Division of Compensation Analysis and Support	Document Number: DCAS-PR-004 Effective Date: 04/15/2011 Revision No. 1
Internal Procedures for the Processing of Special Exposure Cohort Petitions	Page 1 of 48
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TABLE OF CONTENTS

RECORD OF ISSUE/REVISIONS

ISSUE AUTHORIZATION DATE	EFFECTIVE DATE	REV. NO.	DESCRIPTION
9/23/2004	9/23/2004	0	New document to establish the requirements for processing Special Exposure Cohort Petitions
xx/xx/2011	04/15/2011	1	Revision to incorporate changes resulting from amendments to 42 C.F.R. Part 83 and other updates

1.0 PURPOSE

The purpose of this internal procedure is to provide general guidance for the staff of the National Institute for Occupational Safety and Health's (NIOSH) Division of Compensation Analysis and Support (DCAS) and its technical support contractors concerning processing of Special Exposure Cohort (SEC) petitions under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA) (42 U.S.C. § 7384n(c)(3)(A)). This internal procedure supplements the procedures described under 42 Code of Federal Regulations (C.F.R.) Part 83, related procedures and guidelines for dose reconstruction described under 42 C.F.R. Part 82, and related dose reconstruction implementation guidelines (OCAS-IG-001 and OCAS-IG-002).

2.0 SCOPE

This document applies to all SEC petitions processed by DCAS and its support contractors.

3.0 REFERENCES

3.1 42 C.F.R. pt. 82, *Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol. 67, No. 85/Thursday, May 2, 2002, p. 22,314.

3.2 42 C.F.R. pt. 83, *Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Final Rule, Federal Register/Vol. 69, No.104/Friday May 28, 2004, p. 30,764.

3.3 42 C.F.R. pt. 83, *Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Amendments: Interim Final Rule With Request for Comments, Federal Register/Vol. 70, No. 245/Thursday, December 22, 2005, p. 75,949.

3.4 42 C.F.R. pt. 83, *Procedures for Designating Classes of Employees as Members of the Special Exposure Cohort Under the Energy Employees Occupational Illness Compensation Program Act of 2000*; Amendments, Federal Register/Vol. 72, No. 131/Friday July 10, 2007, p. 37,455.

3.5 NIOSH, (2007) *External Dose Reconstruction Implementation Guideline*, OCAS-IG-001, Rev 3, National Institute for Occupational Safety and Health, Office of Compensation Analysis and Support, Cincinnati, Ohio.

3.6 NIOSH, (2002) *Internal Dose Reconstruction Implementation Guideline*, OCAS-IG-002, Rev 0, National Institute for Occupational Safety and Health, Office of Compensation Analysis and Support, Cincinnati, Ohio.

3.7 OCAS-PR-005 Rev 0, Conduct of Assessments, December 3, 2004.

3.8 OCAS-PR-006 Rev 4, CIC Processing Compensation Cases, November19, 2007.

3.9 42 U.S.C. § 7384n(c)(3)(A) *Energy Employees Occupational Illness Compensation Program Act of 2000* (EEOICPA).

4.0 RESPONSIBILITIES

Described in procedure

5.0 GENERAL

This DCAS procedure supplements the procedures of the Department of Health and Human Services (HHS) published in 42 C.F.R., part 83 for designating classes of employees as members of the SEC. This internal DCAS procedure provides more specific guidance for DCAS and its technical support contractors for performing their respective responsibilities in implementing the EEOICPA program. This procedure does not create any substantive rights on behalf of petitioners.

5.1 Website and Telephone Line

5.1.1 DCAS will maintain the NIOSH/DCAS website (www.cdc.gov/niosh/OCAS). The website will include a posting of the HHS procedures as published in the Federal Register and any subsequent revisions thereto.

5.1.2 DCAS will also post this internal DCAS procedure on the website. Any subsequent revision of the HHS procedures, as announced in the Federal Register, will be evaluated for any impact on DCAS activities and incorporated as necessary in this DCAS procedure. Any subsequent revision of this procedure will be posted on the NIOSH/DCAS website. Comments regarding this internal

procedure or any revisions thereto are welcome, and may be provided at any time to DCAS at DCAS@cdc.gov.

5.1.3 DCAS will post and continuously track the progress of each active petition on the website.

5.1.4 DCAS will support and work with the SEC Petition Counselor and will maintain on the website current information regarding the services provided by the Counselor and contact information.

5.1.5 DCAS will maintain a telephone line (1-877-222-7570) and information on the website in order to respond to requests and to provide detailed instructions for preparing and submitting petitions. Requestors may be sent a copy of, or be referred to, the online version of the petition form.

5.2 Management of documents related to SEC petitions

Note: A number of physical and procedural measures will be implemented in order to protect the privacy of SEC petitioners and to assure the safekeeping of documents received by and produced by DCAS relating to SEC petitions.

5.2.1 Physical management of SEC documents (filing, storage, scanning)

Newly received petitions and supporting documents will be scanned and uploaded to the DCAS SEC Application (DSA) tracking system and hardcopies filed in the appropriate petition folder in locked SEC-dedicated filing cabinets located in a restricted access office area. Documents are to be placed in the petition folder by document type. Electronic documents will not be printed as hardcopies for filing.

5.2.2 Privacy Act compliance

SEC documents in the possession of DCAS will be handled in a manner which will protect the privacy of petitioners or others involved in the petition process. Unless in a restricted access office area, SEC documents that contain information protected by the Privacy Act will not be left accessible at an unattended work station. When SEC reports, decisions, or other releases are to be issued, they must be appropriately redacted to protect the privacy of individuals and must be reviewed by the NIOSH Office of General Counsel (OGC) for privacy and other legal considerations prior to being sent to the intended audience.

5.2.3 Quality Assurance

Conduct periodic Quality Control checks to compare the documents in a petition file with the scanned entries in OSA in order to assure that all documents have been included in the appropriate petition file. This check should be performed following the procedure outlined in DCAS-PR-005, "Conduct of Assessments," and may be scheduled via the DCAS quarterly assessment.

6.0 PROCEDURE

6.1 Determine whether the petition qualifies for evaluation.

Note: The steps and procedures within subsection 6.1 provide guidance for determining whether a petition for cohort status meets the requirements specified under 42 C.F.R., part 83 to qualify for evaluation by DCAS, the Advisory Board on Radiation and Worker Health (Board), and the Secretary of the Department of Health and Human Services (HHS). These requirements, specified under §§ 83.7 and 83.9, are separate and distinct from the criteria by which the Secretary of HHS will determine whether or not to add a class of employees to the Cohort. The steps presented herein for receipt, handling, filing, and responding to petitions are presented to show their relationship to the overall process of evaluating petitions. Specific responsibilities and actions for those elements are presented in DCAS-PR-006, "CIC Processing Compensation Cases."

6.1.1 Receive, acknowledge receipt of, and assign the petition.

6.1.1.1 Petitions must be in writing (includes fax, email, or electronic files). In response to verbal/phone contacts, the petitioner should be instructed on how to properly submit a petition (see Section 5.0). Date-stamp the petition the day it is received by DCAS (except for electronic submissions) and log it into the DCAS SEC Application (OSA) tracking system by completing all the relevant fields. Time periods for the steps of the SEC evaluation process are to be counted as calendar days from the business day of receipt (or 3 business days after initial proof of mailing, whichever time period is shorter).

6.1.1.2 Send acknowledgment of receipt of the petition to the petitioner(s).

6.1.1.3 Assign the petition to a primary reviewer. To address concerns about a possible perceived or actual conflict of interest, DCAS and/or its contractors shall assign a reviewer who has never been employed, either

as a direct employee or as a contractor or subcontractor, at the facility identified by the petition.

6.1.1.4 If appropriate, pend claim(s) associated with the petitioner(s).

6.1.2 Establish the qualifications of the petitioner(s).

6.1.2.1 For petitions covered under 42 C.F.R. § 83.14, verify that the identified petitioner is a claimant for a dose reconstruction that NIOSH found it could not complete.

6.1.2.2 For petitions not covered under 42 C.F.R. § 83.14 by employees and/or their survivors, or by individuals or entities they have authorized to petition on behalf of the class, verify through DCAS records that the employee or survivor is a Department of Energy (DOE) employee, DOE contractor employee, or Atomic Weapons Employer (AWE) employee (or survivor). If DCAS records are insufficient to make this determination, use alternative means, such as requesting information from the petitioner(s) or survivor(s). The employee must also have had employment within the parameters of the class of employees at the DOE facility or AWE facility defined in the petition. To the extent possible, DCAS will work with the petitioners to resolve verification problems. Petitioners and/or others may provide affidavits or other relevant evidence in cases in which records available to DCAS are insufficient to verify that the employee (or survivor) is qualified to petition for the class of employees defined in the petition. In cases where affidavits or other relevant evidence are used for verification, review the affidavits or other relevant evidence for their adequacy and credibility and consult the SEC Health Physics Team Leader of DCAS (or designee) before making a decision. DCAS will make the final decision regarding the qualifications under this step.

6.1.2.3 For petitions by one or more labor organizations, verify that the petition includes documentation that the labor organization represents or represented one or more members of the class of employees at a DOE facility or AWE facility, as defined by the petition. Documentation would typically be a signed contract between the labor organization and the employer, which specifies that the labor organization is, or was, an authorized bargaining unit representing one or more of the employees in the class. For employees who are, or were, members of labor unions that never had a contract with the employer, documentation to be provided by the labor organization could be proof of the union

membership of one or more members of the class. Work with the petitioner(s) to obtain such documentation if it has been omitted.

6.1.2.4 If the qualifications of at least one of the primary petitioners can be verified, continue processing the petition, working only with verified petitioners. If the qualifications of a petitioner cannot be verified, notify the SEC Health Physics Team Leader (or designee) by email. This email should include a complete summary of actions taken to verify the qualifications of the petitioner(s) and the results of these actions. Treat the unqualified petitioner(s) as interested members of the public, not as petitioners, until further notice.

6.1.2.5 If there is more than one petitioner on the petition, inquire of the petitioners if they would prefer that a lead petitioner be selected to serve as the primary point of contact for that petition. If selected, the lead petitioner will be the main point of contact for communication between DCAS and the petitioners.

6.1.3 Confirm the scope of the class of employees intended by the petitioner(s) for petitions not covered under 42 C.F.R. § 83.14.

