Draft

ADVISORY BOARD ON
RADIATION AND WORKER HEALTH

National Institute for Occupational Safety and Health

SC&A'S EVALUATION OF ORAUT-OTIB-0044, REVISION 01, "HISTORICAL EVALUATION OF THE FILM BADGE DOSIMETRY PROGRAM AT THE Y-12 FACILITY IN OAK RIDGE, TENNESSEE: PART 1 – GAMMA RADIATION"

Contract No. 211-2014-58081
SCA-TR-2017-PR006, Revision 0

Prepared by

Ron Buchanan, PhD, CHP
Harry Chmelynski, PhD

SC&A, Inc.
2200 Wilson Boulevard, Suite 300
Arlington, Virginia, 22201

Saliant, Inc.
5579 Catholic Church Road
Jefferson, Maryland 21755

July 2017

SC&A, INC.: ***Technical Support for the Advisory Board on Radiation and Worker Health Review of NIOSH Dose Reconstruction Program***

DOCUMENT TITLE:	SC&A's Evaluation of ORAUT-OTIB-0044, Revision 01, "Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee: Part 1 – Gamma Radiation"
DOCUMENT NUMBER/ DESCRIPTION:	SCA-TR-2017-PR006
REVISION NO.:	01 (Draft)
SUPERSEDES:	Revision 0
EFFECTIVE DATE:	July 17, 2017
TASK MANAGER:	Kathy Behling, MS [signature on file]
PROJECT MANAGER:	John Stiver, MS, CHP [signature on file]
DOCUMENT REVIEWER(S):	Kathy Behling, MS [signature on file] John Stiver, MS, CHP [signature on file]

Record of Revisions

Revision Number	Effective Date	Description of Revision
0 (Draft)	07/17/2017	Initial issue

TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS

α	alpha
β	beta
ABRWH	Advisory Board on Radiation and Worker Health
CER	Center for Epidemiologic Research
d_i	absolute deviation
DR	dose reconstruction
E	true mean value
$\hat{E}_i$	estimate (i)
G_1	group 1
G_2	group 2
GM	geometric mean
GSD	geometric standard deviation
IQR	inter-quartile range
MAD	median absolute deviation
MDL	minimum detection level
ML	maximum likelihood
MLE	maximum likelihood estimate
mlnd2	function for maximum likelihood estimation
mrem	millirem
NADA	Nondetects and Data Analysis
NIOSH	National Institute for Occupational Safety and Health
nlnd	function for computing lognormal likelihood
ORAUT	Oak Ridge Associated Universities Team
Φ	cumulative standard normal distribution
PLE	product limit estimator
Pr	probability
R	R open-source programming language
ros	regression on order statistics
ROS1	regression on order statistics 1
φ	scaling factor
σ	sigma

μ	mu
u	generic symbol for a variable
|u|	absolute value of u
x_i	random draw
Y-12	Y-12 Plant

1.0 INTRODUCTION AND BACKGROUND

At the Advisory Board on Radiation and Worker Health (ABRWH) meeting of January 25, 2017, SC&A was tasked with a technical review of ORAUT-OTIB-0044, Revision 01, *Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee: Part 1 – Gamma Radiation*, issued April 29, 2013 (NIOSH 2013a, referred to as "OTIB-0044"). The National Institute for Occupational Safety and Health (NIOSH) also issued a similar document for beta radiation, ORAUT-OTIB-0046, Revision 00, *Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Plant in Oak Ridge, Tennessee: Part 3 – Beta Radiation*, June 22, 2007 (NIOSH 2007, referred to as "OTIB-0046"). In another document, ORAUT-OTIB-0064, Revision 02, *Coworker External Dosimetry Data for the Y-12 National Security Complex*, issued April 29, 2013 (NIOSH 2013b, referred to as "OTIB-0064"), NIOSH used external gamma dose data from OTIB-0044 and external beta dose data from OTIB-0046 to derive the 50th and 95th percentile coworker gamma and beta doses during the period 1947–1979 for use in dose reconstruction (DR). This report presents SC&A's evaluation of the technical approach and statistical methods used by NIOSH in OTIB-0044 for gamma radiation exposures at Y-12.

2.0 OVERVIEW OF ORAUT-OTIB-0044

OTIB-0044 is a detailed document, and, for evaluation purposes, it is advantageous to provide a brief outline as follows:

- **Purpose** – The purpose of the document was to provide parameters for lognormal prediction density of gamma doses for Y-12 workers during the period 1947–1979 (Table 7-1, page 33) to be used to derive coworker 50th and 95th percentile gamma doses in OTIB-0064 (Tables 7-1b and 7-1c).

- **Y-12 Film Badge Program** – Section 3.0 (pages 10–16) outlines the film badge program at Y-12 during the period 1947–1979 to assist in analyzing the recorded dose data. Table 3-3 (page 12) lists the dosimetry minimum detection level (MDL) as a function of time.

- **Y-12 External Dose Database** – Section 4.0 (pages 16–18) discusses the external dose data available on the Center for Epidemiologic Research (CER) database, and also the need to use regression analysis of data from 147 Y-12 workers monitored during the period 1956–1965 for assigning coworker doses prior to 1957.

- **Statistical Methods** – Section 5.0 (pages 18–20) presents the statistical methods used to analyze the recorded dose data in deriving the parameters for the lognormal prediction density, such as those listed in Table 7-1. It also presents the method used to derive the scaling factor to be applied for unmonitored periods before 1961.

- **Evaluation of Film Badge Doses Over Time** – Section 6.0 (pages 20–31) provides an evaluation of the Y-12 external doses during the period 1947–1979. Figure 6-2 (page 23) shows a summary view of these data and indicates that the data follow a lognormal distribution after 1956, but earlier data do not follow a definable distribution. Therefore, there is a need to use an alternate method during the period 1947–1956: the regression

analysis of the data from 147 monitored workers during the period 1956–1965. This method is analyzed further in Sections 6.4 and 6.5, including Figures 6-3 and 6-4, and Tables 6-1, 6-2, and 6-3.

- **Estimates for Unmonitored Doses** – Section 7.0 provides the key results of OTIB-0044 in Table 7-1 (pages 33–35). This table lists the quarterly parameters for lognormal prediction density of gamma doses for Y-12 workers during the period 1947–1979 to be used to derive coworker 50th and 95th percentile gamma doses in OTIB-0064 (Tables 7-1b and 7-1c). The parameters in Table 7-1 of OTIB-0044 for the period 1947 through the third quarter of 1956 were derived from the regression analysis of data from the 147 monitored workers, and the parameters for the fourth quarter of 1956 through 1979 were derived from the lognormal model of quarterly doses in the CER database (Section 7.3, page 35).

- **Individual Scaling Factor** – Section 7.4 (pages 35–37) discusses the need for an individual scaling factor to be applied to an unmonitored worker prior to1961, if the worker was monitored for at least five quarters during 1961–1965, and the worker's duties remained essentially the same during the 1950s and early 1960s. The parameters (based on data from Table 7-1 and an MDL of 30 millirem [mrem]) are listed in Table 7-2, and the scaling factor equation is provided at the bottom of page 36. An example of the application of a scaling factor to an individual worker is provided on page 37 using the individualized data from Table 7-3.

- **Comparison of Model/Scaling Dose to Recorded Dose** – Section 7.5 (pages 38–41) provides the resulting dose assignment using the regression analysis of the 147 workers' data compared to the dose assignment using the workers' recorded data prior to 1961. Figures 7-2 through 7-6 show this comparison for several different categories of exposure scenarios. It is indicated that the overall results show that it is generally claimant favorable to use the regression analysis for assigning doses prior to 1961.

- **Summary** – Section 8.0 (pages 41–42) summarized the key points of OTIB-0044:

  - Prior to 1957, the prediction densities were derived from a maximum likelihood (ML) regression based on data from a subgroup of 147 carefully selected Y-12 workers.

  - During 1957–1979, the recorded quarterly doses for workers were used to derive parameter estimates by ML methods for quarterly lognormal prediction densities.

  - Evidence indicates that the highest exposed workers were monitored before 1961.

  - Beginning in 1961, all Y-12 workers were monitored.

  - A scaling factor can be applied to unmonitored workers before 1961, if the worker has at least five quarters of recorded dose data during the period 1961–1965 and had similar job duties during the 1950s and early 1960s.

- **Attachment A** – Pages 49–76 provide bar graphs of the frequency of occurrence versus the recorded gamma dose (mrem) on a quarterly basis for Y-12 workers for the period 1952–1979. The main point illustrated by these plots is that for the period 1952 to the early part of 1956 (page 53), the data do not follow a definable distribution; whereas for the period of the latter part of 1956 through 1979, the data can generally be modeled using a lognormal distribution.

- **Attachment B** – Pages 77–104 provide quantile-quantile plots of the quarterly gamma doses for the period 1952–1979. The main point illustrated by these plots is that for the period 1952 to the early part of 1956 (page 81), the data do not follow a definable distribution; whereas for the latter part of 1956 through 1979, the data can generally be modeled using a lognormal distribution.

3.0 SC&A'S EVALUATION OF ORAUT-OTIB-0044

The following is a summary of SC&A's evaluation of the approach, statistical analysis, and documentation used by NIOSH in developing OTIB-0044.

