is less than \( \xi^0 \), where we recall that \( \xi_p = \mu + z_p \sigma \), \( z_p \) being the 100th percentile of the standard normal distribution. An upper confidence limit
for $\xi_p$ is well known in the statistics literature (see Krishnamoorthy and Mathew, 2009, Chapter 2) and is based on the non-central $t$ distribution with non-centrality parameter $z_p \sqrt{n}$ and degrees of freedom $n - 1$. Let $t_{n-1,1-\alpha}(z_p \sqrt{n})$ denote the 100(1 - $\alpha$)th percentile of such a non-central $t$ distribution. Then, a 100(1 - $\alpha$)% upper confidence limit for $\xi_p$ is given by $\bar{X} + \frac{1}{\sqrt{n}} t_{n-1,1-\alpha}(z_p \sqrt{n}) S$ and a test for equation (3) consists of rejecting $H_0$ if

$$\bar{X} + \frac{1}{\sqrt{n}} t_{n-1,1-\alpha}(z_p \sqrt{n}) S < \xi^0_p$$

equivalently, if

$$\frac{\xi^0_p - \bar{X}}{S} > \frac{1}{\sqrt{n}} t_{n-1,1-\alpha}(z_p \sqrt{n}).$$

(4)

To compute the power function of such a test, we note that

$$\frac{\xi^0_p - \bar{X}}{S} = \frac{\xi^0_p - \xi_p + \xi_p - \bar{X}}{S} = \frac{(\xi^0_p - \xi_p + \mu + z_p \sigma - \bar{X})/\sqrt{n}}{S/\sqrt{n}}$$

$$= \frac{\xi^0_p - \xi_p}{\sigma} + \frac{z_p \sqrt{n} + z}{\sqrt{n-1}},$$

where the standard normal random variable $Z = (\mu - \bar{X})/\sigma$ and the chi-square random variable $\chi^2 = (n - 1)S^2/\sigma^2$ are independent. By writing $X \sim Y$, we mean that the two random variables $X$ and $Y$ are identically distributed. Thus, standard distributional results imply that

$$\frac{\xi^0_p - \bar{X}}{S} = \frac{1}{\sqrt{n}} t_{n-1}(\delta + z_p \sqrt{n}),$$

with

$$\sqrt{n} \left( \frac{\xi^0_p - \xi_p}{\sigma} \right)$$

(5)

Here, $t_{n-1}(\eta)$ denotes a non-central $t$ distribution with the degrees of freedom $m$ and non-centrality parameter $\eta$. The power function, which follows from equations (4) and (5), is given by

$$P \left( t_{n-1}(\delta + z_p \sqrt{n}) > t_{n-1,1-\alpha}(z_p \sqrt{n}) \right).$$

(6)

Using the result that the non-central $t_m(\eta)$ distribution is stochastically increasing with respect to the non-centrality parameter $\eta$, we see that, for a fixed $(p, \alpha, n)$, the above power function is increasing with increasing value of $\delta$. In other words, the power function is increasing with increasing value of $\delta^*$, where

$$\delta^* = \frac{\xi^0_p - \xi_p}{\sigma}.$$  

(7)

Consequently, the smaller $\xi_p$ is compared with $\xi^0_p$, the larger the power. After specifying a value of $\delta^*$ in equation (7), it is possible to determine the sample size $n$ so that the test provides a given power, say 80%. We shall not go into further details concerning this, since this is available in the literature, and our primary interest is with the exposure data subject to DLs.

**Test procedures in the presence of non-detects**

We shall consider two test procedures: a test based on an approximate pivotal quantity and a likelihood-based test procedure.

**A pivotal test.** Suppose samples include multiple DLs $DL_1, \ldots, DL_k$. Let $\hat{\mu}$ and $\hat{\sigma}$ denote, respectively, the MLEs of $\mu$ and $\sigma$ based on log-transformed samples. Recently, Krishnamoorthy and Xu (2011) showed that

$$Q_p = \frac{\xi^0_p - \hat{\mu} - z_p \hat{\sigma}}{\hat{\sigma}}$$

where $\hat{\mu}^*$ and $\hat{\sigma}^*$ are the MLEs based on a sample of size $n$ from a standard normal distribution with DLs $DL_i^\prime = (\ln DL_i - \hat{\mu})/\hat{\sigma}$. That is, $\hat{\mu}^*$ and $\hat{\sigma}^*$ are the values of $\mu$ and $\sigma$, respectively, which maximize the log-likelihood function in equation (2) with $X_1, X_2, \ldots, X_{n-m}$ being a sample from a $N(0,1)$ distribution with DLs $DL_i^\prime = (\ln DL_i - \hat{\mu})/\hat{\sigma}$. An approximate 100(1 - $\alpha$)% upper confidence limit for $\xi_p = \mu + z_p \sigma$, based on the above distributional result, is given by

$$\hat{\mu} + Q^\ast_{p,1-\alpha} \hat{\sigma},$$

(9)

where $Q^\ast_{p,1-\alpha}$ is the 100(1 - $\alpha$) percentile of $Q^\ast_p = (z_p - \hat{\mu}^*)/\hat{\sigma}$. Note that $Q^\ast_{p,1-\alpha}$ can be estimated by simulating samples from the standard normal distribution $N(0,1)$; see Algorithm 1.