6.1.3.1 Evaluate the definition of the class of employees included in the petition to ensure that the class is limited to employees who worked at a single DOE or AWE facility, as defined under 42 U.S.C. §§ 7384 *l* (5) and (12). A facility could, among other possibilities, constitute a single building or structure, including the grounds upon which it is located, or a site encompassing multiple buildings or structures, including the grounds upon which they are located. A petition cannot cover employees from more than one facility. If necessary, counsel the petitioner(s) to submit additional petitions such that each petition is specific to a class of employees at a single facility.

6.1.3.2 Review the class definition to ensure that it represents a class of employees that worked at a DOE or AWE facility, versus an individual employee. As required under EEOICPA and defined by 42 C.F.R. § 83.5(d), a "class of employees" for purposes of additions to the Cohort must be a "group of employees", rather than a single individual. Furthermore, as specified under 42 C.F.R. § 83.1, the Special Exposure Cohort procedures are not intended to provide a second opportunity to qualify a claim for compensation, once DCAS has completed the dose reconstruction and the Department of Labor (DOL) has determined that the cancer subject to the claim was not "at least as likely as not" caused

by the estimated radiation doses. DOL has established procedures separate from those in 42 C.F.R., part 83 for cancer claimants who want to contest the factual findings upon which DCAS based its dose reconstruction or the application of the DCAS dose reconstruction methodology to those facts. A petition on behalf of an individual employee does not meet the requirements of 42 C.F.R. § 83.9 (c).

6.1.3.3 Review the class definition to identify the applicable time period(s), locations, processes, job titles, exposure incidents and other specific parameters included by the petitioner(s). If time periods and other required parameters are not specified, or if some parameters are broader than might be expected in light of the petition justification, consult the petitioner(s) to remedy any deficiencies and to confirm that the definition is as specific as intended or possible.

The justifying information upon which the class definition is to be based must be reasonably applicable to the entire time period, to any identified occupations and to any other specific characterizing elements of the class definition. If the qualifying information clearly only pertains to a portion of the total period defined in the class definition, or only to a specific subgroup of workers with unique exposures or uniquely missing exposure monitoring records, then the petition should be qualified for only those periods or subgroups of workers for which there is justification. Where there is uncertainty, err on the side of inclusion.

Example 1: A petitioner provides information indicating that guards at a facility were unmonitored and potentially exposed, but he/she petitions on behalf of everyone at the facility. DCAS would qualify the petition for guards but not for all employees at the facility. The petitioner could then seek NIOSH review as to whether the rest of the class (all non-guard employees) should be qualified for evaluation. However, if the petitioner provided no evidence that other employees were unmonitored, nor was such evident to DCAS, then the petition would not be qualified for those other employees.

Example 2: An individual petitions for the entire operational period of a facility but provides evidence that there was no monitoring only during the initial start-up of the operation. DCAS might confirm that monitoring was deficient during that start-up time period, but was implemented as a full program at a certain later date. DCAS would not qualify the petition for the entire operational period, but only for the period until a full monitoring program was put into operation.

6.1.3.4 If the petitioner(s) changes the class definition to remedy any deficiencies or to provide greater specificity, DCAS or its technical support contractors should provide the petitioner(s) with written documentation of changes in an e-mail, fax or letter that is added to the record. The petitioner(s) should be given 10 days to respond if they have any changes to what is in the e-mail, fax, or letter. If the class definition is deficient in terms of required parameters and the petitioner(s) cannot remedy such deficiencies, notify the SEC Health Physics Team Leader of DCAS (or designee).

6.1.3.5 If the petition is based on circumstances related to an exposure incident, confirm the occurrence of the exposure incident through records or information from DCAS, DOE, an AWE, or other sources. If its occurrence cannot be confirmed by any of these sources, request confirmation from the petitioner(s), as provided for under 42 C.F.R. § 83.9(c)(3). Such requests should first be made orally with explanation, and then by a follow-up letter summarizing the discussion and documenting the request. Responses to such requests should be provided to the SEC Health Physics Team Leader of DCAS (or designee). A failure to respond to such requests within 30 days following the initial oral request should be followed-up with a documented telephone call to the petitioner(s) to determine the cause for delay and to provide guidance, as appropriate. The further lack of a response within the subsequent 15 days following that call, unless DCAS had previously granted a request from the petitioner(s) for an extension of time, should also be followed up with a documented call to the petitioner(s). If, on the basis of the last call, verification from the petitioner(s) is not available or forthcoming, notify the SEC Health Physics Team Leader of DCAS (or designee).

6.1.3.6 For petitions based on circumstances related to a confirmed exposure incident, establish parameters defining the class of employees potentially exposed with as much specificity as can be substantiated by the information currently held by DCAS.

6.1.4 For petitions not covered under 42 C.F.R. § 83.14, determine whether DCAS is in receipt of other petitions on behalf of the same class of employees and take appropriate actions accordingly, as provided for under 42 C.F.R. § 83.12(b).

6.1.4.1 If another petition under consideration completely covers the class defined in the new petition and NIOSH has not published a Federal Register notice under 42 C.F.R. § 83.15(a) with respect to the petition

under consideration, then combine the petitions for the purposes of all steps in these procedures, providing that the new petition is determined to be qualified for evaluation. If, under these circumstances, another petition only partially covers the class defined in the new petition, then combine the petitions for the purposes of all steps in these procedures for the overlapping class only. The class members proposed by the new petition, but not covered by the petition under consideration, should be handled as a separate class for the purposes of all steps in these procedures. If two or more petitions are combined, send a Privacy Act waiver to the petitioners on each petition, asking if they would like to share their name and contact information with all the petitioners. Due to Privacy Act concerns, DCAS cannot share names and contact information between petitioners without consent from the individuals. Once the petitioner agrees to share his or her information, DCAS will provide that information to all parties involved in the combined petition.

6.1.4.2 If another petition under consideration completely covers the class defined in the new petition, and NIOSH has already published a Federal Register notice under 42 C.F.R. § 83.15(a) with respect to the petition under consideration, notify the SEC Health Physics Team Leader of DCAS (or designee). A determination will have to be made as to whether the new petition presents substantial new information germane to the criteria for adding a class to the Cohort. If the new petition presents such new information, it would be further considered as a new petition, following the steps in these procedures, providing that the new petition is determined to be qualified for evaluation. If the new petition does not present such new information, it does not satisfy the requirement under 42 C.F.R. § 83.9(c)(5), and the petitioner(s) should be notified. Go to step 6.1.6.

6.1.4.3 If another petition under consideration partially covers the class defined in the new petition, and NIOSH has already published a Federal Register notice under 42 C.F.R. § 83.15(a) with respect to the petition under consideration, then notify the SEC Health Physics Team Leader of DCAS (or designee). A determination will have to be made as to whether, with respect to the class covered by both petitions, the new petition presents substantial new information germane to the criteria for adding a class to the Cohort. If so, it would be further considered in its entirety as a new petition, following the steps in these procedures, providing that the new petition is determined to be qualified for evaluation under 42 C.F.R. § 83.9. If not, the petition would be further considered with respect to the part of the class defined in the new

petition that is not covered by the petition already under consideration. These class members should be handled as a separate class for the purposes of all steps in these procedures, providing that the new petition is determined to be qualified for evaluation under 42 C.F.R. § 83.9. For the part of the class for which the new petition does not present new information as required under 42 C.F.R. § 83.9(c)(5), go to step 6.1.6.

6.1.4.4 If HHS has already made its decisions with respect to the designation of a class covered in part or in its entirety by the new petition, notify the petitioner(s) of these decisions. If the petition covers class members who have not been designated for addition to the Cohort, notify the SEC Health Physics Team Leader of DCAS (or designee). When appropriate, as described under steps 6.1.4.2 and 6.1.4.3, determine whether the new petition provides, with respect to the class or part of the class, substantial new information germane to the criteria for adding a class to the Cohort and proceed accordingly to consider the petition and/or to step 6.1.6.

6.1.5 For petitions not covered under 42 C.F.R. § 83.14, review the petitioner's basis for believing records and information available are inadequate to estimate the radiation doses incurred by members of the proposed class with sufficient accuracy.

6.1.5.1 Under paragraphs (i) and (ii) of 42 C.F.R. § 83.9(c)(2) and (ii) of § 83.9(c)(3), affidavits must be sufficiently specific and factual to indicate the assertion in the affidavit(s) is based on the experience of employees who are members of the class covered by the petition or other witnesses, as appropriate. In addition: (1) consider the applicability of assertions to the circumstances of the petitioning class of employees when such assertions are based on circumstances among classes of employees at the facility who might reasonably be considered to be separate from the petitioning class of employees; examples of such classes are employees who worked during a different time period, under different management, or under different exposure, monitoring, or record keeping procedures; and (2) consider the adequacy and credibility of assertions in consultation with the SEC Health Physics Team Leader of DCAS (or designee). In some cases, it may be useful to involve persons with a variety of perspectives to thoroughly consider concerns about the adequacy and credibility of an assertion.

Discussion: "Adequacy" and "credibility" are not judgments subject to any rigid criteria. Since each case is likely to be unique, "adequacy" and "credibility" will be determined on a case-by-case basis, based on a totality of the circumstances.

6.1.5.2 Under paragraphs (i) and (ii) of 42 C.F.R. § 83.9(c)(2), if the documentation provided by the petitioner consists solely of communications from DOE or an AWE to the petitioner indicating that it lacks monitoring records on any members of the proposed class, attempt to determine whether DCAS has access to records on the class members. Make this determination within 30 days of receipt of the petition. If the records are available to DCAS, notify the petitioner that DCAS has access to the information it needs to begin a dose reconstruction. If the petitioner still seeks to petition, the petitioner will be required to provide another basis to satisfy the requirements of this subsection.

6.1.5.3 Under paragraph (iv) of 42 C.F.R. § 83.9(c)(2), note that the scientific or technical report can be from the Government Accounting Office, the Defense Nuclear Facilities Safety Board, the Nuclear Regulatory Commission, or from any level of the Executive Branch of government, including federal, state, and local executive agencies. It is possible, for example, that a state environmental or public health agency might have examined the availability of dosimetry and related information with respect to an AWE.

6.1.6 Within 30 calendar days from the receipt of a petition, DCAS or its technical support contractor shall produce a draft professional judgment that includes a preliminary qualification determination based on the petition and supporting documentation received.