3.1 EVALUATION OF NIOSH'S APPROACH TO COWORKER DOSE

SC&A evaluated (1) NIOSH's approach and methods used in OTIB-0044 to develop coworker gamma dose parameters (mainly mu [μ)] sigma [σ], geometric mean [GM], geometric standard deviation [GSD], and expected dose values), which are summarized in Table 7-1 of OTIB-0044, and (2) the derivation and application of scaling factor in Section 7.4 of OTIB-0044, for the period 1947–1979. SC&A did not identify any issues with the general approach and methods used by NIOSH in OTIB-0044 outlined in Section 2.0 of this report.

3.2 EVALUATION OF NIOSH'S STATISTICAL METHODS

SC&A evaluated the statistical methods employed by NIOSH in OTIB-0044 for developing coworker gamma dose parameters, as discussed below. A detailed analysis for each of the following sections is provided in Appendix A to this report.

3.2.1 Sections 5.1–5.6 (pages 18–20): MLE Statistical Method

SC&A found that the maximum likelihood estimation (MLE) method was shown to perform at least as well as the other two estimation methods—regression on order statistics 1 (ROS1) (NIOSH 2006) and regression on order statistics (*ros*) (Helsel 2005)—in all simulations. The original ROS1 method recommended by NIOSH 2006 performed almost as well as the MLE method. The *ros* program from the Nondetects and Data Analysis (NADA) package showed somewhat higher percentage errors at higher values of the GSD. SC&A had no issues concerning statistics in these sections.

3.2.2 Section 6.4 (pages 23–27): 1961 Versus 1960 Doses

When SC&A used the lognormal parameters estimated from the median and inter-quartile range (IQR) obtained from Table 6-1 for Quarters 3 and 4, the results were $Pr\{G_1 > G_2\} = 0.75$ in

Quarter 3 and $Pr\{G_1 > G_2\} = 0.72$ in Quarter 4. These probabilities were in close agreement with the estimates obtained directly from the lognormal parameter values in Figure 6-3.

The values for all four quarters are somewhat higher than the 50% expected if the two distributions were identical. However, this does not demonstrate convincingly that the distribution of doses for Group 2 is sufficiently different than for Group 1 to support the use of a separate missed dose model for workers before 1961 based on the 147-worker data regression.

Finding 1. The actual data distributions should be retained rather than replaced with predictions generated using data from a possibly non-representative subset of 147 workers. This issue is also addressed later in this report in the review of Section 7-1, which provides details of SC&A's regression modeling.

3.2.3 Section 6.5 (pages 27–31): Limitations of Doses for Dose Reconstruction

Table 6-3 contains dose estimates derived using the ML lognormal parameters discussed previously. The table also contains estimates from the product limit estimator (PLE) method, which are somewhat lower than the lognormal base estimates. However, the lognormal estimates recommended for use by NIOSH are more claimant favorable. SC&A agrees with this approach and had no issues in this section.

3.2.4 Section 7.1 (pages 31–33): Procedure Used through Third Quarter of 1956

Figure 7-1 (page 32) of OTIB-0044 shows the quarterly doses from 1956 through 1965 for 147 workers and the regression line obtained using the ML method for data with nondetects. Extrapolation of time series regression results outside the sampling period is generally suspect. There is no assurance that the log-linear model applies outside the sampling period. The agreement of the predictions with the data observed in the years following the sampling period does not guarantee similar agreement in the years before the sampling period. There are two main concerns with out-of-sample prediction using time series models, one of which SC&A submits as Finding 2 of this report:

1) **Finding 2.** The validity of the model may not extend beyond the sampling period due to changes in the underlying processes.

2) If the model does apply, the estimated prediction errors derived from within-sample data may not be appropriate outside of the sampling period.

The good fit of the model predictions shown in Figure 8 of Appendix A to this report in the post-sampling period provides some assurance against Finding 1, but the validity of the model in the years before the sample period remains a major concern that should be addressed by comparison with observed data. The issues raised in Finding 2 are related to the problem of over-fitting. These issues are discussed further in the following section under the review of Table 7-1.

3.2.5 Sections 7.2 and 7.3 (pages 33–35): Procedure Used after Third Quarter of 1956

In Table 7-1, the forecasts extend out 9 years prior to the10-year sampling period. It is difficult to accept this high a degree of confidence in the out-of-sample model predictions. In most

applications of time series forecasting (or back-casting), the width of the prediction interval has a funnel shape, with larger predictive errors as the forecasts extend out farther from the sampling period.

The unusually slow rate of increase in the width of the ML predictive interval outside of the sampling period is due, in part, to the very large sample size used to estimate the model. The model estimates presented in Section 7.1 of OTIB-0044 show very tight confidence bounds on both parameters: $se(\hat{\alpha})/\hat{\alpha} = 0.0045$ and $se(\hat{\beta})/\hat{\beta} = 0.045$. These precise estimates of the ML lognormal parameters result from the very large number (5,686) of quarterly samples used to estimate the 147-worker model.

Finding 3. Despite this apparent precision, it is highly unlikely that the uncertainty in predictions outside the sampling period should be as small as indicated by the precise estimates from the ML regression model. The issue of out-of-sample validation is not resolved by using a large number of samples in the sampling period.

3.2.6 Section 7.4 (pages 35–37): Application of the Scaling Procedure

It makes sense that the estimated missed dose for a worker who has some data available should be a function of those data, in addition to other sources of information used to construct the coworker model. Data are available prior to 1961 for some of these workers with missing doses.

Finding 4. The scaling procedures should also address the worker's pre-1961 data where available. Additionally, it is not clear that historical records will be sufficient to document that the worker's exposure potential remained fairly constant over the time period required for workers with missed doses.

3.3 EVALUATION OF DOCUMENTATION IN ORAUT-OTIB-0044

SC&A's review of OTIB-0044 identified four findings regarding statistical methods used in Sections 6.4 and 7.1 through 7.4, as discussed above, and four observations of where clarification or correction of errors would facilitate understanding and application of the document for DR purposes, as discussed below.

Observation 1. Page 33: The units of mrem need to be added to Table 7-1, as appropriate.

Observation 2. Page 33: The caption for Table 7-1 should include the period 1947 to 1979, not 1947 to 1965 as it presently states.

Observation 3. Page 36: The second line of the second paragraph states, "*with the appropriate quarterly GM and GSD from Table 7-1 and applying an individual scaling factor φ…*" However, it appears that the GM values are not used in Tables 7-2 and7-3. Should "GM" be replaced with "μ"?

Observation 4. Page 36: The end of the second paragraph states, "*Any calculated scaling factor that is less than one is changed to one so that the value of the expected quarterly dose can be increased but not decreased*." Because the scaling factor (φ) appears in the exponent, shouldn't

this sentence read: "*Any calculated scaling factor that is less than zero is changed to zero so that the value of the expected quarterly dose can be increased but not decreased*"?

4.0 SUMMARY AND CONCLUSIONS

Approach – SC&A found the approach used to derive recommended Y-12 coworker gamma doses in OTIB-0044 to be reasonable and generally technically correct.

Statistical Methods – SC&A's analysis of NIOSH's statistical methods used to derive coworker gamma doses determined them to be acceptable in certain sections of OTIB-0044. However, SC&A found some issues with the statistical methods used in other sections of OTIB-0044. The following is a summary of SC&A's analysis of NIOSH's statistical methods.

- **Sections 5.1–5.6 (pages 18–20): MLE Statistical Method**
  SC&A found the MLE method to perform at least as well as the other two estimators in all simulations. SC&A had no issues concerning statistics in these sections.

- **Section 6.4 (pages 23–27): 1961 Versus 1960 Doses**
  SC&A's analysis of the data indicates that the actual data distributions should be retained rather than replaced with data from a possibly non-representative subset of 147 workers (Finding 1). This issue was also addressed in the review of Section 7-1, which provided details of SC&A's regression modeling.

- **Section 6.5 (pages 27–31): Limitations of Doses for Dose Reconstruction**
  SC&A agrees with NIOSH's conclusion to use the more claimant favorable lognormal estimates in Table 6-3. SC&A found no issues concerning statistics in these sections.

- **Section 7.1 (pages 31–33): Procedure Used through Third Quarter of 1956**
  The validity of the model used for the years before the sample period remains a major concern (Finding 2), and if the model does apply, the estimated prediction errors derived from within-sample data may not be appropriate outside of the sampling period.

- **Sections 7.2 and 7.3 (pages 33–35): Procedure Used after Third Quarter of 1956**
  It is highly unlikely that the uncertainty in predictions outside the sampling period should be as small as indicated by the precise estimates from the ML regression model (Finding 3).

- **Section 7.4 (pages 35–37): Application of the Scaling Procedure**
  The scaling procedures should also address the worker's prior data, where available (Finding 4). Additionally, it is not clear that historical records will be sufficient to document that the worker's exposure potential remained fairly constant over the time period required for workers with missed doses.

Documentation – In Section 3.3 of this report, SC&A identified four observations that would facilitate the document's readability, help to clarify the methods used to derive the coworker data, and make OTIB-0044 consistent with OTIB-0046 and OTIB-0064.

5.0 REFERENCES

Helsel 2005. D.R. Helsel, *Nondetects and Data Analysis: Statistics for Censored Environmental Data*, John Wiley and Sons, NJ. 2005. [SRDB Ref. ID 139734]

NIOSH 2006. *Generating Summary Statistics for Coworker Bioassay Data*, ORAUT-PROC-0095, Revision 00, National Institute for Occupational Safety and Health, Cincinnati, Ohio. June 5, 2006.

NIOSH 2007. *Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Plant in Oak Ridge, Tennessee: Part 3 – Beta Radiation*, ORAUT-OTIB-0046, Revision 00, National Institute for Occupational Safety and Health, Cincinnati, Ohio. June 22, 2007.

