# Division of Compensation Analysis and Support

## Criteria for the Evaluation and Use of Co-Exposure Datasets

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# 1.0 INTRODUCTION

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 often 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 workers' 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 available for a co-exposure model 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 co-exposure models that whenever possible cover a wide range of workers for a specific radionuclide at a specific time.

The objective of this document is to provide guidance for the evaluation of personnel monitoring data used in the reconstruction of doses to unmonitored workers who are covered under the EEOICPA. As such, the criteria in this Implementation Guide are to be applied to the development of new co-exposure models, as well as retrospectively in the review of existing coworker models.

# 2.0 CRITERIA FOR THE EVALUATION OF THE ADEQUACY OF AND COMPLETENESS OF CO-EXPOSURE DATA

As indicated above, co-exposure datasets should be established from monitored workers with comparable activities and relationships to the radiation environment. To accomplish this, one must carefully evaluate each co-exposure 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]. Additional guidance on how to establish this is provided later in this document. Prior to this, however, it is necessary to establish that the available internal or external monitoring measurements were technically capable of evaluating the monitored worker's exposure environment. If the techniques used to monitor exposed workers were inadequate, they clearly cannot be used to assess exposures for unmonitored workers. Criteria to consider when determining the technical adequacy of a dataset are provided below.

## *2.1 Data Adequacy*

Co-exposure models are developed using individual bioassay[2] or personal dosimeter measurements. The measurement techniques employed must be evaluated to ensure that they are capable of quantitatively measuring the exposure of interest. When urine samples are used, this 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. If workers were exposed to a mixture of radionuclides (e.g., a combination of fission and activation products or actinides), and the samples were measured using a non-specific assay (beta, gamma, or alpha counting), the relative contribution of each radionuclide in the mixture must be evaluated.

When *in vivo* measurements are used, the overall measurement program must be carefully reviewed to ensure that the data accurately represent the quantity of the radionuclide in the organ of interest. This includes the adequacy of the phantoms used to calibrate the partial or whole body measurement geometries and a review of the methodology used to quantify a measurement's limit of detection. For the measurement of low energy photons (e.g., those below 100 keV) emitted from the lungs, the program's ability to correct for self-absorption due to varying chest wall thickness should be considered. Because certain radionuclides of interest do not emit photons that can be detected by an in *in vivo* measurement, facilities sometimes infer the radionuclide of interest based on the measurement of one of its progeny. In this case, it is important to verify the validity of the assumptions that were made regarding the degree of radionuclide equilibrium between the progeny and its parent. Similarly, if ratios are employed to infer the amount of a contaminant (e.g., quantifying the amount of $^{239}$Pu based on a measurement of $^{241}$Am in the lung), the ratio that is applied should be based on a well-established analysis of exposure conditions within the facility. For external exposure monitoring, it is important to consider the ability of the monitoring devices (e.g., film badges or thermoluminescent

[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.

[2] While urinalysis is the bioassay method most often used for developing co-exposure models, *in vivo* measurements (e.g., lung or whole body counts) are sometimes used. If lapel breathing zone air samples are available, these may also be used, provided they have been determined to meet the data adequacy and completeness criteria outlined in this document.

dosimeters) to detect the energies and types (beta, gamma, or neutron) of radiation that were present in the workplace. For those situations in which there is a measurement bias, corrections to the measured readings must be established prior to use in a co-exposure model. In addition, a review of the adequacy of the calibration methods employed and the extent that fading is a factor should be addressed.

The quality of the available data also needs to be considered. This would include a review of the appropriate collection and analysis of blank samples. When paired measurements are available, the precision between measurements should be examined. If widely different results from the same aliquot are observed, the effect this might have on the usefulness of the data should be considered. At facilities where chelation therapy may have been used (e.g., the administration of DTPA), the data should be reviewed to ensure that samples taken from personnel who were administered chelating agents are removed from the data set.

Finally, the amount of dose that could have been received, but not detected by a routine monitoring program, must be evaluated to determine if the magnitude of this "missed" dose is within the plausible bounds of exposures received by the workers. In certain cases, where the monitoring frequency was low (e.g. one measurement per year) and the limit of detection of the measurement is high, the co-exposure model might predict exposures that are well above any credible scenarios for that facility.

## *2.2 Data Completeness*

Once the measurement techniques have been found to be technically acceptable, the amount of available monitoring data must be evaluated to determine if there are sufficient measurements to ensure that the data are either bounding or representative of the exposure potential for each job/exposure category at the facility. This analysis should look, not only at the total amount of data that are available, but also consider any temporal trends in data availability. A useful technique to establish this is to conduct a gap analysis. That is, the available monitoring data should be reviewed against the number and types of workers that were involved in radiological activities over time at the facility. As part of this analysis, the number of monitoring samples for each identifiable job category should be compared to the total number of workers who were potentially exposed in that job category. For the purposes of this effort a job category need not be an individual job title. Instead, a job category could consist of several job titles if there is reason to believe that exposures in those job categories would be similar.

