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IDEAS Guidelines (Version 2) for the Estimation of Committed Doses from Incorporation Monitoring Data

Work of Task 7.1 "Update of IDEAS Guidelines and Databases" of EURADOS WG7 "Internal Dosimetry"

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Editorial

This report is Version 2 of the report "General Guidelines for the Estimation of Committed Effective Dose from Incorporation Monitoring Data (IDEAS Guidelines)" edited as a Forschungszentrum Karlsruhe Wissenschaftliche Berichte FZKA 7243 in 2006. Large parts of this report are taken from the previous FZKA 7243 report so acknowledgement is provided to the authors that contributed to that report: H. Doerfel, A. Andrasi, M. Bailey, V. Berkovski. , B. Le Guen, I. Malatova, J. Stather.

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Content:

Glossary

Absorbed dose (See also 'mean absorbed dose')

The physical dose quantity given by

$$D = \frac{d\bar{e}}{dm}$$

where de is the mean energy imparted by ionising radiation to the matter in a volume element and dm is the mass of the matter in the volume element. The SI unit for absorbed dose is joule per kilogram (J kg^{-1}) and its name is Gray (Gy).

Absorption

Movement of material to blood regardless of mechanism. In the respiratory tract, it generally applies to dissociation of particles and the uptake into blood of soluble substances and material dissociated from particles

Absorption type

Classification of inhaled materials according to their rates of absorption from the respiratory tract into body fluids. The absorption types are defined in ICRP Publication 66 as follows.

Type F materials (deposited materials that are readily absorbed into body fluids from the respiratory tract; fast rate of absorption)

Type M materials (deposited materials that have intermediate rates of absorption into body fluids from the respiratory tract; moderate rate of absorption)

Type S materials (deposited materials that are relative insoluble in the respiratory tract; slow rate of absorption)

Type V materials (deposited materials that are assumed, for dosimetric purposes, to be instantaneously absorbed into body fluids from the respiratory tract - applied only to certain gases and vapours - very rapid absorption).

The default absorption parameter values for each absorption Type given in ICRP Publication 66 will be revised in the forthcoming ICRP OIR document based on reviews of experimental data.

Activity

Physical quantity for the number of disintegrations per unit time (s) of a radioactive material. The SI-unit of the activity is Becquerel (Bq): 1 Bq = 1 s^{-1}

Activity Median Aerodynamic Diameter (AMAD)

Physical parameter for the description of the particle size of radioactive aerosols. Fifty percent of the activity in the aerosol is associated with particles of aerodynamic diameter (d_{ae}) greater than the AMAD. The AMAD is used for particle sizes for which deposition depends principally on inertial impaction and sedimentation: typically those greater than about 0.5 μm. For smaller particles, deposition typically depends primarily on diffusion, and the activity median thermodynamic diameter (AMTD) - defined in an analogous way to the AMAD, but with reference to the thermodynamic diameter of the particles - is used.

Bioassay

Any procedure used to determine the nature, activity, location or retention of radionuclides in the body by direct (*in vivo*) measurement or by indirect (*in vitro*) analysis of material excreted or otherwise removed from the body.

Biokinetic model

A mathematical model describing the intake, uptake and retention of a radionuclide in various organs or tissues of the body and the subsequent excretion from the body by various pathways.

Biokinetic or reference bioassay function

A mathematical function describing the time course of the activity in the body (retention function) or the activity excreted via urine or faeces (excretion function) following a single intake at time $t = 0$. In general, the retention function $m(t)$ represents the predicted body or organ activity at the time t after the intake, whereas the excretion function $m(t)$ represents the integral of the excretion rate from $t - 1$ days until t days. The radioactive decay in the sample during the sample collection period is taken into account. Tabulated values of $m(t)$ are given in ICRP Publication 78 but these will be updated in the forthcoming ICRP OIR document.

Biological half-life

The time taken for the quantity of a material in a specified tissue, organ or region of the body (or any other specified biota) to halve as a result of biological processes.

Committed Effective Dose ($E(\tau)$). See also 'Effective dose'

The sum of the products of the committed equivalent doses in organs or tissues and the appropriate organ or tissue weighting factors (w_T), where τ is the integration time in years following the intake. The integration time is 50 y for workers. In accordance with ICRP Publication

103, *E*(50) is calculated with the use of male and female committed equivalent doses to individual organs or tissue regions as follows:

$$E(50) = \sum_T w_T \cdot \left[\frac{H_T^M(50) + H_T^F(50)}{2} \right]$$

The SI unit for committed effective dose is the same as for absorbed dose, J kg^{-1}, and its special name is sievert (Sv).

Committed Equivalent Dose ($H_T(\tau)$)

The time integral of the equivalent dose rate in a particular tissue or organ that will be received by an individual following intake of radioactive material into the body by a Reference Person, where τ is the integration time in years following the intake. The integration time is 50 y for workers.

Compartment

Pool of radioactive materials in the body which can be characterised by first order kinetics; a compartment can be an organ (as for example the liver), a part of an organ (as for example the bronchial region of the lungs), a tissue (as for example the bone), a part of a tissue (as for example the bone surface) or another substance of the body (as for example the body fluids). Activity is considered to be uniformly distributed in a compartment.

Computational phantom (voxel)

Computational anthropomorphic phantom based on medical tomographic images where the anatomy is described by small three-dimensional volume elements (voxels) specifying the density and the atomic composition of the various organs and tissues of the human body.

Critical monitoring quantity (M_c)

If the measured quantity, M, from a routine monitoring program, is less than M_c then the potential intakes during the accounting year is assumed to result in an annual dose less than 0.1 mSv. M_c is the amount of activity retained or excreted at the end of a monitoring period that determines an intake that, if it was repeated for all monitoring periods during the accounting year, would result in a value of committed effective dose of 0.1 mSv in a year. In the absence of knowledge of the exact time of intake, it is assumed that intake took place at the mid-point of the monitoring period (T/2).

Decision threshold and detection limit

- Decision Threshold (DT)

  Fixed value of a measured quantity that, when exceeded by the result of an actual measurement quantifying a physical effect (e.g. the presence of a radionuclide in a sample), may be taken to indicate that the physical effect is present (ISO, 2010a, 2010b). The decision threshold is the critical value of a statistical test for the decision between the hypothesis that the physical effect is not present and the alternative hypothesis that it is present. When the critical value is exceeded by the result of an actual measurement, this is taken to indicate that the hypothesis should be rejected. The statistical test is designed in such a way that the probability of wrongly rejecting the hypothesis (Type I error) is at most equal to a given value, α. The decision threshold is an *a posteriori* quantity, evaluated after a particular measurement in order to decide whether the result of the measurement is significant. The decision threshold is sometimes referred to as the critical level, decision level or minimum significant activity.

- Detection Limit (DL)

  The smallest true value of a measured quantity which ensures a specified probability of being detectable by the measurement procedure (ISO, 2010a, 2010b). The DL is the smallest true value that is associated with the statistical test and hypothesis in accordance with the Decision Threshold, as follows: if in reality the true value is equal to or exceeds the DL, the probability of wrongly not rejecting the hypothesis (Type II error) is at most equal to a given value, β. The DL is an *a priori* quantity, evaluated for a particular measurement method in advance of the performance of a measurement. The detection limit is sometimes referred to as the minimum detectable activity (MDA), lower limit of detection (LLD) or limit of detection (LOD).

Decorporation therapy

Use of chelating agents to enhance the elimination of radionuclides from the body in order to reduce the radiation dose to an individual accidentally contaminated internally with radionuclides.

Deposition

The initial processes determining how much of a material in inhaled air remains in the respiratory tract after exhalation. Deposition of material may occur during both inhalation and exhalation. The distribution of the deposition of inhaled materials in the different regions of the respiratory tract depends on factors including the Activity Median Aerodynamic Diameter (AMAD) and the breathing pattern of the subject.

ICRP Publication 66 establishes three classes of gases and vapours on the basis of the initial pattern of respiratory tract deposition: Class SR-1 (soluble or reactive: deposition throughout the respiratory tract), Class SR-2 (highly soluble or reactive: deposition in ET) and Class SR-0 (insoluble

and non-reactive: negligible deposition). However, in the forthcoming ICRP OIR document, a simpler classification will be made for gases and vapours.

Direct measurement

Generic term for any kind of *in vivo* measurement of incorporated radionuclides (i.e. whole body counting, lung counting, thyroid counting etc.)

Dose Coefficient

Committed equivalent dose in organ or tissue T per unit intake $h_T(\tau)$ or committed effective dose per unit intake $e(\tau)$, where τ is the time period in years over which the dose is calculated. The integration time is 50 y for adults

Effective Dose (E)

In ICRP Publication 103, the effective dose was defined for the purposes of radiological protection as a sex-average quantity and is given by:

$$E = \sum_T w_T \left[\frac{H_T{}^M + H_T{}^F}{2} \right]$$

where $H_T{}^M$ and $H_T{}^F$ are the equivalent doses to the tissues or organs T of the Reference Adult Male and Reference Adult Female, respectively, and w_T is the tissue weighting factor for tissue T, with $\sum_T w_T = 1$.

The sum is performed over all organs and tissues of the human body considered to be sensitive to the induction of stochastic effects. Because w_R and w_T are dimensionless, the SI unit for effective dose is the same as for absorbed dose, J kg^{-1}, and its special name is sievert (Sv).

Equivalent dose (H_T)

The equivalent dose, $H_{T,R}$, in tissue or organ T due to radiation type R, is given by:

$$H_{T,R} = w_R \cdot D_{T,R}$$

where $D_{T,R}$ is the average absorbed dose from radiation type R in tissue T of the Reference Adult Male or Reference Adult Female, and w_R is the radiation weighting factor for radiation type R. Since w_R is dimensionless, the unit is the same as for absorbed dose, J kg^{-1}, and its name is Sievert (Sv). The total equivalent dose, H_T, is the sum of $H_{T,R}$ over all radiation types

$$H_T = \sum_R w_R \cdot D_{T,R}$$

The equivalent dose is a radiation protection quantity.

Excretion analysis

Procedure for the assessment of the activity in the urine or faeces or in the exhaled air. The excretion analysis includes radiochemical separation, preparation of measuring samples and the evaluation of the measuring samples by spectrometric or other techniques (i.e. α-spectrometry or ICP-MS)

Excretion rate

In general, the excretion rate is the amount of activity which is excreted via urine or faeces during 24 hours, with the decay of the radionuclide having been corrected for the end of the 24 hour sampling period. A special case is HTO where the excretion rate in general is given in terms of the activity concentration in the excreted material.

Exposure

The state or condition of being subject to irradiation.

Fractional absorption in the gastrointestinal tract (f_1)

The f_1 value is the fraction of an element directly absorbed from the gut to body fluids, used in the ICRP 30 gastrointestinal tract model. See also 'Human Alimentary Tract Model (HATM)'.

Human Alimentary Tract Model (HATM)

Biokinetic model for describing the movement of ingested materials through the human alimentary tract; published in Publication 100 (ICRP, 2006). In the model, the alimentary tract transfer factor (f_A) is defined as the fraction of activity entering the alimentary tract that is absorbed to blood, taking no account of losses due to radioactive decay or endogenous input of activity into the tract.

Human Respiratory Tract Model (HRTM)

Biokinetic model for describing the deposition, translocation and absorption of inhaled materials in the human respiratory tract; published in ICRP Publication 66 (ICRP, 1994) and will be updated in the forthcoming ICRP OIR document. The HRTM defines the following regions:

- Extrathoracic (ET) airways.

  The anterior nose (ET_1) and the posterior nasal passages, mouth, pharynx and larynx (ET_2).

- Bronchial (BB) region.

  The trachea and bronchi; airway generations 0-8.

- Bronchiolar (bb) region.

  The bronchioles and terminal bronchioles; airway generations 9-15.

- Alveolar-interstitial (AI) region.

  The respiratory bronchioles, alveolar ducts and sacs with their alveoli, and the interstitial connective tissue.

Indirect measurement

Generic term for any kind of *in vitro* analysis of material excreted or otherwise removed from the body (e.g. urine and faecal analysis). The term is also used to include air sampling measurements.

Intake

The processes and the activity of radioactive material entering the body, the principal routes being inhalation, ingestion or through intact or wounded skin (note in the case of inhalation of aerosols the intake is greater than the amount which is deposited in the body).

Acute intake

An intake occurring within a time period short enough that it can be treated as instantaneous for the purposes of assessing the resulting committed dose.

Chronic intake

An intake over an extended period of time, such that it cannot be treated as a single instantaneous intake for the purposes of assessing the resulting committed dose.

Mean absorbed dose, D_T

The mean absorbed dose in a specified organ or tissue region T is given by $D_T = 1/m_T \int D \, dm$, where m_T is the mass of the organ or tissue, and D is the absorbed dose in the mass element dm. The SI unit of mean absorbed dose is joule per kilogram (J kg^{-1}), and its special name is gray (Gy).

Occupational exposure

Exposure to radiation incurred at work as the result of situations that can reasonably be regarded as the responsibility of the operating management.

OIR document

The forthcoming ICRP Occupational Intake of radionuclides (OIR) document series will provide revised dose coefficients for worker by inhalation and ingestion replacing the ICRP Publication 30 series and Publication 68. It will also provides data for the interpretation of bioassay measurements, replacing Publications 54 and 78. Further information regarding this forthcoming document is given in Section 1.2.7.

Radiation weighting factor, w_R

A dimensionless factor by which the organ or tissue absorbed dose component of radiation type R is multiplied to reflect the relative biological effectiveness of the radiation in inducing stochastic effects at low doses. It is used to derive the organ equivalent dose from the mean absorbed dose in an organ or tissue. The values are chosen by ICRP for radiation protection purposes only.

Reference male and reference female (reference individual)

An idealised male or female with anatomical and physiological characteristics defined by the ICRP for the purpose of radiological protection. The anatomical and physiological characteristics are defined in the report of the ICRP Task Group on Reference Man (Publication 89, ICRP 2002).

Reference person

In ICRP Publication 103, a reference person was defined as an idealised person, for whom the equivalent doses to organs and tissues are calculated by averaging the corresponding doses of the Reference Male and Reference Female. The equivalent doses of the Reference person are used for the calculation of the effective dose

Relative biological effectiveness (RBE)

The ratio of a dose of a low-LET reference radiation to a dose of the radiation considered that gives an identical biological effect. RBE values vary with the dose, dose rate, and biological endpoint considered. In radiological protection, the RBE for stochastic effects at low doses (RBE_M) is of particular interest.

Rogue data

Rogue or outlier data are data that are numerically distant from the rest of the data. In other words, an outlier is one that appears to deviate markedly from other members of the sample in which it occurs. An outlier is considered as a rogue data point, if it is not part of the sample population in which the other members occur. In terms of bioassay data, outliers above and below the trend of the other data have different significance – See Section 6.1.

Scattering Factor (SF)

The scattering factor (SF) is a measure of the uncertainty of an individual monitoring value. It is assumed that the overall uncertainty on an individual monitoring value can be described in terms of a log-normal distribution and the scattering factor (SF) is defined as its geometric standard deviation. In this report, the uncertainty is divided into two main categories referred to as Type A and Type B uncertainties. Type A uncertainties are taken to arise from counting statistics only whereas Type B components are due to all other sources of uncertainty.

Specific Effective Energy (SEE)

The Specific Effective Energy, SEE(T $\leftarrow$ S) is the equivalent dose in target region or organ, T per nuclear transformation of a given radionuclide in source region, S. Units are: Sv per disintegration = Sv (Bq s)$^{-1}$ In the forthcoming ICRP OIR document, the SEE is referred to as the S-coefficient (radiation-weighted) and is correspondingly defined for the Reference Adult Male and Reference Adult Female.

Structured approach to dose assessment

The structured approach consists of a series of stages (or flow charts) for the assessment of dose based on the principles of harmonisation, accuracy and proportionality (i.e. the effort applied to the evaluation should be proportionate to the dose – the lower the dose, the simpler the process should be). See chapters 7-11.

Tissue weighting factor, w_T. See also 'Effective Dose'.

The factor by which the equivalent dose to an organ or tissue is weighted to represent the relative contribution of that organ or tissue to overall radiation detriment from stochastic effects resulting from uniform irradiation of the body. It is defined such that

$$\sum_{T} w_T = 1$$

Transfer compartment

The compartment introduced for mathematical convenience into most of the biokinetic models used in ICRP and IAEA publications to account for the translocation of the radioactive material through the body fluids from where they are deposited in tissues.

Uptake

The processes by which radionuclides enter the body fluids from the respiratory tract, gastrointestinal tract or through the skin, or the fraction of an intake that enters the body fluids by these processes.

Abstract

Doses from intakes of radionuclides cannot be measured but must be assessed from monitoring data, such as whole body, urine or faecal data. Such assessments require application of biokinetic and dosimetric models, and the assessor may well have to make assumptions about factors such as the pattern of intake and properties of the material. Intercomparison exercises (Doerfel 2000) have shown a wide range in doses that can be obtained from the same data set as a result of such factors and hence the need for guidance on harmonising evaluations. As a result a European project in the EC 5th Framework programme was established to give guidance on internal dose assessments from monitoring data (Project IDEAS). In 2006, a document giving such guidance was published (Doerfel 2006) and is commonly referred to as the IDEAS Guidelines. Following its publication, a working group within European network CONRAD and EURADOS was established to improve and update the IDEAS Guidelines, and to take account of recent developments in the field of internal dosimetry. This document is the result of such work.

The IDEAS Guidelines are based on a general philosophy of:

- Harmonisation: by following the Guidelines any two assessors should obtain the same estimate of dose from a given data set.
- Accuracy: the "best" estimate of dose should be obtained from the available data.
- Proportionality: the effort applied to the evaluation should be proportionate to the dose - the lower the dose, the simpler the process should be.

Following these principles, the Guidelines use the following "Levels of task" to structure the approach to an evaluation: Level 0: Annual dose <0.1 mSv. No dose evaluation; Level 1: Simple evaluation normally using ICRP reference parameter values (typical dose 0.1 - 1 mSv); Level 2: Sophisticated evaluation using additional information to give more realistic assessment (typical dose 1 - 6 mSv); Level 3: More sophisticated evaluation, for cases with comprehensive data (typical dose > 6 mSv).

In this new version the following revisions have been made:

- Additional information and literature review on values of excretion of U, Th, Ra, Po in different bioassay types (urine and faeces) and places due to alimentary introduction.
- Collection of typical and achievable values for detection limits for different bioassay measurement techniques.
- New default measurement uncertainties (i.e. scattering values, SF) for different types of monitoring data.
- Additional information on the minimum number and type of data required for dose assessment.
- Additional information on the calculation of the effective AMAD.
- Additional information on data fitting and autocorrelation test statistics.
- Introduction of a special procedure for wound cases, following the publication of the NCRP 156 wound model.
- Introduction of the description of the direct dose assessment method (tritium case).

- Example evaluations showing the correct application of the guidelines taken from the recent EURADOS/IAEA advanced training course on internal dose assessment.
- Typical uranium and plutonium isotopic compositions encountered in the nuclear industry.

This version takes account of the forthcoming ICRP Occupational Intakes of Radionuclides (OIR) document series, so that these Guidelines can still be applied following their publication. A brief description of the ISO standard on dose assessment for monitoring of workers for internal radiation exposure is also included and compared with the IDEAS Guidelines.

1. Introduction

1.1 The IDEAS project

1.1.1 Introduction

The need for harmonisation of the procedures for internal dose assessment has been the aim of the project IDEAS, partly funded by the European Commission under contract No. FIKR-CT2001-00160. The IDEAS project started in October 2001 and ended in June 2005. The following partner institutions were involved in the project: Forschungszentrum Karlsruhe (FZK), Germany;Belgian Nuclear Research Centre (SCK•CEN), Belgium; Electricité de France (EDF), France; Italian National Agency for New Technology, Energy and the Environment (ENEA), Italy; Institut de Radioprotection et de Sûreté Nucléaire (IRSN), France; KFKI Atomic Energy Research Institute (AEKI), Hungary; Radiation Protection Institute (RPI), Ukraine; National Radiological Protection Board (NRPB), now Health Protection Agency, Radiation Protection Division, (HPA-RPD), United Kingdom. The IDEAS project was divided into Work Packages (WP), one for each of the five major tasks:

WP1 - *Collection of incorporation cases* - was devoted to the collection of data by means of bibliographic research. Two databases were prepared: the *IDEAS Bibliography Database* and the *IDEAS Internal Contamination Database* (Hurtgen 2007); http://www.sckcen.be/ideas/). The *IDEAS Bibliography Database* collects information present in the open literature or in other reports dealing with internal contamination cases. The *IDEAS Internal Contamination Database* was set up to collate the descriptions of selected well documented cases in a specific format providing all the information needed for internal dose assessment.

In WP2 - *Preparation of evaluation software* - the existing computer code IMIE (Individual Monitoring of the Internal Exposure, (Berkovski 2000, Berkovski 2002), was used as a platform for testing existing methods and approaches for bioassay data interpretation and methods developed in the project. IMIE permits the user to review and compare simultaneously different possible exposure condition combinations and to select the degree of automation from fully automated to completely manual.

In WP3 - *Evaluation of incorporation cases* - 52 selected cases were evaluated using IMIE and another computer code, IMBA (Integrated Modules for Bioassay Analysis, (Birchall 2003). From the evaluations various items were identified where guidance was needed. General features of the evaluation of monitoring data, were consequently defined (Castellani 2004).

In WP4 - *Development of the general guidelines* - the partners derived a common strategy for the evaluation of monitoring data, drafted the general guidelines and discussed it with internal dosimetry experts by means of a "virtual" workshop based on the internet in early 2004. The discussion was used to improve the common strategy and the general guidelines.