NIOSH 2013a. *Historical Evaluation of the Film Badge Dosimetry Program at the Y-12 Facility in Oak Ridge, Tennessee: Part 1 – Gamma Radiation*, ORAUT-OTIB-0044, Revision 01, National Institute for Occupational Safety and Health, Cincinnati, Ohio. April 29, 2013.

NIOSH 2013b. *Coworker External Dosimetry Data for the Y-12 National Security Complex*, ORAUT-OTIB-0064, Revision 02, National Institute for Occupational Safety and Health, Cincinnati, Ohio. April 29, 2013.

APPENDIX A: SC&A'S EVALUATION OF STATISICAL METHODS USED IN ORAUT-OTIB-0044

SECTIONS 5.1–5.6 (PAGES 18–20): MLE STATISTICAL METHOD

The MLEs for samples from a lognormal distribution with nondetects are obtained using the R function *mlnd2* described in Frome and Watkins (2004). This function and a companion function, *nlnd*, are used within the base R system to obtain MLEs for the parameters of lognormal data sets with nondetects. The ML functions are applied to many different data sets, and parameter estimates obtained using these functions are the basis for many of the dose distributions presented in the tables reported in OTIB-0044. The upper confidence limit for pth percentile, the prediction density, and the scaling procedure are all derived from the MLEs of the lognormal parameters.

A simulation was conducted to compare the performance of the *mlnd2* and *nlnd* programs for the MLEs of the parameters of a lognormal distribution in the presence of nondetects versus two previous methods used for data with nondetects. The MLEs are compared with the estimates generated by the original ROS1 estimates recommended in ORAUT-PROC-0095, Revision 00, *Generating Summary Statistics for Coworker Bioassay Data* (NIOSH 2006), and with estimates produced by the R program *ros* from the NADA package (Lee and Helsel 2005, Helsel 2005).

The simulation compared estimates of the mean of the lognormal distribution produced by each of the three methods for a wide range of sample sizes (n = 20, 40, 60, 100, 200, 500), geometric standard deviations (GSD = 1.5, 2, 3, 4, 5, 7) and the percentage of nondetects in the samples (5%, 10%, 25%, 50%, 75%). Numerical results of the comparison are reported in Tables 1 through 5, and the simulation results are compared in Figures 1 through 5.

The six log-log plots in Figure 1 show comparisons of the estimation errors obtained when there are 5% nondetects in the samples. The value of the GSD varies from 1.5 to 7 in the six plots. The simulation for each plot consisted of 2,000 sets of random lognormal samples, with the specified GSD for each of the six sample sizes noted above. The three estimates of the expected value of the lognormal distribution were computed from each sample. The absolute deviation (d_i) of each estimate ($\widehat{E}_i$) was calculated as a percentage of the true mean value (E) of the underlying lognormal distribution:

$$d_i = \frac{100\left|\widehat{E}_i - E\right|}{E}, i = 1, \cdots, 2000$$

where the symbol $|u|$ denotes the absolute value of u. The median absolute deviation (MAD) over the 2,000 simulations was obtained for each of the three estimators: $MAD = median(d_1, d_2, \cdots, d_{2000})$. The MAD criterion was used for the comparison because it is known to be a robust measure that is not sensitive to outliers. The resulting median absolute percentage errors of estimation for the three methods are compared in the six plots. Figures 2, 3, 4, and 5 contain similar comparison plots for data sets containing lognormal samples with 10%, 25%, 50%, and 75% nondetects, respectively.

In each figure, the horizontal scales for the six plots are the same, but the vertical scales differ as larger percentage errors occur for larger values of the GSD. At a sample size of 20, the highest percentage errors for a GSD of 1.5 are under 7%, while the maximum error for a sample size of 20 at a GSD of 7 are barely under 50%. Smaller errors occur for larger sample sizes in each plot. These same patterns are observed in all five figures, with larger errors occurring for a larger percentage of nondetects.

Inspection of the first four figures reveals only minor differences in performance between the original ROS1 method and the MLE estimator from 5% up to 50% nondetects. At GSDs of 2 or less, all three estimators yield almost identical results, while the *ros* estimates from the NADA package show somewhat larger errors than the other two estimators when the GSD exceeds 2. At 75% nondetects in Figure 5, the MLE estimator shows noticeably better performance than the other two estimators when the GSD is 2 or less. At higher GSDs, the three estimators have similar performance.

In summary, the MLE method was shown to perform at least as well as the other two estimators in all simulations. The original ROS1 method, recommended 10 years ago, performed almost as well as the MLE method. The *ros* program from the NADA package showed somewhat higher percentage errors at higher values of the GSD.

Figure 1. Median Absolute Deviation for Three Estimates of Lognormal Mean, 5% Nondetects

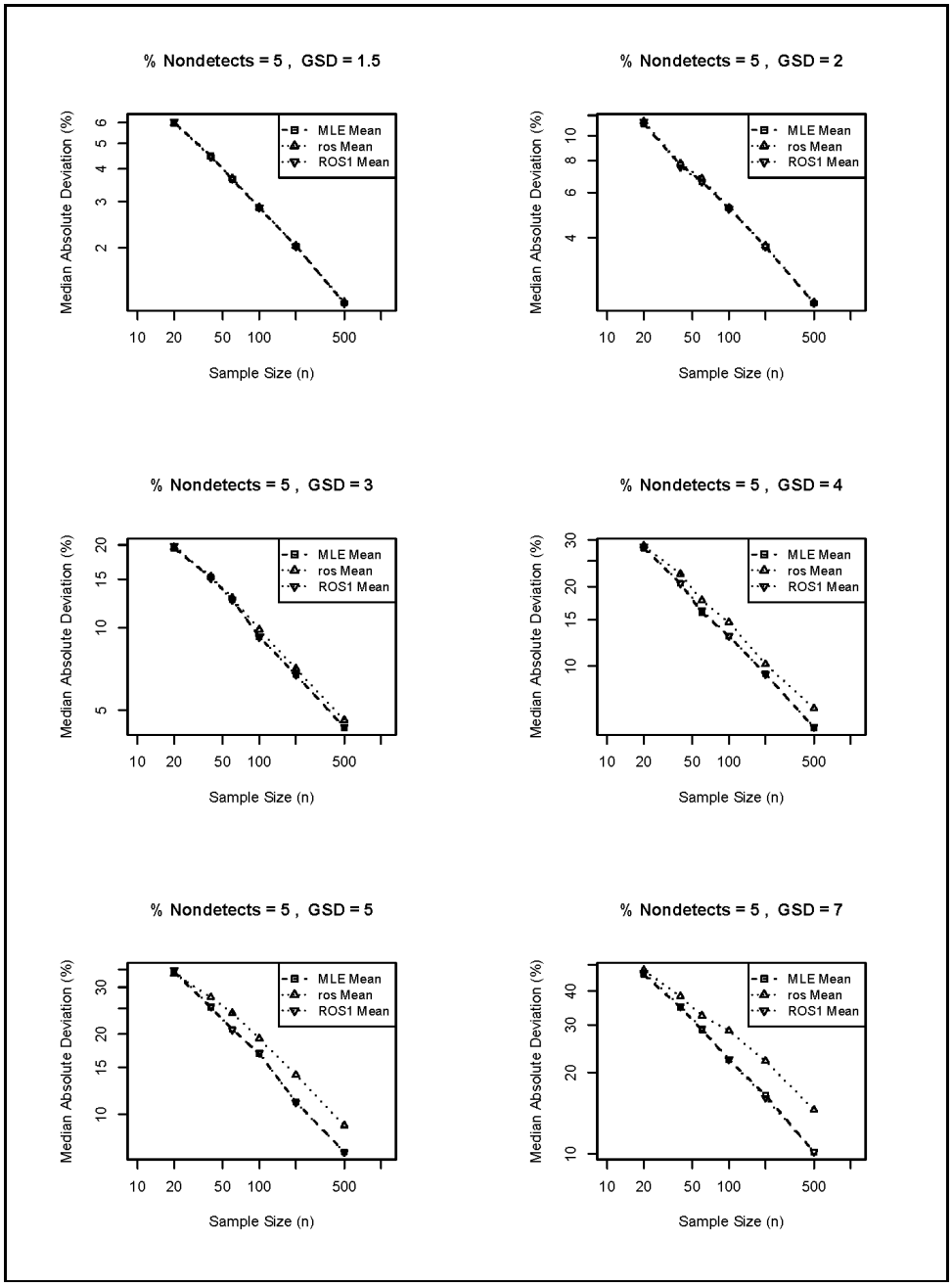


Figure 2. Median Absolute Deviation for Three Estimates of Lognormal Mean, 10% Nondetects

