DRAFT

ADVISORY BOARD ON RADIATION AND WORKER HEALTH

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

A REVIEW OF NIOSH'S PROGRAM EVALUATION REPORT OCAS-PER-012, "EVALUATION OF HIGHLY INSOLUBLE PLUTONIUM COMPOUNDS"

Contract No. 200-2004-03805
SCA-TR-PR2010-0001, Rev. 0

Prepared by

SC&A, Inc.
S. Cohen & Associates
1608 Spring Hill Road, Suite 400
Vienna, VA 22182

March 2010

Disclaimer

This document is made available in accordance with the unanimous desire of the Advisory Board on Radiation and Worker Health (ABRWH) to maintain all possible openness in its deliberations. However, the ABRWH and its contractor, SC&A, caution the reader that at the time of its release, this report is pre-decisional and has not been reviewed by the Board for factual accuracy or applicability within the requirements of 42 CFR 82. This implies that once reviewed by the ABRWH, the Board's position may differ from the report's conclusions. Thus, the reader should be cautioned that this report is for information only and that premature interpretations regarding its conclusions are unwarranted.

S. COHEN & ASSOCIATES: ***Technical Support for the Advisory Board on Radiation & Worker Health Review of NIOSH Dose Reconstruction Program***	Document No. SCA-TR-PR2010-0001 Effective Date: Draft – March 18, 2010
A PRELIMINARY REVIEW OF NIOSH'S PROGRAM EVALUATION REPORT OCAS-PER-012, "EVALUATION OF HIGHLY INSOLUBLE PLUTONIUM COMPOUNDS"	Page 2 of 16
Task Manager: _____ Date: _____ U. Hans Behling, PhD, MPH	Supersedes: N/A
Project Manager: _____ Date: _____ John Mauro, PhD, CHP	

TABLE OF CONTENTS

1.0 STATEMENT OF PURPOSE

To support dose reconstruction (DR), the National Institute for Occupational Safety and Health (NIOSH) and the Oak Ridge Associated Universities Team (ORAUT) have assembled a large body of guidance documents, workbooks, computer codes, and tools. In recognition of the fact that all of these supporting elements in dose reconstruction may be subject to revisions, provisions exist for evaluating the effect of such programmatic revisions on the outcome of previously completed DRs. Such revisions may be prompted by document revisions due to new information, misinterpretation of guidance, changes in policy, and/or programmatic improvements.

The process for evaluating potential impacts of programmatic changes on previously completed DRs has been proceduralized in OCAS-PR-008, *Preparation of Program Evaluation Reports and Program Evaluation Plans* (OCAS 2006), Revision 2, dated December 6, 2006. This procedure describes the format and methodology to be employed in preparing a Program Evaluation Report (PER) and a Program Evaluation Plan (PEP).

A PER provides a critical evaluation of the effect(s) that a given issue/programmatic change may have on previously completed DRs. This includes a qualitative and quantitative assessment of potential impacts. Most important in this assessment is the potential impacts on the Probability of Causation (POC) of previously completed DRs with POCs of <50%.

As needed, a PEP may be issued that serves as a formal notification of an impending PER. The PEP provides a preliminary description of the issue(s) that will be addressed in the PER, and summarizes the likely scope of the effort required to complete the PER.

During an Advisory Board meeting on October 22, 2009, SC&A was tasked by the Board to conduct a review of OCAS-PER-012, *Evaluation of Highly Insoluble Plutonium Compounds* (OCAS 2007a). In conducting a PER review, SC&A is committed to perform the following five subtasks, each of which is discussed in this report:

Subtask 1: Assess NIOSH's evaluation/characterization of the "issue" and its potential impacts on DR. Our assessment intends to ensure that the "issue" was fully understood and characterized in the PER.

Subtask 2: Assess NIOSH's specific methods for corrective action. In instances where the PER involves a technical issue that is supported by document(s) (e.g., white papers, technical information bulletins, procedures) that have not yet been subjected to a formal SC&A review, Subtask 2 will include a review of the scientific basis and/or sources of information to ensure the credibility of the corrective action and its consistency with current/consensus science. Conversely, if such technical documentation has been formalized and previously subjected to a review by SC&A, Subtask 2 will simply provide a brief summary/conclusion of this review process.