The test on the basis of the upper confidence limit in equation (9) rejects the null hypothesis in equation (3) when
\( \hat{\mu} + Q_{p;1-\alpha}^* < \xi_p^0, \) equivalently, \( \frac{\xi_p^0 - \hat{\mu}}{\hat{\sigma}} > Q_{p;1-\alpha}^* \). (10)

We shall refer to this test as the pivotal test because the confidence limit in equation (9) is based on the approximate pivotal quantity in equation (8).

Algorithm 1. Let \( m_i \) denote the number of non-detects below the DL \( DL_i \) in a set of \( n_i \) measurements that were made by the \( i \)th sampling device (or laboratory method) with DL \( DL_i; i = 1, \ldots, k \). Compute the MLEs \( \hat{\mu} \) and \( \hat{\sigma} \) based on log-transformed sample and set \( DL_i^* = \frac{\ln DL_i - \hat{\mu}}{\hat{\sigma}}, i = 1, \ldots, k \).

1. Generate a sample of size \( n_i \) from \( N(0,1) \), \( i = 1, \ldots, k \). Discard the observations from the \( i \)th sample that are less than \( DL_i^* \), \( i = 1, \ldots, k \). Let \( m_i \) denote the number of observations below \( DL_i^* \), \( i = 1, \ldots, k \), so that \( m = \sum_{i=1}^{k} m_i \).
2. Compute the MLEs \( \hat{\mu}^* \) and \( \hat{\sigma}^* \) using the sample in step 1.
3. Set \( Q_{p}^* = \frac{z_p - \hat{\mu}^*}{\hat{\sigma}^*}, \) where \( z_p \) is the 100\( p \) percentile of \( N(0,1) \) distribution.
4. Repeat steps 1–4 for a large number of times, say, \( M \).
5. The 100(1–\( \alpha \)) percentile of these \( Q_{p}^* \)s generated above is a Monte Carlo estimate of \( Q_{p;1-\alpha}^* \).

An R program to compute \( Q_{p;1-\alpha}^* \) along with a help file is posted at www.ucs.louisiana.edu/~kxx4695.

**The signed likelihood ratio test.** The signed likelihood ratio test (SLRT) is equivalent to the usual likelihood ratio test. In addition to the MLEs \( \hat{\mu} \) and \( \hat{\sigma} \), it requires the MLE of the parameters computed under the constraint specified in the null hypothesis in equation (3). Since \( H_0 \) states that \( \mu + z_p \sigma = \xi_p^0 \), we have \( \mu = \xi_p^0 - z_p \sigma \). In other words, under \( H_0 \), we only need to compute the MLE of \( \sigma \), say, \( \sigma_{\xi_p^0}^0 \), and the MLE of \( \mu \) (under \( H_0 \)) is then given by \( \mu_{\xi_p^0} = \xi_p^0 - z_p \sigma_{\xi_p^0}^0 \). The MLE \( \sigma_{\xi_p^0}^2 \) of \( \sigma \) is referred to as its constrained MLE since it is obtained under the constraint specified in \( H_0 \). It is readily verified that \( \sigma_{\xi_p^0} \) is the value of \( \sigma \) that maximizes the log-likelihood function

\[
I(\xi_p^0, \sigma^2) = \sum_{i=1}^{k} m_i \ln \Phi \left( \frac{z_{\xi_p^0}}{\sigma} \right) - (n - m) \ln (\sigma) - \frac{n - m}{2\sigma^2} \left( \bar{S}_d^2 + \left( \bar{x}_d - \xi_p^0 + z_p \sigma \right)^2 \right), \tag{11}
\]

where \( z_{\xi_p^0} = \frac{\ln DL_i - \xi_p^0}{\sigma} + z_p \), and \( \bar{S}_d \) and \( S_d^2 \) are the observed values of \( \bar{x}_d \) and \( S_d^2 \), respectively, defined in equation (1). Computational details on the constrained MLE can be found in a study by K. Krishnamoorthy, T. Mathew and Z. Xu (unpublished data).