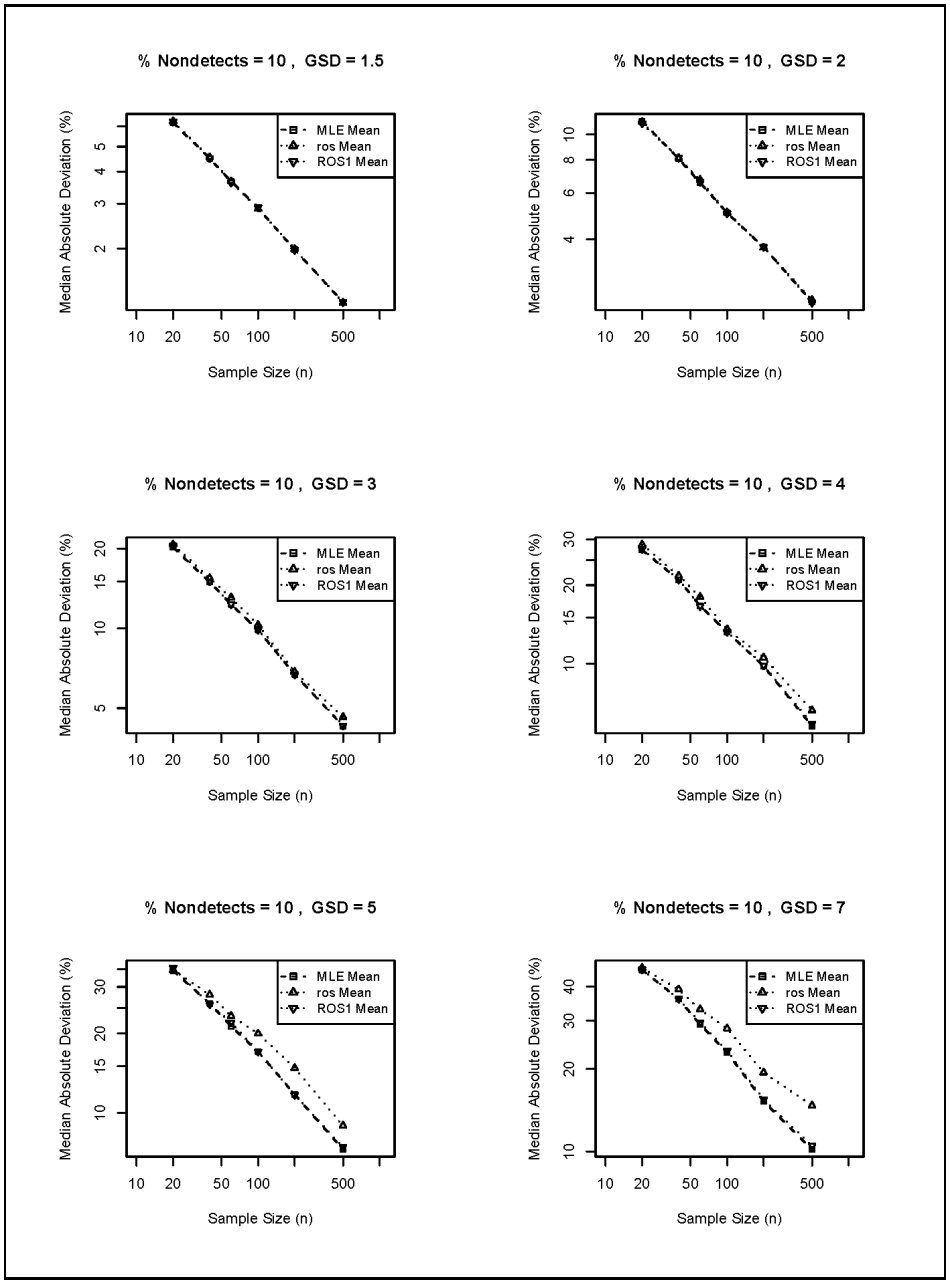


Figure 3. Median Absolute Deviation for Three Estimates of Lognormal Mean, 25% Nondetects

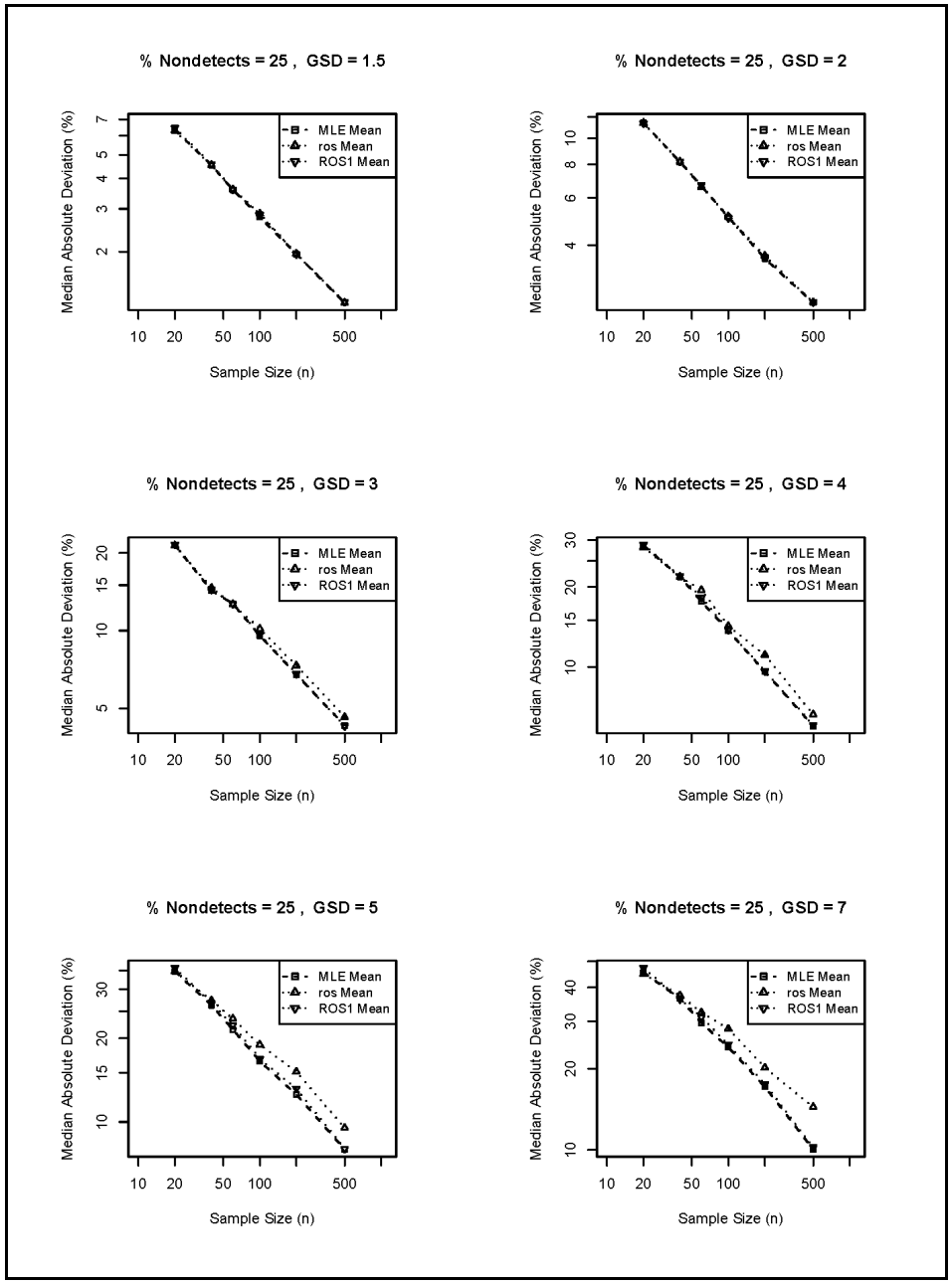


Figure 4. Median Absolute Deviation for Three Estimates of Lognormal Mean, 50% Nondetects

