
Draft

Advisory Board on Radiation and Worker Health
National Institute for Occupational Safety and Health

**SC&A's Evaluation of ORAUT-OTIB-0049, Revision 02,
"Estimating Doses for Plutonium Strongly Retained
in the Lung"**

**Contract No. 75D30119C04183
Document No. SCA-TR-2021-PR049, Revision 0**

Prepared by

Joyce Lipsztein, PhD, CHP
Bob Barton, CHP
Rose Gogliotti, MS
Ron Buchanan, PhD, CHP

SC&A, Inc.
2200 Wilson Blvd., Suite 300
Arlington, VA 22201-3324

October 7, 2021

DISCLAIMER

This is a working document provided by the Centers for Disease Control and Prevention (CDC) technical support contractor, SC&A for use in discussions with the National Institute for Occupational Safety and Health (NIOSH) and the Advisory Board on Radiation and Worker Health (ABRWH), including its Working Groups or Subcommittees. Documents produced by SC&A, such as memorandum, white paper, draft or working documents are not final NIOSH or ABRWH products or positions, unless specifically marked as such. This document prepared by SC&A represents its preliminary evaluation on technical issues.

NOTICE: This document has been reviewed to identify and redact any information that is protected by the [Privacy Act 5 U.S.C. § 552a](#) and had been cleared for distribution.

Effective date: 10/7/2021	Revision No. 0 (Draft)	Document No.: SCA-TR-2021-PR049	Page 2 of 39
---------------------------	------------------------	---------------------------------	--------------

SC&A, Inc. technical support for the Advisory Board on Radiation and Worker Health's review of NIOSH dose reconstruction program

Document title	SC&A's Evaluation of ORAUT-OTIB-0049, Revision 02, "Estimating Doses for Plutonium Strongly Retained in the Lung"
Document number	SCA-TR-2021-PR049
Revision number	0 (Draft)
Supersedes	NA
Effective date	October 7, 2021
Task manager	Kathy Behling [signature on file]
Project manager	Bob Barton, CHP [signature on file]
Document reviewer(s)	Kathy Behling [signature on file]

Record of revisions

Revision number	Effective date	Description of revision
0 (Draft)	10/7/2021	Initial issue

Table of Contents

List of Tables.....	4
List of Figures.....	4
Abbreviations and Acronyms.....	5
1 Introduction and Background.....	7
2 Overview of ORAUT-OTIB-0049, Revision 02.....	8
3 SC&A’s Evaluation of ORAUT-OTIB-0049, Revision 02	11
3.1 Evaluation of biokinetic model used in ORAUT-OTIB-0049.....	11
3.2 Evaluation of attachment A, “Determination of solubility parameters for Super S model”	12
3.3 Evaluation of the long-term absorption parameter	13
3.4 Evaluation of the short-term absorption parameters	14
3.5 Binding of plutonium in the respiratory tract.....	15
3.6 Systemic distribution, retention, and excretion of plutonium	15
4 Application of OTIB-0049 and IDOT_SS to Dose Reconstructions.....	17
4.1 Overview of IDOT_SS tool and user guide	17
4.2 Comparison of doses derived using IDOT_SS for OTIB-0049, revision 02, with doses using previous OTIB-0049 guidance	18
4.3 Comparison of absorption parameters between OTIB-0049, revision 02, and ICRP Publication 141	30
5 Summary of SC&A’s Evaluation of OTIB-0049, Revision 02	36
6 References	38

List of Tables

Table 1. Case A chronic Pu-239 IDOT_SS and Revision 01 (2010) derived doses and dose ratios.....	23
Table 2. Case A acute Pu-239 IDOT_SS and Revision 01 (2010) derived doses and dose ratios.....	25
Table 3. Case B chronic Pu-239 IDOT_SS and Revision 01 (2010) derived doses and dose ratios.....	27
Table 4. Case B chronic Am-241 IDOT_SS and Revision 01 (2010) derived doses and dose ratios.....	28
Table 5. Comparison of ORAUT-0049, revision 02, and ICRP Publication 141 absorption parameters	30
Table 6. Comparison of organ-specific committed doses for the HAN-1 case	31

List of Figures

Figure 1. Comparisons of acute Pu-239 intake of 1,000 dpm for the Revision 01 (2010) and revision 02 methods	20
Figure 2. Comparisons of the chronic Pu-239 intake of 100 dpm/d for 5 years for the Revision 01 (2010) and revision 02 methods	21
Figure 3. Case A ratio of IDOT_SS to Revision 01 (2010) derived total type SS Pu-239 chronic doses	24
Figure 4. Case A ratio of IDOT_SS to Revision 01 (2010) derived total type SS Pu-239 acute doses	26
Figure 5. Case B ratio of IDOT_SS to Revision 01 (2010) derived total type SS chronic Pu-239 doses	28
Figure 6. Case B ratio of IDOT_SS to Revision 01 (2020) derived total chronic type Am-241 doses	29
Figure 7. Comparison of bioassay projections for the HAN-1 case using absorption parameters derived in OTIB-0049 and ICRP 141	33
Figure 8. Comparison of bioassay projections for the HAN-1 case using absorption parameters derived in OTIB-0049 and ICRP 141 (y-axis truncated at 0.006 Bq/d)	34
Figure 9. Comparison of bioassay projections for the HAN-1 case using absorption parameters derived in OTIB-0049 and ICRP 141 (y-axis in logarithmic form)	35

Abbreviations and Acronyms

ABRWH	Advisory Board on Radiation and Worker Health
AF	absorbed fraction
AI	alveolar-interstitial
ALV	alveolar
Am	americium
BB	bronchial (region)
BB _{BAS}	tissue in the bronchial region through which basal cells are distributed
Bq/d	becquerel per day
d ⁻¹	per day
DOE	U.S. Department of Energy
dpm	disintegrations per minute
dpm/d	disintegrations per minute per day
DR	dose reconstruction
ET	extrathoracic
ET1	anterior nasal passage
ET2	posterior nasal passage
f _i	GI tract fraction
f _A	absorption from the alimentary tract
f _b	bound fraction
F _r	fraction of inhaled material absorbed by blood relatively rapidly
GI	gastrointestinal
Gy	gray
HRTM	human respiratory tract model
ICRP	International Commission on Radiological Protection
IDOT_SS	Internal Dose Tool, Super S
IMBA	Integrated Modules for Bioassay Analysis
INT	interstitial
LLI	lower large intestine
LN(ET)	lymph nodes associated with the extrathoracic region
LN(TH)	lymph nodes associated with the thoracic region
Mayak	Mayak Production Association

NIOSH	National Institute for Occupational Safety and Health
OIR	Occupational Intakes of Radionuclides
ORAUT	Oak Ridge Associated Universities Team
OTIB	ORAUT technical information bulletin
Pu	plutonium
RBM	red bone marrow
RFP	Rocky Flats Plant
SEE	specific effective energy
S _b	bound dissolution rate
S _r	rate at which the material is absorbed
S _s	slow absorption rate
SS	Super S
TB _{BAS}	tissue in the thoracic region through which basal cells are distributed
TB _{SEC}	tissue in the thoracic region
ULI	upper large intestine
USTUR	United States Transuranium and Uranium Registries

1 Introduction and Background

On February 18, 2021, the Advisory Board on Radiation and Worker Health tasked SC&A with a technical review of ORAUT-OTIB-0049, revision 02, “Estimating Doses for Plutonium Strongly Retained in the Lung,” issued September 1, 2020 (NIOSH, 2020; “OTIB-0049”). This revision was issued to update the guidance for reconstructing intakes and doses from type Super S (SS) plutonium. The model couples the International Commission on Radiological Protection (ICRP) Publication 130 (ICRP, 2015) human respiratory tract model (HRTM) with the ICRP Publication 67 (ICRP, 1993) systemic model and Publication 30 (ICRP, 1979) gastrointestinal (GI) tract model. OTIB-0049, revision 02, constitutes a complete rewrite of the guidance document.

This report presents SC&A’s evaluation of the technical approach, methods used, and documentation in OTIB-0049, revision 02. SC&A notes that updated dose evaluation guidance has been issued by the ICRP and the appropriate mechanisms can be automated into the dose reconstructor’s existing tools, which would ensure consistency with current guidance and methodologies (ICRP, 2019).

2 Overview of ORAUT-OTIB-0049, Revision 02

The following is a brief outline of OTIB-0049:

- Purpose – Specifies a biokinetic model that merges guidance from ICRP Publication 130 with Publications 67 and 30 to evaluate the deposition, retention, and removal of inhaled very insoluble (type SS) plutonium particulates from the respiratory tract.
- Background:
 - Historical studies have shown that, in some instances, the rate of removal of plutonium from the lung was slower than predicted by type S. This phenomenon is known as type SS.
 - Prior versions of OTIB-0049 adjusted type S doses to account for type SS by increasing organ dose through the use of dose adjustment factors, which are summarized in table 4-8 of revision 01 PC-2 (NIOSH, 2010). In some cases, this approach uses an adjustment factor of 4, which the National Institute for Occupational Safety and Health (NIOSH) considered to be bounding.
 - The current revision does not use adjustment factors and instead uses guidance from ICRP Publication 130 to develop new parameters to model type SS intakes and dose directly.
- Technical Basis – Section 4.0, pages 6–8, of OTIB-0049 provides the scientific basis for developing a new approach for assessing doses from type SS plutonium intakes.
 - Biokinetic model (section 4.1):
 - Discusses that the revised HRTM in ICRP Publication 130, “Occupational Intakes of Radionuclides: Part 1” (ICRP, 2015), is specifically designed to model biokinetics of type SS materials in the respiratory tract. By coupling Publication 130 with Publication 67, “Age-Dependent Doses to Members of the Public from Intake of Radionuclides: Part 2 Ingestion Dose Coefficients” (ICRP, 1993), and Publication 30, “Limits for Intakes of Radionuclides by Workers” (ICRP, 1979), a fully specified biokinetic model for type SS plutonium can be created.
 - NIOSH’s “hybrid” model introduced modified dissolution parameters that lower predicted urinary excretion per unit intake to better match observed excretion in workers with type SS plutonium intakes, as follows:
 - fraction of inhaled material absorbed by blood relatively rapidly (F_r) = 0.001029
 - rate at which material is absorbed (S_r) = 100.1
 - remaining fraction of material ($1 - F_r$) absorbed as slower rate (S_s) = 1×10^{-6}

- Dosimetric model (section 4.2):
 - The ICRP system uses specific effective energy (SEE) to convert decays in a source region to dose in a target region. SEEs exist as source and target pairs, and their calculations include conversion factors, energy, yield, and the radiation weighting factor of the emitted radiation. The calculation also included an absorbed fraction (AF) and the mass of the target tissue.
 - While it is not explicitly stated in ICRP Publication 130, NIOSH believes “it is clear that the ALV and INT compartments are also just two mathematical clearance rates from the same physical source region” (NIOSH, 2020, pp. 7–8). A single alveolar-interstitial (AI) source region will be assigned for decays in the alveolar (ALV) and interstitial (INT) compartments.
 - ICRP Publication 130 combines regions BB1 and BB2 into a single bronchial (BB) region. The weighting factors are used to produce a single BB AF that NIOSH will apply to the type SS model.
 - ICRP Publication 130 removes the thoracic lymph nodes (LN(TH)) from the lung dose weighting factors. NIOSH indicates that, “Because ICRP has not yet published all parts of its new system, the system cannot yet be used in its entirety Therefore, the original Publication 66 tissue weighting for calculating ‘lung’ dose will continue to be used” (NIOSH, 2020, p. 8).
- Attachment A discusses the development and verification of solubility parameters for assessing type SS plutonium. Attachment A provides information on the derivation of the following parameters:
 - Isotopic ratio – Section A.1 discusses the development of isotopic ratios for plutonium (Pu)-241 to americium (Am)-241 activity for assessing lung counting data and Pu-239 to Am-241 activity for assessing urine data.
 - Data – Section A.2 discusses NIOSH’s assumptions regarding lung count data and urine data used to derive the isotopic ratios.
 - Long-term absorption parameter – Section A.3 presents the approach used to derive the slow absorption rate (S_s) of 1×10^{-6} using Am-241 lung count data.
 - Short-term absorption parameters – Section A.4 discusses the deviation of short-term absorption parameters F_r and S_r using the same lung count data and the derived slow absorption rate.
 - Verification of type SS model parameters – Section A.5 describes NIOSH’s verification process using the new type SS parameters and the HAN-1 case.
 - Note on chelation therapy – Section A.8 discusses that chelation therapy was performed on the HAN-1 case, but it was determined to be ineffective. However,

since chelation therapy was administered, early urine samples were eliminated from the modeling process.