Subtask 3: Evaluate the PER's stated **approach** for identifying the universe of potentially affected DRs, and assess the **criteria** by which a subset of potentially affected DRs was selected for re-evaluation. The second step may have important implications in instances where the universe of previously denied DRs is very large and, for reasons of practicality, NIOSH's re-evaluation is confined to a subset of DRs that, based on their scientific judgment, have the potential to be significantly affected by the PER. In behalf of Subtask 3, SC&A will also evaluate the timeliness for the completion of the PER.

Subtask 4: Conduct audits of DRs affected by the PER under review. Based on information contained in Table 1 (and discussed in Section 3.1 below), the number of DRs selected for audit for a given PER will vary. (It is assumed that the selection of the DRs and the total number of DR audits per PER will be made by the Advisory Board.)

Subtask 5: Prepare a comprehensive written report that contains the results of the above-stated subtasks, along with our review conclusions.

2.0 SUBTASK 1: IDENTIFY THE CIRCUMSTANCES THAT NECESSITATED THE NEED FOR OCAS-PER-012

On January 12, 2004, NIOSH issued the technical basis document (TBD) entitled, *Technical Basis Document for the Rocky Flats Plant – Occupational Internal Dose*, ORAUT-TKBS-0011-5 (ORAUT 2004). Section 5.2.1.2 of the TBD provided a brief discussion of plutonium solubility and particle size that included the following statements:

> *Most plutonium in metalworking operations and involved in fires is insoluble (i.e., type S). . . .*
>
> *The plutonium fire on October 15, 1965, in Buildings 776 and 777, is a **special** case. The plutonium, which was strongly retained in the lungs of exposed workers with relatively low transfer to the urine, exhibited **highly** insoluble (super type S) characteristics.*
>
> *. . . A claimant-favorable approach is to assume **insoluble** plutonium if the qualifying cancer is of the respiratory system and to assume soluble plutonium for **all** other cases.*
>
> *In general, particle size and distributions are not available for work areas or incidents at RFP. Therefore, dose reconstructions should use the default value of 5-µm activity median aerodynamic diameter (AMAD).*
>
> *One exception is the plutonium fire on October 15, 1965, in Buildings 776 and 777, for which Mann and Kirchner (1967) measured a mass median diameter of 0.3 µm (1-µm AMAD) with a geometric deviation of 1.83. An approach that is favorable to claimants is to assume 1-µm AMAD for **all** plutonium fires unless the qualifying cancer involves the tissues of the extrathoracic regions.* [Emphasis added.]

2.1 DEVELOPMENT OF ORAUT-OTIB-0049

While ORAUT-TKBS-0011-5 of the RFP's Site Profile acknowledged the unique characteristics of plutonium particulates associated with fires by referring to its ". . highly insoluble (super type S) characteristics" (and smaller particle size), there was **no special** guidance provided in the TBD that would account for the reduced solubility and resultant higher doses.

NIOSH's failure to account for the high level of insolubility of Type Super S plutonium in DR, however, can be understood when viewed in context with the existing regulatory framework that governs the Energy Employees Occupational Illness Compensation Program Act (EEOICPA). Under 42 CFR 82, Section §82.18(b) states the following:

> *NIOSH will calculate the dose to the organ or tissue of concern using the appropriate **current** metabolic models published by ICRP.* [Emphasis added.]

For the inhalation of plutonium, **current** International Commission on Radiological Protection (ICRP) models include ICRP Publication 66 (ICRP 1993) and ICRP Publication 67 (ICRP 1994). Both of these ICRP publications are correctly identified/referenced for use in OCAS-IG-002 (OCAS 2002). Important to note is that both ICRP publications limit their biokinetic models to three solubility classes (i.e., Types F, M, and S) that do **not** include the **highly** insoluble or Type Super S form.

From a regulatory view point, NIOSH was, therefore, compliant in deriving doses based on Type S plutonium, since current ICRP models do not include Type Super S as a distinct solubility class. Nevertheless, NIOSH's acknowledgement of the existence of highly insoluble plutonium prompted further discussions and the decision to investigate the potential impacts of Type Super S plutonium on organ doses to exposed workers at RFP, as well as other facilities.

