APPENDIX D

SELECTION OF DOSE METHODOLOGY

D. SELECTION OF DOSE METHODOLOGY

D.1. REVIEW OF INTERNAL DOSIMETRY METHODS

Exposure to radiation can occur from sources of penetrating radiation outside the body, such as x-ray machines or industrial radiography sources, or from sources of radioactive materials, such as plutonium or uranium, that enter the body, locate in an internal organ or organs, and irradiate the tissues of those internal organs. The problem of calculating the dose depends on many factors such as the shape of the organ, the type of radiation, the amount of the deposit, and the distribution of the deposit. Each of these individual factors is subject to considerable variability and difficulty in determining accurately. Once a dose is calculated, effectively communicating the possible effect of the dose on health requires additional skill and effort.

The current approach to limiting radiation exposure in the United States is derived from recommendations in ICRP Publications 26 and 30. The ICRP approach uses the concept of Committed Effective Dose Equivalent (CEDE) - a cumulative dose, weighted for the contributions of individual organs, and summed over a 50-year period for workers. Quantities derived from the CEDE such as the Annual Limit on Intake (ALI) and the Derived Air Concentration (DAC) provide operational limits for workers so that the overall guidelines will not be exceeded. The ALI is the activity of a radionuclide that would irradiate a person to the limit set by the ICRP for each year of occupational exposure. The DAC is found by dividing the ALI by the volume of air inhaled (2,400 m^3) in a working year (2,000 hours) (ICRP 1979).

For internal exposures, determining the dose requires knowledge of the following questions:

- How does the material get into the body?
- Once in the body, how quickly does the material move to other organs?
- Does the material in the initial organ leave the organ or does some remain?
- Once in an organ, how does the material irradiate the organ and other organs?
- Once in an organ, how does the material move to other organs?
- Finally, how does is the material eliminated from the body if at all?

Answers to these provide the basis for developing an approach to calculate the dose to organs, the effective dose equivalent to the body, and interpreting the effects of the dose.

D.1.1. Internal Dosimetry Methods

The methods for estimating organ dose from internal radionuclides have evolved since radioactive materials were discovered and used. Until 1979, ICRP Publication 2 provided the guidelines and methodology. In 1979, ICRP Publications 26 and 30 changed the basic approach to limiting radiation, and for internal radionuclides in particular. That approach currently remains the accepted approach in the United States for purposes of regulation. However, progress in all areas of radiation effects and the behavior of radionuclides in the body have produced more recent recommendations on a number of key elements in the process as presented in ICRP Publications 54, 60 and 66. As for any dynamic area of study, continued improvements in the understanding of plutonium's behavior in the body, improved methods for estimating body

content, and more accurate mathematical models for estimating intake and dose from body content will evolve.

D.1.1.1. ICRP Publication 2 Methods

The models of ICRP-2 assumed that a single organ could be considered the critical organ; that the organ retention could be represented by a single exponential term; that the physical characteristics, such as intake parameters, transfer functions, and tissue size and weight, could be represented by "Standard Man" data; that organs could be assumed to be spherical; and that scattered radiation could be ignored. In performing the dosimetry, it was assumed that the material was distributed uniformly throughout the organ and that the energy absorbed equaled the energy emitted. Doses were limited to a specified annual dose to the critical organ.

Intakes of radionuclides were controlled by limiting "Maximum Permissible Concentration" (MPC) values in air and water for workers so that the annual dose limit to the critical organ would not be exceeded. The annual limit on dose to the critical organ applied over a 50-year intake period so that the limit would not be exceeded even if a radionuclide were taken in continuously over 50 years. An associated limit, called the "Maximum Permissible Body Burden," was that amount of a material in the body that would not exceed the annual dose limit to the critical organ. The ICRP-2 method was in effect and adopted for the Palomares accident.

D.1.1.2. ICRP-30 Models and Methods

The ICRP changed its basic recommendations and revised the system of dose limitation in ICRP Publication 26 based on risk. This approach acknowledged the availability of sufficient information about the effects of radiation to estimate risk for fatal cancer from a unit dose equivalent in exposed people and in the risk of serious disease to offspring of exposed people. The basic recommendations addressed both stochastic effects and non-stochastic effects. For stochastic effects, such as cancer and hereditary effects, risks are assumed to be directly related to dose equivalent with no threshold, meaning that the probability of the effect occurring, rather than the severity, is related to the dose equivalent. The severity of non-stochastic effects, such as cataracts and erythema, varies with dose, usually above a threshold or minimum dose.

ICRP Publication 30 provided revised dosimetry models that assume organ retention is represented by one or more exponential expressions, the critical organ concept no longer applies, the dose in an organ must consider radiation emitted by other organs in the body, and the physical characteristics are represented by "Reference Man" data in ICRP Publication 23 (ICRP 1975). The model assumes that deposition in an organ is uniform, and that the total dose is averaged over the organ.

Under the revised system, dose equivalent limits are intended to prevent non-stochastic effects and to limit stochastic effects to acceptable levels. To meet this end, an annual occupational limit of 50 rem (0.5 Sv) to any organ was established (ICRP 1979). For stochastic effects, the limit on risk is the same whether the whole body is irradiated or organs are non-uniformly irradiated. This is accomplished by assigning organ weighting factors, w_t, that represent the ratio of the risk for the effect in an organ to the risk for whole body irradiation. The limit on risk to the whole body is then determined by summing the contributions for each irradiated organ and is given by:

$$\sum_{T} w_T H_{50,\,T} \leq 5\,\text{rem}\ (0.05\ \text{Sv})$$

where $w_t H_{50,T}$ is called the weighted committed dose equivalent or the committed effective dose equivalent (CEDE), and $H_{50,T}$, called the committed dose equivalent (CDE), is the total dose equivalent averaged over tissue (T) in the 50 years following intake and is limited to 50 rem (0.5 Sv). Table D-1 contains the organ weighting factors from ICRP-30.

The dosimetry model calculates the absorbed dose averaged over the organ mass during 50 years following intake. It considers each radiation type and applies a radiation weighting factor, sometimes called the quality factor, which has the following value:

Q=1 for beta particles, electrons and all electromagnetic radiation.

Q=10 for fission neutrons emitted in spontaneous fission and protons.

Q=20 for alpha particles from nuclear transformations, for heavy recoil particles, and for fission fragments.

Table D- 1. ICRP-30 Tissue weighting factors, w_T (ICRP 1979).

Tissue	Weighting Factor, w_T
Gonads	0.25
Red Marrow	0.12
Lung	0.12
Breast	0.15
Thyroid	0.03
Bone Surface	0.03
Remainder 0.06 for the organs with the five highest dose.	0.30

Additional modifying factors, not discussed here, that consider irradiation from other organs and radionuclides are used to calculate the final organ dose equivalent.

For inhaled radionuclides, the Task Group on Lung Dynamics developed a respiratory tract model, which uses the approach shown in Figure D-1. That approach considers three classes (D, W, and Y) of material based on retention in the deep or pulmonary section of the lung. The classification depends on a range of retention half-times: D < 10 days; 10 days < W < 100 days; and Y > 100 days. ICRP-30 contains metabolic data for certain chemical forms of the materials.

The model defines three regions of deposition: nasal-pharyngeal (N-P), tracheo-bronchial (T-B) and pulmonary (P). Fractions initially deposited in these regions are D_{N-P}, D_{T-B}, and D_P and are based on an aerosol particle size of 1 μm. As Figure D-1 indicates, each section is divided into compartments that are associated with clearance pathways and have an established clearance half-time T and fraction F for removal of material. Compartments a, c, and e represent direct transfer to body fluids, known as the transfer compartment, for further transfer to other organs or excretion. Compartment g represents indirect transfer to body fluids through lymph nodes. For Class Y material, only some material is transferred (in compartment i) to other bodily fluids. The remainder stays indefinitely in compartment j. Compartments b, d, f and h transfer material to the

		Class					
		D		W		Y	
Region	Compartment	T Day	F	T day	F	T day	F
N-P	a	0.01	0.5	0.01	0.1	0.01	0.01
(D_{N-P} = 0.25)	b	0.01	0.5	0.4	0.9	0.4	0.00
T-B	c	0.01	0.95	0.01	0.5	0.01	0.01
(D_{T-B} = 0.08)	d	0.2	0.05	0.2	0.5	0.2	0.99
	e	0.5	0.8	50	0.15	500	0.05
P	f	n.a.	n.a	1.0	0.4	1.0	0.4
(D_P = 0.25)	g	n.a.	n.a	50	0.4	500	0.4
	h	0.5	0.2	50	0.05	500	0.15
L	i	0.5	1.0	50	1.0	1000	0.9
	j	n.a.	n.a.	n.a.	n.a.		0.1