Let \( \hat{\sigma}_{\xi_p^0}^2 \) denote the constrained MLE of \( \sigma^2 \) specified above and let \( \hat{\xi}_p = \hat{\mu} + z_p \hat{\sigma} \). The SLRT statistic is written as

\[
R_p = \text{sign}(\hat{\xi}_p - \xi_p^0) \left[ 2 \left( I(\hat{\xi}_p, \hat{\sigma}^2) - I(\xi_p^0, \hat{\sigma}_{\xi_p^0}^2) \right) \right]^{1/2}, \tag{12}
\]

where \( \text{sign}(x) = 1 \) if \( x > 0 \), and \( -1 \) otherwise. The above SLRT statistic \( R_p \) follows the standard normal distribution asymptotically. This is a large sample result and the simulation study by K. Krishnamoorthy, T. Mathew and Z. Xu (unpublished data) indicated that the SLRT based on this large sample, normal approximation is not satisfactory even for large samples. Alternatively, as argued in a study by Krishnamoorthy and Xu (2011), we can estimate the percentiles of \( R_p \) using simulated samples from the standard normal distribution; see Algorithm 2 given below. Let \( R_{p;\alpha}^* \) denote the 100\( \alpha \) percentile of the distribution of \( R_p \) so obtained, when \( \hat{\xi}_p = \xi_p^0 \). The SLRT rejects \( H_0 \) in equation (3) when \( R_p < R_{p;\alpha}^* \). The power of the SLRT is given by

\[
P(R_p < R_{p;\alpha}^*), \tag{13}
\]

where \( R_p \) in equation (12) is a function of the MLEs \( \hat{\mu} \) and \( \hat{\sigma} \) and the constrained MLE \( \hat{\sigma}_{\xi_p^0}^2 \) based on a random sample from the \( N(\mu, \sigma^2) \) distribution. The percentile \( R_{p;\alpha}^* \) can be estimated using the following algorithm.

Algorithm 2. For a given sample of size \( n \) with DLs \( DL_1, \ldots, DL_k \), let \( n_i \) denote the size of the sample analyzed by the \( i \)th laboratory, \( i = 1, \ldots, k \) so that \( \sum_{i=1}^{k} n_i = n \), where we also note that \( n_i \geq m_i \) for each \( i \).
1. Compute the MLEs $\hat{\mu}$, $\hat{\sigma}^2$ and for a given $\xi_p^0$, compute the constrained MLE $\hat{\sigma}^2_{\xi_p^0}$, we refer to K. Krishnamoorthy, T. Mathew and Z. Xu (unpublished data) for details regarding the computation of these. Set $\hat{\mu}_0 = \xi_p^0 - \hat{z}_p \hat{\sigma}$. 
2. Generate a sample of size $n$, from $N\left(\hat{\mu}_0, \hat{\sigma}^2_{\xi_p^0}\right)$, 
3. Discard the observations from the $i$ th sample, which are less than $\ln DL_{i}$, $i=1,\ldots,k$. Let $m_i$ denote the number of observations below $\ln DL_{i}$, $i=1,\ldots,k$, so that $m = \sum_i m_i$.
4. Based on the sample in step 3, compute the MLEs $\hat{\mu}$ and $\hat{\sigma}^2$ by maximizing equation (2) and the constrained MLE $\hat{\sigma}^2_{\xi_p}$ by maximizing equation (11).
5. Compute $R = \text{sign}\left(\xi_p - \xi_p^0\right)2\left(l\left(\xi_p, \hat{\sigma}^2\right) - l\left(\xi_p, \hat{\sigma}^2_{\xi_p}\right)\right)^{1/2}$, where $\xi_p = \hat{\mu} + z_p \hat{\sigma}$.
6. Repeat steps 1–4 for a large number of times, say, $M$.
7. The $100\alpha$ percentile of these $10\,000$ $R^*$ is an estimate of $R^*_{p,\alpha}$ defined in equation (13).

TYPE 1 ERROR AND POWER STUDIES

The power of the pivotal test is given by

$$P \left( \frac{\xi_p - \hat{\mu}}{\hat{\sigma}} > Q^*_{p,1-\alpha} \right)$$

where $\hat{\mu}$ and $\hat{\sigma}$ are the MLEs based on a random sample from the $N(\mu, \sigma^2)$ distribution, and $Q^*_{p,1-\alpha}$ is defined below equation (9). Following the arguments of Krishnamoorthy and Xu (2011), the power function can be expressed as

$$P \left( \frac{\xi_p - \hat{\mu}}{\hat{\sigma}} > Q^*_{p,1-\alpha} \right) = P \left( \frac{\hat{\sigma} + \hat{z}_p - \hat{\mu}}{\hat{\sigma}^*} > Q^*_{p,1-\alpha} \right)$$

(14)

where $\hat{\sigma}^*$ is defined in equation (7) and $\left(\hat{\mu}^*, \hat{\sigma}^*\right)$ is as defined in equation (8). It is clear from the power function in equation (14) that the power of the pivotal test depends on the parameters only via $\hat{\sigma}^* = \left(\xi_p^0 - \hat{z}_p\right)/\hat{\sigma}$. However, it is difficult to derive the power function explicitly and simulation studies should be carried out to understand its power properties. The powers of the pivotal test can be estimated using the following algorithm.