2.2 ISSUANCE OF ORAUT-OTIB-0049

On February 6, 2007, NIOSH issued ORAUT-OTIB-0049, Rev. 00, *Estimating Doses for Plutonium Strongly Retained in the Lung* (ORAUT 2007). This document provided guidance for reassessing organ doses for highly insoluble plutonium designated as Type Super S that have been shown to be retained in the lung longer than predicted by the ICRP Task Group Lung Model for Type S. Revision 00 was amended on December 18, 2007, to include guidance for dose reassessment based on **coworker-derived** intakes; and Revision 01 was further amended on September 26, 2008 (ORAUT 2008), to provide guidance for dose reassessment in instances where the original DR was based on fecal data.

2.3 ISSUANCE OF OCAS-PEP-012

With the issuance of ORAUT-OTIB-0049 and the realization of increased doses that needed to be assigned to workers exposed to Type Super S plutonium, NIOSH issued a Program Evaluation Plan (OCAS-PEP-012) on March 29, 2007 (OCAS 2007b).

Section 3.0 of PEP-012 describes the methodology/criteria for identifying the universe of claims potentially affected by ORAUT-OTIB-0049 and screening these claims on the basis of their original POC (i.e., <50% but >20% for claims with target organs other than lung or LN_{TH}. The threshold POC level of >20% is based on the fact that the Pu Type Super S correction factor of 4 will not result in a revised POC >50% for an original POC of <20%.)

Based on the PEP's stated inclusion criteria, the universe of potentially affected cases totaled 3,451. This number was reduced to 2,725 cases, when cases with <20% POC were eliminated. PEP-012 concluded with the following statement:

> *After the potential affected claims have been evaluated, a Program Evaluation Report (PER) will be written to summarize the results. As part of the report, claims that were not evaluated further due to the POC cut point will be reviewed to determine if they are also affected by another PER. The PER will contain additional analysis for these cases including additional evaluations if necessary.*

2.4 ISSUANCE OF PER-012

On August 6, 2007 (or about four months after PEP-012 had been issued), NIOSH issued PER-012 (OCAS 2007a). Section 3.1 of PER-012 identified four selection criteria, which were more conservative and differed from those cited in PEP-012 for identifying the universe of potentially affected claims. As a result, a new total of 4,865 cases were identified that had the potential for being affected by OTIB-0049.

The universe of 4,865 potentially affected cases was reduced to 1,757 claims that would require a reassessment of dose based on ORAUT-OTIB-0049 guidance. The elimination of 3,108 cases from the universe of 4,865 cases reflects the application of two screening criteria that are discussed in greater detail under Subtask 3.

2.5 SC&A'S COMMENTS PERTAINING TO THE DEVELOPMENT OF PER-0012 AND SUPPORTING DOCUMENTS

Our review of ORAUT-OTIB-0049, OCAS-PEP-012, and OCAS-PER-012 indicates that NIOSH properly characterized the significance of highly insoluble plutonium and complied with the process for evaluating potential impacts of programmatic changes on previously completed dose reconstructions, as proceduralized in OCAS-PR-008, *Preparation of Program Evaluation Reports and Program Evaluation Plans*, Rev. 2 (OCAS 2006).

3.0 SUBTASK 2: ASSESS NIOSH'S SPECIFIC METHODS FOR CORRECTIVE ACTION

In instances where the PER involves a technical issue that is supported by documents [e.g., white paper(s), technical information bulletin(s), and/or procedure(s)] that have not yet been subjected to a formal SC&A review, Subtask 2 will assess the scientific basis and/or sources of information to ensure the credibility of the corrective action and its consistency with current/consensus science.