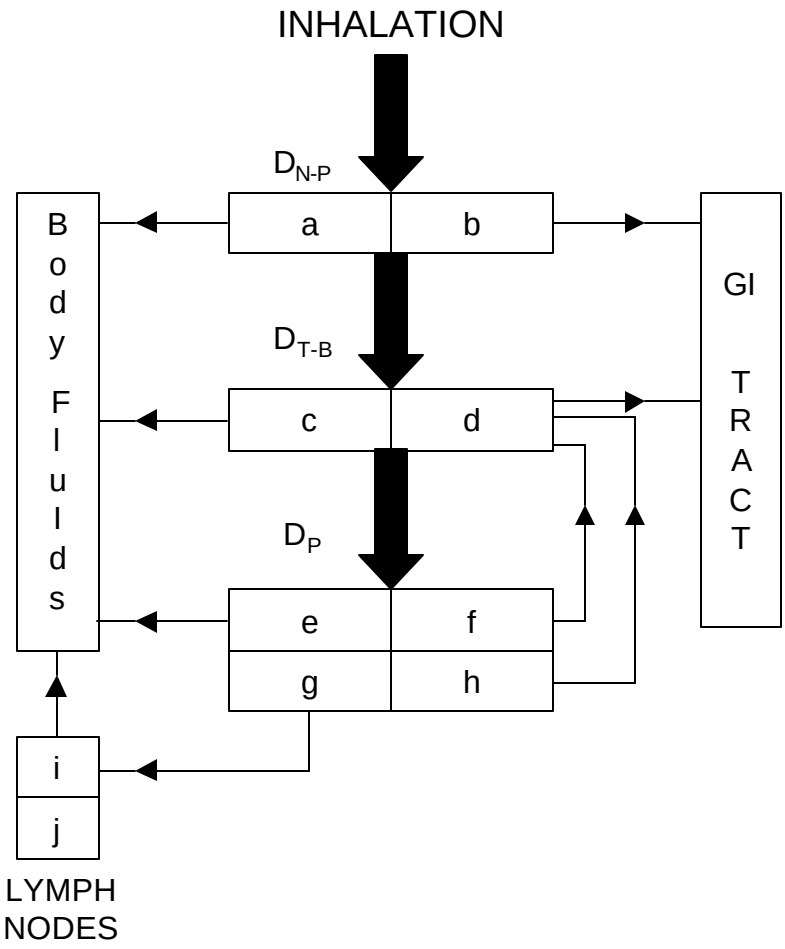

Figure D- 1. ICRP-30 Model of the respiratory tract (ICRP 1979).

gastro-intestinal tract (GI tract). Once a radionuclide reaches other organs, its behavior is then governed by the metabolic model.

The gastro-intestinal tract model is based on the fraction transferred from the GI tract to the systemic system (f_1). Since f_1 for Class Y plutonium is 0.00001, ingestion is not considered significant for evaluation of the Palomares responders and the GI tract will not be considered further.

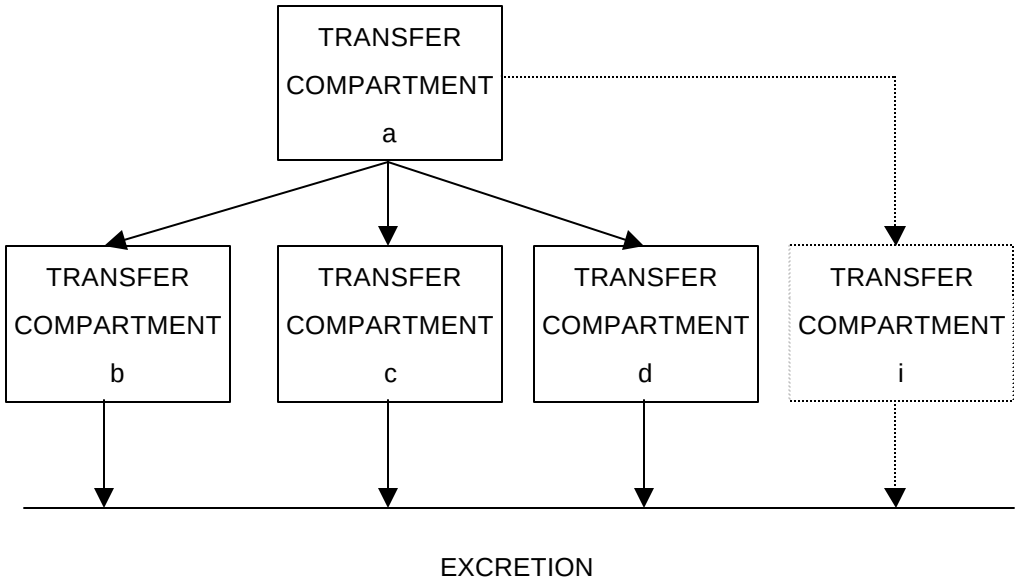

Figure D- 2. ICRP-30 Transfer Compartment Model (ICRP 1979).

Material that has been transferred to bodily fluids and other compartments of various tissues are indicated in Figure D-2, taken from ICRP-30. The time a material takes to transfer from the deposition site is represented by transfer compartment a. The clearance half-time for this compartment is 0.25 day unless stated otherwise. Each tissue that receives the radionuclide will have one or more compartments with an associated elimination rate. The model assumes that there is no feedback, or recycling, of a material to an original compartment. That means the model is a one-pass, or pass-through, model. Figure D-3 shows the ICRP-30 model for a Class Y plutonium aerosol.

Calculation of the committed dose equivalent (CDE) for a given organ is the sum of the product of two factors: U_s, the total number of transformations of the radionuclide in the source organ (S) over 50-years following intake, and SEE (T←S), the energy absorbed in the target tissue (T), modified by the quality factor, for each type of radiation emitted in S. ICRP tables of SEE values are available for estimating the committed dose equivalent for an organ.

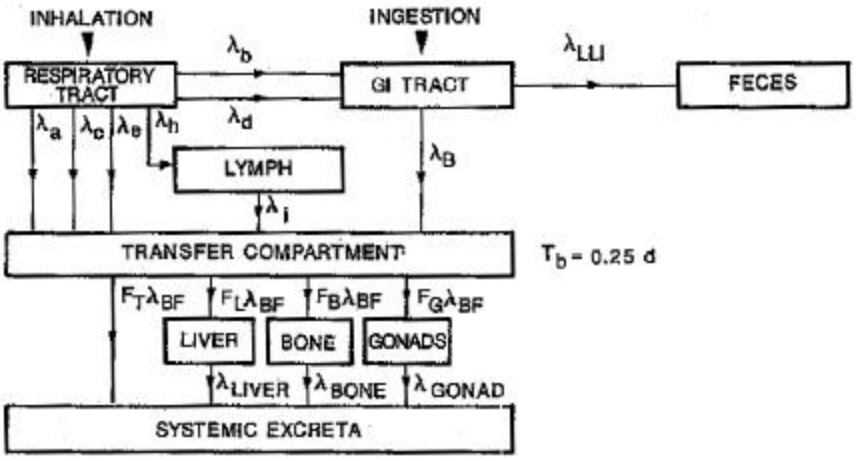

Figure D- 3. ICRP-30 Pu Metabolic Model (ICRP 1979).

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D.1.1.3. ICRP-60 and 66 Methods

Further refinement in the basic recommendations of the ICRP and in certain models have been achieved since the revisions of ICRP-26 and 30. Most notable is a revision of the Respiratory Tract Model by the Task Group on Lung Dynamics, approved by the ICRP and published in Publication 66 (ICRP 1994). That model represents an update to ICRP-30 that provides a broader scope, having been designed not only to evaluate secondary limits on intake of radionuclides by inhalation for a worker, but also to:

- Provide a realistic framework for modeling lung retention and excretion characteristics in an individual case, and the resulting lung and systemic organ doses, based on bioassay data;
- Take into account factors such as cigarette smoking and lung disease which influence lung particle retention;
- Enable knowledge of the dissolution and absorption behavior of specific materials to be used in the calculation of the lung dose, systemic absorption and excretion of the materials;
- Apply explicitly to age-dependent members of a population; and
- Calculate biologically meaningful doses in a manner that is consistent with the morphological, physiological, and radiobiological characteristics of the various tissues of the respiratory tract.

The ICRP-66 lung model consists of three parts:

- A particle deposition model,
- A particle transport model, and
- A particle absorption model.

The new lung model is fundamentally different from the lung model published in ICRP-30, which calculates only the average dose to the lungs. It accounts for the differences in

radiosensitivity of the respiratory tract tissues, and the wide range of doses they may receive, and calculates doses to the specific tissues in the respiratory tract.

The respiratory tract is represented by five regions (Figure D-4): the nasal and oral passageways termed the "extrathoracic" (ET) airways; three thoracic regions termed the Bronchial region (BB); the Bronchiolar region (bb), and the Alveolar-Interstitial region (AI, the gas exchange region); and the lymphatics associated with the extrathoracic (LN_{ET}) and thoracic airways (LN_{TH}). The model evaluates the risks of lung and other cancers by calculating the doses received by tissues in each of the regions, then summing and weighting those doses to obtain equivalent doses, and finally applying the tissue weighting factors in ICRP Publication 60 (ICRP 1991).

The new model accommodates calculating the intake of different individuals (adults and children), although that feature is not pertinent to this project. Intake depends on two factors: inhalability and breathing rate. Inhalability is the ratio of the concentration of particles or gases in air entering the respiratory tract to the concentration in ambient or surrounding air. Larger particles (20 µm and larger) have higher inertia and therefore are not inhaled as easily as smaller particles under most conditions. The breathing rate depends on age and physical activity. The model provides tables of reference values of breathing rates for men and women as well as children aged 15, 10, 5, and 1 year, and 3 months for different levels of activity. The reference values for adults were developed to simulate common activity levels in the workplace that combine periods of sitting and exercise. The "reference male worker" is assumed to spend 3% of an 8-hour work period sitting and 69% at "light exercise."

Deposition is provided for each of the five regions of the lung for the various categories of activity and breathing type – nose or mouth.

The model contains three clearance pathways: material in ET_1 clears by direct means such as nose blowing; in other regions clearance may be to GI tract and lymphs or absorption into blood. Once cleared, particle transport is represented by the model in Figure D-5 that shows 14 compartments with individual values of the particle transport rate constant. Absorption into blood is treated as a two-stage process involving dissociation into material that can be absorbed (called dissolution) and absorption into blood of soluble material and material dissociated from particles (called uptake). In addressing absorption, the model uses three material "Types": F (fast), M (moderate), and S (slow). These Types correspond to Classes D, W, and Y of ICRP-30.