In WP5 - *Practical testing of general guideline*s - the validity of the draft guidelines was tested by means of a joint IDEAS/IAEA dose assessment intercomparison exercise open to participants from all over the world. Some 76 participants provided answers to all or some of the 6 cases proposed for evaluation. The results were discussed with the participants in a workshop in April 2005 and have been evaluated and discussed in a report (Hurtgen 2005). Based on these discussions the IDEAS general guidelines were finalised.

1.1.2 The IDEAS/IAEA intercomparison exercise

The intercomparison exercise begins with the announcement at the beginning of August 2004. The selection of cases was done up to September 2004. The cases were posted on the IDEAS web page at the beginning of October 2004.

The cases were available for evaluation up to the end of January 2005, so 4 months had been available to perform evaluation and to submit results in a dedicated web page. The analyses of results were performed during February and March 2005 and the final workshop was held in IAEA on April 2005.

Table 1.1 summarizes results the radionuclides considered in the six cases and the results obtained in terms of committed effective doses, E(50) (geometric mean and geometric standard deviation values, calculated by excluding outliers). Outliers were identified on the basis of the statistical procedure used in a previous exercise (Doerfel 2000). Number of participants and outliers for each study case are also reported in the table.

Table 1.1: Statistical evaluations of the E(50) results of the IDEAS/IAEA intercomparison exercise (excluding outliers) (76 participants)

Case number	Radionuclide	E(50) Geometric mean (mSv)	E(50) Geometric standard dev.	Number of results[(a)]
1	^{3}H	25.8	1.06	46 (12)
2	^{137}Cs	0.66	1.16	52 (6)
	^{90}Sr	7.22	1.94	48 (10)
3	^{60}Co	5.0	1.4	56 (6)
4	^{131}I	2.57	1.07	50 (13)
5	Enriched Uranium	36.8	2.4	38 (3)
6	^{241}Am	52	2.1	32 (3)
	^{239}Pu	140	1.58	31 (5)

[(a)] number of outliers in brackets

The results were discussed with the participants during a workshop held by IAEA in April 2005. Of the 76 participants who assessed at least one case, 36% provided an answer to all six cases. The highest participation (84%) was for the cobalt and iodine cases and the lowest (57%) was for the americium part of case 6.

Even if the direct comparison on the spread of results between the previous 3rd European Intercomparison Exercise (Doerfel 2000) and the IDEAS/IAEA Intercomparison Exercise (Hurtgen 2005) cannot be accomplished, the application of the draft guidelines seems to produce an improvement i.e. a reduction of the spread of results, as the geometric standard deviation values tend to be smaller. Some 20% of participants used the IDEAS Guidelines correctly and reached results that can be considered to be completely accurate.

Another important finding of the IDEAS/IAEA intercomparison exercise was the lower occurrence of outlying values among those who applied the Guidelines than among those who did not. So it can be affirmed that the IDEAS Guidelines have a positive influence on the harmonisation of reported intakes and doses.

However, even very detailed guidelines cannot help if unrealistic assumptions or simple mistakes are made. As a final outcome of the intercomparison the authors indicated that more effort should be done for the promotion and correct application of such guidelines in the international internal dosimetry community, together with dedicated training.

1.1.3 The 2006 IDEAS Guidelines

The IDEAS guidelines, updated according to the outcomes of the intercomparison exercise, were published as FZKA report in 2006 (Doerfel 2006).

The general philosophy of the guidelines focuses on the principles of:

- harmonization; any assessors should obtain the same estimate of dose from a given data set.
- accuracy; the "best" estimate of dose should be obtained from the available data.
- proportionality; the effort applied to the evaluation should be proportionate to the dose – the lower the dose, the simpler the process should be.

A level of task to structure the approach of internal dose evaluation was proposed as well as special procedures for the different paths of intake.

The IDEAS 2006 publication describes ICRP biokinetic models (ICRP 1998) and provides advice on the handling of bioassay monitoring data for the purpose of dose calculation. A quantification of measurement uncertainties by a scattering factor (SF) is proposed as well as statistical tools to make judgement on the fit of the model to the data and on the most likely value of intake. A standardized procedure for the evaluation of committed effective dose is structured through flowcharts along four levels of increasing complexity depending on the expected order of magnitude of the dose:

- At level 0, when the measured activity is less than a threshold value determined in advance from the biokinetic model, the monitoring period and technique, the annual dose is likely to be less than 0.1 mSv and no further dosimetric evaluation is needed.
- At level 1, for a dose in the order of 0.1 to 1 mSv, a simple evaluation is performed using reference ICRP parameters unless specific information is available: inhalation at the middle of the monitoring interval, AMAD 1 or 5 µm and absorption type F, M or S.
- At level 2, if the dose may exceed 1 mSv or in case of established incident, it is advised to perform several measurements with different techniques and/or at different times. The most likely time of intake, AMAD and absorption type are obtained by fitting the prediction of the model to the measurement data.
- At level 3, if the dose is estimated to be more than 6 mSv, a more sophisticated evaluation is performed by fitting all the model parameters in a specific order until a reasonable consistency between model prediction and the measurement data is obtained.

1.2 Recent reference documents of interest for internal dose assessment

1.2.1 The 2007 recommendations of the ICRP on effective dose

The ICRP Publication 103 of the 2007 Recommendations (ICRP 2008) introduced changes in the definition of effective dose leading to an on-going process of revision of the biokinetic model and dose coefficients.

The protection quantities are used to specify exposure limits to ensure that the occurrence of stochastic health effects is kept below unacceptable levels and that tissue reactions are avoided. The definition of the protection quantities is based on the average absorbed dose, $D_{T,R}$ in the volume of a specified organ or tissue T, due to radiation of type R. The radiation R is given by the type and energy of radiation either incident on the body or emitted by radionuclides residing within it. Computational representations of the Reference Male and Reference Female are used to compute the mean absorbed dose, D_T, in an organ or tissue T, from decay of radionuclides after incorporation. These organ and tissue doses are multiplied with the radiation weighting factor w_R (Table 1.2) to yield the equivalent doses in the tissues and organs of the Reference Male and the Reference Female:

$$H_T = \sum_R w_R D_{T,R}$$

The sum is performed over all types of radiations involved. The unit of equivalent dose is J kg^{-1} and has the special name sievert (Sv).

Table 1.2 : Reference values for the radiation weighting factors (ICRP, 2008)

Radiation type	Radiation weighting factor, w_R
Photons	1
Electrons and muons	1
Protons and charged pions	2
Alpha particles, fission fragments, heavy ions	20
Neutrons	$2.5+18.2e^{-(\ln(E_n)^2/6}$, for $E_n < 1$ MeV $5.0+17.0e^{-(\ln(2E_n)^2/6}$, for 1 MeV $\leq E_n \leq$ 50 MeV $2.5+3.25e^{-(\ln(0.04E_n)^2/6}$, for $E_n > 50$ MeV

The equivalent doses in the organs and tissues of the Reference Male and the Reference Female are averaged. The averaged dose is multiplied with the corresponding tissue weighting factor (Table 1.3). The sum of these products yields the sex-averaged effective dose for the Reference Person. The effective dose is thus computed from the equivalent doses assessed for organ or tissue T of the Reference Male, H_T^M, and Reference Female, H_T^F, according to the following equation:

$$E = \sum_T w_T \left[\frac{H_T^M + H_T^F}{2} \right] \qquad (1.1)$$

The tissue weighting factors of Table 3 are sex- and age-averaged values for all organs and tissues, including the male and female breast, testis, and ovary (gonads: carcinogenic and heritable effects). This averaging implies that the application of this approach is restricted to the determination of effective dose in radiological protection and, in particular, cannot be used for the assessment of individual risk.

Analogous to the approach for other organs and tissues, the equivalent dose to the remainder is defined separately for the Reference Male and the Reference Female. The equivalent dose to the remainder tissues is computed as the arithmetic mean of the equivalent doses to the tissues listed in the footnote to Table 3. The equivalent doses to the remainder tissues of the Reference Male, H_{rmd}^M, and the Reference Female, H_{rmd}^F, are computed as

$$H_{rmd}^M = \frac{1}{13} \sum_T^{13} H_T^M \quad \text{and} \quad H_{rmd}^F = \frac{1}{13} \sum_T^{13} H_T^F$$

Table 1.3: Reference values for tissue weighting factors (ICRP 2008)

Tissue	Tissue weighting factor, w_T
Bone marrow (red), colon, lungs, stomach, breast, remainder tissues[a]	0.12
gonads	0.08
Bladder, oesophagus, liver, thyroid	0.04
Bone surface, brain, salivary glands, skin	0.01

[a] Adrenals, extra-thoracic region, biliary vesicle, heart, kidney, small intestine, lymphatic nodes, muscle, oral mucosa, pancreas, prostate (male), spleen, thymus, uterus (female).

The quantities equivalent dose and effective dose are not measurable in practice. For the calculation of dose coefficients from intakes of radionuclides, biokinetic models for radionuclides, reference physiological data, and computational phantoms are used.

ICRP Publication 103 (ICRP 2008) acknowledges that there may be some circumstances in which the values of material specific parameters, such as absorption parameters, gastrointestinal uptake factors and aerosol parameters may be changed from the reference values in the calculation of effective dose. However, as the effective dose applies to a reference person, individual specific parameter values should not be changed. Examples of individual specific parameters that should not be changed include particle transport parameters of the Human Respiratory Tract model (HRTM), transit parameters of Human Alimentary Tract Model (HATM) and systemic biokinetic model parameters.

In the last stages of these Guidelines, which apply to cases with good quality and comprehensive data, it may be necessary to alter individual specific parameter values to obtain good fits to bioassay data. However, these apply to cases where the assessed dose to the individual is high and in such situations risk assessments may be necessary. It is also noted that the cases for which a

detailed risk assessment is necessary are in the minority and will require an expert dosimetrist to assess them.

It is emphasised that effective dose is a radiation protection quantity and neither it nor the quantity equivalent dose to organs should be used for individual risk assessments or epidemiological evaluations. Rather, the absorbed dose should be used with the most appropriate biokinetic biological effectiveness and risk factor data (ICRP, 2007).

Since the publication of reference dose coefficients and bioassay data for the individual monitoring for internal exposure of workers (ICRP 1997), the ICRP is updating the models to be used for the calculation of new values of these reference quantities. A brief summary is provided in the following paragraphs.

1.2.2 Human Alimentary Tract Model

The ICRP has published a new age- and sex-dependent Human Alimentary Tract Model (HATM) in its publication 100 (ICRP 2006) . The structure of the model is presented in Figure 1.1, while Table 1.4 presents the transfer rates for the movements of the alimentary tract contents.

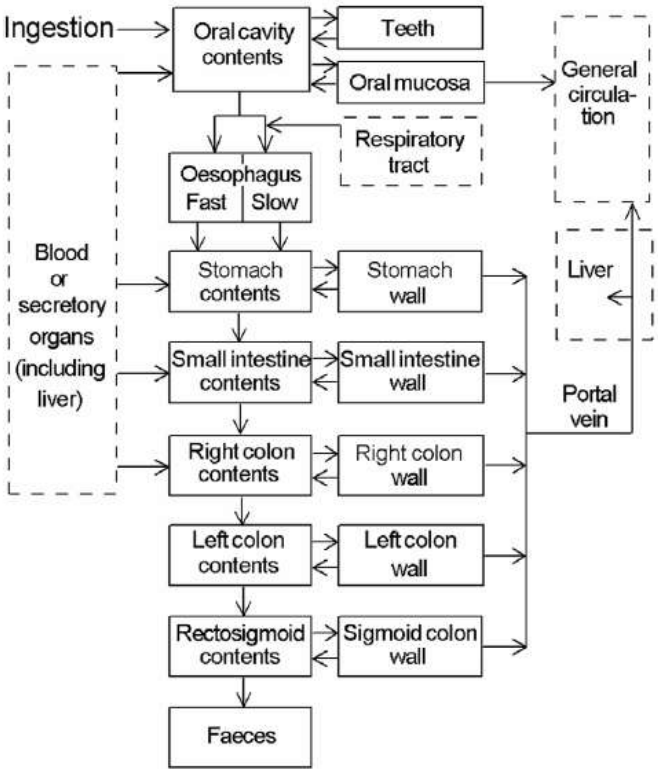


Figure 1.1: Structure of the HATM .The dashed boxes show connections with the other models (ICRP 2006).

Compared to the old gastrointestinal model of ICRP Publication 30 (ICRP 1979) the most significant changes in biokinetics are the addition of the initial compartments of oral cavity and oesophagus with mean retention times of only several seconds and the possibility of absorption not only directly from the small intestine but from nearly all sites of the tract with potential retention in the walls and subsequent recycling into the contents of the tract. The total fractional absorption in the alimentary tract is quantified by the parameter f_A.

Table 1.4 : Transfer rates (d^{-1}) for the movement of alimentary tract contents in the HATM (ICRP 2006)

Region	Adult male	Adult female
Mouth		
Solids	5760	5760
Liquids	43,200	43,200
Total Diet	7200	7200
Oesophagus (fast)		
Solids	10,800	10,800
Liquids	17,280	17,280
Total diet	12,343	12,343
Oesophagus (slow)		
Solids	1920	1920
Liquids	2880	2880
Total diet	2160	2160

Region	Adult male	Adult female
Stomach		
Solids	19.2	13.71
Caloric liquids	32	24
Non-caloric liquids	48	48
Total diet	20.57	15.16
Small intestine	6	6
Right colon	2	1.5
Left colon	2	1.5
Rectosigmoid	2	1.5

1.2.3 Physical data for dose calculation

The ICRP publication 107 (ICRP 2008b) provides an electronic database of the physical data needed in calculations of radionuclide-specific protection. This database supersedes the data of ICRP publication 38 (ICRP 1983). The database contains information on the half-lives, decay chains, and yields and energies of radiations emitted in nuclear transformations of 1252 radionuclides of 97 elements. The CD accompanying the publication provides electronic access to complete tables of the emitted radiations, as well as the beta and neutron spectra. The database has been constructed such that user-developed software can extract the data needed for further calculations of a radionuclide of interest. A Windows-based application is provided to display summary information on a user-specified radionuclide, as well as the general characterisation of the nuclides contained in the database. In addition, the application provides a means by which the user can export the emissions of a specified radionuclide for use in subsequent calculations.

1.2.4 Adult reference computational phantoms

The evaluation of equivalent doses for the Reference Male and Female and of effective dose for the Reference Person is based on the use of anthropomorphic models (phantoms). In the past, the ICRP did not specify a particular phantom, and in fact various mathematical phantoms have been used. The ICRP now uses reference computational phantoms of the adult Reference Male and adult Reference Female for the calculation of equivalent doses for organs and tissues. ICRP publication 110 (ICRP 2009) describes the development and intended use of the computational phantoms of

the Reference Male and Reference Female. The phantoms are based on medical image data of real people, yet are consistent with the data given in Publication 89 (ICRP 2002a) on the reference anatomical and physiological parameters for both male and female subjects. The reference phantoms are constructed after modifying the voxel models of two individuals whose body height and mass resembled the reference data. The organ masses of both models were adjusted to the ICRP data on the adult Reference Male and Reference Female, without compromising their anatomic realism. The numerical data representing the phantoms are contained on an electronic data storage medium (CD-ROM) that accompanies the printed publication.

1.2.5 NCRP wound model

The United States National Council on Radiation Protection and Measurements (NCRP) developed and published a new biokinetic wound model (NCRP 2006, Guilmette 2003) consisting of five compartments describing the clearance from the wound site by transport directly into blood or via the regional lymph nodes into blood.

This NCRP model defines seven default wound retention categories which are to be used according to the material involved: There are four categories for soluble material (with weak, moderate, strong and avid retention at the wound site) and categories for colloids, particles and fragments. There are different uptake compartments for soluble material, colloids, particles and fragments and for each of these default categories only some of the five wound compartments are used.

The structure of the model is composed by 5 compartments linked together with a first order kinetics (see Figure 1.2). They have been named:

- Soluble,
- Colloidal and Intermediate State (CIS),
- Particles Aggregates and Bound State (PABS),
- Trapped Particles and Aggregates (TPA), and
- Fragment.

The whole structure of the model is presented in Figure 1.2.

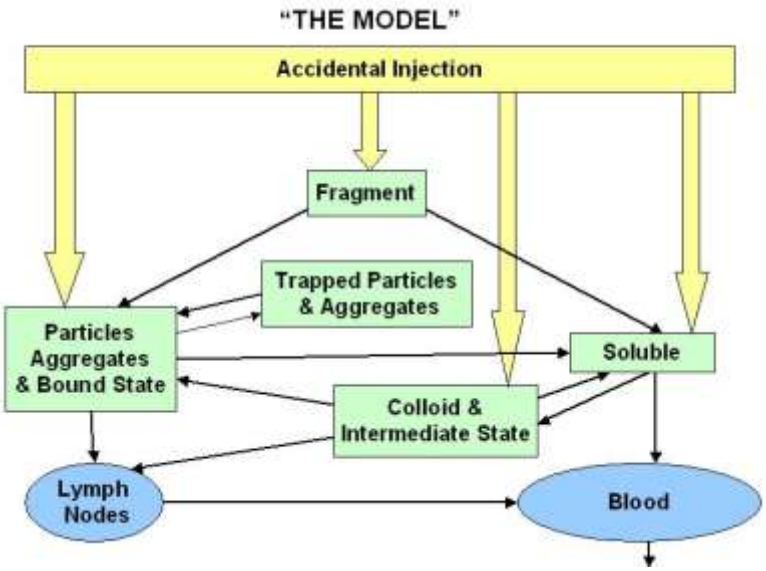


Figure 1.2: General structure of the NCRP wound model

These compartments are designed to describe some physical or chemical state of the radionuclide. The overall structure of the model is intended to describe in a general way both soluble and insoluble materials. For soluble materials, the principal clearance pathway from the wound site is via the blood whereas for particulates it is via the lymph nodes (LN). Further dissolution of particulates in LN also results in transfer of nuclides to blood. The Blood compartment is the compartment that links the wound model to the systemic model of each radioelement. The behaviour of a radionuclide that reaches the blood is the same as that if it had been injected directly into blood in a soluble form.

The behaviour of a soluble materials in the wound is strongly influenced by aqueous solution chemistry, in particular the element's tendency to hydrolyze. This affects its physicochemical state as well as its tendency as a charged molecule to bind locally to tissue molecules (NCRP, 2006). For insoluble materials other mechanisms such as phagocytosis, and fibrous tissue encapsulation play the major role. Different sub-models (categories) have therefore been suggested in the NCRP report in relationship to the chemical and physical status of the material (NCRP, 2006).

In Table 1.5 the default values for the transfer rates for soluble and insoluble materials are presented.

Table 1.5: Default transfer rates of the NCRP wound model. CIS, colloid and intermediate state; PABS, particles aggregates and bound state; LN, lymph nodes

	Transfer rate (d^{-1})						
Transfer	**Weak**	**Moderate**	**Strong**	**Avid**	**Colloid**	**Particle**	**Fragment**
Soluble to Blood	45	45	0.67	7.0	0.5	100	-
Soluble to CIS	20	30	0.6	30	2.5	-	-
CIS to Soluble	2.8	0.4	0.024	0.03	0.025	-	-
CIS to PABS	0.25	0.065	0.01	10	0.05	-	-
CIS to LN	$2 \circ 10^{-5}$	$2 \circ 10^{-5}$	2×10^{-5}	2×10^{-5}	2×10^{-3}	-	-
PABS to Soluble	0.08	0.02	0.0012	0.005	0.0015	2×10^{-4}	-
PABS to LN	$2 \circ 10^{-5}$	$2 \circ 10^{-5}$	2×10^{-5}	2×10^{-5}	4×10^{-4}	3.6×10^{-3}	0.004
PABS to TPA	–	–	-	-	-	0.04	0.7
TPA to PABS	–	–	-	-	-	0.0036	0.0005
LN to Blood	–	–	-	-	0.03	6×10^{-4}	0.03
Fragment to Soluble	–	–	-	-	-	-	-
Fragment to PABS	–	–	-	-	-	-	0.008

For soluble compounds the chemical behaviour is the most important factor. For these soluble categories the general model, as depicted in Figure 1.2, is reduced to 3 compartments and there is no transfer from the LN to blood (Figure 1.3).

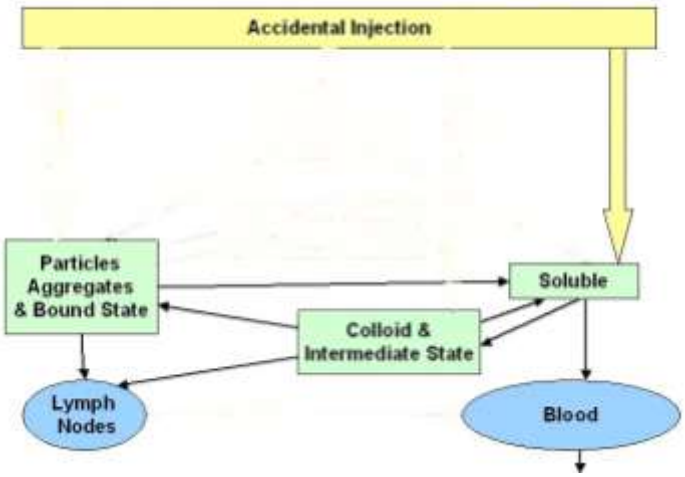


Figure 1.3 : The Soluble model

The retention in the wound for the four soluble default categories is presented in Figure 1.4.

