

# *DQO Statistics Bulletin*

Statistical Methods for the Data Quality Objectives Process

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## **Preface**

I hope you were stimulated by the discussion of ranked set sampling (RSS) in our first issue of the *DQO Statistics Bulletin* (Gilbert 1995a). This second issue begins with Nancy Hassig's highlights of two products from the DQO Training and Support Project:

- *DQO Training and Information Center on the Internet*
- *DQO Video: Software Tools Useful in Implementing the DQO Process*

Next, our feature article, written primarily by Joanne Wendelberger (Los Alamos National Laboratory), discusses statistical tools and approaches for analyzing data sets that contain nondetects. Joanne's contribution is complemented by a discussion of the need for using the DQO planning process and the Data Quality Assessment (DQA) data evaluation process when nondetects are expected to be a problem.

I am interested in receiving any comments (pro or con) you may have on this issue. Also, if you wish to contact Joanne Wendelberger, you may do so at 505-665-4840 (phone), 505-667-4470 (fax), or joanne@lanl.gov (e-mail).

Because of budget reductions at DOE, the *DQO Statistics Bulletin* is not funded beyond the current issue. Do any of you know of funding sources that might support the continued publication of the *Bulletin*? If so, please give me a call.

-- Richard O. Gilbert, bulletin manager

## **DQO Training and Support Project Highlights**

*DQO Training and Information Center on the Internet*

A DQO Home Page on the Internet has been established so that you can obtain more information about the DQO process. The Home Page contains a wide variety of multimedia material on training, case study results, topical papers, and downloadable software. The Home Page can be accessed using any web browser such as Netscape or Mosaic. The URL is

<http://terrassa.pnl.gov:2080/DQO/home.html>

Note that "DQO" are the only letters that are capitalized. This Home Page is supported by DOE's Laboratory Management Division and is on a server at the Pacific Northwest National Laboratory in Richland, Washington.

## *DQO Video: Software Tools Useful in Implementing the DQO Process*

A 23-minute video gives an introduction to three software tools that can be useful in implementing Step 7 of the DQO process: Optimize the Sampling Design. The tools presented have logic for calculating a sample size or grid spacing based on user-supplied input. Key inputs include desired limits on decision errors, the way the sample data will be used to make decisions, and assumptions about the site. Users develop these inputs while working through the DQO process. The video demonstrates each of the tools using a case-study that identifies the problem, assumptions, and decisions to be made.

The *DQO Statistics Bulletin* is produced for the U.S. Department of Energy, Laboratory Management Division, EM-763, as a deliverable of the Data Quality Objectives Training and Support project. Pacific Northwest National Laboratory (PNNL) manages the project for DOE.

We encourage readers to contact us with ideas, questions, comments, and article contributions.

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The three software-tool case-study combinations are

- cadmium-contaminated fly ash waste using DEFT (Decision Evaluation Feasibility Trials) software

This case study is taken from Appendix B of USEPA (1994a). The DEFT software was developed by EPA Quality Assurance Division; contact John Warren at (202) 260-9464.

- Waterville Municipal Landfill Superfund Site using POWER software

This case study is from Appendix II of USEPA (1993). The software code, *Statistical POWER Analysis: A Computer Program* (ISBN-008-8), was developed by Borenstein and Cohen (1988) for the National Institutes of Mental Health through the Small Business Innovative Research Program. It is available from Lawrence Erlbaum Associates, Inc., at 201- 666-4110 (phone).

- Leadbury Superfund Site with ELIPGRID-PC software

This case study is from Appendix II of USEPA (1993). The *ELIPGRID-PC* software was developed by Jim Davidson, Oak Ridge National Laboratory, Grand Junction, for the U.S. Department of Energy. Contact Jim at 303-248-6259 to obtain a copy of the software and the accompanying report (Davidson 1995).