6.1.6.1 If a draft professional judgment is not provided within the 30-day period, the SEC Health Physics Team Leader will brief the DCAS Director, Deputy Director, and the Associate Director for Science (ADS) on the reasons the draft professional judgment is delayed. After this briefing, the Director or his designee will determine whether the petition should be qualified with the information on hand, or whether the staff should continue to work with the petitioner to help him/her qualify the petition. If the petition does not qualify as received, the petitioner will be advised of the deficiencies and provided 30 calendar days (which may be extended) to submit additional information to remedy those deficiencies. Time during which DCAS is awaiting additional

information from the petitioner is not counted toward the 30 calendar days allowed to reach a draft qualification determination.

6.1.6.2 The draft professional judgment should be used to determine whether an evaluation team should be selected and a project planning schedule developed for completion of the evaluation report.

6.1.7 Within 75 calendar days from receipt of a petition, DCAS shall produce a final professional judgment, which includes the qualification decision. This decision will be reviewed by the DCAS SEC Health Physics Team Leader and approved by the ADS (or by their respective designees).

6.1.7.1 If a final professional judgment is not provided within 75 calendar days, the SEC Health Physics Team Leader will brief the DCAS Director, Deputy Director, and the ADS on the issues that are causing the delay. After evaluating the supporting documentation submitted at that time with the Deputy Director and the ADS, the Director shall determine whether: i) the professional judgment should be completed directly, based on currently available information; or ii) staff should continue to work with the petitioner to help him/her qualify the petition.

6.1.7.2 If a petitioner repeatedly submits new information after the consult call in an attempt to get a petition qualified, a considerable number of the 180 calendar days for completing an the SEC evaluation report may elapse. If 75 calendar days have been spent trying to qualify a petition, staff must notify the DCAS Director that additional qualification time is required, along with the reason(s) why, and that completion of the evaluation within 180 days may be affected.

6.1.8 Based upon new information, NIOSH may reconsider a decision that a petition does not satisfy the qualification requirements. For purposes of these criteria, the date of the receipt of the new information that leads to the petition's qualification will be the new submittal date. All information previously submitted by the petitioner will be added to the qualified petition's file.

6.1.9 For petitions which initially, or after addressing deficiencies, meet all relevant requirements under 42 C.F.R. §§ 83.7 - 83.9, proceed to subsection 6.3. For petitions that do not satisfy all relevant requirements under 42 C.F.R. §§ 83.7 - 83.9, notify petitioners in writing.

6.1.9.1 Upon request by the Director of DCAS (or designee), prepare for his/her signature a letter to the petitioner(s) that notifies the petitioner(s)

of any requirements that are not met by the petition, providing a summary of prior discussions with the petitioner(s) concerning such deficiencies, and providing guidance on how such deficiencies could be remedied, if possible. The letter should notify the petitioner(s) of a 30-calendar-day time limit to remedy the identified deficiencies, or of a specific extended time period when an extension has been granted. Use standard format and prepared text inserts. The Director of DCAS (or designee) is solely authorized to issue such notification.

Provide further oral or written guidance to the petitioner(s) upon request and to a reasonable extent. Document all oral and written communications with the petitioner(s) with appropriate annotation to the administrative record (both hard copy file and in OSA). Any verbal guidance provided to the petitioner addressing substantive issues must also be documented in a follow-up letter to the petitioner.

6.1.10 Notify the SEC Health Physics Team Leader of DCAS (or designee) of petitions that remain deficient after 30 calendar days or an extended period, if granted, from the date of notification to the petitioner(s) under step 6.1.6, reporting any oral or written communications that have occurred during this period. A draft notification letter should be prepared for the SEC Health Physics Team Leader (or designee) and Office of General Counsel (OGC) for review prior to the expiration of the 30 days, in order to expedite issuance of this final letter.

6.1.11 Thirty calendar days after the written notice of deficiency (step 6.1.6.1), the Director of DCAS will establish and notify the petitioner(s) of proposed findings that a petition fails to meet the specified requirements, as well as the basis for this finding. The Director is solely authorized to issue such notification, which must be appropriately redacted to protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the petitioner(s). Include in the notification to the petitioner(s) information about the right to seek an administrative review of the proposed findings within 30 calendar days after the notice, and a copy of, or reference to, the associated procedures for requesting such a review.

6.1.12 Proposed findings that a petition fails to meet the specified qualification requirements are subject to administrative review, as specified under 42 C.F.R. § 83.11. Upon the written request of the petitioner(s) pursuant to 42 C.F.R. § 83.11(c), the Director of NIOSH will appoint three HHS personnel to conduct a review. Such personnel will not have ever been employed at the DOE site in question or by DOE headquarters offices responsible for the DOE site in question, nor will they have ever been employed by DCAS.

6.1.12.1 If an administrative review is conducted, upon the appointment of reviewers, the administrative record associated with the petition must be provided to the reviewers. The administrative record will include the petition request, the petition review, related records, materials and communications, and the request by the petitioner(s) for a review of the proposed finding. The panel must complete its review of the proposed finding within 30 work days of the petitioner's request.

6.1.12.2 Upon the completion of an administrative review, the Director of NIOSH will directly transmit to the petitioner(s) a report on the review and its outcome, which must be reviewed by OGC prior to being sent to the petitioner(s). Enter the report and associated transmittal communications into the administrative record for the petition.

6.1.13 If a request for an administrative review is not received from the petitioner(s) within 31 calendar days of notification of a proposed finding that a petition fails to meet specified qualification requirements, the proposed finding becomes a final decision. Provide to the SEC Health Physics Team Leader (or designee), for the signature of the Director of DCAS, a draft notice to the petitioners documenting that the petitioners did not request a review and that the proposed finding now represents a final decision. This notice must be reviewed by OGC prior to being sent to the petitioner(s). A signed copy of the final notice shall be entered into the administrative record.

6.1.14 For any petition for which the petitioner(s) had to revise the petition before it could qualify for evaluation, restart the qualification review process at step 6.1.2 of this procedure, focusing on the new information, but considering all information provided up to the point of the start of the re-review.

6.1.15 A decision to deny a petition which failed to meet the qualification requirements may be reconsidered if new information relevant to the class becomes available to DCAS. Review the new information to determine its applicability to qualifying the petition. DCAS or technical contractor staff should notify the SEC Health Physics Team Leader (or designee) when new information is identified that is relevant to a class of employees whose petition has been denied. If the new information is found sufficient to reconsider the qualification of the petition, restart the qualification review process at step 6.1.2 of this procedure, focusing on the new information, but considering all information provided up to the point of the start of the re-review.

6.1.16 The submitter(s) of a deficient petition may submit a new petition for the identical class of employees at any time on the basis of new information. In such cases, the

normal qualification review process for new petitions would be followed, beginning at step 6.1.1. The new petition may, if appropriate, be combined with the original petition (step 6.1.4)

6.2 Provide notification to petitioners, the Board, and the public of a petition that has been selected for evaluation. Notification should also be given for any additional potential class identified during the review of a petition under 42 C.F.R. **§** 83.14 (see step 6.5.4) for which an evaluation is to be initiated.

Note: The steps under subsection 6.2 provide guidance for issuing appropriate notification to petitioners, the Board, and the public that a petition will be evaluated by DCAS, the Board, and HHS because it meets the requirements of subsection 6.1.

6.2.1 Provide written notification to the petitioner(s) that their petition will be evaluated. Notification should include the appropriate standard notification letter and the SEC Evaluation Process Summary (Attachment 1).

6.2.2 The Director of DCAS (or designee) will issue the notification to the petitioner(s).

6.2.3 Prepare and submit to the Director of DCAS (or designee) an evaluation package for the Board, which must be appropriately redacted to protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the Board. The evaluation package should include the following: (A) the petition or petitions (multiple petitions may have been received representing a single class of employees) and (B) an evaluation plan for the class addressed in the petition(s). The evaluation plan should include the following, as required under 42 C.F.R. § 83.12(b) and (c): (1) an initial, proposed definition for the class of employees based on the petition, when applicable, and on DCAS information that would establish a definition (for petitions submitted under 42 C.F.R. § 83.14), or modify the definition proposed by the petitioner(s), and (2) a list of activities for evaluating the radiation exposure potential of the class of employees and the adequacy of existing records and information to support dose reconstructions for members of the class of employees.

6.2.4 If resources are available, initiate work to evaluate the petition immediately. In accordance with 42 C.F.R. § 83.12(d), DCAS may begin the evaluation prior to presenting the petition and evaluation plan to the Board.

6.2.5 Prepare a monthly Federal Register Notice (when necessary) notifying the public of the decision(s) to evaluate petitions.

6.2.6 Upon publication of the Federal Register Notice, post the notice to the NIOSH/DCAS Web page. DCAS may also disseminate the notice through direct and media contacts.

6.3 Establish time-line decision points for evaluating an SEC petition.

Note: The steps and procedures under section 6.3 are to be used as decision points during the evaluation process to ensure DCAS management is made aware of issues associated with an SEC petition evaluation that could affect the timely completion of the petition and provide insurance that decisions made in support of the evaluation are in accordance with current policies and procedures.

6.3.1 Starting from the date a petition qualified, DCAS or its technical support contractor shall promptly develop and submit a detailed evaluation plan documented in an SEC Evaluation Report project planning chart that identifies the process and timeline for submitting an SEC Petition Evaluation Report.

6.3.1.1 There may be instances when, in developing the detailed evaluation plan and performing the evaluation, it becomes clear that the evaluation cannot be completed within the 180-calendar-day period. This may be caused by one or more of the following: an abnormally long qualification period, a very broad class and time period for evaluation (e.g., all Hanford employees 1942 through 1996), data captures delayed for numerous reasons (e.g., legal issues, classification issues, DOE funding, site access limitations), DOE/DOL resolution of facility designation issues identified during the evaluation, and other possible factors outside DCAS' control. As soon as such a situation arises, staff shall inform the Director of DCAS. If the DCAS Director approves an extension of time, he shall direct staff to notify the petitioner, Advisory Board, Designated Federal Official for the Advisory Board, and Congressional liaison of the delay. They should also be informed of the reasons for the delay and the expected completion date of the report.

