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USNRC/Office of Nuclear Regulatory Research

Health Physics "Brownbag" Lunch Meeting

NRC HQ White Flint North Building

Wednesday April 14th, 11:30 am – 1:00 pm

The IMBA Expert™/Professional Plus Approach to Implementing ICRP Recommendations for Internal Dose Assessment: Adaptation for U.S. Regulatory Requirements

by

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"Learning from Plutonium and Uranium Workers"

What Is "IMBA"?

- The acronym "IMBA" stands for Integrated Modules for Bioassay Analysis.

- During 1997-1999, the UK National Radiological Protection Board (NRPB), in collaboration with British Nuclear Fuels plc (BNFL) and Westlakes Research Institute developed IMBA:
  - a suite of software modules that implement the current, i.e., ICRP Publication 68 (1994), models for estimation of intakes and doses.

- The resulting product, NRPB's "IMBA modules," went through extensive (well documented) quality assurance, and:
  - By 2000 were adopted for routine formal dose assessment by Approved Dosimetry Services (ADS) throughout the UK.

Why Was IMBA Necessary?

- The increased complexity of models representing the biokinetic behavior of radionuclides in the body following intake, that were introduced in ICRP Publication 68, posed major problems for people who were required to implement these models, e.g., UK Approved Dosimetry Services (ADS).

- Prior to ICRP 68, in common with international (and U.S.) practice, UK ADSs were set up to use the ICRP Publication 26 methodology (ICRP, 1977) for calculating doses together with empirically-based metabolic models from ICRP Publication 30 (ICRP, 1979; 1980; 1984).

- In 2000, the UK (mandatorily) introduced new regulations that implemented the 1996 Euratom Directive:
  - In compliance with the Euratom Directive, the 2000 UK regulations required all ADSs to apply ICRP's basic 1990 Recommendations (Publication 60; ICRP, 1991) for calculating doses together with Publication 68's (ICRP, 1994) physiologically-based biokinetic models.

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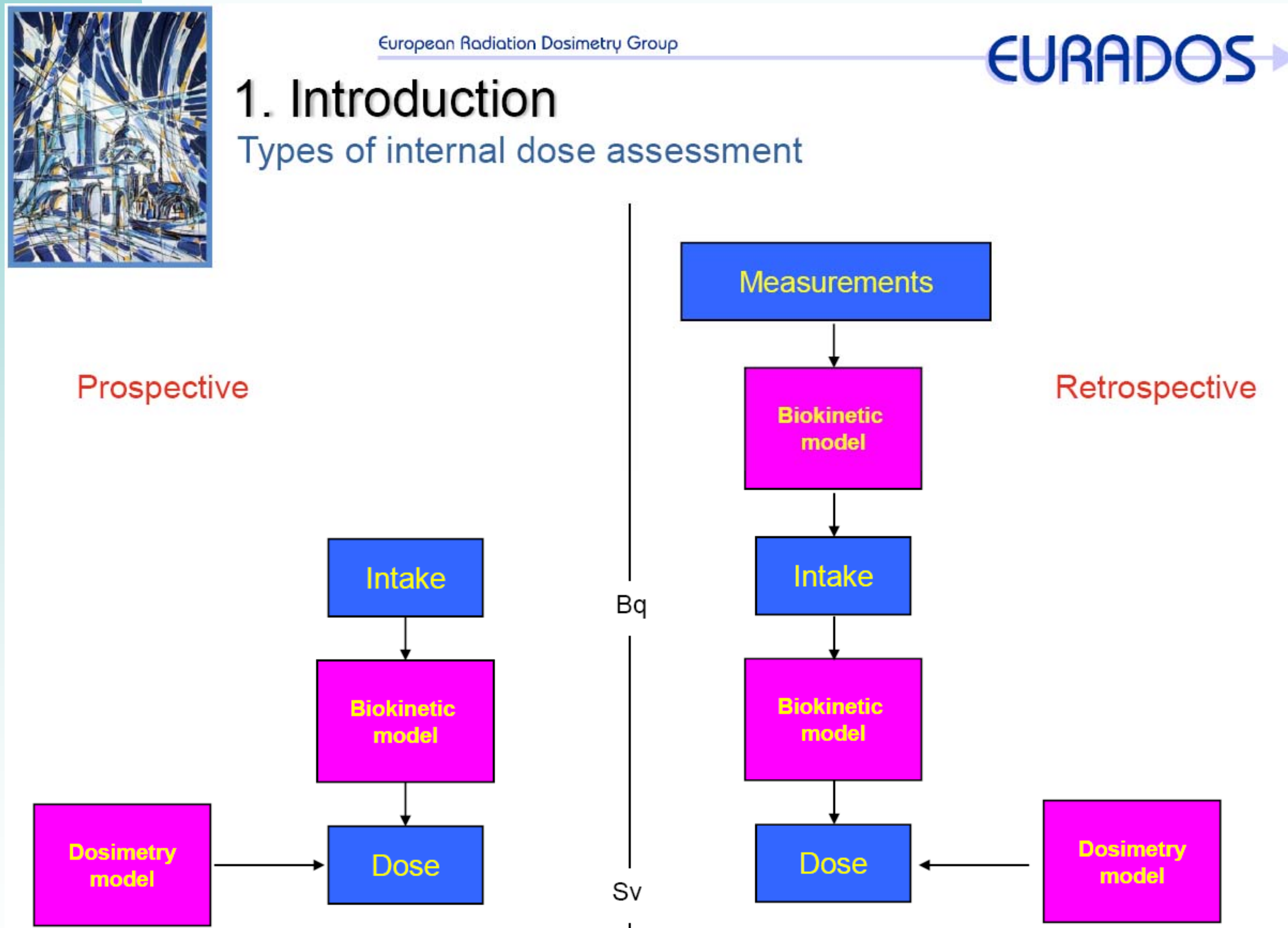
What Did IMBA Achieve?

- UK ADSs were able to substitute the "computational" cores of their existing "dose assessment systems" with compatible "modules" that performed the necessary new calculations:
  - E.g., BNFL already had a sophisticated "user-interface" system that enabled relatively unskilled operators to perform routine dose assessments – using input "bioassay" data – according to ICRP 26/30 "rules" and models.
  - Replacement of the "core" ICRP 26/30 computational models with the new "IMBA" modules provided "seamless" transition to compliance with the new (2000) UK regulatiuons.
- Common adoption of the IMBA modules by ALL UK ADSs introduced UNIFORMITY in dose assessments throughout the UK – with LOW system programming overhead for the UK ADSs.

What Is Internal Dose Assessment?



Courtesy of Dr. Matt Puncher, HPA-RPD

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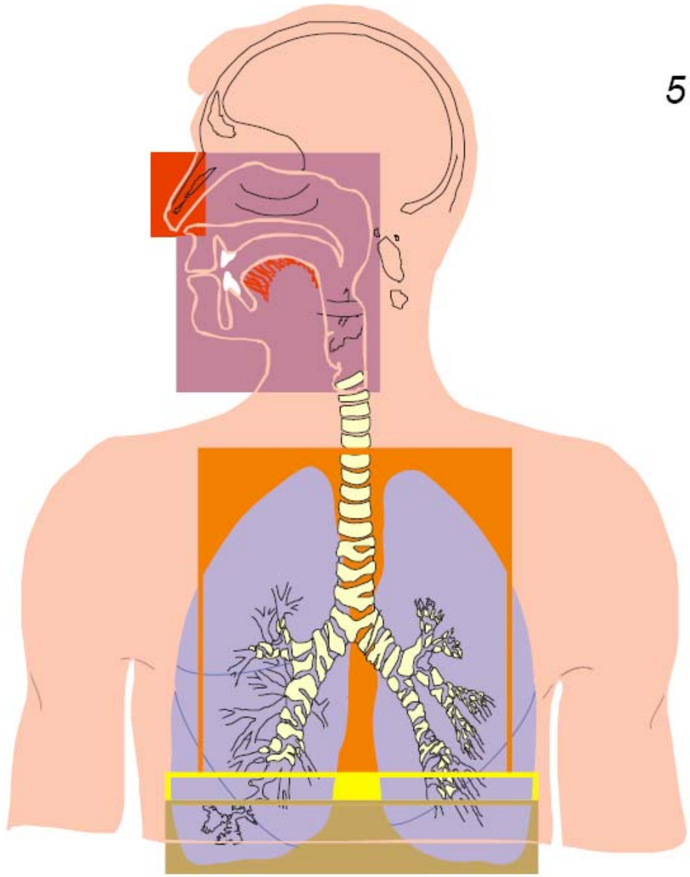
What Does It Involve?

European Radiation Dosimetry Group

EURADOS

1. Introduction

Example: Respiratory tract model (structure)



5 main regions

Extrathoracic airways	ET_1
	ET_2
Bronchial	BB
Bronchiolar	bb
Alveolar interstitial	AI

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How Is the Respiratory Tract "Modeled"?
– The ICRP 66 (1994) Human Respiratory Tract Model (HRTM)

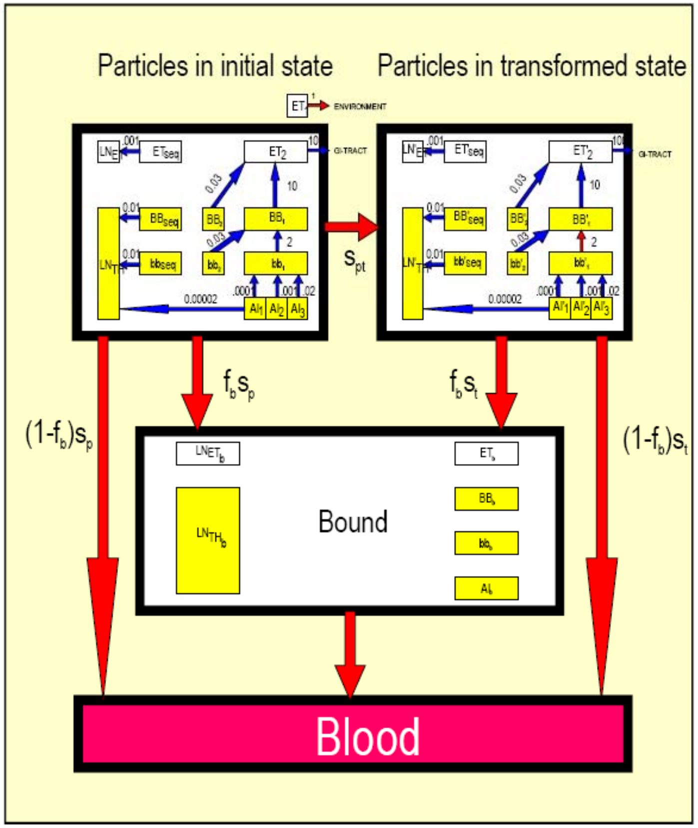
European Radiation Dosimetry Group

EURADOS

1. Introduction

Example: Respiratory tract model (biokinetics)

Particle transport



Absorption

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How Are HRTM Tissue Doses Calculated?

European Radiation Dosimetry Group

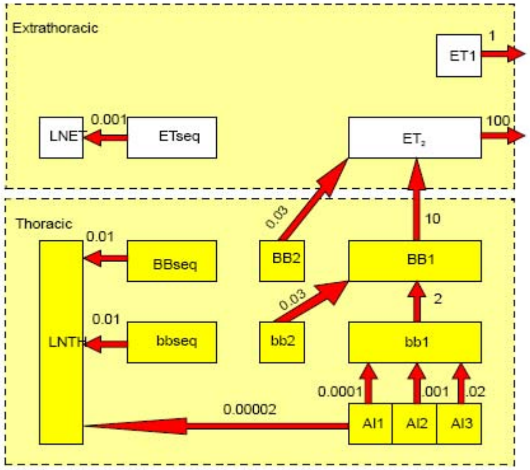
EURADOS

1. Introduction

Example: Respiratory tract model (dosimetry)

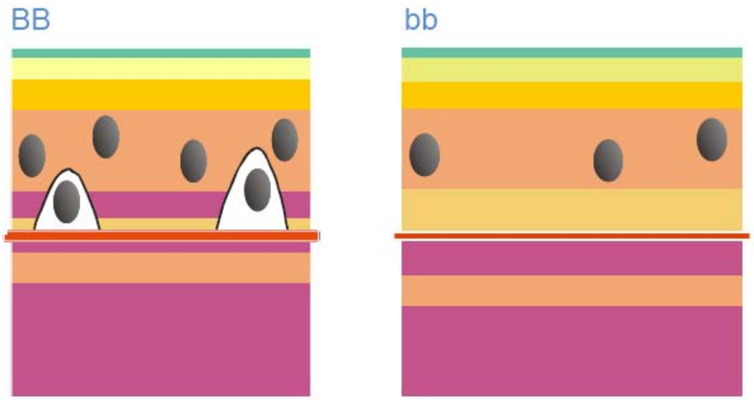
Source regions

regions (5)	sources (17)
ET_1	surf
ET_2	surf, seq,bnd
BB	fast, slow, seq, bnd, AI
bb	fast, slow, seq, bnd, AI
AI	all cells
Lymph	LN_{ET} LN_{TH}



Target regions

regions (5)	targets (17)
ET_1	basal
ET_2	basal
BB	basal + secretory
bb	basal
AI	all cells
Lymph	all cells



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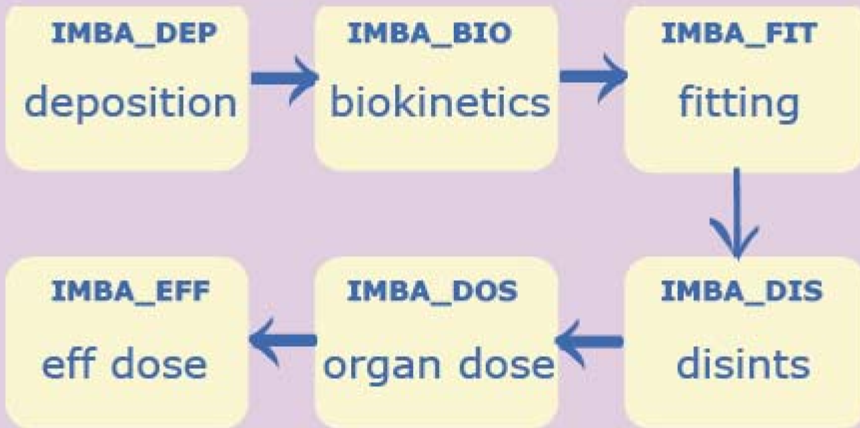
How Do the IMBA Modules Put All These Calculations Together?



Program Modules	Function
IMBA_DEP	calculates fractional deposition in each region of the repiratory tract
IMBA_BIO	predicts values of bioassay quantity per unit intake (lung or whole body retention, daily urinary or faecal excretion)
IMBA_FIT	estimates intake by comparing measured activity and predicted retention or excretion
IMBA_DIS	calculates disintegrations in each organ per unit intake
IMBA_DOS	calculates organ doses using the estimated intake
IMBA_EFF	calculates weighted organ doses using tissue weighting factors from ICRP Publication 60 as updated in ICRP Publication 68

Six independent modules – integrated via standard ASCII INPUT/OUTPUT data sets – can be run in any order to perform ALL required dose calculations:

Prospective – dose per unit intake
Retrospective – dose from bioassay measurements

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What Are the Advantages of the Modular Design Ethos?

- Symbiotic relationship with quality assurance – the same (generic) modules act for ALL elements (and radiouclides).
- Readily enables each component of the (complex) dose calculation to be tested (to whatever precision is necessary to identify “anomolies” – not just one final dose coefficient.
- Applies previously quality assured code, e.g., LUDEP (in IMBA_DEP) – LUDEP was used to generate the reference regional deposition values for the HRTM (ICRP 66).
- The original IMBA modules were developed independently by separate teams (using different mathematical and coding approaches) – and results were rigorously compared with the output of NRPB’s PLEIADES code (one of the codes used to generate ICRP reference dose coefficients).
- The same modules can be run in different orders – for different types of calculation (prospective or retrospective).
- The modules can readily be controlled by an external code, e.g., they can be incorporated into existing (or specially developed) software by treating them as subroutines.

The First "User Friendly Interfaces" for IMBA: *IMBA-CALC* and *IMBA-URAN*

Figure 1
Main screen of IMBA-CALC. This was one of the first programs to utilise the IMBA modules.

The first stand alone implementations of the IMBA modules were IMBA-CALC and IMBA-URAN. Both programs were designed to be extremely simple to use as opposed to utilising the full capabilities of the IMBA modules. IMBA-CALC estimates intakes and calculates internal doses for a limited number of radionuclides at the click of a button. IMBA-URAN was designed specifically for uranium dosimetry.

Both programs show how the interfaces to the modules can be customised to meet the precise requirements of the end user.