- IDOT_SS (Internal Dose Tool, Super S) – NIOSH has also developed a tool, IDOT_SS, to implement the assessment of type SS plutonium. The IDOT_SS tool provides dose reconstructors with a consistent method of determining dose from inhalation of type SS plutonium using the methods outlined in OTIB-0049.

3 SC&A's Evaluation of ORAUT-OTIB-0049, Revision 02

The following sections summarize SC&A's evaluation of the technical approach, methods used, and documentation in OTIB-0049. In addition, SC&A preliminarily reviewed the IDOT_SS tool to ensure that the tool is consistently and correctly implemented using guidance in OTIB-0049.

3.1 Evaluation of biokinetic model used in ORAUT-OTIB-0049

Section 2.0 of ORAUT-OTIB-0049, revision 02 (NIOSH, 2020, p. 5), states the following:

The purpose of this document is to specify a biokinetic model that is used to evaluate the deposition, retention, and removal of inhaled very insoluble (type SS) plutonium particulates from the respiratory tract. This model merges the latest International Commission on Radiological Protection (ICRP) Publication 130 human respiratory tract model (HRTM) with the current Publication 67 plutonium systemic model and Publication 30 gastrointestinal (GI) tract model.

NIOSH further states in section 3.0:

The Publication 130 lung model is intended to be coupled to new biokinetic models that have not yet been published. [NIOSH, 2020, p. 6]

3.1.1 SC&A's comments on the biokinetic models

Reference biokinetic models were used here (i.e., by the ICRP Task Group) for analysis of the data. The ICRP published a new lung model as part of Publication 130 (ICRP, 2015) that represents a modification to the Publication 66 model (ICRP, 1994). The pertinent modification in the context of OTIB-0049 is that it slows down the mechanical clearance rate to a level that absorption parameters can be developed to account for highly insoluble plutonium (i.e., type SS material). In 2019, ICRP Publication 141 "Occupational Intakes of Radionuclides: Part 4" was issued, which provided new biokinetic models for actinides, including americium and plutonium.

Observation 1: ICRP has published updated biokinetic models appropriate for type SS plutonium

SC&A suggests that (1) ICRP Publication 141 (ICRP, 2019) should be used to determine the Pu-239 dioxide absorption parameters and (2) absorption parameters from the alimentary tract should be used for all type SS plutonium exposure estimates. Further, NIOSH should consider use of the dosimetric guidance for dose per activity content in the lungs and models for daily excretion in urine and feces.

Specifically, SC&A suggests that:

1. ICRP Publication 141 should be used to determine the Pu-239 dioxide absorption parameters, and the absorption parameters from the alimentary tract should be used for all other type SS plutonium dioxides.
2. The ICRP Publication 141 value for S_r of 0.4 d^{-1} , the rate at which the material is absorbed, should be used.

3. The dosimetric data from ICRP Publication 141 should be used to determine the parameters for the inhalation of Pu-239 dioxide for all type SS plutonium. The dosimetric data should also be used to determine the parameters for the dose per activity content in the lungs and in daily excretion of urine and feces.

As specified in Section 3.0 of OTIB-0049 (NIOSH, 2020, p. 5),

a handful of accidental intakes of plutonium oxides at the DOE Rocky Flats Plant (RFP) (Mann and Kirchner 1967), Hanford Site (Carbaugh, Bihl, and Sula 1991; Carbaugh and LaBone 2003; Bihl et al. 1988), Los Alamos National Laboratory . . . , and Savannah River Site (Carbaugh and LaBone 2003) have exhibited long-term retention of plutonium in the lung exceeding that predicted by the standard type S model. Recent autopsies on workers exposed to plutonium at the Mayak Production Association (Mayak) in Russia revealed a similar effect.

ICRP Publication 141 (2019), using similar literature, provided absorption parameters for very insoluble Pu-239 oxides: $F_r = 0.004$, $S_s = 1 \times 10^{-5}$ per day (d^{-1}), $S_r = 0.4d^{-1}$, and $F_A = 2 \times 10^{-6}$ (ICRP, 2019, p. 337).

3.1.2 SC&A's comments on data in the technical basis section for biokinetic models

The technical basis for the biokinetic model is discussed in section 4.1 of OTIB-0049, revision 02 (NIOSH, 2020, pp. 6–7). This section lists NIOSH's dissolution parameters for its hybrid model and identifies the fraction of inhaled material absorbed by blood relatively rapidly (F_r) as 0.001209.

Observation 2: Section 4.1 of ORAUT-OTIB-0049, revision 02, lists an incorrect F_r value

The F_r value calculated by NIOSH, listed in attachment A of OTIB-0049, revision 02, and used in the IDOT_SS tool, is 0.001029. Section 4.1 of OTIB-0049 erroneously identifies the F_r value as 0.001209.

3.2 Evaluation of attachment A, "Determination of solubility parameters for Super S model"

The first two sentences in attachment A of OTIB-0049 (NIOSH, 2020, p. 13) state:

While ICRP has published a new lung model, it has not published solubility parameters for plutonium. Therefore, solubility parameters are evaluated here for use with the type SS model.

3.2.1 SC&A's comments on stated purpose of attachment A

As identified in observation 1, ICRP issued new biokinetic models in Publication 141, "Occupational Intakes of Radionuclides: Part 4," in 2019. Publication 141 provides data concerning plutonium radioisotopes and presents information on chemical forms encountered in the workplace, data on inhalation, ingestion, and systemic biokinetics (including a review and discussion of the parameter values of the reference biokinetic models).

ICRP Publication 141 has suggested specific default absorption parameters values for Pu-239 dioxide, $F_r = 0.004$, $S_s = 1 \times 10^{-5} \text{d}^{-1}$, $S_r = 0.4 \text{d}^{-1}$, and a default absorption parameter from the alimentary tract, $F_A = 2 \times 10^{-6}$.

SC&A suggests that the Pu-239 dioxide absorption parameters and the absorption parameters from the alimentary tract specified in ICRP Publication 141 should be used for all other “Super S” plutonium dioxides, as implied in observation 1.

3.3 Evaluation of the long-term absorption parameter

In OTIB-0049, attachment A, pages 13–14, NIOSH states the following:

The original version of this TIB evaluated selected cases from RFP and Hanford that exhibited type SS behavior. A combination of one RFP case (RFP 872) and one Hanford case (HAN-1) resulted in worst-case correction factors at various times after an intake. However, in developing parameters for an actual model, it is not possible to use two different cases as one. . . .

The solubility parameters considered are F_r , S_r , and S_s . The parameter F_r represents the fraction of the inhaled material that is absorbed by the blood relatively rapidly. S_r represents that rate at which the material is absorbed. The remaining fraction of the material ($1 - F_r$) is absorbed as a slower rate represented by S_s

In order to determine the appropriate solubility parameters, intakes were calculated a number of times from either lung or urine data. All the intake calculations discussed were performed using a least squares fit of the applicable data.

The slow absorption rate parameter was calculated using the data on Am-241 retention in the lung. The default type S value from ICRP Publication 66 was reduced by a factor of 10, and the Am-241 intake calculated. The results for several iterations of reducing the value by factors of 10 at each interaction showed that, once reduced below 1×10^{-6} , there was essentially no difference in the results. Thus, OTIB-0049 (NIOSH, 2020) assigned the value of $S_s = 10^{-6} \text{d}^{-1}$ as the slow dissolution rate.

3.3.1 SC&A's comments on long-term absorption parameters

According to ICRP Publication 141, the most informative case study is the 35-year followup of a group of workers who inhaled plutonium dioxide in the 1965 Rocky Flat Plant Fire, described in revision 01 PC-2 of OTIB-0049 (NIOSH, 2010) and Mann and Kirchner (1967). Gregoratto et al. (2010) analyzed nine cases based on lung measurements obtained from NIOSH (2007) on behalf of ICRP. Six RFP workers were exposed to plutonium from a fire in October 1965. Gregoratto et al. (2010) analyzed the lung and urine data for the six workers; the median values were $F_r = 0.005$ and $S_s = 4 \times 10^{-6} \text{d}^{-1}$, as specified in ICRP Publication 141 (ICRP, 2019, p. 295).

In addition, ICRP analyzed the United States Transuranium and Uranium Registries (USTUR) autopsy and bioassay data of two workers involved in the 1965 RFP fire with the two highest exposures (Avtandilashvili et al., 2012, 2013). For both cases, around 1 percent was absorbed

relatively rapidly, with half-times of around 8 hours ($S_r = 1 \text{ d}^{-1}$) and 16 hours ($S_r = 2 \text{ d}^{-1}$). The estimated value of S_s in both cases is $5 \times 10^{-6} \text{ d}^{-1}$ (ICRP, 2019, p. 295). ICRP explains that the factors giving credence to this value of the slow dissolution rate are (1) it is a human study, (2) it contains detailed measurements, (3) it analyzes both bioassay and autopsy data, and (4) the long duration (many years between exposure and autopsy). However, the measurements are on two subjects who received unusually high exposures (3 gray (Gy) to AI region by 18 years post intake, and 3 Gy to AI region by 43 years post intake). One subject also had previous exposure to coal mine dust and was a smoker. The values of S_s for the human studies range from 4×10^{-6} to 4.5×10^{-5} , with a geometric mean of $9 \times 10^{-6} \text{ d}^{-1}$.