6.3.1.2 Any time the 180-calendar-day timeline is in jeopardy of not being met, the DCAS Director shall be provided with the following information: a description of the petition and the class being evaluated, a description of the issue that is delaying the completion of the evaluation, a description of how the issue is being resolved and a timeline for completion, a statement explaining whether additional resources can be applied to meet the original deadline or reduce the delay and whether utilizing those resources may affect other projects, and a statement describing the SEC class that would have to be proposed in order to

resolve the issue (see 6.3.1.3 below). This information will be used by the DCAS Director to make an informed decision about whether to approve an extension of time.

6.3.1.3 Should the DCAS Director determine that the information necessary to complete the evaluation of the petition will not be available on a timely basis, he may direct DCAS to complete its petition evaluation based on the information at hand, which may result in an addition of an SEC class. If an extension of time is required to support a data capture because the data are not readily available from the site, the DCAS Director will only approve an extension of time beyond 360 calendar days of receipt of a petition where circumstances indicate that data will be available within a recognizable and reasonable time frame.

6.3.1.4 If an extension of time is granted, the DCAS ER Lead and the DCAS SEC Health Physics Team Leader will provide a status update on completion of the evaluation to the DCAS Director, Deputy Director, and the ADS every 90 calendar days.

6.4 Evaluate a petition qualifying for evaluation under 42 C.F.R. § 83.13.

6.4.1 The steps and procedures under subsection 6.4 provide guidance for DCAS to conduct its evaluation of a petition when the petitioner is <u>not</u> a claimant for whom DCAS has already found that it cannot complete a dose reconstruction. The guidance attempts to balance the NIOSH goal of addressing the issues raised by petitioners thoroughly, whenever possible, with the importance of timely completion of petition evaluations. For this purpose, it limits collecting records and information from sources outside of DCAS, whenever possible, but may also consider SEC issues raised by the Board, by the Board's technical support contractor, or issues developed internally by DCAS. Procedures for determining feasibility include: (1) The principal guidelines for evaluating feasibility for petitions qualifying for evaluation under subsection 6.4 are established under 42 C.F.R. § 83.13(c)(1). (2) The technical issues involved in evaluating the availability and adequacy of records and information relevant to feasibility determinations are addressed in the implementation guidelines for internal and external dose reconstructions. These dose reconstruction guidelines generally explain the types of information that can be used in dose reconstructions, and approaches for examining the availability and adequacy of information, as well as describing how such information should be used. These guidelines also provide general guidance concerning how maximum doses can be estimated when necessary, and the information essential to such estimates, under section 5.3 of the

internal dose reconstruction guidelines (DCAS-IG-002) and sections 3.1.3, 3.1.4, 3.2.3, 3.3.3, and 3.3.4 of the external dose reconstruction guidelines (DCAS-IG-001). The efficiency measures in the internal dose reconstruction guidelines (e.g., high dose potential and low dose potential preliminary estimates), however, are not applicable to evaluating feasibility with respect to a class of employees (see step 6.4.6). (3) Subject to 42 C.F.R. § 83.13(c)(1) and the procedures provided under steps 6.4.9 and 6.4.10 below addressing timeliness, feasibility should be determined by evaluating the availability and adequacy of records and information in the order established by the hierarchy of dose reconstruction information specified under 42 C.F.R. § 82.2, addressing the informational sources, types, and the adequacy of information as specified under 42 C.F.R., parts 82 and 83, and under the DCAS implementation guidelines for dose reconstruction. Sites which have been issued site profiles will find that the profiles provide an important resource of information to assist in evaluating feasibility (recognizing, however, that petitioners, the Board, or internal DCAS SEC developments may raise issues not yet identified through the site profile development process). (4) Positive determinations of feasibility under steps 6.4.1 and 6.4.6 – 6.4.8 must be applicable to dose reconstruction for *any* type of cancer; otherwise, dose reconstruction must be deemed not feasible for the class of employees.

6.4.2 Procedures for determining the extent and specificity of evaluations supporting positive determinations: Positive determinations of feasibility under steps 6.4.1 and 6.4. 7-6.4.9 are not required to be supported by evaluations that are more extensive or more specific in scope than the information provided by the petitioner(s) under 42 C.F.R. § 83.9(c)(2) to support the belief of the petitioner(s) concerning the infeasibility of dose reconstruction. A petition based on alleged informational deficiencies relating to a group of employees at a facility can be addressed by determining the availability and adequacy of such information for the group as a whole, without examining all potentially different subgroups or individuals thereof. A petition submitted on the basis of alleged informational deficiencies relating to particular individuals can be addressed by determining the availability and adequacy of information germane to dose reconstruction for those particular individuals.

Example 1: The petition asserts that personnel monitoring was not conducted for a group of maintenance workers when they were engaged in a particular operation.

An examination of records shows that the maintenance workers covered by the petition were not monitored while engaged in the particular operation, but that another group of maintenance workers were monitored while engaged in the same operation involving comparable exposure conditions at another location at the facility.

This information might be sufficient to determine that dose reconstruction is feasible for the group of maintenance workers covered by the petition, while engaged in the particular operation. It would not be necessary to evaluate the availability and adequacy of records concerning the work of the group of maintenance workers while engaged in other operations not addressed by the petition.

Example 2: The petition asserts on the basis of the records of specific individual employees that personnel monitoring records are not available for employees who worked at facility "S" from 1943 – 1946. On the basis of this evidence, the petitioners believe dose reconstruction is not feasible for employees at the facility during this time period.

An examination of records shows that the personnel monitoring program in place at facility "S" at that time relied on a "co-worker approach" to monitoring, such that not all workers who could have been monitored were monitored. The records also indicate that the individual cases identified are consistent with the co-worker monitoring practice employed at the time.

This information might be sufficient to determine that dose reconstruction is generally feasible for employees who worked at facility "S" during this time period. It is not necessary to examine whether this finding is applicable to every employee who worked at the facility during the specified time period. In this case, the evaluation need only examine the circumstances of individuals for which the petitioners provided information specifically supporting their belief that dose reconstruction may not be feasible.

Example 3: The petition asserts that employees who worked at facility "B" were not monitored during a particular operation that occurred in 1955. Based on this evidence, the petitioner believes that dose reconstruction is not feasible for employees who worked in the operation.

An examination of records shows that DCAS has completed dose reconstructions without personnel monitoring data to estimate the radiation doses of employees who worked in the operation.

This information might be sufficient to determine that dose reconstruction is generally feasible for employees who worked in the operation. It is not necessary for DCAS to examine whether this finding is applicable to any possible subgroups of employees who worked in the operation, as the information provided in the petition did not suggest feasibility issues associated with any specific subgroup of employees.

6.4.3 From the date a petition is qualified, DCAS shall promptly develop an "issues matrix", which includes issues that qualified the petition, issues from the Petition Matrix, any applicable SEC issues from an Advisory Board review of related technical documents and any other SEC issue of which DCAS or its technical support contractor is aware. Before finalization, this issues matrix must be approved by the DCAS Evaluation Team lead, the SEC Health Physics Team Leader and the Associate Director for Science.

6.4.4 In evaluating the qualified SEC petition, the SEC Evaluation Team shall identify data gaps and how they can be resolved. For example, if data are currently unavailable, additional required data captures and interviews may be identified. The SEC Evaluation Team should identify alternative approaches for resolving issues and attempt to capture required data during the initial data capture to support all alternative approaches. In most cases, this can be done with minimal additional duration of the data capture. The project planning chart detailing the evaluation should be adjusted for the additional data capture as needed.

6.4.5 The baseline project schedule for all DCAS SEC evaluations includes 92 calendar days for the completion of the petition evaluation, including approval by DCAS. This timeline is adjusted for each petition to reflect specific circumstances surrounding the petition. The items below reflect additional decision points/notification requirements in the evaluation phase, which may affect timely completion of the evaluation report.

6.4.5.1 If a required change in the project schedule pushes the evaluation report completion past the 180-calendar-day time frame, refer to sections 6.3.1.1 - 6.3.1.3.

6.4.5.2 The DCAS Evaluation Team Lead should receive weekly status updates during the time that data captures or interviews are being scheduled and conducted. If delays are encountered, they should be reflected in the project schedule and discussed with both the DCAS Evaluation Team Lead and the DCAS SEC Health Physics Team Leader.

6.4.5.3 If, after the initial data capture, the evaluation team determines that an alternative approach for resolution (necessitating additional data capture or additional interviews) is required, the Evaluation Team will draft a schedule that includes all tasks which must be completed to permit the alternative approach and the estimated amount of time necessary to complete them. If the amount of time required will extend the completion of the report beyond the 180-calendar-day time frame, or beyond the 360-calendar-day interval described in 6.3.1.3, the project team should prepare all of the items outlined in 6.3.1.2 above. The DCAS Evaluation Team Lead and the DCAS SEC Team Leader will then brief the DCAS Director, Deputy Director, and the Associate Director for Science, and the Director will act in accordance with 6.3.1.3.

6.4.5.4 If the approach for resolving an issue is not a standard approach used in other approved documents, it should be discussed with the Associate Director for Science to ensure the approach is acceptable.

6.4.6 Determine whether one or more dose reconstructions have been completed and/or initiated, demonstrating that dose reconstructions are feasible for the class of employees identified in the petition, or, if they are appropriate under step 6.4.2, for a subgroup thereof, in light of the information provided in the petition concerning the feasibility of estimating radiation doses for the class of employees identified in the petition.

When such dose reconstructions are identified, consult the SEC Health Physics Team Leader to determine whether any such dose reconstructions have been, or are presently being considered by DOL's Final Adjudication Branch (FAB), pursuant to an objection by a claimant under 20 C.F.R. § 30.318 in response to a recommended decision by DOL to deny the claim. If so, do not use as examples of the feasibility of dose reconstruction any dose reconstructions which have been returned by the FAB for further consideration by HHS, or any dose reconstructions which are currently pending a FAB hearing or review, since this may take up to one year, per 20 C.F.R. § 30.316(c).

Also, note that some previously completed dose reconstructions for individuals may not be applicable for demonstrating feasibility for the class of employees identified in the petition. For example, "efficiency" dose reconstructions (high dose potential or low dose potential preliminary estimates) performed to expedite certain claims may utilize approaches not appropriate for reconstructing the dose for individuals in the class under consideration (see step 6.4.1(2)).

