FINAL DRAFT

CRITERIA FOR THE USE OF SURROGATE DATA

Prepared by the ABRWH Work Group on Use of Surrogate Data

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For the purposes of this report, the term "surrogate data" will refer to the use of exposure data from one site for individual dose reconstruction for workers at another site. In reviewing this topic for the Work Group SC&A distinguished between "Type I" surrogate data use (as described above) and "Type II" surrogate data where these data are used as part of a scientific effort to develop parameters for use in dose reconstruction activity calculations rather than as a substitute for the lack of adequate data needed for dose reconstruction.

"Surrogate data" are used in the NIOSH dose reconstruction program because of the lack of complete and comprehensive exposure monitoring records for many of the workers at the sites covered by the program (SC&A September 2007). It is more often considered for dose reconstruction during the early years of some DOE and AWE facilities because of the lack of reliable monitoring methods, the urgency of developing production capabilities, and other reasons.

This report will review a number of criteria that need to be considered in determining whether the specific use of surrogate data for individual dose reconstruction is scientifically sound and appropriate for that particular application.

1. Hierarchy of Data – It should be assumed that the usual hierarchy of data would apply to dose reconstructions for that site (Individual worker monitoring data followed by co-worker data followed by workplace monitoring data such as area sampling followed by process and source term data.) This hierarchy should be considered when evaluating the potential use of surrogate data. Surrogate data should only be used to replace data if the surrogate data have some distinct advantages over the available data and then only after the appropriate adjustments have been made to reflect the uncertainty inherent in this substitution.

2. Exclusivity Constraints – In many cases, surrogate data are used to supplement the available monitoring data from a site. In those cases, the surrogate data is usually used to justify certain assumptions about the distribution or range of possible exposures or assumptions about the source terms. In those cases, no special justification is necessary beyond the usual scientific evaluation. This is akin to the Type II use decribed above. However, in other situations, there are no or very little monitoring data available. In those cases, the use of the surrogate data as

the basis for individual dose reconstruction would need to be stringently justified. This judgment needs to take into account not only the amount of surrogate data being relied on relative to data from the site but also the quality and completeness of that surrogate data.

3. Site or Process Similarities – One of the key criteria for judging the appropriateness of the use of surrogate data would be the similarities between the site (or sites) where the data were generated and the site where the surrogate data are being utilized. The application of any surrogate data to an individual dose reconstruction at a site should include a careful review of the rationale for utilizing that source of data. Factors that could be considered include, but are not limited to, similarity of the production processes, presence or absence of conditions that might affect exposure, and monitoring methods employed at the site(s). The potential availability of other sources of surrogate data needs to be considered and the selection of the surrogate data used for dose reconstruction justified. Some of the questions to be considered where appropriate are:

    - Are there other sources of surrogate data that were not used ?
    - Do these other potential sources contradict or undermine the application of the data from the selected site?
    - Are there adequate data characterizing the site being used that would help support its application to other sites?
    - Do the surrogate data reflect the type of operations and work practices in use at the facilities in question?

    Surrogate data should not be used if the equivalence of working conditions, source terms, and processes of the surrogate facility to the one for which dose reconstructions are being done cannot be established with reasonable scientific or technical certainty as outlined here.

4. Temporal Considerations: Consideration also needs to be given to the period in question, since working conditions and processes varied in different periods. Surrogate data should belong in the same general period as the period for which doses are sought to be reconstructed unless it can be demonstrated that the working conditions, procedures, monitoring methods, and (perhaps) legal requirements were comparable to the period in question.

5. Plausibility: The manner in which the surrogate data are to be used must be “plausible” with regard to the reasonableness of the assumptions made. The plausibility determination should address issues of:

- Scientific plausibility. Are the assumed models (e.g., bioassay, concentration gradients) scientifically appropriate? Have the models been validated (where feasible) using actual monitoring data collected in a similar situation?

- Workplace plausibility. Are the assumed processes and procedures (including monitoring) plausible for the facility in question? Have all of the factors that could significantly impact exposure been taken into account? Is adequate information available about the facility in order to be able to make a fair assessment?

Claimants will have significant concerns about the credibility of using surrogate data. To the extent that the use of surrogate data for individual dose reconstruction can be avoided, this will help to minimize concerns about the credibility of the individual dose reconstruction process. This is especially important given that the use of surrogate data often relies on information on the operations and characteristics of industrial facilities operated many years ago. Many of the people knowledgable about the facility have died, and records are usually incomplete (which is the reason for needing to use surrogate data in the first place). Given the difficulties in obtaining the comprehensive information needed for validating the use of surrogate data for individual dose reconstruction and the inherent concerns about its use by claimants, the Work Group recommends that the use of surrogate data be limited to the circumstances where other approaches are not feasible and then only after the rigorous review of the proposed use to determine if the above criteria have been fully met.