Algorithm 3. For given values of $(n, p, \alpha, DL_1, \ldots, DL_k, \delta, \hat{\sigma}, \xi_p^0, \sigma)$:

1. Calculate $z_p$ and $\mu = \xi_p^0 - (\delta^* + \hat{z}_p)\sigma$.
2. Generate a sample of size $n$ from a $N(\mu, \sigma^2)$ distribution with DLs $\ln DL_1, \ldots, \ln DL_k$.
3. Compute the MLEs $\hat{\mu}$ and $\hat{\sigma}$ based on the sample in step 2 and set $Q^*_p = (\xi_p^0 - \hat{\mu})/\hat{\sigma}$.
4. Set $DL^*_i = \ln DL_i - \hat{\mu}/\hat{\sigma}$, $i=1,\ldots,k$ . Use Algorithm 1 with $(\hat{\mu}, \hat{\sigma}, DL^*_i)$ and $M = 5000$ runs to find $Q^*_{p,1-\alpha}$.
5. Repeat steps 2–4 for $N$ times.
6. The percentage of these $N Q^*_p$ s that are greater than $Q^*_{p,1-\alpha}$ is an estimate of the exact power on the left-hand side of equation (14).

The powers of the SLRT can be estimated using an algorithm similar to Algorithm 3. Note that the power calculation in Algorithm 3 involves a total of $M \times N$ simulation runs. Based on our experience, $M = 2500$ and $N = 5000$ would produce reasonably accurate estimates of the power. However, Algorithm 3 with these choices of $M$ and $N$ involves $2500 \times 5000 = 17\,500\,000$ runs so it could be very time consuming. An alternative calculation based on the approximation in equation (14) is much faster and is described in Algorithm 4.

Algorithm 4. For given values of $(n, p, \alpha, DL_1, \ldots, DL_k, \delta, \xi_p^0, \sigma)$:

1. Calculate $z_p$ and $\mu = \xi_p^0 - (\delta^* + \hat{z}_p)\sigma$ and set $\text{DL}_i^* = \ln DL_i - \hat{\mu}/\sigma$, $i=1,\ldots,k$ .
2. Generate a sample of size $n$ from a $N(0,1)$ distribution with DLs $\text{DL}_1^*, \ldots, \text{DL}_k^*$.
3. Compute the MLEs $\hat{\mu}^*$ and $\hat{\sigma}^*$ based on the generated sample in step 2. Set $Q^*_p = (\xi_p^0 - \hat{\mu})/\hat{\sigma}$ and $Q = (\delta^* + \hat{z}_p - \hat{\mu})/\hat{\sigma}$.
4. Repeat steps 2 and 3 for $10\,000$ times.
5. Find the $100(1-\alpha)$ percentile of $10\,000$ $Q^*_p$ s, and call it $Q^*_{p,1-\alpha}$. The percentage of these $10\,000$ $Q$ s that are greater than $Q^*_{p,1-\alpha}$ is an estimate of the approximate power on the right-hand side of equation (14).

Note that Algorithm 4 involves only $10\,000$ runs so it is much less time consuming than Algorithm 3. Furthermore, our extensive simulation studies indicated that the results based on Algorithms 3 and 4 are very similar. Therefore, we shall use Algorithm 4 for power calculation in the sequel.
Table 1. Type I error rates and powers of the pivotal test and the SLRT (in parentheses) for $H_0: \xi_{0.95} \geq \xi_{0.95}$ versus $H_a: \xi_{0.95} < \xi_{0.95}$ as a function of $(\mu, \sigma)$ at 5% significance level, two DLs.

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<thead>
<tr>
<th>Type I error rates when $\xi_{0.95} = 2$, $\mu = \xi_{0.95} - \sigma (\delta + z_{0.95})$, $\delta^* = (\xi_{0.95} - \xi_{0.95})/\sigma = 0$</th>
<th>(n = 10)</th>
<th>(n = 20)</th>
<th>(n = 30)</th>
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<tbody>
<tr>
<td>$(p_1, p_2)$</td>
<td>$\sigma$</td>
<td>$\sigma$</td>
<td>$\sigma$</td>
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<tr>
<td>0.5</td>
<td>1</td>
<td>1.5</td>
<td>0.5</td>
</tr>
<tr>
<td>(0.2,0.3)</td>
<td>0.05(0.05)</td>
<td>0.05(0.05)</td>
<td>0.05(0.05)</td>
</tr>
<tr>
<td>(0.3,0.4)</td>
<td>0.05(0.05)</td>
<td>0.05(0.05)</td>
<td>0.05(0.05)</td>
</tr>
<tr>
<td>(0.3,0.5)</td>
<td>0.05(0.05)</td>
<td>0.05(0.05)</td>
<td>0.05(0.05)</td>
</tr>
<tr>
<td>(0.5,0.6)</td>
<td>0.05(0.05)</td>
<td>0.05(0.05)</td>
<td>0.05(0.05)</td>
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<tr>
<td>(0.7,0.8)</td>
<td>0.06(0.05)</td>
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<td>0.05(0.06)</td>
</tr>
<tr>
<td>Uncensored</td>
<td>0.05</td>
<td>0.05</td>
<td>0.05</td>
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Powers when $\xi_{0.95} = 2$, $\mu = \xi_{0.95} - \sigma (\delta + z_{0.95})$, $\delta^* = (\xi_{0.95} - \xi_{0.95})/\sigma = 1$