However, in behalf of PER-012, such technical documentation was previously formalized by means of ORAUT-OTIB-0049, **Rev. 00**, dated February 6, 2007. SC&A issued a critical review of this document in a draft report dated October 29, 2007 (SC&A 2007). Our review of ORAUT-OTIB-0049, Rev. 00, concluded with the following statements:

> *SC&A examined OTIB-0049 in terms of its conceptual approach, including the overall technical approach used, scientific validity, and sufficient degree of conservatism. SC&A is in agreement with the NIOSH approach for estimating annual dose from intakes of Pu-239 that are retained in the lung longer than predicted by the normal absorption Type S model, based on the applicability of empirically derived adjustment factors for the lung, systemic organs, GI tract organ and tissues, and extra-thoracic regions.*

In light of the existence of OTIB-0049 and corresponding conclusions reached by SC&A, Subtask 2 for PER-012 is reduced to a brief summary of key technical elements that define OTIB-0049, which in turn will prepare the reader for Subtasks 3 and 4 that follow.

3.1 A TECHNICAL OVERVIEW OF OTIB-0049

Empirical human data have shown that high-fired plutonium oxides exhibit a longer retention in the lung than currently predicted by the ICRP 66 Human Respiratory Track Model for solubility class Type S. Based on the method by which individuals were monitored, the reduced solubility and enhanced retention of PuO_2 in the lung may significantly impact estimates of tissue/organ doses of the exposed worker.

Due to the fact that the ICRP model at present does not address the dosimetric impacts of Type Super S plutonium oxides, NIOSH selected human empirical data representing 10 cases that were called the "design cases." Data for the design cases were fitted by means of the IMBA computer code to lung data using the default ICRP Type S model. Annual dose adjustment factors were principally derived from the ratios of observed plutonium lung retentions projected annually for the actual cases to those projected for the ICRP 66 default Type S model for the two cases that yielded the maximum ratios.

A summary of dose adjustment factors is provided in Table 8 of ORAUT-OTIB-0049, which is reproduced herein as Table 1. Inspection of Table 1 shows that adjustment factors are provided for four groupings of target tissues/organs and are based on the type of monitoring data that were

used in the original dose reconstruction. Included are lung counting, air monitoring, and urinalysis.

Not included in Rev. 00 of ORAUT-OTIB-0049 were dose adjustment factors for original dose reconstructions that were based on fecal bioassay data. Also not included in Rev. 00 was any mention/guidance pertaining to the "unmonitored worker," whose previous DR had been based on coworker urinalysis data. Due to the fact that these amendments to OTIB-0049 were not previously reviewed by SC&A, a technical review of these amendments is provided below.

Table 1. Summary of Type SS Adjustment Factors

	Lung counts	Air concentrations	Urinalysis
Lungs	Table D (normalized to last chest count)	Table D	Factor of 4 followed by Table D adjustment
Extra-thoracic	None	None	Factor of 4
GI tract	No adjustment	None	Factor of 4
Systemic organs	None	None	Prior to last urine sample: none Post last urine sample: factor of 4

3.1.1 Review of Section 4.1.3.4.2 Unmonitored Individual (Coworker Model)

Section 4.1.3.4.2 specifies guidance in behalf of a worker who may have potentially been exposed to Type Super S plutonium, but was **un**monitored at a facility for which a coworker model has been developed by means of urinalysis data.

In order to account for the fact that the existing coworker model assumed Type S plutonium for converting urine data into inhalation quantity, the intake adjustment factor of "4" is applied to the unmonitored exposure that may have involved Type Super S plutonium. The generic adjustment factor of "4" for the coworker model/unmonitored worker was derived in Attachment C of OTIB-0049 and accounts for the **higher** retention rate in the lung and, therefore, the lower urine excretion rate for Type SS plutonium when compared to Type S.

Important to note, however, is that the application of the adjustment factor is restricted to those years that **post-date** the period of time that defines the coworker intake model.

Regarding the guidance provided for the revision of dose to the unmonitored worker by means of a coworker model that was based on urinalysis data, SC&A concludes the following:

- The adjustment factor of 4 is technically defensible, since it is based on conservative selection of empirical human data as cited in Appendix C of OTIB-0049.
- The adjustment factor of 4 for use in a coworker model is consistent with its general use as the adjustment factor when urinalysis data were used in the original dose reconstruction.

- The restrictive use of the adjustment factor for only those years that post-date the period for which coworker data are available is technically defensible, conservative, and consistent with the guidance prescribed for the monitored worker.