6.4.6.1 If one or more dose reconstructions have been completed or initiated and demonstrate feasibility for the petitioning class of employees, go to step 6.4.13.

6.4.6.2 If one or more dose reconstructions have been completed or initiated and they demonstrate feasibility only for a subgroup of the petitioning class of employees, as appropriate under 6.4.2, define two separate classes of employees, accordingly (one class of employees for which dose reconstruction is feasible, and one class for which feasibility must still be determined). Go to step 6.4.13 for the class for which dose reconstruction is feasible and go to step 6.4.7 for the class for which the feasibility of dose reconstruction must still be determined.

6.4.6.3 If dose reconstructions that have been completed or initiated do not demonstrate feasibility for any subgroup of the petitioning class of employees, go to step 6.4.7.

Example: The petition asserts on the basis of affidavits that employees who worked at facility "B", a single building, were not monitored during two phases of a specified operation that occurred in 1955. Based on this evidence, the petitioner believes that dose reconstruction is not feasible for employees who worked in the operation.

An examination of records shows that DCAS has completed dose reconstructions in which DCAS used area monitoring data, without personnel monitoring data, to estimate the radiation doses of employees who worked in the specified operation at facility "B." The examination confirms, however, that there were two distinct phases of the operation, "phase 1" and "phase 2". It also finds that exposures and record availability might differ substantially between these two phases, and documents that DCAS dose reconstructions have only addressed "phase 1."

This information might be sufficient to determine that dose reconstruction is generally feasible for employees who worked in "phase 1" of the operation at facility "B." It is not necessary for DCAS to examine whether this finding is applicable to specific subgroups of employees who worked in "phase 1" of the operation, as distinctions concerning subgroups were not addressed by the evidence provided in the petition. This information is not sufficient to evaluate the feasibility of dose reconstruction for employees who worked in "phase 2." The feasibility of dose reconstruction for employees who worked in "phase 2" should be evaluated further, treating these employees as a class distinct and apart from employees who worked in "phase 1."

6.4.7 If current and/or completed dose reconstructions do not fully address the information provided by a petition, then determine whether personnel and/or area monitoring data are available and are adequate to conduct dose reconstructions for members of the petitioning class of employees, or, if appropriate under 6.4.2, for a subgroup thereof.

In determining the adequacy of data for use in conducting dose reconstructions, the "pedigree" of the data should be considered before performing a feasibility evaluation. Data pedigree addresses the background, history, and origin of the data or any other factors which could affect its current accuracy. It requires looking at site methodologies that may have changed over time, primary, versus secondary, data sources and whether they match, and whether data are internally consistent. All these issues form the bedrock of the researcher's confidence and subsequent conclusions about the data's quality, credibility, reliability, representativeness, and sufficiency for determining the feasibility of dose reconstruction. The feasibility evaluation presupposes that data pedigree issues have been settled.

6.4.7.1 If the personnel and/or area monitoring data are available and adequate to conduct dose reconstructions for the class of employees considered in this step, go to step 6.4.13.

6.4.7.2 If the personnel and/or area monitoring data are available and adequate to conduct dose reconstructions only for a subgroup of the class of employees considered in this step, as appropriate under 6.4.2, define two separate classes of employees accordingly (one class of employees for which dose reconstruction is feasible, and one class for which it is not). Go to step 6.4.13 for the class for which dose reconstruction is feasible and go to step 6.4.8 for the class for which personnel and/or area monitoring data are not available and adequate.

6.4.7.3 If personnel and/or area monitoring data are not available and adequate to conduct dose reconstructions for any subgroup of the class of employees considered in this step, go to step 6.4.8.

6.4.8 If, under step 6.4.7, personnel and/or area monitoring data are not available and adequate to conduct dose reconstructions for members of the petitioning class of employees or a subgroup thereof, then determine whether the radiation source term, source, and process information are available and adequate to conduct dose reconstructions without monitoring data or in combination with any monitoring data available.

6.4.8.1 If the radiation source term, source, or process information are available and adequate to conduct dose reconstructions without monitoring data or in combination with any monitoring data available, go to step 6.4.13.

6.4.8.2 If the radiation source term, source, or process information are available and adequate to conduct dose reconstructions only for a subgroup of the class of employees considered in this step, as appropriate under 6.4.2, define two separate classes of employees accordingly (one class of employees for which dose reconstruction is feasible, and one class for which it is not). Go to step 6.4.13 for the class for which dose reconstruction is feasible and go to step 6.4.15 for the class for which dose reconstruction is not feasible.

6.4.8.3 If available radiation source term, source, and process information are not adequate to conduct dose reconstructions for any subgroup of the class of employees considered in this step, without monitoring data or in combination with any monitoring data available, go to step 6.4.14.

6.4.8.3.1 If there is no monitoring, source, source term, or process information from the site where the employee worked (i.e., the DOE or AWE facility addressed in the petition) to serve as the basis for a dose reconstruction, then a dose reconstruction is not feasible. Go to step 6.4.14. EEOICPA requires that probability of causation determinations be based on information from the site where the employee worked. Such information must, at a minimum, include some monitoring, source, source term, or process information from the site where the employee worked, rather than from a comparable site. This requirement does not limit DCAS to using only or primarily information from the site where the employee worked, but the dose reconstruction must have, as a basis, some information from the site where the employee worked.

6.4.9 Timeliness Procedures: To achieve timeliness in conducting steps 6.4.7 and 6.4.8: (a) Research records and data in DCAS's possession should be evaluated and used, if sufficient, without requesting additional records from DOE, an AWE, or other resources; (b) When records or information from DOE, an AWE, or another resource are necessary, request simultaneously the records or information for steps 6.4.7 and 6.4.8; (c) Minimize the scope and extent of records requests to support a timely evaluation (see procedures under step 6.4.11); (d) If records or information requested under (b) above are not provided within 60 days, or if a

resource indicates such records cannot be provided within 120 days, notify the DCAS SEC Health Physics Team Leader (or designee).

6.4.10 Timeliness Policy: Under 42 C.F.R. § 83.13(b), the Director of DCAS may determine that records and/or information requested from DOE, an AWE, or another resource to evaluate a petition is not, or will not be, available on a timely basis. Such a determination will be treated, for the purposes of the petition evaluation, as equivalent to a finding that the records and/or information requested are not available.

6.4.10.1 Before the Director of DCAS makes such a determination, the resource(s) potentially in possession of such records and/or information will be allowed a reasonable amount of time, as determined by the Director of DCAS, to provide the records and/or information

6.4.10.2 Such a determination may take into account the types and quantity of records and/or information requested from the resource, as well as any other factors that might be relevant to the judgment under paragraph (1) regarding the amount of time that is reasonable to provide the records and/or information, which the Director of DCAS would decide on a case-by-case basis.

6.4.11 Guideline for Requesting Records and Information: Potential sources of information for determining feasibility include: (1) The petition(s); (2) DOE and AWE facility records and information; (3) Potential members of the class and their survivors; (4) Labor organizations during the relevant period of employment; (5) Managers, radiation safety officials, and other witnesses; (6) NIOSH records from epidemiological research on DOE populations and records from dose reconstructions; (7) Records from research, dose reconstructions, medical screening programs, and other activities conducted to evaluate the health and/or radiation exposures of employees; and (8) Other sources.

DCAS should only request such records and information from resources external to DCAS that are necessary to make feasibility determinations with respect to the class, and, when necessary, to evaluate issues of health endangerment with respect to the class. The purpose of requesting records is *not* to obtain all the records that might be required to actually conduct dose reconstructions for members of the class of employees. For example, it may only be necessary to obtain a sample of personnel and/or area monitoring records pertaining to the class to evaluate the feasibility of dose reconstruction.

Note 1: The purpose of requesting personnel records, when necessary, is to obtain reasonable evidence to evaluate more general information provided by the resource to determine whether dose reconstruction is feasible. Do not request a larger sample of records than is necessary, since this can affect the timeliness of the response.

Note 2: In cases in which the evaluation has already determined the feasibility of dose reconstruction but the petition raised issues that have not been fully addressed, achieving a reasonable balance between comprehensiveness and timeliness is important. If conducting a comprehensive evaluation would delay the completion of the petition evaluation substantially (e.g., by more than 60 days), consult with the SEC Health Physics Team Leader (or designee). It may be appropriate to complete the petition evaluation sooner, based on minimally sufficient information, and to complete the evaluation of monitoring practices separately.

6.4.12 Once all issues have been resolved, the evaluation team should meet with the DCAS SEC Team Leader, DCAS Dose Reconstruction Team Leader, and the ADS to review results of the evaluation. The team should: (i) describe the facility (including facility operations), the DOE facility designation, and the petition. The petition description should include: the petitioner-proposed class; the class evaluated; and the basis or bases for qualification.; (ii) describe the issues identified in the issues matrix; (iii) discuss the data available; (iv) describe the data captures and interviews conducted to resolve the issues; and (v) discuss proposed resolutions of the issues and any class or classes that are being recommended. If a class is being recommended, provide justification for any limitations of the class. For example, if the proposed class ends before the end of the covered period, justification must be provided as to why dose reconstruction became feasible at that time.

If, after the completion of the meeting, the ADS is not satisfied with the resolution of an issue, a determination must be made by the project team and the ADS whether additional work could resolve the issues, and if that resolution will require exceeding the 180-calendar-day timeframe or the 360-calendar-day interval described in 6.3.1.3. If such a determination is made, the DCAS Evaluation Team Lead and the DCAS SEC Health Physics Team Leader will inform the DCAS Director and provide the information identified in 6.3.1.2 above. The Director will act in accordance with 6.3.1.3.

6.4.13 For classes of employees for which dose reconstruction is feasible (i.e., when it is feasible to estimate doses with sufficient accuracy), prepare a finding explaining the basis for the determination. Document the findings of the feasibility determination in the Evaluation Report (subsection 6.6).

6.4.13.1 Describe the approach or approaches to dose reconstruction that could be used.

6.4.13.2 Procedures for explaining feasibility when dose reconstruction is feasible: (1) Address directly the rationale and information provided by the petitioner(s) to support the petition. Explain whether the rationale and information are accurate and relevant, and explain why they are not an impediment to dose reconstruction. (2) Identify the types and limitations of data that are available for dose reconstruction and include an explanation of methods that could be used to conduct dose reconstructions using these types of data and accounting for the limitations specified. (3) Reference relevant sections of the DCAS dose reconstruction implementation guidelines and other relevant documents that relate to the approach or approaches that could be used for the dose reconstructions discussed. (4) Explain that the methods used for actual dose reconstructions for members of the class of employees may differ from the methods discussed, based on the work history, cancer, and other characteristics of the individual employee whose doses are being reconstructed, and based on the records available at the time the dose reconstruction is conducted.