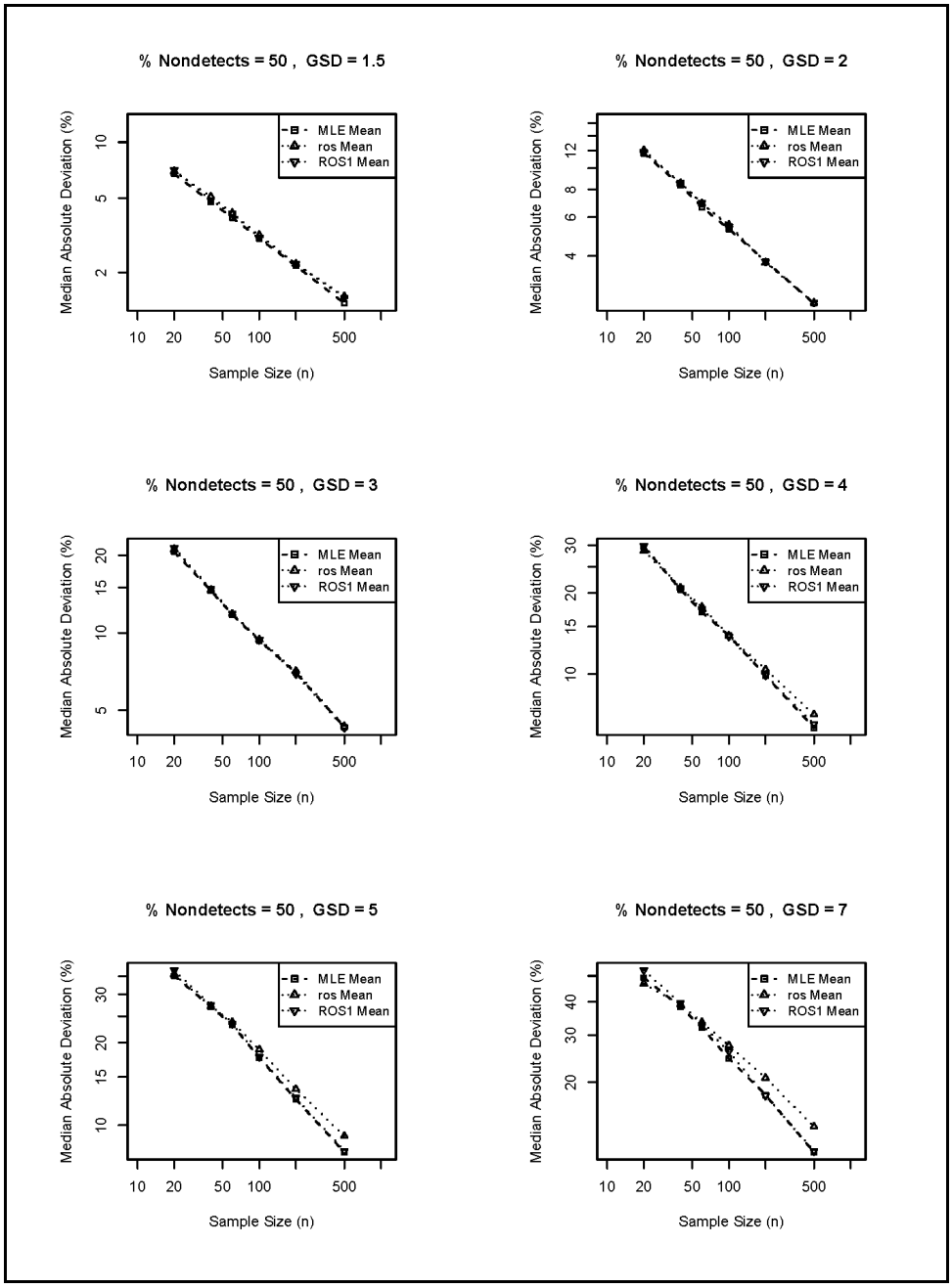


Figure 5. Median Absolute Deviation for Three Estimates of Lognormal Mean, 75% Nondetects

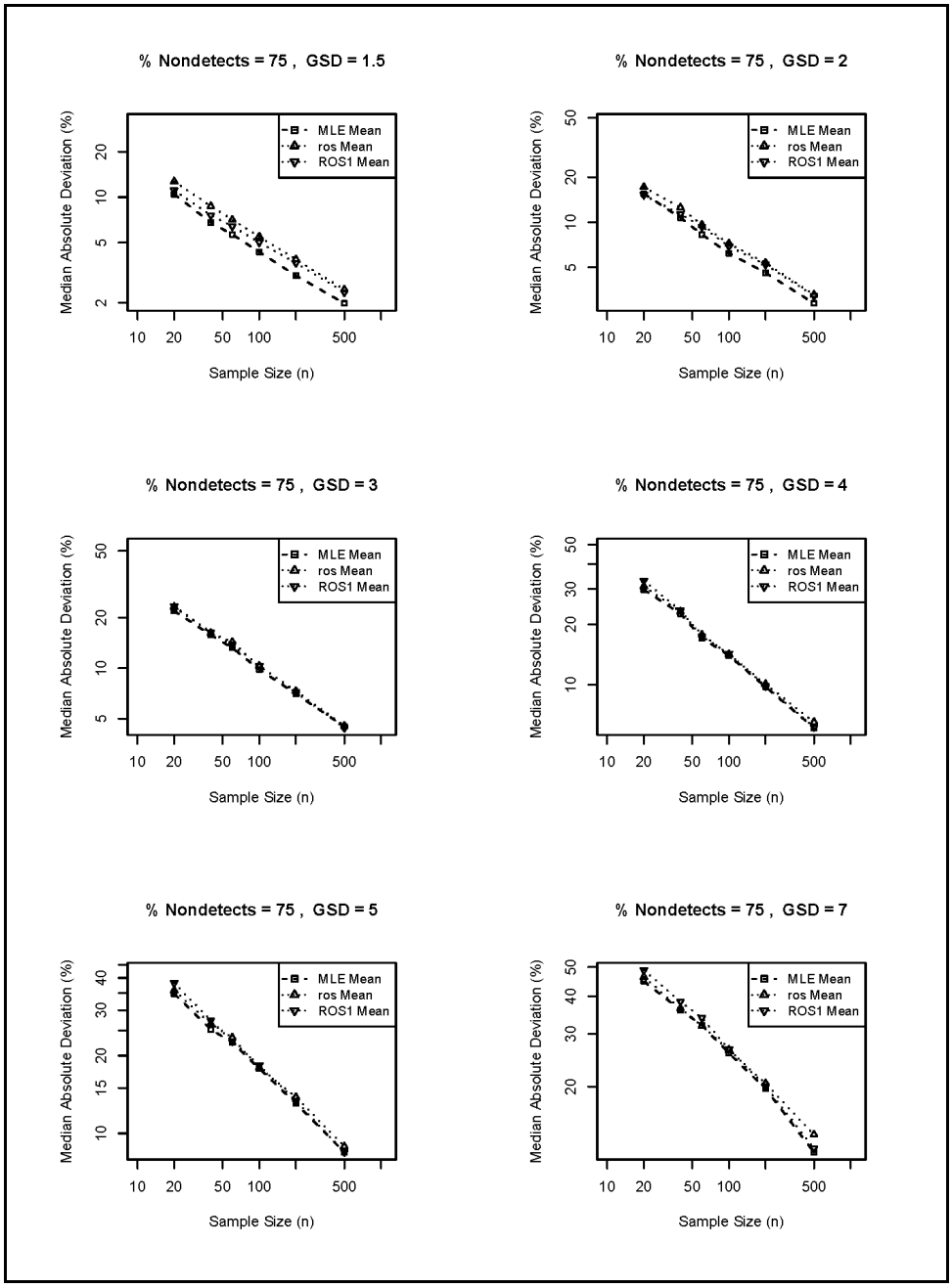


Table 1. Median Absolute Deviation for Three Estimates of Lognormal Mean, 5% Nondetects

GSD	N	MLE	*ros*	ROS1
1.5	20	6.0	6.0	6.1
2	20	11.1	11.4	11.3
3	20	19.4	19.6	19.9
4	20	27.9	28.6	28.3
5	20	34.2	33.8	34.8
7	20	46.0	47.8	46.8
1.5	40	4.5	4.4	4.4
2	40	7.7	7.8	7.5
3	40	15.3	15.3	15.1
4	40	20.5	22.3	20.6
5	40	25.2	27.5	25.4
7	40	34.8	38.2	35.1
1.5	60	3.6	3.7	3.7
2	60	6.6	6.8	6.6
3	60	12.6	12.8	12.6
4	60	15.9	17.7	16.3
5	60	20.9	24.0	20.8
7	60	28.7	32.5	29.1
1.5	100	2.8	2.9	2.9
2	100	5.2	5.2	5.2
3	100	9.3	9.8	9.2
4	100	13.0	14.6	13.0
5	100	16.9	19.2	17.0
7	100	22.3	28.5	22.4
1.5	200	2.0	2.0	2.0
2	200	3.7	3.7	3.7
3	200	6.7	7.1	6.7
4	200	9.3	10.2	9.3
5	200	11.1	14.0	11.1
7	200	16.5	22.1	16.1
1.5	500	1.2	1.2	1.2
2	500	2.2	2.2	2.2
3	500	4.3	4.6	4.4
4	500	5.8	6.9	5.9
5	500	7.2	9.1	7.2
7	500	10.1	14.5	10.2

Table 2. Median Absolute Deviation for Three Estimates of Lognormal Mean, 10% Nondetects

GSD	N	MLE	*ros*	ROS1
1.5	20	6.2	6.3	6.3
2	20	11.2	11.2	11.0
3	20	20.2	20.7	20.5
4	20	27.3	28.7	27.5
5	20	34.5	34.8	35.4
7	20	46.0	46.8	46.2
1.5	40	4.5	4.5	4.5
2	40	8.1	8.1	8.2
3	40	14.9	15.5	15.1
4	40	20.9	21.7	21.0
5	40	26.0	28.0	25.8
7	40	36.0	39.1	36.1
1.5	60	3.7	3.7	3.6
2	60	6.5	6.7	6.6
3	60	12.3	13.1	12.3
4	60	16.7	18.0	16.6
5	60	21.3	23.3	22.0
7	60	29.1	33.0	29.6
1.5	100	2.9	2.9	2.9
2	100	5.0	5.1	5.0
3	100	9.9	10.3	9.9
4	100	13.2	13.6	13.2
5	100	17.1	20.0	17.0
7	100	23.0	28.1	23.3
1.5	200	2.0	2.0	2.0
2	200	3.7	3.7	3.7
3	200	6.7	6.9	6.7
4	200	9.8	10.5	9.8
5	200	11.7	14.8	11.7
7	200	15.2	19.4	15.5
1.5	500	1.2	1.2	1.2
2	500	2.3	2.4	2.3
3	500	4.3	4.6	4.3
4	500	5.8	6.6	5.9
5	500	7.3	9.0	7.4
7	500	10.2	14.7	10.5

Table 3. Median Absolute Deviation for Three Estimates of Lognormal Mean, 25% Nondetects