Extension of the IMBA Modules to Accommodate Different Dosimetry Rules and Regulatory Practices: The IMBA Expert™ Concept

- Develop an intuitive (i.e., user friendly) MS Windows®-based interface that can be customized for any dose assessment application or methodology.
- Extend core IMBA modules to introduce new computational capabilities, e.g.:
  - Substitute the dosimetry rules mandated by 10CFR835 for the ICRP Publication 60/68 rules.
  - Provide simultaneous statistical analyses (fitting) of multiple bioassay data and different types of data (bioassay quantities).

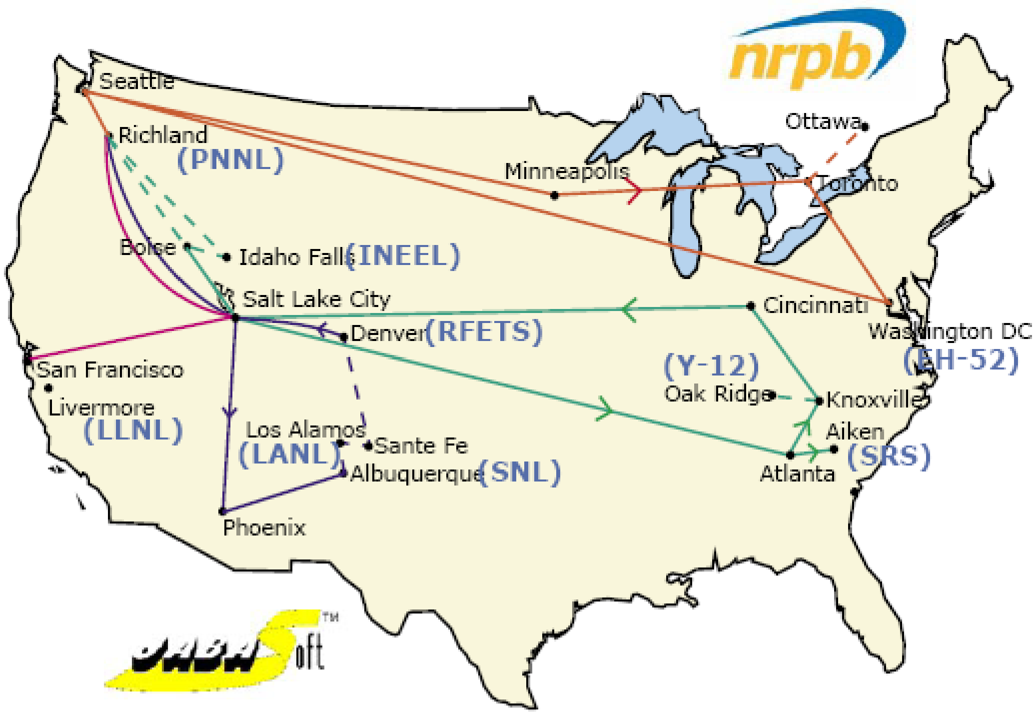
"Exporting" the Concept of National Uniformity in Internal Dose Assessments to the U.S.!

- In 2000, Drs. Birchall and James (representing ACJ & Associates, Inc., Richland, WA) "floated" the possibility of applying NRPB's "IMBA" concept to provide a common "tool" to USDOE's site dosimetry services – which would:
  - Give USDOE sites the capability of applying "uniformly" the current (ICRP 68) biokinetic models and the ICRP 66 HRTM – whilst preserving their compliance with 10CFR835.

- DOE's Office of Worker Protection Policy and Programs (EH-32) recognized the benefits of such an approach:
  - EH-32 encouraged Birchall and James to seek the funding for the necessary development effort directly from the major individual DOE sites (the "Users") – whilst also establishing the "special requirements" (product specifications) for each site.

The Outcome: IMBA Expert™ USDOE-Edition

Following visits in October 2000 to nine major USDOE nuclear sites, an ambitious project to develop a single software package to satisfy all of their requirements for internal dosimetry was established.



IMBA Expert™ USDOE-Edition was developed in two phases – under an umbrella contract between USDOE and ACJ & Associates, Inc. (ACJ).

ACJ sub-contracted the UK NRPB (the IPR owner of IMBA) to co-develop IMBA Expert™ USDOE-Edition (and write the code). ACJ and NRPB shared the resulting IPR.

The final "product" (Phase II) was delivered in 2004 – and subsequently "licensed" by 26 DOE sites.

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Features of *IMBA Expert™ USDOE-Edition*

Different Routes of Intake:
- Inhalation (Aerosols and Vapours)
- Ingestion
- Injection
- Wound

Different Modes of Intake:
- Acute
- Chronic
- 10 intake regimes simultaneously
- Mixed intakes e.g. inhalation and ingestion

Bioassay Calculations:
- Calculate bioassay quantities (urine, faeces, whole body, lung, organ retentions)
- Estimate up to 10 intakes simultaneously
- Deal with data recorded at less than limit of detection using the maximum likelihood method
- Deal with different errors and error assumptions on each data point
- Simultaneously fit to more than one bioassay type (e.g. urine and lung data)

Built-in Databases of Parameter Values:
- All ICRP defaults
- Bioassay functions
- Biokinetic models
- Nuclear decay data

Simple and Easy to use!

Ability to Change Parameters:
- Aerosol (size, density etc)
- Particle transport
- Absorption rates
- Retention/excretion functions
- Wound model paramaters
- GI-tract model parameters, f_1

Other Features
- Produce graphical output
- Download to spreadsheets
- Enter Time or Dates
- Generate reports
- Access help files and technical documentation

Dose Calculations:
- Equivalent Dose to all organs
- Effective Dose
- CFR/ICRP/User defined tissue weighting factors and remainder rules
- Up to 30 associated radionuclides

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"User Interface" of *IMBA Expert™ USDOE-Edition*

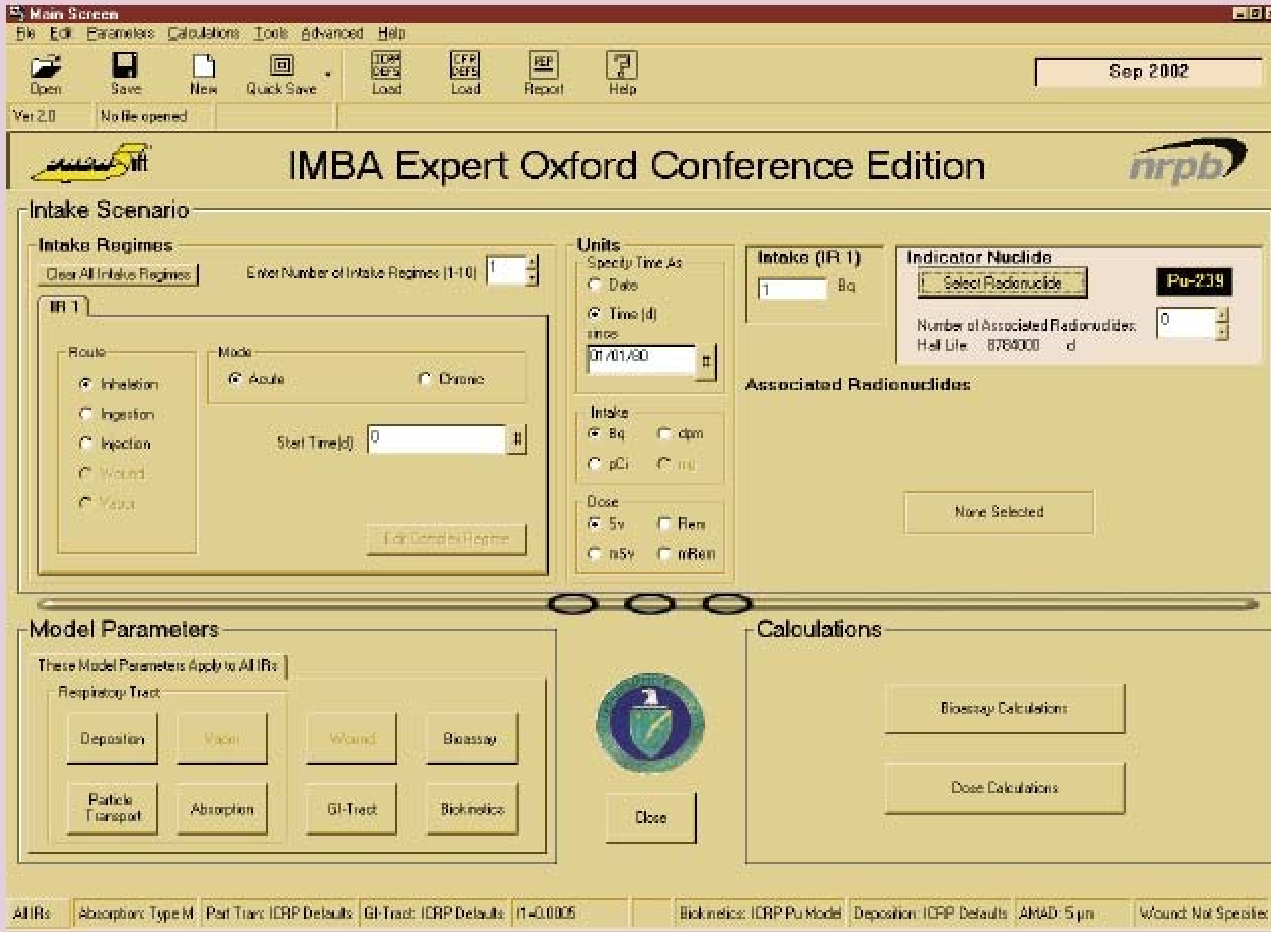

Figure 2

Main screen of IMBA Expert™. Radionuclides and intake regime(s) are specified in the upper part of the screen, while the model parameters and types of calculation are specified in the lower part.

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"Bioassay Calculations" in *IMBA Expert™ USDOE-Edition*

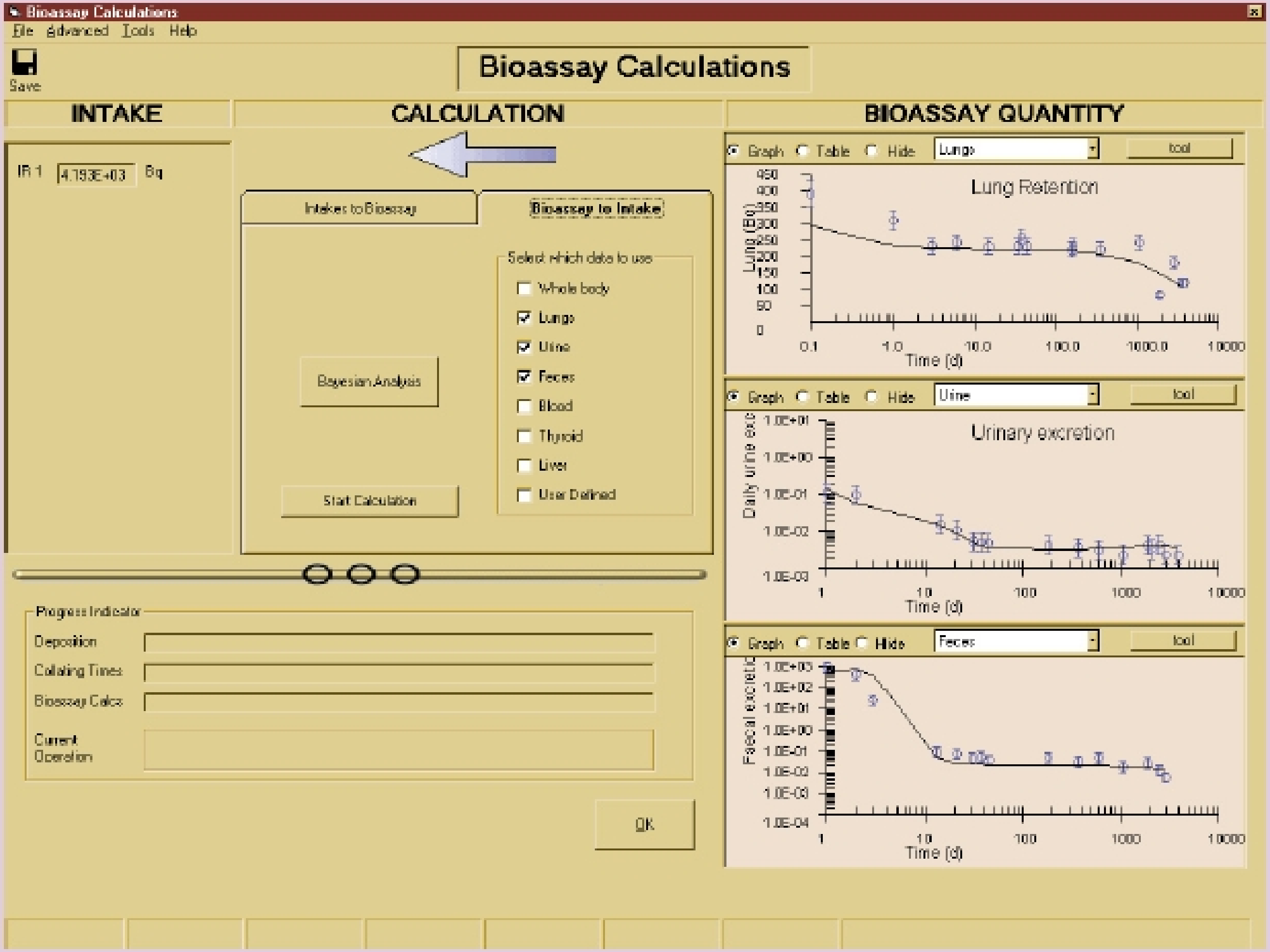

Figure 3

Bioassay screen of IMBA Expert™. The software can perform a variety of calculations including calculating an intake from several bioassay data sets simultaneously.

Special Feature of *IMBA Expert™ USDOE-Edition*: Ability to "Select" Tissue Weighting Factors

Table A.3.2. Comparison of "**Default**" tissue weighting factors implemented in IMBA Expert™ OCAS/ORAU-Edition.

Organ or tissue (*T*)	**ICRP60/68 Default**	**10-CFR-835 Default**	**ICRP26/30 Default**
Gonads[1]	0.20	0.25	0.25
Bone marrow (red)	0.12	0.12	0.12
Colon[2]	0.12	-	-
Lung	0.12	0.12	0.12
Stomach wall	0.12	-	-
Urinary bladder	0.05	-	-
Breast	0.05	0.15	0.15
Liver	0.05	-	-
Esophagus	0.05	-	-
Thyroid	0.05	0.03	0.03
Skin	0.01	-	-
Bone surface (endosteal)	0.01	0.03	0.03
Remainder	0.05	0.3	0.3

[1]The dose to the **gonads** is calculated as the higher of those calculated for the testes and ovaries (in the hermaphrodite worker considered by ICRP).
[2]The dose to the colon is calculated as the **mass-weighted-average** of that to the walls of the upper large intestine (**ULI**) and lower large intestine (**LLI**).

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Ability to "Select" Remainder Tissue and "Splitting" Rules

Table A.3.3 Comparison of "**Default**" remainder tissues implemented in IMBA Expert™ OCAS/ORAU-Edition.

Organ or tissue (*T*)	ICRP60/68	10 CFR 835	ICRP26/30
Muscle	•	•	•
Brain[1]	•	(•)	
Small intestine wall	•	•	•
Kidneys	•	•	•
Pancreas	•	•	•
Spleen	•	•	•
Thymus	•	•	•
Uterus	•	•	•
Adrenals	•	•	•
Extrathoracic airways[1]	•	(•)	
Gall bladder[1]		(•)	
Heart wall[1]		(•)	
Urinary bladder[2]		•	•
Esophagus wall[1,2]		•	
Liver[2]		•	•
Stomach wall[2]		•	•
Upper large intestine wall[3]		•	•
Lower large intestine wall[3]		•	•

[1]These organs were not considered explicitly in the ICRP26/30 recommendations. However, with the endorsement of OCAS/EH-31, IMBA Expert™ OCAS/ORAU-Edition includes them in the default list of "candidate" remainder tissues.
[2]These organs are given specific tissue weighting factors in ICRP60/68.
[3]These organs are included in the Colon, which is given a specific weighting factor in ICRP60/68.

DOE Gap Analysis Recommending "Adoption"

DOE/EH-0711

Gap Analysis for IMBA and

DOE Safety Software Central Registry Recommendation

Final

U.S. Department of Energy
Office of Environment, Safety and Health
1000 Independence Avenue, S.W.
Washington, D.C. 20585-2040

August 2006

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Parallel Developments to *IMBA Expert™ USDOE-Edition*

- *IMBA Expert™ NIOSH-Edition* – custom-developed for CDC/NIOSH/OCAS as a 'bread-board' calculator for them to carry out preliminary assessments in support of the 2000 Energy Employees Occupational Injury Compensation Program Act (EEOICPA). Delivered in 2002.
- *IMBA Expert™ CANDU-Edition* – custom-developed for the (Canadian) CANDU Owners Group, Toronto, Ontario. Delivered in 2004.
- *IMBA Expert™ UK-Edition* – custom-developed for UK ADs. Delivered in 2004.
- *IMBA Expert™ OCAS/ORAU-Edition* – custom-developed for Oak Ridge Associated Universities (ORAU) to enable HP dose-assessors to perform the standardized calculations of annual tissue doses required for substitution in the *Interactive RadioEpidemiology Program* (*IREP*) for cancer causation probability determination. Delivered in several phases (through 2005).

