Draft Criteria for the Evaluation and Use of Internal Exposure Coworker Datasets

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1.0 INRODUCTION

Under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), NIOSH completes dose reconstructions for employees with cancer who are covered under the provisions of the Act. The methods used to complete these dose reconstructions are prescribed in 42 C.F.R. Part 82 (USHHS 2002). While the use of individual personnel monitoring is preferred in the completion of dose reconstructions, these data are oftentimes not available because either the worker was monitored and the data have been lost or the worker was potentially exposed and not monitored. In the latter case, NIOSH has observed that, in accordance with the practices in effect at the time, only workers with the highest exposure potential were monitored or, in some cases, monitoring was conducted on representative members of the exposed population. In the absence of individual monitoring data, 42 C.F.R. Part 82 allows for the use other worker's data to complete dose reconstructions. Section 82.2 (b) states:

> *If individual monitoring data are not available or adequate, dose reconstructions may use monitoring results for groups of workers with comparable activities and relationships to the radiation environment.*

The groups of workers specified in §82.2(b) are generically known as coworkers. Coworkers are considered to be workers at the same site whose radiation monitoring measurements are considered to be representative or plausibly bounding of those received by one or more workers with no individual monitoring data. Depending on the amount and specificity of the available worker and workplace data, the level of detail included in coworker models can vary greatly. For dose reconstructions under EEOICPA, it is often difficult to locate a worker in a specific job at a specific location. Because of this, NIOSH has chosen to develop coworker models that cover a wide range of workers for a specific radionuclide at a specific time.

2.0 CRITERIA FOR THE EVALUATION OF THE ADEQUACY OF COWORKER DATASETS

As indicated above, coworker datasets should be established from monitored workers with comparable activities and relationships to the radiation environment. To accomplish this, one must carefully evaluate each coworker dataset to ensure that it is either representative of the distribution of exposures for the

intended population or that it provides a plausible upper bound for those workers[1]. Criteria to consider when determining the adequacy of a dataset are provided below.

2.1 Data Adequacy

The measurement technique used to monitor the worker should be evaluated to ensure that the technique can quantitatively measure the exposure of interest. For internal exposure monitoring, this evaluation should include a review of the sample collection methods, any chemical processes employed, and the radiation counting equipment used. Among the items to be considered are: 1) representativeness of the bioassay sample collection method; 2) radiochemical recovery if chemical extraction techniques are used; 3) reduction in counting efficiency for alpha emitters due to self –absorption; and 4) reliability of the radiation counting equipment. For external exposure monitoring, it is important to consider the ability of the monitoring devices to detect the energies and types (beta, gamma, or neutron) of radiation that were present in the workplace. In addition, a review of the adequacy of the calibration methods employed and the extent that fading is a factor should be addressed.

The amount of the available monitoring data should also be evaluated to determine if there are sufficient measurements to ensure that the data are either bounding or representative of the exposure potential at the facility. Facilities with the potential for internal and/or external exposure to a large percentage of the workforce would require many more samples than one in which the potential for exposure was limited to just a few workers. In addition, the variability of the exposure potential should be considered. It has been observed, for example, that some National Laboratories conducted work under many different experimental configurations, resulting in a wide variety of exposure potentials. In this case, it might not be possible to generate a single coworker model that adequately captures all categories of unmonitored worker doses.

Although there is no hard and fast rule for the minimum number of data points required to represent a given time interval, approximately fifteen values has been cited as a reasonable number for performing statistical tests on censored datasets (Singh et al. 2010). Because our program estimates parameters from the data, a default minimum of 30 values is recommended per modeled interval. The minimum number of samples should, of course, be considered in light of the number of worker's potentially expose to the airborne source-term. For example, the number of samples necessary to be representative of the exposures at a uranium foundry, where airborne activity is generally widespread, will be greater that the number required of a small glove box operation involved in the manipulation of plutonium parts.

[1] Under 42 CFR 83.13(c)(1), radiation doses are considered to be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose, for every type of cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances.

Finally, if electronic records or summary databases are used to develop the coworker model, these should be reviewed against a representative sampling of original data where possible to ensure that they contain a complete and unbiased listing of all the data collected by the site.

2.2 Application of Monitoring Data to Unmonitored Workers

Prior to applying a site's worker monitoring data to estimate the exposures of unmonitored workers, the type of personnel monitoring program employed at the covered facility must be established. In general, three types of monitoring programs have been employed at sites covered under EEOICPA. These programs, listed in hierarchical order of preference for use in coworker modeling are: 1) routine, representative sampling of the workers; 2) routine measurement of workers with the highest exposure potential; and 3) the collection of samples after the identification of an incident. Because they are not representative of the overall distribution of exposures, programs that rely on measurement of the highest exposed workers or are incident based require more careful consideration.