<table>
<thead>
<tr>
<th>(p_1, p_2)</th>
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<th>(n = 20)</th>
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<tr>
<td>$(\mu, \sigma)$</td>
<td>$\sigma$</td>
<td>$\sigma$</td>
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<tr>
<td>0.5</td>
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<tr>
<td>(0.2,0.3)</td>
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<td>0.36(0.37)</td>
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<tr>
<td>(0.3,0.4)</td>
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<td>0.32(0.34)</td>
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<tr>
<td>(0.3,0.5)</td>
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<td>0.32(0.31)</td>
</tr>
<tr>
<td>(0.5,0.6)</td>
<td>0.27(0.27)</td>
<td>0.26(0.27)</td>
<td>0.27(0.28)</td>
</tr>
<tr>
<td>(0.7,0.8)</td>
<td>0.28(0.27)</td>
<td>0.27(0.28)</td>
<td>0.28(0.27)</td>
</tr>
<tr>
<td>Uncensored</td>
<td>0.41</td>
<td>0.41</td>
<td>0.41</td>
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</tbody>
</table>

Powers when $\xi_{0.95} = 3$, $\mu = \xi_{0.95} - \sigma (\delta + z_{0.95})$, $\delta^* = (\xi_{0.95} - \xi_{0.95})/\sigma = 1$

<table>
<thead>
<tr>
<th>(p_1, p_2)</th>
<th>(n = 10)</th>
<th>(n = 20)</th>
<th>(n = 30)</th>
</tr>
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<tbody>
<tr>
<td>$\mu$</td>
<td>$\mu$</td>
<td>$\mu$</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>2.5</td>
<td>1</td>
</tr>
<tr>
<td>(0.2,0.3)</td>
<td>0.35(0.35)</td>
<td>0.36(0.35)</td>
<td>0.35(0.36)</td>
</tr>
<tr>
<td>(0.3,0.4)</td>
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<td>0.34(0.35)</td>
</tr>
<tr>
<td>(0.3,0.5)</td>
<td>0.33(0.32)</td>
<td>0.31(0.33)</td>
<td>0.31(0.32)</td>
</tr>
<tr>
<td>(0.5,0.6)</td>
<td>0.25(0.28)</td>
<td>0.28(0.28)</td>
<td>0.27(0.29)</td>
</tr>
<tr>
<td>(0.7,0.8)</td>
<td>0.28(0.25)</td>
<td>0.27(0.26)</td>
<td>0.29(0.26)</td>
</tr>
<tr>
<td>Uncensored</td>
<td>0.41</td>
<td>0.41</td>
<td>0.41</td>
</tr>
</tbody>
</table>

$\xi_{0.95}$, true unknown 95th percentile to be tested; $\xi_{0.95}^{\text{spec}}$ specified value of the 95th percentile; $p_i$, proportion of non-detects below DL; $\ln DL_i = \mu + z_{0.9} \sigma$; uncensored: sample with no non-detects, i.e., $(p_1, p_2) = (0, 0)$; $z_{0.95}$, 95th percentile of a standard normal.
It should also be noted that the powers become equal to the type I error rates when \( \delta^* = (\xi_{p}^* - \bar{\xi}_{p}) / \sigma = 0 \). In order to compare the type I error rates of the pivotal test and the SLRT, we estimated the type I error rates of both tests and reported them in the first part of Table 1 for sample sizes 10, 20, and 30, with two DLs, as indicated in Table 1. Estimated type I error rates in Table 1 are very close to the nominal level 0.05 for all the cases considered, which indicate that both tests control the type I error rates very satisfactorily.