ICRP Publication 141 (2019) derived specific absorption parameter values from a study by Carbaugh and La Bone (2003). This study provided the data for the “HAN-1” case, which NIOSH used to develop the solubility parameters for type SS plutonium. According to ICRP Publication 141, information on the early rapid absorption phase was difficult to analyze because of the possible enhancement of urine excretion due to the administration of diethylene triamine pentaacetic acid. ICRP’s estimated value of the slow dissolution rate was of the order of $S_s = 10^{-5} \text{ d}^{-1}$ (p. 297) for the Hanford case study (HAN-1), while NIOSH derived $S_s = 1 \times 10^{-6} \text{ d}^{-1}$.

ICRP also analyzed autopsy data from 20 former Mayak workers considered to be exposed to plutonium oxide alone (Puncher et al., 2017). ICRP estimated a value of $S_s = 4.5 \times 10^{-5} \text{ d}^{-1}$, (ICRP, 2019, p. 296). According to ICRP Publication 141 (2019), factors giving credence to these data include (1) it is a human study, (2) it contains a large number of subjects, and (3) the evaluation covers a sufficiently long duration. However, the exposures are less well characterized than in the other studies considered, and there is very limited bioassay information.

Based on these studies and some limited animal studies, ICRP derived a specific default slow dissolution rate of $S_s = 1 \times 10^{-5} \text{ d}^{-1}$ (ICRP, 2019, p. 305). SC&A considers the ICRP default S_s value to be an appropriate long-term absorption rate.

3.4 Evaluation of the short-term absorption parameters

To assess the rapid dissolution rate (S_r), OTIB-0049 assumed a constant value for the slow dissolution rate of $S_s = 1 \times 10^{-6} \text{ d}^{-1}$ and then used the HAN-1 lung counting data for americium while varying the short-term absorption parameters. NIOSH concluded that varying the fraction of rapidly dissolved material (F_r) and S_r had little effect on the calculated intake. Urine data were then applied, even though the individual was chelated. Varying the F_r value had a large effect on the calculated intake, while the S_r showed a smaller effect. NIOSH ultimately assigned the rapid absorption parameters for the type SS model as $F_r = 0.001029$ and $S_r = 100.1$.

3.4.1 SC&A’s comments on short-term absorption parameters

ICRP Publication 141 (2019) assigned the value of 0.4 d^{-1} for the rapid dissolution rate (S_r) based on animal and human studies but did not consider it appropriate to use urine excretion rates from chelated individuals, citing and showing the importance of early excretion rates and its dependence on S_r .

As identified in observation 1, new biokinetic models have been published in ICRP Publication 141. SC&A suggests that NIOSH consider using the ICRP Publication 141 value of 0.4 d^{-1} for its rapid dissolution rate (S_r).

3.5 Binding of plutonium in the respiratory tract

ICRP Publication 141 gave consideration to a long-term “bound” state of plutonium. Specifically, it states:

For some elements, a significant fraction of the dissolved material is absorbed slowly. In some cases, this can be represented by formation of particulate material (which is subject to clearance by particle transport). In others, some dissolved material appears to be attached to lung structural components, and removed only by absorption to blood. To represent the latter type of time-dependent uptake, it is assumed that a fraction, f_b , of the dissolved material is retained in the ‘bound’ state, from which it goes into blood at a rate s_b . Evidence for retention in the bound state, rather than by transformation into particulate material, may be in one or more forms, such as systemic uptake rather than faecal clearance of the retained material; slower clearance than for insoluble particles deposited in the same region of the respiratory tract; or autoradiography showing diffuse rather than focal retention of activity. [ICRP, 2019, p. 15]

As binding occurs after dissolution of the inhaled material, it is assumed to be independent of the initial chemical form. After reviewing human and animal data, ICRP assigned the value of 0.2 percent for the bound fraction (f_b) to be applied to the whole respiratory tract, except for the ET1 region, for all plutonium compounds, and a bound dissolution rate (S_b) equal to zero.

Observation 3: NIOSH failed to consider long-term binding of plutonium

There is no reference to long-term binding of plutonium in OTIB-0049.

3.6 Systemic distribution, retention, and excretion of plutonium

The plutonium model of ICRP Publication 67 (1993) was updated and is described in detail in ICRP Publication 141 (2019). Publication 141 summarizes the main differences from the previous model, which include:

- deposition fractions to bone and liver
- circulation in blood and turnover to tissues and clearance from blood to urine
- rapid, intermediate, and slow phases of removal from liver
- circulation deposits in trabecular and cortical bone and removal and change with time in urinary clearance of circulating plutonium
- transfer of plutonium from blood to kidneys and urinary bladder

Observation 4: Rev. 02, has not used ICRP 141 updates to the ICRP 67 systemic model

OTIB-0049, revision 02 (NIOSH, 2020), uses the ICRP Publication 67 (“ICRP 67”) systemic model instead of the updated model described in ICRP Publication 141 (“ICRP 141”). Excretion rates using the two models should be compared.

As identified in observation 1, new biokinetic models have been published in ICRP Publication 141 (2019). SC&A suggest that the dosimetric data for the inhalation of Pu-239 dioxide should be used for all type SS plutonium as given in ICRP Publication 141, as well as the dose per activity content in the lungs and in daily excretion of urine and feces.

Observation 5: NIOSH should consider using the OIR Data Viewer software

SC&A suggests that the Occupational Intakes of Radionuclides (OIR) Data Viewer software (the electronic annex to the OIR series), as described in ICRP Publication 134 (ICRP, 2016), Publication 137 (ICRP, 2017), and Publication 141 (ICRP, 2019), should be used to calculate dose per intake coefficients, dose per content functions, and reference bioassay functions for Pu-239 dioxides (type SS plutonium). Data for intake by inhalation, ingestion, and for direct uptake to the blood are provided. The electronic annex covers a range of physicochemical forms of aerosols with median sizes ranging from an activity median thermodynamic diameter of 0.001 micrometer to an activity median aerodynamic diameter of 20 micrometers. The dataset was calculated for the reference worker.

4 Application of OTIB-0049 and IDOT_SS to Dose Reconstructions

SC&A notes that OTIB-0049 lacks guidance on how to apply type SS plutonium and makes no mention of the tool developed for its implementation. SC&A only became aware of the IDOT_SS tool when they inquired if NIOSH had created a tool to support OTIB-0049.

The following sections present SC&A's review of the basic functionality of the tool as well as some scoping calculations to better understand the practical implications the new methodology has for dose reconstructions (DRs). Section 4.1 provides a basic description of the tool. Section 4.2 compares the use of absorption parameters derived in attachment A of OTIB-0049, revision 02, with the absorption parameters in ICRP Publication 141 (2019). This comparison includes scoping calculations using typical claimant bioassay data to understand the practical difference between the newer method for assessing plutonium strongly retained in the lung (OTIB-0049, revision 02, with the IDOT_SS tool) and the older method (OTIB-0049, revision 01 PC-2, with the Integrated Modules for Bioassay Analysis (IMBA) program). To illustrate this comparison, SC&A used the bioassay data for the HAN-1 case discussed in attachment A of OTIB-0049, revision 02, and provided by NIOSH in the example input file, "Example_Lung.IDOT."

Observation 6: OTIB-0049 lacks information about its application to dose reconstruction

SC&A found limited guidance for dose reconstructors on how to apply the guidance in OTIB-0049 to a DR. Clear, unambiguous guidance is necessary to ensure cases are processed consistently. OTIB-0049 should specify that the IDOT_SS tool has been developed for the implementation of its guidance.

4.1 Overview of IDOT_SS tool and user guide

NIOSH provided SC&A with version 1.02, dated July 20, 2021, of the IDOT_SS tool. It is SC&A's understanding that all DRs that assess type SS plutonium and/or americium will use this tool. NIOSH also provided SC&A with a user's guide for the tool. The tool is a Microsoft Excel macro file with four primary pages:

- **Main:** This tab allows the input of up to 10 intakes of a single americium or plutonium radionuclide. The solubility type defaults to type SS with the option to modify the solubility parameters. The page also allows users to select the activity and dose units used in calculations. The tab is comparable in functionality to the home/start page in the IMBA program.
- **BIO:** This tab allows users to input bioassay data from urine, fecal, lung, and whole-body counts. A button allows users to calculate intakes from bioassay data. A second button allows users to calculate projected bioassay data from intakes. This tab has similar functionality to the "Bioassay Calculation" page in IMBA.
- **Annual Dose:** This tab allows users to input cancer information and exposure start date. A single button allows users to calculate annual organ doses from the intake information that is input or derived in previous tabs.

- Committed: A single button on the page allows users to calculate the committed dose to various organs and a committed effective dose.

For this review, SC&A did not review the calculations used in the tool or implementation of the tool through the user's guide. The calculations in the tool are completed in a password-protected part of the tool, and SC&A does not currently have access to view how they are being implemented. The calculations supporting the tool are documented in DCAS-RPT-007 (NIOSH, 2019). According to DCAS-RPT-007, additional benchmarking data are provided in a June 20, 2019, "IDOT Bioassay and Dose Benchmark" file. Detailed review of these documents and the tool calculations are outside of the scope of this tasking and would require subsequent tasking by the Subcommittee for Procedure Reviews.

4.2 Comparison of doses derived using IDOT_SS for OTIB-0049, revision 02, with doses using previous OTIB-0049 guidance

SC&A used the IDOT_SS tool to perform scoping calculations to better understand and characterize the effects on DR using the new methodology for assessing doses to plutonium strongly retained in the lung. The scoping calculations are intended to assist in this determination but are illustrative and do not encompass all of the many potential exposure assessment scenarios.

This section compares doses derived using the following new and previous versions of OTIB-0049 guidance:

- OTIB-0049, revision 02 (NIOSH, 2020), using IDOT_SS
- OTIB-0049, revision 01 PC-2 (NIOSH, 2010); as the guidance in this 2010 page-change revision is essentially unchanged from revision 01 (NIOSH, 2007), this report will hereafter use "Revision 01 (2010)" as shorthand to indicate the relevant previous guidance