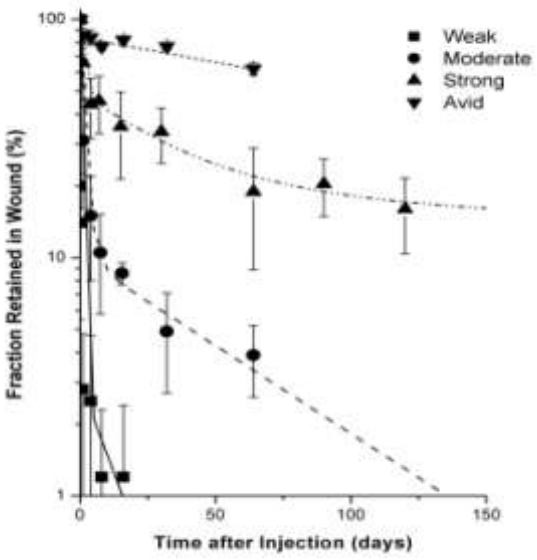


Figure 1.4: Default retention in wound for reference soluble materials.

The behaviour of particulate radionuclides in wounds has been grouped into three main categories; colloid, particle and fragment. These three categories are based on the physical properties of the deposited material and on their retention pattern. Fragments and particles are both solid materials, which may be solid materials contaminated with radionuclides or may be essentially pure substances like plutonium, depleted uranium metal or oxides. However, colloids are most commonly formed as hydrolysis products of radioactive metals and also have particulate properties. Insoluble particulates can have significant clearance to the lymph nodes whereas soluble materials typically do not.

Wounds can also contain significant masses of material, which may cause inflammatory reactions in the wound tissue. As a result biological sequestration and capsule formation may occur, which

provides a biological barrier to clearance from the wound site. This is modelled with the 'trapped particles and aggregates' compartment.

The Colloid category consists of radionuclides that exist as colloidal material prior to deposition, and typically have small fractions of the deposited amount that clear rapidly from the wound site. For this category the general model reduces to that presented in Figure 1.5.

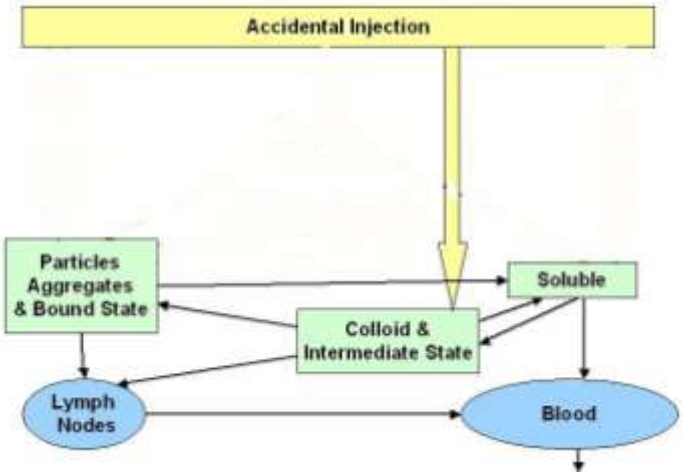


Figure 1.5 : The Colloid Model

The Particle category represents material, typically relatively insoluble, whose individual physical sizes are ≤ 20 μm. This upper limit generally bounds the size of particles that can be phagocytised by tissue macrophages or can be moved to lymphatics via fluid flows to collecting lymph nodes. In this case the model reduces to that presented in Figure 1.6.

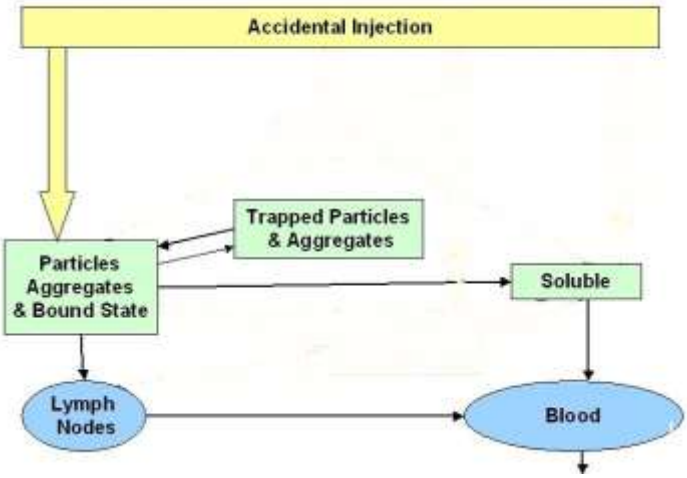


Figure 1.6: The Particle model

The Fragment category includes large particles and fragments whose size and/or quantity of material are sufficient to cause a foreign body tissue reaction, in which fibrous connective tissue encapsulates the deposited material, and is thought to retard the physical and chemical movement of material from the wound site. The Fragment model is presented in Figure 1.7.

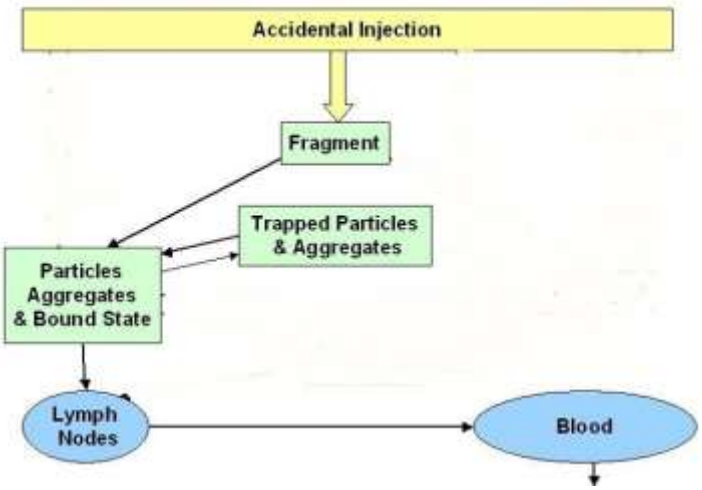


Figure 1.7: The fragment model

The most consistent observation for the retention of these three categories (colloid, particle and fragments) is the very long retention of the majority of the deposited material. This long-term retention is surmised to be due to the intrinsic insolubility of the forms of materials that have been studied, mainly Pu and U, and the foreign-body encapsulation phenomenon, although the latter may not be required for long retention.

For each default retention category, the retention in the wound can be expressed as a sum of up to three exponential functions:

$$R(t) = \sum_i a_i \cdot e^{-\lambda_i t}$$

with at t=0 $R(t)$=1

The coefficients a_i and λ_i of these exponential expressions, which give the "exact" solution for each default retention category, are given in Table 1.6 (Nosske 2008). For the calculation of the wound retention function of a given radionuclide, the corresponding decay constant has to be considered additionally in the exponent.

Table 1.6 : Coefficients a_i and λ_i (d^{-1}) of the exponential functions describing the wound retention of the NCRP wound model.

Category	a_1	λ_1	a_2	λ_2	a_3	λ_3
weak	0.6734	65.89	0.2897	2.16	0.0369	0.077
moderate	0.5974	75.16	0.3099	0.306	0.0927	0.018
strong	0.518	1.28	0.261	0.023	0.221	9.60E-04
avid	0.1888	37.03	0.0007	10	0.8105	9.70E-04
colloid	0.0966	0.057	0.9048	7.70E-04	-0.0014	3.02
particle	0.075	0.047	0.925	2.90E-04	-	-
fragment	0.9947	2.84E-06	0.0054	8.00E-03	-0.0001	7.00E-01

To combine the NCRP wound model with a systemic model of the element in question, the rate to blood from both wound and lymph nodes is required. The retention in the wound and in the lymps nodes can be described as a sum of exponential terms as given in Table 1.7. These values are the analytical solutions of the model. This can be combined with the systemic model considering a delayed chronic intake into the blood compartment. In other words the retention in wound plus lymph nodes, expressed as a sum of exponentials, is required. This is given in Table 1.7.

Table 1.7: Coefficients a_i and λ_i (d^{-1}) of the exponential functions describing the wound plus lymph node retention of the NCRP wound model.

Category	a_1	λ_1	a_2	λ_2	a_3	λ_3	a_4	λ_4
weak	0.6735	65.89	0.2897	2.16	0.0369	0.0771	0.000012	0
moderate	0.5974	75.16	0.3099	0.306	0.0926	0.018	0.000122	0
strong	0.518	1.28	0.261	0.0227	0.216	9.59E-04	0.004819	0
avid	0.1888	37.03	0.00072	10.0	0.7937	9.68E-04	0.01675	0
colloid	-0.00139	3.02	0.0375	0.057	0.0457	0.03	0.9183	0.000771
particle	-2.00E-06	100	0.003031	0.047	-0.75	0.0006	1.7470	0.00029
fragment	2.90E-06	0.7045	-0.00212	0.03	0.007345	0.008	0.9948	2.84E-06

1.2.6 The ISO 27048 International Standard

The International Standard on dose assessment for the monitoring of workers for internal radiation exposure (ISO, 2011) was developed to improve the reproducibility of dose assessments carried out by different Dosimetry Services while ensuring that the level of effort required is proportional to the magnitude of the exposure. The IDEAS Guidelines and ISO 27048 both address the topic of internal dose assessment, but their aims are different. ISO 27048 specifies the *minimum* requirements for the evaluation of data from the monitoring of workers, and defines standard procedures and assumptions for the standardised interpretation of monitoring data in order to achieve acceptable levels of reliability for the purpose of demonstrating compliance with regulations. To comply with the Standard, dose assessments must follow all those procedures and assumptions that are defined as normative. However, Dosimetry Services are not prevented from adopting additional procedures or methods, or adopting more limiting dose criteria than are presented in the Standard.

The general approach to standardised dose assessments is similar in ISO 27048 to that adopted in the IDEAS Guidelines (Doerfel 2006), although there are some differences, as described below. A major difference is that ISO 7048 does not specify dose assessment methods for cases where the annual dose limit could be exceeded, the reason being that a standardised method is considered inappropriate for such cases. ISO 27048 indicates that the IDEAS Guidelines provided guidance for such cases.

ISO 27048 addresses:

a) Procedures for dose assessment;

b) Assumptions for the selection of dose-critical parameter values;

c) Criteria for determining the significance of monitoring results;

d) Interpretation of workplace airborne monitoring results;

e) Uncertainties arising from sampling, measurement techniques and working conditions;

f) Special topics:

- Interpretation of multiple data arising from different measurement methods at different times;
- Handling data below the decision threshold;
- Rogue data;
- Calculation of doses to the embryo/foetus and infant;

g) Reporting / documentation;

h) Quality assurance.

The procedures described in ISO 27048 for dose assessment based on reference levels for routine and special monitoring programmes are briefly described below. For more details, reference should be made to the Standard (ISO, 2011).

As in the IDEAS Guidelines, ISO 27048 states that no dose evaluation is required if the potential intakes in the accounting year would result in an annual dose of less than 0.1 mSv. This criterion is satisfied if the measurement value is below the critical value M_c. Values of M_c are presented in both the guidelines (Section 3.3) and in ISO 27048.

If comparison with M_c indicates that the potential annual effective dose is greater than 0.1 mSv, and a new intake could have occurred, then the measurement may be interpreted by following a standard assessment method. The standard assessment is carried out with the ICRP biokinetic and dosimetric models assuming exposure via inhalation. The time of intake is assumed to be at the mid-point of the monitoring interval and ICRP default values for the AMAD and absorption type are assumed. However, where site-specific default values are available and documented, these may be used in the assessment.

There is no need for further evaluation if one of the following criteria is met:

a If the 97.5% confidence level of the assessed potential annual dose is less than 5% of the annual dose limit (e.g. < 1 mSv). The confidence level is determined by considering measurement uncertainties alone.

b If the annual dose limit could not be potentially exceeded. The decision whether or not the dose limit could be exceeded should be based upon a procedure that considers the uncertainty or possible ranges of material specific parameter values as well as the uncertainty in the time of intake. ISO 27048 provides the data required by this procedure for all radionuclides of interest. Alternatively, the assessed dose may be compared to the investigation level as defined in ISO 20553:2006 (ISO 2006) in order to decide whether the dose limit could be exceeded. The investigation level is set at a level which is no higher than 30% of the annual dose limit (i.e. ≤ 6 mSv).

c If this analysis indicates that the annual dose limit could potentially be exceeded, then case-specific information should be obtained and applied in order to decrease uncertainties. The case-specific information may be on: contributions to measurements from earlier intakes; the time pattern of intake; values of AMAD

differing from the default; absorption types or absorption parameter values differing from the default; intake pathways other than inhalation; and results of workplace monitoring. A comparison with dose limits similar to that described in (b) is then repeated.

If the analysis indicates that the annual dose limit may still potentially be exceeded, a more sophisticated analysis shall be applied by an expert. As noted above, expert assessment is considered to be beyond the scope of the Standard.

1.2.7 Forthcoming ICRP publication on Occupational Intakes of Radionuclides (OIR)

ICRP is in the process of providing revised dose coefficients for Occupational Intakes of Radionuclides (OIR) by inhalation and ingestion. In the revision of the dose coefficient, ICRP has taken the opportunity to update its biokinetic and dosimetric models. ICRP will also provide information on absorption to blood following inhalation of different chemical forms of elements.

One important aspect of this revision is changes to the Human Respiratory Tract Model (HRTM, ICRP 1994; 2002b), which take account of data accumulated over the last two decades, although the basic features of the model remain unchanged (Bailey, 2009). Inhaled particles containing radionuclides deposit in the nose, the bronchial and bronchiolar airways of the lung and the alveolar respiratory region, with deposition in the different regions being dependent on particle size. Removal from the lungs occurs mainly by dissolution and absorption to blood and the competing process of clearance of particles from the lung to the throat followed by their entry into the alimentary tract. The proportions absorbed to blood or escalated depend on the solubility of the material and on the radioactive half-life of the radionuclide. The ICRP model for the respiratory tract is also applicable to vapours and to inhalation of radon and its radioactive progeny.

For absorption to blood, the main changes are:

- Material specific parameter values for dissolution (f_r, s_r and s_s) in cases where sufficient information was available (eg. compounds of U).
- Redefinition of F, M and S absorption default values.
- Revised treatment of gases and vapours.

For particle clearance the main changes are:

- Realistic nasal particle transport, including transfer from the anterior to the posterior region, based on studies using gamma-tagged particles.
- Revised characteristics of particle retention in the bronchial tree.
- Longer retention in the alveolar region of the lung, with a revised model structure, based on long term retention data of the lung (Gregoratto 2010) .

The updated biokinetic models have been made to be physiologically realistic with regard to the dynamics of organ retention and excretion so that they are applicable to the interpretation of bioassay data as well as the calculation of dose coefficients.

The modifications to the definition of effective dose, radiation and tissue weighting factors, basic radiation physical data, updated biokinetic and dosimetric models will be implemented in the forthcoming Occupational Intakes of Radionuclides (OIR) documents to update the dose coefficients and reference bioassay functions.

The OIR Document will also provide values of effective dose per unit content, in the accompanying CD-ROM, of a given bioassay quantity. These values could be used for the simple reference evaluation at Level 1 (Section 2.2).

These guidelines will be still applicable for dose assessment following the publication of OIR Document series. However these revised ICRP biokinetic and dosimetric models should be applied depending upon national regulations. For example the critical monitoring quantities M_c for routine monitoring will need to be re-calculated. Default absorption parameter values (Type F, M and S) or specific absorption parameter values for compounds (f_r, s_r, s_s, f_b, s_b) given in the OIR series should also be used.

1.3 Recent activities within the European networks CONRAD and EURADOS

1.3.1 Activities within CONRAD

The Coordination Action CONRAD (Coordinated Network for Radiation Dosimetry) has been funded by the European Commission (EC) within the 6th Framework Programme (2005–08) for research and training in nuclear energy (Contract No FI6R-012684). The objective of CONRAD was to generate a European Network in the field of Radiation Dosimetry, to promote both research activities and dissemination of knowledge.

Work Package 5 within CONRAD Project dealt with the Coordination of Research on Internal Dosimetry (Lopez 2008). The research to be coordinated had a general objective to improve the reliability in the assessment of exposures resulting from the intake of radionuclides into the body. Members coming from 20 institutes from 14 countries participated in WP5, and CIEMAT (Spain) chaired the group.

Some of the tasks performed within CONRAD WP5 dealt with topics of interest for the application of the Guidelines:

- calculation of values of the Scattering Factors (SF) for different radionuclides and types of monitoring data, using real cases selected from IDEAS databases (Marsh, 2007). The calculated values were, in general, in agreement with the previous SF values originally suggested by IDEAS on the basis of expert's judgement, only SFs for faecal excretion were at the lower end of the range suggested by IDEAS;
- implementation of the new NCRP wound model (NCRP 2006) – see section 1.2.5. Evaluations of wound contamination cases have been done with the application of IDEAS guidelines philosophy;
- use of a partitioning factor of the activity between skeleton and liver in fitting systemic model parameters for actinides;
- refinements of methodologies for the determination of an effective AMAD in the case of special evaluation;
- suggestion of criteria to be applied (number and type of monitoring data) as requirements for internal dose assessments;
- replacement of former IDEAS web page with the IDEAS/ENEA website (www.bologna.enea.it/attivita/ideas.html). The results of the IDEAS/IAEA intercomparison exercise on internal dose assessments can be downloaded from this site, as well as other important reports and documents related to IDEAS, CONRAD and ICRP activities;

- update of IDEAS internal contamination databases with new cases. IDEAS Bibliography and IDEAS Internal Contamination Databases were updated with new inputs. All three IDEAS databases are now available to the internal dosimetry community on SCK.CEN website (www.sckcen.be/ideas/) (Marsh 2008).

After completion of the CONRAD project the Work Package on internal dosimetry has been transformed into a stable Working Group of EURADOS (WG7; eurados.org).

1.3.2 The EURADOS IAEA Training Course

To take care of the need of advanced training in application of IDEAS guidelines, EURADOS WG 7 (internal dosimetry) promoted jointly with IAEA an advanced training course on internal dose assessment. The course was held in Prague (Czech Republic) in February 2009, and was aimed to train dosimetrists as well as to disseminate the main outcomes of the research performed during the CONRAD project. Theoretical lessons on the application of the IDEAS guidelines were performed together with numerous examples and exercises to be explained during the 5 days course.

The course used a dedicated web site to share documents and exercises to participants and to collect their results of proposed evaluations.

At the final stage of the course there was the submission to participants of 4 cases called "Exercises Left to Participants - ELP cases". This is a kind of peculiar "intercomparison exercise" performed at the end of a training course. The participants had to evaluate the 4 cases in a 7 hour period.

The main results of the "intercomparison" can be summarized as follows: half of those who addressed the exercise did it correctly, using the IDEAS GLs. Compared to the previous IDEAS/IAEA intercomparison (see paragraph 1.1.2 The IDEAS/IAEA intercomparison exercise) the percentage of those who performed the evaluation correctly following the guidelines, increased from 20 % to 50% .

Also in this case it has been possible to find out errors of different species: trivial (mainly transcription errors), conceptual errors and also related to the correct use of data scattering factors in routine monitoring. The coherence between models used for m(t) (retention curves) and for e(50) (dose coefficients) values was still a source of errors, also for trained personnel. (Castellani 2010)

1.4 Revision of the IDEAS Guidelines

Following the developments occurred after the publication of the 2006 Guidelines, EURADOS WG7 set up a Task group to update the Guidelines in order to include:

- the work that was undertaken within CONRAD project: New values of SF , refinements of the evaluation of effective AMAD and additional information on the minimum number and type of data required for dose assessment.
- a special procedure for wound cases, following the publication of the wound model
- procedure for direct dose assessment methods.
- examples for the correct application of the guidelines taken from the recent EURADOS/IAEA advanced training course on internal dose assessment.

- acknowledgment of the ISO standard on dose assessment for monitoring of workers for internal radiation exposure.
- acknowledgment of the forthcoming ICRP OIR Documents.
- more detailed description on data fitting.
- additional test statistic for data fitting.
- typical uranium and plutonium isotopic compositions.

The document will give guidance on:

- General principles to be applied in internal dosimetry, namely: harmonization, accuracy, proportionality.
- Detailed information about the handling and evaluation of monitoring data, comprising data processing and estimation of uncertainty.
- Detailed procedure to intake estimation with single or multiple datasets.
- Special aspects of data handling: values below the detection limit, influence of decorporation therapy, minimum number and type of data required for dose assessment.
- Criteria for rejecting a fit of model predictions to monitoring data.
- A structured approach to dose assessment consisting of a step-by-step procedure described in well defined flow charts with accompanying explanatory text.

There is a chapter giving reference solutions of example cases of contamination (Section 13). There are also Annexes (Section 14) on data fitting, test statistics and on typical values for isotopic composition of uranium and plutonium materials encountered in the nuclear industry.

2. Overview of the IDEAS guidelines

The approach here presented is related to the evaluation of the best evaluable intake and related committed effective or organ doses.

Over the recent years a Bayesian approach has become increasingly available also in light of the need for assessing the uncertainty related to the evaluated doses. In this case a probability distribution instead of a unique "best estimate value" can be provided. (e.g. G. Etherington 2006, Miller 2003).

The authors acknowledge that the Bayesian approach provides more information about the real situation of internal exposure even taking into account the probability of occurrence of rare introductions, nevertheless suggest the application of these guidelines based on the three principles listed below, for the sake of harmonisation of the assessed doses in the majority of cases to evaluate.

