



# Special Exposure Cohort (SEC) Update

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**Advisory Board on Radiation and Worker Health, 137<sup>th</sup> Meeting**

Teleconference | December 8, 2020

# Purpose

- Update the Advisory Board on Radiation and Worker Health (Advisory Board)
- Special Exposure Cohort (SEC) summary of petitions
  - in qualification
  - under evaluation
  - currently under Advisory Board review
  - potential SEC petitions (83.14)

# Summary

- Petitions received – **258**<sup>\*</sup>
  - Petitions in qualification process – **2**
  - Petitions qualified for evaluation – **153**
  - NIOSH new petition evaluations in progress – **1**
  - NIOSH evaluation completed – **152**
- Reports with the Advisory Board – **11**
- Petitions not qualifying for evaluation – **103**

\*NOTE: 258 includes 5 petitions received prior to the issuance of the SEC regulation

# SEC Petitions in Qualification

- Rocky Flats Plant
  - Golden, Colorado
  - Petition SEC-0257
  - 1984-1989
  - All Employees
  - Expected completion: Additional information provided to Petitioner in November 2020

# SEC Petitions in Qualification (cont.)

- Pantex Plant
  - Amarillo, Texas
  - Petition SEC-0258
  - January 1992 – December 2000
  - All Employees
  - Expected completion: December 2020

# SEC Petitions under Evaluation

- Pinellas Plant 1957-1990
  - Clearwater, FL
  - Petition SEC-0256
  - All employees
  - Expected completion: March 2020

# SEC Petitions under Evaluation (cont.)

- Lawrence Livermore National Laboratory 1990-2014
  - Livermore, CA
  - Petition SEC-0221
  - Addendum to address remaining years
  - All employees
  - Expected completion: March 2021

# SEC Petitions under Evaluation (cont.)

- Y-12 Plant 1987-1994
  - Oak Ridge, TN
  - Petition SEC-0250
  - Addendum to address remaining years
  - All employees
  - Expected completion: February 2021

# Under Advisory Board Review

- Hanford (SEC-0056) – All SEC issues are closed. NIOSH working on Co-exposure model
- Savannah River Site (SEC-0103) – An update is scheduled for this meeting
- Los Alamos National Lab (SEC-0109) – NIOSH working to resolve issues raised by SC&A and the work group
- Sandia National Laboratory (SEC-0188) – SC&A will soon be releasing their review of the NIOSH addendum

## Under Advisory Board Review (cont.)

- Idaho National Lab (SEC-0219) – NIOSH is working to resolve issues raised by SC&A and the work group
- Argonne National Laboratory - West (SEC-0224) – NIOSH is working to resolve issues raised by SC&A and the work group
- Area IV Santa Susanna (SEC-0235) – NIOSH is waiting on records to be released from EMCBC
- Metals and Controls (SEC-0236) – NIOSH is preparing a response to the work group. An update is scheduled for this meeting

## Under Advisory Board Review (cont.)

- De Soto Avenue Facility (SEC-0246) – SC&A is reviewing information submitted by the petitioner and NIOSH is working to provide clarification on a few remaining issues
- Reduction Pilot Plant (SEC-0253) – The work group and SC&A are reviewing the NIOSH evaluation report

## Sites with evaluation period awaiting action

- Hanford (SEC-0057) 1984-1990  
(Primes only)
- Savannah River Site (SEC-0103) 1973-2007
- Los Alamos National Laboratories-A (SEC-0109) 1996-2005
- Sandia National Laboratory (SEC-0188) 1997-2011
- Idaho National Laboratory (SEC-00219) 1949-1970

## Sites with evaluation period awaiting action (cont.)

- Lawrence Livermore National Lab (SEC-0221) 1990-2014
- Argonne National Laboratory – West (SEC-0224) 1958-1979
- Area IV Santa Susanna (SEC- 0235) 1991-1993
- Metals and Controls (SEC- 0236) 1968-1997 (Res)
- De Soto Avenue Facility (SEC-0246) 1965-1995
- Reduction Pilot Plant (SEC-0253) 1976-1978

# Potential SEC Petitions (83.14)

- West Valley Demonstration Project
  - NIOSH evaluating a potential SEC for the AWE period 1966-1968



# Special Exposure Cohort (SEC) Qualification Process

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# Purpose

- Describe the SEC qualification process
- Describe process improvements made based on:
  - Petitioner Input
  - Advisory Board Work Group recommendation
  - Administrative Review findings and recommendations

# SEC Petitioning Process: Overview

- There are seven main steps that a petition may go through before it can be added as a new SEC class:
  - Petition submission
  - Qualification
  - Evaluation
  - Evaluation Report presented to the Advisory Board
  - Advisory Board's recommendation and NIOSH Director's proposed decision
  - Secretary of HHS's designation or determination
  - Submission to Congress