The Types are characterized by the amount of deposit that enters the blood and an approximate half-life according to the following:

- Type F: 100% at 10 minutes.
- Type M: 10% at 10 minutes and 90% at 140 days.
- Type S: 0.1% at 10 minutes and 99.9% at 7000 days.

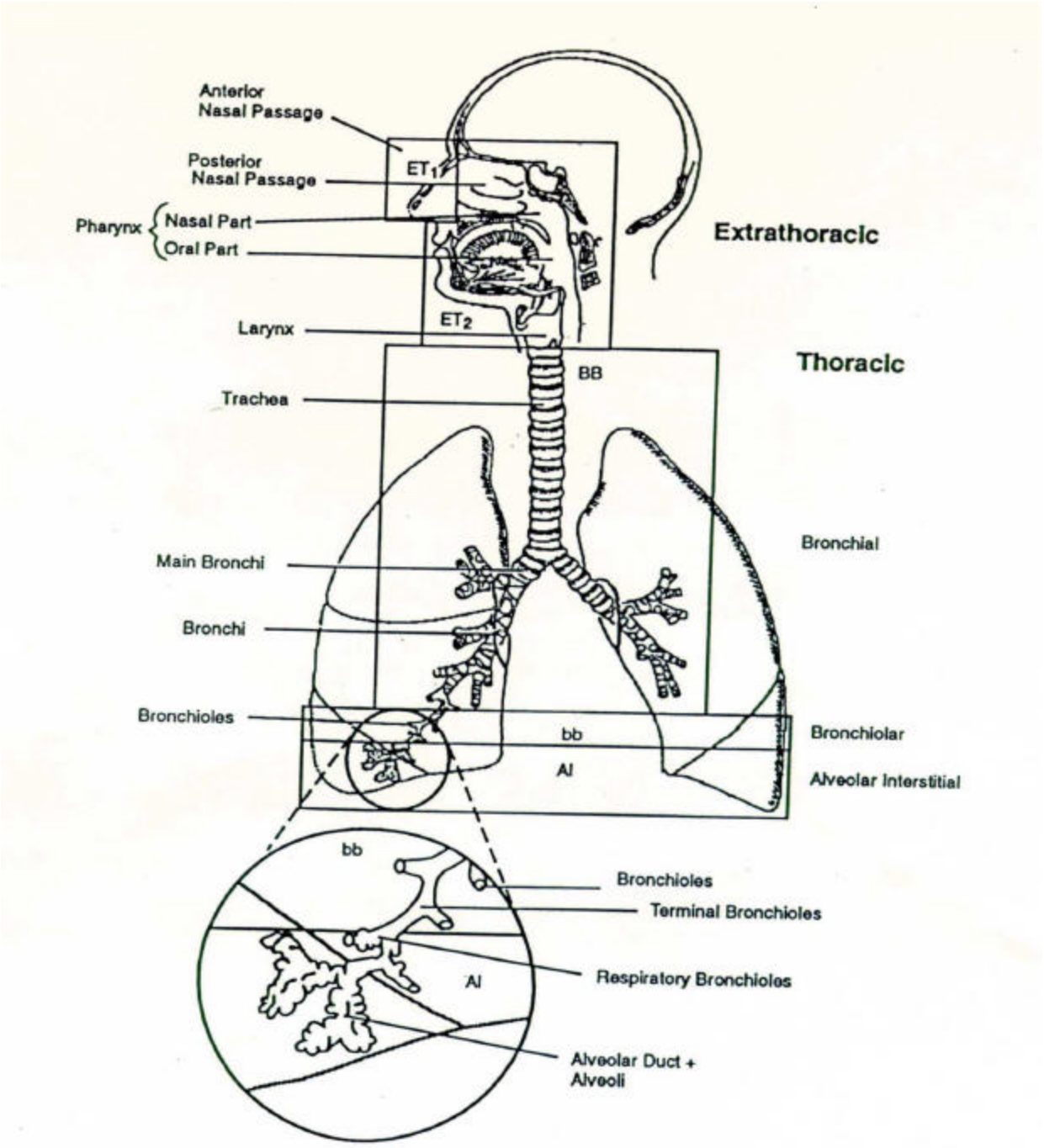

Figure D- 4. Anatomical Regions of the Respiratory Tract (ICRP 1994).

The dose to each region is determined according to ICRP's general approach of averaging the dose to target tissue in each region. Target cells in ET_1, ET_2, BB, and bb are calculated, and then modified by a risk apportionment factor that represents the relative sensitivity of the region to the whole organ. Finally, the ICRP tissue weighting factors are applied.

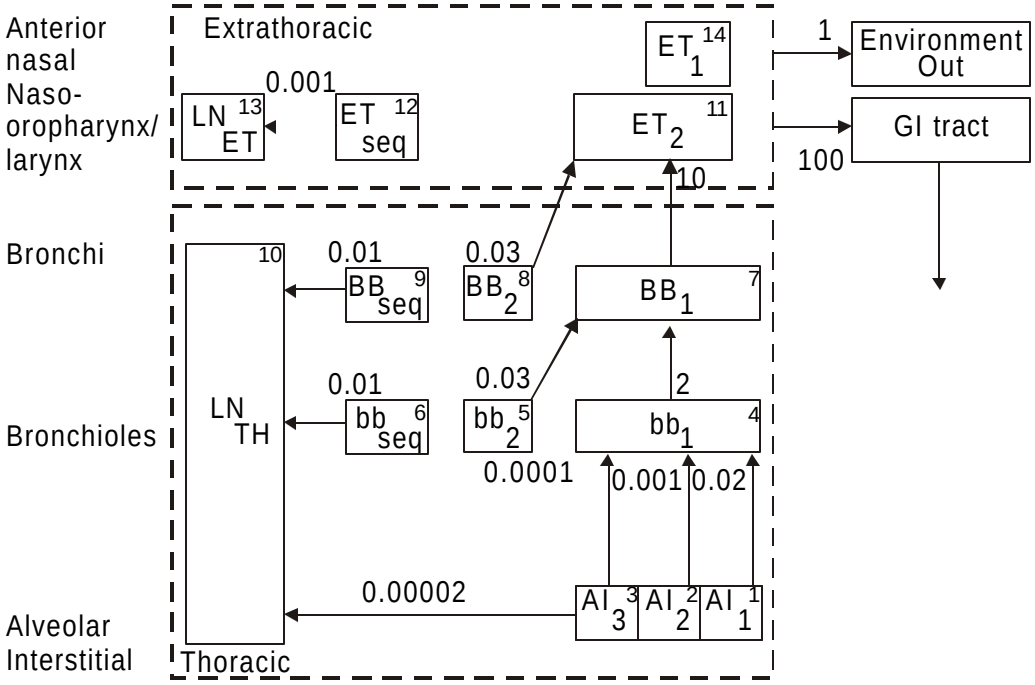

Figure D- 5. Compartment Model of ICRP-66 (ICRP 1994).

Assessment of intake presents one of the more difficult problems for estimating organ dose and the CEDE. Commonly applied methods include in-vitro bioassay of the amount of the material excreted, measurements of body content or organ content by external whole body counting, or for inhalation or ingestion, estimating the amount of material in the air or water using air or water samplers. Each method has its advantages and disadvantages. For this case, the in-vitro bioassay measurements of urine samples from 1966 and 1967 provided the best available method for assessing the intake based on a substantial amount of recorded urinary excretion results.

Organ or tissue weighting factors affect the calculation of committed effective dose equivalent from the effective dose equivalent for each organ or tissue. The ICRP's 1990 recommendations (ICRP 1991) provide weighting factors for a number of tissues that were part of the remainder in the 1979 recommendations of ICRP-26 (ICRP 1979). Table D-2 lists the tissue weighting factors of ICRP-60 as well as those of ICRP-26 for comparison. Substantial differences between the two sets of weighting factors include a reduction in the bone surface and breast factors by three times, a 67 percent increase in the thyroid factor, and assignment of factors for additional organs, including the skin of the whole body.

D.1.1.4. Effect of Respiratory Tract Model on Dose

The differences between the two ICRP models for the respiratory tract could be expected to produce differences in estimated doses. During development of the updated respiratory tract model, its performance was tested in detail to determine the affects of various parameters taken alone and in combination. Some examples of the performance of both systems provide useful information about likely differences in estimating both equivalent dose and effective dose equivalent.

Table D- 2. Tissue Weighting Factors (ICRP 1991).

	ICRP Recommendations	
Tissue or organ	1979	1990
Gonads	0.25	0.20
Red Marrow	0.12	0.12
Colon		0.12
Lung	0.12	0.12
Stomach		0.12
Bladder		0.05
Breast	0.15	0.05
Liver		0.05
Esophagus		0.05
Thyroid	0.03	0.05
Skin		0.01
Bone Surface	0.03	0.01
Remainder	30[1]	.05[2]

[1] A value of 0.06 is applicable to each of the five remaining organs or tissues receiving the highest equivalent doses.
[2] The remainder is composed of the following tissues or organs: adrenals, brain, small intestine, kidney, muscle, pancreas, spleen, thymus and uterus.