*Feature article:*

## **NONDETECTS: PLANNING AND STATISTICAL ANALYSES TO MITIGATE THEIR EFFECTS**

### **1.0 INTRODUCTION**

Before proceeding, some definitions will be helpful:

- *nondetects* - measurements reported by the analytical laboratory as being less than some reporting limit or some defined detection limit for individual samples
- *less-than values* - nondetects reported by the laboratory in the form of being less than the reporting or detection limit, for example, "< 1.2," where 1.2 is the detection limit for the sample
- *left-censored data sets* - data sets that contain nondetects, where nondetects are defined as above - The reference to *left* refers to the left-hand tail of the data distribution.

It is well known that many environmental data sets contain nondetects. These nondetects indicate a loss of information that create problems for decision makers when action levels (e.g., a concentration value above which remedial action is needed) are near the detection or reporting limit. The best way to mitigate this problem is to use

- the DQO process (USEPA 1993, 1994a)
- the data quality assessment (DQA) process (USEPA 1995)

- statistical analysis tools developed specifically for left-censored data sets.

### **1.1 Data Quality Objectives Process**

Before data are collected, the first step in handling data analysis problems caused by nondetects is to use the DQO planning process to determine the DQOs and the impact that nondetects could have in their achievement. If all nondetects are expected to be less than some threshold value or action level, then they may not be a critical concern. In other cases, 1) better measurement methods may be developed to reduce or eliminate nondetects in future studies; and 2) the format used by analytical laboratories to report analytical results should be reviewed and improved, if necessary, to ensure that information about the uncertainty in each measurement is documented and reported.

### **1.2 Data Quality Assessment Process**

Once data are in hand, the DQA process (USEPA 1995) is used to determine if the collected data meet the established DQOs. For example, the number of nondetects values reported may be greater than expected when the DQOs were specified, or the laboratory reporting procedures may not meet requirements. If there are too many nondetects, it may not be possible to achieve the tolerable limits on decision errors that were specified by decision makers in Step 6 of the DQO process. Changes to the sampling plan and/or laboratory measurement and reporting procedures may then be required.

### **1.3 Statistical Analysis**

The statistician, as a member of the study team implementing the DQO/DQA processes, will provide guidance on which statistical tools should be used to analyze data sets that contain nondetects. The goal is to use statistical tools that use all the information contained in the entire data set, including the nondetects. (Yes, nondetects do

contain some information.) This approach provides the decision maker with maximum information for making correct data-driven decisions.

Many papers that discuss the statistical analysis of censored data sets have appeared in the statistical literature. Many ideas in these papers can be applied, sometimes with modifications, to environmental left-censored data sets (see, for example, Akritas et al. 1994; Helsel and Hirsch 1992; Atwood et al. 1991; Millard and Deverel 1988), as discussed in Sections 4 through 6 below.

## 2.0 Detection Limits

When chemical analyses of environmental samples are conducted, measured values may fall below some specified limit. In this case, the analytical laboratory often reports measurement results as being less than the limit of detection. The detection limit may be either an actual instrument or measurement detection limit, or a reporting limit the laboratory uses. Detection limits have been defined in different ways by different authors for different analytical methods and in different situations. Limits may or may not have a statistical basis. Detection limits may vary for sample and reference (background) data sets or even for individual observations. Gibbons (1994) describes and critiques methods for computing the method detection limit. His criticisms of the method by Glaser et al. (1981) are of particular interest, as that method appears to be the basis of the method in 10 CFR 136, Appendix B.

An important step in determining how to handle nondetects is to understand the type of detection limit being used. Many different definitions of nondetect values appear in the scientific literature (Currie 1984, 1968). In addition, there is a lack of standardization regarding the time period, number of samples, technicians, instruments and laboratories for which samples should be analyzed to determine the variance in the analysis method. This variance is

a key parameter in determining the detection limit and other limits. The lack of standardization should be addressed during the DQO process.

In actual practice, the exact nature of the nondetect values may be unknown. In this case, the analyst knows only that the measured value is less than or equal to the specified detection limit. USEPA (1989b, 1992a, 1992b) describes some of the types of nondetect values that can occur with analytical data and makes some limited suggestions about how to treat this type of data.