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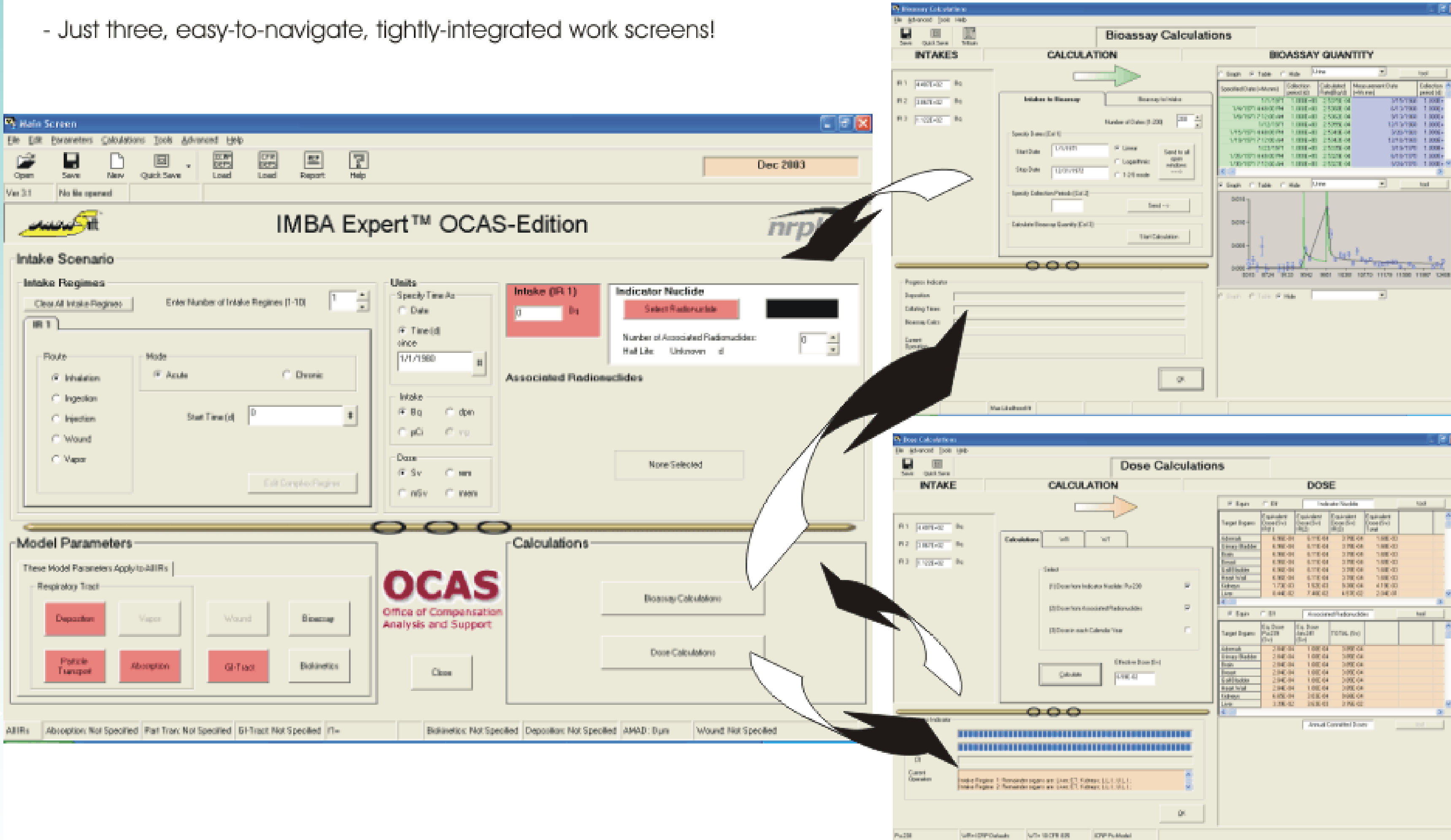
IMBA Expert™ OCAS/ORAU-Edition

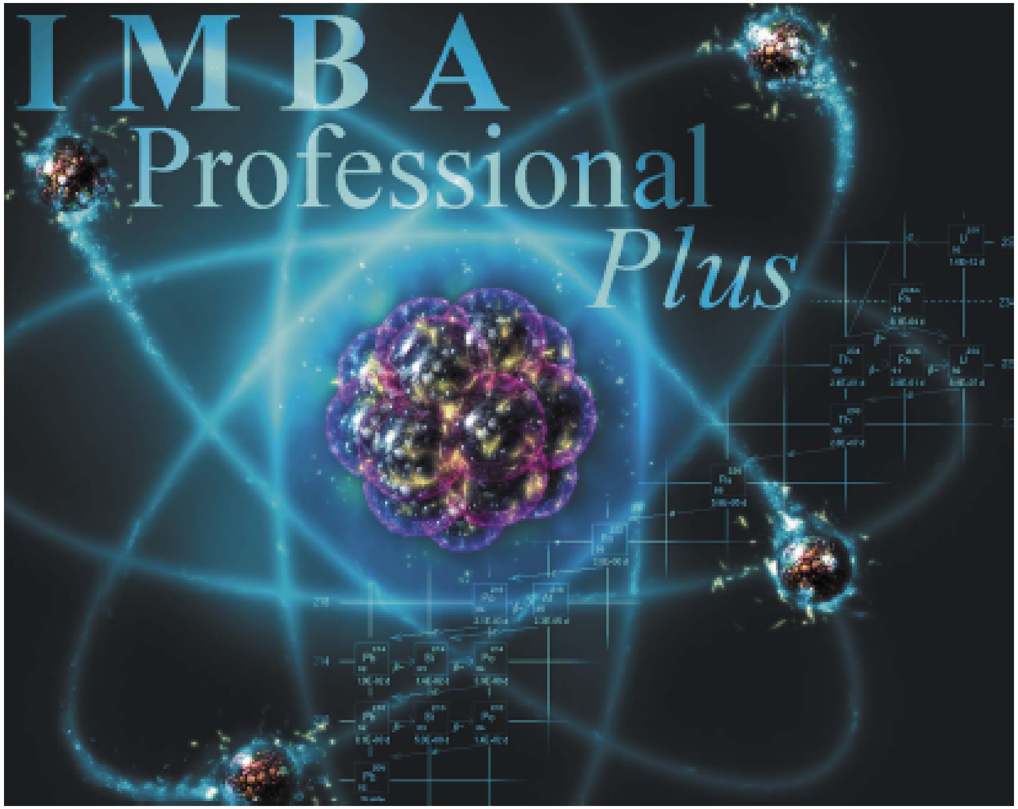
IMBA Expert™ OCAS-Edition

- Just three, easy-to-navigate, tightly-integrated work screens!



"Internationalizing" the IMBA Concept: The UK HPA-RPD's *IMBA Professional Plus (IPP)*

IMPA Professional Plus is the successor of the IMBA Professional and IMBA Expert™ series. It is more flexible, more powerful and 6 - 10 times faster. The central concept behind the software is that the nucleus of the program (called the Base Unit) can be installed and run as a separate entity, enabling basic internal dosimetry calculations to be performed. More powerful capabilities (called Add-ons) can be added to the Base Unit as required. Each Add-On can be installed independently, and increases the functionality of the software. The users can thus build up the software to meet their precise requirements.



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http://www.imbaprofessional.com/

IPP Provides Bioassay Analysis Software in a Range of Standard (off-the-Shelf) "Packages"

Add-On	Description of Add-On
1	Enables up to 10 independent intake regimes to be specified and used together in calculations
2	Allows different types of measurement data to be used simultaneously in the assessment of intake(s)
3	Enables up to 30 associated radionuclides to be specified and used in dose calculations
4	Used to enable different isotopic mixtures of uranium (eg, enriched, natural) to be specified and used in calculations
5	Implements a generic wound model, enabling intakes via wound to be dealt with
6	In cases where the data is normally distributed, and there is only 1 intake, this Add-On will automatically calculate the error on the estimate of intake
7	Incorporates a Bayesian fitting methodology allowing the user to investigate the effects of different 'prior' knowledge on intake estimates, combine bioassay data with PAS data, and obtain uncertainties in estimates of intakes
8	A tool used to analyse measurements of tritium in urine from a routine tritium monitoring procedure
9	Specifically designed for calculating doses to a specified organ in each calendar year. Used for input into compensation type calculations
10	Enables the ingrowth of ^{241}Am from ^{241}Pu to be automatically allowed for in calculations (Chronic intakes cannot be used with this Add-On)
11	A statistics package giving a quantitative judgement as to the goodness of fit of the assumed models to the measurement data

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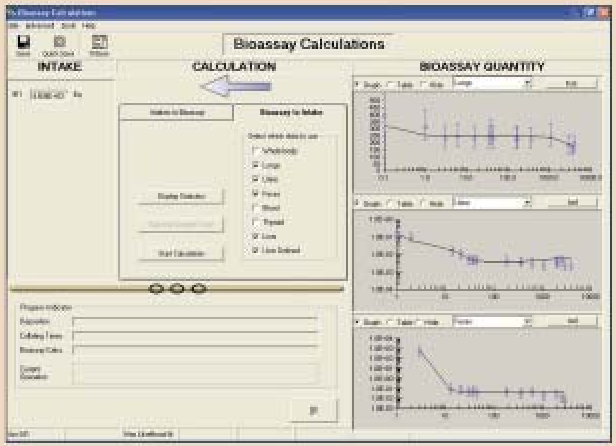
The "Basic" package can be "enhanced" with off-the-shelf "Add-Ons" – to suit Users with different needs (and budgets!)

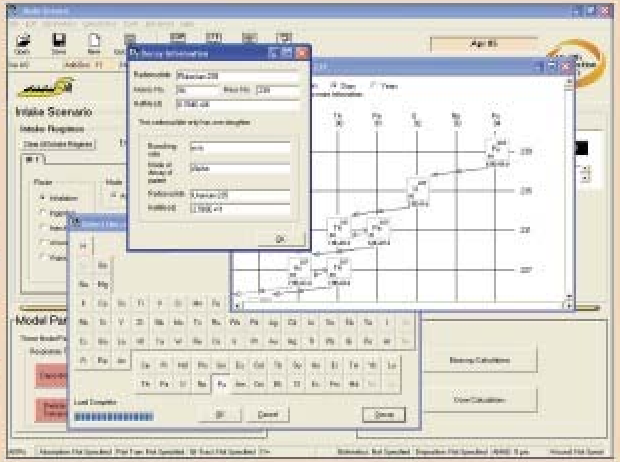
IPP Maintains the "Look and Feel" of *IMBA Expert*™: But with Significantly Enhanced Features and Capabilities

Main screen. Upper screen defines intake scenario, while parameters can be changed in the bottom half.



A simultaneous fit to the bioassay data in the IDEAS International Intercomparison exercise (case 6).

Radionuclides are selected from a periodic table from which further decay information may be viewed.



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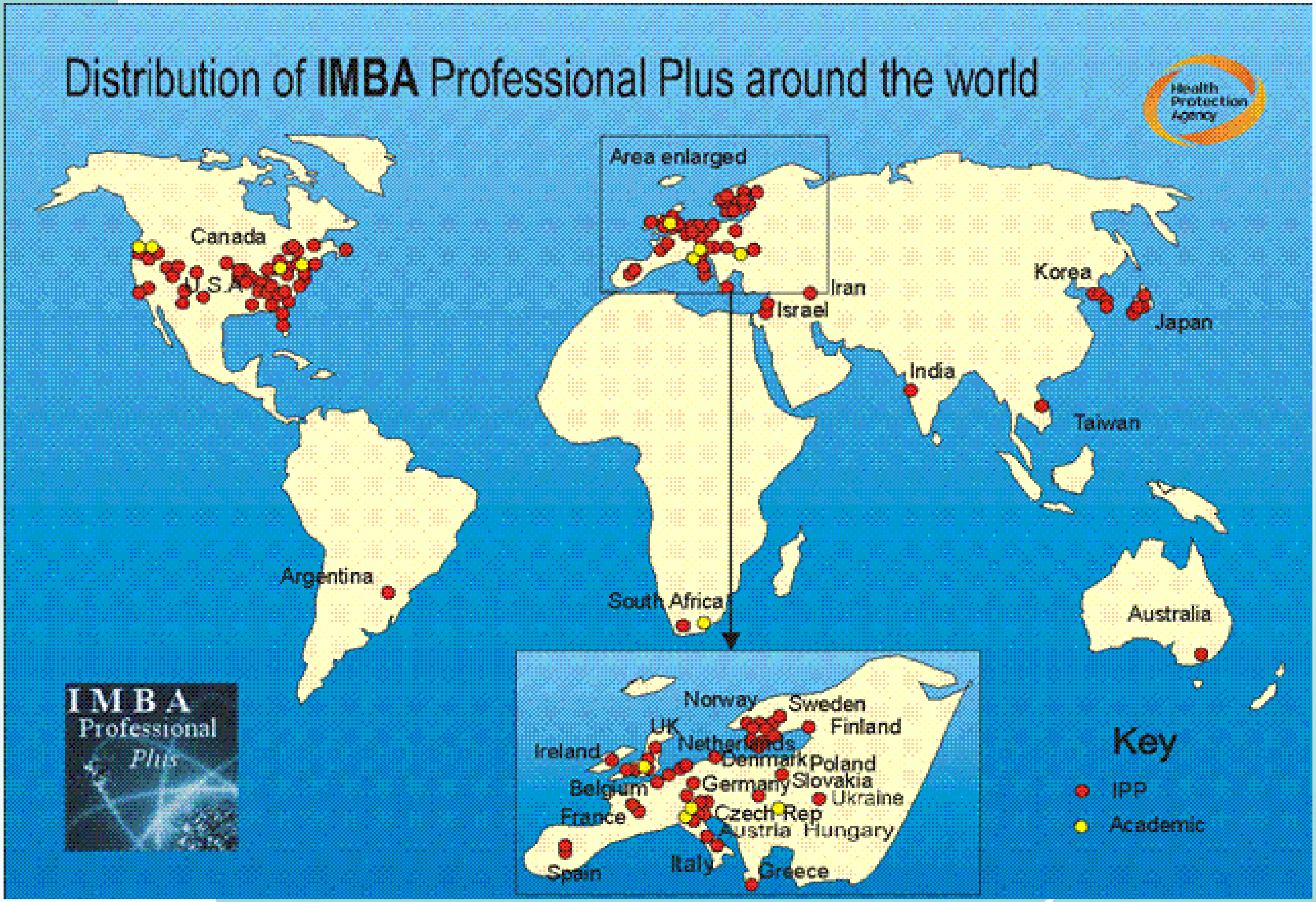
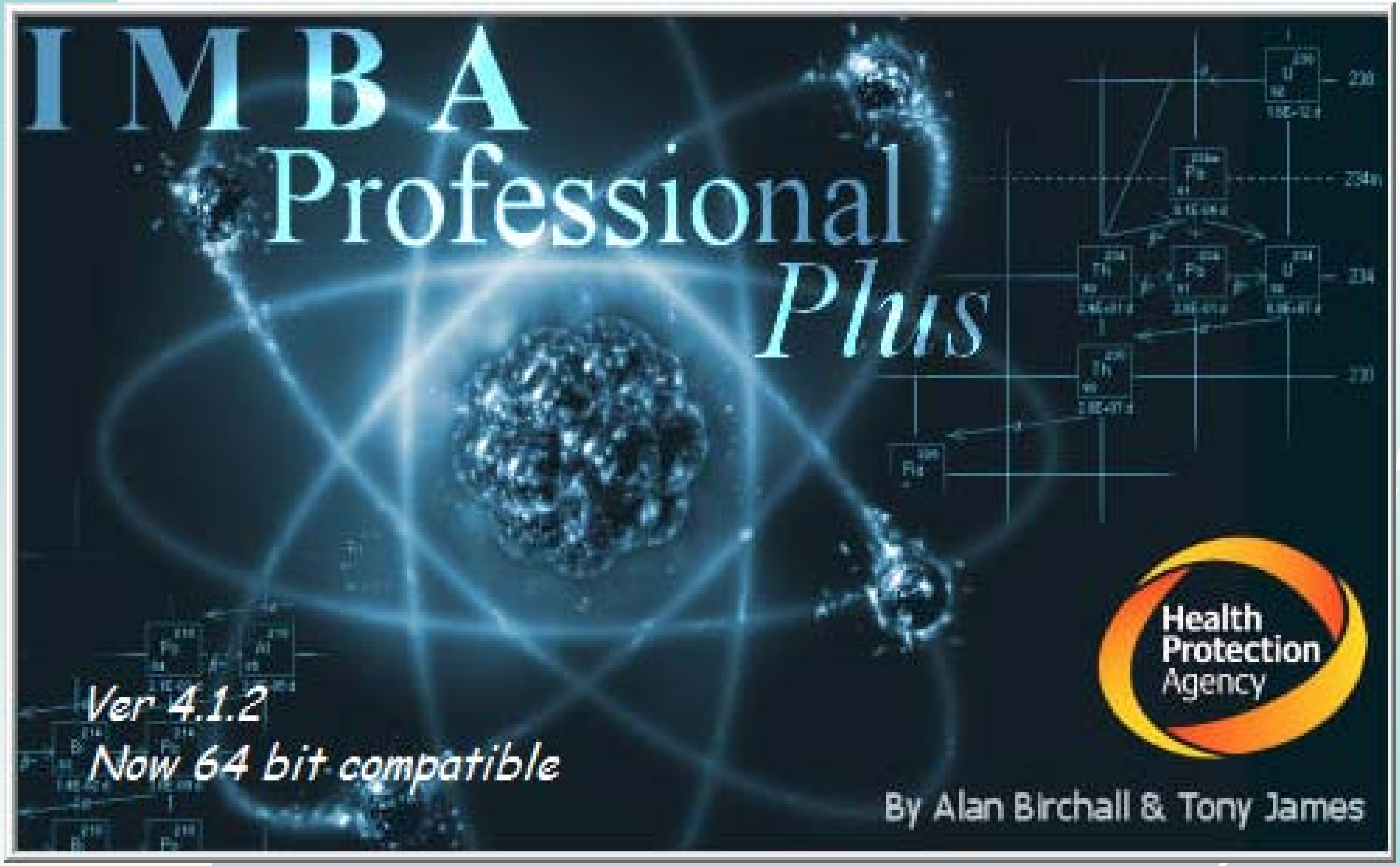
ALL versions of IMBA are "backwards compatible" – and share a standard ascii data file format ("*.ix" case data).