GSD	N	MLE	*ros*	ROS1
1.5	20	6.3	6.3	6.5
2	20	11.4	11.4	11.4
3	20	21.4	21.4	21.6
4	20	28.6	28.2	28.8
5	20	34.8	34.8	35.8
7	20	45.5	44.9	47.3
1.5	40	4.5	4.5	4.6
2	40	8.2	8.2	8.2
3	40	14.3	14.6	14.4
4	40	21.8	21.8	22.0
5	40	26.3	27.4	26.7
7	40	36.4	37.4	36.2
1.5	60	3.6	3.6	3.6
2	60	6.6	6.6	6.7
3	60	12.7	12.7	12.7
4	60	17.6	19.5	18.3
5	60	21.5	23.5	22.3
7	60	29.6	32.3	31.0
1.5	100	2.8	2.9	2.8
2	100	5.1	5.1	5.1
3	100	9.6	10.2	9.6
4	100	13.7	14.3	13.8
5	100	16.5	19.0	16.9
7	100	24.0	28.1	24.6
1.5	200	2.0	2.0	1.9
2	200	3.6	3.7	3.6
3	200	6.8	7.3	6.8
4	200	9.6	11.1	9.7
5	200	12.6	15.2	13.2
7	200	17.1	20.2	17.5
1.5	500	1.2	1.2	1.2
2	500	2.4	2.5	2.5
3	500	4.3	4.6	4.3
4	500	6.0	6.7	6.1
5	500	8.0	9.5	8.0
7	500	10.0	14.4	10.2

Table 4. Median Absolute Deviation for Three Estimates of Lognormal Mean, 50% Nondetects

GSD	N	MLE	*ros*	ROS1
1.5	20	6.8	7.0	7.1
2	20	11.7	12.1	11.8
3	20	20.7	21.1	21.4
4	20	29.6	28.6	29.9
5	20	35.1	35.5	36.8
7	20	49.2	46.8	52.5
1.5	40	4.8	5.1	4.9
2	40	8.4	8.6	8.6
3	40	14.6	14.7	14.8
4	40	20.6	20.9	20.9
5	40	27.1	27.2	27.5
7	40	38.3	39.0	39.6
1.5	60	3.9	4.2	4.1
2	60	6.7	6.9	7.0
3	60	11.8	11.8	11.9
4	60	17.0	17.7	17.4
5	60	23.2	23.8	23.4
7	60	32.0	33.5	32.8
1.5	100	3.0	3.2	3.1
2	100	5.3	5.5	5.4
3	100	9.3	9.4	9.4
4	100	13.9	13.9	13.8
5	100	17.6	18.9	17.8
7	100	24.5	27.5	26.1
1.5	200	2.2	2.2	2.2
2	200	3.8	3.7	3.8
3	200	7.0	7.1	6.9
4	200	9.9	10.4	9.9
5	200	12.4	13.5	12.6
7	200	17.9	20.7	17.8
1.5	500	1.4	1.5	1.5
2	500	2.4	2.5	2.5
3	500	4.3	4.3	4.3
4	500	6.3	7.1	6.5
5	500	8.0	9.1	8.1
7	500	10.9	13.6	11.0

Table 5. Median Absolute Deviation for Three Estimates of Lognormal Mean, 75% Nondetects

GSD	N	MLE	*ros*	ROS1
1.5	20	10.5	12.7	11.1
2	20	15.5	17.1	15.2
3	20	21.9	23.2	23.5
4	20	29.8	30.9	33.0
5	20	34.7	35.7	38.3
7	20	44.8	46.4	48.8
1.5	40	6.8	8.7	7.6
2	40	10.7	12.5	11.3
3	40	15.8	16.2	16.4
4	40	22.6	23.1	23.4
5	40	25.3	26.6	27.3
7	40	36.0	36.4	38.4
1.5	60	5.7	7.1	6.4
2	60	8.3	9.6	9.3
3	60	13.2	14.3	13.8
4	60	17.1	17.7	17.4
5	60	22.5	23.5	22.8
7	60	32.0	31.9	33.9
1.5	100	4.3	5.5	5.0
2	100	6.2	7.2	6.9
3	100	9.8	10.3	10.3
4	100	14.0	14.2	14.3
5	100	17.8	18.0	18.4
7	100	25.8	26.5	26.6
1.5	200	3.0	3.9	3.7
2	200	4.6	5.3	5.2
3	200	7.0	7.3	7.2
4	200	9.8	10.1	9.8
5	200	13.1	13.8	13.3
7	200	19.7	20.5	20.1
1.5	500	2.0	2.4	2.3
2	500	2.9	3.3	3.2
3	500	4.5	4.5	4.4
4	500	6.1	6.5	6.1
5	500	8.5	8.9	8.5
7	500	12.1	13.8	12.4

SECTIONS 6.3 AND 6.4 (PAGES 22–27): QUARTERLY GAMMA DOSES AND 1960–1961 DOSES

The plot in Figure 6-2 presents results derived using the PLE, which generates estimates of the percentiles of the distribution taking nondetects into account. The PLE is a nonparametric estimator, which does not depend on the assumption of lognormal data. The figure summarizes 24 years of quarterly data in a single plot, showing the quartiles and outliers in each quarter.

A regression line derived from data for a limited number of workers covering the time span from 1956 to 1965 is shown on the plot. The regression line is derived from data on the 147 long-term Y-12 workers acquired by Oak Ridge Associated Universities/CER from the Y-12 Plant. The regression results are discussed later in the review of Section 7.1 of OTIB-0044.

Section 6.4 of OTIB-0044 presents an extended argument based on the Y-12 quarterly gamma doses in 1961 for two groups of workers partitioned by monitoring status in 1960. NIOSH states that "reportedly workers monitored before 1961 were selected because of higher dose potential." This premise is supported by Figure 6-3, where two quarters of data are compared for Group 1 (Y-12 workers monitored in 1961 who were also monitored in 1960) versus Group 2 (Y-12 workers monitored in 1961 who were not monitored in 1960.) NIOSH argues that Group 1 should have higher doses than Group 2 because of the change in monitoring protocols that occurred at the beginning of 1961. No formal statistical comparison is presented to support this viewpoint. However, the histograms shown in Figure 6-3 tend to support the premise that workers not monitored in 1960 received lower doses in both quarters than the workers who were monitored in both 1960 and 1961.

In Quarter 3, the expected value and standard deviation of the fitted lognormal distribution are 52 and 56, respectively, for Group 1, versus 24 and 22 for Group 2. In Quarter 4, the values for Group 1 are 82 and 48, while for Group 2, the values are 54 and 28. Despite the apparent difference between groups, we note that the difference from Quarter 3 to Quarter 4 for Group 1 (30 mrem) is larger than the differences observed between the groups (28 mrem). This also is true for Group 2. Moreover, Group 1 in Quarter 3 has a lower expected value than Group 2 in Quarter 4. Again in Table 6-1, the Quarter 2 Group 2 mean exceeds the Quarter 1 Group 1 mean. These facts suggest that any observed difference between groups may possibly have arisen due to quarterly variations in workloads and work hazards at Y-12. Large variations in quarterly dose data are observed in Table 6-3, discussed below.

Figure 6-3 shows the lognormal distribution parameter estimates obtained from Group 1 and Group 2 workers in Quarter 3 and Quarter 4. These estimates were used to determine the probability that a worker selected at random from the Group 1 distribution would have a higher dose than a worker selected at random from the Group 2 distribution. If the distribution were the same, this probability would be 0.50 (50%). When the distribution for Group 1 is higher than the distribution for Group 2 workers, then this probability increases toward 100%. To determine this probability, let $G_i = log(x_i)$, where x_i denotes a random draw from the lognormal distribution with parameters μ_i and σ_i shown in Figure 6-3 for Group i, $i = 1, 2$ in a specified quarter. Then,

$$Pr\{G_1 > G_2\} = 1 - Pr\{G_1 - G_2 \leq 0\}$$

The random variable $G_1 - G_2$ has a normal distribution with mean $\mu = \mu_1 - \mu_2$ and standard deviation $\sigma = \sqrt{\sigma_1^2 + \sigma_2^2}$. Hence,

$$Pr\{G_1 - G_2 \leq 0\} = \Pr\left\{\frac{(G_1 - G_2) - \mu}{\sigma} \leq \frac{0 - \mu}{\sigma}\right\} = \Phi\left(\frac{-\mu}{\sigma}\right)$$

and

$$Pr\{G_1 > G_2\} = 1 - \Phi\left(\frac{-\mu}{\sigma}\right)$$

where Φ denotes the cumulative standard normal distribution.

When the above formulae are applied to the lognormal distributions reported in Figure 6-3, the results are $Pr\{G_1 > G_2\} = 0.72$ in Quarter 3 and $Pr\{G_1 > G_2\} = 0.71$ in Quarter 4. These results are depicted graphically in Figure 6, which shows the distribution of $\Delta = G_1 - G_2$. The probability that a worker selected at random from Group 1 has a higher dose than a worker selected at random from Group 2 is approximately 0.71 (71%) in both quarters. This value is somewhat higher than the 50% expected when the two distributions are identical, but it is not high enough to demonstrate convincingly that the distribution of doses for Group 1 is sufficiently higher than Group 2 to require, in itself, use of the 147-worker regression model for missed doses for workers before 1961.

NIOSH chose to report only comparisons for Quarters 3 and 4 in Figure 6-3. Information for comparing workers in Groups 1 and 2 in Quarters 1 and 2 is provided in Table 6-1, but the table does not include the estimated lognormal parameters. Estimates of the lognormal parameters for the two groups in Quarter 1 and 2 were derived from the median, 25th percentile, and 75th percentile reported in the table. The lognormal parameter μ was estimated by the logarithm of the median, and σ was estimated by the IQR on the log scale divided by 1.35.