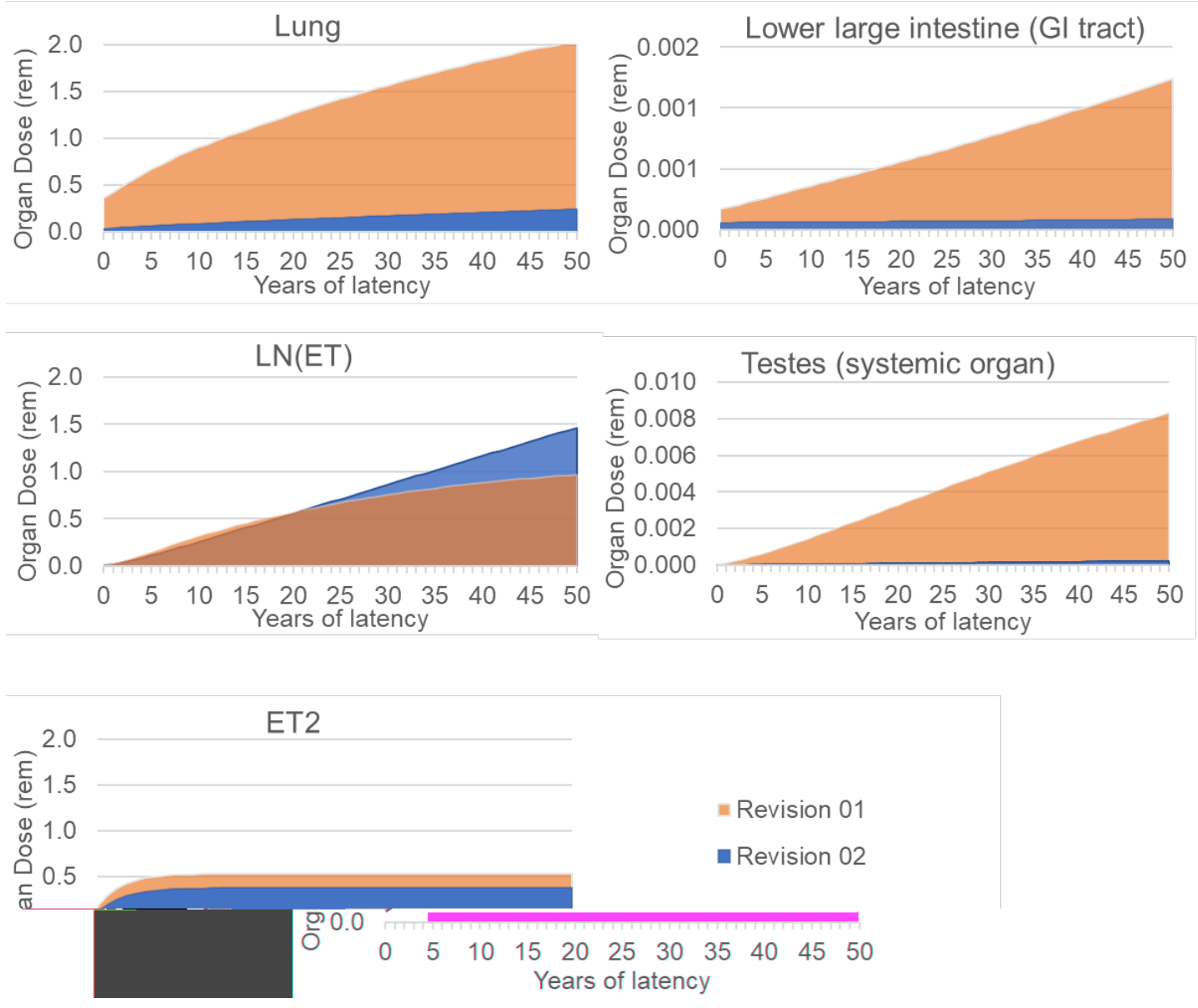
To assess the impacts of the revision to OTIB-0049, SC&A first modeled equal intakes of type SS with the new and previous revision methodology for two scenarios:

1. an acute Pu-239 intake of 1,000 disintegrations per minute (dpm)
2. a chronic Pu-239 intake of 100 disintegrations per minute per day (dpm/d) for 5 years

Each scenario assumed that the intake was detected by urinalysis. A cancer was modeled from each of the organ groups in table 4-8 of revision 01 PC-2: lungs, extra-thoracic (ET), GI tract, and systemic organs. Two organs from the ET group, lymph nodes associated with the extrathoracic region (LN(ET)) and the posterior nasal passage (ET2), were selected because of the variation expected within the organ grouping. SC&A modeled the organ dose up to 50 years post exposure and compared the results of the two models. The results of this assessment are shown in figures 1 and 2. As expected, these figures clearly show that the calculation of equal intakes of type SS Pu-239 using the OTIB-0049 Revision 01 (2010) and revision 02 approaches can lead to vastly different organ doses. In these examples, the Revision 01 (2010) method resulted in the calculation of a larger dose than the newer method except for LN(ET).

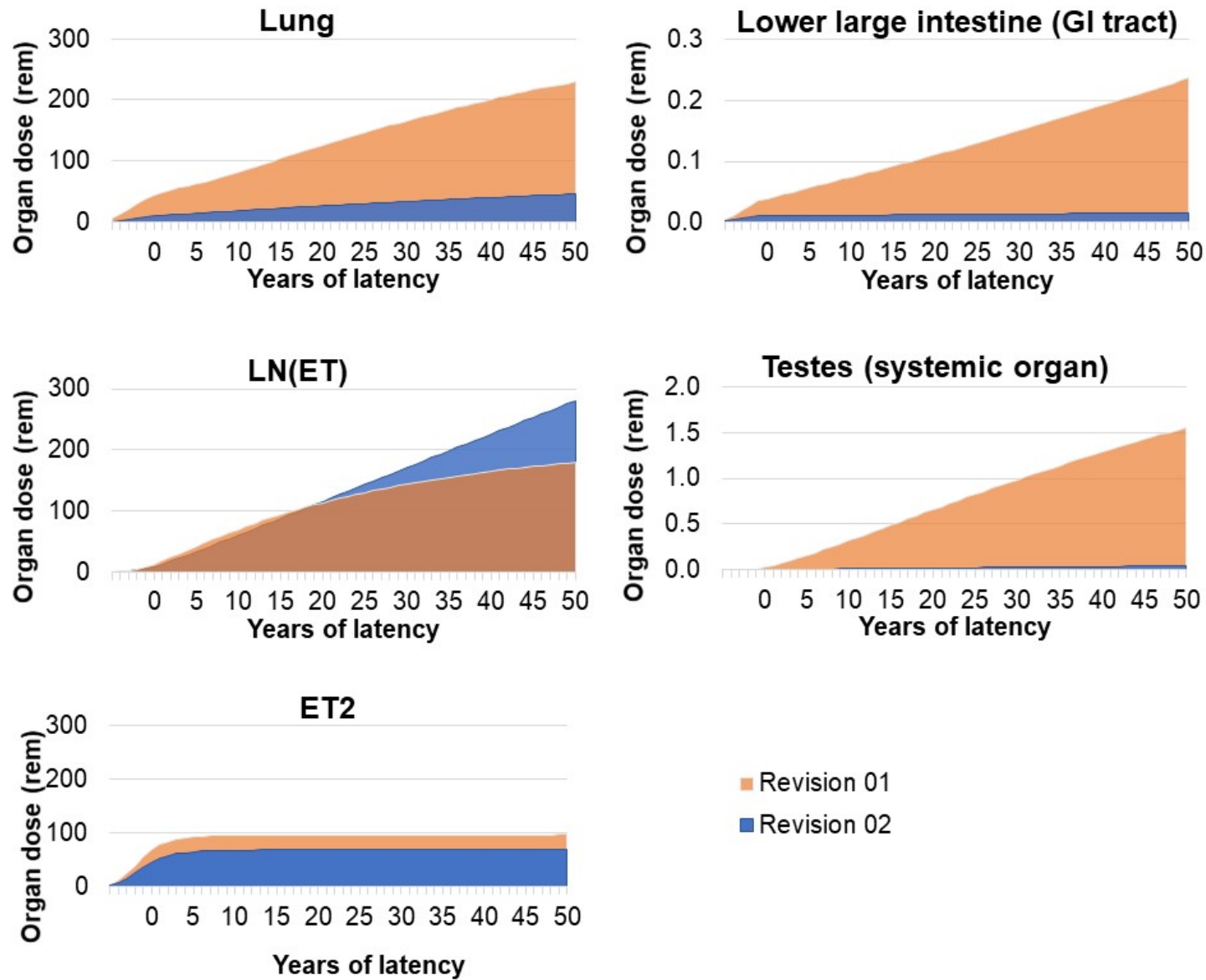
Additionally, SC&A modeled intakes and corresponding doses using bioassay results from two typical cases. These calculations and the quantitative results are presented and discussed in sections 4.2.1–4.2.3.

Figure 1. Comparisons of acute Pu-239 intake of 1,000 dpm for the Revision 01 (2010) and revision 02 methods



NOTICE: This document has been reviewed to identify and redact any information that is protected by the Privacy Act 5 U.S.C. § 552a and has been cleared for distribution.

Figure 2. Comparisons of the chronic Pu-239 intake of 100 dpm/d for 5 years for the Revision 01 (2010) and revision 02 methods



4.2.1 Purpose of scoping calculations

As part of its review of the IDOT_SS tool, SC&A performed scoping calculations designed to evaluate the following:

- Compare IDOT_SS organ doses to the previous method, Revision 01 (2010) (which used IMBA and revision 01 PC-2 of OTIB-0049), when typical claimant data are used. In this context, the term “organ” refers to either an organ or tissue, whichever is appropriate.
- Determine the ratio of derived doses for the thoracic, extrathoracic, GI tract, and systemic organs using IDOT_SS compared to using Revision 01 (2010).
- OTIB-0049, revision 02, indicates a slower removal rate for Pu-239 and Am-241 solubility type SS compared to Revision 01 (2010). Therefore, SC&A performed analyses to determine if the derived doses using IDOT_SS compared to using the previous guidance are generally:
 - greater for organs in the thoracic and extrathoracic regions because of longer retention times
 - less for systemic organs because of slower release from the thoracic and extrathoracic regions
- Determine if there are DR situations where the organ doses, especially to the thoracic and extrathoracic regions, could be greater when using IDOT_SS compared to using Revision 01 (2010). If so, a program evaluation report would be necessary to rework previous DR cases involving type SS solubility.

4.2.2 Analysis results for two evaluated cases

SC&A used typical DR data to analysis two cases, designated A and B,¹ in the evaluation of IDOT_SS. Case A represents a typical case with a relatively short exposure period (several years) but a long latent period. Case B represents a typical case with a relatively long exposure period compared to the latent period. SC&A performed the following analyses:

- The bioassay data from each of the cases were used in IDOT_SS to derive projected Pu-239, or Am-241, chronic and acute intakes. IDOT_SS was then used to derive the annual type SS doses and the total dose up until the selected date of cancer diagnosis for each organ of interest.
- The bioassay data from each of the cases were used in IMBA to derive projected Pu-239, or Am-241, chronic and acute intakes for type S solubility. Revision 01 PC-2 of OTIB-0049 was then used to adjust the type S annual dose to type SS annual dose to each of the organs of interest (as recommended in table 4-8 and table D-1 of revision 01 PC-2 of

¹ “A” and “B” are arbitrary labels SC&A assigned for purposes of this discussion to protect the confidentiality of the data.

OTIB-0049) (NIOSH, 2010). The total dose up until the date of cancer diagnosis for each organ of interest was determined.

- The ratio of the resulting total dose derived using IDOT_SS compared to the total dose derived using the previous guidance was determined for each organ of interest up until the date of cancer diagnosis, and a summary plot was constructed. For plutonium, 17 total organs were analyzed in each case; these included the common cancer sites in the DR plus the organs with the highest committed dose. The organs with the highest committed dose included organs in the thoracic and extrathoracic regions. Only Case B was analyzed for americium. Dose comparisons from Am-241 intakes were performed for 25 organs; these included the common cancer sites in the DR plus additional organs selected to include the thoracic and extrathoracic regions, which are important for type SS solubility analysis.

The analyses for Cases A and B are presented in sections 4.2.2.1 and 4.2.2.2, respectively.

4.2.2.1 Case A

Exposure: Pu-239 at a U.S. Department of Energy (DOE) site. Relatively short exposure period (several years).