IPP Has Been Adopted Very Widely!



So how can an "IMBA-derived" code system help the U.S. Nuclear Regulatory Commission?

The Future of "IMBA" – Ongoing Research & Development



The U.S. Transuranium & Uranium Registries is actively collaborating with Drs. Birchall and Puncher to TEST novel (IMBA-based) analytical capabilities (and methods) with Registries case studies.

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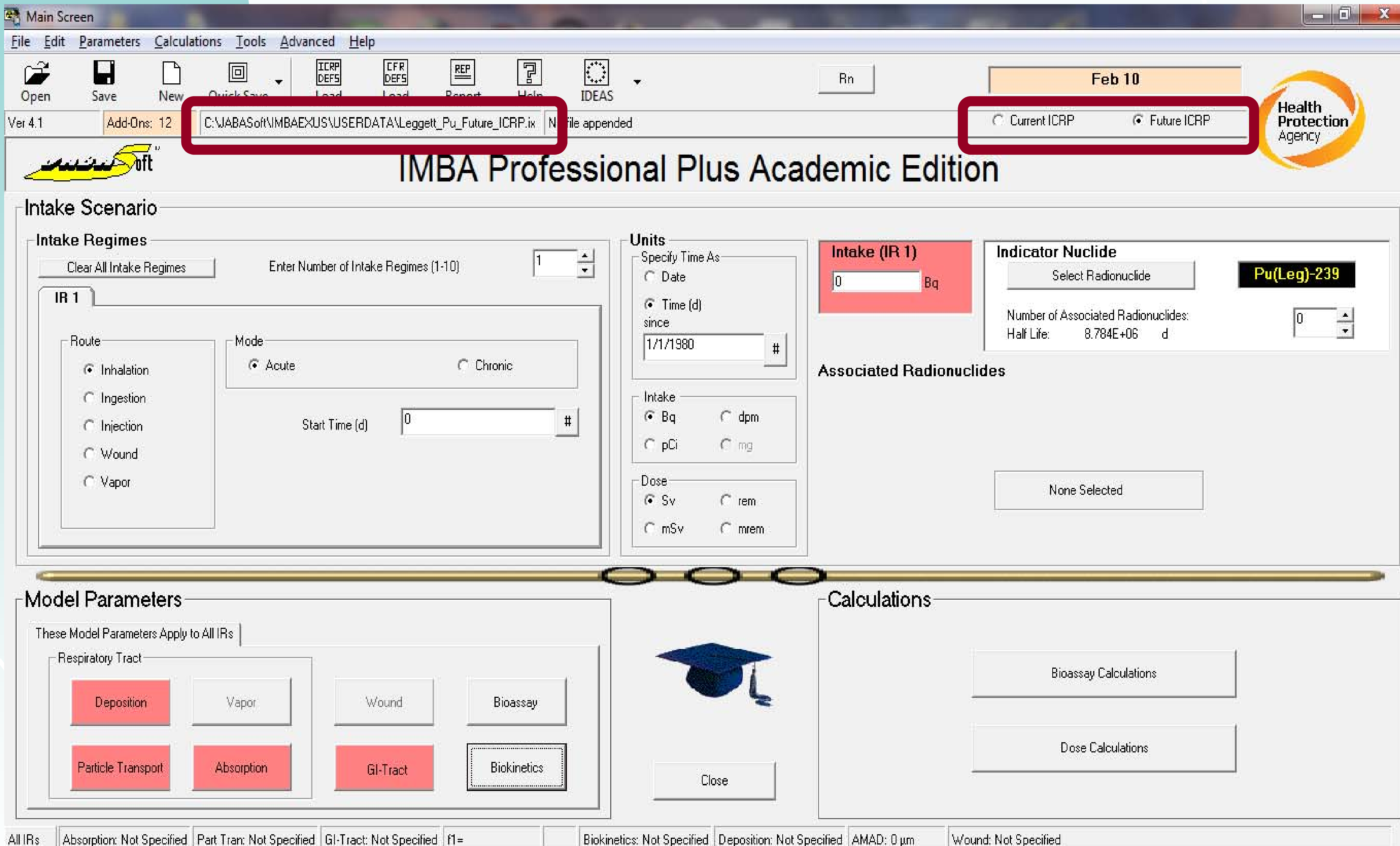
Implementation (and Testing) of Proposed New ICRP Models



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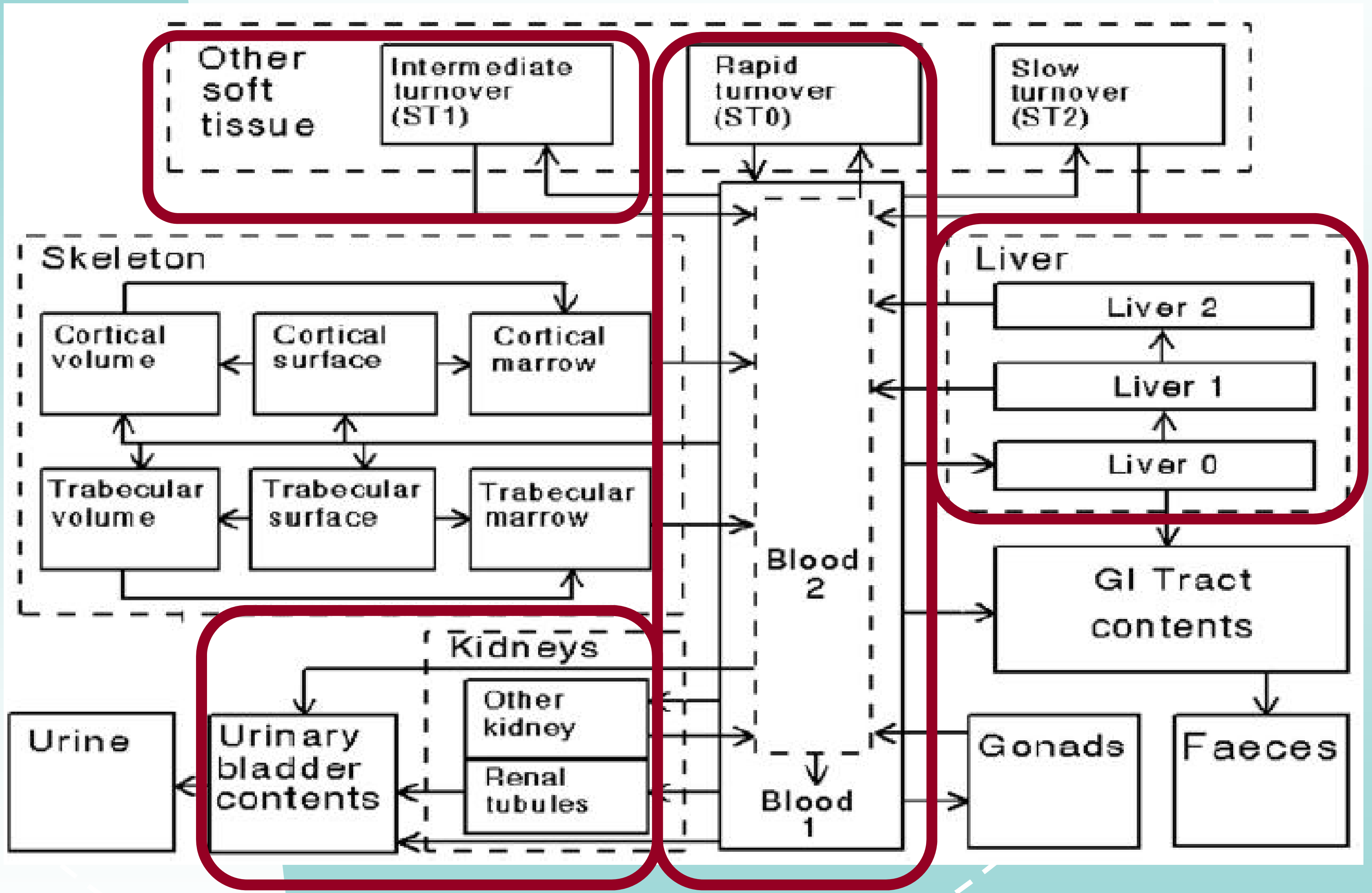
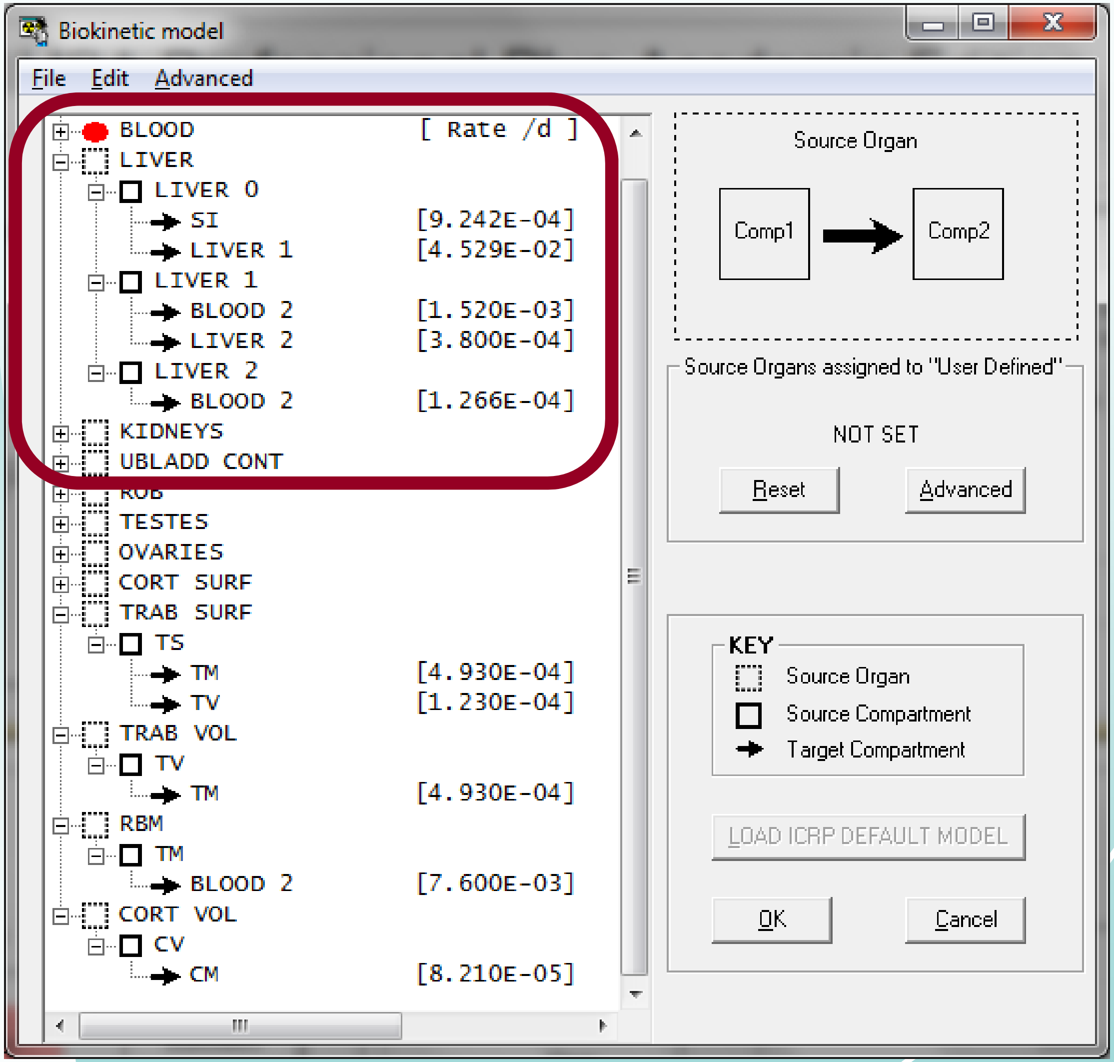
Leggett et al. (2005) – Revised (Improved?) Pu Biokinetics



New Capability: “Build Your Own” Biokinetic Model in IPP!



Recycling model now solved “live” – does not require “pre-cooked” equivalent set of exponential terms (non-recycling approximation)