One such evaluation, reported by James (James 1994) compared the lung dose equivalent and effective dose for several categories of radionuclides, including insoluble alpha emitters, such as plutonium at Palomares. In those illustrations, James compared doses for intakes of 1 μm activity median aerodynamic diameter (AMAD) particles although ICRP recommends 5 μm AMAD for workers. For 1 μm AMAD, Type S (Class Y) ^{239}Pu, the ICRP-30 and ICRP-66 equivalent dose per unit intakes were 320 μSv/Bq and 84 μSv/Bq, respectively. The ICRP-66 equivalent dose was lower by about a factor of 3.8. For 5 μm AMAD particles, ICRP-66 estimated 50 μSv/Bq, or about 6 times lower. Calculating effective dose for the same conditions, ICRP-30 produced 60 μSv/Bq and ICRP-66 produced 16 μSv/Bq for 1 μm AMAD particles and 9.1 μSv/Bq for 5 μm AMAD particles, representing reductions of about 3.7 and 6.5, respectively. Thus, other factors being equal, the ICRP-66 respiratory tract model can produce equivalent doses that are roughly 3 to 6 times lower for the same intake than the ICRP-30 model. This difference, attributed to the modified model for lung deposition and clearance and revised tissue weighting factors – must be recognized in evaluating methods for this project.

D.1.1.5. Intake Assessment

Intake assessment presents one of the more difficult problems for estimating the dose in affected organs and the CEDE. Commonly applied methods include in-vitro bioassay of the amount of the material excreted, measurements of body content or organ content by external whole body counting, or for inhalation or ingestion, estimating the amount of material in the air or water using air or water samplers. Each method has it advantages and disadvantages. For the case at hand, in-vitro bioassay of urine samples provides the best available method for assessing the intake.

This problem is common to the models discussed above. At the present time, either or both models can assist in calculating an estimate of the intake from knowledge of in-vitro bioassay, whole body counting, or measurement of air concentrations. Assessment of intake using in-vitro bioassay is the primary method of interest in this case because urine sample results are available for those who responded.

The models discussed above provide mathematical expressions, supported by a body of reference data to determine the amount of a radionuclide that can be excreted. Special excretion functions have been derived and are recommended for specific materials (ICRP 1988). In general, the amount of a radionuclide excreted in urine per day is related to the amount of radioactivity in one or more systemic retention compartments and fractional transfer parameters from those compartments to urine or feces. For plutonium, two special models have been developed and are commonly used. These are the "Jones" model and the "Durbin" model.

The Jones model (Jones 1985; Strong and Jones 1989) describes how plutonium excretion in urine varies with time. The model is used with the standard intake models (respiratory tract, gastro-intestinal tract, and direct), and models the material leaving those models as going directly into the four Jones model compartments. The Jones model was originally developed to describe the excretion rate of plutonium following intravenous injection. However, it has been modified for use in estimating chronic and acute inhalation and ingestion exposures. The Jones model is described by the following expression:

$$E_u = \sum_{j=1}^{4} F_{jj} \exp(-k_{jj} t)$$

where E_u = urinary excretion rate of plutonium at time t, in pCi/d

F_{jj} = fraction of injected activity that excretes according to exponential term j, in pCi/d per pCi injected.

k_{jj} = rate constant for decrease of excretion for exponential term j, in d^{-1}.

t = time, d.

The Jones Model transfer parameters are provided in Table D-3.

A second model, known as the Durbin Plutonium Excretion Model (ICRP 1988) performs in a similar fashion to the Jones model. As with the Jones model, material leaving the intake models (respiratory tract, gastro-intestinal tract, and direct) is modeled as going directly to the Durbin

model excretion compartments. The Durbin model is characterized by five compartments and has the following form:

$$E_{u,t} = \sum_{j=1}^{5} F_{pj} \exp(-k_{pj} t)$$

where $E_{u,t}$ = urinary excretion rate of plutonium at time t, in pCi/d
F_{Pj} = fraction of injected activity that excretes according to exponential term j, in pCi/d per pCi injected.
k_{Pj} = rate constant for decrease of excretion for exponential term j, in d^{-1}.
t = time, d.

Table D- 3. Jones Model Transfer Parameters (Strong and Jones 1989).

Compartment	Rate Constant, d^{-1}	Fractional Excretion Rate by Compartment, d^{-1}
1	5.58×10^{-1}	4.75×10^{-3}
2	4.42×10^{-2}	2.39×10^{-4}
3	3.80×10^{-3}	8.55×10^{-5}
4	2.84×10^{-5}	1.42×10^{-5}

The Durbin Model parameters are given in Table D-4.

Table D- 4. Durbin Model Transfer Parameters (ICRP 1988).

	Urine Excretion		Fecal Excretion	
Excretion Compartment	Fractional Rate, d^{-1}	Rate Constant, d^{-1}	Fractional Rate, d^{-1}	Rate Constant, d^{-1}
1	4.1×10^{-3}	5.78×10^{-1}	6.0×10^{-3}	3.47×10^{-1}
2	1.2×10^{-3}	1.26×10^{-1}	1.6×10^{-3}	1.05×10^{-1}
3	1.3×10^{-4}	1.65×10^{-2}	1.2×10^{-4}	1.24×10^{-2}
4	3.0×10^{-5}	2.31×10^{-3}	2.0×10^{-5}	1.82×10^{-3}
5	1.2×10^{-5}	1.73×10^{-4}	1.2×10^{-5}	1.73×10^{-4}

D.1.2. Description of Computer Models

Many computer programs have been developed and are available for performing the calculations of the models discussed above. Currently more programs implement the ICRP-30 system than the ICRP-66 model. This comes as no surprise since the ICRP-30 system remains the current system for regulation of the doses from radioactive materials in the United States. However, one

objective for this project included the evaluation and recommendation or the best calculation method. Since ICRP provisions are usually adopted in the U.S., investigating at least one software program that implemented the most recent approach seemed reasonable. After some review of the available software, three programs were selected for further study – the Radiological Bioassay and Dosimetry Program (RBD) as modified for the Air Force, Code for Internal Dosimetry (CINDY), and Lung Dose Evaluation Program (LUDEP ver 2.06). This section provides a general description of each program and some salient features. Later sections discuss the approach and results of testing the methods for this report.

D.1.2.1. Radiological Bioassay and Dosimetry Program (RBD)

The RBD software package (ORNL 1993) was developed for the U.S. Army and modified for the U.S. Air Force (Version RBD/AF) by Oak Ridge National Laboratory to demonstrate compliance with Federal radiation protection guidance.

The algorithms within the RBD and RBD/AF programs are the same. The RBD/AF program contains the following changes and enhancements to RBD:

- Increased number of organs for which committed dose can be calculated.
- Replacement of the "department identifier" input with "base code."
- Addition of an identifier field for gender of individual assayed.
- The display of the allowable lifetime intake (ALI) for a radionuclide was changed to the calculation of the fraction of the ALI received by the individual.
- The format of the committed effective dose report was revised to reflect Air Force reporting requirements.

The RBD model implements the ICRP-30 lung model and a urinary excretion model adapted from Leggett and Eckerman (Eckerman 1987). The software package was designed to run interactively on an IBM-compatible personal computer. RBD consists of a data base module to manage bioassay data and a computational module that incorporates algorithms for estimating radionuclide intakes from either acute or chronic exposures. These calculated results are based on the measurement of the worker's rate of excretion of the radionuclide or the retained activity in the body using the approach contained in ICRP-30. RBD estimates an intake using a separate file for each radionuclide containing parametric representations of the retention and excretion functions. These files also contain dose-per-unit intake coefficients used to compute the committed dose equivalent. Computed results derived from bioassay data (estimates of intake and committed dose equivalent) are stored in separate databases, and the bioassay measurements used to compute a given result can be identified.

D.1.2.2. Code for Internal Dosimetry (CINDY)

The Code for Internal Dosimetry (CINDY) (v.1.4) is a menu-driven interactive computer program that was developed to address the Department of Energy Order 5480.11 and the Nuclear Regulatory Commission's Standards for Protection Against Radiation (10 CFR Part 20). The CINDY software package (PNL 1992) was developed by Pacific Northwest National Laboratory

to provide the capabilities to calculate organ dose equivalents and effective dose equivalents using the approach contained in ICRP-30.

CINDY supports calculation of organ dose equivalents, effective dose equivalents and committed effective dose equivalents; interpretation of bioassay data; and evaluation of committed and calendar-year doses from intake or bioassay measurement data.

For inhalation exposures, CINDY uses the ICRP-30 lung model and approach for calculation of organ dose equivalents and effective dose equivalents, which is described in the previous discussion of the RBD/AF model. Biokinetic models are used to estimate intakes based on bioassay data. For intake and urinary excretion of plutonium, the Jones and Durbin models are both available, as in the LUDEP program.

The metabolic and excretion models available in CINDY are:

- ICRP-30 Lung model
- ICRP-30 Gastrointestinal (GI) model
- ICRP-30 General systemic model
- Jones and Durbin Plutonium Excretion Models

CINDY uses the quality factors and tissue or organ weighting factors published in ICRP-26.

D.1.2.3. Lung Dose Evaluation Program (LUDEP ver 2.06)

The Lung Dose Evaluation Program (LUDEP) (v. 2.0) is a personal computer program for calculating internal doses using the ICRP-66 respiratory tract model. The LUDEP program runs on an IBM-compatible personal computer in a DOS or Windows environment.

LUDEP was designed initially for two applications: (1) to help the ICRP Task Group examine the ICRP-66 lung model (during its proposal stage) in detail, by testing the predictions of deposition, clearance, and retention against experimental data, and by determining the model's implications for doses to the respiratory tract; and (2) to test the practicality of implementing the model.

LUDEP calculates doses to all body organs. It includes a bioassay module that allows calculations of excreted activity and retention in the lungs, other organs, and whole body.

The model contains several built-in databases, including radionuclide decay data from Oak Ridge National Laboratory and from ICRP-38; biokinetic models from ICRP-30; and bioassay functions from ICRP-54. ICRP data are generally used as the default values within the model, although the user is given the option to input case-specific parameters.

The ICRP-66 model that is implemented in LUDEP 2.06 was designed to realistically represent the deposition of inhaled particles in the respiratory tract, the subsequent biokinetic behavior of inhaled radionuclides, and the doses delivered to the respiratory tract.