If the number of potentially exposed workers in each category is unknown, a useful starting point is to look at the distribution of samples among the various categories of workers represented in the claimant population at that site. Table 1 provides an example of this for the categories of workers who were monitored for $^{239}$Pu at the Nevada Test Site. In this particular analysis, the radiation safety staff was monitored to a larger extent than workers directly involved in site activities. Thus, a co-exposure model based on these data would not necessarily reflect the

exposure conditions of the unmonitored production/process workers. If, in fact, it can be established that the categories of workers were potentially exposed, yet inadequately monitored, it could preclude the development of a sufficiently accurate co-exposure model, unless it can be established that the exposures to another, adequately monitored category of workers reliably bounds the initial category's exposures.

**Table 1: Number of Pu-239 Samples (Percent of Samples) by Time Period and Job Category at the Nevada Test Site[3]**

| N/A | All Job-Specific Workers | Radsafety Staff | Laborers | Welders | Wiremen | Miners | Security |
|---|---|---|---|---|---|---|---|
| **Total Number of Samples** | 290 | 206 | 2 | 0 | 0 | 8 | 74 |
| **1963–1967** | 30 (10.34%) | 28 (13.59%) | 2 (100.00%) | - | - | 0 (0.00%) | 0 (0.00%) |
| **1968–1970** | 34 (11.72%) | 31 (15.05%) | 0 (0.00%) | - | - | 2 (25.00%) | 1 (1.35%) |
| **1971–1980** | 79 (27.24%) | 76 (36.89%) | 0 (0.00%) | - | - | 3 (37.50%) | 0 (0.00%) |
| **1981–1992** | 147 (50.69%) | 71 (34.47%) | 0 (0.00%) | - | - | 3 (37.50%) | 73 (98.65%) |

Any identified gaps (i.e., periods of time where a small percentage of the workers were monitored) in the monitoring data should be reviewed to determine if there is a reasonable basis for the lack of monitoring data. For example, there may have been a temporary stoppage in the work at a facility due to the initiation of maintenance operations or facility upgrades. If the monitoring gap is found to exist during long periods of potentially elevated exposure, it may not be possible to develop representative co-exposure models during this time period.

The number and types of discreetly identified activities will vary widely among covered facilities. At Atomic Weapons Employer (AWE) facilities that worked with uranium metal, there may only be one activity, while large Department of Energy (DOE) facilities will likely have multiple operations. One area that needs to be considered at each facility is the difference in exposure potential between maintenance and trades workers versus those involved in routine process operations.

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

[3] Adapted from SC&A's white paper on bioassay evaluation at the Nevada Test Site, dated October 21, 2008.

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 co-exposure 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 person measurements is recommended per each discrete time interval and/or stratum being evaluated (e.g., 30 measurements per year if a co-exposure model is being developed based on annual samples or measurements). The minimum number of samples should, of course, be considered in light of the number of workers potentially exposed 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 than the number required of a small glove box operation where six workers were involved in the manipulation of plutonium parts. In the latter situation, it may be that samples for three out of six workers could be used to bound exposures for the three who were not monitored. Where the distribution of the data has large geometric means and/or standard deviations, the number of samples required will also be greater.

Finally, if electronic records or summary databases are used to develop the co-exposure model, these should be reviewed against a representative sampling of original data where possible to verify that they contain a complete and unbiased listing of all the data collected by the site. Documents to be considered in this review will vary depending on availability, but examples include hard copy lab records, summary health and safety reports, and NOCTS claimant file data. If hard copy records are being used, the legibility of the information should be carefully examined. For hard copy records that are manually entered by NIOSH, a quality control program to optimize the accuracy of data transcription should be established. If electronic records cannot be audited or are not an accurate representation of the monitoring records, they should not be used.

## 3.0 REVIEW AND ANALYSIS OF MONITORING PROGRAM DATA

Finalized co-exposure datasets reside in an electronic database, usually in the form of a spreadsheet or relational database. The original data that goes into the final co-exposure model is provided electronically to NIOSH in the form of various historical databases or in hardcopy format. In the process of converting the original data (electronic or hardcopy) into a single final co-exposure dataset, a log of the various manipulations that were required to produce the data in final form should be maintained, so that the final process is reproducible. This includes such practices as: 1) the deletion of any suspect outliers; 2) the removal of urine samples for workers on chelation therapy; and, 3) the conversion to units consistent with programmatic needs. Each

version of any manipulated dataset should be maintained for future reference. The following sections provide guidance on evaluating the applicability of the finalized co-exposure's dataset to the unmonitored workforce.

## *3.1 Applicability 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 co-exposure 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. This can most easily be established through a review of the site's radiological control program documentation. In this evaluation there must be a 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 co-exposure dose from the distribution of measured values would either be representative of the worker's exposure in the first case or claimant favorable in the second case. Even though the program documentation might indicate that routine sampling was conducted, it is important to verify that the site's procedures were followed by a review of the samples that were actually collected.