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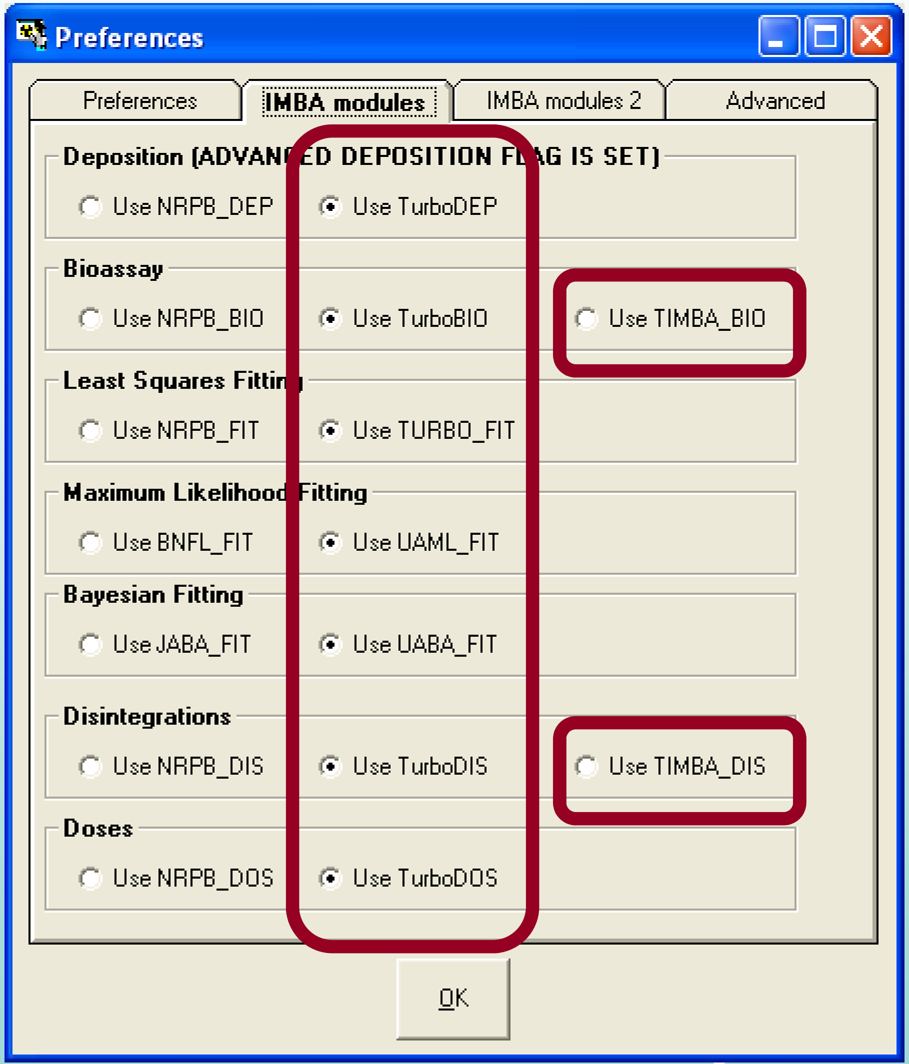
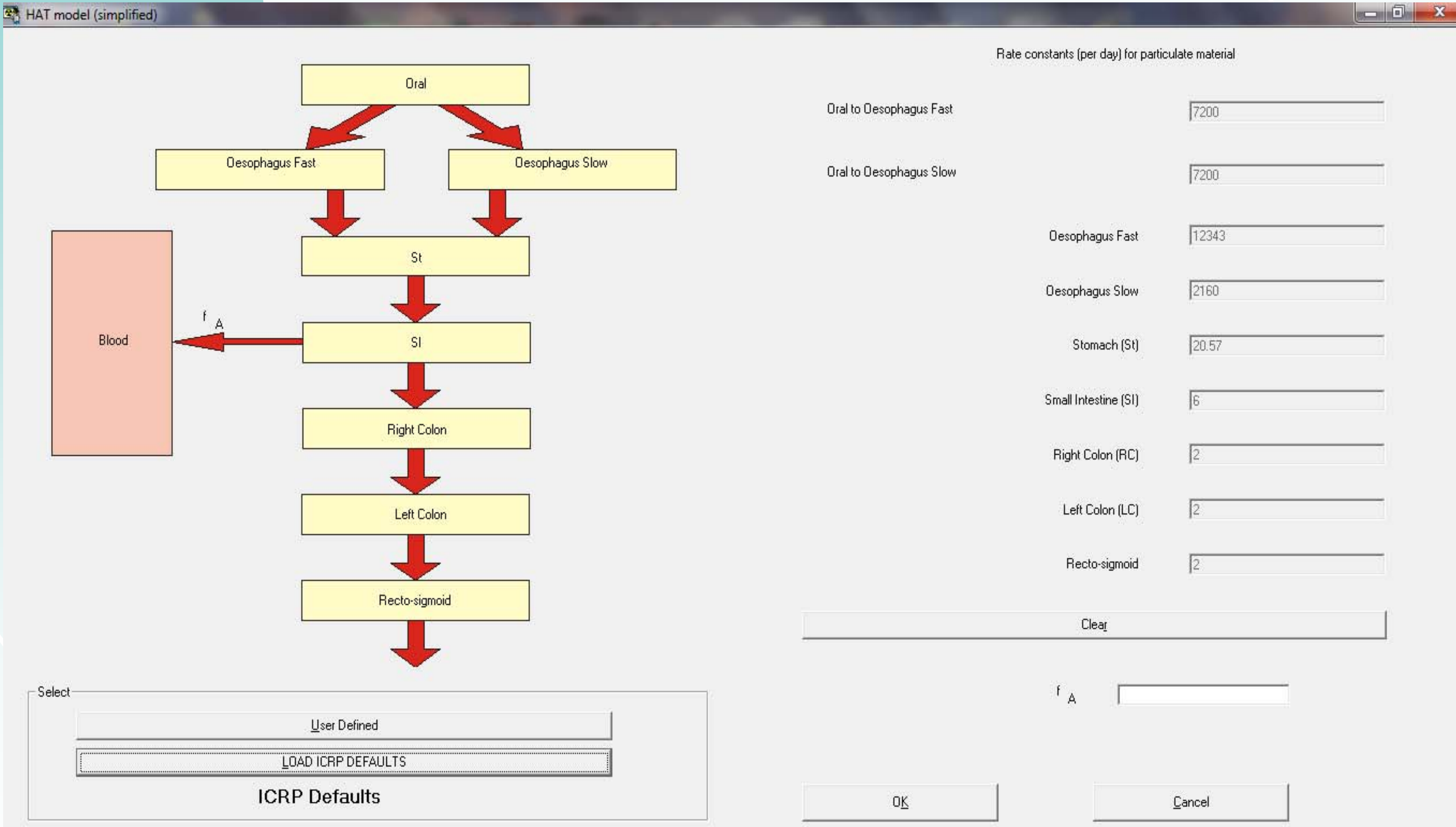
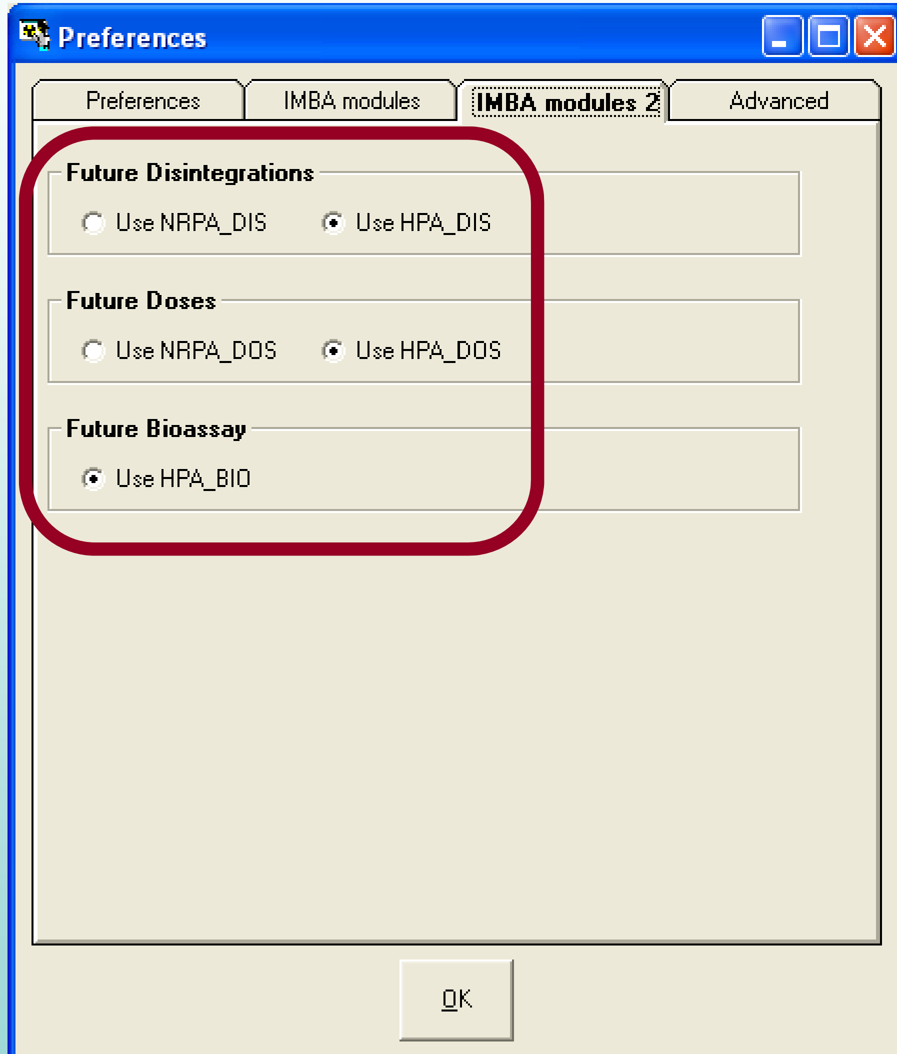
"IMBA" Computational Module Options Available in IPP Vers. 4.1.2 (64-bit Compatible)



Can Implement – and Vary Parameter Values in – the ICRP 100 Human Alimentary Tract (HAT) Model



New "IMBA Dosimetry" Modules for "Future" ICRP Dose Calculations



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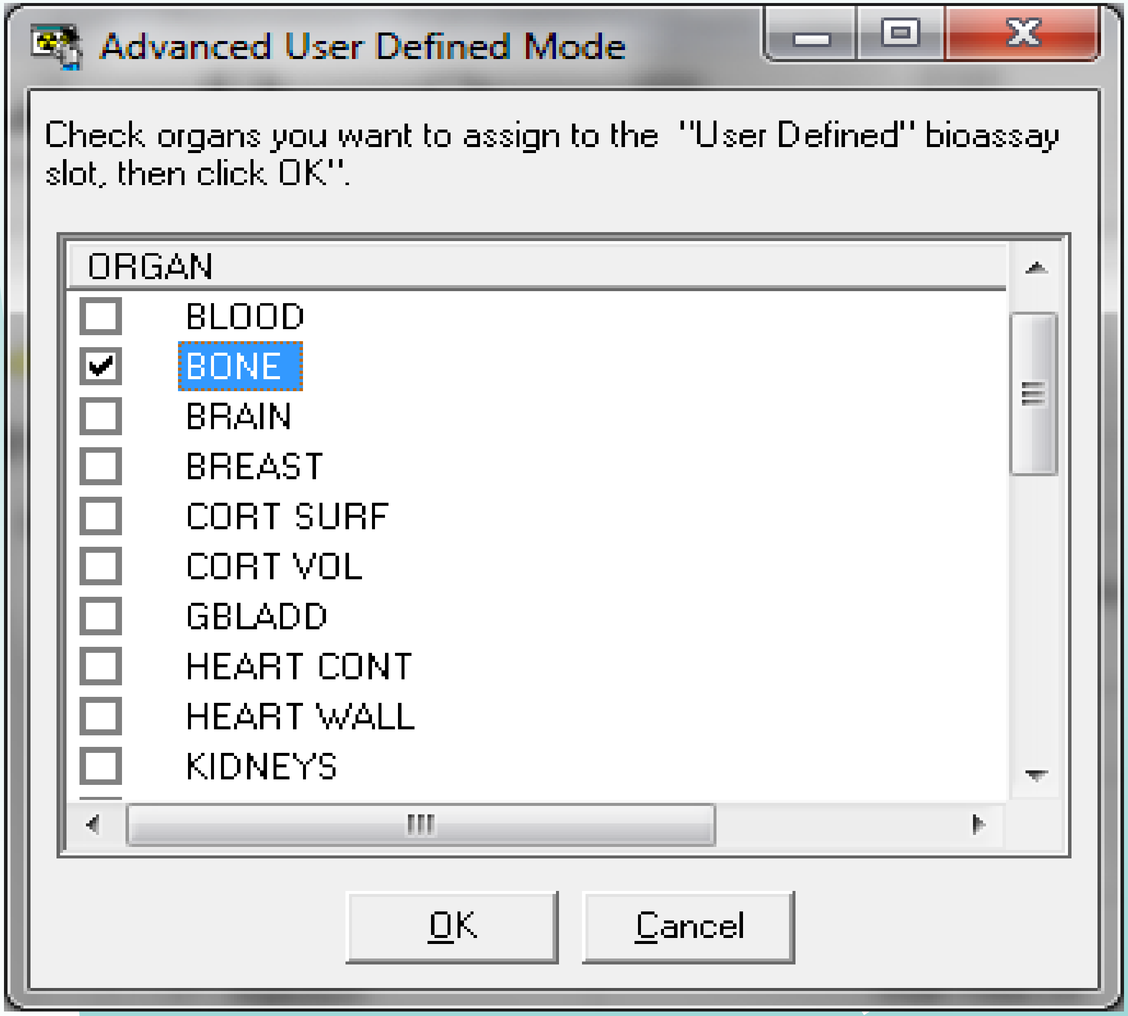
Can Select Any "Compartment" of a Biokinetic Model as a New "Bioassay Quantity"



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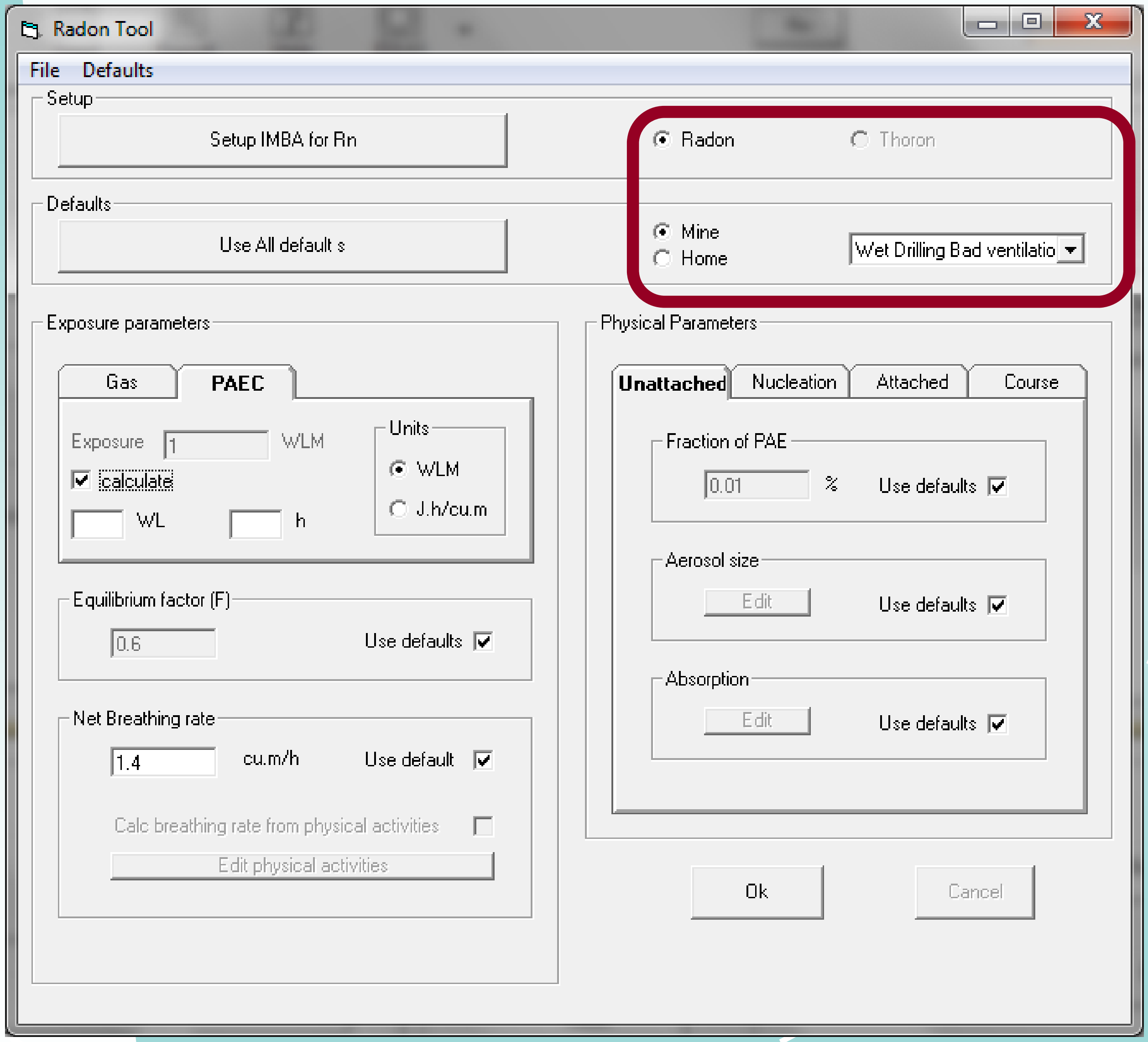
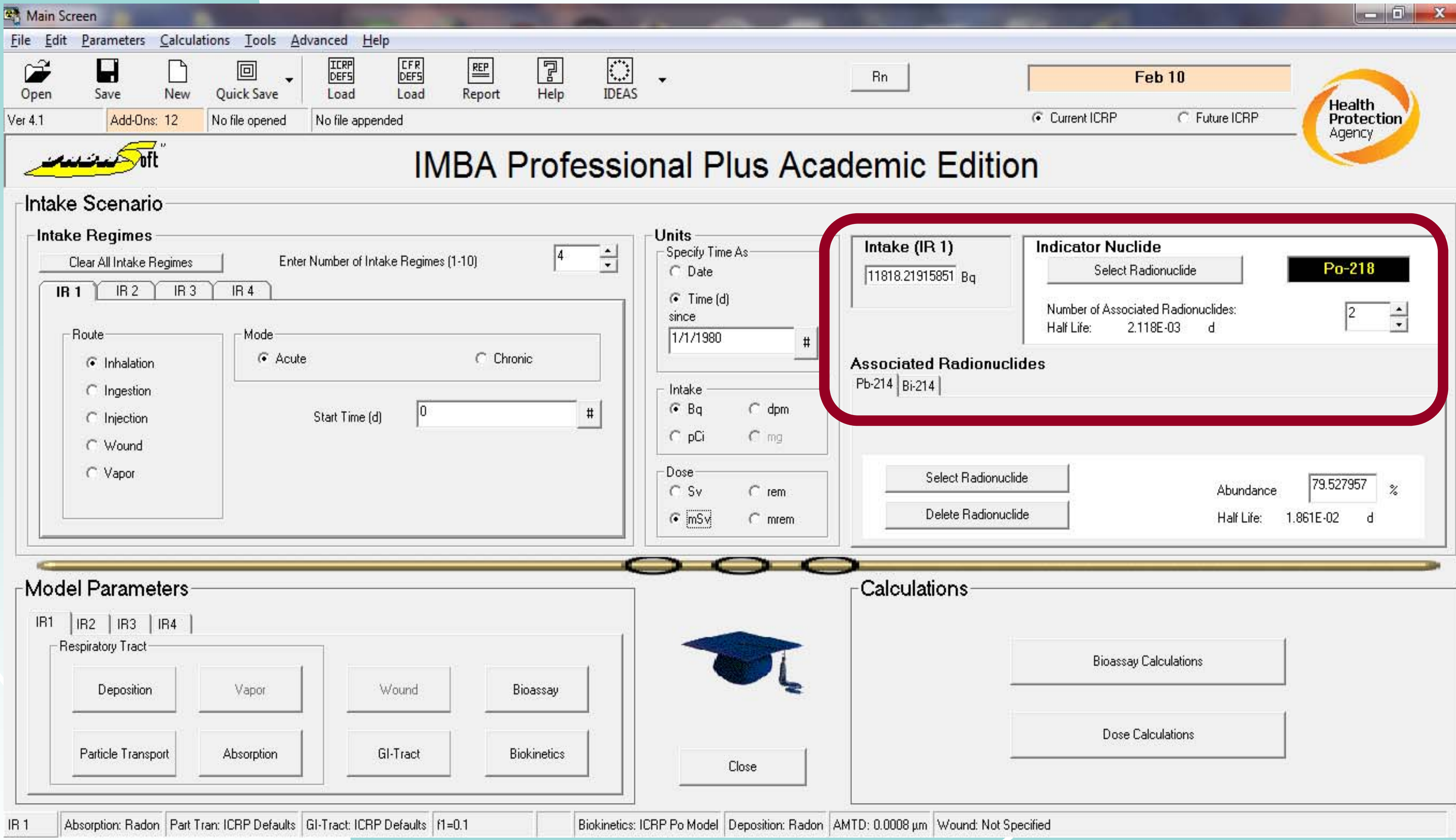
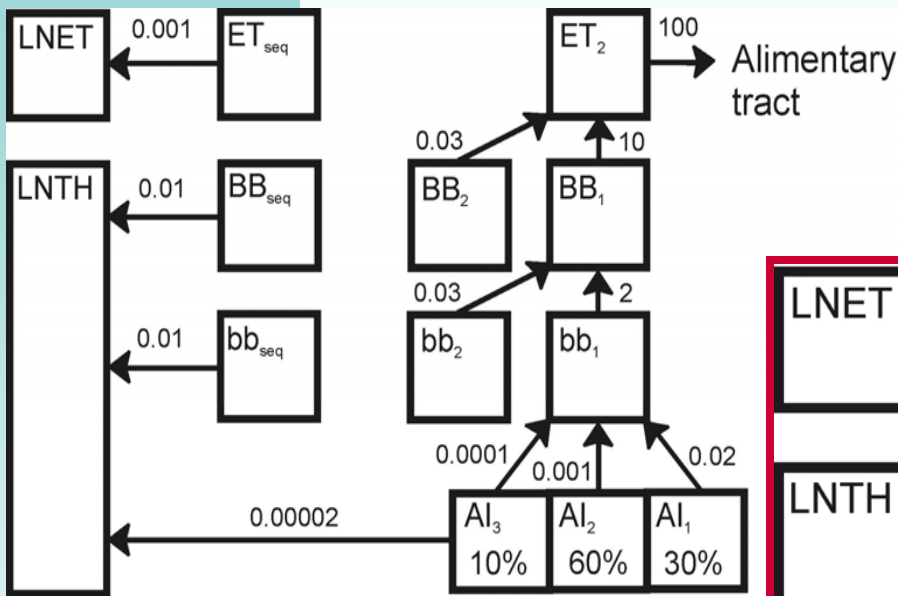
New Radon (and Thoron) Progeny Dosimetry "Tool"



