

APPENDIX A

Descriptions of Key Program Functions and Program Support functions

A. KEY PROGRAM FUNCTIONS

Key Program functions are listed below, based on which entities carry them out, in the following order: 1) NIOSH-only; 2) NIOSH/Program Contractor; 3) Contractor-only.

NIOSH-Only KPFs

1. Document Approval Authority (NIOSH)

The **Document Approval Authority** exercises approval authority by signature to permit use by the Program of a Dose Reconstruction Report, Site Profile Document, SEC Petition Evaluation Report, Site-Specific Technical Information Bulletin (TIB), and/or any other key Program function document created for use by the Program. Any exercise of such approval authority is treated as a key Program function under this policy, and the individual who exercises that authority shall ensure to the best of his/her ability, by a review of the document and the sources and preparers described within, that the exclusions and attributions required by these Implementing Procedures have been met before signing the document and approving it for use in the Program.

2. NIOSH AOB/COB Officer (NIOSH)

The **NIOSH AOB/COB Officer**, who reports directly to the NIOSH Director, is responsible for ensuring to the best of his/her ability that any key Program function document disseminated by NIOSH conforms substantively and procedurally to all the provisions contained in this COB Policy Statement. In that regard, the AOB/COB Officer manages the process to ensure that all key Program function documents conform to the NIOSH AOB Policy and its Implementing Procedures. For example, the AOB/COB Officer will review all disclosures brought to his/her attention due to potential conflicts or concerns; investigate and resolve complaints about failure to disclose; may examine key Program documents for proper attribution; and examine the roles of the document owner, site, and subject experts, among others, in key Program documents. With regard to documents disseminated by Program contractors, the NIOSH AOB/COB Officer shall exercise similar oversight in consultation with the respective NIOSH Contact Officer Technical Representatives. In all instances, the NIOSH AOB/COB Officer may carry out his/her responsibilities in consultation with the NIOSH Director and/or other NIOSH and HHS employees as needed.

NIOSH/Program Contractor KPFs

1. Site Profile Document Owner (NIOSH/ORAU)

A **Site Profile Document¹ Owner** is responsible for coordinating and drafting all Site Profile Documents, ensuring that all relevant information is captured in the document,

¹ "Site profile document" also includes any "Technical Basis Documents," or TBDs, related to the site.

evaluating information, and establishing or setting forth specific findings or conclusions. The Site Profile Document Owner is the primary writer/editor of the Site Profile Document. The Site Profile Document Owner has an affirmative duty to seek out all relevant data and to objectively evaluate all relevant input with no special consideration given due to the source (*e.g.*, Site Expert or Subject Expert/Technical Specialist). All narrative or quantitative input to Site Profile Documents shall be clearly attributed² to each source(s), including both Site and Subject Experts/Technical Specialists, wherever it appears or is relied upon within a Site Profile document. In addition, both Site and Subject Experts/Technical Specialists shall be clearly identified on the approval page of every Site Profile Document to which they contributed. A Site Profile Document Owner is responsible for any and all revisions to a Site Profile Document.

2. Site Expert (NIOSH/All Program Contractors)

A **Site Expert** is responsible for advising on site-specific issues and incidents as necessary to ensure the completeness and accuracy of Dose Reconstructions, Site Profile Documents and Special Exposure Cohort Petition Evaluation Reports, or to conduct Advisory Board-related reviews of such products, documents and reports. Site Experts are those individuals who, because of current or prior work experience (including consulting) at or for the site, possess or are aware of information that is relevant for reconstructing radiation doses experienced by claimants who worked at the site. Because of their work experience at or for sites under Program review and the need to prevent or remedy conflicts, Site Experts, if first provided a waiver, authorization, or approval to participate, shall play only a very limited role in accomplishing key Program functions. They may be used by a document owner in crafting a key Program document, to assist with data collection, and provide both data and opinions on data to that document owner. In all cases where such actions, information or prior studies or writings are included or relied upon by a key Program document owner, those actions and/or materials shall be both fully attributed to the Site Expert and reprinted, if at all, only in an Appendix of the key Program document. The Site Expert's input shall also be maintained as appropriate elsewhere in the document record (for instance, in notes of formal interviews conducted with the Site Expert to obtain information).

Site Experts are not permitted to serve as document owners or authors, or to make formal public presentations on a key Program document. However, at a formal public presentation, a Site Expert may be called upon to answer questions and serve as a source of information to the presenter in response to questions that arise during a presentation.

3. Site-Specific Technical Information Bulletin Owner (NIOSH/ORAU)

A **Site-Specific Technical Information Bulletin Owner** is responsible for coordinating and drafting a TIB which addresses a technical issue or concern regarding dose reconstructions for a specific exposure that may occur at one or more specific DOE or

² "*Attributed*" means the inclusion of footnotes, endnotes, a list of references, or other markings to identify the person, organization, or document sources for information in Program documents. The level of specificity of the attribution shall be appropriate to the importance of the information and may include, for example, document sections, paragraphs, tables or figures, or other key components of the document.

