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PUBLICATION RECORD

EFFECTIVE DATE	REVISION NUMBER	DESCRIPTION
12/29/2004	00	New technical information bulletin for the analysis of coworker bioassay data for internal dose assignment. First approved issue. Initiated by Elizabeth M. Brackett.
10/07/2005	01	Revision to update and expand current practices. Approved issue of Revision 01. Training required: As determined by the Task Manager. Initiated by Joseph Lochamy.

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ACRONYMS AND ABBREVIATIONS

GM	geometric mean
GSD	geometric standard deviation
MDA	minimum detectable activity or amount
SME	subject matter expert
TIB	technical information bulletin
U.S.C	United States Code

1.0 PURPOSE

Technical information bulletins (TIBs) are general working documents that provide guidance concerning the preparation of dose reconstructions at particular sites or categories of sites. They will be revised in the event additional relevant information is obtained. TIBs may be used to assist the National Institute for Occupational Safety and Health in the completion of individual dose reconstructions.

In this document the word "facility" is used as a general term for an area, building, or group of buildings that served a specific purpose at a site. It does not necessarily connote an "atomic weapons employer facility" or a "Department of Energy facility" as defined in the Energy Employees Occupational Illness Compensation Program Act of 2000 [42 U.S.C. Sections 7384l(5) and (12)].

This document provides technical guidance and assigns responsibilities for analyzing coworker internal bioassay data to develop intake values for assigning doses to unmonitored or partially monitored workers. Deviation from the guidance may be necessary because each bioassay data set has unique characteristics based on facility procedures, monitoring periods and methods, and other factors.

Each analysis of coworker internal dosimetry data, including the results and deviations from the process, will be documented in a site-specific TIB or a site profile.

2.0 BACKGROUND

In general, participation in a bioassay program involves workers who have the largest potential for exposure. While there are exceptions to this generality such as accidents involving unmonitored workers, it is unlikely that an unmonitored worker would have received a larger dose than the most highly exposed monitored worker at a site.

The analytical method described in this document assumes that the bioassay results for groups of workers have a lognormal distribution. Studies of worker dosimetry results (bioassay results, dosimeter results, etc.) tend to support this assumption. Alternate distributions may be used if a lognormal fit is not deemed satisfactory.

To calculate internal dose, intake rates must be determined. To determine coworker intake rates from bioassay, the 50th-percentile (median) and 84th-percentile bioassay results are calculated for specific periods from the available data. The R^2 fit parameter is also calculated as an indicator of reasonableness of fit for each distribution of bioassay results. Coworker intake rates are determined from the resultant two data sets, and the geometric standard deviation (GSD) of the coworker intake distribution is calculated by dividing the 84th-percentile intake(s) and/or intake rate(s) by the 50th-percentile intake rate(s).

This statistical method eliminates the need to define the minimum detectable activity or amount (MDA) for uncensored data sets (that is, data sets that include all values regardless of statistical significance). However, where the data sets are censored, there may be insufficient information for performing a fit to obtain the 50th- and 84th-percentile values. These censored data often are recorded as zeroes, numbers preceded by a less-than symbol (<) or as a code such as "ND." In such cases, a method for substituting a range of values for that censored data may be used, if the reporting level or cutoff value is specified or can be determined. This method is only to be used for cases where the fitting of the positive data yields unsatisfactory results. If the reporting level cannot be determined, the data may need to be used without modification. In some cases, such as when

monitored individuals typically had a measurable body burden from natural or manmade sources (e.g., atmospheric nuclear testing), substituting a range of values below the reporting level could be inappropriate. These cases are usually obvious because they often create a sharp bend in the plot where the substituted values join the uncensored data. As with the rest of this analytical process, professional judgment is important for extracting the best possible information from the data.

The statistical calculations described in this document may be by month, quarter, year, or even multiple years depending on the size of the data set and the number of positive values.

All decisions regarding the statistical analysis are recorded in instructions to the statistics analyst and in a site-specific document such as the site profile or a TIB.

This method eliminates the need to remove what could appear to be unreasonable outliers because the data distribution is evaluated rather than each datum. However, outliers may be removed at the discretion of the site team leader and the subject matter expert (SME).

3.0 RESPONSIBILITIES AND PROCESS

The following sections describe the analysis process and responsibilities for the following functions:

- Site team leader
- SME
- Coworker statistics team leader
- Data statistics analyst
- Validator
- Modeler
- Tools Development Group

Attachment A depicts these functions and the process in a flow chart. For smaller sites with limited data, one individual may serve in many of these roles.