2.1 Principles

In carrying out the assessment (evaluation) of committed doses from monitoring data following intakes of radionuclides, the assessor may well have to make assumptions about factors such as the pattern of intake and properties of the material. When more than one measurement is available, issues such as the weighting applied to the different data can substantially affect the result. The recent intercomparison exercises have shown that wide range in doses can still be obtained from the same data set as a result of such factors, and hence the need for guidance on harmonising evaluations.

The procedures proposed in this chapter are based on the following principles:

Harmonisation: by following the procedures any two assessors should obtain the same estimate of dose from a given data set or at least understand why differences have occurred

Accuracy: the "best" estimate of dose should be obtained from the available data

Proportionality: the effort applied to the evaluation should be proportionate to the dose – the lower the dose, the simpler the process should be.

2.1.1 Harmonization

A well-defined procedure is needed and for this reason the process is defined here primarily by means of a series of flow-charts. So far as possible, the structured process has been made widely applicable, i.e., it does not assume that the assessor has the use of sophisticated bioassay interpretation software. For routine monitoring situations, where typically there is only one measurement relating to each intake, it is reasonably straightforward to define a procedure. However, in special monitoring situations, where typically there is more than one measurement and quite possibly more than one type of measurement (urine, faeces…) different options for data handling can easily lead to different evaluated doses, even when the same model, parameter values and software are used. Another range of options, and opportunities for different evaluated doses, arises in situations where it is appropriate to consider changing parameter values from the ICRP defaults. Proposals are made here for a systematic approach to dose assessment in all these situations. In each case, however, it is important to record all departures from the use of default model parameter values.

2.1.2 Accuracy

It is recognised that the uncertainties associated with assessed internal dose can be considerable, especially for actinides which are difficult to detect in the body and have relatively high dose coefficients (Sv Bq^{-1}). If the initial estimate of dose exceeds 1 mSv, it could well be that the possibility of a substantially higher dose (eg. 6 mSv) cannot easily be excluded. It is then important to make best use of the available information. To do so may well involve changing parameter values from their ICRP default values and guidance is therefore needed on which parameter values might reasonably be varied according to the circumstances.

2.1.3 Proportionality

The effort applied to the evaluation of incorporation monitoring data should broadly correspond to the expected level of exposure, and the complexity of the case. On the one hand, if the exposure is likely to be very low with respect to the dose limits, simple evaluation procedures with a relatively high uncertainty may be applied. On the other hand, if the monitoring values indicate the exposure to be close to or even above the dose limits, much more sophisticated evaluation procedures will need to be applied. These take account of any case-specific information available, so that the uncertainty and bias on the best estimate are as low as reasonably achievable.

2.2 Levels of task

The effort needed for the evaluation of monitoring data for internal exposure from intakes of radionuclides should correspond to the anticipated level of exposure in the particular facility area or group of workers. An "annual dose" can be defined as the committed effective dose from intakes of radionuclides that occur during the accounting year. The expected annual dose to workers assessed prospectively may be used as a quantitative criterion for planning the scope of the procedures needed for individual monitoring and interpretation of monitoring data. The structured approach was widely discussed through open consultation on the web during Working Package 4 of the IDEAS project. It is considered that this approach can be of general value for dose assessment purposes and its key features are described below. The structured approach is given in terms of levels of task that can be chosen depending upon the circumstances of any exposure.

With respect to operational radiation protection the following structure of "Levels of Task" is proposed.

2.2.1 Level 0 (committed effective dose less than 0.1 mSv/a)

Potential intakes that could result in an annual dose less than 0.1 mSv. No evaluation of dose is needed. This would be most likely even if there should be similar intakes in each monitoring interval of the year. At this level there is *generally* no need to evaluate the measured values explicitly, and the effective dose can be set to zero in analogy to the rounding of doses in external dosimetry. However, the measured value should be recorded with respect to further assessments in the future.

A measured quantity M (retention or daily excretion measurement) can be allocated to Level 0 if it is below a given value defined as "critical monitoring quantity" Mc. Details about Mc are given in paragraph 3.3 Determination of M_c values.

2.2.2 Level 1 (0.1 mSv/a < committed effective dose < 1 mSv)

Simple, "reference" evaluation, with ICRP defaults used for all parameter values. At Level 1 the user will be generally concerned with radionuclides that are straightforward to measure, e.g. high-energy gamma emitters that can be measured at levels of activity that would correspond to small intakes and doses and for which there are unlikely to be real problems of data handling.

When there is better *a priori* information available, (e.g. information on the particle size distribution for inhalation intakes), the user may wish to perform a more sophisticated evaluation (Level 2).

2.2.3 Level 2 (1 mSv < committed effective dose < 6 mSv)

Sophisticated evaluation generally using additional information from the workplace to give a more realistic assessment of dose. Level 2 users might be concerned with radionuclides that are difficult to measure at levels that would correspond to small doses. Examples are isotopes of uranium, thorium, plutonium or ^{241}Am, for routine inhalation intakes. Level 2 might also be used for an accidental intake. Comparisons would be made of the model predictions ("the fit") with the data, to choose between alternative parameter values, or to find optimum parameter values (*a posteriori*). At this Level, only the parameters related to the material characteristics, and to the time of intake (if unknown) should be adjusted.

2.2.4 Level 3 (committed effective dose ≥ 6 mSv)

More sophisticated evaluation performed by an expert user. It applies to cases where there are comprehensive data available, as would be the case for exposures near the dose limit and probably relating to an accident. The evaluation is an extension of Level 2, also to parameters relating to the subject (e.g. for inhalation intakes the HRTM particle transport rates). The fundamental approach at this Level is to adjust the model parameter values systematically, in a specific order ("step-by-step" approach), until the goodness of fit is acceptable (i.e. the fits obtained to all the data are not rejected by the specified criteria). If any parameter values in the ICRP models are changed from the defaults, then these values are recorded and used to calculate committed equivalent and effective doses. Such a procedure may need to be approved by the national regulatory authority.

3. Monitoring programmes

3.1 Objective and nature of monitoring programmes

The general objective of operational monitoring programmes for the internal exposure has been indicated in the safety guide IAEA RS-G-1.2 (IAEA 1999). In the same guide a criterion for the assessment to undertake individual monitoring of the occupationally exposed persons, has been suggested. Types of monitoring are explained, and routine and special monitoring are presented.

The International Standard ISO 20553 (ISO 2006) provides guidance for the decision whether a monitoring program is required and how it should be designed. Its intention is to optimize the efforts for such a monitoring program consistent with legal requirements and with the purpose of the general radiation protection program. In particular the suggested maximum monitoring periods for the different radionuclides with the tolerances for routine monitoring are reported, as well as the recommended methods for special monitoring programs after inhalation.

The purpose of monitoring for internal exposure to radionuclides is to verify and document that the worker is protected adequately against radiological risks, and that the protection afforded complies with legal requirements. Two types of monitoring of internal exposures of workers can be identified: workplace monitoring and individual monitoring.

Individual monitoring gives information needed to assess the exposure of a single worker by measuring individual body activities, excretion rates or activity inhaled (using personal air samplers). Workplace monitoring, which includes collective monitoring, provides exposure assessments for a group of workers assuming identical working conditions i.e. risks of intake as well as all factors influencing the resulting doses. An example of workplace monitoring is the measurement of radionuclide concentration(s) in air using static air samplers. In some cases, results of workplace monitoring are needed to support individual dose assessments (e.g. air monitoring can provide information on the time of an intake). It can indicate the release of radionuclides into the working environment and trigger subsequent bioassay measurements. ISO (2006) recommends initiating workplace (resp. individual) monitoring if the likely annual committed effective dose exceeds 1 mSv (resp. 6 mSv)

Different categories of individual monitoring exist. Routine monitoring for internal exposure is conducted on a fixed schedule to ensure acceptably safe and satisfactory radiological conditions for the potentially exposed workers in the workplace. ISO (2006) recommends defining the measurement period of routine monitoring so that intakes contributing to a total annual dose of 1 mSv can reliably be detected and that the maximum potential underestimation shall not exceed a factor of three assuming that a single intake occurred in the middle of the monitoring interval.

Special monitoring programmes are investigative; they are usually based on a suitable combination of in vivo measurements and in vitro analyses according to the appropriate biokinetic model. Special monitoring may be necessary as a result of a known or a suspected exposure; it is most often triggered by a result of a routine bioassay measurement that exceeds some pre-defined derived reference levels. It should provide enough data for a precise dose assessment and usually benefit from more information on the circumstances of an intake event, especially relating to the time between measurement and intake.

Other monitoring programmes may be conducted in relation to a particular task, or to determine intakes in actual or suspected abnormal conditions. In these circumstances, the time of intake, or potential intake, is likely to be known and workplace monitoring programmes may provide some information on the physical and chemical nature of any contamination. Confirmatory monitoring programmes can be required to check the assumptions about exposure conditions underlying the procedures selected, e.g. the effectiveness of protection measures. It may consist of workplace or individual monitoring.

3.2 Decision threshold and detection limit

A nuclear transition is a random process following Poisson statistics. Furthermore, the counting of a radioactive sample is affected by a background resulting from natural radiation or from the activity of radionuclides other than the nuclide of interest. This background is commonly assumed also to follow Poisson statistics. In case of measurement of a naturally occurring radionuclide, the uncertainty on the background measurement result is mostly due to the contribution of the alimentary intake (Section 4.1.3).

The total or measured number of gross counts, N_G is the sum of counts induced by background radiation, N_B and counts induced by the activity of interest contained in the sample (*in vitro*) or in the body (*in vivo*) (net counting) N_n:

$$N_G = N_B + N_n$$

N_B can be determined by measuring the background effect count rate (λ_B) from the background radiation in the absence of the activity of interest contained in the sample. Thus $N_B = \lambda_B T_S$, where T_S is the duration of the sample (gross) effect measurement. However, the background is variable and fluctuates around its mean value according to a Poisson distribution. Therefore, a measured low but positive count N_n may be the consequence of a mere fluctuation of the background rather than the presence of an activity of interest.

To take this into account, a decision threshold (*DT*) is defined such that if the result of an actual measurement quantifying a physical effect (e.g. the presence of a radionuclide in a sample) is greater than the *DT*, then it is decided that the physical effect is present (ISO, 2010a, 2010b). If the measurement result < DT, then the result cannot be attributed to the physical effect, nevertheless it cannot be concluded that it is really absent. The statistical test is designed in such a way that if the radionuclide is really absent (i.e. that only a background effect exists), then the probability of taking a wrong decision that the nuclide is present is equal to the specific probability α (ISO, 2010). For cases where N_B is large enough (> about 30) so that the Poisson distribution can be approximated by a normal (Gaussian) distribution, the *DT* (expressed in terms of Bq) can be calculated as follows:

$$DT = C_{rn}\ k_{1-\alpha}\sqrt{\lambda_B\left(\frac{1}{T_B}+\frac{1}{T_S}\right)} \qquad \text{(ISO, 2000)}$$

where

- C_{rn} is the normalisation factor converting count rate to activity (Bq per count/s)

- T_B is the duration of the background effect measurement
- T_S is the duration of the sample (gross) effect measurement
- λ_B is the background effect counting rate equal to the ratio of the background counts, N_o counted during the preselected duration of the background measurement, T_B and the duration of the background measurement, T_B: $\lambda_B = N_0 / T_B$.
- $k_{1-\alpha}$ is the desired 1- α percentile of the normal distribution. For an α risk of 5 %, $k_{1-\alpha}$ =1.645.

Because of the overall variability of the counting, it cannot be concluded that the radionuclide is really absent if the measurement result < DT; it can only be stated that the radionuclide was not detected by the measurement procedure. A detection limit (*DL*) is defined as the smallest true value of a measured quantity which ensures a specified probability of being detectable by the measurement procedure if the nuclide is actually present (ISO, 2010a, 2010b). Given that the radionuclide is present in the sample or body, the *DL* shall refer to the smallest true value of the measured quantity, for which, by applying the decision rule above, the probability of the wrong assumption that the nuclide is absent does not exceed the specified probability, β. Again, for cases where N_B is large enough (> about 30) so that the Poisson distribution can be approximated by a normal (Gaussian) distribution, the *DL* (expressed in terms of Bq) can be calculated as follows:

$$DL = C_{rn}\left(k_{1-\alpha} + k_{1-\beta}\right)\sqrt{\lambda_B\left(\frac{1}{T_B}+\frac{1}{T_S}\right)} \qquad \text{(ISO, 2000)}$$

For an error probability of 5% for α and for β, the values of $k_{1-\alpha}$ and $k_{1-\beta}$ are 1.645. Therefore, $k_{1-\alpha}$ + $k_{1-\beta}$ = 3.29. Typically, if β=α and N_G is large enough then $DT = \frac{1}{2}DL$. The DT and DL are described graphically in Figure 3.1.

The DL allows a decision to be made as to whether a measuring method satisfies certain requirements and is consequently suitable for the given purpose of measurement (ISO, 2010). In other words, to check whether a measurement procedure is suitable for measuring the measurand, the calculated detection limit shall be compared with a specified guideline value, for instance according to specified requirements on sensitivity of the measurement procedure for scientific, legal or other reasons. If the calculated detection limit value is smaller than the guideline value, the procedure is suitable for the measurements, otherwise it is not.

The typical *DL* can be determined *a priori* for a given radionuclide and measurement procedure before the sample measurement takes place. In contrast, the *DL* and *DT* associated with the actual measurement are evaluated *a posteriori* after the measurement has taken place.

Sometimes the decision threshold is frequently referred to as the critical level, decision level or minimum significant activity. Also the detection limit is sometimes referred to as the minimum detectable activity or lower limit of detection.

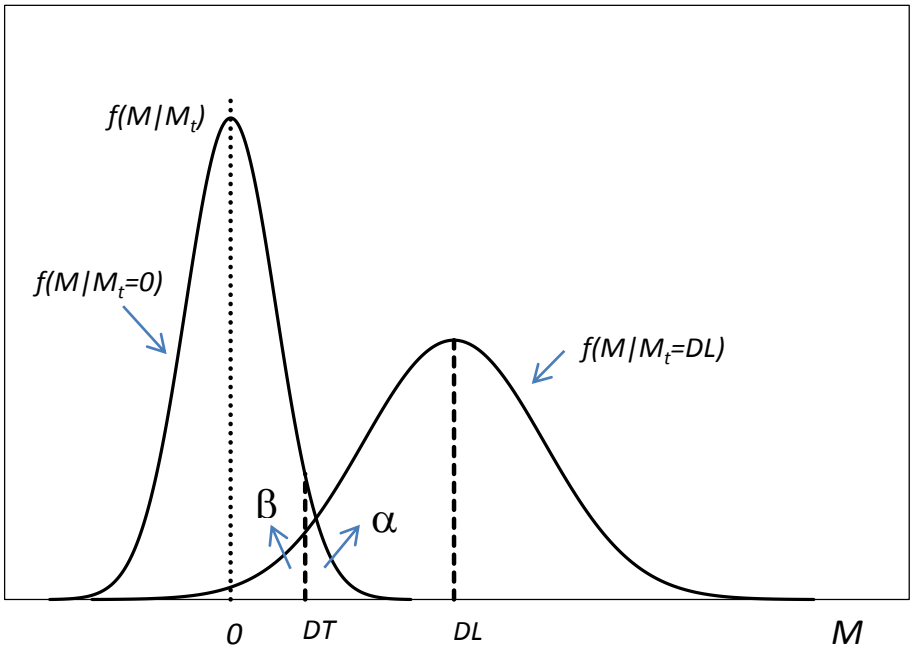


Figure 3.1 Decision threshold (DT) and detection limit (DL). The probability density distribution $f(M|M_t)$ is the conditional distribution of the measurement estimates, M given the true value M_t of the measured quantity.

To summarize, having performed the measurement, the measurement result is compared with the DT. If the measurement result > DT then one decides that the nuclide is present with an activity equal to the measured activity. If the measurement result is less than the DT, then one can say that the nuclide or its activity was not detected with the measurement procedure, but it cannot be concluded that the nuclide is absent. In such cases, if any activity is present, it is generally indicated as being less than the DL.

In recent ISO standards (e.g. ISO 11929:2010; ISO 2010a), statistical equations for the, DT, DL and measurement uncertainty have been developed based on Bayesian statistics. The application of these procedures to radiobioassay measurements and the subsequent calculations of the characteristics limits are reported in the standard ISO 28218:2010 (ISO 2010b). For example, Annex B of ISO 28128:2010 (ISO 2010b) presents four application examples with the detailed calculations and analytical equations to be applied for the following bioassay types: Whole body counter measurement, Pu determination by alpha spectroscopy, determination of U in urine by means of ICP – MS and tritium measurement in urine samples with liquid scintillation counting. The reader is referred to the ISO standards for further clarification and for the application of these procedures to practical examples.

In the following Tables (collected for bioassay types) the typical and the achievable detection limit values for different radionuclides and methods of measurements, are reported (Hurtgen 2012).

The reported values are expected to be consistent with the values to be issued by ICRP in the forthcoming OIR documents. It is however recommended that the typical and achievable detection limit values that will be given in the ICRP OIR series documents should always be used in preference to these values.

The reported values have not been derived from equations reported in the recent ISO standards (ISO, 2010a, 2010b). However, they provide a basis for assessing the sensitivity of a detection method, developed by a specific laboratory, and for comparing it with the state of the art sensitivity, internationally recognized for the type of bioassay measurement under consideration.

Table 3.1 : Detection limit values for urine bioassay.

Isotope	Method of measurement	Typical	Achievable	Units
H-3	Liquid scintillation counting	100	10	Bq/L
C-14	Liquid scintillation counting	60	5	Bq/L
P-32	Liquid scintillation counting	15	0.02	Bq/L
S-35	Liquid scintillation counting	15	5	Bq/L
Co-57	Gamma ray spectrometry	1	0.2	Bq/L
Co-58	Gamma ray spectrometry	0.4	0.1	Bq/L
Co-60	Gamma ray spectrometry	0.4	0.1	Bq/L
Sr-85	Gamma ray spectrometry	5	1	Bq/L
Sr-89	Beta proportional counting	1	0.05	Bq/L
Sr-90	Beta proportional counting	0.4	0.05	Bq/L
Sr-90	Liquid scintillation counting	0.4	0.1	Bq/L
Zr-95	Gamma ray spectrometry	5	0.1	Bq/L
Nb-95	Gamma ray spectrometry	4	0.5	Bq/L
Cs-134	Gamma ray spectrometry	1	0.04	Bq/L
Cs-137	Gamma ray spectrometry	2	0.1	Bq/L
Ra-226	Alpha spectrometry	10		mBq/L
Ra-226	Emanations method	5		mBq/L
Ra-226	Proportional counting	4		mBq/L
Ra-226	Liquid scintillation counting	3		mBq/L
Th-228	Alpha spectrometry	1	0.1	mBq/L
Th-230	Alpha spectrometry	1	0.05	mBq/L
Th-232	Alpha spectrometry	1	0.05	mBq/L
Th-232	ICP-MS	0.3	0.06	mBq/L
U-234	Alpha spectrometry	0.3	0.05	mBq/L

U-235	Alpha spectrometry	0.3	0.05	mBq/L
U-235	ICP-MS	0.001		µg/L
U-235	ICP-MS	0.08		mBq/L
U-238	Alpha spectrometry	0.3	0.05	mBq/L
U-238	ICPMS	0.0015		µg/L
U-238	ICPMS	0.02		mBq/L
U-238	Tr-KPA	0.1	0.06	µg/L
U-238	Fluorimetry	1		µg/L
Np-237	Alpha spectrometry	1	0.1	mBq/L
Pu-238	Alpha spectrometry	0.3	0.05	mBq/L
Pu-239	Alpha spectrometry	0.3	0.05	mBq/L
Pu-239	Thermal Ionization Mass Spectrometry (TIMS)	0.01	0.004	mBq/L
Pu-241	Liquid scintillation counting	30 (direct measurement)	0.03*	Bq/L
Am-241	Alpha spectrometry	0.3	0.05	mBq/L
Cm-244	Alpha spectrometry	0.3	0.05	mBq/L

* After chemical separation and redissolution of the tray from alpha spectrometry.

Table 3.2 : Detection limit values for faeces bioassay.

Isotope	**Method of measurement**	**Typical**	**Achievable**	**Units**
Ra-226	Proportional counting	16		mBq/24h
U-234	Alpha spectrometry	1	0.2	mBq/24h
U-235	Alpha spectrometry	1	0.2	mBq/24h
U-238	Alpha spectrometry	2	0.2	mBq/24h
Th-228	Alpha spectrometry	2	0.2	mBq/24h
Th-230	Alpha spectrometry	2	0.2	mBq/24h
Th-232	Alpha spectrometry	2	0.2	mBq/24h
Np-237	Alpha spectrometry	1	1	mBq/24h
Pu-238	Alpha spectrometry	2	0.2	mBq/24h
Pu-239	Alpha spectrometry	2	0.2	mBq/24h
Am-241	Alpha spectrometry	2	0.5	mBq/24h
Cm-244	Alpha spectrometry	2	0.5	mBq/24h

Table 3.3 : Detection limit values for lung measurements.

Isotope	Method of measurement	Typical	Achievable	Units
U-235	Gamma ray spectrometry	8	3	Bq
U-238	Gamma ray spectrometry	50	30	Bq
Th-228	Gamma-ray spectrometry of Pb-212	10	8	Bq
Th-232	Gamma-ray spectrometry of Ac-228	20	10	Bq
Np-237	Gamma-ray spectrometry of Pa-233	25	13	Bq
Pu-239	Gamma-ray spectrometry of Am-241	10	4	Bq
Am-241	Gamma-ray spectrometry	10	4	Bq

Table 3.4: Detection limit values for whole body counting by gamma ray spectrometry.