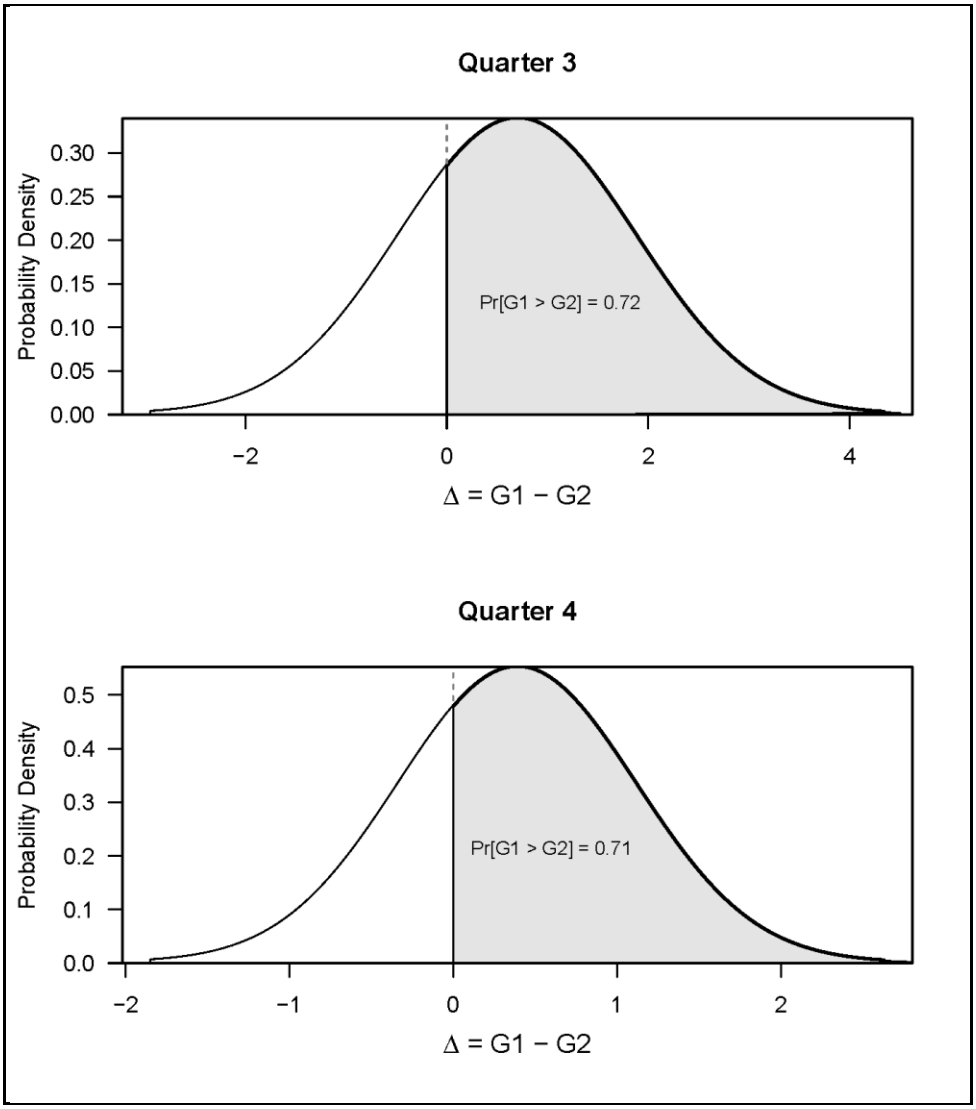
The results are $Pr\{G_1 > G_2\} = 0.56$ in Quarter 1 and $Pr\{G_1 > G_2\} = 0.76$ in Quarter 2. The estimate of 0.56 (56%) for Quarter 1 is surprisingly low, considering that a probability of 0.50 (50%) is obtained when the distributions are the same. We note that NIOSH failed to report a comparison for Quarter 1 data in Figure 6-3, but the information in Table 6-1 suggests there is a much smaller difference between the two groups when comparing Quarter 1 data, while Quarter 2 is comparable with Quarters 3 and 4 in the lower 70% range.

Using the lognormal parameters estimated from the median and IQR obtained from Table 6-1 for Quarter 3 and 4, the results are $Pr\{G_1 > G_2\} = 0.75$ in Quarter 3 and $Pr\{G_1 > G_2\} = 0.72$ in Quarter 4. These probabilities are in close agreement with the estimates obtained directly from the lognormal parameter values in Figure 6-3.

The values for all four quarters are somewhat higher than the 50% expected when the two distributions are identical, but they do not demonstrate convincingly that the distribution of doses for Group 2 is sufficiently different than for Group 1 to support use of a separate missed dose model for workers before 1961 based on the 147-worker regression. In this situation, the actual data distributions should be retained rather than replaced with data from a possibly non-

representative subset of 147 workers. This issue is also addressed in the review of Section 7-1, which reports detail of the regression modeling.

Figure 6. The Probability that a Worker Selected at Random from Group 1 Has a Higher Dose than a Worker Selected at Random from Group 2

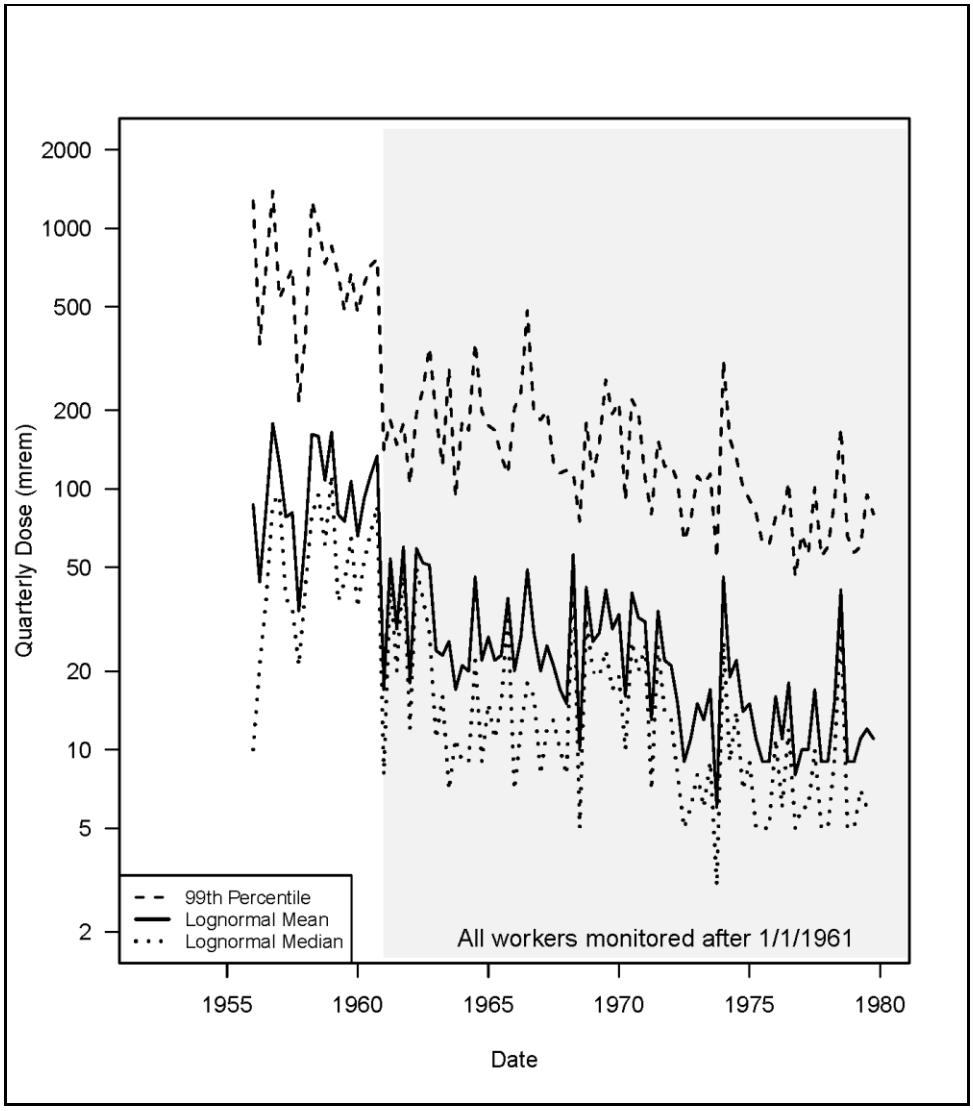


SECTION 6.5 (PAGES 27–31): LIMITATIONS OF DOSES FOR DOSE RECONSTRUCTION

Table 6-3 contains dose estimates derived using the ML lognormal parameters discussed previously. The table also contains estimates from the PLE method that are somewhat lower than the lognormal base estimates. However, the lognormal estimates are recommended for use by NIOSH as more claimant favorable. SC&A agrees with this conclusion.

Data in Table 6-3 were used to create the time series plot in Figure 7. This figure provides another view of the changes in monitoring protocols that occurred after the beginning of 1961 (shaded region in plot). Graphs of the empirical 99th percentile, lognormal mean, and lognormal median dose by quarter from Table 6-3 are shown in this figure. The three time series show a steady reduction in quarterly doses over the 24-year period. All three time series show a distinct downward change at the beginning of 1961, but we note that changes of similar proportion (both positive and negative) occur in all three series both before and after that date.

Figure 7. Lognormal Mean and Median and Empirical 99th Percentile of Y-12 Quarterly Gamma Dose Data



SECTION 7.1 (PAGES 31–33): PROCEDURE USED THROUGH THIRD QUARTER OF 1956

Figure 7-1 of OTIB-0044 shows the quarterly doses from 1956 to 1965 for 147 workers and the regression line obtained using the ML method for data with nondetects. No information is

provided as to how the 147 workers were selected, and why a larger number were not selected for this analysis. Most data sets of this type are collected by happenstance and/or convenience. It is difficult to determine the validity of using this type of data to represent the population of workers. Lacking evidence that these 147 workers are truly representative of the thousands of workers at Y-12 over this time period, the regression line and other results derived from the 147-worker data set should be considered as anecdotal evidence, and not as representative of all workers during any time period.