# Petition Submission

- Information on filing and forms can be found:
  - On our Web site at <https://www.cdc.gov/niosh/ocas/how2add.html>
  - By contacting our SEC Petition Counselor at 513-533-6831 or by email at [jkinman@cdc.gov](mailto:jkinman@cdc.gov)
- Forms are optional and provide guidance as to what type of information will be used by NIOSH to qualify a petition
  - Form A should be used if NIOSH has notified the claimant/petitioner that a dose reconstruction cannot be completed
  - Form B should be used if petitioner(s) believes a class should be added and are requesting NIOSH evaluate a class for addition to the SEC under 83.13

# Qualification Process

- Once a petition is submitted it is reviewed to determine whether it meets the minimum requirements established in the SEC rule, 42 CFR part 83
- In order to qualify for evaluation, the petition must include:
  - Identifying and contact information for the petitioner(s)
  - A proposed class definition
    - **Specifying a single DOE or AWE facility**
    - **Location(s) at the facility that are included**
    - **Job titles and/or job duties of the class members; and**
    - **Period of employment relevant to the petition**

# Qualification Process (cont.)

- A description of the basis for believing records and information available are inadequate to estimate radiation doses, based on one of the following:
  - 1) Lack of monitoring
  - 2) Destruction, falsification, or loss of records
  - 3) Expert report
  - 4) Scientific or technical report
  - 5) Exposure incident involving a high level of radiation dose
- Documentation or statements in the form of an affidavit must be provided to support (1), (2), and (5) bases.
- NIOSH works closely with petitioners during the qualification process to develop relevant information and explain any deficiencies in the petition and to aid in submitting any needed materials

## Qualification Process (cont.)

- Of the 258 petitions received 103 have not qualified
- Below are the main reasons they did not qualify:
  - Submitted documents or affidavits do not support the qualification basis (67)
  - Is voluntarily withdrawn by the petitioner (9)
  - Covers an already existing SEC class (7)
  - Not a covered site under the program (6)
  - Petitions received prior to rule promulgated (5)
  - Other (9)

## Qualification Process (cont.)

- If a petition qualifies for evaluation, NIOSH reviews the petition as submitted and evaluates it according to the SEC Rule
- Appropriate notices are sent to:
  - Petitioner(s)
  - The Advisory Board on Radiation and Worker Health
  - Congressional Staff
- Notices are also:
  - Published in the Federal Register
  - Posted on the NIOSH Web site

## Qualification Process (cont.)

- If a petition is not qualified for evaluation, the proposed decision not to qualify becomes a final decision in 31 calendar days, but:
  - The petitioner can provide new information within this 30-day period for consideration, OR
  - Petitioner(s) can request an administrative review of the proposed finding (see next slide)
    - A written review request to NIOSH Director must be submitted within 30 calendar days of the notification that the petition did not qualify
  - Petitioner can file a new petition for the same class thereafter with new information

# Qualification Process (cont.)

## ■ **NIOSH Administrative Review**

- NIOSH Director appoints three HHS personnel who
  - Are not involved in developing the proposed finding
  - Have never been employed at DOE site in question or by DOE HQ
  - Have never been employed at DCAS
- The Administrative Review Panel reviews the administrative record and the petitioner's request
  - 30 workdays to complete its review
- NIOSH Director communicates his final decision to the petitioner

# Process Improvements

- NIOSH has found one of the hardest things to communicate to petitioners is why their petition does not qualify
  - Explaining a technical reason in terms that anyone can understand
  - Explaining how an accident does or does not have the potential for high radiation exposure
- The difficulty in communicating these findings have been recognized in communications with petitioners, Advisory Board Work Group, and administrative review panels.

# Process Improvements (cont.)

- Petitioner Input

- Early in the process, we established an SEC Petition Counselor to communicate with the petitioners
- NIOSH Ombudsman was established to support petitioners and claimants involved in the dose reconstruction and SEC process
- Increased communications between petitioner, SEC Petition Counselor, and NIOSH Lead HP during the qualification period

## Process Improvements (cont.)

- The Advisory Board established a work group to review petitions that did not qualify
  - The charge of this Work Group was to review disqualified special exposure cohort petitions and the process followed by NIOSH and the rationale for petition disqualification
  - Task completed May 02, 2007
  - The conclusions of the Work Group were that the final rule as reflected in the legislation was followed, and NIOSH's review of the petition was claimant friendly. The Work Group provided several recommendations regarding making the process of submitting a Special Exposure Cohort more user friendly
    - The key part of the recommendations focused on communication with the petitioner

# Process Improvements (cont.)

- Administrative Review Findings and Recommendations
  - The Administrative Review Panel has reviewed 27 petitions as requested
  - The panel has agreed with NIOSH's proposed decision not to qualify 23 of 27 petitions
  - The four where they did not agree and recommended qualifying the petition were due to a lack of clear communication to the petitioner explaining the reason for the disqualification
- Based on the Administrative Review Panel findings and recommendations, we have tried to provide more information in our proposed finding letters to make it easier for the petitioner to understand our decision not to qualify a petition.

# Process Improvements (cont.)

- Changes we are making based on recent petitioner concerns and Administrative Review Panel's findings
  - Adding non-technical reviewers to review the proposed finding notification to petitioner
  - Providing additional opportunities to petitioners to receive verbal explanation on the proposed finding
  - Including a more robust explanation on the proposed finding in the notification letter to the petitioner

# Questions?