Diagnosis: Relatively long latent period.

Bioassays: Urinalysis for Pu-239. Assumed continuous monitoring during employment that indicated both potential chronic and acute exposures.

IDOT_SS projected intakes: 8,100 dpm/d chronic Pu-239 and 6.78E6 dpm acute Pu-239. Annual and total Pu-239 type SS chronic and acute doses up until the date of cancer diagnosis for 17 organs of interest were derived.

IMBA projected intakes: 1,772 dpm/d chronic Pu-239 S and 1.49E6 dpm acute Pu-239 type S. Type S annual doses were derived in IMBA and adjusted to type SS annual doses as recommended in table 4-8 and table D-1 of revision 01 PC-2 of OTIB-0049. Annual and total Pu-239 type SS chronic and acute doses up until the date of cancer diagnosis for 17 organs of interest were derived.

Table 1 lists the derived doses and the ratios of IDOT_SS-derived total chronic type SS Pu-239 doses compared to the total chronic type SS doses derived using Revision 01 (2010).

Table 1. Case A chronic Pu-239 IDOT_SS and Revision 01 (2010) derived doses and dose ratios

Organ	IDOT_SS dose (rem)	Revision 01 (2010) dose (rem)	Dose ratio (IDOT_SS/ Revision 01 (2010))
Testes	1.52E+00	1.20E+01	0.13
Ovaries	1.49E+00	1.18E+01	0.13
Liver	2.39E+01	1.89E+02	0.13

Organ	IDOT_SS dose (rem)	Revision 01 (2010) dose (rem)	Dose ratio (IDOT_SS/ Revision 01 (2010))
Bone surface	1.14E+02	8.97E+02	0.13
Uterus	1.92E-01	1.51E+00	0.13
Skin	1.93E-01	1.52E+00	0.13
RBM	5.58E+00	4.29E+01	0.13
Stomach	2.12E-01	1.61E+00	0.13
LLI	5.64E-01	1.82E+00	0.31
LN(TH)	8.89E+04	2.10E+05	0.42
Lung	1.59E+03	2.92E+03	0.55
AI	3.83E+03	6.46E+03	0.59
BB	5.78E+02	9.47E+02	0.61
ET1	1.03E+01	1.46E+01	0.70
TBBAS OF BBAS	1.63E+02	2.01E+02	0.81
ET2	2.33E+03	7.17E+02	3.24
LN(ET)	9.89E+03	1.35E+03	7.35

Figure 3 shows a summary plot of the ratio of IDOT_SS-derived total chronic type SS Pu-239 doses compared to the total chronic type SS doses derived using the Revision 01 (2010) method.

Figure 3. Case A ratio of IDOT_SS to Revision 01 (2010) derived total type SS Pu-239 chronic doses

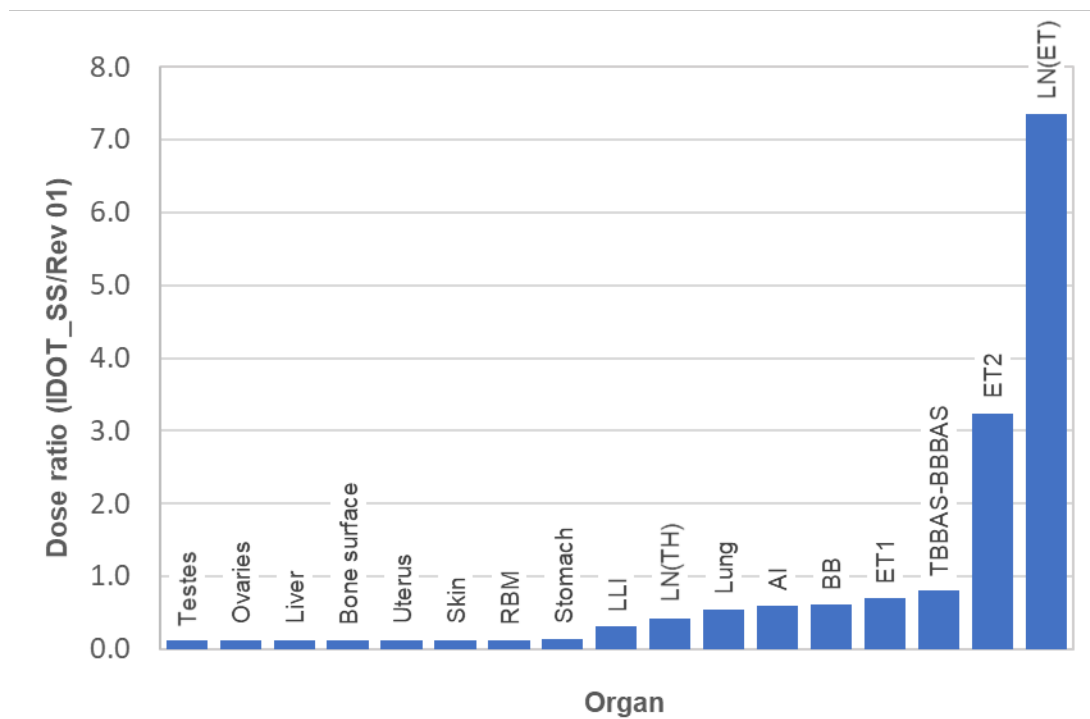


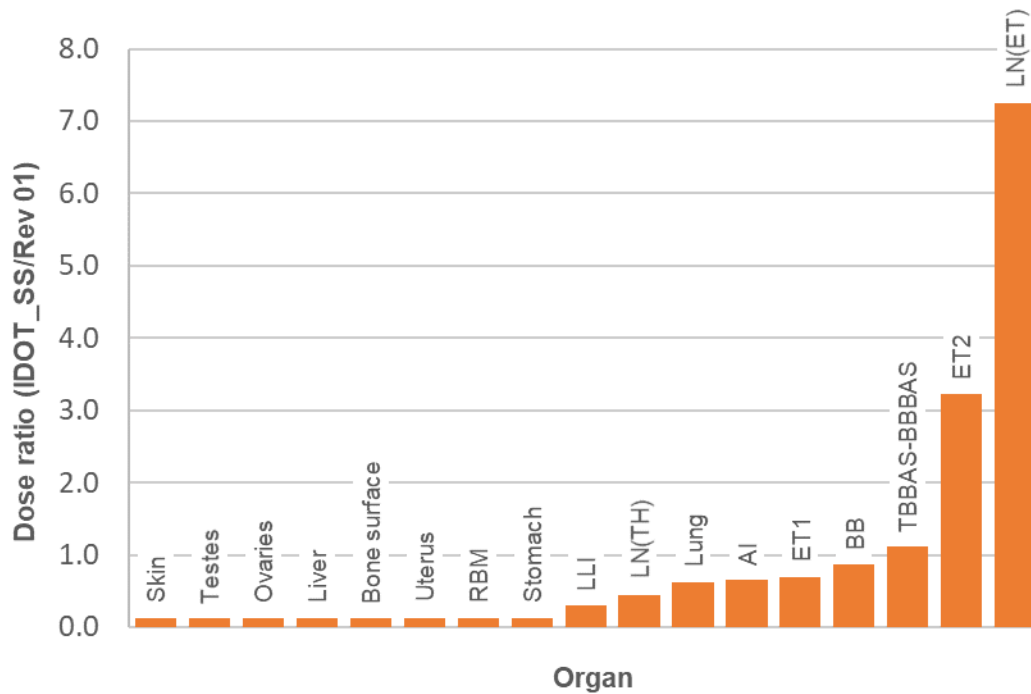
Table 2 lists the derived doses and the ratio comparing IDOT_SS-derived total acute type SS Pu-239 doses with the total acute type SS doses derived using the Revision 01 (2010) method.

Table 2. Case A acute Pu-239 IDOT_SS and Revision 01 (2010) derived doses and dose ratios

Organ	IDOT_SS dose (rem)	Revision 01 (2010) dose (rem)	Dose ratio (IDOT_SS/ Revision 01 (2010))
Skin	2.04E-01	1.67E+00	0.12
Testes	1.65E+00	1.32E+01	0.12
Ovaries	1.62E+00	1.30E+01	0.12
Liver	2.60E+01	2.08E+02	0.13
Bone surface	1.24E+02	9.88E+02	0.13
Uterus	2.08E-01	1.66E+00	0.13
RBM	6.08E+00	4.76E+01	0.13
Stomach	2.29E-01	1.76E+00	0.13
LLI	6.18E-01	2.00E+00	0.31
LN(TH)	9.58E+04	2.16E+05	0.44
Lung	1.74E+03	2.77E+03	0.63
AI	4.19E+03	6.46E+03	0.65
ET1	1.13E+01	1.62E+01	0.70
BB	6.35E+02	7.33E+02	0.87
TB _{BAS} or BB _{BAS}	1.79E+02	1.60E+02	1.12
ET2	2.56E+03	7.95E+02	3.22
LN(ET)	1.08E+04	1.49E+03	7.24

Figure 4 shows a summary plot of the ratio of IDOT_SS-derived total acute type SS Pu-239 doses compared to the total acute type SS doses derived using the Revision 01 (2010) method.

Figure 4. Case A ratio of IDOT_SS to Revision 01 (2010) derived total type SS Pu-239 acute doses



4.2.2.2 Case B

Exposure: Pu-239 and Am-241 at a DOE site, relatively long exposure period.

Diagnosis: Relatively short latent period.

Bioassays: Urinalysis for Pu-239 and chest counts for Am-241. Assumed continuous monitoring during employment that indicated only chronic exposure for both Pu-239 and Am-241.

IDOT_SS projected intakes: 117 dpm/d chronic Pu-239 and 0.644 dpm/d chronic Am-241. Annual and total chronic doses up until date of cancer diagnosis for Pu-239 type SS for 17 organs of interest and Am-241 for 25 organs of interest were derived.

IMBA projected intakes: 12.78 dpm/d chronic Pu-239 S and 0.0690 dpm/d chronic Am-241. Type S annual Pu-239 and Am-241 doses were derived in IMBA and adjusted to type SS annual doses as recommended in table 4-8 and table D-1 of revision 01 PC-2 of OTIB-0049. Organs of highest dose were all systemic for Am-241 intakes and did not require type SS adjustment factors. Therefore, additional organs were analyzed to include the thoracic and extrathoracic regions that would require type SS dose adjustments, for a total of 25 organs. Annual and total chronic doses up until the date of cancer diagnosis for Pu-239 type SS and Am-241 were derived for the organs of interest.

Table 3 lists the derived doses and the ratios of IDOT_SS-derived total chronic type SS Pu-239 doses compared to the total chronic type SS doses derived using the Revision 01 (2010) method.