We note that Clark and Whitfield (1994) review the sources of uncertainty in environmental data and the conceptual basis of various limits of detection. They recommend a procedure for reporting laboratory analysis results when nondetects are present. Their paper provides a useful perspective on issues discussed in this Bulletin.

## 3.0 Examples of Left-Censored Data Sets

Table 1 shows two cesium-137 ( $^{137}\text{Cs}$ ) data sets that contain less-than values. These data are part of larger data sets collected at a study site and a background area at the Los Alamos National Laboratory by staff of the Environmental Restoration Program during site assessment activities. At the time these data were collected, a screening level of 4 picocuries per gram (pCi/g) was being used as an upper bound on acceptable levels of  $^{137}\text{Cs}$ . The detection limits are well below the screening level, so the data are adequate for this type of screening comparison.

In addition to comparing data to fixed screening levels, comparisons are frequently made to data from a relevant background area. In Table 1, the detection limits of background data are generally lower than the detection limits for the contaminated site data. Also, there tends to be a

**Table 1.** <sup>137</sup>Cs Site and Background Data

Site, pCi/g				Background, pCi/g			
<0.05	<0.10	<0.21	<0.21	0.08	0.08	0.11	0.09
<0.09	<0.15	<0.09	<0.16	0.14	0.16	0.20	0.18
<0.15	<0.23	<0.11	0.33	0.12	0.09	0.06	0.09
0.36	1.28	1.22	0.43	0.28	0.13	0.17	0.40
0.40	0.30	0.43	0.30	<0.01	0.15	0.12	0.10
0.26	<0.14	9.72	0.65	0.23	0.17	0.38	<0.02
0.75	<0.11	<0.12	<0.12	0.28	<0.05	0.03	0.05

lower frequency of nondetects in the background data set than in the site data set. These phenomena suggest there may have been differences in the analytical processes and censoring mechanisms for the two data sets. This, in turn, raises questions about how to conduct a statistically defensible comparison of the site and background data.

The potential for obtaining less-than values during the data collection process leads to many important questions. Examples include

- How will nondetects be handled if a comparison to a fixed value is required? (See Section 4.3.)
- How will two different populations be compared? (See Section 4.4.)
- How will risk assessment calculations be performed in the presence of nondetects? (See Section 4.5.)
- How will trend analyses or spatial analyses be affected by nondetects? (See Section 4.6.)

During the DQO process, investigators must clearly state the problem at hand and identify the decision that must be made. After identifying important factors and defining the study domain, the stakeholders and investigators develop a decision rule and specify uncertainty limits. This uncertainty assessment should address the possibility of obtaining nondetect values.

Selection of a design for collecting data (Step 7 of the DQO process) must consider the anticipated detection limits of different measurement methods that might be used and whether a decision can be made from the resulting data. Historical information may be useful for determining the likely range of values that will be encountered. Detection limits may vary depending on the concentration levels encountered because of factors such as dilution ratios required to perform the analyses. Stakeholders and planning team members must take care to ensure that the methods selected will yield data with appropriate detection limits for the decision of interest.

## 4.0 Statistical Methods for Data Sets Containing Less-Than Values

There are two general approaches to statistically analyzing data sets that contain less-than values:

- Replace each less-than value with a substitute (replacement) value.
- Employ statistical techniques that can handle less-than data in some acceptable way.

A commonly used replacement method is to replace each less-than value with half the detection limit for that sample. Other commonly used replacement values are zero or the detection limit itself. Also, if there are several less-than values with the same detection limit, the values might be evenly spaced between 0 and the detection limit or according to some specified probability distribution such as a normal or log-normal distribution. Each method has the potential for introducing bias into the statistical data analysis results, which could lead to inappropriate decisions by decision makers.

The second approach—employing statistical techniques that can handle data sets with less-than values—is generally preferred over the use of replacement values. Techniques used in this second approach are discussed below.

### 4.1 Data Summaries

Environmental investigations can result in the collection of large volumes of chemical analysis data. A single environmental sample may be subdivided and analyzed for hundreds of different radiological or chemical constituents. Depending on the size of the site under investigation, the number of samples collected may range from less than 10 to several hundred.