6.4.13.3 As a demonstration of the feasibility of reconstructing doses for members of the class of employees using the identified approach(es) (step 6.4.13.1), and considering any limitations of the data or information (step 6.4.13.2), perform "example" (or sample) dose reconstructions for a hypothetical worker. Several scenarios covering the range of potential job and/or incident exposures should be used in the dose reconstructions. The scenarios created, as well as the demographic parameters of the hypothetical worker and the cancer organs selected to be used in the example dose reconstruction, should be chosen so as to demonstrate that the dose for the maximally exposed individual can be bounded, using available data and information. In some cases, actual data may be available from an existing claim for a worker with a similar work description.

6.4.14 For classes of employees for which dose reconstruction is not feasible, prepare a finding explaining the basis of the determination.

6.4.14.1 Describe the informational limitations established by the DCAS evaluation, and explain why these limitations make it infeasible for DCAS to complete dose reconstructions for the class of employees.

6.4.14.2 Procedures for explaining feasibility when dose reconstruction is not feasible: (1) Identify the information that, at minimum, must be available to reconstruct the doses of members of the class of employees, and summarize how such information would be used in dose reconstructions. (2) Summarize the actions taken to obtain sufficient information for dose reconstruction. (3) Identify the information that DCAS obtained and the necessary information that DCAS was unable to obtain, and document how DCAS determined that necessary information is not available. (4) Although DCAS may conclude that there are inadequate data to permit sufficiently accurate reconstruction of doses for employees in the class, any available data that may reside in an individual's file (and that can be interpreted using existing NIOSH dose reconstruction processes or procedures) could be used to support partial dose reconstructions (i.e., does not include all elements of radiation dose) for claimants not qualifying for inclusion in the SEC who incur a cancer not included among the 22 specified SEC cancers and, hence, require a dose reconstruction (or they would otherwise be left without a remedy).

6.4.15 For classes of employees for which dose reconstruction is not feasible, determine if there is a reasonable likelihood that radiation doses may have endangered the health of members of the class. Evaluate potential health endangerment due to 1) exposure during incidents with exceptionally high-level radiation exposures or 2) chronic exposures at lower levels of radiation.

6.4.15.1 Characterize the source(s) and circumstances of radiation exposure to the class of employees.

6.4.15.2 Establish whether the sources and circumstances indicate that the class of employees was likely to have received exceptionally high-level radiation exposures, comparable to the levels of exposure in nuclear criticality incidents. The analysis should use comparative information when feasible, considering comparable exposure incidents in which radiation levels or related health effects were documented.

6.4.15.3 For the purpose of determination of health endangerment involving incidents of exceptionally high-level radiation exposure, there is no minimum time requirement (42 C.F.R. § 83.13(c)(3)(i) states that any duration of unprotected exposure could cause a specified cancer). Exceptionally high levels of radiation exposure, as defined, typically have resulted from a recognized breakdown of radiological controls, and such levels of exposure typically cause acute, radiation-related health effects.

6.4.15.4 If no evidence is found that members of the class experienced a discrete incident of high-level radiation exposure, then determine if some workers in the class may have accumulated chronic radiation exposures through intakes of radionuclides and/or from direct exposure to radioactive materials. For such non-discrete low-level exposures, the minimum duration of employment to satisfy the health endangerment criterion, per 42 C.F.R. § 83.13(c)(3)(ii), is a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees in the SEC.

6.4.16 Define the class or classes of employees evaluated in response to the petition.

6.4.16.1 Define the class (or classes), taking into account the class definition proposed by the petition and modified as necessary, resulting from the evaluation of the petition. A defined class should comprise a group of employees for whom the availability of data and information on radiation exposures is comparable. If there are dissimilarities in such information sufficient that the evaluation produces separate determinations of feasibility of dose reconstruction, then separate classes may need to be defined. For example, if the petition evaluation were to find that it is feasible to conduct dose reconstructions for one group of employees using monitoring data and a second group using source term and process data, and that it is not feasible to conduct dose reconstructions for a third group of employees, then define three classes of employees.

6.4.16.2 Define the class of employees as completely and precisely as possible. The definitions are important to potential petitioners, who need to be able to recognize whether or not they are included in the class. The definitions are also important to DOL, which will make compensation decisions on the basis of class definitions for classes of employees that are added to the Cohort. The definition should provide information sufficient to clearly distinguish between employees who are included in, and those who are excluded from, the class. In addition to addressing the employment parameters defined under 42 C.F.R. § 83.13(c)(2), consider whether it is necessary to specify work operations, employers (e.g., contractor, subcontractor), work schedule, and/or any other characteristics that help precisely define the membership of the class of employees. Also, note that a class should always be defined by generic employment parameters as described above; it may not name individuals and it must potentially include more than one individual.

6.4.16.2.1 The Director of DCAS (or designee) will consult with DOL to determine whether the class definition is specified by parameters that will allow DOL to determine whether a claimant is, or is not, a member of the class. In some cases, it is possible that DCAS would be able to define a class of employees by more precise parameters than those DOL would be able to apply in making such determinations. In such cases, DCAS should consider whether to limit the class definition to the parameters of utility to DOL. The feasibility determination under step 6.4.14.2 could separately define the more specific class parameters upon which the determination is based.

6.4.16.3 For each class of employees for which dose reconstruction is not feasible, indicate within the class definition whether the minimum 250-work-days employment requirement for health endangerment applies to the class of employees, based on the analysis under step 6.4.15.

6.4.16.4 For each class of employees for which the 250-work-days employment requirement for health endangerment applies, include a statement specifying that health was endangered for those workers who were employed for a number of work days aggregating at least 250 work days within the parameters established for the class, or in combination with work days within the parameters established for one or more other classes of employees in the SEC.

6.5 Evaluate the petition qualifying for evaluation under 42 C.F.R. § 83.14, for a claimant for whom DCAS was unable to complete a dose reconstruction.

Note: The steps and procedures under subsection 6.5 provide guidance for DCAS to evaluate a petition by a claimant for whom DCAS found it was unable to complete a dose reconstruction. In these situations, as provided for by 42 C.F.R. § 83.14, DCAS has already determined that it is not feasible to estimate the levels of radiation doses of individual members of the class with sufficient accuracy. This guidance concerns the remaining steps of defining the class of employees, addressing health endangerment, and determining whether there may be a more extensive class of employees that requires further evaluation and consideration for addition to the Cohort as a separate class of employees.

6.5.1 Define the class of employees for whom dose reconstruction is not feasible.

6.5.1.1 Review the information obtained by DCAS and the rationale justifying the DCAS finding that a dose reconstruction could not be completed for the employee(s) identified in the petition.

6.5.1.2 Define the class of employees for which the information under step 6.5.1.1 applies, using the procedures under 6.4.16. As noted under step 6.4.16.2, a class should always be defined by generic employment parameters; it may not name individuals and it must potentially include more than one individual.

6.5.2 Evaluate the likelihood that radiation doses may have endangered the health of members of the class of employees defined under step 6.5.1. Use the procedure under step 6.4.15.

6.5.3 Based on the evaluation under step 6.5.2 and the definition under step 6.5.1, define a class of employees for which it can be determined that: (1) it is not feasible to estimate the radiation doses of individual members of the class of employees with sufficient accuracy; and (2) there is a reasonable likelihood that such radiation dose may have endangered the health of members of the class of employees. For the class of employees defined under this step, go to subsection 6.6 to prepare a report of the evaluation findings.

6.5.4 Determine whether the existing information under 6.4.16.1 indicates the potential for another class of employees for which dose reconstruction might not be feasible, beyond the scope of the group defined under step 6.4.16.2. If such a potential exists, initiate an evaluation under subsection 6.2.

Example: DCAS found it could not complete a dose reconstruction for employee John Q. Public. Mr. Public was exposed to radiation during an incident for which there were no monitoring data and inadequate source term and process data. Under step 6.5.1.2, all workers employed in the immediate area of the incident, or in responding to the incident, were included in the group. However, the records reviewed during the attempted dose reconstruction for Mr. Public were not sufficient to determine whether workers were employed in areas proximate to the incident and might have been similarly exposed. This possibility will need further investigation.

6.6 Prepare an evaluation report responding to the petition(s).

Note: The steps and procedures under subsection 6.6 provide guidance for DCAS to prepare a report of its evaluation findings.

6.6.1 For petitions for classes that qualified under 42 C.F.R. § 83.13, prepare an evaluation report according to the requirements of 42 C.F.R. § 83.13(d). Use the appropriate DCAS template for this report from Attachment 1.

6.6.2 For petitions qualified under 42 C.F.R. § 83.14, prepare an evaluation report according to the requirements of 42 C.F.R. § 83.13(d)(1)-(3) and (5) and § 83.14(b). The report must also provide notification of whether a determination has been made under step 6.5.4 that the existing information under step 6.5.1.1 indicates the potential for another class of employees for which dose reconstruction might not be feasible, extending beyond the scope of the group defined under step 6.5.1.2. If such a potential exists, explain that an evaluation under subsection 6.4 will be conducted, and explain the basis for this decision. Use the appropriate DCAS template from Attachment 1 for this report, and be certain that appropriate redactions have been made to protect the privacy of individuals.

6.6.3 OGC must review the petition evaluation report for privacy and other legal considerations and the Director of DCAS must approve it before it can be transmitted to the Board and other parties under step 6.7.

6.7 Transmit and publicize the evaluation report.

Note: The steps under subsection 6.7 provide guidance for DCAS to transmit its evaluation findings to petitioners, the Board, and the public.

6.7.1 The report of evaluation findings prepared under subsection 6.6 must be completed and submitted to the Board within 180 calendar days of DCAS receiving the petition. The 180 calendar days shall not include: days when the petitioner is remedying deficiencies reported by DCAS under step 6.1.6, days when the petitioner may request review of a proposed finding under step 6.1.8, or days when conducting an administrative review under step 6.1.9.