AWE facilities³, ensuring that all relevant information is captured in the document, evaluating information, and establishing or setting forth a specific approach to resolve the technical issue or concern. The Site-Specific TIB Owner is the primary writer/editor of the subject TIB. The Site-Specific TIB Owner has an affirmative duty to seek out all relevant information, and to objectively evaluate all relevant input with no special consideration given due to the source (*e.g.*, Site Expert or Subject Expert/Technical Specialist).

All narrative or quantitative input to a Site-Specific TIB shall be clearly attributed to each source(s), including both Site and Subject Experts/Technical Specialists, wherever it appears or is relied upon within a TIB. The specific DOE or AWE site to which the TIB applies shall be listed in the TIB. In addition, both Site and Subject Experts/Technical Specialists shall be clearly identified on the approval page of every Site-Specific TIB to which they contributed. A Site-Specific Technical Information Bulletin Owner is responsible for any and all revisions to a Site-Specific TIB.

4. Special Exposure Cohort Petition Evaluation Report Owner (NIOSH/ORAU)

A **Special Exposure Cohort (SEC) Petition Evaluation Report Owner** is responsible for leading and documenting the evaluation of a qualified SEC petition to determine the feasibility of performing dose reconstruction. This individual is the primary writer/editor of the SEC Petition Evaluation Report. The SEC Petition Evaluation Report Owner has an affirmative duty to seek out all relevant data and to objectively evaluate all relevant input with no special consideration given due to the source (*e.g.*, Site Expert or Subject Expert/Technical Specialist).

All narrative or quantitative input to SEC Petition Evaluation Reports shall be clearly attributed to each source(s), including both Site and Subject Experts/Technical Specialists, wherever it appears or is relied upon within the SEC Petition Evaluation Report. In addition, both Site and Subject Experts/Technical Specialists shall be clearly identified on the approval page of every SEC Petition Evaluation Report to which they contributed. An SEC Petition Evaluation Report Owner is responsible for any and all revisions to an SEC Petition Evaluation Report.

5. Scientific/Technical Peer Reviewer (NIOSH/All Program Contractors)

A **Scientific/Technical Peer Reviewer** is responsible for conducting a scientific and technical review of key Program documents (*e.g.*, Dose Reconstruction Report, Site Profile Document, SEC Petition Evaluation Report, Site-Specific TIB, or materials responding to such documents as prepared by the technical contractor supporting the Advisory Board), and any other Program document created for use by the Program, to ensure the completeness and accuracy of such documents in that regard. Although classified as a KPF, a Scientific/Technical Peer Reviewer may be permitted to review a document pertaining to a site at which s/he is conflicted, subject to first obtaining the necessary remedial documentation to do so. As with Site Experts, this is done to balance the use of scientific and technical expertise important to the Program against the need to minimize the occurrence of conflicts of interest.

³ “*Site-Specific*” TIB is one that applies to a single site, or a limited number of sites where those sites are identified by name in the document.

6. Author/Owner of Site-Specific “White Paper” or Other Product Prepared for Purposes of Board, Working Group and/or Subcommittee Discussion (NIOSH/All Program Contractors)

An Author/Owner is considered responsible for drafting and/or leading the preparation of a site-specific “white paper” or other product that is created upon request of the Advisory Board or one of its Working Groups or Subcommittees, via the DFO, for purposes of assisting in Board members’ discussions and deliberations with regard to a specific site or sites.

Contractor-Only KPFs

1. Case Manager (SC&A)

A **Case Manager** is directly responsible for one or more cases under review by SC&A, and for directing those **Technical Specialists** who assist them in the case reviews. These responsibilities include planning, scheduling and cost control, as well as the technical quality of the end-product. Specifically, **Case Managers** supervise all work performed by the staff assigned to their cases; ensure that the work is performed in accordance with SC&A program procedures and quality assurance requirements; and report the status of assigned work to the **Project Manager**.

2. Dose Reconstructor (ORAU/SC&A)

A **Dose Reconstructor** is responsible for conducting dose reconstructions for the Program which include, but are not limited to, analyzing monitoring methods, performing uncertainty analyses, estimating organ or effective dose from available monitoring data, and incorporating any comments from Dose Reconstruction Report Reviewers. A Dose Reconstructor is responsible for any and all revisions to a Dose Reconstruction Report.

3. Dose Reconstruction Reviewer (ORAU/SC&A)

A **Dose Reconstruction Reviewer** works under the supervision of a Lead Dose Reconstruction Reviewer, Case Manager or other managing individual to ensure that the dose reconstruction under review was performed in accordance with NIOSH regulations, procedures and guidelines, and (for advanced reviews) placing special emphasis on the NIOSH data collection process and on whether the review suggests flaws or biases in the dose reconstruction process.

4. Dose Reconstruction Report Peer Reviewer (ORAU/SC&A)

A **Dose Reconstruction Report Peer Reviewer** is responsible for conducting a review of the Dose Reconstruction Report to ensure that all appropriate sources of information for possible doses are included and that all calculations are accurate.