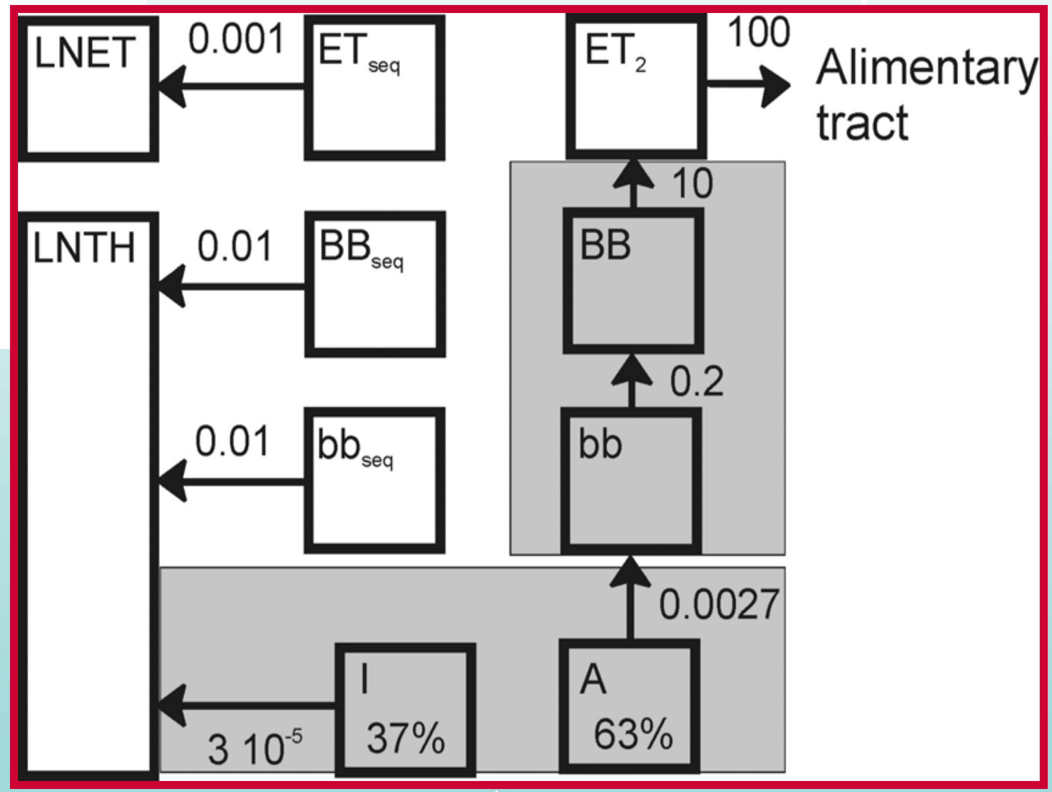
Radon (and Thoron) Progeny Dose Calculations



Proposed Improvement of HRTM



ICRP Publication 66 (1994)



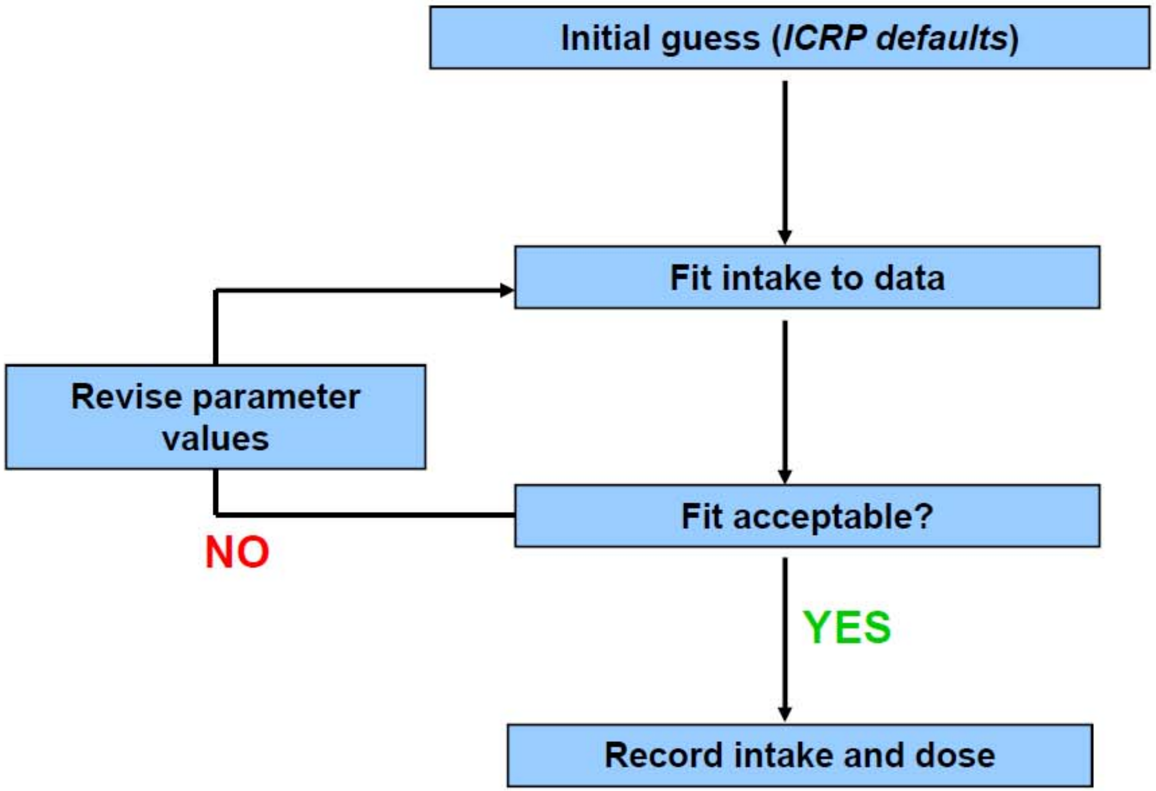
Gregoratto et al. (in press)

European Radiation Dosimetry Group

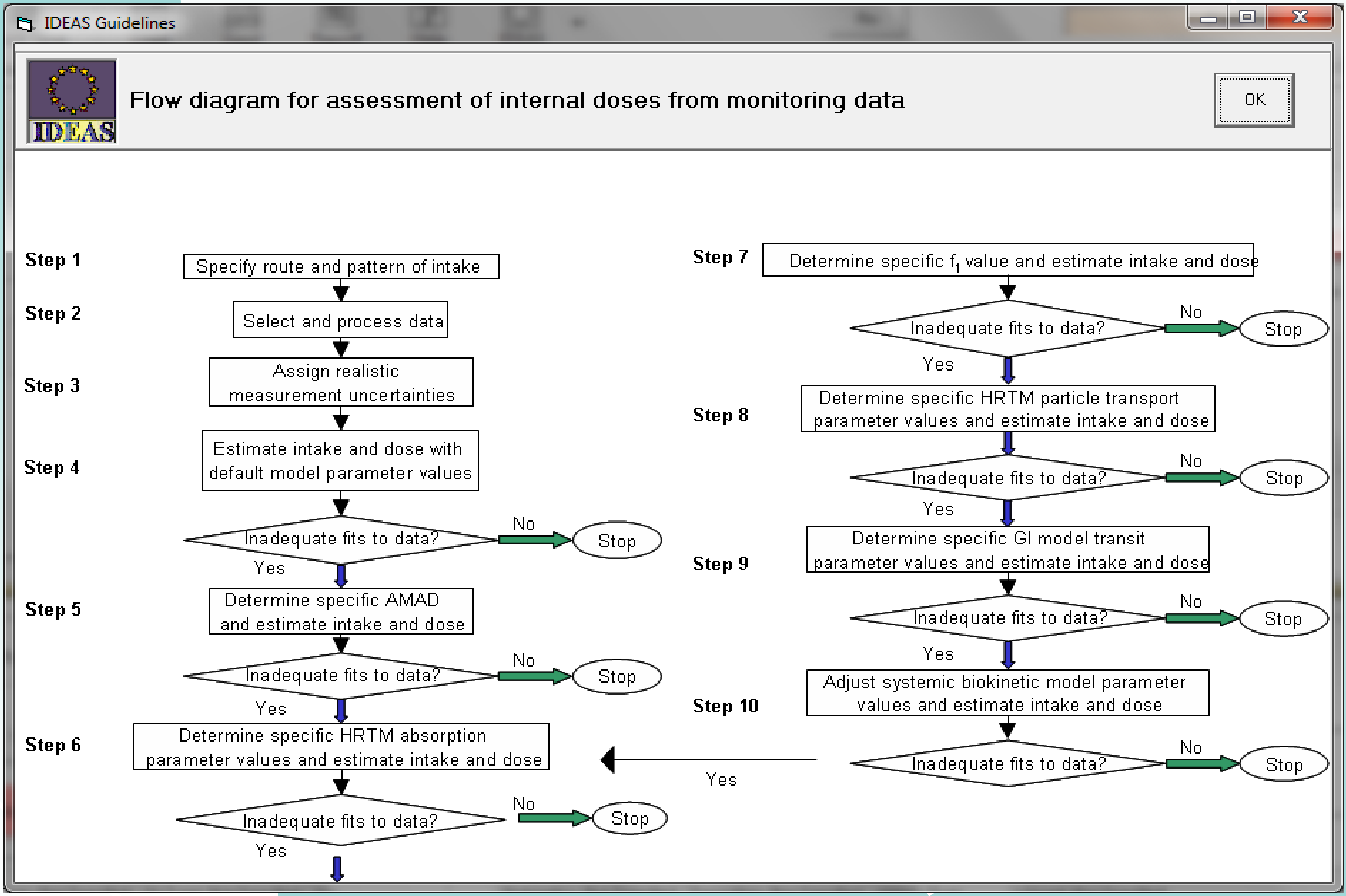
EURADOS

3. Fitting parameters

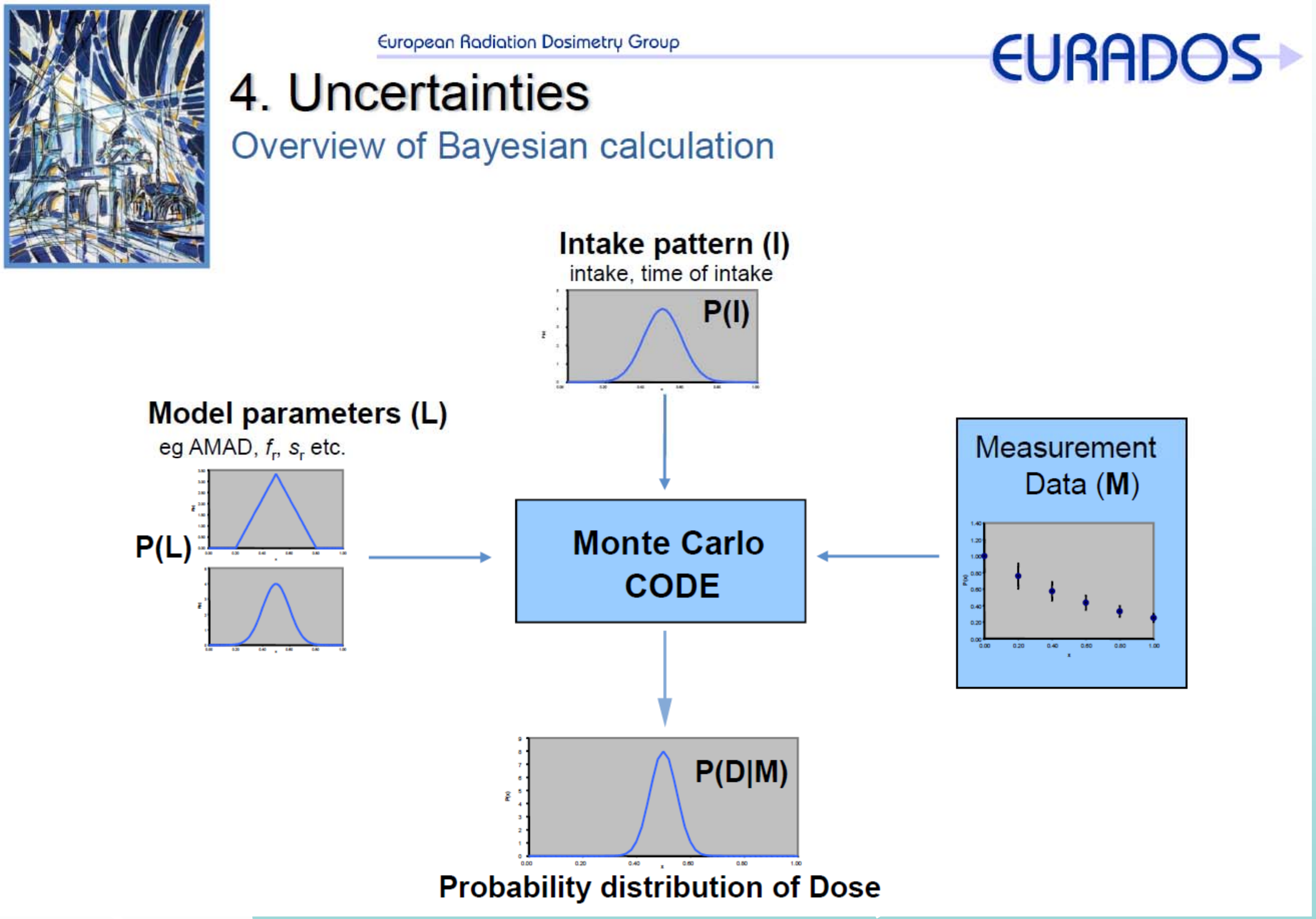
Overview



Internal Dose Assessment by "Rule Book" Can Get Very Complicated!!