For routine monitoring programs, a review of the program should be conducted to determine the basis for the selection of program participants. It must be established who was monitored and why they were monitored. In this evaluation there must be some demonstration that the monitored population consisted of: 1) a representative sample of the exposed population or 2) the workers with the highest exposure potentia1. In these cases, the assignment of a coworker dose from the distribution of measured values would either be claimant favorable in the first case or representative of the worker's exposure in the second case.

In some situations, sites have relied on incident-based sampling to monitor worker's exposure. Because there are temporal gaps in the monitoring data, it is more difficult to demonstrate that this type of sampling can be used to develop representative or plausibly bounding coworker models. Prior to the use of incident-based sampling in a coworker model, the effectiveness of workplace controls, must be demonstrated through the review of routine air monitoring samples and/or periodic contamination surveys. If one can demonstrate that the effectiveness of workplace administrative and/or engineering controls was adequate to prevent exposures, except during upset conditions, it may be possible to use incident-based sampling in a coworker model

2.3 Appropriateness of the Modeled Data for the Unmonitored Population

The appropriateness of the application of the monitored population's data to those workers who were unmonitored should be evaluated. It is important to establish the exposure types and work activities of the unmonitored workers. A review of the job types and categories of the unmonitored workers should be conducted to determine if there are special exposure categories that might not be covered by the monitored population.

If the unmonitored population can be determined through a source term evaluation to have no potential for exposure, then it is not necessary to establish a coworker model. In this case, it might be sufficient to include ambient environmental dose in the dose reconstructions.

3.0 ANALYSIS OF MONITORING DATA

If after review of the monitoring program data, it is established that: 1) there is sufficient data to construct a general coworker model; and 2) the data can reasonably be represented by a log-normal distribution: the geometric mean and geometric standard deviation can be used to represent the distribution of exposures observed in the overall monitored population. For workers that are considered to have worked in environments with a potential for elevated exposure, the 95th percentile of the distribution should be used as an upper bound of their exposure during the modeled time period. (*Note: Although it could be argued that the job categories that fall under this criterion should be listed, any attempt to do so might be artificially restrictive. Based on past practice, NIOSH believes that this decision is most accurately made using the information available in the site profiles, the claimant interview and other documents that might be in the worker's records. This also applies to the following category of intermittently exposed workers.)* For workers who were less likely to be highly and/or were intermittently exposed in the workplace, the full distribution (i.e., the geometric mean and its associated standard distribution) should be used as representative of their potential for exposure during the modeled period.

Note: NIOSH is considering a modification of the OPOS approach to include a time-weighted average analysis. We have conducted an analysis of the SRS americium coworker model using a time-weighted averaging technique and have determined that this method more appropriately accounts for the variability in excretion patterns, including this issue associated with carry-over from positive bioassay results in previous years. NIOSH is interested in further discussions on this.

3.1 Time Interval of the Modeled Data

The amount of data that are available will directly influence the time intervals used in the coworker model. As stated in section 2.2, a minimum number of 30 samples per monitored interval is recommended. Based on a review of the currently available datasets, a modeled interval of one year strikes a good compromise between the availability of data and the need to ensure that the samples are contemporaneous with ongoing operations. In certain situations, there are sufficient data to develop quarterly models, but this is the exception rather than the norm. If, because of data limitations, it is necessary to consider time intervals beyond on year in the coworker model, any changes in site practices or operations should be evaluated to ensure that the data can be validly combined.

4.0 EVALUATION OF STRATIFICATION

The general coworker model described above could contain a combination of several different distributions. As such, the basic criteria discussed above might not sufficiently cover the range of exposures encountered by certain sub-populations of workers. There may be an underlying job category that is from a more highly exposed stratum of workers that would not be adequately bounded. Although this could occur with any job category/classification, it has often times been a concern when building trades workers are included in the general distribution with all monitored workers. If accurate job categories and/or descriptions can be obtained for the worker's making up the general dataset, and there is reason to believe that one of the categories is more highly exposed, the distribution of the potentially more highly exposed population should be evaluated as a separate standalone distribution.

As described above, workers with a higher potential for exposure would be considered to have been exposed at the 95th percentile of the general worker distribution. Thus, the geometric mean and standard deviation of the stratified subset should be compared to the 95th percentile of the general distribution. If it can be shown that the use of the full distribution in the stratified subset is more favorable than using the 95th percentile of the general distribution, the full distribution of the stratified subset should be used for those workers that fall into this category.

Note: NIOSH is working on the feasibility of such an evaluation and hopes to provide input on how this might be accomplished in the near future. Reliance on the probability of causation (PC) to make such a determination, although somewhat complicated, seems doable. If a predictable relationship between the PC generated for the full distribution and the use of the 95th percentile as a constant for the general distribution can be established, one might be able to establish a truly practically significant difference. Preliminary results seem to indicate that PC outcome associated with the full distribution can be generated by using a constant value that is around the 84th percentile. If this were true, then it would make sense to stratify distributions only if the ~84th percentile of the full distribution of the stratified dataset is larger than the 95th percentile of the general distribution of all monitored workers.

5.0 REFERENCES

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