An important step in the statistical analysis of large data sets is to summarize or "describe" the data. The presence of less-than values can make this a nontrivial task. Indeed, the numerical value of sample (descriptive) statistics such as the mean, median, standard deviation, maximum, and minimum can be misleading when less-than values are present.

As USEPA (1989b) urges,

*"Do not simply omit the nondetected results..."*

Clearly, omission of less-than values (or more generally, nondetects) can seriously bias summary statistics computed from the data. To convey meaningful information, the summary must meet at least one of three criteria:

- Provide separate information for detected data and less-than values.
- Follow a specified procedure for replacing less-than values with proxy values prior to computing sample statistics.
- Use statistical techniques to provide estimates of sample quantities based on the full data set (detects and nondetects).

The method of handling nondetects may also depend on what type of constituent is being examined. When a number of closely related constituents are being considered, the replacement of nondetects may be achieved from a multiple constituent standpoint. For example, one method proposed for polycyclic aromatic hydrocarbons (PAHs), which tend to occur together, is to set all nondetects to zero if there are no detected PAHs in a given sample, and to set all nondetects to their corresponding detection limits if one or more of the PAHs is present above a detection limit.

Data summaries and descriptive statistics for data sets containing nondetects are discussed further by Helsel (1990) and Helsel and Cohn (1988).

## 4.2 Estimation

Typically, statistical estimation in the environmental setting involves estimating sample statistics (such as the mean, standard deviation, and percentiles) using representative data from a specified population. These estimates may be needed to check for trends over time as part of a long-term monitoring program. The estimates may also be needed to make inferences using statistical tests, confidence limits, or tolerance limits.

A replacement approach (discussed on page 6) would use standard formulas to calculate sample statistics after substituting values such as zero, one half of the detection limit, or the detection limit itself for the less-than values. Most authors, including Helsel and Hirsch (1992) and Atwood et al. (1991), do not recommend using these techniques. However, Atwood et al. (1991) indicated that substitution may be appropriate when the goal is to perform tests of statistical hypotheses rather than to estimate population parameters.

Other estimation techniques have been proposed, most of which involve either maximum likelihood estimation or probability plotting techniques. So-called "robust" versions of these techniques reduce the impact of misspecification of the underlying distribution. Maximum likelihood techniques assume that the data come from a probability distribution that can be written down using a specific parametric form. Likelihood equations are then generated from the assumed probability distribution. These equations are then maximized to obtain parameter estimates. Specific estimation techniques are discussed in Gilbert (1995b) and Wendelberger (1995).

Probability plotting techniques, which are easier to use than maximum likelihood methods, are also

based on assuming that the underlying data distribution is known. The data values are plotted against the percentiles of the assumed distribution. If the assumed distribution is, in fact, correct, the data plot will be linear, and parameter estimates may then be obtained graphically from the plot. Probability plotting techniques are described in, for example, Gilbert (1987) and Ott (1995).

## 4.3 Comparisons to Fixed Values

In some cases, individual values or sample means must be compared to specified fixed levels to make a decision about whether further action is required. If the detection limit is well below the decision level, the nondetect values will have little or no impact on the decision. However, in some cases, the detection limit may be only slightly below or even above the decision level. Comparisons can be difficult in this situation.

When a simple comparison cannot be made because of the presence of nondetects, alternative evaluation methods may be used. For example, historical knowledge of the site and the frequency of detected values in the data set may be considered in making inferences. Comparisons may involve simply flagging values above allowable limits or using statistical tests to determine whether the mean or some population quantile is above the allowable limit. Exceedance criteria may be used to examine the probability of obtaining various numbers of values above a threshold value under specified assumptions about the underlying population. USEPA (1989a) describes the use of simple exceedance-based rules. See also Leadbetter (1993). Using exceedance-based rules that focus on the high values in the upper tail of the data distribution may avoid the problems encountered with analyses that require all values to be above the detection limit.

