# OCAS-PER-012

## Evaluation of Highly Insoluble Plutonium Compounds

Report from the Procedures Review Subcommittee

Presented to the
Advisory Board on Radiation and Worker Health
Denver, Colorado

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# OCAS-PER-012 Summary

- Important variable for internal dose reconstruction is the solubility type of a given radionuclide, i.e. Types F, M, and S.
- Under unique circumstances, plutonium (Pu) exists in highly insoluble forms, referred to as Type Super S (Type SS).
- Inhaled, this highly insoluble form of Pu has extended residence time in the lung, proportionately increasing dose to that tissue.
- Impact of Type SS Pu target tissue dose was assessed in ORAUT-OTIB-0049 “Estimating Doses for Pu Strongly Retained in Lung”.
- That assessment prompted the issuance of OCAS-PER-012.

# OCAS-PER-012 Timeline

- January 12, 2004 - NIOSH issued TBD for Rocky Flats Plant (RFP)-Occupational Internal Dose. Key element in TBD was existence of high-fired, highly insoluble form of Pu.

- February 6, 2007 – NIOSH issued ORAUT-OTIB-0049 "Estimating Doses for Plutonium Strongly Retained in Lung."

- March 29, 2007 – NIOSH issued OCAS-PEP-012 " Evaluation of Highly Insoluble Plutonium Compounds."

- August 7, 2007 – NIOSH issued OCAS-PER-012 "Evaluation of Highly Insoluble Plutonium Compounds."

# Summary Timeline for SC&A's Audit Report

- March 18, 2010 – SC&A submitted draft review of OCAS-PER-012 (SCA-TR-PR2010-00012, Rev. 0) to Procedures SC and NIOSH.
- January 5, 2011 – SC&A presented findings to the Procedures Subcommittee; SC accepted findings.
- July 15, 2011 – NIOSH provided SC a list of 50 cases from all potential categories except fecal sample monitoring for extrathoracic and GI tract; SC selected 9 DRs representing 8 of 10 categories for SC&A's review under Subtask 4.
- July 20, 2012 – SC&A submitted to SC and NIOSH a draft review of 9 DRs affected by OCAS-PER-012 (SCA-TR-PR2012-0012, Rev. 0).
- July 31, 2012 – SC&A presented its findings to the Procedures Subcommittee; SC accepted findings.

# Audit of OCAS-PER-012
# Subtask 1: Assess Circumstances that Necessitated the Need for the PER

- In development of Site Profile, NIOSH noted highly insoluble Type S Pu and need to assess its impact on internal dose.

- NIOSH faced dilemma: Regulations defined in 42 CRF 82 require dose to be calculated using current ICRP metabolic models. Current ICRP Publication 66 models do not address highly insoluble form of Pu defined as Type Super S or Type SS.

- To account for longer retention and increased organ doses from Type SS Pu, NIOSH developed and issued ORAUT-OTIB-0049 on 2/6/2007.

# Subtask 1 (Continued): Assess Circumstances that Necessitated the Need for the PER

- For ORAUT-OTIB-0049, NIOSH developed "dose adjustment factors" (generally a factor of 4) from cases of RFP and Hanford workers exposed to Type SS Pu for 4 target organs and intakes based on lung counts, air concentrations, urinalysis, and fecal analysis.
- Given the magnitude of this effort, SC&A recognized that 3-year time period for development of OTIB-0049 was understandable.
- SC&A's review of OTIB-0049, OCAS-PEP-012, and OCAS-PER-012 found that NIOSH properly characterized the significance of highly insoluble Pu and complied with OCAS-PR-008 in evaluating impact of the programmatic changes on previously completed DRs.
- SC&A had no findings under Subtask 1 of the review.

# Subtask 2 : Assess Specific Methods for Corrective Action

- When a PER involves a technical issue supported by documents such as white papers, OTIBs, procedures that have not yet been formally reviewed by SC&A, Subtask 2 assesses the scientific basis to ensure credibility of the corrective action.

- OCAS-PER-012 was prompted by ORAUT-OTIB-0049 issuance, critically reviewed by SC&A in an October 29, 2007 draft report (SCA-TR-TASK3-0003). In brief, SC&A was in full agreement with NIOSH's approach for dose modeling of Pu Type SS.

- Subtask 2 was reduced to a brief summary of key technical elements defining ORAUT-OTIB-0049; there were no findings.

# Subtask 3: Evaluate Approach for Identifying the Number of DRs Requiring Reevaluation

- To determine total population of DRs potentially affected by OTIB-0049, PER-012 cited these criteria:
  - (1) DR had been completed on or before 2/6/2007,
  - (2) DR involved facilities with exposure to Type SS Pu, and
  - (3) POC was < 50%.

  This identified 4,865 potential cases.
- Imbedded in OTIB-0049 are 2 additional screening criteria:
- (1) POC >16.97% for cancers other than lung and thoracic lymph node ($LN_{TH}$) and
- (2) No Pu dose was assigned, or Pu intake was based on air monitoring.
  This reduced potential cases to 1,757
- SC&A agreed with methodology used to identify and quantify claims potentially affected by OTIB-0049 and had no findings under Subtask 3 of the review.

# Subtask4: Recommend a Sample of Affected DRs for Evaluation

- PER-012 indicates need for dose reevaluation for 4 groupings of target tissues: (1) lungs and LNTH, (2) extrathoracic tissues of respiratory tract, (3) tissues of GI tract, and (4) other systemic organs.
- Reevaluation of dose for these four groupings is dictated by 1 of 4 monitoring methods employed in original DR: (1) air sampling, (2) urinalysis, (3) in-vivo lung counting, and (4) fecal analysis.

# Subtask 4: Review of Sample Sets of DRs Affected by PER-012

SC&A recommended a minimum of 1 case be selected from 10 permutations:

| Target Organ | Uranalysis | Lung Counts | Fecal Sample | Air Sampling |
|---|---|---|---|---|
| Lung/LN | Yes | Yes | Yes[1] | Yes |
| Extrathoracic | Yes | No | Yes[2] | No |
| GI Tract | Yes | No | Yes[2] | No |
| Systemic Organs | Yes | No | Yes[2] | No |

[1] Reevaluation is required regardless of time interval between exposure and fecal sampling.

[2] Reevaluation is required only if time intervals are >2 months between end of exposure and fecal sampling.

# Subtask 4: Review of Sample Set of DRs Affected by PER-012

- As directed by the Procedures SC, audit of the selected 9 DRs is limited to evaluating methods/corrective actions in the DRs that relate only to issues addressed in OCAS-PER-012. Audit focused on determining whether internal doses associated with potential exposure to Type SS Pu were performed accurately and in accordance with guidance in ORAUT-OTIB-0049.

- SC&A's audit concurred with NIOSH's approach and assumptions in calculating internal doses from exposure to highly insoluble Pu for all 9 cases.

- SC&A found that NIOSH reevaluated each of these DRs using methodology consistent with guidance in ORAUT-OTIB-0049. The review had no findings.

- SC&A found development of OTIB-0049 Workbook, assisting DR in (1) entering appropriate data, (2) calculating fitted and missed organ doses and making comparisons of these data, and (3) generating IREP input, was very instrumental in successful implementation of OCAS-PER-012.

# Questions?