Isotope	Typical	Achievable	Units
Mn-54	20		Bq
Co-57	40	30	Bq
Co-58	40	10	Bq
Co-60	40	10	Bq
Se-75	40		Bq
Sr-85	50	20	Bq
Zr-95	50	20	Bq
Nb-95	40	12	Bq
Ag-110m	20		Bq
Cs-134	40	10	Bq
Cs-137	60	15	Bq
U-235	60	40	Bq

Table 3.5: Detection limit values for thyroid counting by gamma ray spectrometry.

Isotope	Typical	Achievable	Units
I-125	40	10	Bq
I-131	25	1	Bq

3.3 Determination of M_c values

In routine monitoring, an explicit assessment of the dose is required only if the observed bioassay measurement exceeds a pre-defined critical monitoring quantity. This critical monitoring quantity M_c can be considered as the amount of activity retained or excreted at the end of a monitoring period that determines an intake that, if it was repeated for all monitoring periods during the accounting year, would result in a value of committed effective dose of 0.1 mSv in a year. In the absence of knowledge of the exact time of intake, the adopted assumption is to consider that intake took place at the central value of the monitoring period (T/2), according to the indication of the ICRP publication 78 (ICRP 1997). A recent confirmation of this methodology is also reported in the ISO 20553 standard (ISO 2006).

To calculate the values of M_c using the values of the monitoring period T the following equation can be used.

$$M_c = \frac{10^{-4} \cdot m(T/2)}{e(50)} \cdot \frac{T}{365} \qquad (3.1)$$

with

M_c Critical monitoring quantity for Level 0 (Bq or Bq/d)

T monitoring interval for the monitoring quantity considered (d)

$m(T/2)$ corresponding retention or excretion function for the monitoring quantity at time t = T/2 (Bq per Bq intake or Bq/d per Bq intake). It is assumed that the intake occurs at the mid-point of the monitoring interval.

$e(50)$ Dose coefficient (Sv Bq^{-1})

Values of the critical monitoring quantity, M_c, as assessed for selected radionuclides by the above equation, in case of inhalation of 5 μm AMAD aerosols, are given in Tables from 3.6 to 3.10, in relationship to different bioassay types. However these values may need to be updated using the revised dose coefficients and bioassay quantities given in the OIR Documents. For other radionuclides or monitoring periods, the equation (3.1) can be used to evaluate the specific M_c value to be applied.

The values reported in Tables from 3.6 to 3.10 are numerically equal to those reported in Tables 1 to 5 of ISO 27048 (ISO 2011).

Table 3.6: Critical monitoring quantities M_C for routine monitoring programme corresponding to 0.1 mSv/y: Urine measurements.

Radionuclide	Absorption type	Maximum time interval (days)	M_c (Bq / 24h)
^{3}H	HTO	30	4000
^{14}C	Organic	7	10
^{14}C	Dioxide	180	300
^{32}P	F	30	10
^{33}P	F	30	100
^{35}S	F	7	20
^{63}Ni	M	15	3
^{89}Sr	F	30	10
^{89}Sr	S	30	5E-2
^{90}Sr	F	30	1
^{90}Sr	S	180	3E-3
^{226}Ra	M	180	1E-4
Uranium (natural) exafluoride	F	90	1E-2
Uranium (natural) peroxide, nitrate, ammonium diuranate	F	30	2E-2
Uranium (natural) tetrafluoride,trioxide	M	90	3E-3
Uranium (natural) dioxide, octoxide	S	90	2E-5
^{237}Np	M	180	1E-4
^{238}Pu	S	180	7E-7
^{239}Pu	S	180	1E-6
^{239}Pu	M	180	1E-5
^{241}Am	M	180	3E-5
^{244}Cm	M	180	3E-5

Table 3.7: Critical monitoring quantities M_C for routine monitoring programme corresponding to 0.1 mSv/y: Faecal measurements.

Radionuclide	Absorption type	Maximum time interval (days)	M_c (Bq / 24h)
Uranium (natural) tetrafluoride, trioxide	M	180	2E-3
Uranium (natural) dioxide, octoxide	S	180	9E-4
^{228}Th	S	180	2E-4
^{232}Th	S	180	5E-4
^{232}Th	M	180	2E-4
^{237}Np	M	180	7E-2
^{238}Pu	S	180	5E-4
^{239}Pu	S	180	7E-4
^{239}Pu	M	180	1E-4
^{241}Am	M	180	2E-4
^{244}Cm	M	180	4E-4

Table 3.8: Critical monitoring quantities M_C for routine monitoring programme corresponding to 0.1 mSv/y: Whole body measurements.

Radionuclide	Absorption type	Maximum time interval (days)	M_c (Bq)
^{51}Cr	F	15	20000
^{54}Mn	M	90	1000
^{59}Fe	M	90	400
^{57}Co	S	180	2000
^{58}Co	S	180	500
^{60}Co	S	180	100
^{75}Se	M	180	4000
^{110m}Ag	S	180	200
^{137}Cs	F	180	2000

Table 3.9: Critical monitoring quantities M_C for routine monitoring programme corresponding to 0.1 mSv/a: Lung measurements.

Radionuclide	Absorption type	Maximum time interval (days)	M_c (Bq)
^{235}U tetrafluoride, trioxide	M	180	0.6
^{235}U dioxide, octoxide	S	180	0.3
^{241}Am	M	180	0.04

Table 3.10: Critical monitoring quantities M_C for routine monitoring programme corresponding to 0.1 mSv/y: Thyroid measurements.

Radionuclide	Absorption type	Maximum time interval (days)	M_c (Bq)
^{125}I	F	90	200
^{131}I	F	15	30

As can be seen, M_C values are above the detection limit (DL) for the fission and activation products whereas they are below the DL for the considered actinides. So in case of the actinides, any significant monitoring value is likely to result in an annual dose of more than 0.1 mSv and thus has to be evaluated. In the case of the fission or activation products, however, there might be significant monitoring values which result in an annual dose less than 0.1 mSv.

4. Handling of Monitoring data

4.1 Data Collection and Processing Before Use

4.1.1 Normalisation of an activity measurement

Some types of measurement data may need processing before use. Examples include:

- Lung. Generally, the combined activity in lungs and thoracic lymph nodes is referred to as 'lung' activity, and it is this quantity that is calculated by internal dosimetry software. Where estimates of lung and lymph activity are given separately, they should be summed. "Chest" measurements may also include counts from activity in liver and skeleton for radionuclides that concentrate in these tissues, and their contributions will be need to be subtracted.
- Faeces. The transit time through the alimentary tract is subject to large inter- (and intra-) subject variations. Moreover, while for ease of computation transit through the alimentary tract is represented by a series of compartments that clear exponentially, in practice, the movement is more like "slug" flow. It is therefore unlikely that individual daily faecal clearance measurements in the first few days after intake will follow the predicted pattern, and so it is best to consider cumulative excretion over the first three days. The uncertainty associated with cumulative excretion in the first three days will be lower compared with that from daily excretion especially as the daily faecal excretion over the first three days after intake is likely to be correlated.
- Urine and faecal samples collected over periods less than 24 hours should in general be normalized to an equivalent 24 hour value. This can be achieved by multiplying by the ratio of the reference 24 hour excretion volume or mass to the volume or mass of the sample. The reference volumes, for males and females respectively, are: for urine 1.6 L and 1.2 L; and for faeces 150 g and 120 g (ICRP 2002a). For urine sampling, another widely used method is to normalise to the amount of creatinine excreted per day; 1.7 g and 1.0 g for males and females respectively (ICRP 2002a).
- A critical case may arise when the sample, indicated as full 24-hour sample, is less than 500 mL for urine or less than 60 g for faeces. In such cases it can reasonably be assumed that it has not been collected over a full 24 hour period, and normalization by volume/mass should be considered.
- A special case is the monitoring of intakes of tritiated water. In this case the collection of spot samples is sufficient because tritium is considered to be uniformly distributed in the body fluids.

4.1.2 Exposure to multiple radionuclides

In many situations exposure will be to a single radionuclide or a limited number of radionuclides. In such situations it should be clear how best to establish an appropriate monitoring programme. For some complex mixtures, however, or for some elements with many isotopes with different decay properties, care is needed in the development of a monitoring programme. Some examples to illustrate the potential for exposure to complex mixtures are given below and in Annex 1 for uranium and plutonium.

- Uranium: Excretion data (especially faecal) may need correction for dietary intakes of uranium (Section 4.1.3 Subtraction of the alimentary background). Doses need to be calculated for the other isotopes in addition to those measured. In particular, for enriched uranium ^{235}U may be measured, while the highest dose comes from ^{234}U. Tables given in Annex 1 show the isotopic composition terms of mass or activity for enriched or depleted uranium. Note that the composition in terms of mass is completely different from that in terms of activity. The isotopic composition for natural uranium and the specific activities of the different uranium isotopes are given in Section 14.1 Annex 1 – Isotopic composition of natural, enriched and depleted uranium and plutonium materials encountered in the nuclear industry.
- Plutonium and americium: If the measurement is expressed simply as "Pu" (without further details) assume that the given value actually refers to total Pu alpha-activity (^{238}Pu, ^{239}Pu, and ^{240}Pu). If the measurement is expressed as "^{239}Pu" (without further details) assume that the given values actually represent ^{239}Pu+^{240}Pu, because these two nuclides cannot be separated by alpha spectrometry. If ^{241}Pu was not measured, then assume a typical ratio to total plutonium alpha activity, for use as default. For those cases where no specific information is available the typical plutonium isotopic ratios given in Annex 1 could be used as default. However, there are widely different chemical characteristics and composition of Pu mixtures encountered in the nuclear industry. Because ^{241}Pu decays into ^{241}Am with a period of 14.32 y, an increase of ^{241}Am fraction in an incorporated Pu-Am mixture may be observed. This contribution of ^{241}Am from decay of ^{241}Pu should be accounted for when interpreting ^{241}Am bioassay data (i.e. *in-vivo* and excretion data).

4.1.3 Subtraction of the alimentary background

Radionuclides from the three natural radioactive decay series are present in all environmental media, and thus are also contained in foodstuffs, drinking water and in the air, leading to intakes by human populations.

ICRP Publication 23 on Reference Man gives data on the daily intake and losses for different elements. For uranium, daily losses range from 0.05 – 0.5 µg (1.25 – 12.5 mBq) in urine and from 1.4 – 1.8 µg (35 – 45 mBq) in faeces. For thorium, these losses are 0.1 µg (0.4 mBq) and 2.9 µg (12 mBq) in urine and faeces respectively. For radium these losses are 3 mBq in urine and 80 mBq in faeces.

As can be seen from the tables 4.1 and 4.2, a wide range of activity concentration is observed in different world area with exceptionally high value observed for uranium in Finland. (For homogeneity and comparison purpose the activity concentration have been calculated from the authors data and taking the daily urine excretion as 1.6 L (ICRP, 2002a) and the faecal ashes as 4 g per day.)

Table 4.1. Background uranium activity concentration in urine.

^{234}U (mBq/d)		^{238}U (mBq/d)		Comments	Reference
Mean	Range	Mean	Range		
1.41	0.25 - 2.5	1.30	0.17 - 2.6	control subjects US	Fisher 1983
0.89		0.52		dietary study UK	Spencer 1990
		0.46		non-occupationally exposed volunteers US	Wrenn 1992
		0.26		normal background environment, IN	Dang 1992
0.23	0.056 - 2.7	0.20	0.051 - 0.94	worker potentially exposed, Mol, BE	Hurtgen 2001
		8437	20 - 112000	population from Southern Finland	Kurttio 2002
		3.95	0.23 - 15.2	unexposed subjects, JO	Al-Jundi 2004
0.46	0 - 2.5	0.41	0 - 3.0	Dounreay not exposed to uranium UK	Spencer 2007
		0.17	0.037 - 0.29	unexposed subjects from South of DE	Oeh 2007
		0.17	0.032 - 0.44	general population CZ	Malatova 2011
		0.53	0.19 - 1.26	U worker family CZ	Malatova 2011

Data given in mass have been recalculated and expressed in mBq/d for ^{238}U. The daily urinary excretion has been taken as 1.6 L (ICRP2002a).

Table 4.2 Background uranium activity concentration in faeces.

^{234}U (mBq/d)		^{238}U (mBq/d)		comments	Reference
Mean	Range	Mean	Range		
37		26		dietary study, US	Spencer 1990
		17.4	5.0 - 27	persons in the Berlin area, DE	Naumann 1998
14	9.2 – 19.2	13.5	8.0 – 18.0	Poços de Caldas, BR	Taddei 2001
32	7.3 - 225	22	3.8 - 170	worker potentially exposed, BE	Hurtgen 2001
46		47		Buena, BR	Juliao 2003
32		28.5		Rio de Janeiro, BR	Juliao 2003

Table 4.3 Background thorium activity concentration in urine

^{228}Th (mBq/d)		^{230}Th (mBq/d)		^{232}Th (mBq/d)		Comments	Reference
Mean	Range	Mean	Range	Mean	Range		
				0.03		urine natural background (DE)	Dalheimer 1994
				2.1		daily excretion in Buena (BR)	Juliao 1998
0.63	0.19 - 2.6	0.53	0.11 - 3.7	0.23	0.11 - 0.50	worker not exposed to Th, (BE)	Hurtgen 2001
				0.007		unexposed adult (DE)	Roth 2005

Table 4.4. Background thorium activity concentration in faeces.

^{228}Th (mBq/d)		^{230}Th (mBq/d)		^{232}Th (mBq/d)		Comments	Reference
Mean	Range	Mean	Range	Mean	Range		
				12		faeces natural background (DE)	Dalheimer 1994
23	11 - 39	9.8	1.7 - 16	5.4	1.6 - 12	persons in the Berlin area (DE)	Naumann 1998
				30	5.6 - 104	daily excretion in Buena (BR)	Juliao 1998
35	5.8 - 161	7.7	1.87 - 31	3.4	0.97 - 22	worker not exposed to Th (BE)	Hurtgen 2001
290	218 - 442	12.4	7.5 - 17.5	7.4	4.5 - 12.0	Poços de Caldas (BR)	Taddei 2001
947				26		inhabitants of Buena (BR)	Juliao 2003
60				10		inhabitants of Rio de Janeiro(BR)	
		4.1	1.0 - 34			general population (DE)	Schäfer 2006

Table 4.5. Background radium activity concentration in urine and faeces.

Urine Excretion ^{226}Ra (mBq/d)		Faecal excretion ^{226}Ra (mBq/d)		Comments	Reference
Mean	Range	Mean	Range		
0.6	0.22 - 1.22	29	20 - 43	male patient (US)	Spence 1973
		65	38 - 121	persons in the Berlin area (DE)	Naumann 1998
3.8	0.47 - 18.5	109	36 - 240	non exposed worker (BE)	Hurtgen 2001
		581		inhabitants of Buena (BR)	Juliao 2003
		71		inhabitants of Rio de Janeiro (BR)	Juliao 2003
9.9	0.6 - 29	66	6 - 212	general population (DE)	Schäfer 2004
8.1	2.0 - 75	21	2 - 442	general population (DE)	Schäfer 2006

A knowledge of the natural background activity found in the bioassay is absolutely necessary if occupational intake has to be assessed. So, blank bioassay sample should be obtained prior to the effective work in potentially contaminating area. This is to be able to distinguish between natural or non-occupational intake and occupational intake.

These blank bioassay samples can be obtained from the worker before or at the beginning of their employment, from non-occupationally exposed workers or from the population living in the area, including some members of the worker's family. Alternatively during the intake assessment, and to take care of the natural radioactivity contained in the foodstuff and drinking water, a chronic ingestion intake can be assumed during the all period of occupational exposure.

Table 4.6. Background polonium activity concentration in urine and faeces.

Urine excretion ^{210}Po (mBq/d)		Faecal excretion ^{210}Po (mBq/d)		Comments	Reference
Mean	Range	Mean	Range		
0.41				non smoker	Radford 1964
2.4				smoker	Radford 1964
2.2	0.26 - 9.3			adult hospital patient	Taylor 1964
13.6				-	Hölgye 1969
5	3.3 - 9.1			-	De Boeck 1971
1.4				pooled sample	Bale 1975
25	7.1 - 62			non-smokers	Okabayashi 1975
66	33 - 118			smokers	Okabayashi 1975
14.0	7.4 - 27	236	63 - 938	one individual non smokers	Okabayashi 1975
9.3	1.85 - 18.9	64	48 - 73	adult males	Spencer 1977
1.78				-	Helmkamp 1979
41				non uranium mine worker	Okabayashi 1982
26				local control individuals (mining area)	Fenzi 1986
12.4				Milan area (IT)	Fenzi 1986
5.2				non-smokers	Azeredo 1991
9.9				smokers	Azeredo 1991
8.3	4.6 - 11			non-smokers	Santos 1994
15.7	11 - 24			smokers	Santos 1994
8.5	6.4 - 10.4			farmers	Santos 1995
6	2(LD) - 9.9			persons in the Berlin area (DE)	Naumann 1998
12	2 - 35	45	16 - 85	14 caucasians volunteers	Thomas 2001
5.2				non-smokers	Lipsztein 2003
9.9				smokers	Lipsztein 2003
		514	240 - 890	alimentary tract study (5 volunteers)	Hunt 2004
9.4	2.4 - 16			non-smokers	Al-Arifi 2006
14.2	5.3 - 25			smokers	Al-Arifi 2006
13.0	3.5 - 31			shiha smokers	Al-Arifi 2006
3.5	1.0 to 248*			general population	Schäfer 2006
56	16 - 172	239	32 - 936	alimentary tract study (7 volunteers)	Hunt 2007

* Maximum value taking into account the workers.

4.2 Assessment of uncertainty on data

The uncertainties on the data are of great importance for the evaluation for several reasons:

- They enable an objective decision to be made on whether a measured value is due to a new intake, or due to previous intakes that already have been evaluated.
- They enable an objective decision to be made on whether a measured value is consistent with previous evaluations, or if it indicates the previous evaluations to be wrong.
- They can have a strong influence on all evaluations using weighted fitting procedures (i.e. where there is more than one data point).
- They enable rogue data to be identified objectively.
- They enable objective (statistical) criteria (goodness-of-fit) to be calculated, which are used to determine whether the predictions of the biokinetic model (with a given set of parameter values) used to assess the intake and dose are inconsistent with the data.
- They enable statistics to be calculated, such as the chi-squared (χ^2), which can be used to compare the fits to the data of different models/parameter values.

Uncertainties in measurements of activity in the body or in biological samples have been discussed in IAEA publications (IAEA 1996, 2000). There are no standard procedures for indirect or direct bioassay measurements, although some examples of bioassay methods are given in these publications and elsewhere. The choice of the procedure, detector or facility will depend on the specific needs such as the nuclides of interest, detection limits (DL), and budget. All procedures used to quantify the activity of a radionuclide are sources of random and systematic errors. Uncertainties in measurements typically are due mainly to counting statistics, validity of the calibration procedures, possible contamination of the source or the measurement system, and random fluctuations in background.

In estimating the overall uncertainty in a measurement, it may be necessary to take each source of uncertainty and treat it separately to obtain the contribution from that source. Each of the separate contributions to uncertainty is referred to as an uncertainty component.

The components of uncertainty in a quantity may be divided into two main categories referred to as Type A and Type B uncertainties. ISO's Guide to the Expression of Uncertainty in Measurement (BIPM *et al.*, 2010) discriminates between the Type A evaluation of uncertainty - that based on statistical means - and the Type B evaluation of uncertainty - that based on non-statistical means. However, as noted in a publication of the UK National Physical Laboratory (Cox and Harris, 2004), it is sometimes more useful to make a distinction between effects that can be regarded as random, and those that can be regarded as systematic. Cox and Harris note that the subdivision into Type A and Type B evaluations of uncertainty will correspond in some instances to random and systematic effects, respectively, but not in all circumstances.

In the case of a measurement of activity in the body or in a biological sample, Type A uncertainties are taken to arise only from counting statistics, which can be described by the Poisson distribution and Type B components are due to all other sources of uncertainty.

Examples of Type B components for *in vitro* measurements include the quantification of the sample volume or weight; errors in dilution and pipetting; evaporation of solution in storage; stability and activity of standards used for calibration; similarity of chemical yield between tracer and radioelement of interest; blank corrections; background radionuclide excretion contributions

and fluctuations; electronic stability; spectroscopy resolution and peak overlap; contamination of sample and impurities; source positioning for counting; density and shape variation from calibration model and assumptions about homogeneity in calibration (Skrable et al, 1994). These uncertainties apply to the measurement of activity in the sample. With excretion measurements, the activity in the sample is used to provide an estimate of the subject's average excretion rate over 24 hours for comparison with the model predictions. If the samples are collected over periods less than 24 hours then they should be normalised to an equivalent 24 hour value. This introduces additional sources of Type B uncertainty: the uncertainty in the collection period, which depends on the sampling procedures and the techniques used to calculate the collect period, and the uncertainty relating to biological (inter-and intra-subject) variability. This uncertainty may well be greater than the uncertainty in the measured sample activity.

In vivo measurements can be performed in different geometries (whole body measurements, and organ or site specific measurement such as measurement over the lung, thyroid, skull, or liver, or over a wound). Each type of geometry needs specialized detector systems and calibration methods. The IAEA (1996) and the ICRU (2003) have published reviews of direct bioassay methods that include discussions of sensitivity and accuracy of the measurements.