5. Lead Dose Reconstruction Reviewer (ORAU/SC&A)

A **Lead Dose Reconstruction Reviewer** is directly responsible for all dose reconstruction reviews and blind dose reconstructions performed for the Program, and ensures that all individuals performing dose reconstruction reviews and blind dose reconstructions do so in accordance with applicable procedures, and that any deviation from those procedures receives proper review, approval and documentation.

6. Worker/Site Profile Reviewer (ORAU/SC&A)

A **Worker/Site Profile Reviewer** conducts reviews of worker and site profiles and related data and analyses, pursuant to tasking by the appropriate COTR at the request of the Advisory Board or NIOSH, under the direction of the Lead Worker/Site Profile Reviewer. The Worker/Site Profile Reviewer determines whether NIOSH followed its applicable regulations, procedures and guidelines in assembling the Profiles, data and/or analyses and has met NIOSH and Board requirements (both explicit and as determined in specific cases) for ensuring validity and scientific quality.

7. Lead Worker/Site Profile Reviewer (ORAU/SC&A)

A **Lead Worker/Site Profile Reviewer** is responsible for conducting and overseeing independent reviews of worker and site profiles and databases, as tasked by the Advisory Board or NIOSH. S/he also supports Case Managers and/or Project Managers in performing both basic and advanced reviews and blind dose reconstructions, and may support SEC Petition reviews.

8. SEC Petition Reviewer (ORAU/SC&A)

An **SEC Petition Reviewer** reviews SEC petitions and petition evaluations, pursuant to tasking by the appropriate COTR at the request of the Advisory Board or NIOSH, under the supervision of the Lead SEC Petition Reviewer or other manager. The Reviewer evaluates whether an SEC petition was handled in accordance with applicable NIOSH procedures, as well as other technical issues as deemed necessary by the Advisory Board or NIOSH.

9. Lead SEC Petition Reviewer (ORAU/SC&A)

A **Lead SEC Petition Reviewer** is responsible for overseeing SEC petition reviews by ORAU or SC&A to ensure that the reviews are performed in accordance with Program-specific procedures, and that any deviation from those procedures receives proper review, approval and documentation.

B. PROGRAM SUPPORT FUNCTIONS

1. Implementation Guide/General Guidance Owner (NIOSH/ORAU)

An **Implementation Guide/General Guidance (IG/GG) Owner** is responsible for providing basic guidelines on the general methods employed in reconstructing either internal or external doses, or other general (*i.e.*, not site-specific) guidance on carrying out NIOSH responsibilities under the Program. The IG/GG Owner is the primary writer/editor of the Implementation Guide or other guidance document and is responsible for coordinating and drafting that respective document. The IG/GG Owner has an affirmative duty to seek out all relevant information, and to objectively evaluate all relevant input with no special consideration given due to the source (*e.g.*, Site Expert or Subject Expert/Technical Specialist).

All narrative or quantitative input to IG/GG shall be clearly attributed to each source(s), including both Site and Subject Experts/Technical Specialists, wherever it appears or is relied upon within the pertinent document. In addition, both Site and Subject Experts/Technical Specialists shall be clearly identified on the approval page of every IG/GG to which they contributed.

2. Multiple-Site Technical Information Bulletin Owner (NIOSH/ORAU)

A **Multiple-Site Technical Information Bulletin Owner** is responsible for coordinating and drafting a TIB which addresses a technical issue or concern regarding dose reconstructions for a specific exposure that may occur at multiple DOE or at AWE facilities⁴, ensuring that all relevant information is captured in the document, evaluating information, and establishing or setting forth a specific approach to resolve the technical issue or concern. The Multiple-Site TIB Owner is the primary writer/editor of the TIB. The Multiple-Site TIB Owner has an affirmative duty to seek out all relevant information, and to objectively evaluate all relevant input with no special consideration given due to the source (*e.g.*, site expert or subject expert). All narrative or quantitative input to a Multiple-Site TIB shall be clearly attributed to each source(s), including both Site and Subject Experts/Technical Specialists, wherever it appears or is relied upon within such a TIB. Each DOE or AWE site to which the TIB applies shall be listed in the TIB. In addition, both Site and Subject Experts/Technical Specialists shall be clearly identified on the approval page of every TIB to which they contributed. A Multiple-Site Technical Information Bulletin Document Owner is responsible for any and all revisions to a Multiple-Site TIB.

3. Subject Expert/Technical Specialist (NIOSH/All Program Contractors)

A **Subject Expert/Technical Specialist** is responsible for advising on scientific and technical issues and incidents as necessary to ensure the completeness and accuracy of Site Profile Documents and SEC Petition Evaluation Reports and/or reviews and evaluations of documents, analyses and data conducted by NIOSH and/or its Program contractors, as appropriate. In contrast with Site Experts, Subject Experts and Technical Specialists are those individuals who have expertise in the subject matter of certain activities performed at a site, but do not necessarily have any current or prior work experience at or for the subject site itself.

⁴ A “*multiple-site*” TIB is one that applies in a generic fashion to a number of sites that are not designated as such in the document.