## 4.4 Comparing Populations

Nondetect values can pose an especially difficult problem when the goal is to compare two

different populations. For example, data collected from an area suspected of being contaminated might be compared to data collected from some suitable background area that is otherwise similar, but presumed to be uncontaminated. Because the values sampled from the two populations may involve different censoring mechanisms and different limits of detection, care must be taken to arrive at valid conclusions. USEPA (1994b) discusses several methods for comparing sample and reference populations and provides some advice on dealing with nondetects.

One simple approach is to apply standard parametric techniques such as the two-sample t test (Iman and Conover 1983), with nondetects replaced by substitute values. Davis (1994, p. 848) discusses comparing two populations for this replacement approach. A preferred approach may be to use nonparametric techniques. These do not depend upon assuming a specific underlying data distribution as do parametric techniques. Helsel (1987) discusses the advantages of nonparametric techniques for assessing environmental data. Some nonparametric methods can handle nondetect values directly. Others may require the replacement of nondetect values, but that replacement approach may have less impact on results than what occurs for parametric approaches. In other cases, the nonparametric techniques can handle nondetect values if certain assumptions may be made; for example, that all the nondetect values are less than all values above the detection limits.

The nonparametric Wilcoxon Rank Sum (WRS) test (Gilbert 1987; USEPA 1994b) may be used to compare data from two populations. The test is effective for detecting when the median of one population is greater than that of the other population. An example is comparing site data to background data (Table 1). The test consists of ranking the combined data from the two populations and then using the sum of the ranks from one of the populations as the test statistic. The WRS test may be modified to handle less-than values. Examples

are the Gehan test and the Peto-Prentice test, which were included in Latta's (1981) Monte Carlo study of several nonparametric approaches. Millard and Deverel (1988) used computer simulations to evaluate these two tests and several other nonparametric tests for comparing two populations when there are multiple detection limits.

Also potentially appropriate for environmental applications is a quantile test developed by Johnson et al. (1987). This method examines the upper tail behavior of two populations by computing the probability that  $k$  out of the  $n$  largest values from the combined data sets would come from one of the populations when the two populations in fact have the same distribution. This method can detect differences in the upper tails of the two distributions if the number of samples is reasonably large. In environmental applications, extreme values are often of most interest. As nondetects tend to occur in the lower (left) end of the distribution, the quantile test in Johnson et al. (1987) can be used in the presence of nondetect data, provided that the nondetect values are not among the  $n$  largest values. USEPA (1994b) shows how to use the quantile test in tandem with the WRS test to improve the chances of detecting when site concentrations are larger than background concentrations. Hardin and Gilbert (1993) used computer simulations to evaluate the performance of the quantile test relative to the WRS and other two-sample tests.

Helsel and Hirsch (1992) discuss additional data analysis methods for left-censored data sets, including the use of tobit regression and contingency table analysis for comparing or estimating relationships among populations. Contingency table analysis is particularly useful when data sets contain a large proportion of nondetects.

## 4.5 Risk Assessment

If contaminants are found at a site, a risk assessment may be performed to decide if



remediation is required. Risk assessment involves summarizing contaminant concentrations over areas called exposure units that represent physical areas of a size encountered by individuals under a given land use scenario. The risk assessment process included using sample information about average contaminant concentrations to determine whether a particular area poses a human health risk.

Because of uncertainty in estimating the average exposure to a pollutant received over time, the USEPA uses the 95% upper confidence limit (UCL) on the mean concentration in computing the intake of chemicals into the body (USEPA 1989b, pp. 6-19). To examine the impact of nondetect values on the risk assessment, consider the formula used in computing the 95% UCL on the mean of a normal distribution from a sample of size  $n$ :