3.1 SITE TEAM LEADER

The team leader's tasks are:

- Coordinate all aspects of the coworker statistical analysis process for the site

- Provide information to and answer the questions of those involved in the analysis, maintain schedules, and compile the statistical analysis information into a TIB

- Review the data to be analyzed and provide information to the statistics analyst. The information consists of at least the following items:
    - Site name
    - Radionuclides of interest
    - Database names and locations
    - Fields (columns) of interest in each database (e.g., results, dates, and identifiers)
    - Years to be included in analyses
    - Analytical periods (e.g., quarterly or annually)
    - Data units and any factors for normalizing or converting the data to other units
    - Censored data (i.e., where a reporting level was used) identified by year
    - Criteria for handling censored data

- Exclusion criteria by year (e.g., inadequate sample volumes)
- Code explanations for fields that have a bearing on the data
- Special exclusions (e.g., entry errors and medical intakes)
- Other information the data analyst could need to do the analyses

When compiling the site TIB, the site team leader documents:

- The information listed above
- Deviations from the process and recommendations in this TIB
- A summary of the results of the statistical analyses
- Unmonitored radionuclides associated with the primary radionuclides and the relative activities to include in intake calculations
- Intake periods and intake rates of primary (monitored) radionuclides and associated absorption types

3.2 SUBJECT MATTER EXPERT

The SME's tasks are:

- Review the data and related technical information to determine their completeness and usability, identify problems, and recommend solutions
- In concert with the site team leader, determine which data sets are useful for assigning coworker doses and, for sites with several methods of monitoring (e.g., urine and lung counting), determine which methods to use to assign best estimates of dose and which data to use to verify that the results are reasonable
- Assist and support the site team leader in compiling the detailed technical information used in the statistical analyses and provide a review prior to statistical analysis
- Review and approve the completed statistical analyses and modeled intake results

3.3 COWORKER BIOASSAY STATISTICS TEAM LEADER

The coworker bioassay statistics team leader provides overall statistical analysis coordination, technical support, and interface assistance between those involved in the analyses. This person works closely with the SME, the site team leader, the data statistics analyst, and the data validator.

3.4 DATA STATISTICS ANALYST

The analyst performs the statistical analyses in accordance with the site team leader's detailed instructions.

If there are unexpected data anomalies not fully addressed by the instructions, the analyst consults the site team leader. The site team leader and the SME may recommend deviations from the data analysis instructions.

The data statistics analyst performs the following tasks (as the data allow or as makes sense for the data set), typically using one or more spreadsheets designed to automate most of the analyses. Detailed guidance for performing these calculations are documented in ORAUT-PROC-0095, Generating Summary Statistics for Coworker Bioassay Data.

- Sort the data for each identified period from low to high results, rank the data using the midpoint of each percentile (e.g., given 10 results, the midpoint of the percentile for the first ranked datum is 0.05), and determine the 50th- and 84th-percentile values for the ranked data. If the data are censored, rank all the data, but fit only the uncensored data unless directed to substitute a linear distribution (or another approved distribution) of values for the censored data.

- Log-transform the data, calculate the *z*-score for each transformed data point, and plot the *z*-scores on the *x*-axis and the natural logarithms of their respective data on the *y*-axis.

- Use a line equation to calculate the 50th-percentile value, the GSD, and the 84th-percentile value for each period of dosimetry data.

- Calculate the associated R^2 fit parameter. A value greater than 0.9 indicates a very good fit; however, values as low as 0.7 are acceptable, and even lower values may be acceptable if no better equation seems appropriate.

- Build a summary table of the results for site team leader and SME review. The table design should enable easy transfer into internal dosimetry modeling programs such as IMBA. The columns should include the period of the data, an effective bioassay date (midpoint of the analysis period), the 50th-percentile values, and the 84th-percentile values.

- Document any items not covered by the written instructions from the team leader and SME (e.g., averaging of results, exclusion of anomalous results). Any such deviation should be discussed with the team leader and SME prior to application.

3.5 VALIDATOR

The validator's tasks are:

- Verify the analyst's results by performing essentially the same analyses.

- If there are discrepancies between the sets of results, resolve them with the analyst.

- Issue a summary report showing the percent variations between the sets of results. There should not be differences if rounding is discounted. Differences of up to 1% are not considered significant.

3.6 MODELER

The modeler determines intake rates by performing fits of the two data bioassay data sets (50th- and 84th-percentile results) associated with each radionuclide. For most data sets, intakes will be assumed to be chronic. There could be large, short-term releases that need to be addressed individually. The modeler's tasks are:

- Use site information (e.g., dates of shutdowns and known operating periods) where possible to break chronic intakes into periods. These periods should be adjusted as necessary to obtain a reasonable fit, but the assumed intake periods should generally not be very short.

- Assess intakes for each of the absorption types associated with the site and document the intake regimes and rationales for assumptions.

- Provide the site team leader with these data in a form suitable for the site TIB.

3.7 TOOLS DEVELOPMENT GROUP

The tools development group builds software tools for dosimetrists to use to determine organ doses in accordance with the site TIB and the site profile.

Attachment A
Responsibilities and Process for Coworker Bioassay Data for Internal Dose Assignment