3.1.2 Review of Section 4.1.4 Doses Based on Fecal Bioassay Data

This new section in Rev. 01 provides guidance for the re-evaluation of organ/tissue doses that had previously been derived for Type S plutonium from fecal data. Potential revision to organ/tissue dose is based on two timeframes. In brief, for fecal sample data obtained less than 2 months after an acute exposure or the cessation of chronic exposure, a dose adjustment is required for the lung and LN_{TH} that involves data contained in Table D of OTIB-0049. (All other organs/tissues do not require re-evaluation.)

For fecal sampling data that were taken more than 2 months following an acute or prolonged chronic exposure, NIOSH provides the following guidance:

> *Fecal samples . . . should be modeled as if they were urine samples (Section 4.1.3). For example, if the 24-hour fecal sample contained 1 dpm it should be modeled as if it were a 24-hour urine sample that contained 1 dpm. Once the dose to the organ/tissue of interest is calculated, it is adjusted upward by a factor of 3.*

The technical bases that support this guidance are presented in Attachment E of OTIB-0049 and are briefly summarized below.

3.1.3 Technical Basis for < 2 Months Fecal Data

Based on kinetics defined by the ICRP lung model, plutonium activity in fecal samples collected **less** than 2 months following either an acute or a chronic exposure principally reflects the **mechanical** clearing of plutonium from compartments of the respiratory system.

Because mechanical clearance rates are largely unaffected by solubility, Type S and Type Super S plutonium can be assumed to have nearly identical transfer rates to the GI tract/feces within the first 2 months, as shown in Figures E-1 and E-2 of OTIB-0049, Attachment E. Thus, the fecal data may be converted to an **air inhalation** intake(s) (either acute or chronic) by means of IMBA that assumes Type S plutonium. Once the inhalation intake has been determined, a dose adjustment that accounts for the lower solubility for Type SS is required only for the lung and LN_{TH}, as specified for air sampling data in Section 4.1.1 of OTIB-0049 and noted in Table 1 above.

3.1.4 Technical Basis for > 2 Months Fecal Data

For time periods greater than 2 months following **inhalation** exposure, Attachment E states that no model currently exists for interpreting fecal data. However, a bounding interpretation may be derived from a comparison of fecal excretion fractions to urine excretion fractions following an **intravenous** (IV) injection of plutonium.

Attachment E of OTIB-0049 provides Figures E-3 and E-4, which show that after 2 months following an IV injection of plutonium, the activity levels in a 24-hour urine sample are between 2 and 3 times higher than that of a 24-hour fecal sample. By means of this relationship, guidance provided in Attachment E states the following:

> *. . . An upper estimate of an intake calculated from a fecal sample following an inhalation intake of Type SS plutonium is therefore taken to be 3 times the intake estimated assuming that the **fecal** sample was a **urine** sample and **applying the methodology in this OTIB for a urine sample**.* [Emphasis added.]

The above-stated guidance can be illustrated by the following example. If a given 24-hour fecal sample contained 1 dpm of plutonium, the dose reconstructor may assume that a 24-hour urine sample would have contained 3 dpm of plutonium. Using the 3 dpm per 24-hour urine excretion, an organ dose would be calculated for plutonium Type S. Estimate of Type SS dose would now follow the additional guidance provided in Section 4.1.3, "Dose Based on Urinalysis Data," of OTIB-0049. Thus, if the target organ was either the lung or LN_{TH}, yearly doses would first require the proper **dose adjustment factors** specified in Table D-1 of Attachment D and the **intake adjustment factor** of 4 in order to obtain a final yearly Type SS dose to the lung (or LN_{TH}).

3.2 SC&A COMMENTS PERTAINING TO THE USE OF FECAL DATA FOR DOSE RE-EVALUATION

SC&A critically reviewed Attachment E of OTIB-0049, which provides the technical bases for guidance in the re-evaluation of doses derived from fecal bioassay data, as stated in Section 4.1.4. Separate guidance is provided for bioassay data that are less than or greater than 2 months duration following an exposure to Type SS plutonium.

SC&A concludes that the protocols for both timeframes are (1) based on reasonable scientific principles/assumptions, (2) consistent with other protocols defined in OTIB-0049, and (3) likely to yield organ tissues that are claimant favorable.