We estimated the powers of the pivotal test and the SLRT using Algorithm 4 and presented them in Table 1. For convenience and ease of tabulation, we presented the powers after specifying values for the proportions of non-detects \( p_1, \ldots, p_k \). Recall that DLs and \( p_i \) are related through the equation \( \ln DL_i = \mu + z_{p_i} \sigma, i = 1, \ldots, k \). The powers were estimated as a function of \( (\mu, \sigma) \) while \( \delta^* = (\xi_{p} - \bar{\xi}_{p}) / \sigma \) is fixed. Note that for a fixed \( \delta^* \), \( \mu = \bar{\xi}_{p} - (\delta^* + z_{p}) \sigma \). We computed the powers for different values of \( \sigma \) while \( \delta^* \) is fixed at the value 1 and \( \xi_{p}^* = 2 \), and presented them in the second part of Table 1. Examination of powers clearly indicate that the powers of the SLRT do not depend on individual values of \( \sigma \) and \( \mu \) (that produce \( \delta^* = 1 \)). Specifically, we see that when \( (p_1, p_2) = (0.2, 0.3) \), \( n = 10 \), \( \xi_{p}^* = 2 \), and \( \delta^* = 1 \), the powers for various values of \( \sigma \) are approximately the same. These small differences among the powers for various values of \( \sigma \), while \( p_i \) s and \( \delta^* \) are fixed, could be due to simulation errors. The values in the third part of Table 1 are the estimated powers at \( \xi_{p}^* = 3 \) and \( \delta^* = 1 \). We once again note that the powers in the third part of Table 1 are close to the corresponding ones in the second part; see, for example, the powers in the row corresponding to \( (p_1, p_2) = (0.7, 0.8) \) in the second part and those in the third part of Table 1. Thus, it is clear that for a fixed \( n, (p_1, p_2), \alpha \), the powers of both tests are comparable and they depend on the parameters only via \( \delta^* = (\xi_{p}^* - \bar{\xi}_{p}) / \sigma \).

Here, we would like to point out that the missing mechanism when DLs are present is ‘missing at random’ and not ‘missing completely at random’; the latter scenario results in a reduced sample size consisting of uncensored data. How does the powers of the tests compared when we have reduced number of observations resulting from the presence of DLs and that resulting from data missing completely at random? Such a power comparison can be done using the power values reported in Table 1. For example, consider a sample of size 20 with two DLs and \((p_1, p_2) = (0.5, 0.6) \). Then, the expected number of non-detects is 11 and the expected number of detected observations is 9 in the sample. The power values in such a scenario will be larger compared with that based on an uncensored sample of size 9. This should be clear by comparing the power values in Table 1 corresponding to an uncensored sample of size 10 (we did not compute them for a sample of size 9). We notice that an uncensored sample of size 10 gives a smaller power compared with a sample of size 20 with two DLs and \((p_1, p_2) = (0.5, 0.6) \). The conclusion is that data missing at random due to the presence of DLs is more informative than data missing completely at random.

**SAMPLE-SIZE CALCULATION**

We shall now address sample-size determination in the context of testing the hypotheses in equation (3). The problem is of practical relevance since it is important to know if increased sample size is necessary due to the presence of DLs and if so by how much. We first note that although the pivotal test and the SLRT are comparable in terms of type I error rates and powers, the pivotal test has an edge over the SLRT because the former does not require additional computation of the constrained MLE of \( \sigma^2 \). Therefore, we shall describe the sample-size calculation only for the pivotal test. As noted earlier, the power of the pivotal test depends only on \( \delta^* \) and not on the individual values that make up \( \delta^* \) or \( \xi_{p}^* \). Thus, it is enough to calculate the sample sizes for various values of \( \delta^* \) and the proportions of non-detects.

In Table 2, sample sizes are given when one, two, or three DLs are anticipated in the sample. These sample sizes were calculated to attain a power close to 0.80 and 0.90 for testing if the 95th percentile of an exposure distribution is less than a specified value, when the test is carried out at a level of 5%. As the sample size for the censored case must be larger than the one for the uncensored case, we first computed the sample size required for the uncensored case using equation (6). Using this sample size as a starting value, we found the required sample size for the censored case by trial-error method; more details with an illustrative example are given in the next section. We observe from Table 2 that the sample size to attain the specified power increases with increasing proportion(s) of non-detects and decreases with increasing scaled difference \( \delta^* \).
Finally, an important observation from Table 2 is that the sample size is mainly affected by the overall percentage of non-detects and not by the number of DLs. For instance, we see from Table 2 that when \( (p_1, p_2) = (0.3, 0.4, 0.5) \) so that the average proportion of non-detects is 0.4, the required sample sizes to attain a power of 0.80 (or 0.90) are approximately the same as those corresponding to a single DL and proportion of non-detects \( p_1 = 0.4 \); see the values in Table 2 under ‘single DL’, \( p_1 = 0.4 \) and power = 0.80 (or 0.90). These sample sizes are also approximately the same as the ones for the case of two DLs with \( (p_1, p_2) = (0.3, 0.5) \) so that the average proportion of non-detects is once again 0.4. Similarly, by comparing the sample sizes for \( (p_1, p_2, p_3) = (0.6, 0.7, 0.8) \) with the corresponding ones for \( p_1 = 0.7 \) (in single DL case), we see that the sample sizes to attain a specified power is mainly affected by the overall percentage of non-detects. This finding suggests that information on the overall percentage of non-detects is enough to determine the sample size to attain a specified power; see also the illustrative example in the next section.