Table 3. Case B chronic Pu-239 IDOT_SS and Revision 01 (2010) derived doses and dose ratios

Organ	IDOT_SS dose	Revision 01 (2010) dose	Dose ratio (IDOT_SS/ Revision 01 (2010))
Liver	4.88E-01	1.10E+00	0.44
Testes	2.98E-02	6.72E-02	0.44
Ovaries	2.93E-02	6.60E-02	0.44
Bone surface	2.27E+00	5.08E+00	0.45
Thyroid	3.65E-03	8.07E-03	0.45
Skin	3.79E-03	8.33E-03	0.45
RBM	1.64E-01	3.60E-01	0.46
Kidney	1.61E-02	3.39E-02	0.48
Lung	5.61E+01	7.03E+01	0.80
BB	4.55E+01	4.77E+01	0.95
AI	1.12E+02	1.13E+02	0.99
LN(TH)	4.85E+02	3.59E+02	1.35
ET1	9.68E-01	6.36E-01	1.52
LLI	3.85E-02	2.48E-02	1.55
TB _{BAS} Or BB _{BAS}	1.52E+01	8.30E+00	1.83
ET2	2.17E+02	3.35E+01	6.48
LN(ET)	1.72E+02	2.17E+01	7.91

Figure 5 shows a summary plot of the ratio of IDOT_SS-derived total chronic type SS doses compared to the total chronic type SS Pu-239 doses derived using the Revision 01 (2010) method.

Figure 5. Case B ratio of IDOT_SS to Revision 01 (2010) derived total type SS chronic Pu-239 doses

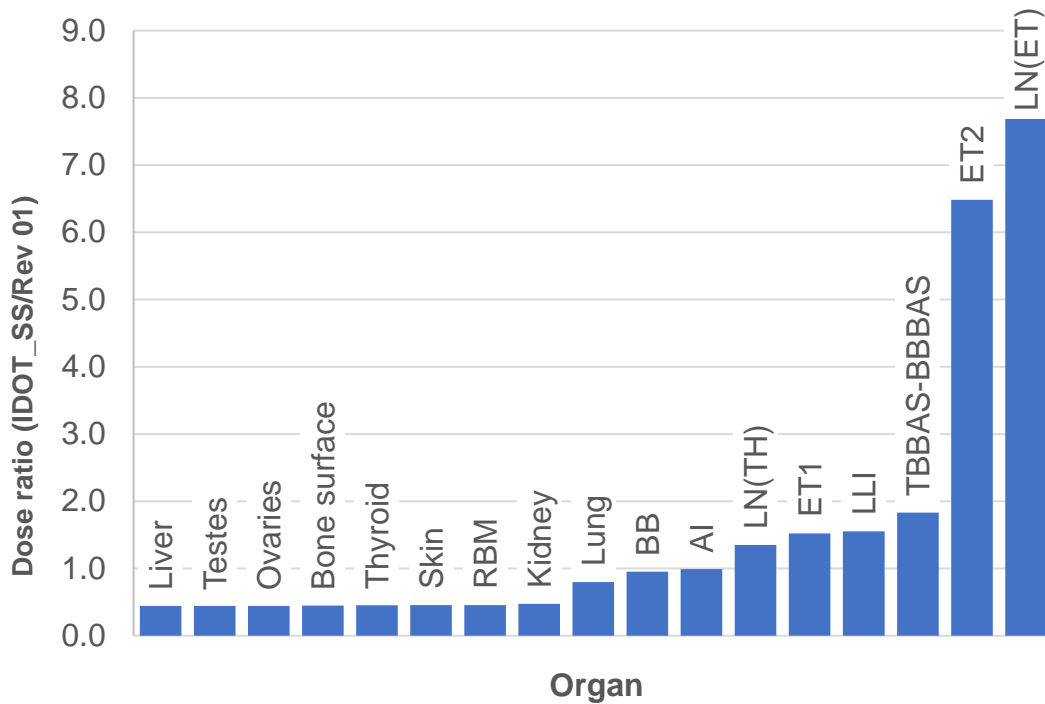


Table 4 lists the derived doses and the ratios of IDOT_SS-derived total chronic Am-241 doses compared to the total chronic doses derived using the Revision 01 (2010) method.

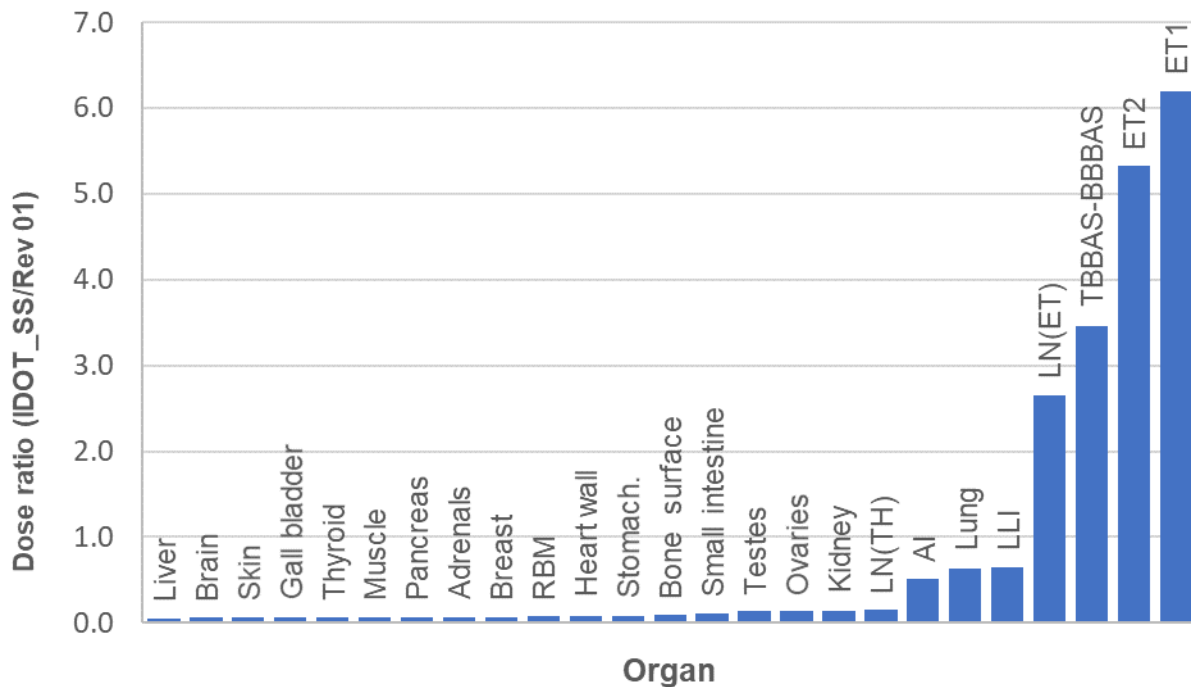
Table 4. Case B chronic Am-241 IDOT_SS and Revision 01 (2010) derived doses and dose ratios

Organ	IDOT_SS dose	Revision 01 (2010) dose	Dose ratio (IDOT_SS /Revision 01 (2010))
Liver	3.80E-03	7.39E-02	0.051
Brain	3.22E-05	5.39E-04	0.060
Skin	3.29E-05	5.40E-04	0.061
Gall bladder	3.35E-05	5.42E-04	0.062
Thyroid	3.19E-05	5.05E-04	0.063
Muscle	3.53E-05	5.41E-04	0.065
Pancreas	3.56E-05	5.41E-04	0.066
Adrenals	3.70E-05	5.42E-04	0.068
Breast	3.72E-05	5.41E-04	0.069
RBM	1.81E-03	2.35E-02	0.077
Heart wall	4.34E-05	5.44E-04	0.080
Stomach	4.53E-05	5.46E-04	0.083
Bone surface	3.21E-02	3.48E-01	0.092
Small intestine	5.92E-05	5.53E-04	0.107
Testes	6.40E-04	4.87E-03	0.131

Organ	IDOT_SS dose	Revision 01 (2010) dose	Dose ratio (IDOT_SS /Revision 01 (2010))
Ovaries	6.45E-04	4.79E-03	0.135
Kidney	3.12E-04	2.23E-03	0.140
LN(TH)	6.24E+00	4.23E+01	0.148
AI	1.44E+00	2.79E+00	0.517
Lung	7.36E-01	1.16E+00	0.634
LLI	5.05E-04	7.77E-04	0.650
LN(ET)	2.21E+00	8.35E-01	2.652
TBBAS or BBAS	2.05E-01	5.93E-02	3.463
ET2	2.74E+00	5.16E-01	5.324
ET1	2.31E-01	3.73E-02	6.198

Figure 6 shows a summary plot of the ratio of IDOT_SS-derived total chronic Am-241 doses compared to the total chronic Am-241 doses derived using the Revision 01 (2010) method.

Figure 6. Case B ratio of IDOT_SS to Revision 01 (2020) derived total chronic type Am-241 doses



4.2.3 Summary conclusions from Case A and B analysis

SC&A's analysis of Case A and Case B bioassay data using both IDOT_SS and Revision 01 (2010) identified the following observation:

Observation 7: A program evaluation report may be required

NIOSH should specify if the dose results using the methods in revision 02 have been compared to the doses derived using the former methods for assessing intakes of type SS plutonium. It is important to establish if there are situations where the doses derived using revision 02 are greater than those derived using the previous OTIB-0049 methods, which may necessitate a program evaluation report.

SC&A’s analysis of two DR cases using typical bioassay data comparing the older and newer methods for assessing plutonium strongly retained in the lung found that organ doses in the thoracic and extrathoracic regions increased with the new method, while doses to other systemic organs decreased. Therefore, a program evaluation report would appear warranted for noncompensated cases with covered illnesses involving the thoracic and extrathoracic regions.

Finding 1: IDOT_SS does not provide annual doses for the urinary bladder

SC&A found that, while IDOT_SS would calculate a total committed dose to the urinary bladder, the results returned for the annual doses to the urinary bladder were “N/A.” This occurs for all examples analyzed by SC&A.

4.3 Comparison of absorption parameters between OTIB-0049, revision 02, and ICRP Publication 141

As noted in Sections 2 and 3, the main purpose of OTIB-0049 was to derive absorption parameters for use in assessing exposures to plutonium strongly retained in the lung (i.e., type SS). Absorption parameters designed to address exposures to plutonium exhibiting this behavior were also developed in ICRP Publication 141 (ICRP, 2019). Table 5 compares the two sets of absorption parameters.

Table 5. Comparison of ORAUT-0049, revision 02, and ICRP Publication 141 absorption parameters

Parameter description	ORAUT-0049, rev. 02, value	ICRP 141 value
Fraction of rapidly dissolved material (F_r)	0.001029	0.004
Rapid dissolution rate (S_r)	100.1	0.4
Slow dissolution rate (S_s)	1×10^{-6}	1×10^{-5}
Fraction of dissolved material retained in a bound state (f_b)	Not evaluated (default value in IDOT_SS is 0)	0.002
Bound dissolution rate (S_b)	Not evaluated (default value in IDOT_SS is 0)	0
GI tract fraction (f_1) or fraction to the alimentary tract (f_A)	1×10^{-5}	2×10^{-6}

SC&A entered the absorption parameters in table 5 into the IDOT_SS tool along with the exposure information (e.g., date and type of exposure, subsequent urinalysis measurements, etc.) for the HAN-1 case as provided by NIOSH in the calculation file. “Example_Lung.IDOT.” SC&A then ran the tool to compare the resulting doses as well as the general fit of the projected bioassay results to the actual observed bioassay results. SC&A found that, for the HAN-1 case, the total committed effective dose using the OTIB-0049 absorption parameters was

approximately 80 percent of the committed effective dose using the ICRP Publication 141 parameters. Table 6 displays the ratio of the organ-specific committed effective doses (OTIB-0049, revision 02/ICRP 141) as a percentage of the ICRP Publication 141 dose estimate. Percentages ranged from 20 percent to 87 percent.