$$UCL = \bar{x} + t_{0.95, n-1} s / n^{1/2}$$

where  $\bar{x}$  is the sample mean,  $s$  is the sample standard deviation, and  $t_{0.95, n-1}$  is the 95th percentile of the  $t$  distribution with  $n-1$  degrees of freedom. Replacement of nondetect values by their detection limits is generally regarded as conservative when estimating the true mean because it will provide an estimate of the true mean that is greater than or equal to the estimated mean that would be obtained if the nondetect values were replaced by actual measurements. However, this replacement method will produce a smaller than desired standard deviation. The overall impact of replacing nondetects by their detection limits will depend on the relative magnitudes of the differences in the resulting estimated mean and standard deviation from their values that result from the replacement of the nondetects. If a replacement method is used, the resulting impact on the computed UCL should be determined. If the particular replacement method used affects the computed UCL to such an extent that decisions about the site could be affected, this is a warning that additional information is needed to make the decision.

## 4.6 Trend Detection

Changes and trends over time are often important in environmental decision making. The presence of nondetect data complicates the process of looking for trends. Gillom et al. (1984) examined the effect of nondetects on the ability to detect trends. In general, nonparametric tests for trend (Gilbert 1987) are capable of handling a moderate number of nondetects.

Neerchal and Brunenmeister (1994) describe a weighted regression approach as a modification of the replacement approach. The novel aspect of this approach is that the detection limit is used as a measure of data precision. Conservative lower bounds on the precision of trend estimates are provided. Their approach incorporates application-specific information into the data analysis process, thus adding to the information typically used in estimating trends.

## 4.7 Spatial Analysis

Spatial analyses may be used to analyze data that contains location information. Kriging is one spatial averaging technique which has been applied to environmental data. Kriging has been described in detail by Cressie (1991). Cox and Piegorsch (1994) discuss the use of kriging as a method of combining data to estimate nondetect values in spatial data. An important feature of this approach is that it may be used to combine data collected at locations from different sampling schemes.

## 5.0 Alternative Approaches

Alternatives to the use of traditional detection limits have been proposed for use with environmental data. These innovative approaches try to incorporate additional information available about the data collection process and the behavior of the measurements.

Lambert et al. (1991) reexamined the detection limit problem from a new perspective. Instead of looking at fixed detection limits, they considered functions that quantify the probability of acceptance and the probability of detection. Information on the actual measured values associated with nondetect values was used to show that common reporting practices used by analytical laboratories can throw out valuable information. This approach is radically different from the typical use of detection limits and leads to different analysis needs.

Gibbons (1995) discusses a calibration approach as an alternative to estimating a method detection limit using a single concentration point design. Instead of looking at single detection limits derived from data collected at a single concentration, the calibration approach examines variability of measurements over a range of concentration values. This approach requires more information than the traditional assessment of variability at a single concentration value, but the calibration is useful over a broader concentration range.

## **6.0 Discussion and Needed Developments**

Nondetect issues considered during the DQO process should include

- developing consistent definitions and determination of detection limits among analytical laboratories
- improved data reporting procedures by analytical laboratories
- greater interaction among statisticians and laboratory personnel at early planning stages
- improved field and laboratory measurement procedures to detect smaller amounts of contaminants

- selecting appropriate statistical data analysis methods.

The selection of an appropriate statistical analysis method depends on the decision that is being made using the data. Other important factors to consider are the frequency of nondetects, magnitudes of the detection limits relative to decision values, amount of data, chemical analysis techniques being used, complexity of the available statistical methods, and resources available for data analysis.

Selection of methods for handling nondetects must be determined within the DQO framework to ensure that the resulting estimates are useful for decision-making. If the nondetects are small in magnitude or low in frequency, the method of handling the nondetects will probably have minimal impact on the final outcome of the analysis. However, if the detection limits are close to important decision values, or if the frequency of nondetects is high, the treatment of the nondetect values can greatly influence resulting decisions. The complexity of the available methods and the resources available for data analysis must also be considered.

Further investigation of statistical methods for handling nondetects should be considered in several areas, including

- evaluating methods via computer simulation guided by experiences with actual environmental data
- developing guidelines for deciding when simple methods are appropriate
- developing methods to handle multiple detection limits
- integrating existing statistical methods with environmental applications.

Statistical theory and computer simulation provide a variety of tools that may be used to examine these issues.

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