In view of the above findings, we calculated sample sizes required to attain powers 0.80 and 0.90 for various values of scaled difference \( \delta^* \) ranging from 0.5 to 2.2 and overall proportion of non-detects denoted by \( p_1 \), ranging from 0 to 0.85. Note that the uncensored case corresponds to \( p_1 = 0 \). These sample sizes are reported in Table 3 for power 0.80 and in Table 4 for power 0.90. As an illustration, suppose it is desired to determine the sample size to attain a power of 0.80 when \( \delta^* = 1.1 \) and the overall proportion of non-detects is 0.45; the required sample size is 28. If no non-detected is anticipated, then the required sample size is 20.
Remark 2. Obviously, the power should decrease as the percentage of non-detects increases. Specifically, the power of the test based on a sample of size \( n = 30 \) with proportion of non-detects \( p = 0.20 \) should be larger than the power based on \( n = 30 \) and \( p = 0.50 \). However, the relationship between the power and the censoring intensity is not obvious. For example, we observe from Table 3 that an uncensored sample of size \( n = 9 \) is required to attain a power of 0.80 when \( \delta^* = 2 \). If a sample is expected to include about 85% non-detects, then for the same \( \delta^* = 2 \), a sample of size 23 is required to attain the power of 0.80. Note that a sample of size 23 with \( p = 0.85 \) is expected to include only \((1 - 0.85) \times 23 = 3\) detected observations, not 9. This implies that our testing method utilizes the information provided by the values of the DLs and the number of non-detects.

**AN ILLUSTRATIVE EXAMPLE**

We shall now illustrate the sample-size methodology that we have developed by considering the assessment of carbon monoxide levels at a
workplace. The Occupational Safety and Health Administration permissible exposure limit for carbon monoxide is 50 p.p.m. It is desired to test if the 95th percentile of the contaminant distribution is indeed less than 50 p.p.m. In the notations of this study, the hypotheses of interest are

$$H_0 : \xi_{0.95} \leq \xi_{0.95}^0$$ versus $$H_a : \xi_{0.95} > \xi_{0.95}^0,$$ (15)

where $$\xi_{0.95}$$ is the true log-transformed 95th percentile of the contaminant distribution in the workplace and $$\xi_{0.95}^0 = \ln(50) = 3.912$$. An industrial hygienist, based on his preliminary inspection, guesstimates that the 95th percentile of the concentration distribution in his workplace is around 20 p.p.m.; that is, $$\xi_{0.95} = \ln(20)$$. It is desired to determine the sample size so that the test would reject $$H_0$$ in equation (15) with probability (power) 0.90, when the true 95th percentile is 20 p.p.m. On the basis of past data or based on data from a similar workplace, suppose the value of the geometric standard deviation is guessed to be 2.015 p.p.m. Then from equation (7),

<table>
<thead>
<tr>
<th>$p_a$</th>
<th>$\delta = (\xi_{0.95} - \xi_{0.95}^0) / \sigma$</th>
</tr>
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<tr>
<td>0.5</td>
<td>0.99 71 55 44 36 30 26 23 20 18 17 15 14 12 11 10</td>
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<tr>
<td>0.6</td>
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<td>0.7</td>
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<tr>
<td>0.8</td>
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<td>0.9</td>
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<td>0.400 96 78 55 36 31 27 24 22 20 18 16 14 13 12 11</td>
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<td>0.650 111 93 70 41 36 32 29 26 24 22 20 18 16 14 12</td>
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<td>1.9</td>
<td>0.700 114 96 73 42 37 33 30 27 25 23 21 19 18 16 12</td>
</tr>
<tr>
<td>2.0</td>
<td>0.750 117 99 76 43 38 34 31 28 26 24 22 20 18 16 12</td>
</tr>
<tr>
<td>2.1</td>
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</tr>
<tr>
<td>2.2</td>
<td>0.850 123 105 83 45 40 36 33 31 28 26 24 22 20 18 12</td>
</tr>
</tbody>
</table>

$\xi_{0.95}$, true unknown 95th percentile to be tested; $\xi_{0.95}^0$, specified value of the 95th percentile; $p_a$, overall proportion of non-detects.
\[ \delta = \frac{\phi - \xi}{\sigma} = \frac{(\ln(50) - \ln(20))}{\ln(2.015)} = 1.309. \]

Since we are computing the power at the value \( \xi_{0.95} = \ln(20) \), the value of \( \mu \) is \( \mu = \ln(20) - 0.95z \), \( \sigma = \ln(20) - 1.645 \times \ln(2.015) = 1.8485 \). In other words, the power is to be calculated at the parameter values \( \xi_{0.95} = \ln(20), \sigma = \ln(2.015) \), or equivalently, \( \mu = 1.8485, \sigma = \ln(2.015) = 0.701 \).