The parameters for the estimated ML regression line are presented in Section 7.1 of OTIB-0044. These parameters were used to compute the estimated regression line and the 99th percentile of the predictive distribution. The regression line and the predicted 99th percentile (abbreviated as ML Predicted 99th %tile) are plotted in gray in Figure 8, superimposed on the graphs of quarterly data shown in Figure 7. The regression line closely follows the graph of the lognormal mean, and the predicted 99th percentile closely follows the empirical 99th percentile graph. This is true both inside the 10-year within-sample time period used to estimate the regression and in the years following the within-sample time period shown on the figure. However, the out-of-sample performance of the regression in the years before the sample period is an open question that requires validation.

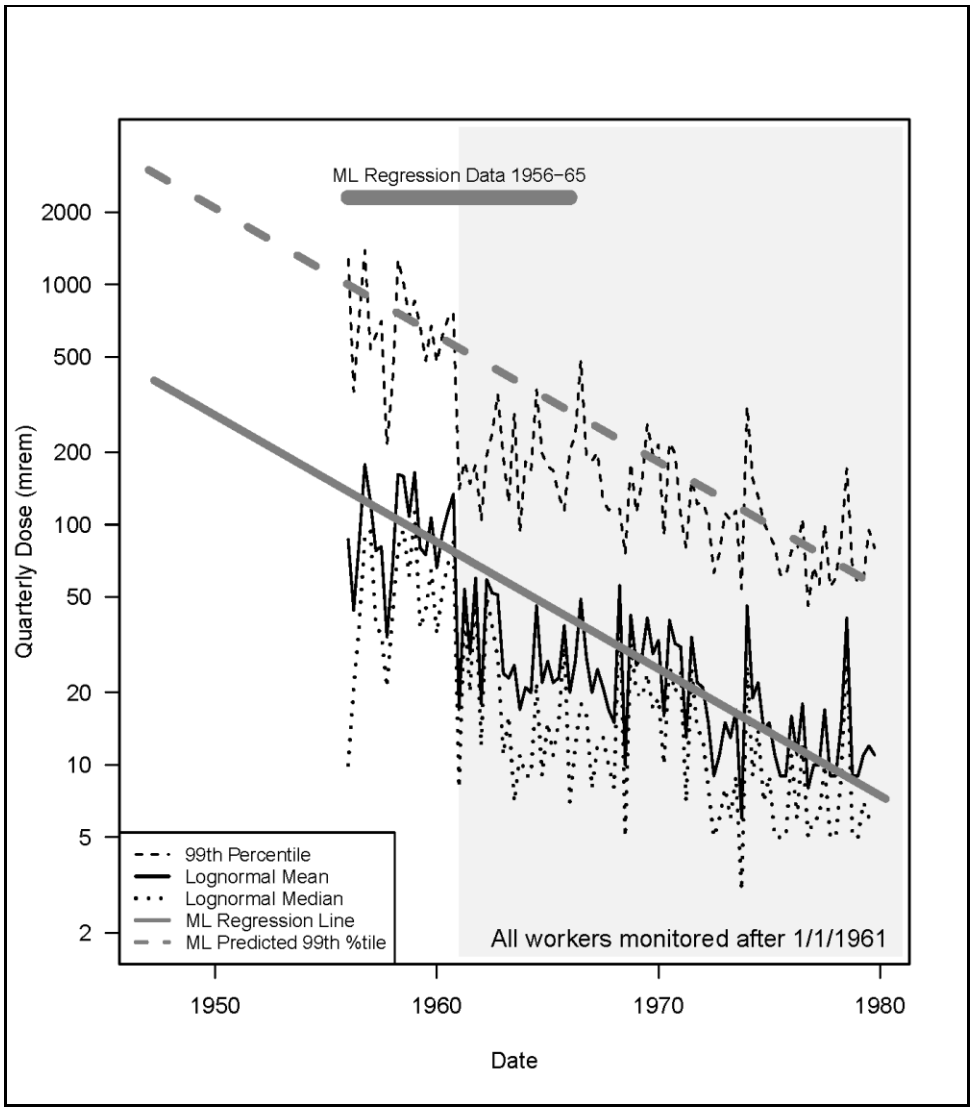
Extrapolation of time series regression results outside the sampling period is generally suspect. There is no assurance that the log-linear model applies outside the sampling period. The agreement of the predictions with the data observed in the years following the sampling period does not guarantee similar agreement in the years before the sampling period. There are two main concerns with out-of-sample prediction using time series models:

1) The validity of the model may not extend beyond the sampling period due to changes in the underlying processes.

2) If the model does apply, the estimated prediction errors derived from within-sample data may not be appropriate outside of the sampling period.

The good fit of the model predictions shown in Figure 8 in the post-sampling period provides some assurance against concern 1, but the validity of the model in the years before the sample period remains a major concern that should be addressed by comparison with observed data. The issues raised in concern 2 are related to the problem of over-fitting. These issues are discussed further in the review of Table 7-1 that follows.

Figure 8. Lognormal Mean and Median and Empirical 99th Percentile of Y-12 Quarterly Gamma Dose Data with ML Regression Line and 99th Percentile of the ML Predictive Distribution



SECTIONS 7.2 AND 7.3 (PAGES 33–35): PROCEDURE USED AFTER THIRD QUARTER OF 1956

The predictions from the ML regression model were applied to estimate missed doses in the out-of-sample period from Quarter 3 1947 to Quarter 3 1956. The dose estimates are shown in Table 7-1 of OTIB-0044. The table shows the parameters used for the lognormal missed dose distributions in each quarter. Prior to Quarter 3 1956, these parameter estimates are derived from the ML regression model.

Close inspection of the μ and σ columns of the table show the steady decline in μ as time progresses at a rate of approximately 0.03 per quarter. As expected, this value is approximately

equal to $\hat{\beta}/4$, where $\hat{\beta}$ is the estimated slope of the regression line reported in Section 7.1 of OTIB-0044. There is also a change in σ over time but at a much smaller rate—less than 0.0001 per quarter. The prediction errors are larger in the earlier quarters, but the differences are so small as to be of no practical significance. This implies the model is using almost the same magnitude of prediction errors for all quarters prior to the sampling period.

The forecasts extend out 9 years prior to the10-year sampling period. It is difficult to accept this high a degree of confidence in the out-of-sample model predictions. In most applications of time series forecasting (or back-casting), the width of the prediction interval has a funnel shape, with larger predictive errors as the forecasts extend out farther from the sampling period.

The unusually slow rate of increase in the width of the ML predictive interval outside of the sampling period is due in part to the very large sample size used to estimate the model. The model estimates presented in Section 7.1 of OTIB-0044 show very tight confidence bounds on both parameters: $se(\hat{\alpha})/\hat{\alpha} = 0.0045$ and $se(\hat{\beta})/\hat{\beta} = 0.045$. These precise estimates of the ML lognormal parameters result from the very large number of quarterly samples used to estimate the 147-worker model (5,686). Despite this apparent precision, it is highly unlikely that the uncertainty in predictions outside the sampling period should be as small as indicated by the precise estimates from the ML regression model. The issue of out-of-sample validation is not resolved by using a large number of samples in the sampling period.

SECTION 7.4 (PAGE 35–37): APPLICATION OF THE SCALING PROCEDURE

The use of individual scaling factors is an important addition to the missed dose estimation procedures employed by NIOSH. It makes sense that the estimated missed dose for a worker who has some data available should be a function of that data, in addition to other sources of information used to construct the coworker model. It is also notable that the scaling factors can only be used to increase the missing dose estimate. But the conditions for use of these scaling factors, as proposed by NIOSH, are quite restrictive:

> *This factor could be applied for any worker with unmonitored quarterly data before 1961 and satisfying these two conditions: (1) the worker must have monitoring data for at least five calendar quarters from 1961 through 1965, (2) the worker's routine duties and work location must have remained essentially the same during the 1950s and early 1960s.* [pages 35–36]

Data are available prior to 1961 for some of these workers with missing doses. The scaling procedures should also address these data where available. Additionally, it is not clear that historical records will be sufficient to document the second requirement for all workers with missed doses.

REFERENCES

Frome and Watkins 2004. E.L. Frome and J.P. Watkins, *Statistical Analysis of Data with Non-Detectable Values*, ORNL/TM-2004/146, Oak Ridge National Laboratory, Oak Ridge, Tennessee. August 2004. [SRDB Ref. ID 24176]

Helsel 2005. D.R. Helsel, *Nondetects and Data Analysis: Statistics for Censored Environmental Data*, John Wiley and Sons, NJ. 2005. [SRDB Ref. ID 139734]

Lee and Helsel 2005. L. Lee and D.R. Helsel, "Statistical Analysis of Water-Quality Data Containing Multiple Detection Limits: S-Language Software for Regression on Order Statistics," *Journal of Computers & Geosciences,* Vol. 31, No. 10 (2005), pp. 1241–1248.

NIOSH 2006. *Generating Summary Statistics for Coworker Bioassay Data*, ORAUT-PROC-0095, Revision 00, National Institute for Occupational Safety and Health, Cincinnati, Ohio. June 5, 2006.