Examples of Type B components for i*n vivo* monitoring include counting geometry errors; positioning of the individual in relation to the detector and movement of the person during counting; chest wall thickness determination; differences between phantom and individual or organ being measured, including geometric characteristics, density, distribution of the radionuclide within the body and organ and linear attenuation coefficient; interference from radioactive material deposits in adjacent body regions; spectroscopy resolution and peak overlap; electronic stability; interference from other radionuclides; variation in background radiation; activity of the standard radionuclide used for calibration; surface external contamination of the person; interference from natural radioactive elements present in the body; and calibration source uncertainties (IAEA,1996, Skrable et al, 1994).

For partial body measurements it is generally difficult to interpret the result in terms of activity in a specific organ because radiation from other regions of the body may be detected. Interpretation of such measurements may require assumptions concerning the biokinetics of the radionuclide and any radioactive progeny produced *in vivo*. An illustration using ^{241}Am is given in the IAEA Safety Report on Direct Methods for Measuring Radionuclides in the Human Body (IAEA 1996). A fundamental assumption made in calibrating a lung measurement system is that the deposition of radioactivity in the lung is homogeneous, but depositions rarely follow this pattern.

Measurement errors associated with counting statistics (Type A uncertainties) decrease with increasing activity or with increasing counting time, whereas the Type B components of measurement uncertainty may be largely independent of the activity or the counting time. Therefore, when activity levels are low and close to the detection limit the total uncertainty is often dominated by the Type A component (i.e. by counting statistics). For radionuclides that are easily detected and present in sufficient quantity, the total uncertainty is often dominated by the Type B components (i.e. by uncertainties other than counting statistics).

In these Guidelines, for simplicity, it is assumed that the overall uncertainty on an individual monitoring value can be described in terms of a log-normal distribution and the scattering factor (SF) is defined as its geometric standard deviation. This approximation is reasonable when Type A

uncertainties are relative small. However, in cases where the counts are low (i.e. Type A errors are large), Miller et al. (2002) considers that the exact likelihood function they describe should be used. This function, which gives the probability distribution of measurements given an intake, describes uncertainties due to counting statistics (Type A errors) with a Poisson distribution whereas all other uncertainties (Type B) are described by a single log-normal distribution.

Table 4.7 lists typical values for the various components of uncertainty of *in vivo* measurements (Doerfel 2006). The uncertainty is given in terms of the scattering factors (SF) assuming that the distributions of the measurements can be described by a log-normal distribution. For example, the SF due to counting statistics is given as SF_A = 1.07 for high photon energy counting. This means that the scattering of the measured values due to counting statistics would result in 68% of the values to be in the range between x_{50}/1.07 and x_{50}*1.07, where x_{50} is the median of all measured values.

Based on the experience gained in the IDEAS project (Castellani 2004), as well as on the grounds of simplicity and practicality, the following general approach for the calculation of the total uncertainty may be applied:

$$SF = \exp\left[\sqrt{\sum_i \ln^2(SF_i)}\right] \qquad (4.1)$$

with SF total scattering factor

SF_i scattering factor due to component i

When applying this approach on the SF values given in Table 4.7, the values in Table 4.8 are derived for the total scattering factors. However, it is noted that Miller, 2007 considers the assumption that the overall uncertainty on an individual monitoring value can be described in terms of a log-normal distribution is reasonable if the ratio $\ln(SF_A) : \ln(SF_B)$ is less than one-third.

The SF values suggested in Tables 4.7 and 4.8 for *in vivo* measurements are applicable to chest and total body in-vivo measurements. It is noted that specialised *in-vivo* measurements such as knee and head measurements to determine skeleton activity, may have larger uncertainties compared with chest and total body activity measurements.

Table 4.7 Typical values for the components of log-normal uncertainty for *in vivo* measurements of radionuclides emitting low, intermediate and high photon energy radiation.

Source of uncertainty (Type)	Scattering factor SF		
	Low photon energy E < 20 keV	Intermediate photon energy 20 keV < E < 100 keV	High photon energy E > 100 keV
Counting statistics (A)	1.5	1.3	1.07
Variation of detector positioning (B)	1.2	1.05	< 1.05
Variation of background signal (B)	1.5	1.1	< 1.05
Variation in body dimensions (B)	1.5	1.12	1.07
Variation of overlaying structures (B)	1.3	1.15	1.12
Variation of activity distribution (B)	1.3	1.05	< 1.05
Calibration (B)	1.05	1.05	1.05
Spectrum evaluation[(a)] (B)	1.15	1.05	1.03

(a) HPGe detector spectra

Table 4.8: Typical values for the total type A and type B log-normal uncertainty for *in vivo* measurements of radionuclides emitting low, intermediate and high photon energy radiation

Uncertainty type	Scattering factor SF		
	Low photon energy E < 20 keV	Intermediate photon energy 20 keV < E < 100 keV	High photon energy E > 100 keV
Total type A	1.5	1.3	1.07
Total type B	2.06	1.25	1.15
Total	2.3	1.4	1.2

Specific treatments, like measurement of the actinides activity in the skull or knee, needs careful estimation of the SF_B. General estimations of the SF does not have robustness, because particular value depends strongly on the measurement geometry and detection system property. Therefore, an appropriate uncertainty analysis is required. Crude estimation for simple two detector geometry facing temporal bones based on general assumptions was published by Malátová and Foltánová (Malátová 2000). Detailed analyses for the same geometry based on the best available data and Monte Carlo calibration was published by Vrba (Vrba 2010). The overall uncertainty was estimated with two methods: the first method combined uncertainties as described in the present report and the second method applied Monte Carlo sampling. Based on these publications, suggested values of type B uncertainties for the assessment of ^{241}Am activity in the skull are given in Table 4.9.

Table 4.9. Suggested values of uncertainties (type B) for the assessment of ^{241}Am activity in the skull.

Source of uncertainty	**SF_B**
calibration phantom	1.06
detector positions	1.13
skull size dependence	1.24
activity distribution	1.11*
spectra analyses	1.08
Total	**1.33**

* Possible source distribution difference between calibration phantom and measured subject

Whole skeleton activity is required in biokinetic models, therefore uncertainty of the skull to skeleton ratio, which is about SF_B =1.16, will contribute too. Thus the overall SF_B uncertainty of ^{241}Am skeleton activity based on skull measurement can be evaluated as SF_B=1.38.

The measured activity, M and its Type A uncertainty, σ_A are given in terms of measured quantities by:

$$M = C_{rn} \cdot \left(\frac{N_G}{T_S} - \frac{N_B}{T_B} \right) = \frac{C_{rn}}{T_S} \cdot \left(N_G - \frac{N_B}{R_B} \right)$$

$$\sigma_A = \frac{C_{rn}}{T_S} \sqrt{N_G + \frac{N_B}{R_B^2}} \qquad (4.2)$$

Where, N_G is the number of measured counts, N_B is the number of measured background counts, R_B is the ratio of background count time to sample count time $R_B=T_B/T_S$, and C_{rn} is the normalisation factor converting count rate to activity (Bq per counts/s).

Note that N_G can be calculated by rearranging equation 3.2, and knowing M, C_{rn}, T_S, N_B and R_B.

Therefore, the Type A uncertainty, σ_A can be determined from equation 3.2 given M, C_{rn}, T_S, N_B and R_B.

The SF for Type A uncertainties is given by:

$$SF_A = \exp\left[\frac{\sigma_A}{M} \right] \qquad (4.3)$$

The SF for Type B uncertainties is given by:

$$SF_B = \exp\left[\frac{\sigma_{C_{rn}}}{C_{rn}} \right] \qquad (4.4)$$

Where $\sigma_{C_{rn}}$ is the uncertainty on the normalisation factor.

Typical values for Type B scattering factors for *in-vitro* measurements are given in Table 4.10. In practice, routine urinary excretion data from plutonium workers is often found to have a log-normal distribution with a SF ranging from 1.3 to about 2.4 (Moss et al, 1969; Riddell et al, 1994, Miller et al 2007 and Marsh et al, 2007, 2008)). However, Moss et al. (1969), showed that when the sampling method and analytical procedures are carefully controlled for true 24-h urine samples, over 5 days, then the SF is significantly less (1.1). This is in agreement with the SF values calculated from data obtained from a volunteer experiment where sampling procedures were carefully controlled (Marsh et al. 2007). This shows that for routine urinary excretion data the uncertainty associated with the unknown collection period is the main source of uncertainty.

Scattering factors have been evaluated from urine monitoring data where urine samples were averaged (Marsh et al.,2007). Scattering factors of 1.7, 1.7 and 1.4 were calculated from three uranium inhalation cases where the urine data mainly consisted of an average of 2 to 6 urine samples.

For intakes of tritiated water (HTO), the activity concentration in urine is used and not the 24-h excretion rate. As a result SF_B is lower (1.1).

Marsh et al. 2007 calculated SF values for faecal monitoring using real data contained in the IDEAS Internal Contamination Database (Hurtgen et al. 2007). Ten cases involving intakes of plutonium and americium were assessed and the SF values ranged from 1.9 to 3.5 for the individual cases. Combining these cases gave an overall SF of 2.7. Bull (2005) determined SF values between 2 and 3 for systemic faecal from volunteer data, which is in agreement with the values calculated by Marsh et al. 2007. The scattering factors estimated from the 24-h faecal excretion data of Juliao et al. 2007 for ^{234}U are also consistent with these values. .

Table 4.10 Typical values for the scattering factor SF for various types of *in-vitro* measurements from different studies (Type B errors). Ranges are given in parentheses.

Quantity	Scattering factor SF_B
True 24-hr urine	1.1[(a)]
Activity concentration of ^{3}H (HTO) in urine	1.1[(b)]
Simulated 24-hr urine, creatinine, volume or specific gravity normalised.	1.6[(b)] (1.3[(c)] - 1.8[(d)])
Spot urine sample [(e)]	2.0[(a)]
Faecal 24-hr sample	3 (2 - 4)[(b)]
Faecal 72-hr sample	2 (1.5 – 2.2)[(f)]

(a) Value given by Moss et al, 1969 based on plutonium in urine measurements of workers at Los Alamos.

(b) Value based on judgement and on values calculated by Marsh et al. (2007, 2008).

(c) At Los Alamos, Type B uncertainties, in terms of the coefficient of variation, for urine samples normalised using volume and specific gravity have been found to be 30% (i.e. a SF of 1.3).

(d) Value given by Riddell et al, 1994 based on plutonium in urine measurements of Sellafield workers. Because sampling procedures and measurements techniques have improve over the years, recent measurements are likely to have a SF less than 1.8.

(e) A spot urine sample is a single void which is used to estimate a 24-h urine sample by normalisation.

(f) The SF values for 72-hr faecal samples were calculated from the SF values for 24-hr faecal samples.

Hurtgen (2003) calculated Type A uncertainties for urine and faecal measurements by alpha spectrometry for actinides as a function of activity assuming optimum analytical conditions. For the readers' convenience, the figure giving the relative uncertainty as a function of activity in urine and faeces using optimum analytical conditions is reproduced here (Figure 4.1). The graph represents mainly Type A uncertainties at least for activities less than 100 mBq.

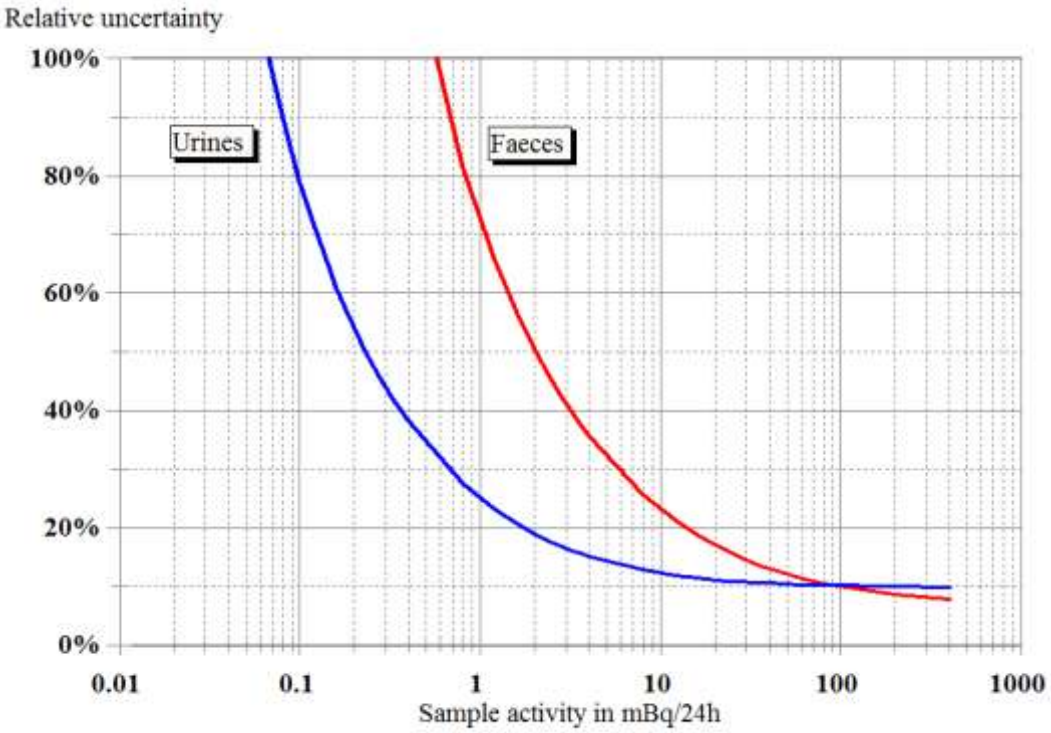


Figure 4.1 Relative uncertainty (%) as a function of sample activity (mBq per 24 h) in urine and faeces using optimum analytical conditions (Hurtgen and Cossonnet, 2003).

For cases with comprehensive high quality data, it may be possible to determine the SF value using the approach described by (Marsh 2007). In this approach the trend of the data is determined by fitting a sum of exponential terms to the data assuming the errors are log-normally distributed. The SF is then determined by calculating the geometric standard deviation of the data around the trend.

5. Processing of measurement data

5.1 Introduction

Direct and indirect measurements provide information about the amounts of radionuclides present in the body, in parts of the body including specific body organs or tissues, or in biological samples. The ICRP biokinetic models which describe body and organ contents, and activity in excreta, as a function of time following intake, are used for this purpose. These models are used to calculate values of the measured quantities for unit intake, *m(t)*, at a time *t* after the intake. These functions will be published in terms of tables and figures in the OIR Publication series. For the time being the values are reported in ICRP Publication 78 (ICRP 1997) and in IAEA Safety Reports Series 37 (IAEA 2004). Once the intake is estimated, the committed effective dose is then computed from the product of the intake and the appropriate dose coefficient. Alternatively, measurements of activity in the body can be used to estimate dose rates directly, if a sufficient number of measurements are available to determine retention functions. This direct dose assessment approach can be used for intakes of tritiated water, as described in Section 12 (IAEA, 2004, Hurtgen et al. 2005, IAEA, 2007).

When only a single bioassay datum is available, a point estimate of the intake is made. If multiple measurements are available, a best estimate of intake may be obtained by applying a statistical fitting method.

5.2 Single measurements, acute intakes

Special monitoring

For special or task-related monitoring when the time of intake is known, the intake can be estimated from the measured results comparing them with the corresponding predicted values of the retention or excretion functions (m(t) values) at time t after intake. If only a single measurement is made, the intake, *I*, can be determined from the measured quantity, *M*, by:

$$I = \frac{M}{m(t)} \qquad (5.1)$$

Care must be taken to ensure that the measurement result, *M*, and *m(t)* are comparable; for example, in the case of urinalysis, the bioassay result must be expressed as the total activity in a 24-hour urine sample at the end of collection (not at analysis).

The intake can be multiplied by the appropriate dose coefficient to give the committed effective dose; this can then be compared with the dose limit or any pre-determined investigation level based on dose. If the measurement indicates that an investigation level has been exceeded, further investigation is required.

Routine monitoring

For routine monitoring, it might be necessary to estimate an intake from a measurement made at the end of a monitoring interval. When the time of intake is not known and cannot be estimated

from workplace analysis and/or workers interviews, it should be assumed that the intake occurred at the mid-point of the monitoring interval of T days. For a given measured quantity, M, obtained at the end of the monitoring interval, the intake is:

$$I = \frac{M}{m(T/2)} \qquad (5.2)$$

where m(T/2) is the predicted value of the measured quantity for a unit intake assumed to occur at the mid-point of the monitoring interval.

An intake in a preceding monitoring interval may influence the actual measurement result obtained. For a series of measurements in a routine monitoring programme, the following procedure may be followed:

- Determine the magnitude of the intake in the first monitoring interval.
- Predict the contribution to each of the subsequent measurements from this intake.
- Subtract the corresponding contributions from all subsequent data.
- Repeat above for the next monitoring interval.

Both the ISO 27048 standard (ISO 2011) and these guidelines (Section 7.3) suggest taking account of the measurement uncertainty (i.e. the SF value) in determining whether a measured value is due to a new intake, or due to previous intakes that already have been evaluated.

The dose from the intake in the monitoring interval is obtained by multiplying the intake by the appropriate dose coefficient. The dose can be compared with the pro-rata fraction of the dose limit. Alternatively, the dose or intake can be compared with predetermined investigation levels. However, if a measured value in a routine monitoring programme exceeds a pre-determined investigation level (or dose level), special monitoring is started so that the intake and the dose can be assessed more accurately (Section 7.5).

5.3 Multiple measurements

Usually, a special monitoring program consists of results for different measurements performed at different times, and even from different monitoring techniques, e.g. direct and indirect measurements.

To determine the best estimate of a single intake, when the time of intake is known, it is first necessary to calculate the predicted values, $m(t_i)$, for unit intake of the measured quantities. It is then required to determine the best estimate of the intake, I, such that the product $I\, m(t_i)$ "best fits" the measurement data (t_i, M_i). In cases where multiple types of bioassay data sets are available, it is recommended to assess the intake and dose by fitting predicted values to the different types of measurement data simultaneously. For example, if urine and faecal data sets are available then, the intake is assessed by fitting predicted values to both data sets simultaneously.

Numerous statistical methods for data fitting are available (IAEA, 2004). The two methods that are most widely applicable are the maximum likelihood method and the Bayesian approach. Other methods, such as the least squares method and the geometric mean of the point estimates can be justified on the basis of the maximum likelihood method for certain assumptions on the error associated with the data. For example, the least square method can be derived from the maximum likelihood method if it is assumed that the uncertainty on the data can be characterised by a

normal distribution. The assumed distribution (e.g. normal or lognormal) can have a dramatic influence on the assessed intake and dose if the model is a poor fit to the data. However, as the fit of the model to the data improves, the influence of the data uncertainties on the assessed intake and dose reduces (Marsh et al. 2007).

The following section gives simple equations for estimating the intake from multiple bioassay data based on the maximum likelihood method assuming the uncertainty on the data can be characterised by a lognormal distribution with a given SF. A detailed description of the derivation of these equations is given in Annex 2.

Maximum likelihood method

The likelihood function is the probability density function of observing the measurement data given the intake and model parameter values. The "best fit" value of the intake, *I* is the intake for which the likelihood function is a maximum. Assuming the probability distribution of measurements can be approximated by a log-normal distribution with a given SF (Section 4.2), the best estimate of intake is given by the following equation.

$$\ln(I) = \frac{\sum_{i=1}^{n} \frac{\ln(I_i)}{[\ln(SF_i)]^2}}{\sum_{i=1}^{n} \frac{1}{[\ln(SF_i)]^2}} \qquad (5.3)$$

Where, the point estimate, I_i is the intake calculated from the i^{th} measurement and is given by:

$$I_i = \frac{M_i}{m(t_i)}$$

So $\ln(I)$ is a weighted average of $\ln(I_i)$, the log of the individual intake estimates calculated from a single bioassay measurement M_i, using as weight the inverse of the square of the log of the scattering factor of the same measurement.

Generally, the scattering factor is dominated by Type B uncertainties (i.e. uncertainties other than counting errors, such as calibration errors or errors related to sampling procedures as for excretion data), thus the SF can be assumed to be constant, i.e. the same for each measurement (within the same type of monitoring data). Therefore, the best estimate of intake is given by the following equation.

$$\ln(I) = \frac{1}{n}\sum_{i=1}^{n}\ln(I_i) = \ln\left[\left(\prod_{i=1}^{n} I_i\right)^{\frac{1}{n}}\right]$$

So in this case, the best estimate of the intake, I is simply the geometric mean of the point estimates, I_i.

$$I = \sqrt[n]{\prod_{i=1}^{n} I_i} \qquad (5.4)$$

In such a case, the best estimate turns out to be independent of the SF value.

Consider cases where data sets from different monitoring techniques are available, and where the scattering factor is different for each data point. For example, if n_u urine and n_f faecal data are available and the scattering factors for the urine and faecal data are $SF_{u,i}$ and $SF_{f,j}$ respectively, then equation (5.3) becomes:

$$\ln(I) = \frac{\sum_{i=1}^{n_u} \frac{\ln(I_i)}{(\ln(SF_{u,i}))^2} + \sum_{j=1}^{n_f} \frac{\ln(I_j)}{(\ln(SF_{f,j}))^2}}{\sum_{i=1}^{n_u} \frac{1}{(\ln(SF_{u,i}))^2} + \sum_{j=1}^{n_f} \frac{1}{(\ln(SF_{f,j}))^2}} \qquad (5.5)$$

where I_i refers to the individual intake estimates from the urine data and I_j refers to the individual intake estimates from the faecal data. Also in this case, if the scattering factor is dominated by Type B uncertainties, the SF value can be considered to be the same for all the measurements of a certain bioassay type, e.g. for urine data, $SF_{u,i} \equiv SF_u$ for all i =1,..,n_u data.