For this particular example, if no non-detect is expected, then the required sample size \( n \) is determined by the equation (6):

\[ P \left( t_{n-1} \left( 2.954\sqrt{n} \right) > t_{n-1,0.95} \left( 1.645\sqrt{n} \right) \right) = 0.90. \]

The power at \( n = 18 \) is 0.867; at \( n = 19 \), it is 0.887; and at \( n = 20 \), it is 0.904. So if no non-detect is expected, then the required sample size to attain the power of 0.90 is 20.

Suppose the samples will be analyzed by three laboratory methods or devices with the DLs \( \ln DL_1, \ln DL_2, \ln DL_3 = (1.3, 1.5, 1.7) \). Then, the sample sizes and powers can be calculated using Algorithm 4 as shown below.

1. Assume a value for \( n \) that is at least 20, say 21. Recall that \( \sigma = 0.701, \mu = 1.8485, z_{0.95} = 1.645, \) and \( \delta^* = 1.309 \).
2. Use Algorithm 4 with

\[ DL_1^* = \frac{\ln DL_1^* - \mu}{\sigma} = \frac{1.3 - 1.844}{0.701} = -0.7776, \]
\[ DL_2^* = \frac{\ln 1.5 - 1.844}{0.701} = 0.4919, \text{ and} \]
\[ DL_3^* = \frac{\ln 1.7 - 1.844}{0.701} = -0.2062 \text{ to compute the power.} \]
3. Repeat step 2 by increasing sample size by 1 unit at a time, until the power becomes close to 0.90.

Our calculation based on Algorithm 4 with 10,000 simulation runs produced the results as given in Table 5. We see from Table 5 that a sample of size 25 would be enough to attain a power of 0.90. An R program for calculating sample size is posted at www.ucs.louisiana.edu/~kxk4695.

The sample size for the above problem can also be obtained from Table 4 as follows. Note that proportion of non-detects from the laboratory 1 is \( p_1 = \Phi \left( \frac{1.3 - \mu}{\sigma} \right) = 0.217 \), from laboratory 2 is \( p_2 = \Phi \left( \frac{1.5 - \mu}{\sigma} \right) = 0.310 \), and from laboratory 3 is \( p_3 = \Phi \left( \frac{1.7 - \mu}{\sigma} \right) = 0.416 \). The average of these proportions is 0.314. Referring to Table 4 with \( \delta^* = 1.309 \) and \( p_a = 0.314 = 0.3 \), we find the sample size to be 24. If we take \( p_a = 0.314 = 0.325 \), then the sample size is 26. Thus, we see that a sample of size 25 is required to attain a power close to 0.90.

### DISCUSSION

Proper analysis of exposure data is crucial for setting exposure limits and for drawing valid conclusions regarding the exposure levels. In this context, one of the complicating issues is the presence of DLs. Standard results based on large sample theory are usually not applicable here since typical exposure samples are seldom large due to the cost involved in obtaining the data. Thus, accurate small sample methodology is highly desirable. In particular, it is important to determine the required sample size so as to have methodologies that guarantee a specified level of statistical accuracy. This work has been motivated by all these considerations in the context of exposure data where multiple DLs are anticipated.

If the problem of interest concerns an upper percentile of the exposure profile, then our work can be readily extended to any distribution that has one-to-one relation (at least approximately) with the normal distribution. For example, if the exposure data follow a gamma distribution, our method can be applied after taking cube root transformation of the data (see Krishnamoorthy and Xu, 2011). If an upper

<table>
<thead>
<tr>
<th>( n )</th>
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<th>22</th>
<th>23</th>
<th>24</th>
<th>25</th>
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</thead>
<tbody>
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<td>2.518</td>
<td>2.488</td>
<td>2.464</td>
<td>2.439</td>
<td>2.415</td>
</tr>
<tr>
<td>Power</td>
<td>0.845</td>
<td>0.862</td>
<td>0.877</td>
<td>0.897</td>
<td>0.907</td>
</tr>
</tbody>
</table>
percentile is below an OEL, then we can conclude that majority of the exposures are below the OEL. Consequently, it is of interest to test if the upper percentile is below the OEL. It is in this context that we have investigated the sample size issue when single or multiple DLs are present. We have developed the necessary algorithm for the sample-size determination and have also provided tables of the sample sizes. Our investigation shows that the required sample size is not affected by the number of DLs; rather, it is affected by the overall proportion of the data below the DLs.

In spite of the extensive industrial hygiene literature on the DL problem, satisfactory confidence intervals and test procedures have been lacking; in fact, it appears that sample size determination has not been addressed at all. It is hoped that this present study will be beneficial to industrial hygienists in terms of drawing their attention to accurate data analysis strategies and in terms of providing sample-size guidelines, when non-detects are to be expected due to the presence of single or multiple DLs.

**FUNDING**

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**REFERENCES**