4.0 SUBTASK 3: EVALUATE THE PER's STATED APPROACH FOR IDENTIFYING THE NUMBER OF DRs REQUIRING RE-EVALUATION OF DOSE

Section 3.0 of PER-012 identified the set of criteria used to determine the total population of claims that had the **potential** of being "affected" by ORAUT-OTIB-0049. Here, the word "affected" refers to all claims/DRs that (1) had been completed on or before February 6, 2007 (i.e., the date of issue for OTIB-0049), (2) involved facilities with potential exposure to Type SS plutonium, and (3) resulted in a POC of less than 50%. Based on these criteria, NIOSH identified a total of 4,865 of potential cases.

In principle, each of the 4,865 cases thus identified would require a re-evaluation of dose, unless it could be shown that the application of OTIB-0049 could **not** advance the POC to 45% or greater. NIOSH selected the lower value of 45% POC for reasons of conservatism and efficiency, since any claim with a revised POC greater than 45% is required to have 30 IREP runs, each with 10,000 iterations.

Imbedded in OTIB-0049, however, are two screening criteria, which significantly reduced the number of claims required to be re-evaluated. The first screening criterion that can be applied to the 4,865 potential claims is defined by a threshold POC value. With the exception of the lung and LN_{TH}, Table 1 above shows that the application of OTIB-0049 can, under the most conservative assumption (i.e., when the organ dose/POC was exclusively based on the internal exposure to Type SS plutonium), be increased by a factor of 4. Thus, for the revised POC of 45% as a screening criterion, any of the 4,865 claims with POCs less than 16.97% can be eliminated from further consideration, as shown in Equation 1 below:

$$POC = \frac{ERR}{1 + ERR} \; x \; 100 \qquad \text{Eq. 1}$$

For a revised POC to reach 45%, the Excess Relative Risk (ERR) must equal 0.81818, or 4 times the original ERR value of 0.20454, which corresponds to the original POC of 16.97%.

A second screening criterion applied to the 4,865 total claims identified those claims for which either no plutonium dose (independent of solubility class) was assigned, or a plutonium intake was based on air monitoring data, but did **not** involve the lung or LN_{TH} as target organs.

When combined, the two screening criteria eliminated 3,108 cases from further consideration/ dose re-evaluation from among the initial 4,865 total cases.

In Section 3.4, "Path Forward," of OCAS-PER-012, NIOSH concluded with the following statement:

> *NIOSH has determined that **1,757** of these claims required a new dose estimate to determine the effect of this change. NIOSH is requesting that DOL return these claims to NIOSH for a new Dose Reconstruction*. [Emphasis added.]

SC&A's Comments Regarding NIOSH's Approach

SC&A was not given access to the primary data used by NIOSH to identify and quantify those claims that will require re-evaluation of dose. SC&A is, therefore, not able to verify the accuracy of the above-cited number of 1,757 claims that will require dose re-evaluation. **At a minimum, however, SC&A assumes that the number 1,757 is a typographic error that was meant to be 1,577 claims (4,685 – 3,108 = 1,577).**

Our review was, therefore, limited to the **methodology** used by NIOSH to identify and quantify those claims that are potentially affected by OTIB-0049. SC&A concludes that the selection and screening criteria of claims described in Section 3.0 of OCAS-PER-012 are scientifically sound, inclusive of all potential variables affecting original DR, and maximally conservative. The high degree of conservatism is principally driven by the 16.97% POC screening criterion and the bounding assumption that this value could potentially reflect an organ dose that was 100% assigned to a plutonium intake.

5.0 SUBTASK 4: CONDUCT AUDITS OF A SAMPLE SET OF DRs AFFECTED BY OCAS-PER-012

Selection of DRs

Among the DRs that may require audit from among the 1,577 claims that have been re-evaluated in accordance with ORAUT-OTIB-0049 are DRs that include the following:

- The number of target organs/tissues that may be impacted by PER-012
- The method/data that were employed in the original DR
- The time period, work location, and job function(s) that characterize the DR of a claim

A review of PER-012 indicates the need for dose re-evaluation for four groupings of target tissues that include (1) lungs and thoracic lymph nodes (LN_{TH}), (2) extrathoracic tissues of the respiratory tract, (3) tissues of the gastro-intestinal tract, and (4) other systemic organs.