6.7.2 Transmit the approved evaluation report to the petitioner(s) and members of the Board as soon as possible after approval and post on the NIOSH/DCAS website.

6.7.3 Prepare an entry for the Federal Register Notice of the next Board meeting, summarizing the petition and the findings of the DCAS evaluation report. This notice must appropriately protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the Federal Register.

6.7.4 Post the Federal Register Notice on the NIOSH/DCAS website as soon as possible after publication.

6.7.5 If, for some reason, NIOSH is unable to submit the report to the Board within 180 calendar days, DCAS will, as soon as it is apparent that the 180 period will be exceeded, submit a letter to the Board explaining the reasons and proposing a new report submittal date. Notification will also be sent to the petitioners, the Congressional Liaison, and the Designated Federal Official.

6.8 Schedule a presentation to the Board.

Note: The procedures under subsection 6.8 provide guidance for DCAS to schedule a presentation of the evaluation report prepared under step 6.7 to the Board.

6.8.1 Schedule the presentation to the Board of the petition and the DCAS evaluation as soon as possible, taking into account such matters as the need for Board members to review the report prior to the meeting, the requirements of the Federal Advisory Committee Act (FACA), and, when possible, the scheduling needs of the petitioner(s).

6.8.2 It is essential to obtain the Board's review of petitions qualifying under 42 C.F.R. § 83.14 as soon as possible, since these petitions involve a claim for which DCAS has already determined that dose reconstruction is not feasible, meaning that adjudication of the claim by DOL relies on completion of the petition evaluation process. Make every effort to schedule consideration of these petitions as soon as possible, consistent with step 6.8.1.

6.8.3 As provided in 42 C.F.R. § 83.15(b), in considering the petition, both DCAS and the members of the Board will take all steps necessary to prevent the disclosure of information of a personal nature, concerning the petitioners or others, where disclosure would constitute a clearly unwarranted invasion of personal privacy. This may include such steps as making appropriate redactions of documents and holding closed meetings of the Board under FACA.

6.8.4 Upon request of the Board, DCAS may conduct further evaluation of a petition. If DCAS conducts further evaluation, it will report new findings to the Board and the petitioner(s).

6.9 Establish a proposed decision on the outcome of the petition(s).

Note: The steps and procedures under subsection 6.9 provide guidance for DCAS to support the Director of NIOSH in establishing proposed decisions.

6.9.1 Proposed decisions will take into account the petition, the DCAS evaluation(s), and the report and recommendations of the Board, and may also take into account other information presented or submitted to the Board, as well as the deliberations of the Board.

6.9.2 Proposed decisions must comply with the provisions of 42 C.F.R. §§ 83.13(c) or 83.14(b), as appropriate.

6.9.3 A single petition may result in one or more proposed decisions to add a class of employees to the Cohort and/or to deny adding a class of employees to the Cohort. This depends on the number of separate classes of employees defined by the Director of NIOSH, based on the information identified under step 6.4.16.

6.9.4 The Director of NIOSH will issue the proposed decision.

6.9.5 DCAS will prepare a report of the proposed decision, which must be appropriately redacted to protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the Secretary. The report of the proposed decision must include a detailed definition of the class of employees, an iteration of the relevant criteria, as specified under 42 C.F.R. § 83.13(c), and a summary of the information and findings on which the proposed decision is based.

6.9.6 The Director of NIOSH (or designee) must approve the report.

6.10 Transmit proposed decisions to the Board and to the Secretary.

Note: The steps and procedures under subsection 6.10 provide guidance for DCAS to transmit proposed decisions established by the Director of NIOSH.

6.10.1 Transmit the approved report(s) to the Board and to the Secretary of HHS as soon as possible after approval. If a petition resulted in multiple decisions and reports, the reports should be accompanied by a summary explaining the basis for distinguishing multiple classes of employees.

6.11 Basis for the Secretary's (or designee's) making and reporting a final decision:

Note: The Secretary of HHS (or designee) will make a final decision whether or not to add a class of employees to the Special Exposure Cohort.

6.11.1 The Secretary of HHS (or designee) will make the final decision to add or deny adding a class to the Cohort after considering information and recommendations provided to the Secretary (or designee) by NIOSH and the Board.

6.11.1.1 The final report will include the decision to add or deny adding a class to the Special Exposure Cohort, an iteration of the relevant criteria, as specified under 42 C.F.R. § 83.13(c), for adding or denying the addition of the class, a summary of the information and findings on which the decision is based and the definition of the class.

6.11.2 Transmit a report of the final decision, which must be appropriately redacted to protect the privacy of individuals, and must be reviewed by OGC, to the petitioner(s). Transmit the approved report(s) to the petitioner(s) as soon as possible after approval. The report(s) should be accompanied by a transmittal letter that notifies the petitioner(s) of the procedures and requirements for contesting a final decision. If a petition results in multiple decisions and reports, the reports should be accompanied by a summary explaining the basis for distinguishing multiple classes of employees.

6.11.3 Publish a notice, which must be appropriately redacted to protect the privacy of individuals, and must be reviewed by OGC, summarizing the final decision in the Federal Register.

6.12 If a class which the Board has recommended be designated is found not to meet the statutory criteria for adding a class, prepare for the Secretary a determination to be submitted to Congress within 30 calendar days following receipt of the Board's recommendation.

6.13 Transmit and publicize final decisions.

Note: The steps and procedures under subsection 6.13 provide guidance for DCAS to transmit and publicize final decisions established by the Secretary of HHS. When the Secretary (or designee) makes the determination to add a class of employees to the Cohort, a report must be submitted to Congress. A final decision to add a class to the Cohort by the Secretary (or designee) will take effect 30 days after the submission of the report to Congress, unless Congress takes an action that reverses or expedites the designation.

6.13.1 Prepare a report on the final decision of the Secretary of HHS to designate a class for addition to the SEC, or not to add a class. The report on the final decision must include a definition of the class of employees, an iteration of the relevant criteria, as specified under 42 C.F.R. § 83.17(a), and a summary of the

information and findings on which the final decision is based. This report must be reviewed by OGC prior to being sent to the Secretary.

6.13.2 Reports of final decisions must be approved by the Secretary of HHS (or designee).

6.13.2.1 If the Secretary (or designee) makes a final determination not to add a class of employees to the Special Exposure Cohort, there is no congressional review of that designation, and it immediately becomes a final agency decision. Go to step 6.13.3.

6.13.2.2 If the Secretary (or designee) designates a class of employees to be added to the Cohort, the Secretary (or designee) will transmit a report of the designation to Congress, pursuant to 42 C.F.R. § 83.17(a).

6.13.2.2.1 The report to Congress will provide the definition of the class of employees covered by the designation, and the criteria and findings upon which the designation was based. The report will be appropriately redacted to protect the privacy of individuals, and be reviewed by OGC. If the Secretary adds a class that does not include a class recommended by the Board, then the 30-calendar-day deadline for transmittal of the decision to Congress does not apply.

6.13.2.2.2 If the Secretary adds a class inclusive of a class which the Board has recommended be designated, then the Secretary (or designee) will transmit a report to Congress within 30 calendar days following receipt of the Board's recommendation in accordance with 42 C.F.R. § 83.17(a), providing the designation, definition of the class covered, and the criteria and findings upon which designation was based. The report will be appropriately redacted to protect the privacy of individuals, and be reviewed by OGC.

6.13.2.2.3 A decision of the Secretary (or designee) to add a class of employees to the Cohort will take effect 30 calendar days after the date on which the report of the Secretary (or designee) is submitted to Congress, unless Congress takes an action that reverses or expedites the effect of the designation.

6.13.3 Transmit the approved report to the petitioner(s) pursuant to 42 C.F.R. § 83.16(b). This report must be appropriately redacted to protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the petitioner(s).

6.13.3.1 If the decision is to add a class of employees, the report must clearly indicate that the designation of additional class members is not final until after the expiration of the 30-day congressional review period, or when Congress takes an action that reverses or expedites the designation, whichever comes first.

6.13.3.2 The report should indicate that a final report, inclusive of congressional action, will be issued at the end of the 30-day congressional review period, or after Congress takes an action that reverses or expedites the designation, whichever comes first. If the report is a final determination not to add a class of employees, it should indicate that it is a final agency decision.

6.13.4 Post the redacted and OGC-cleared report on the NIOSH/DCAS website.

6.13.5 Prepare and publish a Federal Register Notice summarizing the final decision. This notice must appropriately protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the Federal Register.

6.14 Transmit and publicize the outcome of congressional review.

Note: The steps and procedures under subsection 6.14 provide guidance for DCAS to transmit and publicize the outcome of a final decision established by the Secretary of HHS to add a class of employees to the Cohort, following the opportunity for Congress to review the decision.

6.14.1 Prepare a report on the outcome of the HHS decision to add a class to the Cohort. The report must include a detailed definition of the class of employees, the outcome of the decision of HHS, and a summary of any action taken by Congress that affected the outcome of the HHS decision or its implementation. DCAS should prepare and submit the report to the NIOSH Office of the Director a minimum of 7 days prior to the expiration of the 30-day congressional review period. This deadline applies whether or not Congress is actively considering the HHS decision at such time. If Congress concludes its consideration of the HHS decision prior to such time, DCAS should prepare the report as soon as possible.

6.14.2 HHS must approve the report after confirmation of congressional action or after the expiration of the 30 day congressional review period, if Congress does not take action. This report must be appropriately redacted to protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the petitioner(s).

6.14.3 Transmit the redacted and OGC-cleared report to the petitioner(s) and the unredacted version of the report to DOL within five work days of either expiration of the congressional review period or notification of final congressional action, whichever comes first.

6.14.4 Post the approved, redacted and OGC-cleared report on the NIOSH/DCAS website.

6.14.5 Prepare and publish a Federal Register Notice including the report. This notice must appropriately protect the privacy of individuals, and must be reviewed by OGC prior to being sent to the Federal Register.

6.14.6 Provide the Federal Register Notice, and other assistance as necessary, to the NIOSH Public Affairs Officer to assist HHS in publicizing the final decision through appropriate media outlets.

6.14.7 Work with DOL, DOE, and other organizations to publicize the report.

6.14.8 Notify the CDC Washington Office (NIOSH assignee) of availability of the final report.

6.15 Conduct an HHS administrative review of final decisions, as necessary.

Note: Petitioner(s) may request an administrative review of a final decision of the NIOSH Director not to add a class of employees to the Special Exposure Cohort, or a decision that the 250-day health endangerment criterion applies to a class being added.