Bayesian Analysis Goes Directly from Uncertainties in Bioassay Data to Uncertainties in Doses



Example from USTUR Case Study – "In Vivo" Bioassay Data

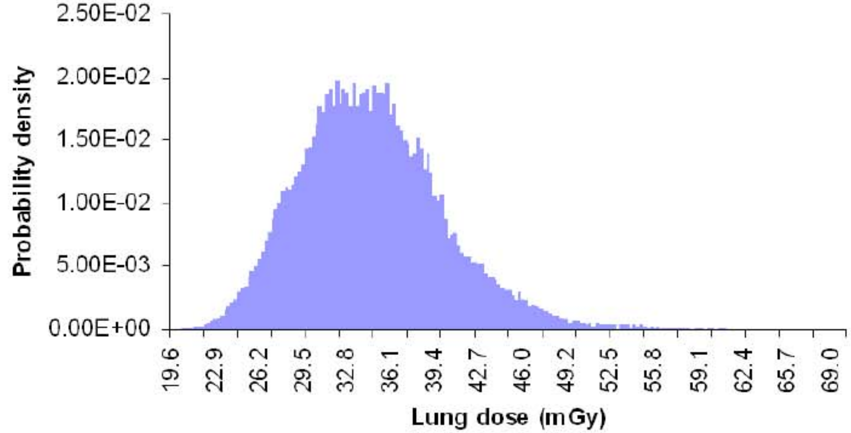
European Radiation Dosimetry Group

EURADOS

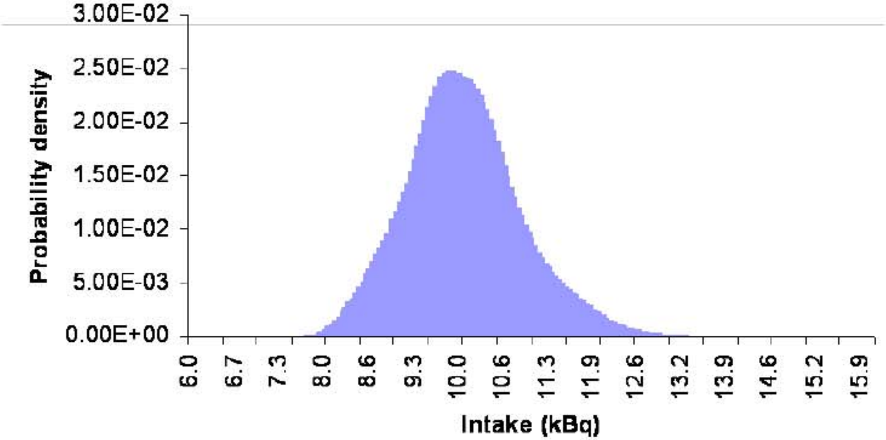
4. Uncertainties

Example: intake of ^{241}Am aerosol

Lung dose (mGy)



Intake (Bq)



Simultaneous Evaluation of Uncertainties in HRTM Model Parameters

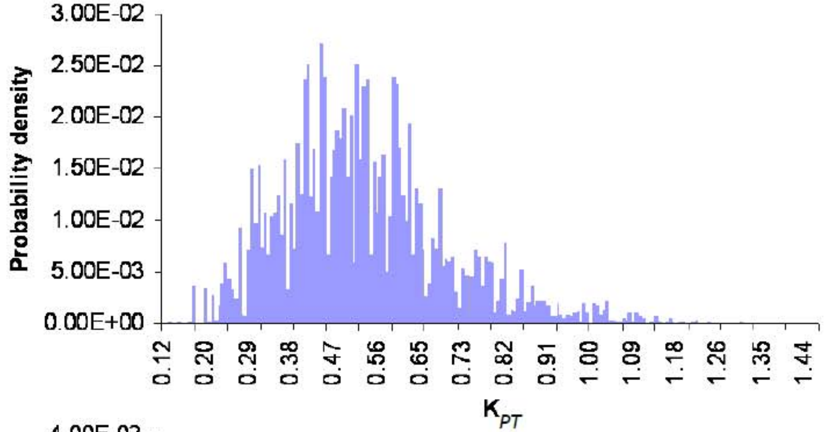
European Radiation Dosimetry Group

EURADOS

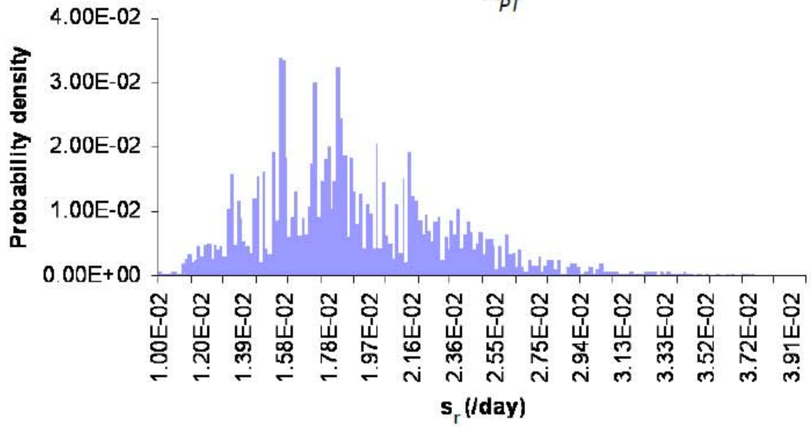
4. Uncertainties

Example: intake of ^{241}Am aerosol

Particle transport K_{PT}



Rapid rate s_r



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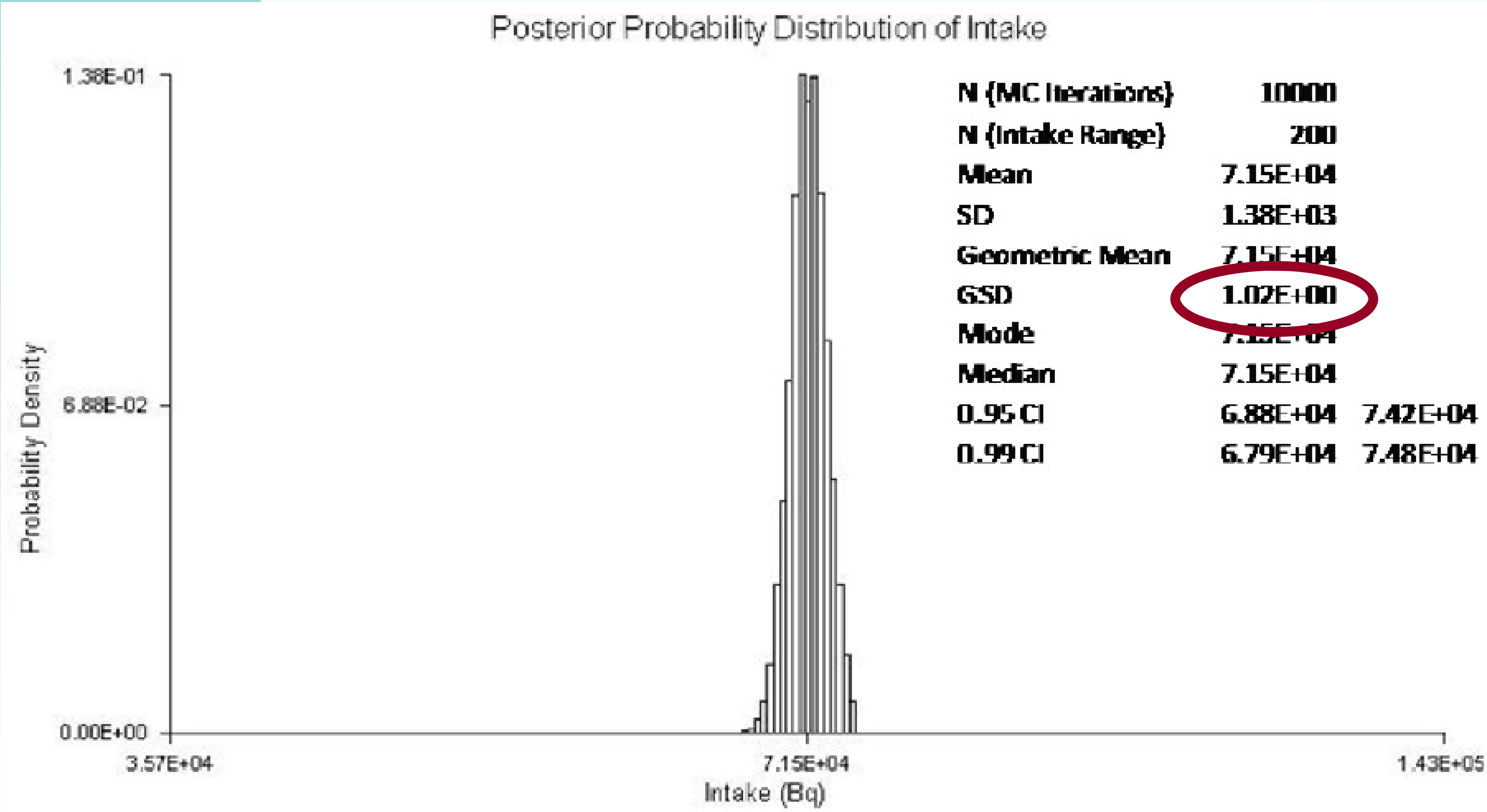
Case 0202 – Bayesian Posterior Distribution of Intake – Pu Fire



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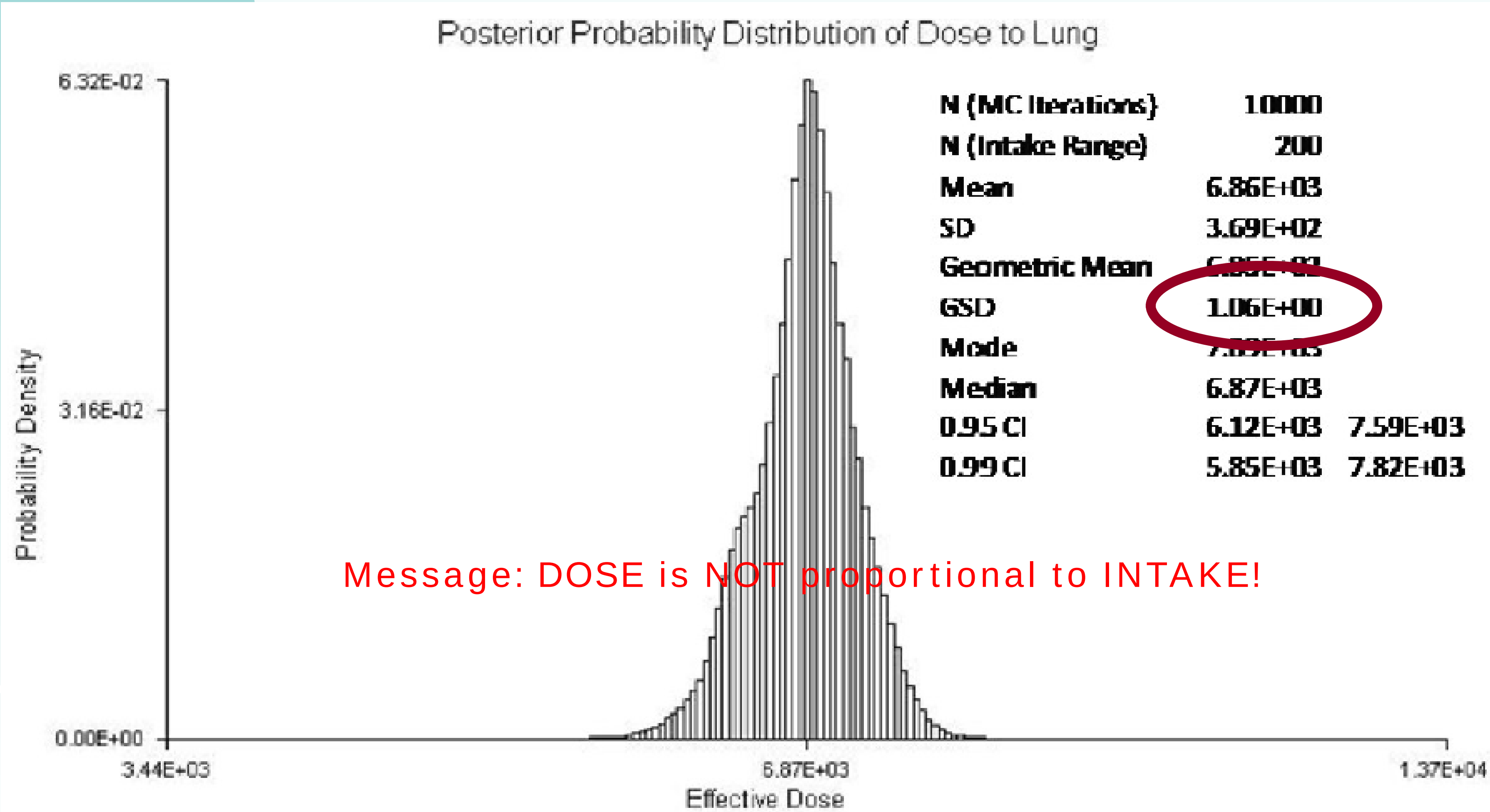
Case 0202 – Bayesian Posterior Distribution of "Effective" Dose to Lung, H_E(lung)



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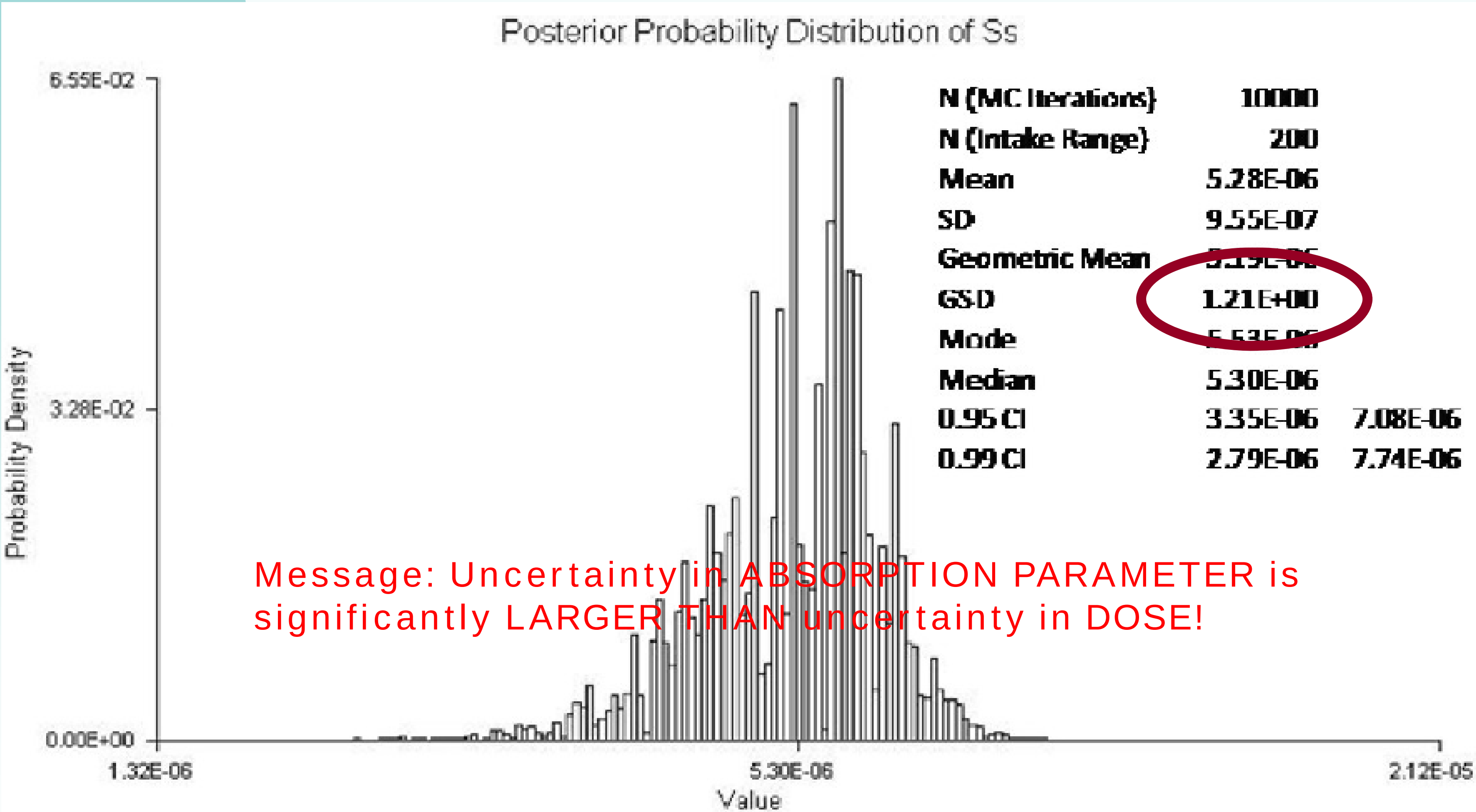
Case 0202 – Bayesian Posterior Distribution of Slow Absorption Rate, s_s



Message: Uncertainty in ABSORPTION PARAMETER is significantly LARGER THAN uncertainty in DOSE!