The LUDEP code allows the user to input the particle size of an airborne concentration or intake. LUDEP allows the user to input the characteristic aerosol AMAD (or activity median thermodynamic diameter - AMTD) for a given airborne concentration or intake. The code contains a biokinetic model and organ dosimetry.

The metabolic and excretion models available in LUDEP are:

- ICRP-66 Lung model
- ICRP-30 Gastrointestinal (GI) model
- ICRP-30 General systemic model
- ICRP-30 Plutonium biokinetic model
- ICRP-54 Durbin Plutonium excretion model
- Jones Plutonium Excretion Model

LUDEP allows users to choose either the quality factors or organ/tissue weighting factors published in ICRP-26, or the radiation weighting factors and organ/tissue weighting factors published in ICRP-60. The bone dosimetry is a recycling model with initial uptake onto bone surfaces, transfer from surface to bone volume, and recycling from bone and other tissues to plasma.

D.2. MODEL TESTING AND COMPARISON

Selection of a computer program to support intake and dose assessment required a set of criteria to guide the testing and evaluation process. Criteria based on the ability to perform credible assessments from the data available were a prime objective. That is, the computer tool should demonstrate an ability to produce credible results with the data from 1966 and 1967. Considering all of this, our approach recognized a need to be able to estimate plutonium intakes from urine bioassay data, to calculate committed effective dose equivalents from those intakes, and to readily accommodate the available data without major conversion efforts.

D.2.1. Performance Criteria

The major task for this project involved an attempt to calculate intake from the urine bioassay information available. Other data from the response and cleanup operation simply do not exist to support intake estimates from air sampling or other means. Studies performed by JEN for decades following that effort offer some data for developing independent intake and dose estimates using environmental data. Nevertheless, the methods for estimating intake of plutonium by inhalation from the urinary data must be evaluated for performance and ease of use. Performing the intake assessment using this approach acknowledges that sizeable uncertainties can be expected because the assessments assume the characteristics of reference man rather than the specific characteristics of the individual involved.

Calculation of the organ dose equivalents and committed effective dose equivalent for each responder based on the intake must also meet accepted performance.

Finally, the selected method must have data requirements that can be met using the available data with as few conversions as possible.

These three criteria formed the primary basis for evaluating the performance of the three computer programs.

Ease of use provided a secondary factor for evaluating each of the three programs. This factor concentrated primarily on requirements for setting up input data sets and producing output data and reports that could be manipulated easily for a number of purposes – comparing the results of

testing the three methods, evaluating trends in intakes and doses for selected groups of subjects, data plotting and report preparation.

D.2.1.1. Performance on Intake Estimates

Review of the documentation for each of the three methods indicated that all employed generally accepted excretion models, i.e., either the ICRP-54 Durbin model, or the Jones model, or both. Implementation of calculation procedures for those excretion models seemed similar in that the approaches involved solutions to differential equations to determine the excretion patterns from estimated intakes.

The common approach among the models involved:

- calculating an initial estimate of intake from urine results,
- calculation of the expected urinary output rate (pCi/d or Bq/d),
- comparison of calculated urinary excretion to measured excretion using a form of statistical goodness of fit, and
- iteration until a selected calculation error was achieved.

The three methods were initially tested with an assumed excretion of 0.1 Bq/day (27 pCi/day) excretion rate at a series of sampling times after acute inhalation intake over one year. That is, for selected days, the urinary output of Class Y (Type S) ^{239}Pu was set at 0.1 Bq/day. The results of that test are shown in Figure D-6. In those tests, LUDEP provided estimates that were typically about 2 times higher than RBD estimates and about 3.5 times higher than CINDY estimates. The committed effective dose equivalents associated with those intakes are shown in Figure D-7.

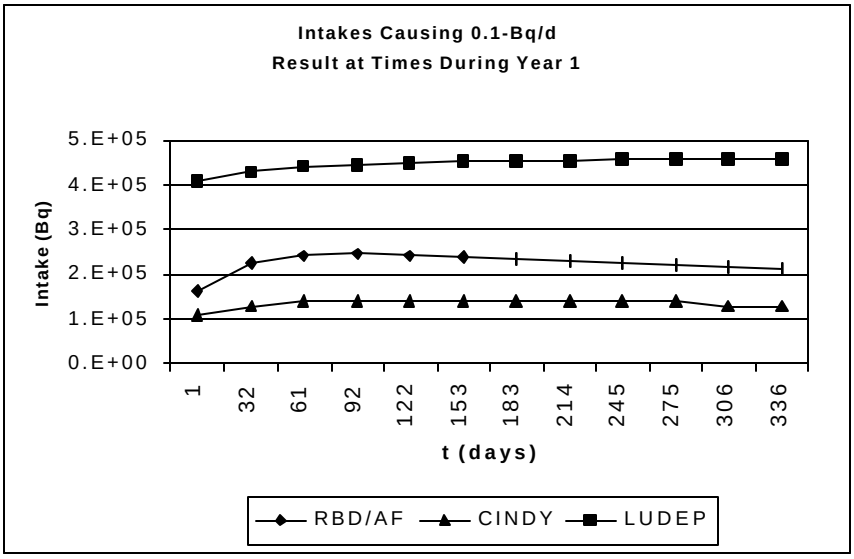

Figure D- 6. Intake estimates of the three methods.

Two of the three models (CINDY and LUDEP) offered options for weighting the measured results in performing the estimate. RBD/AF applied weighting based only on the relative contribution of multiple bioassay methods, e.g., results from urine bioassay and whole body counting.

CINDY's options include:

- Unweighted least squares: The weighting factors are assumed constant and equal, implying that the variance is independent of the magnitude of the measurement.
- Ratio of the means: The weighting factors are assumed inversely proportional to the expected value (as defined by the unit intake function). This assumption implies that the variance is proportional to the magnitude of the expected value.
- Average of the slopes: The weighting factors are assumed inversely proportional to the square of the expected value, implying that the variance is proportional to the square of the expected value.
- User-defined weights: The user supplies the estimate of the variance for each measurement value. The weighting factors are taken to be the inverse of the supplied variance.

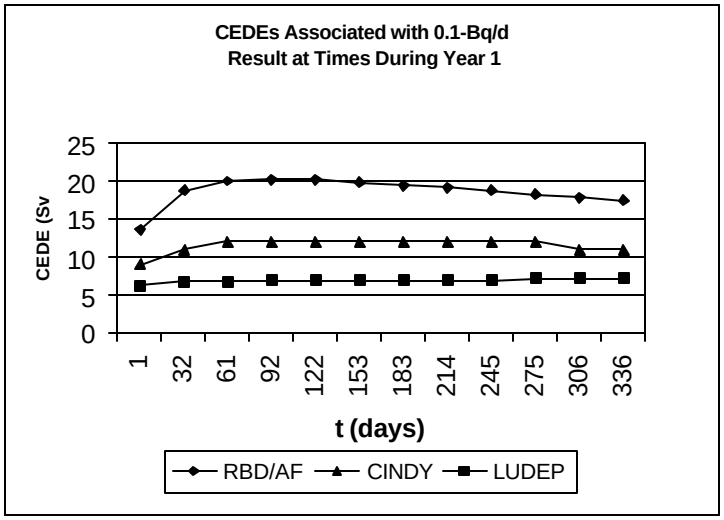

Figure D- 7. Estimated CEDE for three methods.

LUDEP offers the following options:

- Uniform absolute errors: The uncertainty values are a constant value, K.
- Uniform relative errors: Each uncertainty value is a constant proportion of the data point.
- Square root errors: Each uncertainty value is a constant multiple of the square root of the corresponding data point.
- Errors included in data set: The values of the uncertainties in the data, if known, are used.
- Logarithmic errors: Assumes the measured values fall about the true value with a log-normal distribution.

In comparing the approaches available in the two models, CINDY's "unweighted least squares", "ratio-of-the-means", "average-of-the-slopes", and "user-defined weights" methods seem to be roughly similar to LUDEP's methods using "uniform-absolute errors", "uniform-relative errors", "square-root errors", and "errors included in the data set." This conclusion results from evaluation of the discussion on weighting in the CINDY user guide (PNL 1992), summarized below.

Methods for comparing the estimated values with the measured values are based on the basic formula for weighted least-squares regression of a linear relationship with zero intercept as follows:

$$I = \frac{\sum_{i=1}^{n} w_i R_i X_i}{\sum_{i=1}^{n} w_i R_i^2} \qquad (1)$$

where I = estimated intake (pCi for acute intakes and pCi/d for chronic intakes)

w_i = least-squares regression weighting factor.

X_i = bioassay measurement for the ith data point (pCi/d for excretion and pCi for retention).

R_i = fractional retention or excretion estimate.

n = number of bioassay measurement points.

In CINDY, the four methods for intake estimation relate to four methods for defining the weighting factor, w_i. Ideally, the weighting should involve the variance of the measurement value (Bevington 1969). Each of the four methods, therefore, involves a particular assumption about the estimation of the variance.

In general, the intake estimate from the "user-defined weights" method is preferred when the input weighing factors represent good estimates of the variance of the measurement. Alternatively, the "ratio-of-the-means" intake estimate is probably the best estimate because the weighting is based on an estimate of the variance as proportional to estimated bioassay result. This method generally gives better "eyeball" fit to the bioassay data (PNL 1992).

The unweighted least-squares regression analysis is expressed by the following equation:

$$I = \frac{\sum_{i=1}^{n} X_i R_i}{\sum_{i=1}^{n} R_i^2} \qquad (2)$$

where terms are as previously defined. This method may be used when all measurement values are expected to have similar accuracy and all are significantly above the detection limits of the measurement method. This method could also be referred to as "uniform weighting" because all weights, w_i, are assumed equal in derivation of Equation 2 from Equation 1.