6.15.1 After the Director of NIOSH completes the actions required by step 6.11.2, HHS will grant the petitioner(s) 30 calendar days to contest a final decision not to add a class of employees to the Special Exposure Cohort, or to apply the 250-day health endangerment criterion to a class being added.

6.15.1.1 Such challenges must be submitted in writing.

6.15.1.2 The challenge must include evidence that the final decision relies on a record of either substantial factual errors or substantial errors in the implementation of the procedures of 42 C.F.R., part 83.

6.15.1.3 If the petitioner submits a proper, written appeal of the Secretary's final decision not to add a class of employees to the Special Exposure Cohort, the Secretary of HHS (or designee) will appoint a panel of three HHS personnel, independent of NIOSH, who were not previously involved in

the review of the petition(s). The Secretary (or designee) will appoint one member of the panel as the chair, who will be responsible for convening the panel and transmitting the panel's recommendation under step 6.15.4.

6.15.1.4 The appointed panel of three HHS employees will conduct an administrative review based on a challenge submitted by the petitioner(s) and provide recommendations of the panel to the Secretary of HHS (or designee) concerning the merits of the challenge and the resolution of issues contested by the challenge.

6.15.1.5 The panel shall consider whether HHS substantially complied with the procedures of 42 C.F.R., part 83, the factual accuracy of the information supporting the final decision, and the principal findings and recommendations of NIOSH and those of the Board issued under 42 C.F.R. § 83.15.

6.15.1.6 The review will consider, in addition to the views and information submitted by the petitioner(s) in the challenge, the final decision, the DCAS evaluation report(s) and the report containing the recommendations of the Board.

6.15.1.7 The review may also consider information presented or submitted to the Board and the deliberations of the Board prior to the issuance of the recommendations of the Board under 42 C.F.R. § 83.15.

6.15.2 Upon completion of its deliberations, the panel will prepare and transmit to the Secretary of HHS (or designee) a report of the findings of the panel.

6.15.2.1 The report will be based on the majority opinion of the panel. The chair will appoint one member of the majority to write the majority opinion of the panel. The chair can appoint himself/herself to write the majority opinion if he/she is in the majority. The majority report will indicate whether or not the panel supports the final decision made by the Secretary of HHS, and the rationale for the panel's determination.

6.15.2.2 A minority addendum may be prepared by a dissenting member of the panel and be added to the panel's final report, which is being submitted to the Secretary of HHS (or designee) for consideration. A minority addendum, if one is prepared, will indicate whether or not the minority supports the final decision made by the Secretary of HHS, and the rationale for that determination.

6.15.3 If a petitioner(s) contests a final decision, the Secretary of HHS will decide whether or not to revise the final decision contested by the petitioner(s) after considering information and recommendations from the Director of NIOSH, the Board, and any HHS administrative review conducted under 42 C.F.R. § 83.18(b).

6.15.3.1 DCAS will prepare a report of the decision to be transmitted by HHS to the petitioner(s).

6.15.4 If the Secretary of HHS decides under 42 C.F.R. § 83.18(c) to change a designation under 42 CFR § 83.17(a), or a determination under 42 C.F.R. § 83.16(c), the Secretary will submit to Congress a report providing such change, including an iteration of the relevant criteria, as specified under 42 C.F.R. § 83.13(c), and a summary of the information and findings on which the decision is based.

6.15.4.1 NIOSH will publish a notice summarizing the decision in the Federal Register.

6.15.5 The new designation will take effect 30 calendar days after the Secretary of HHS submits the report under § 83.18(d) to Congress, unless Congress takes an action that reverses or expedites the designation.

6.15.5.1 Such new designations and related congressional actions will be further reported by the Secretary of HHS, per paragraphs (d) and (e) of 42 C.F.R. § 83.17.

6.16 Review the utility of newly obtained records and information for classes of employees added to the Cohort.

Note: Steps and procedures to provide guidance related to 42 C.F.R. § 83.19, which addresses how the Secretary of HHS can cancel or modify a final decision to add a class of employees to the Cohort, will be established at such time as they become necessary. At this time, the only activity required of DCAS and its technical contractors is monitoring the identification and collection of records and information by DCAS to determine whether it is new and relevant to classes added to the Cohort by HHS.

6.16.1 DCAS and technical contractor staff should notify the SEC Health Physics Team Leader (or designee) when new records are identified that are relevant to a class of employees added to the Cohort.

7.0 RECORDS

The following records are generated as applicable:

DCAS-FORM-A/DCAS-FORM-B (by petitioner)
Communications with petitioner(s), including Reports of Phone Conversations
Acknowledgement of Receipt letter
Notice of Deficiency
Privacy Act Waiver
Proposed Findings/Final Decision for Deficient Petitions
Notification of Petition Selection for Evaluation
Petition Evaluation Report
Notification package for Board
Report of Proposed Decision
Report of Final Decision
Report of Designation to Congress

8.0 APPLICABLE DOCUMENTS

8.1 Drivers

42 U.S.C. § 7384n(c)(3)(A) Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA)

42 C.F.R., Part 83 and Amendments (see References 3.2, 3.3 and 3.4)

8.2 Forms

8.2.1 DCAS-FORM-A

8.2.2 DCAS-FORM-B

8.3 Procedures

DCAS-PR-005, "Conduct of Assessments"

DCAS-PR-006, "CIC Processing Compensation Cases."

9.0 ACRONYMS

AWE – Atomic Weapons Employer
CIC – Claims Information & Communications Team
DOE – Department of Energy
DOL – Department of Labor
EE – Energy Employee
EEOICPA – Energy Employees Occupational Illness Compensation Program Act of 2000 (42 U.S.C. § 7384n(c)(3)(A)
FACA - Federal Advisory Committee Act
NIOSH – National Institute for Occupational Safety and Health
DCAS – Office of Compensation Analysis and Support
OGC – Office of General Counsel
DSA - DCAS SEC Application Tracking System
SEC – Special Exposure Cohort

Attachment 1 – Evaluation Report Template

Evaluation Summary

This section should fully define the class or classes covered by the evaluation, summarize findings of feasibility and, when appropriate, health endangerment applicable to the class or classes, and briefly summarize the criteria and findings supporting the findings. This section should not explicitly recommend the addition of a class to the Cohort or the denial of the petition, since it will be beneficial to have the Board's evaluation before making such a recommendation on behalf of HHS.

Class Definition Proposed by the Petitioner(s) and Petition Basis

This section should identify the class definition proposed by the petitioner and explain with reasonable detail the basis for the petition.

Data Collection

This section should describe the data collection effort and its results. It should provide information on the following:

- *Specifically, which information resources did we focus on (through DOE, DR records, research records, and/or from other resources, whether queried specifically in response to this petition or through TBD development or DRs)?*
- *What information germane to the evaluation of the class did we obtain from each resource we queried? (These summaries might be organized under each providing resource, according to the hierarchy of information usable for DRs.)*
- *An affirmative statement that we are unaware of any resources of information that we did not query.*
- *When appropriate, we should identify potential information resources that were unable to provide data on a timely basis.*

Summary of Radiological Operations Relevant to the Initial Class

This section should give the reader a holistic understanding of the work process and exposure potentials in the context of the process, such that the reader can judge whether we have evaluated feasibility (or health endangerment) systematically and completely. This section should give the reader an integrated operational understanding of the industrial process during the relevant timeframe and the radiological elements of this process, characterizing radiation sources, the route(s) of exposure to the class, and protective practices as known. Ideally, this section would include narrated graphical depictions of the work process, labeling the various activities and workflow, and each important source of potential radiation exposure

(e.g., shoveling ore, aerosolized dust from a process, proximity to source term, etc.). If including graphics proves too difficult, the process could be described using a narrative sequence without graphics.

Evaluation of Feasibility of Dose Reconstruction

This section should begin with an introduction that summarizes the criteria for determining feasibility and the hierarchical approach NIOSH used to evaluate the adequacy of data for dose reconstruction. It should also explain that this approach was applied to each potential source of radiation exposure for the class (described in detail in the preceding section) to systematically address whether radiation doses could be estimated for all potential sources of radiation exposure to the class.

A series of subsections should then follow. Each section should begin by identifying the potential source of exposure, and discussing the personnel monitoring information and whether it is adequate for DRs, based principally on monitoring data. If not, discuss the area monitoring data and whether it, in combination with the personnel monitoring data, is adequate. If not, discuss the process and source/source-term data and whether it, in combination with personnel and area monitoring data, is adequate. At each level of this analysis, we need to explain why the information is or is not adequate.

The section needs to: (a) explain what amount and/or characteristics of data would be adequate to complete DRs for the class, using the given level of the hierarchy; and (b) describe how the data available fall short within these specific parameters.

If data are adequate to support dose reconstruction, we must explain how such data could be used to reconstruct radiation doses. We should also clearly indicate that actual dose reconstructions for members of the class may employ methods that differ from the methods indicated here to establish feasibility.

If data are not adequate to support dose reconstruction, we must specify criteria that distinguish in bright-line fashion between data that would have been adequate for dose reconstruction and the available data that are not adequate.

Summary of Feasibility Findings

This section should summarize the preceding source-by-source findings of feasibility. A table might be an easy way to do this, the rows being the potential exposure sources and the columns being the determination.

Evaluation of Health Endangerment

When we find that a DR is not feasible for one or more exposure sources, we need to have a section that addresses health endangerment for those sources. When we determine non-feasibility is related to a discrete incident, we need to summarize the data, calculations, and findings from the incident and from other comparable incidents, as applicable, that demonstrate the high exposure potential implicated. When NIOSH has not identified exposure incidents that would constitute a discrete incident as defined under 42 CFR § 83.13(c)(3)(i), we need to specify this finding.

Definition of Class

We need a section following the analyses of feasibility and health endangerment that defines the class or classes established on the basis of the analyses. The definition needs to specify the time period, work locations and other employment parameters (e.g., employment duration to address health endangerment when DR is not feasible), using practical terms that could be applied by NIOSH to identify members of a class that has already been considered or applied by DOL to identify members of a class that could be added to the Cohort. This section also needs to identify and provide the rationale for any changes made by NIOSH to the petitioner-proposed class definition as a result of the evaluation.