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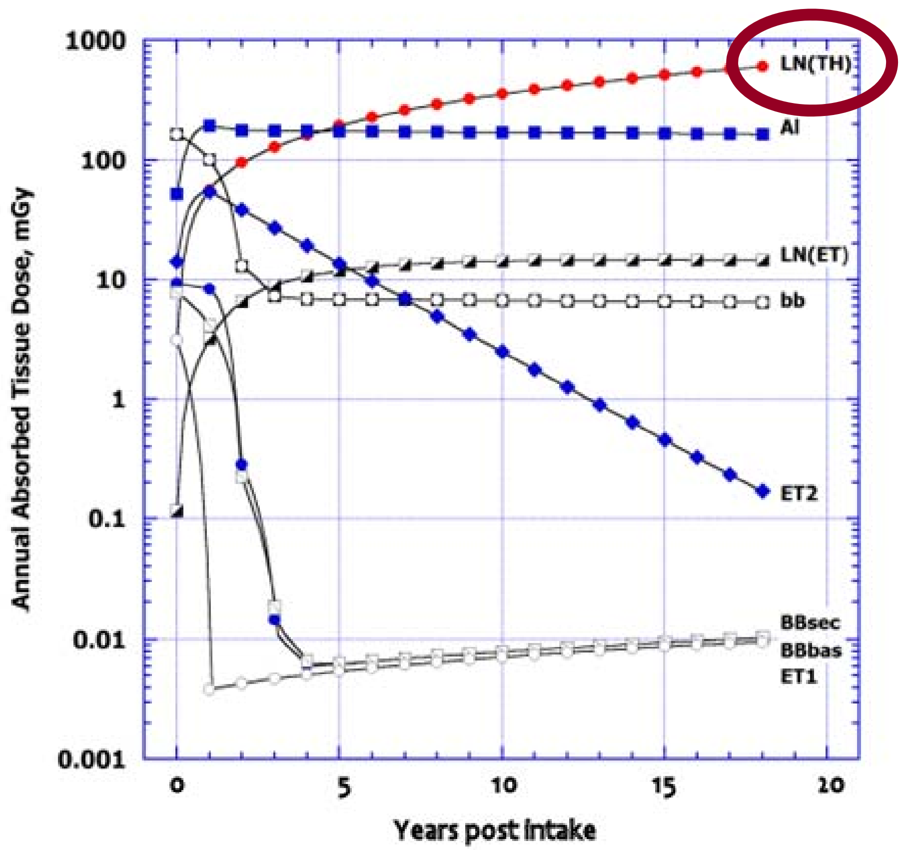
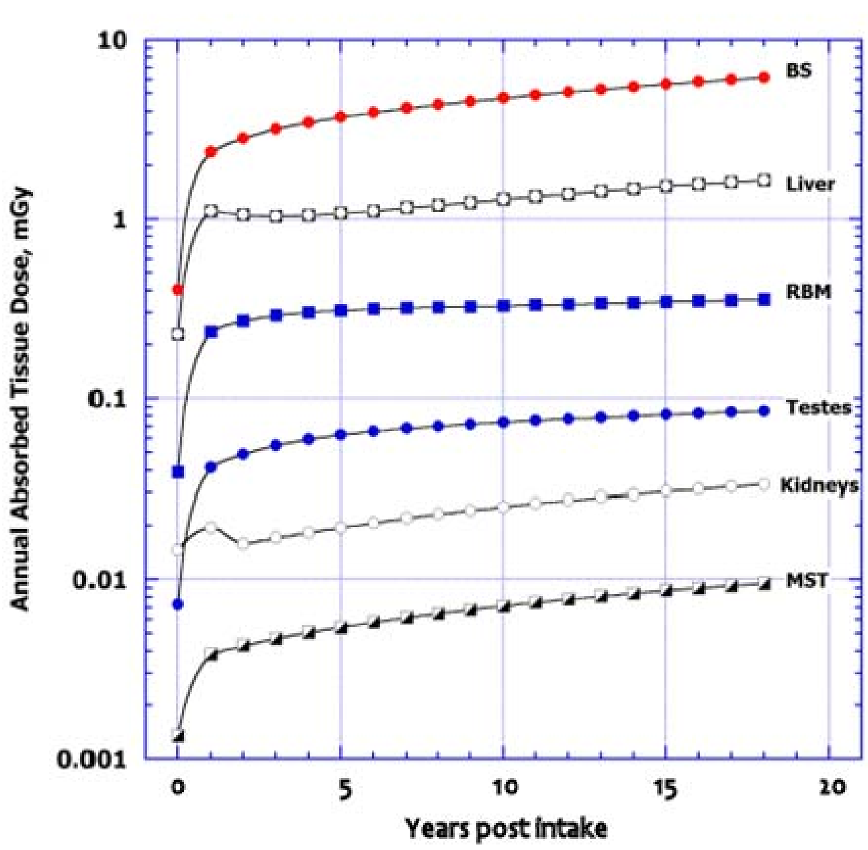
Case 0202 – Predicted Annual Dose Rates (Optimized Gregoratto HRTM)





Comparison of Bronchial Target Cell Dose

Bronchial Target Cells

In this case (Pu fire incident), the OHRTM and OGPT models give significantly different estimates of committed dose to bronchial secretory cells (but not basal cells):

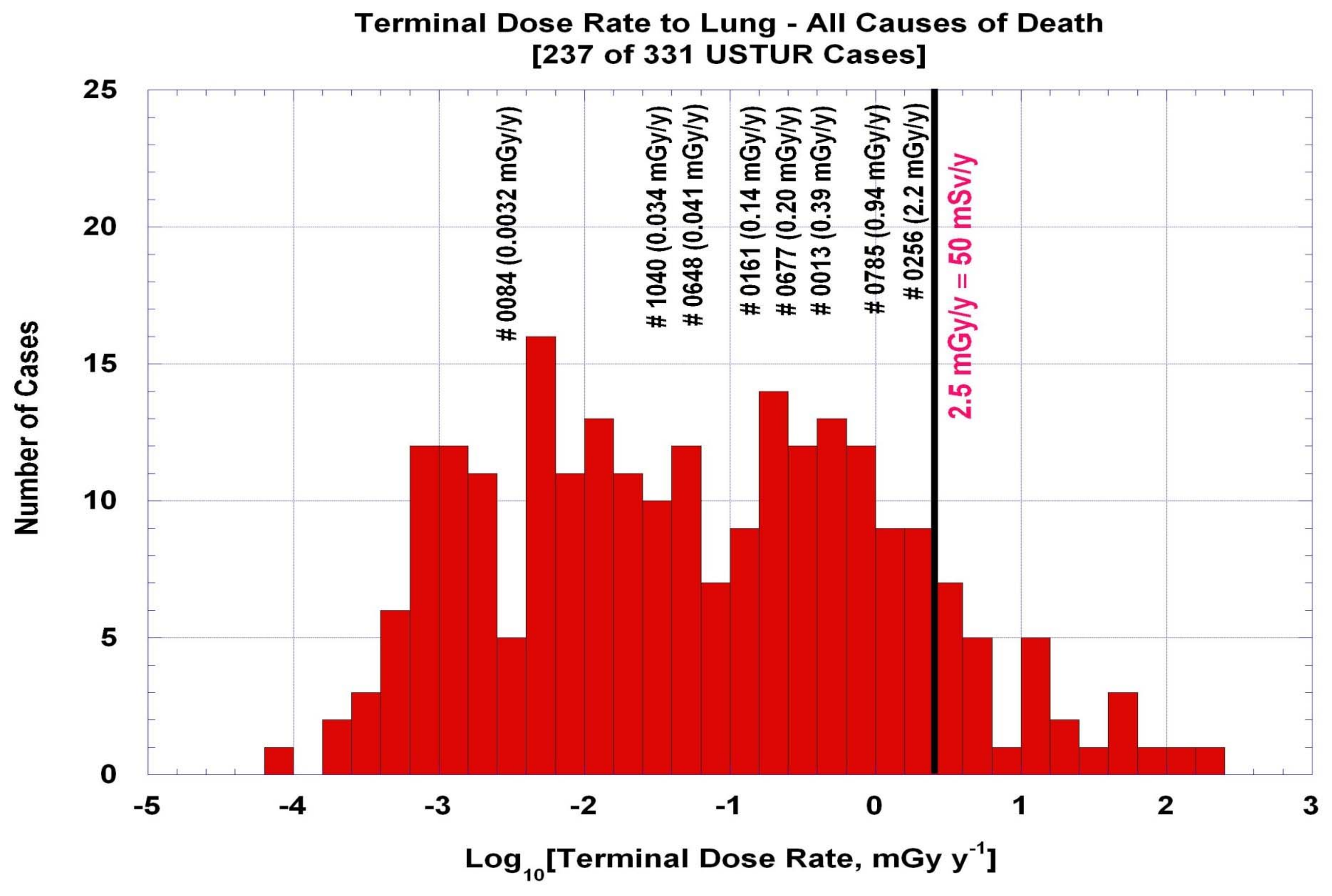
Secretory cells

- OHRTM; 7.71 Sv (GSD = 1.33)
- OGPT; 0.273 Sv (GSD = 1.28).

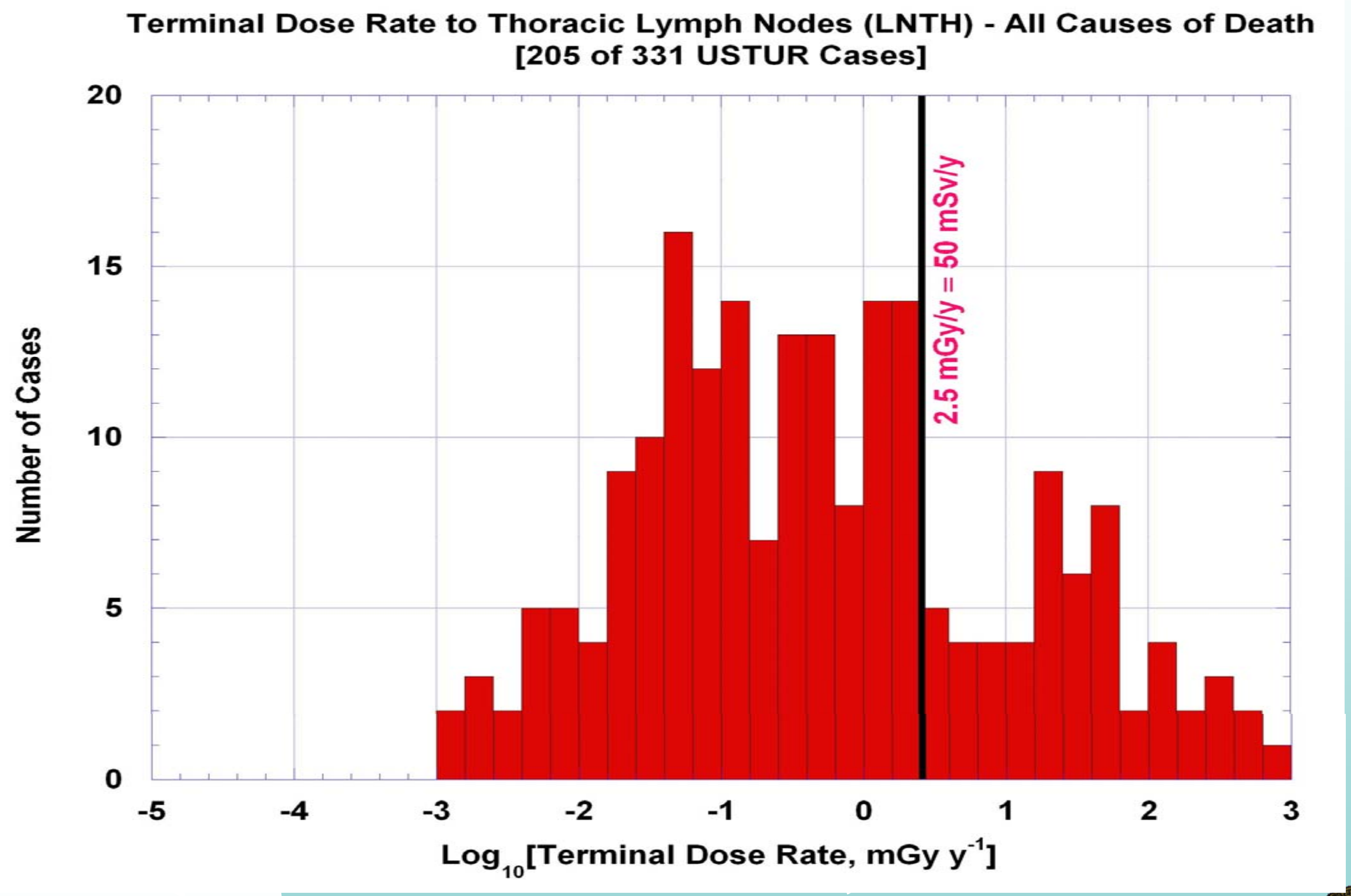
Basal cells

- OHRTM; 0.494 Sv (GSD = 1.32)
- OGPT; 0.398 Sv (GSD = 1.28).

The USTUR Measures α-Dose Rates to Tissues DIRECTLY – From Radiochemical Analyses of Autopsy Samples



Including DIRECT Measurement of Terminal α-Dose Rate to Thoracic (and Axillary) Lymph Nodes



ICRP Publication 103 Has Changed the Treatment of Lymph Nodes – and Remainder Tissues!!

ICRP Publication 103

Table 3. Recommended tissue weighting factors.

Tissue	w_T	$\Sigma\ w_T$
Bone-marrow (red), Colon, Lung, Stomach, Breast, Remainder tissues*	0.12	0.72
Gonads	0.08	0.08
Bladder, Oesophagus, Liver, Thyroid	0.04	0.16
Bone surface, Brain, Salivary glands, Skin	0.01	0.04
	Total	1.00

* Remainder tissues: Adrenals, Extrathoracic (ET) region, Gall bladder, Heart, Kidneys, Lymphatic nodes, Muscle, Oral mucosa, Pancreas, Prostate (male), Small intestine, Spleen, Thymus, Uterus/cervix (female).

Some Potential Issues with New ICRP 103 "Dosimetry"

- **Not stated whether Thoracic Lymph Nodes (LNTH) are included in the "lymph node dose average" – or how to calculate axillary lymph node dose (for a "wound" intake).**

- **If LNTH are included, their w_T value would increase by an order of magnitude – from 0.001 (ICRP 66) to about 0.01 (one-fourteenth of the 0.12 "remainder" value).**

- **At least for the actinides, the radionuclide concentrations (tissue doses) for the Breast, Brain, Salivary glands, Skin, Adrenals, Gall bladder, Heart, Pancreas, Prostate, Spleen, Thymus, Uterix/cervix are not "modeled" – and autopsy data indicates substantial differences from Massive Soft Tissue (MST).**

Concluding Remarks (Personal Observations)

- **As found by many Approved Dosimetry Services (including the USDOE), a "unified" and pre-quality assured approach to formalizing internal dose assessment (such as the "modular" approach embodied in IMBA-based codes) is valuable in "seamlessly" implementing significant changes in regulatory practices.**
- **The developers of IMBA (and the related WeLMoS methodology and "interface") have demonstrated the technical capability to apply these codes flexibly, reliably, and remarkably quickly to help both "Users" and regulators.**
- **I have tried to illustrate the 'holistic' scope and power of this approach in meeting anticipated regulatory needs – and also in stimulating (and facilitating) fundamental research on the quantification (and reduction) of uncertainty in internal dose assessment.**

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Thank you for your attention!

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