The "ratio-of-the-means" method is based on the assumption that the variance of the expected value is proportional to the magnitude of the expected value. The weights are expressed as follows:

$$w_i = \frac{1}{kIR_i} \tag{3}$$

where k is a constant of proportionality. Substitution of Equation 3 into Equation 1 results in the following expression for the intake estimate:

$$I = \frac{\sum_{i=1}^{n} X_i}{\sum_{i=1}^{n} R_i} \tag{4}$$

As can be seen from this expression, the intake estimate is just the ratio of the sum of the measured values to the sum of the unit intake function values. This is equivalent to the ratio of the means of the measured values and the unit intake function values (proportional to the expected values), hence, the name "ratio-of-the-means" method. Note also that from Equation 4, the sum of the measured values is equal to the sum of the expected values:

$$\sum_{i=1}^{n} X_i = \sum_{i=1}^{n} IR_i \tag{5}$$

This method is appropriate when the variance of the measurement is expected to be proportional to the measured value.

The average-of-the-slopes method is derived from Equation 1 by defining the weights as inversely proportional to the square of the unit intake function values:

$$w_i = \frac{1}{kI^2R_i^2} \tag{6}$$

The resulting expression for the intake estimate is as follows:

$$I = \frac{\sum_{i=1}^{n} \frac{X_i}{R_i}}{n} \tag{7}$$

This expression gives the average of the ratios of measurement value to unit intake function value, which is equivalent to the average of the slopes of the equation

$$X_i = IR_i \tag{8}$$

This method is appropriate when the variance of the measurement is expected to be proportional to the square of the expected value.

The user has the option of identifying the variance for each measurement data point. The fourth method (user-defined weights) uses this statistical parameter as an inverse weight in Equation 1:

$$w_i = \frac{1}{V_i} \quad (9)$$

where V_i is the user-supplied statistical parameter value for bioassay measurement i. This method allows the user to implement almost any weighting method desired based on predetermined weights. In evaluating the intake estimate using this method, only the data points having a defined value for V_i are used in the calculation.

As an example of the use of the "user-defined weights" method, consider a set of bioassay data values that includes an estimate of the standard deviation of the measurement value. The user-defined weights method can be used to provide an intake estimate based on the variance of the measurement values. To perform the analysis, the reported standard deviations are squared to provide the values for the weights to be entered into the CINDY program. This results from the assumption that the variance of the measurement is represented by the square of the standard deviation of the measurement. The code will use the inverses of the squared values as weights in Equation 1 to give an estimate of the intake with variance weighting.

As noted above, selection of the weighting method and any factors are important for reasonable results.

A number of cases were developed for testing the performance on estimating intakes. The primary data used were derived from the group of High 26 individuals from the Palomares follow-up. These were the only cases of data available with multiple bioassay measurements taken over an extended period – 12 to 18 months from the time of the accident. Unfortunately even those data raised questions about the actual dates of sampling and exposure, the reliability of results and other matters. Significant concerns arose from the use of gross alpha counting of initial samples and the possibility of contamination of samples collected on site (See Section 2 and Appendix B).

Using the bioassay data for two individuals who each had multiple samples taken, intakes and associated CEDEs were estimated by LUDEP, CINDY, and RBD/AF. The results indicated the estimated intakes were highest using LUDEP, lowest using CINDY, and intermediate using RBD/AF. The 50-year CEDEs were highest using RBD/AF, while the other two models provided lower results—in one case, LUDEP's CEDE was slightly lower than that predicted by CINDY, with the order reversed in the other case. The greatest difference in predicted CEDE was a factor of 2.2.

Using a subset of the bioassay results (all individuals with sample results greater than 10 pCi/sample from the initial spreadsheet provided by the Air Force), CEDEs were estimated by RBD/AF, CINDY, and LUDEP. As in the previously described case, RBD/AF generally predicted higher results, while those of CINDY and LUDEP were more similar.

The bioassay results for the "High 26" were modeled using CINDY and LUDEP to determine intakes and CEDEs. When CINDY doses were estimated using the "ratio-of-the-means" method, the CINDY CEDEs were higher than those predicted by LUDEP by an average factor of 13.5. When the "user-defined weights" method was used in CINDY, the CEDEs exceeded those predicted by LUDEP by an average factor of 1.5.

For CINDY and LUDEP, the estimated errors from counting, as reported on the data forms, or recalculated from the raw data on the forms, were used to calculate the statistical variance, which

was used as the input value in the "user-defined weights" option for CINDY; the counting error itself was used in the "errors included in data set" option for LUDEP. The estimated counting errors involved some inconsistency – they were reported at 95% confidence level for gross alpha results and at the 68% confidence level for alpha spectrometry; this difference was taken into account in calculating the variance used in the CINDY "user-defined weights" option. Often, the later results were reported as No Detectable Activity. In that case, a value of 0.009 pCi/day was assumed for gross alpha results, and a value of 0.003 pCi/day was assumed for alpha spectrometry results. The errors in those were set at 25% of the value; which may be somewhat low for the level of activity.

Using both the CINDY and LUDEP models, the sample data sets for the "High 26" were input to estimate CEDEs for each individual, using first all the samples, then excluding those that were analyzed by gross alpha, which would correspond with the early samples taken onsite. The results show that the CEDEs are generally lower when gross alpha results are excluded, averaging a 24% or 62% decrease in CINDY results (depending on weighting factor used—see next paragraph) and a 6% decrease in LUDEP results. This difference between models may be due to a noted tendency of LUDEP to weight sample results for longer times after exposure more strongly in calculations using multiple bioassay data points.

When gross alpha data were included in the CINDY model runs, the CEDE using the "ratio-of-the-means" method exceeded the CEDE using the "user-defined weights" method by an average factor of 13. The CEDE from the "user-defined weights" method exceeded the CEDE from the "ratio-of-the-means" method in only 2 of the 26 cases. When gross alpha data were excluded, the CEDE from the "ratio-of-the-means" method exceeded the CEDE from the "user-defined weights" method by an average factor of 3.4; in 3 cases the CEDE from the "user-defined weights" method exceeded the CEDE from the ratio-of-the-means" method.

In general, from other tests, the "user-defined weights" estimates tended to apply more significance to measurements taken at longer elapsed times from exposure. Coincidentally, those values were generally much lower than the early measurements and had much lower absolute values for the variance, which was estimated from the counting error.

For LUDEP, similar comparisons of the performance of the assumed errors options revealed reasonable agreement among results from the "uniform-absolute errors", the "uniform-relative errors", the "square-root errors" and the "errors included in the data set" options when applied to the actual urine results of three of the High 26 Cases Group. Those agreements were achieved for reasonable values of K (0.25 to 1), and showed agreement within about 50%, which seems acceptable considering the nature of the data. The logarithmic errors option produced estimates of intake that were 3 to 4 times higher than the other methods.

For CINDY, the "user-defined weights" method also seemed to attribute greater significance to lower values of results, yielding lower values of intake. In effect, the approach seemed to ignore other measured values. After multiple attempts to better characterize CINDY performance and consultation with its developers (Traub 2000), we concluded that the uncertainty in the estimated errors themselves contributed to this performance, and the "user-defined weights" method was no longer used. The "ratio-of-the-means" method, recommended by the CINDY user manual (PNL 1992), showed reasonable performance and was selected as the method to be used.

When other factors were held equal, intakes estimated by CINDY (using the "ratio-of-the-means" weighting method) and LUDEP (using the "errors included in the data set" option)

agreed to within a factor of two for the majority of the High 26 Cases Group. Given the variability of the data, the agreement was deemed reasonable and the performance acceptable for the type of assessment performed.

D.2.1.2. Performance on Dose Calculations

The performance evaluation tested conversion of intakes into committed dose equivalent in organs or tissues and calculation of committed effective dose equivalents with RBD/AF, CINDY and LUDEP. Testing the dose performance involved two separate efforts: basic assessments using assumed intakes, and assessments of selected cases from the High 26 Cases Group.

The basic assessment test consisted of assessments of the same set of Palomares data derived from the first 29 entries in the data listing (see Appendix B) provided by the Air Force. These data consisted of single urine measurements (generally of 10 pCi/day or more), collected at the accident site during the accident response effort. RBD, CINDY, and LUDEP calculated intakes and doses for each of the 29 cases. Committed effective dose estimates from the three programs varied by no more than a factor of about two from the highest dose to the lowest dose estimate for each case, with RBD/AF generally giving the highest estimated CEDE; LUDEP yielding the lowest; and CINDY providing intermediate dose estimates. That LUDEP produced the lowest doses seems consistent with the findings about its performance discussed above.

The second part of the testing involved actual test cases from two members of the High 26 Cases Group. Those cases had several urine measurements taken on site and during the follow-up period. RBD/AF, CINDY, and LUDEP provided estimates of the intake and dose for these two cases. These cases were calculated with several variations involving exclusion of selected urinary measurements for reasons, such as suspected contamination, possible chemical recovery issues, results below the detection limit, or simply to evaluate the behavior of the programs. The results of these tests confirmed the tendency of the methods to favor urine results with lower values, taken at long times after exposure. Generally, the CEDEs were highest for RBD/AF, lowest for LUDEP, and intermediate for CINDY. Again, results differed by no more than a factor of two. That performance seems acceptable.

Finally, CINDY and LUDEP were tested further with the entire High 26 Cases Group. In tests paralleling the intake assessments, CEDEs were also estimated with and without gross alpha results. LUDEP provided estimates that were about 30% lower than CINDY when gross alpha results were excluded, and from about 30% to 90% lower than CINDY when all urine measurements were included. Considering the nature of the data, the results are acceptable.