A variation of the routine monitoring program is one in which workers are intermittently monitored on an as-needed basis (i.e. only when the potential for exposure existed). This would occur, for instance, in a short-duration project that created an internal and/or external exposure potential. Based on the specifications in project work plans or radiological work permits, certain classes of workers would be monitored at the end of the project to document that the exposure controls that were put in place were adequate. In these situations, it may be possible to use the monitoring data collected during the project close-out to place a plausible upper limit on the exposures of the unmonitored workers.

In some situations, sites have relied on incident-based sampling to monitor worker 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 co-exposure models. Prior to the use of incident-based sampling in a co-exposure 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 co-exposure model. When possible, this review should also include interviews with workers to verify that the written program requirements were consistently followed.

It has been observed at a number of sites that different classes of workers during the same time period may have had monitoring programs that were conducted for different purposes. For example, construction and building trade workers, who worked intermittently in radiological areas, may have been monitored only when an incident was thought to have occurred, while those employees involved in routine process operations would have been routinely monitored on a frequency commensurate with their exposure potential. In this case, it would not be appropriate to combine the monitoring data for these two groups of workers into a single co-exposure model that assumes a chronic exposure pattern. Rather, the default in this case should be to consider separate co-exposure models.

## *3.2 Analysis and Application to the Unmonitored Population*

If after review of the monitoring program data, it is established that: 1) there is sufficient data to construct a representative co-exposure model, and; 2) the data can reasonably be represented by a statistical distribution (e.g., a log-normal or a Weibull distribution), the fitted distribution can be used to represent the exposures observed in the overall monitored population. For workers that are considered to have worked in environments with a potential for elevated exposure, the $95^{th}$ percentile of the distribution should be used as an upper bound of their exposure during the modeled time period. 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. 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. For workers who were less likely to be highly exposed and/or were intermittently exposed in the workplace, the full distribution (i.e., the geometric mean and its associated standard distribution if a lognormal fit is used) should be used as representative of their potential for exposure during the modeled period.

When multiple bioassay samples are present during a monitoring period for a given individual, it is appropriate to average the values so that a single statistic can be computed for that individual. The use of a single value for each monitored person in a given monitoring interval is appropriate because the desired co-exposure model represents a distribution of individual worker excretion results, as opposed to a distribution of all samples collected. The use of an average value for each worker has been called the One-Person-One-Statistic (OPOS) method. Rather than compute a simple average of the measured values, each individual bioassay result should be weighted by the fraction of the year it represents (i.e., a time-weighted OPOS). The details of how this calculation is performed is described in other program documentation (ORAU 2014).

### *3.3 Time Interval of the Modeled Data*

The amount of data that are available will directly influence the time intervals used in the co-exposure 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 one year in the co-exposure model, any changes in site practices or operations should be evaluated to ensure that the data can be validly combined. In general, grouped time intervals should not exceed a 3 year period, unless there is stringent justification for doing so.

## 4.0 EVALUATION OF STRATIFICATION

The distribution of a potentially more highly exposed population should be evaluated as a separate standalone distribution in situations where: 1) accurate job categories and/or descriptions can be obtained for all workers making up the general co-exposure dataset; 2) there is reason to believe that one of the job categories is more highly exposed; and, 3) there were unmonitored workers in this job category. If it can be demonstrated, however, that there were no unmonitored workers with the potential for exposure in this more highly exposed population, then stratification would not be necessary.

Once a dataset has been stratified based on job category, a statistical analysis should be conducted to determine if the two datasets should be modeled separately. This analysis consists of a two-tiered evaluation where the stratified distributions are first compared on a year-by-year basis (or other selected monitoring interval) to determine if any of the individual distributions are significantly different If a significant difference is observed in any of the modeled time intervals, then a test of practical significance is employed. This test compares the slopes of the chronic intake models over the time periods where a statistically significant difference in the modeled distributions was observed (ORAU 2014).

## 5.0 REFERENCES

ORAUT 2014. *Analysis of Stratified Coworker Datasets*, ORAUT-RPRT-0053, Rev- 02, Oak Ridge Associated Universities Team, Cincinnati, Ohio. October 2, 2014.

Singh, A., N. Armbya, and A. K. Singh, 2013, *ProUCL Version 5.0.00 Technical Guide*, EPA/600/R-07/041, U.S. Environmental Protection Agency, Office of Research and Development, Washington, D.C., September.

U.S. Department of Health and Human Services. Methods for radiation dose reconstruction under the Energy Employees Occupational Illness Compensation Program Act of 2000, final rule. Washington, DC: U.S. Government Printing Office; 42 CFR Part 82; 2002.

U.S. Department of Health and Human Services. Methods for radiation dose reconstruction under the Energy Employees Occupational Illness Compensation Program Act of 2000, final rule. Washington, DC: U.S. Government Printing Office; 42 CFR Part 83; 2002.