If this holds also for the faecal data (i.e , $SF_{f,i} \equiv SF_f$ for all i =1,..,n_f data), then equation (5.5) becomes:

$$\ln(I) = \frac{\sum_{i=1}^{n_u} \frac{\ln(I_i)}{(\ln(SF_u))^2} + \sum_{j=1}^{n_f} \frac{\ln(I_j)}{(\ln(SF_f))^2}}{\sum_{i=1}^{n_u} \frac{1}{(\ln(SF_u))^2} + \sum_{j=1}^{n_f} \frac{1}{(\ln(SF_f))^2}}$$

Or, in a simpler way ,

$$\ln(I) = \frac{\sum_{i=1}^{n_u} \ln(I_i)}{\frac{(\ln(SF_u))^2}{n_u}} + \frac{\sum_{j=1}^{n_f} \ln(I_j)}{\frac{(\ln(SF_f))^2}{n_f}} \qquad (5.6)$$

5.4 Extended Exposures

One of the factors that influence the interpretation of bioassay results is the temporal variation of the intakes of radioactive material. The pattern of intake, although often poorly characterized, is an important factor in the correct interpretation of measurements and thus for dose assessment. In general, the amount of activity present in the body and the amount excreted daily depend on the length of time the individual has been exposed. Consequently, the correct interpretation of bioassay measurements requires information on the complete exposure history of the worker to the particular radionuclide of interest. The bioassay result obtained, e.g. the amount present in the body, in body organs, or in excreta, will reflect the superposition of all the previous intakes, whether isolated or persistent.

Any previous intakes that influence the actual measurement result need to be taken into account. It is proposed to calculate the net value of the activity of the radionuclide, N_i by subtracting the contributions from previous intakes, P_i from the measurement value (i.e. $N_i = M_i - P_i$). For simplicity,

ignoring the uncertainty in P_i, equation 5.3 can be applied to determine the best estimate of intake but with:

$$I_i = \frac{N_i}{m(t_i)} \qquad (5.7)$$

In applying equation 5.3 to such cases, it is assumed that the net values of the activity are log-normally distributed with a given SF (Section 4.2). It is acknowledged that the actual distribution of the net values is not lognormal because subtracting a value (P_i) from log-normally distributed values (M_i) does not result in another lognormal distribution.

An alternative approach is to fit the previous intakes as well as the intake of interest to all the data simultaneously using the maximum likelihood method. However, this requires appropriate software tools to do this.

Constant chronic exposures

When exposure is known to extend for several days, perhaps as a result of an undetected incident, bioassay results may be interpreted as containing an independent contribution from each day's intake. For example, consider the case where a subject has been exposed at a constant chronic rate of intake over a period of T days (i.e. from 0 to T days) and a measurement is carried out at a time t_i after the start of the chronic period. The calculated value of the measured quantity for unit intake arising from an intake rate of 1/T Bq d^{-1} over a period of T days is approximated by:

$$m_{chr}(t_i) = \frac{1}{T}\sum_{j=1}^{\mathrm{T}} m(t_i - j) \quad if\ \mathrm{T} < t_i$$

or (5.8)

$$m_{chr}(t_i) = \frac{1}{T}\sum_{j=0}^{t_i - 1} m(t_i - j) \quad if\ \mathrm{T} > t_i$$

Again equation 5.3 can be applied to determine the best estimate of the total intake, *I* but with:

$$I_i = \frac{M_i}{m_{chr}(t_i)} \qquad (5.9)$$

Equation 5.8 only gives approximate values for $m_{chr}(t)$ and is not very accurate if m(t) varies a great deal over the period of summation. In such cases appropriate software tools are required to improve the accuracy of the numerical integration over the exposure period.

Chronic and intermittent exposures

In routine monitoring of workers, especially for long-lived radionuclides, it is highly desirable to produce a scheme in which the workers' realistic exposure (e.g., a weekly cycle) is considered. The schedule of work may differ for individual workers and modifications should be introduced as

necessary. The use of an input function that represents the worker's routine intake permits the interpretation of bioassay results according to the day of the week on which samples are taken. In this way the short-term components associated with lung clearance will be better accounted for, since the early clearance component(s) of excretion may introduce a significant difference before and after an interruption in exposure, e.g., the weekend. The interpretation of this data requires, in most cases, appropriate software tools and is beyond the scope of this report.

For long-lived radionuclides, chronic exposures will eventually produce an equilibrium value of activity in the body. Equilibrium values for selected radionuclides have been provided by ICRP Publication 78 (ICRP 1997).

For cases where the exposure is protracted the assumption of a constant chronic intake may be applied by default when the actual schedule of exposure is unknown (intermittent exposures, non constant chronic intake). Assuming a constant chronic as opposed to chronic exposures during only working days makes little differences to the assessed dose for long lived radionuclides.

6. Special aspects of data handling

6.1 Identification of rogue data

A systematic basis to identify outliers and criteria to exclude them are needed. Outliers above and below the trend of the other data have different significance. A point above the trend might indicate another intake and should be investigated; this may mean taking further measurements and/or looking at the workplace conditions. A point below is more likely to result from a transcription or measurement error or from fluctuation of individual metabolism.

The problem of deciding how to identify outliers is not straightforward. Ideally, outliers should be identified before fitting model predictions to the data. If not, then the assessor faces a dilemma when the model does not fit the data: should the model parameters be varied to obtain a fit, or should the data that does not fit be rejected. So ideally, the trend of the data should be obtained first by, for example, fitting a sum of exponentials to the data and then using a statistical test to reject the data (Marsh, et al. 2007). In practice, it is realised that this procedure could be time consuming, and many assessors will rely on judgement when deciding to reject certain data. Specifically, care must be taken in excluding data, particularly if a group of data at early or late times does not appear to be predicted by the model, then model parameters should be varied in preference to excluding data.

For measurement data suspected of being "rogue" a check should be made on whether inclusion or exclusion significantly affects the intake and dose. If it does not, there is no point in expending effort on justifying excluding it: it should be included. If it does have an effect, then a statistical test should be carried out to determine if it is an outlier. If it is an outlier then it should be excluded.

To identify outliers the following statistical test is proposed. A measurement value M(t) is an outlier if it is more than a factor of SF^3 away from the trend of the other data. In other words "the trend value" at time t is calculated on the base of a fit of the other data and compared with the suspected outlier.

If the data set is significantly reduced after excluding outliers, then further measurements may be required for dose assessment.

6.2 Handling data below detection limit

There may be cases where data sets consist of positive values (i.e. values above a decision threshold, DT) and values reported as being below a detection limit (DL). Such data sets are defined as being censored where the number of data values below a DL is known. The definition of the detection limit and the associated decision threshold is given in ISO standards (ISO 2010, ISO 2010b) and Section 3.2. However, it is recommended to keep records of the original counting statistic and associated information for all data including results below the DT. Such information includes background and sample count rates, duration of the background and sample measurements, calibration factors (Bq per count rate) and assessed uncertainty of estimated activity. All original data may be used in the dose assessment taking account of the uncertainty associated with each measurement result. The substitution of the original data by an expression "less than the detection limit" is not recommended.

If some of the data are reported as being below the DL and only the DL value is recorded then the maximum likelihood method can be applied to obtain the best estimate of intake (Annex 2). In

cases, where the uncertainty is dominated by Type B errors, the likelihood function can be described by a lognormal distribution (Section 5.3 and Annex 2). For these cases, it can be shown that for censored data sets the maximum likelihood method leads to an unbiased estimate of the intake if the measurement uncertainty is known (Marsh 2002).

If the application of the maximum likelihood method is not possible because of the lack of available software, then several other simplifying assumptions are possible. Common approaches are to treat each "below DL" value as a positive value equal to the DL value, equal to DL/2 or equal to DT/2. The first approach will clearly lead to an overestimate of the intake, but there is no simple method to quantify the degree of overestimation. The approach to replace the unknown values with DT/2 is recommended here, in the interest of harmonisation with the ISO standard [ISO 27048:2010(E)]. However it is acknowledged that this method has no strong foundation in mathematics.

6.3 Criteria for rejecting a fit

In assessing intakes and doses, the underlying starting assumptions are that:

- the structure of the biokinetic model is a realistic representation of the physical and biological processes, and
- the model parameter values are correct.

Estimates of bioassay quantities will be unbiased only if these conditions are met. These assumptions are analogous to the null hypothesis in classical statistics. In cases where the model predictions are inconsistent with the data (i.e. fits are inadequate), and measurement data have been checked to be accurate and unbiased, this indicates that either the model parameter values, or the structure of the model is incorrect. The classical statistical approach is to reject the model and to repeat the assessment with different model parameter values or with a new model structure so that the predictions are not inconsistent with the data. Before the model structure itself can be rejected, it is necessary to first consider changes to the model parameter values. In these guidelines only changes to the parameter values are considered, not to the model structure.

It is important to remember that it is not possible to prove that the null hypothesis is true. Test statistics are used to indicate that the null hypothesis is false. The criteria for rejecting the null hypothesis, (i.e. stating the fit is inadequate), needs to be defined before the assessment is carried out.

A measure of the "Goodness of fit" (GOF) and the criteria for deciding that the fit is good enough are therefore critical issues. There may be conflict between "harmonisation" and "accuracy". The number of available data could play an important role in rejecting or accepting the fit. Generally the better the data (quality and quantity) the more likely it is that a statistical test will show that the data are inconsistent with the model. If the data are poor it is more likely that the model will fit – in the extreme case of a single measurement any model will fit. It is therefore important that there should be sufficient data available for assessment of a significant dose, and the higher the dose, the better the data should be. Proposals are therefore made for the minimum amounts of data that would be acceptable ("sufficient", see Section 6.5)

A comprehensive discussion of all the possible statistics that can be used to quantify whether a fit is inadequate is beyond the scope of this document. The *chi-squared* test statistic, χ_0^2, is adopted here as part of the criteria for rejecting fit.

If it is assumed that each measurement, M_i, is taken from a lognormal distribution with a scattering factor of SF_i then for n measurements, χ_0^2 is defined as:

$$\chi_o^2 = \sum_{i=1}^{n}\left(\frac{\ln(M_i)-\ln\left[I\, m(t_i)\right]}{\ln(SF_i)}\right)^2 = \sum_{i=1}^{n} R_i^2 \qquad (6.1)$$

The product $I\ m(t_i)$ is the predicted value and R_i are the (normalised) residuals. Under certain assumptions, it can be demonstrated that χ_0^2 is distributed according to a chi-squared distribution.

The above formulae do not apply to data that are reported as below the detection limit (<DL). For left censored data sets (i.e. data with < DL measurements), it is proposed to use the above formula for data above the DL. However, if most of the 'positive' data (i.e. data above the DT) have values which are not very much greater than the DL, then the calculated chi-squared statistic may not be valid.

When fitting predicted values to different types of data simultaneously, the overall χ_0^2 is equal to the sum of the calculated χ_0^2 values for each data set.

If the predictions are inconsistent with the data, then the calculated value of χ_0^2 is inconsistent with the theoretical *chi-squared* (χ^2) distribution for the specific number of degrees of freedom. The actual number of degrees of freedom when varying I parameters for a linear model is $n-I$, and the expected value of χ^2 is equal to the number of degrees of freedom (i.e. $n-I$).

If the intake I is the only parameter to be adjusted, then $I=1$ and the number of degrees of freedom is $n-1$. If some of the other model parameters also need to be modified, then I is greater than one. However, the biokinetic models used in internal dosimetry are not linear with respect to most of their parameters, other than the intake, and therefore the chi-squared statistic with n-I degrees of freedom might not be valid anymore especial for small datasets.

For cases where there is comprehensive data so that $n>>I$, it is proposed to assume $n-1$ degrees of freedom for each step of the procedure given in the flow charts (Sections 8-10). If the fit is rejected assuming $n-1$ degrees of freedom, then the fit would also be rejected if the actual number of degrees of freedom is less.

The probability of observing a larger χ^2 value than χ_0^2 for (n-1) degrees of freedom is given by the p-value, which can be obtained from Statistical Tables. Annex 4 indicates the way to perform a hand evaluation of the p-value. The p-value is the fraction of the theoretical χ^2 distribution that lies above the calculated χ_0^2 value. So if the p-value is very small, the calculated χ_0^2 value is very much larger than expected and therefore it can be concluded that the predictions are likely to be inconsistent with the data and the assumed uncertainties.

It is proposed that the fits to the data are judged to be inadequate (fit rejected) if:

- the probability that χ^2 is greater than χ_0^2 is 5% or less (i.e. if p-value < 0.05). in other words the fit is inadequate at the 5% level of significance, or if
- the fit displayed graphically looks unreasonable by eye.

The χ^2 test uses the assumed uncertainties SF_i. If the assumed uncertainties are overestimated then χ_0^2 is too small and a bad fit is accepted. The converse is also true; if the assumed uncertainties are underestimated then χ_0^2 is too large and a good fit is rejected. This is one of the reasons why it is important to assess realistic uncertainties.

It is also acknowledged that whether or not the fit displayed graphically looks unreasonable by eye is a subjective judgement. Generally, however, a fit would be considered unreasonable if all, or a long series, of data were systematically underestimated or overestimated.

This can be quantified objectively by examining the serial correlation in the residuals (Draper, 1981). The auto-correlation coefficient statistic (Puncher, et al. 2007, Chatfield 2004) or the Durbin-Watson statistic (Durbin and Watson, 1970) are possible statistics and, compared to the χ^2 test statistic, have the advantage of being relatively insensitive to the magnitude of the assumed measurement uncertainties. Annex 3 discusses the auto-correlation coefficient statistic and describes how it can be applied to test whether or not a fit is inadequate.

6.4 Influence of decorporation therapy

Chelating agents such as DTPA, and some other types of complexing agent, can be effective in increasing the rate of elimination of radionuclides from the body. Generally, it should be assumed that urinary and faecal excretion data for actinides and lanthanides are affected by DTPA treatment. If this is the case then systemic organ retention will also be affected. Excretion rates may well be influenced for weeks or months after cessation of treatment.

The analysis of DTPA treatments at CEA and AREVA from 1970 to 2003 (Grappin 2006, Grappin 2007) led to the conclusion that, following a first DTPA treatment, the full efficacy of a next DTPA injection on urinary excretion of plutonium was usually restored after 20 days, indicating that the remaining action of DTPA on urinary excretion lasts for about 20 days. Thus excretion data obtained in the first 20 days after treatment has ceased should be disregarded for the purpose of dose assessment.

An alternative approach is to use a model for the urinary excretion of the chelated actinide that has been modified to compensate for the enhanced excretion (Hall et al. 1978, La Bone, 1994; Bailey et al. 2002). This is preferable, when an early assessment is required, because it makes more use of the available information. It is difficult however to give any specific advice or formulation as the treatment of any excretion data will depend upon the circumstances of the exposure and the need and timescale required for the dose assessment.

6.5 Number and type of data required for assessment of dose

The reliability of the dose assessment depends on the number and type of the monitoring data. Thus, there are minimum requirements for the type and number of monitoring data, depending on the involved radionuclide and the evaluated dose range. The greater the evaluated dose the greater the number of data is required.

The previous version of the IDEAS Guidelines suggested the minimum number and type of monitoring data required for dose assessment for some selected radionuclides. During the CONRAD project the evaluation was extended to different categories of radionuclides, and the results are summarized in Table 6.1. It should always be borne in mind that the table is presented to illustrate the point that more measurements should be taken the greater the dose estimate.

Table 6.1 Minimum number and type of data required for assessment of dose for some categories of radionuclides.

Category of radionuclide	Type of monitoring	Number of required monitoring data		
		D < 1 mSv (minimum requirement)	1 mSv < D < 6 mSv[a]	D > 6 mSv[b]
All type of α-emitters with significant γ-component (^{235}U, ^{241}Am etc.)	Urine	-	2	3
	Faeces	1	2	3
	Whole body, critical organ or wound site, respectively.	-	2	4
All type of α-emitters without significant γ-component (^{210}Po, ^{239}Pu, etc.)	Urine	-	3	5
	Faeces	1	3	5
All type of β-emitters with significant γ-component (^{60}Co, ^{131}I, ^{137}Cs, etc.)	Whole body, critical organ or wound site, respectively.	1	2	4
	Urine	-	2	4
F-type β-emitters without significant γ-component (^{3}H, ^{14}C, etc.)	Urine	1	4	8
M/S-type β-emitters without significant γ-component (^{90}Sr, etc.)	Urine	1	2	4
	Faeces	-	2	4
Pure γ-emitters (^{123}I, etc.)	Whole body or critical organ	1	2	4
	Urine	-	2	4

a) The monitoring data should cover a time range of 30 d; if the effective half-life is less than 30 d, the monitoring data should cover a time range corresponding to the effective half-life.

b) The monitoring data should cover a time range of 60 d; if the effective half-life is less than 30 d, the monitoring data should cover a time range corresponding to twice the effective half-life.

Based upon the information given in Table 6.1, the minimum number and type of monitoring data required for dose assessment for some selected radionuclides are given in Table 6.2.

Ideally the measurements should be distributed appropriately over the relevant time range given in Table 6.1. It is important to remark that the period of time indicated in this table and in the Table 6.2 does not correspond to the period of routine monitoring (e.g. that proposed by the publication ISO 20553).

Table 6.2 Minimum number and type of data required for assessment of dose for some selected radionuclides and the respective monitoring procedures.

Radionuclide	Type of monitoring	Required monitoring data					
		D < 1 mSv		1 mSv < D < 6 mSv		D > 6 mSv	
		Number	Time range (days)	Number	Time range (days)	Number	Time range (days)
H-3	Urine	1	-	4	10	8	20
Co-60	Whole body	1	-	2	30	4	60
	Urine	-	-	2	30	4	60
Sr-90	Urine	1	-	2	10	4	20
	Faeces	-	-	2	10	4	20
I-131	Thyroid	1	-	2	7	4	14
	Urine	-	-	2	7	4	14
Cs-137	Whole body	1	-	2	30	4	60
	Urine	-	-	2	30	4	60
U-235	Urine	-	-	2	30	3	60
	Faeces	1	-	2	30	3	60
	Lungs	-	-	2	30	4	60
Pu-239	Urine	-	-	3	30	5	60
	Faeces	1	-	3	30	5	60
Am-241	Urine	-	-	2	30	3	60
	Faeces	1	-	2	30	3	60
	Lungs	-	-	2	30	4	60
	Skeleton [a]	-	-	1	-	2	60

[a] These measurements are desirable if facilities are available.

6.6 Evaluation of in-growth of ^{241}Am from ^{241}Pu

Plutonium-241, with a radioactive half-life of 14.33 y (5.23 10^3 d), decays into ^{241}Am (Figure 6.1). Americium-241 has a radioactive half-life of 432.6 y (1.58 10^5 d) .

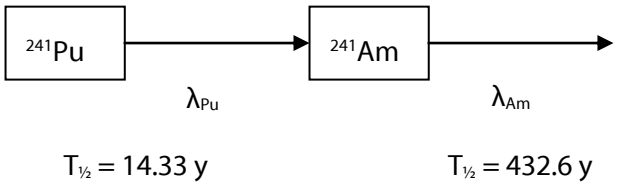


Figure 6.1 Decay of ^{241}Pu to ^{241}Am

To interpret ^{241}Am bioassay data following exposure to a mixture of plutonium and americium nuclides, the in-growth of ^{241}Am from ^{241}Pu should be considered. However, the in-growth of ^{241}Am at early times following intake is negligible but more significant at late times.

Considering radioactive decay, the activity of ^{241}Am due to in-growth from ^{241}Pu is given by:

$$A_I = \frac{A_{Pu}^0 \cdot \lambda_{Am}}{\lambda_{Am} - \lambda_{Pu}} \left(e^{-\lambda_{Pu} t} - e^{-\lambda_{Am} t} \right) \qquad (6.2)$$

Where,

λ_{Pu} is the radioactive decay constant for ^{241}Pu

λ_{Am} is the radioactive decay constant for ^{241}Am, and

A_{Pu}^0 is the initial activiy of ^{241}Pu.

To illustrate how equation (6.2) can be used to take account of in-growth of ^{241}Am from ^{241}Pu, consider the case where a worker is exposed to an acute intake of a mixture of ^{241}Am and plutonium isotopes. The initial activity ratio of ^{241}Pu:^{241}Am at the time of intake is $r_{Pu:Am}$.

If the predicted bioassay quantity per unit intake of ^{241}Am, is $m_{Am}(t)$ neglecting in-growth, then the total activity of ^{241}Am (including in-growth) for unit intake is:

$$m_{Am}^{tot}(t) = m_{Am}(t) + e^{\lambda_{Am} t} \cdot m_{Am}(t) \cdot A_I \qquad (6.3)$$

Where A_I is given by equation (6.2) but with $A_{Pu}^0 = r_{Pu:Am}$.

The value of $e^{\lambda_{Am} t} \cdot m_{Am}(t)$ gives the calculated bioassay quantity of stable americium per unit intake.