D.2.1.3. Ability to Satisfy Data Requirements

Parameters required for calculating estimates of intake from urine bioassay and the associated dose equivalents satisfy the model selected to perform the task. Computer software that implements the models establishes unique processes for satisfying the data input needs. The three computer methods were evaluated for the compatibility with available urine bioassay data. Primary parameters included the date of exposure, date of sample, radionuclide, type of exposure, pathway, particle characteristics, lung type or class, results and units, and sample volume, among others. The requirements of each program are discussed and compatibility with the available data assessed.

RBD

Data items and that may require assumptions to achieve compatibility include:

- **Date** – Since the Palomares data reflect exposure due to an incident, rather than a series of routine monitoring measurements, the date of the exposure incident is required. In some cases, this will have to be estimated based on the data on each dose data card, such as when a range is presented. In some cases, the date of exposure and date of sampling recorded on the dose data cards are the same. Unless adjusted based on additional information or other reasonable assumptions, this will result in an error during model execution.
- **Time** – The time of exposure does not affect the execution of the model if it is left blank.
- **Nuclide** – Data for ^{239}Pu are included in the files of the model.
- **Pathway** – As in the previous studies, inhalation exposure only can be assumed.
- **AMAD** – The default value of 1 μm can be used; range is 0.2 to 10 μm.
- **Class** – For inhalation, ^{239}Pu can be either Class W or Class Y. If it is assumed that all ^{239}Pu is in the form of PuO_2, then Class Y should be assumed, per ICRP-30.
- **Measurement date** – In some cases, this must be assumed due to incomplete data on the dose data cards.
- **Measurement time** – The time of measurement does not affect the execution of the model if it is left blank.
- **Result and Units** – The results on the dose data cards must be converted to units that are accepted by the model. For urinalysis, the options are dpm/mL, dpm/day, dpm/sample, dpm/L, μg/mL, Bq/L, Bq/day.
- **MDA** – The minimum detectable amount does not appear to be generally available on the dose data cards. A value could be estimated. The model will accept a zero value in this field.
- **Volume** – Sample volume is required if results are input in units of dpm/sample; otherwise, it can be left blank.
- **Volume/day** – The urinary volume per day is required for execution. The default is 1400 mL; the existing Palomares reports state that a value of 1200 mL was used as a default.

Overall, data are sufficiently available or can be reasonably estimated to run the RBD/AF model using the Palomares internal dose data. However, the nature of the available data could result in potentially large relative errors in time from exposure to sampling, which could have a significant impact on the validity of any resulting conclusions as to the intake and committed effective dose of a particular individual. It is however, reasonable to assume that these errors will average out over the large data set available, leading to conclusions that are more supportable for the exposure cohort as a whole.

Other model specific parameters are available as defaults appropriate for the model within the program and supporting data files. These seem reasonable or can be readily modified.

CINDY

Most data items required to perform the calculations are available and compatible. Those data items that may require assumptions to achieve compatibility include:

- **Excretion period** – Set to 24 hours if not specified otherwise.
- **Intake mode -** Acute inhalation is assumed; can be changed.
- **Date and time of intake** – Based on data reported on bioassay cards. Time set to 12:00 PM since no times were reported, however the impact is unimportant for the radionuclide involved.
- **Particle size** – 1 ìm assumed.

Overall, data are sufficiently available or can be reasonably estimated to run the CINDY model using the Palomares internal dose data. However, the nature of the available data could result in potentially large relative errors in time from exposure to sampling, which could have a significant impact on the validity of any resulting conclusions as to the intake and committed effective dose of a particular individual. It is however, reasonable to assume that these errors will average out over the large data set available, leading to conclusions that are more supportable for the exposure cohort as a whole.

LUDEP

Most data items required to perform the calculations are available and compatible. Those data items that may require assumptions to achieve compatibility include:

- **Intake -** Acute intake by the inhalation pathway can be assumed.
- **AMAD** – A value of 1 ìm can be assumed.
- **Absorption Type** – This factor introduced in ICRP-66 as F, M, or S for default absorption values corresponding to fast, medium, or slow absorption. Type S, which corresponds to the Class Y designation of PuO_2, can be assumed.
- **Time after intake (days) -** In some cases, this must be assumed due to incomplete data on the dose data cards.

Overall, data are sufficiently available or can be reasonably estimated to run the LUDEP model using the Palomares internal dose data. However, as with the programs, the nature of the available data could result in potentially large relative errors in time from exposure to sampling, which could have a significant impact on the validity of any resulting conclusions as to the intake and committed effective dose of a particular individual. It is however, reasonable to assume that these errors will average out over the large data set available, leading to conclusions that are more supportable for the exposure cohort as a whole.

The three programs provide adequate data compatibility. LUDEP uses SI units of becquerels (Bq) for radioactivity, and sieverts (Sv) for dose equivalent. However, conversion of units from picocuries per day (pCi/d) to becquerels per day (Bq/d) can be easily accommodated.

D.2.1.4. Ease of Use

With over 1,500 individual cases potentially requiring assessment, data input, result output and other manipulations can impact efficiency. Each program was assessed for features of convenience or difficulty that could impact effectiveness.

RBD/AF

Input features of RBD/AF include:

A data input screen for bioassay data with the choices for selectable entries for: gender, base code, assay, reason, nuclide, pathway, AMAD, class, in-vitro assay (measurement date, measurement time), result (unit – for urine, units can be dpm/mL, dpm/day, dpm/sample, dpm/L, ìg/mL, Bq/L, Bq/day), MDA, volume, and volume/day.

The program stores the data in files describing sets of cases, facilities or other convenient means. This allows data preparation, calculation, and reporting to be conducted as separate activities.

Output features of RBD/AF include:

Estimated intake (in Bq and ìCi), estimated intake as a percent of the ALI, ALI (in Bq), committed dose equivalent (in ìSv and mrem, by organ/tissue), and effective dose (in ìSv and mrem). An optional graph of excretion rate vs. time can also be generated.

The summary output report presents, by individual committed dose equivalent (in mrem, by organ/tissue), effective dose (in mrem).

The summary output report is presented in a space-delimited file, that is easily imported into a spreadsheet (with only minor editing required) for manipulation and sorting.

CINDY

Input features of CINDY include:

Subject identification: name, identification number, SSN, dates of birth, sex, file name prefix.

Subject/Bioassay Measurement-Specific: exclusion flag, bioassay type, bioassay radionuclide, sample end date and time, excretion period, measured value, measurement inverse weighting factor, measurement unit numerator (pCi/nCi/dpm/Bq), unit denominator type, sample size and units.

Subject/Intake Specific: exposure duration, intake mode, begin date and time of intake, end date and time of intake, particle size, facility, employer at time of intake, radionuclides of concern, intake estimate.

Run-Specific: dose report times, dose reporting limits, bioassay projection endpoint, bioassay projection report times, bioassay projection graph selections, text report selections, radiological working units options, error tolerances, radionuclide daughter handling, model selection, and model parameter values.

Output features of CINDY include:

- Several different output reports: For the current effort, useful data points are found on the subject report, which reflects data inputs and normalization, as well as the intake assessment summary and dose assessment reports.
- Intake Assessment Report: includes intake estimate, lung model details, mean residence time in each compartment of GI tract, and urinary excretion model details.
- Dose Assessment Report: includes dose equivalent, weighting factors, and organ dose equivalents, by organ; effective dose equivalent; lung model details; and systemic model details.

- Optional display of a urinary excretion curve on the monitor or printed using text characters.

CINDY output formats can be saved in formats that are easily imported into most personal computer application software.

LUDEP

- LUDEP includes data input screens for the sequence of calculations necessary to estimate an acute intake from urine bioassay data that include:
- Intake (acute or chronic, inhalation or ingestion or injection, value entered in Bq (acute) or Bq/day (chronic)), or exposure (concentration in Bq/m^3 and duration in hours);
- Deposition (AMAD (ìm));
- Absorption (F, M, or S),
- Radionuclides;
- Biokinetic model,
- Quantity to calculate (whole body retention, lung retention, urinary excretion rate, fecal excretion rate, or specified organ retention);
- Function (ICRP-54 function or enter own function);
- Number of points: days (in this case) that encompass all sampling intervals;
- Time: enter a start and stop time, in days;
- Urine Sample Activity Data: time after intake (days), measured activity (Bq), and estimated uncertainty (if known)

LUDEP does not generate a printable output report. Results are displayed on-screen. The output for the calculation of intake based on urinary bioassay sample data provides a best estimate of intake (Bq), standard error of intake (Bq), 95% confidence limit on intake, chi square test statistic, and probability.

LUDEP operates solely as an interactive, desktop program that requires substantial effort to set up and operate. Input parameters can be established for exposure scenarios, saved in files, and used for multiple cases. Organ dose results can be saved to files, as can urine excretion data. Overall, LUDEP does not provide the reporting convenience of RBD or CINDY.

D.2.2. Sensitivity of parameters

Estimated intakes and associated doses depend on the selection of the various input parameters and data. These parameters determine how the intake, biokinetic, and excretion models treat the characteristics of each case. Some of those parameters depend on the characteristics of the exposure scenario, while others depend primarily on the models themselves. In the latter case, ICRP provides recommended values for many of these parameters based on calculating estimates for reference man.