Observation 8: ICRP Publication 141 absorption parameters appear to be more claimant favorable

Analysis of the HAN-1 case indicates that use of the ICRP Publication 141-derived absorption parameters results in higher doses to all evaluated organs when compared to the OTIB-0049-derived absorption parameters.

Table 6. Comparison of organ-specific committed doses for the HAN-1 case

Organ	OTIB-0049, rev. 02, committed dose (rem)	ICRP 141 committed dose (rem)	Ratio OTIB-0049/ICRP 141
Adrenals	1.710E-02	7.524E-02	0.23
U. bladder	1.709E-02	7.523E-02	0.23
Brain	1.709E-02	7.523E-02	0.23
Breast	1.710E-02	7.524E-02	0.23
Gall bladder	1.709E-02	7.523E-02	0.23
Heart	1.712E-02	7.527E-02	0.23
Kidney	4.346E-02	2.173E-01	0.20
Liver	2.085E+00	9.550E+00	0.22
Muscle	1.711E-02	7.525E-02	0.23
Ovaries	1.295E-01	5.887E-01	0.22
Pancreas	1.709E-02	7.523E-02	0.23
Testes	1.320E-01	6.001E-01	0.22
Thyroid	1.709E-02	7.523E-02	0.23
RBM	4.939E-01	2.417E+00	0.20
Bone surface	9.842E+00	4.455E+01	0.22
Stomach	1.789E-02	7.627E-02	0.23
Small intestine	1.909E-02	7.781E-02	0.25
ULI	2.921E-02	9.084E-02	0.32
LLI	5.265E-02	1.210E-01	0.44
Skin	1.709E-02	7.523E-02	0.23
Spleen	1.710E-02	7.524E-02	0.23
Thymus	1.709E-02	7.524E-02	0.23
Uterus	1.709E-02	7.523E-02	0.23
ET1	1.006E+00	1.348E+00	0.75
ET2	2.289E+02	2.915E+02	0.79
LN(ET)	8.586E+02	1.012E+03	0.85
TB _{SEC}	4.874E+00	6.409E+00	0.76
TB _{BAS}	1.603E+01	2.057E+01	0.78

Organ	OTIB-0049, rev. 02, committed dose (rem)	ICRP 141 committed dose (rem)	Ratio OTIB-0049/ICRP 141
BB	5.569E+01	7.050E+01	0.79
AI	3.470E+02	4.153E+02	0.84
LN(TH)	7.013E+03	8.088E+03	0.87
Lung	1.446E+02	1.743E+02	0.83
Colon	3.934E-02	1.039E-01	0.38
Esophagus	1.709E-02	7.524E-02	0.23

Figures 7–9 compare the projected bioassay values using the absorption parameters derived in OTIB-0049 versus those derived in ICRP Publication 141. As expected, the projected bioassay calculated using the derived absorption parameters in OTIB-0049 provides a better fit to the actual measured results. This was to be expected, because the absorption parameters were modeled based on the observed bioassay and thus would provide the best estimate of the actual HAN-1 excretion pattern but may be indicative of overfitting. However, it is worth noting that ICRP Publication 141 still provided a reasonably good fit to the observed HAN-1 bioassay data, thus reinforcing the supposition that the ICRP-derived parameters are appropriate for universal modeling of plutonium strongly retained in the lung. While the projected bioassay in the HAN-1 case was more closely approximated using the OTIB-0049 derived absorption parameters, use of the ICRP recommended parameters still resulted in a reasonably good fit to the observed bioassay data in this case. Thus, SC&A maintains that the ICRP Publication 141 parameters are likely more appropriate for generic application in DR cases involving plutonium strongly retained in the lung.

Figure 7. Comparison of bioassay projections for the HAN-1 case using absorption parameters derived in OTIB-0049 and ICRP 141

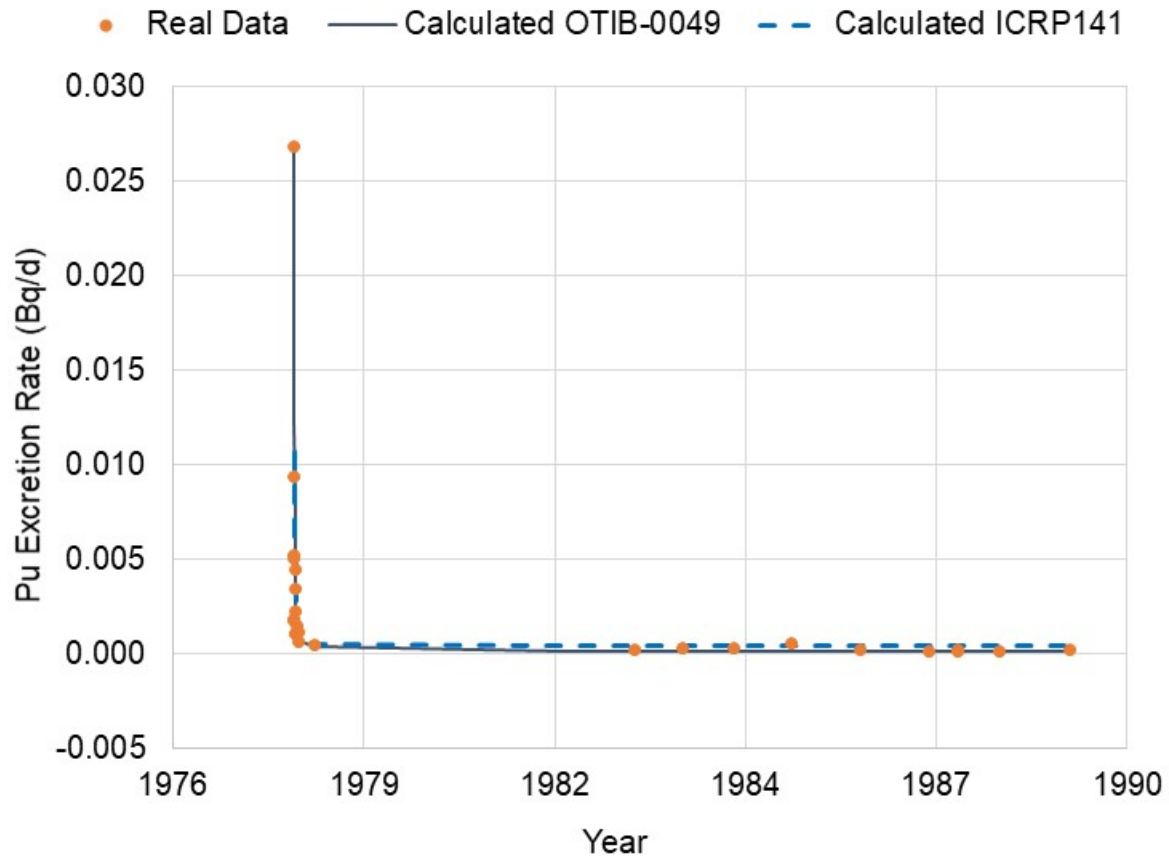


Figure 8. Comparison of bioassay projections for the HAN-1 case using absorption parameters derived in OTIB-0049 and ICRP 141 (y-axis truncated at 0.006 Bq/d)

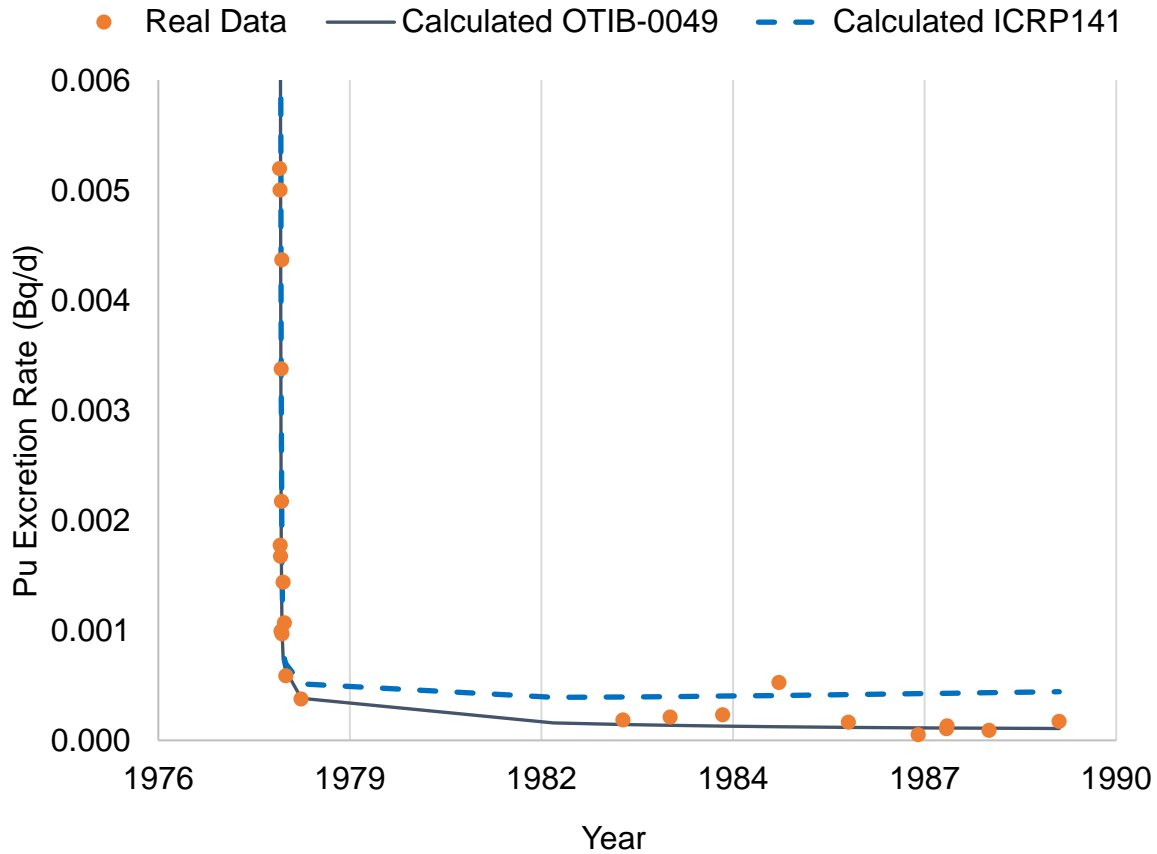
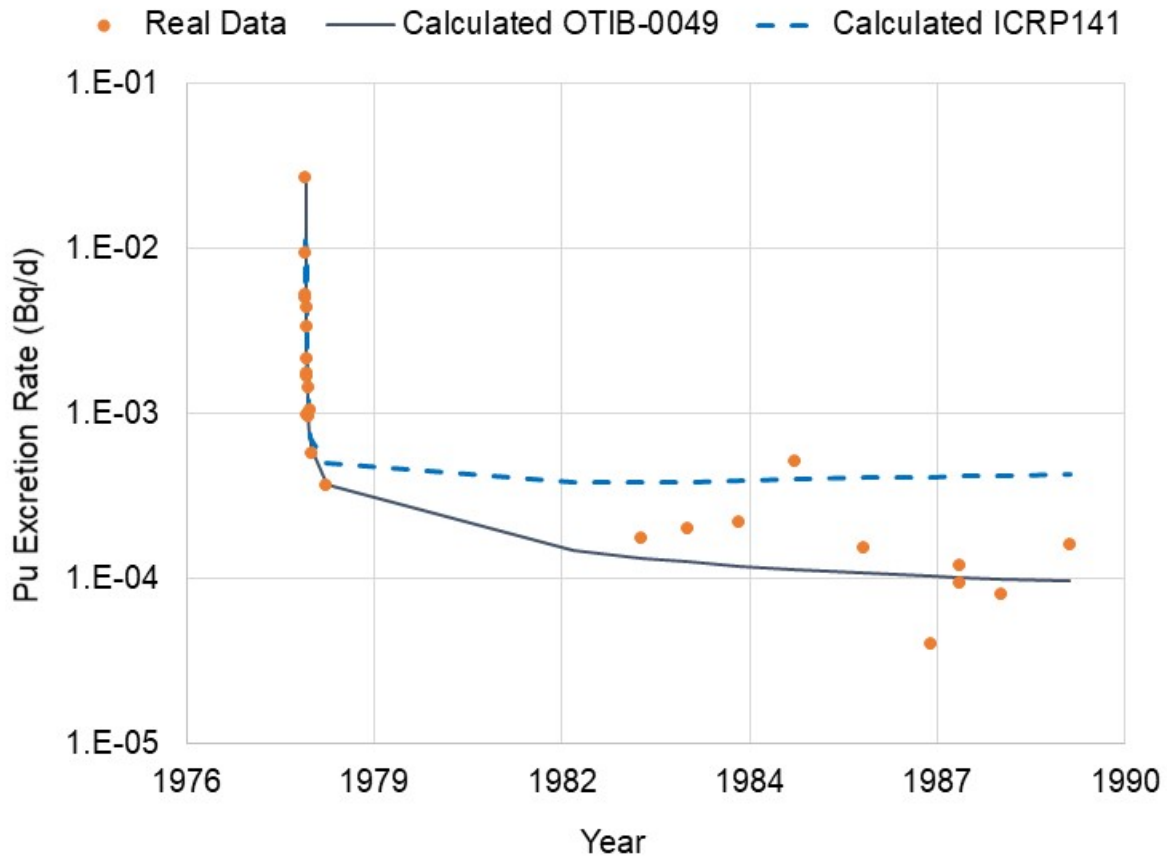