The need for and the method for the re-evaluation of dose in behalf of these four groupings, however, is further dictated by the monitoring methods/data that were used in the original DR, which may have employed one of four possible options: (1) air sampling data, (2) urinalysis, (3) in-vivo lung counting, and (4) fecal analysis (see Table 1 above). Important to note is that for each of the four target organs/tissues, the prescribed method for dose re-evaluation differs. Thus, it would appear that for OCAS-PER-012, a minimum of 10 DRs are needed to assess at least 1 claim for each of the 10 permutations for dose re-evaluation, as shown in Table 2 below. However, this number could be reduced if there are no claims among the 1,577 cases of affected DRs that represent 1 or more of the 10 permutations.

Table 2. Potential Categories of DRs

Target Organ	Urinalysis	Lung Counts	Fecal Sample	Air Sampling
Lung/LN_{TH}	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] Re-evaluation is required regardless of time interval between exposure and fecal sampling.
[2] Re-evaluation is required only if time intervals are >2 months between end of exposure and fecal sampling.

Selections of DRs for audit will require NIOSH to provide the Subcommittee with a distribution of the 1,577 claims based on the 10 categories cited in Table 2 above. It is assumed that the Subcommittee will identify its final choice of DRs for audit by SC&A.

6.0 REFERENCES

42 CFR 82, 2002. *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. 22314.

ICRP (International Commission on Radiological Protection) 1993. "Human Respiratory Tract Model for Radiological Protection," *ICRP Publication 66, Annals of ICRP 24/1-2*, Oxford: Pergamon Press.

ICRP (International Commission on Radiological Protection) 1994. "Age-dependent Doses to Members of the Public from Intake of Radionuclides: Part 2 Ingestion Dose Coefficients," *ICRP Publication 67, Annals of the ICRP 23/3-4*, Oxford: Pergamon Press.

Mann, J. R., and R. A. Kirchner, 1967, "Evaluation of Lung Burden Following Acute Inhalation Exposure to Highly Insoluble PuO2," *Health Physics*, Volume 13, pp. 877–882.

OCAS 2002. *Internal Dose Guidelines*, OCAS-IG-002 Revision 00, NIOSH's Office of Compensation Analysis and Support, Cincinnati, Ohio. August 2002.

OCAS 2006. *Preparation of Program Evaluation Reports and Program Evaluation Plans*, OCAS-PR-008, Revision 2, NIOSH's Office of Compensation Analysis and Support, Cincinnati, Ohio. December 6, 2006

OCAS 2007a. *Evaluation of Highly Insoluble Plutonium Compounds*, OCAS-PER-012, Revision 0, NIOSH's Office of Compensation Analysis and Support, Cincinnati, Ohio. August 6, 2007.

OCAS 2007b. *Program Evaluation Plan: Evaluation of Highly Insoluble Plutonium Compounds*, OCAS-PEP-012, Revision 0, NIOSH's Office of Compensation Analysis and Support, Cincinnati, Ohio. March 29, 2007.

ORAUT 2004. *Technical Basis Document for the Rocky Flats Plant – Occupational Internal Dose*, ORAUT-TKBS-0011-5, Rev. 00, Oak Ridge Associated University Team: Cincinnati, Ohio. January 12, 2004.

ORAUT 2007. *Estimating Doses for Plutonium Strongly Retained in the Lung*, ORAUT-OTIB-0049, Revision 00, Oak Ridge Associated University Team: Cincinnati, Ohio. February 6, 2007.

ORAUT 2008. *Estimating Doses for Plutonium Strongly Retained in the Lung*, ORAUT-OTIB-0049, Revision 01, PC-1 Oak Ridge Associated University Team: Cincinnati, Ohio. September 26, 2008.

SC&A 2007. *Review of the Third Set of Procedures (45 procedure reviews)*, SCA-TR-TASK3-0003, S. Cohen & Associates, Vienna, Virginia, and Saliant Inc., Jefferson, Maryland. October 29, 2007.