D.2.2.1. Time from Exposure to Sampling

Exposure dates and sampling dates in Palomares records have substantial uncertainty. When recorded, the data are quite specific. When not recorded, or when several samples were collected on different dates, determining a representative acute exposure date can involve an element of

subjectivity. This issue also relates to determining the type of exposure – acute or continuous – as discussed in the next section. The effect of the time between exposure and sampling on estimated intake was assessed with a simple test that varied the time only for a fixed urine excretion value. The time values were varied in increments of one month for a period of two years. Estimated intakes from CINDY varied from 15% for the first month to 7% for the second and third months with a total decrease of 18% over the two-year period. LUDEP results decreased by 5% at one month to 2% at the second month with a total decrease over the first year of 12%. At worst, the differences during the first 30 days should be less than 15 % for CINDY and about 5% for LUDEP.

D.2.2.2. Use of Multiple Bioassay Measurements.

Multiple bioassay measurements affect the estimated intake primarily through the process of obtaining the best fit of the calculated expected values of excretion to the measurements. Testing the methods showed that the selection of weighting factors in CINDY (errors in data sets in LUDEP) could have substantial effect on the intakes. The variations in those were discussed in Section D.2.1.1. The methods performed acceptably within the boundaries of the expectations for the available data.

D.2.2.3. Particle Size

Using LUDEP, the estimated intakes of inhaled ^{239}Pu particles of different AMADs were compared. In one test, the series of bioassay results for one individual were input using AMADs of 0.5, 0.6, 0.7, 0.8, and 1.0 µm. Decreasing the AMAD between 1.0 and 0.5 led to a decrease in the estimated intake; the difference over the entire range tested was less than 8% of the intake associated with an AMAD of 1.0 µm. In another evaluation, the organ dose equivalents to organs were modeled using AMADs of 1, 2.5, 5, 7.5, and 10 µm as shown in Figure D-8. In this case, the organ dose equivalents decreased more than 70% over the range from 1 to 10 µm in all organs except the ovaries and the organs of the gastrointestinal (GI) system. There was no change in the doses to the ovaries, and doses to the GI organs increased from 7 to 23%. Overall, there was a decrease of 75% in committed effective dose equivalent (Figure D-9) when AMAD was varied from 1 ìm to 10 ìm, and a decrease of 40% when the AMAD was increased from 1 µm to 5 µm.

These two comparisons indicate that using an AMAD of 1.0 :m in LUDEP leads to the highest estimated doses, and would therefore be the most conservative estimate of particle diameter. ICRP-30 recommended a default AMAD of 1.0 ìm, but ICRP-66 recommended 5 ìm as generally more representative in occupational settings in the absence of specific information. The variation of organ dose equivalents and committed effective dose equivalent with particle size is acknowledged. A value of 1 ìm AMAD was selected for modeling calculations as a conservative measure.

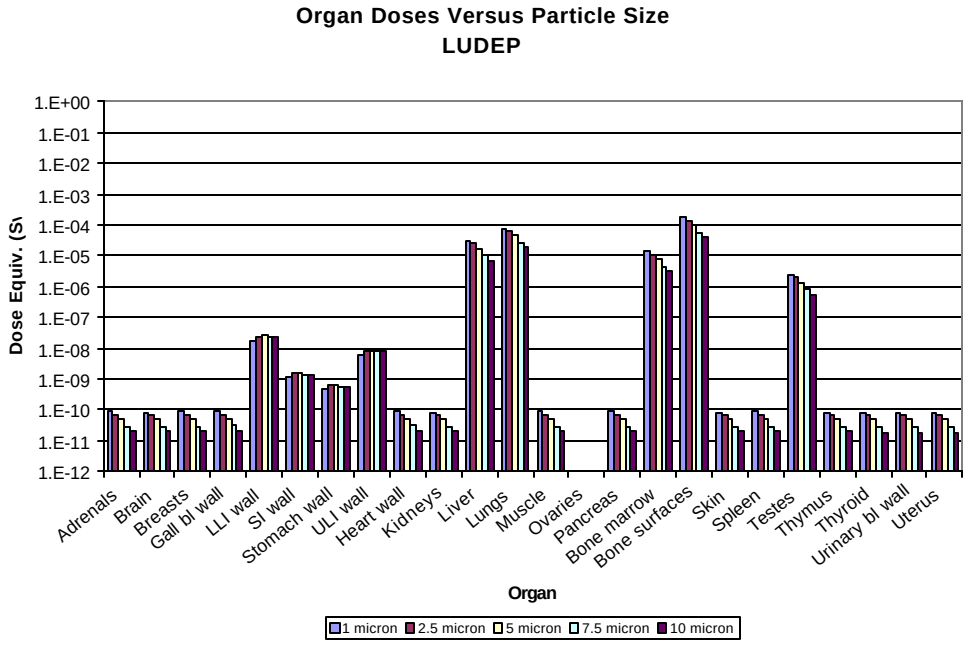

Figure D- 8. Variation of organ dose equivalent with particle size in LUDEP.

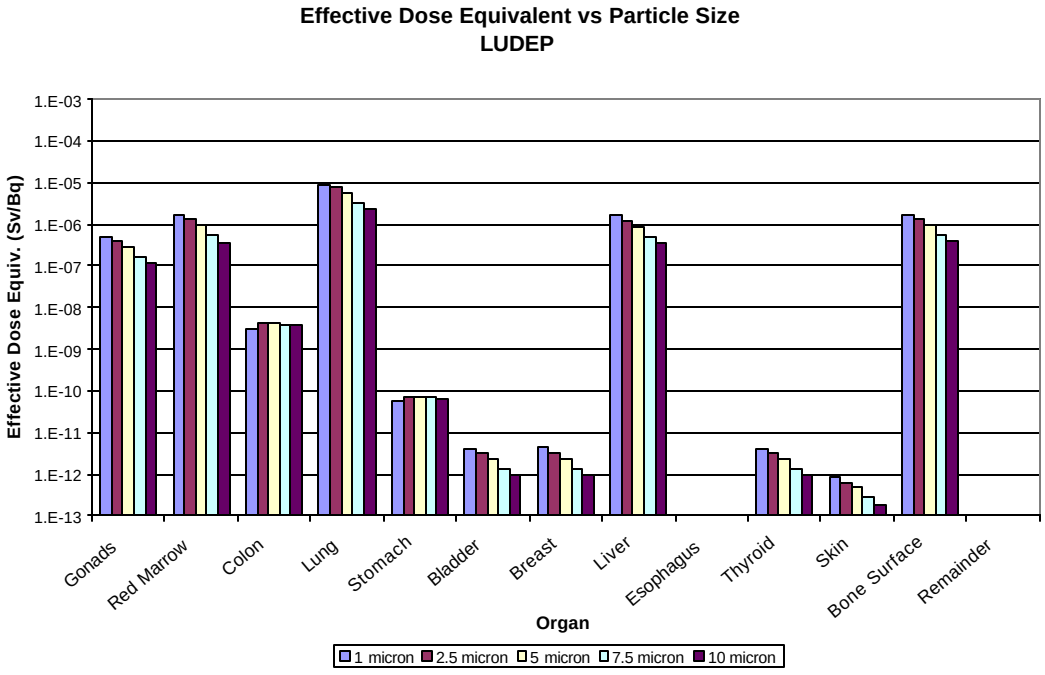

Figure D- 9. Variation of committed effective dose equivalent with particle size from LUDEP.

D.2.2.4. Type of Exposure

The data for some cases indicated possible exposures at several times during the two to three months on site. Evaluation of these cases could assume either a single acute exposure or a series of exposures similar to a continuous intake over the time. CINDY provides for either type of exposure scenario. A quantitative comparison of the two possible exposure scenarios was conducted. In all cases attempted, the estimated intake for an acute exposure was higher than the estimated intake for a continuous exposure, with an average increase of 50% and ranging up to 110%. When the range of exposure dates is reasonably well known, CINDY yields little difference in the results obtained by assuming either an acute (median exposure date) or continuous exposure. The differences in the two methods (acute vs. continuous) become greater as more assumptions are required to establish the dates of exposure. The results were very close when a range of dates was provided, varied significantly when only one date was provided, and showed the largest variation when assumptions were required for both the beginning and end of the exposure period. When only one date was entered on the bioassay data card, significant (>50%) differences resulted for the acute and continuous estimated intakes for 22 of 30 individuals. The highest difference was an 80-percent increase in estimated intake using the acute mode. When a range of dates was entered on the bioassay data card, there were no significant differences in the estimated intakes when either the acute or continuous approach was used. When no exposure date was entered on bioassay data card, significant differences occurred in intakes estimated for seven out of eight individuals, ranging from 70 to 110 percent.

The LUDEP model as currently configured requires significant additional effort to calculate continuous exposures when there is a time lapse between the end of exposure and the collection date for a bioassay sample. The number of manipulations required to perform this assessment were manageable for a few cases; however, the method was very unwieldy, and judged error-prone when applied to hundreds or thousands of cases.

In all comparisons, the estimated intake assuming acute exposure was higher than the estimated intake assuming continuous exposure, with an average increase of 50% and ranging up to 110%. These results emphasize the sensitivity of the estimated intake to the exposure date range.

D.3. MODEL ADOPTION

Taking the four factors considered above, RBD/AF, CINDY, and LUDEP all provide acceptable performance on estimating intake, calculating dose, and providing compatibility with the available data. LUDEP is somewhat less convenient for manipulating large numbers of cases and for generating outputs that can be used in other manipulations; however it implements the current ICRP respiratory tract model.

CINDY and RBD/AF implement the current regulatory system of the NRC and DOE for radiation protection, while LUDEP offers the alternative for applying the respiratory tract model and other features of recent ICRP recommendations. CINDY provides somewhat more flexibility in setup, estimating intakes, and reporting. Consequently, CINDY was chosen as the primary method for assessing the Palomares cases. LUDEP was retained as a reasonable alternate that provides complementary assessments for interesting cases and offers a much-needed point for comparison of results.