Figure 9. Comparison of bioassay projections for the HAN-1 case using absorption parameters derived in OTIB-0049 and ICRP 141 (y-axis in logarithmic form)



5 Summary of SC&A's Evaluation of OTIB-0049, Revision 02

SC&A evaluated OTIB-0049, revision 02, in view of current publications available. The following is a summary of SC&A's finding and observations that indicate that further discussion or clarification is needed.

Finding 1: IDOT_SS does not provide annual doses for the urinary bladder

SC&A found that, while IDOT_SS would calculate a total committed dose to the urinary bladder, the results returned for the annual doses to the urinary bladder were "N/A."

Observation 1: ICRP has published updated biokinetic models appropriate for type SS plutonium

SC&A suggests that (1) ICRP Publication 141 should be used to determine the Pu-239 dioxide absorption parameters and (2) absorption parameters from the alimentary tract should be used for all type SS plutonium exposure estimates. Further, NIOSH should consider use of the dosimetric guidance for dose per activity content in the lungs and models for daily excretion in urine and feces.

Specifically, SC&A suggests that:

1. ICRP Publication 141 should be used to determine the Pu-239 dioxide absorption parameters, and the absorption parameters from the alimentary tract should be used for all other type SS plutonium dioxides.
2. The ICRP Publication 141 value for S_r of 0.4 d^{-1} , the rate at which the material is absorbed, should be used.
3. The dosimetric data from ICRP Publication 141 should be used to determine the parameters for the inhalation of Pu-239 dioxide for all type SS plutonium. The dosimetric data should also be used to determine the parameters for the dose per activity content in the lungs and in daily excretion of urine and feces.

Observation 2: Section 4.1 of ORAUT-OTIB-0049, revision 02, lists an incorrect F_r value

Section 4.1 of OTIB-0049, revision 0,2 cites an F_r value of 0.001209, rather than the NIOSH-calculated value of 0.001029.

Observation 3: NIOSH failed to consider long-term binding of plutonium

There is no reference to long-term binding of plutonium in OTIB-0049.

Observation 4: Rev. 02 has not used ICRP 141 updates to the ICRP 67 systemic model

The plutonium model of ICRP Publication 67 (ICRP, 1993) was updated and is described in detail in ICRP Publication 141 (ICRP, 2019). OTIB-0049, revision 02 (NIOSH, 2020), uses the ICRP Publication 67 systemic model instead of the updated model. Excretion rates using the two models should be compared.

Observation 5: NIOSH should consider using the OIR Data Viewer software

SC&A suggests that the Occupational Intakes of Radionuclides (OIR) Data Viewer software (the electronic annex to the OIR series), ICRP Publication 134 (ICRP, 2016), Publication 137 (ICRP, 2017), and Publication 141 (ICRP, 2019) should be used to calculate dose per intake coefficients, dose per content functions, and reference bioassay functions for Pu-239 dioxides (type SS plutonium).

Observation 6: OTIB-0049 lacks information about its application to dose reconstruction

SC&A found limited guidance for dose reconstructors on how to apply the guidance in OTIB-0049 to a DR. Clear, unambiguous guidance is necessary to ensure cases are processed consistently.

Observation 7: A program evaluation report may be required

NIOSH should specify if the dose results using the methods in revision 02 of OTIB-0049 have been compared to the doses derived using the former methods for assessing intakes of type SS plutonium. In particular, it is important to establish if there are situations where the doses derived using revision 02 are greater than those derived using the previous OTIB-0049 methods, which may necessitate a program evaluation report.

Analysis of two DR cases that compared the older and newer methods for assessing plutonium strongly retained in the lung found that organ doses in the thoracic and extrathoracic regions increased with the new method, while doses to other systemic organs decreased. Therefore, a program evaluation report would appear warranted for noncompensated cases with covered illnesses involving the thoracic and extrathoracic regions.

Observation 8: ICRP Publication 141 absorption parameters appear to be more claimant favorable

Analysis of the HAN-1 case indicates that use of the ICRP Publication 141-derived absorption parameters results in higher doses to all evaluated organs when compared to the OTIB-0049-derived absorption parameters.

6 References

Avtandilashvili, M., Brey, R., & James, A. C. (2012). Maximum likelihood analysis of bioassay data from long-term follow-up of two refractory PuO₂ inhalation cases. *Health Phys.* 103(1), 70–79.

Avtandilashvili, M., Brey, R. R., & Birchall, A. (2013). Application of Bayesian inference to the bioassay data from long-term follow-up of two refractory PuO₂ inhalation cases. *Health Physics*, 104(4), 394–404.

Bihl, D. E., Lynch, T. P., Carbaugh, E. H., & Sula, M. J. (1988). *Methods to improve routine bioassay monitoring for freshly separated, poorly transported plutonium* (PNL-6695). Pacific Northwest Laboratory. <https://www.osti.gov/servlets/purl/6800906>

Carbaugh, E. H., Bihl, D. E., & Sula, M. J. (1991). Long-term follow-up of HAN-1, an acute plutonium oxide inhalation case. *Radiation Protection Dosimetry*, 38(1–3), 99–104. SRDB Ref. ID 18052

Carbaugh, E. H., & La Bone, T. R. (2003). Two case studies of highly insoluble plutonium inhalation with implications for bioassay. *Radiation Protection Dosimetry*, 105(1–4), 133–138. SRDB Ref. ID 18053

Gregoratto, D., Bailey, M. R., & Marsh, J. W. (2010). Modelling particle retention in the alveolar-interstitial region of the human lungs. *J. Radiol. Prot.*, 30, 491–512.

International Commission on Radiological Protection. (1979). Limits for intakes of radionuclides by workers (Publication 30, Part 1). *Ann. ICRP*, 2(3-4).

International Commission for Radiological Protection. (1993). Age-dependent doses to members of the public from intake of radionuclides: Part 2 ingestion dose coefficients (Publication 67). *Ann. ICRP*, 23(3-4).

International Commission on Radiological Protection. (1994). Human respiratory tract model for radiological protection (Publication 66). *Ann. ICRP*, 24(1-3).

International Commission on Radiological Protection. (2006). Human alimentary tract model for radiological protection (Publication 100). *Ann. ICRP*, 36(1-2).

International Commission on Radiological Protection. (2015). Occupational intakes of radionuclides: Part 1 (Publication 130). *Ann. ICRP*, 44(2).

International Commission on Radiological Protection. (2016). Occupational intakes of radionuclides: Part 2 (Publication 134). *Ann. ICRP* 45(3/4).

International Commission on Radiological Protection. (2017). Occupational intakes of radionuclides: Part 3. ICRP Publication 137. *Ann. ICRP* 46(3/4).

International Commission on Radiological Protection. (2019). Occupational intakes of radionuclides: Part 4 (Publication 141). *Ann. ICRP*, 48(2/3).

Mann, J. R., & Kirchner, R. A. (1967). Evaluation of lung burden following acute inhalation exposure to highly insoluble PuO₂. *Health Physics*, 13, 877–882. SRDB Ref. ID 7974

National Institute for Occupational Safety and Health. (2007). *Estimating doses for plutonium strongly retained in the lung* (ORAUT-OTIB-0049, rev. 01).
<https://www.cdc.gov/niosh/ocas/pdfs/arch/tibs/or-t49-r1.pdf>

National Institute for Occupational Safety and Health. (2010). *Estimating doses for plutonium strongly retained in the lung* (ORAUT-OTIB-0049, rev. 01 PC-2).
<https://www.cdc.gov/niosh/ocas/pdfs/arch/tibs/or-t49-r1-p2.pdf>

National Institute for Occupational Safety and Health. (2019). *Technical documentation for the super S internal dosimetry tool (IDOT_SS)* (DCAS-RPT-007, rev. 00). SRDB Ref. ID 178617

National Institute for Occupational Safety and Health. (2020). *Estimating doses for plutonium strongly retained in the lung* (ORAUT-OTIB-0049, rev. 02).
<https://www.cdc.gov/niosh/ocas/pdfs/tibs/or-t49-r2-508.pdf>

Puncher, M., Birchall, A., & Tolmachev, S. Y. (2017). The Mayak worker dosimetry system (MWDS 2013): A re-analysis of USTUR case 0269 to determine whether plutonium binds to the lungs. *Radiat. Prot. Dosim.*, 176, 50–61.