The above equation (6.3) assumes that the biokinetics of ^{241}Pu is the same as ^{241}Am when taking account of in-growth. This assumption is made for simplification. Substituting equation 6.2 into equation 6.3 gives:

$$m_{Am}^{tot}(t) = m_{Am}(t)\left[1 + \frac{r_{Pu:Am} \cdot \lambda_{Am}}{\lambda_{Am} - \lambda_{Pu}}\left(e^{(\lambda_{Am}-\lambda_{Pu})t} - 1\right)\right] \qquad (6.4)$$

The expression in squared parenthesis, can be consider as the multiplying factor in which the predicted bioassay quantity of ^{241}Am increases due to in-growth from ^{241}Pu following acute intake at $t = 0$. This '*in-growth factor*' is plotted as a function of time for the case where the initial activity ratio of ^{241}Pu:^{241}Am , ($r_{Pu:Am}$) is 111 (Figure 6.1). This ratio is typical of spent commercial fuel at 5 years after chemical separation (Table 14.10 of Annex 1). As can be seen from Figure 6.1 the *in-growth factor* is less than 1.1 at times before 200 d but greater than 1.3 for times later than 650 days (1.8 years). The value of the *in-growth factor* depends on the value of $r_{Pu:Am}$ as well as the time, t after intake.

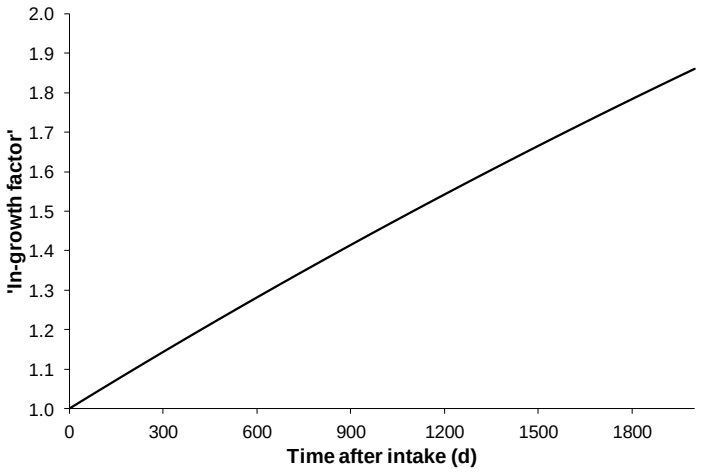


Figure 6.1. The multiplying factor in which the predicted bioassay quantity of ^{241}Am increases due to in-growth from ^{241}Pu following an acute exposure to a mixture of ^{241}Am and plutonium isotopes. In this example, an initial activity ratio of ^{241}Pu: ^{241}Am = 111 was assumed.

The intake of the initial amount of ^{241}Am can be then assessed from the measured ^{241}Am bioassay data by fitting the predicted bioassay quantities, $m_{Am}^{tot}(t)$ to the data, as described in Section 5. The intake of the Pu isotopes can be calculated from the initial activity ratios of the Pu and Am mixture and the intake of ^{241}Am.

7. Structured approach

7.1 Introduction

In the following Sections a structured approach to the assessment (evaluation) of internal doses from monitoring data is described. It consists of a series of "Stages", broadly corresponding to the Levels of task given above. Each Stage consists of a series of "Steps", and is presented diagrammatically in a flow chart, with a brief explanation of each step in the text. Detailed descriptions of some aspects of the evaluation process are given in Chapters 4 and 5. Consideration is also given to the quantity and quality of monitoring data needed for the assessment of doses greater than 1 or 6 mSv.

7.2 All exposures (stage 1)

In the first stage a check is made whether the measurement corresponds to Level 0, where it is expected that the annual dose (committed effective dose from intakes of radionuclides that occur in the accounting year) is likely to be below 0.1 mSv, even if there were similar intakes in each and every monitoring interval during the year, or to higher levels. At Level 0 there is no need to evaluate the intake or dose from the measured values explicitly. The effective dose can be reported as zero, by analogy with the rounding of doses in external dosimetry. However, the measured value should be recorded, because it may provide information useful for further assessments in the future.

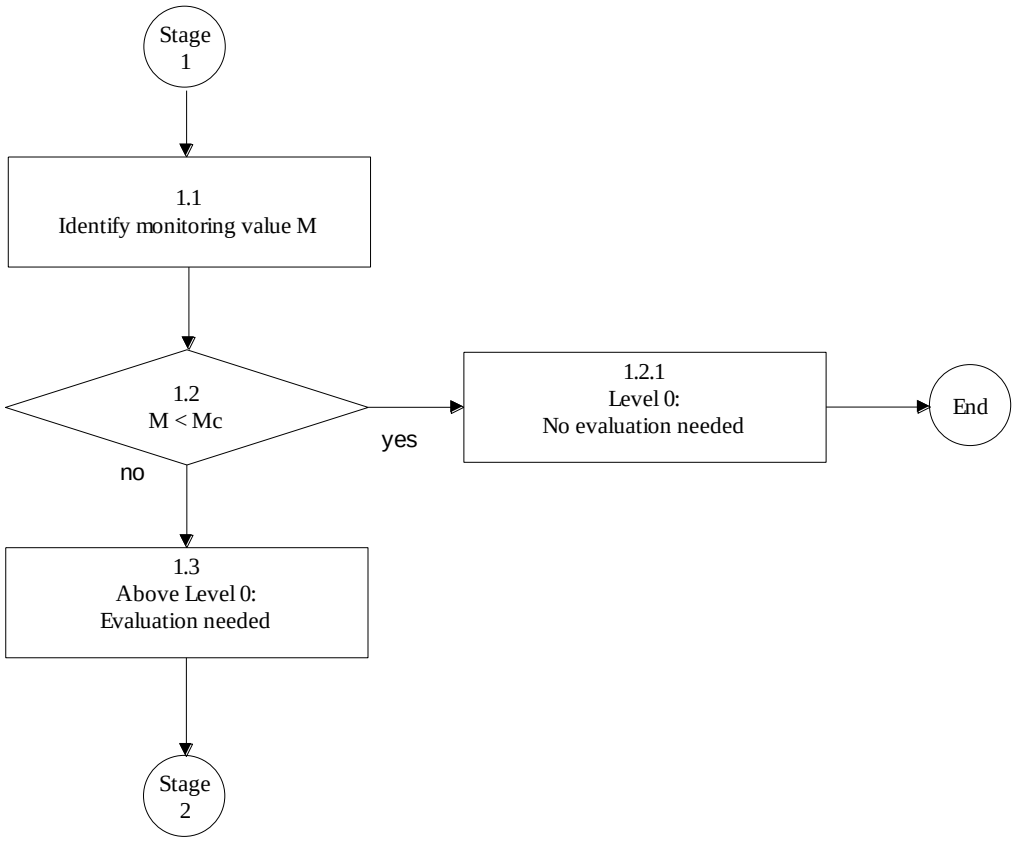


Figure 7.1: Stage 1. Check of need for evaluation.

Step 1.1: Identify monitoring value (*M*) and duration of monitoring interval (*T*). Some treatment of the data may be required before an evaluation can be made. In particular consideration should be given to the presence of other radionuclides, as well as that measured (the indicator nuclide), which may add significantly to the dose, or even exceed that from the radionuclide measured. In case of mixtures the radioisotope which is supposed to provide the greatest contribution to dose should be monitored.

Step 1.2: Compare measurement with critical monitoring quantity M_c. If $M < M_c$ then the annual dose is probably less than 0.1 mSv, even if there were similar intakes in each and every monitoring interval during the year. The evaluation stops and the measured value *M* is recorded together with all relevant information (radionuclide, activity, type of measurement, type of monitoring etc). Note that measurements of actinides are typically above M_c and so there is no need to compare those measurements explicitly with the corresponding critical monitoring quantity.

Step 1.3: Exposure above Level 0. Since $M > M_c$ the annual dose could be more than 0.1 mSv. Go to Stage 2 to check on the statistical significance of the measurement.

7.3 All exposures above Level 0: Check on significance of new measurement and consistency with previous evaluation (stage 2)

Stage 2 refers to cases where it is expected that the annual dose from the intake is likely to be above 0.1 mSv. At this level the intake or dose from the measured values should be calculated explicitly. Before starting the assessment of intake and dose, however, it is recommended to plot the data and to do some simple hand calculations in order to understand the case (Step 2.0). In addition, the statistical significance of the measured value M should be estimated. This includes the assessment of uncertainty on M (Step 2.1) as well as the calculation of the contributions from previous intakes to M (Step 2.2) in order to decide whether M is:

- due to a new intake, or
- due to a previous intake, or
- if it is in contradiction to previous assessments (Steps 2.3 – 2.7).

Step 2.0: Understanding the case. Plot the data (including those from previous measurements if available) and do some simple hand calculations. Evaluate the order of magnitude of the intake and the committed effective dose.

Step 2.1: Assessment of the uncertainty on M. Realistic estimates of the overall uncertainty on each data point are required. Here they are expressed as a total "scattering factor" (SF) (see how to assess uncertainty on data considering measurement uncertainty and all other uncertainty evaluated with SF_B – see paragraph 4.2).

Step 2.2: Calculation of the contributions P from previous intakes. The contributions (P) from all previous intakes of the radionuclide considered are calculated, taking into account all pathways of intake, and all intakes of mixtures where the radionuclide was involved.

$$P = \sum_{i}^{all\ previous} I_i \cdot m(t - t_i)$$

where I_i are the values of intakes evaluated at previous times t_i , and t is the time of measurement M.

Step 2.3: New intake confirmed. If $M / SF^2 > P$ then assume a new intake has occurred. Calculate the net value ($N = M – P$) of the radionuclide by subtracting P from the measured value M and go to Stage 3, in order to perform the standard evaluation at Level 1. Using this criterion there is only a 2.5% probability of a false positive (i.e. assuming a new intake when actually an intake has not occurred).

Step 2.4: New intake not confirmed. If $M/SF^2 < P < M*SF^2$ then the measured value M is consistent with the intakes assessed previously, and there is no evidence of a new intake. The evaluation stops and the measured value M is recorded together with all relevant information (radionuclide, activity, type of measurement, type of monitoring etc).

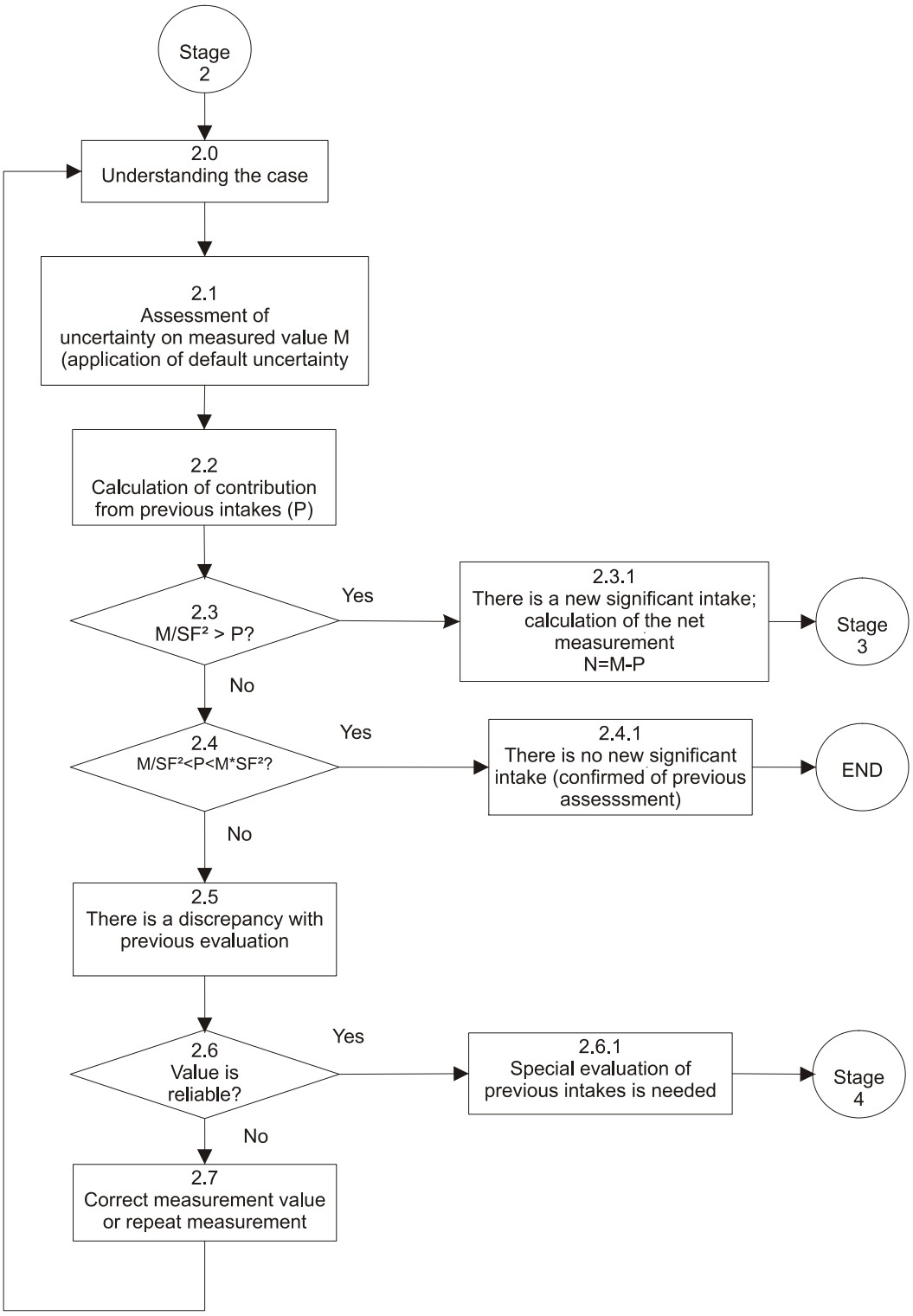


Figure 7.2: Stage 2. Check on significance of new measurement and consistency with previous evaluations.

Step 2.5: Discrepancy with the previous evaluations. If $P > M*SF^2$ then there is a discrepancy with the previous assessments. The reason for the discrepancy could be (i) the measured value M is not reliable and/or (ii) the previous assessments are wrong. For example, an intake occurring near the end of the previous monitoring interval is likely to have been overestimated based on an assumed intake at the mid-point.

Step 2.6: Check on the reliability of M. For whole body counting possibilities for errors include: external contamination, mismatching of calibration and actual activity distribution (i.e. lung activity calculated with whole body efficiency, or lung activity calculated in the presence of residual GI tract activity etc.). For excretion measurements possibilities include contamination of the sample, incomplete collection of the sample, errors in sample processing, etc..

Step 2.6.1: Reassess previous intakes. If it cannot be demonstrated that M is unreliable, then reassess the previous intake(s), i.e. go to the appropriate "Special procedure" at Stage 4.

Step 2.7: Check the measurement M. If it can be demonstrated that M is wrong, make corrections or repeat the measurement if possible and return to Step 2.0.

Figure 7.3 shows as an example a hypothetical value M measured at t = 90 d (purple dot) together with the values of M/SF^2 and $M*SF^2$ (yellow diamond and blue triangle respectively). Also the hypothetical curves of P corresponding to different possible previous measurements made at time t=0 are shown. In the case of the green curve, it lies below the value of M/SF^2, i.e the measurement M can be attributed to a new intake and the standard evaluation procedure can be started. The red curve is included between M/SF^2 and $M*SF^2$, i.e. the measured value M is consistent with the previous measurement at t=0, so that there has been no new intake and no new dose evaluation is required. The blue curve lies above $M*SF^2$, i.e. the measurement M is lower than one should have expected on the basis of the measurement at t=0. There is a discrepancy between M and the previous measurement and a reassessment of M and/or of the previous intake is required.

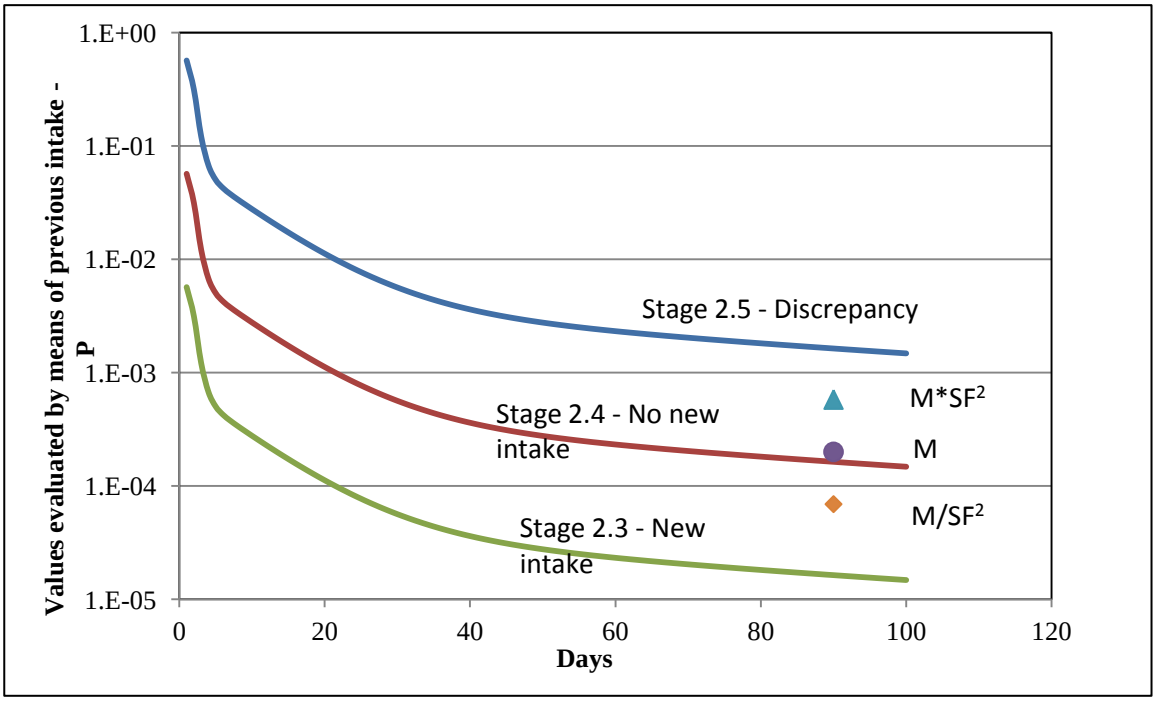


Figure 7.3: Comparison of P value (at 90 d) with M, M/SF^2 and $M*SF^2$ for evaluation of test related to presence of new intake, no new intake and discrepancy with previous data.

7.4 Standard evaluation procedure at Level 1 (stage 3)

Having determined the measured value (M) to be due to a new intake, the intake and dose are evaluated from the net value (N=M-P) using a priori parameters. This standard evaluation procedure should be applied only for routine monitoring.

Step 3.1 : If the measured value is not due to routine monitoring, check for the number of measurements available : go to step 3.1.1.

Step 3.1.1 : If there are available more than one measurements go to special evaluation procedures (Stage 4).If there is only one measurement go to step 3.2.

Step 3.2 : The pathway of intake is identified. In routine monitoring situations the pathway will most likely be inhalation, but it could also be ingestion or a combination of inhalation and ingestion.

However, ingestion should be assumed only in those cases where there is clear evidence for this pathway (well established and documented). Otherwise the inhalation pathway should be assumed.

The situation of a single routine measurement after a wound accident is rare, so if this pathway of intake is confirmed, go directly to step 3.6 to check the availability of other data and follow, after stage 4, the selection of the wound pathway.

Step 3.3 : Assign values for following parameters:

- Mode of intake
- Time of intake
- Particle size, absorption type and f_A value (for inhalation)
- f_A value (for ingestion)

Case or site specific parameter values should be assigned as far as they are available. Such a priori information needs to be well established and documented. Examples might include the Activity Median Aerodynamic Diameter (AMAD) – if it has been determined by appropriate air sampling (e.g. cascade impactor) – or the time of intake, if potential exposure was limited, or an incident was known to occur. Otherwise the following default parameter values should be used:

- Mode of intake: Single intake
- Time of intake: Mid-point of the monitoring interval, i.e. the mid-point of the time range between the date of the measurement being considered and the date of either the previous measurement or the beginning of monitoring
- Inhalation:
- Absorption Type and f_A value: default values as reported in the forthcoming ICRP OIR publication. In the meanwhile according to ICRP Publication 68, Annex F (ICRP 1994b). If the compound is unknown, then for those elements where there is a choice of absorption types, the type for "unspecified compounds" should be used, if available. For uranium, in the absence of specific information, Type M is assumed, as reported in ICRP Publication 71 (ICRP 1995c).
- Particle size: 5 µm AMAD.

- Ingestion:
- f_A value: default values as reported in the forthcoming ICRP OIR publication. In the meanwhile according to ICRP Publication 68, Annex E (ICRP 1994b).

Step 3.4 : Using the assigned a priori parameter values, the intake is estimated by dividing the net value (N) by the appropriate retention or excretion function. The committed effective dose is calculated by multiplying the evaluated intake by the appropriate dose coefficient (dose per unit intake). Care must be taken to ensure that the same assigned a priori parameter values were used for calculating the excretion functions and the dose coefficients. Alternatively the dose per unit content approach can be applied to calculate the dose directly. When doing so, only the dose can be recorded.

Step 3.5 : If the effective dose estimated in step 3.4 is less than 1 mSv, there is no need for further investigation (Step 3.5.1). Otherwise special procedures (Stage 4) are needed for more detailed evaluation of the case.

Step 3.5.1 : The results in terms of intake and committed effective dose from Step 3.5 are recorded together with the corresponding parameter values used in Step 3.4.

Step 3.6 : If dose is greater than 1 mSv, then check for the number of available data. If the number of available data is less than that reported in Table 6.1 for the column corresponding to the assessed dose: get the required number of measurements (go to step 3.6.1); if the number of available data is sufficient go to Stage 4.

Step 3.6.1 : After having got the required number of data, go to Stage 4.

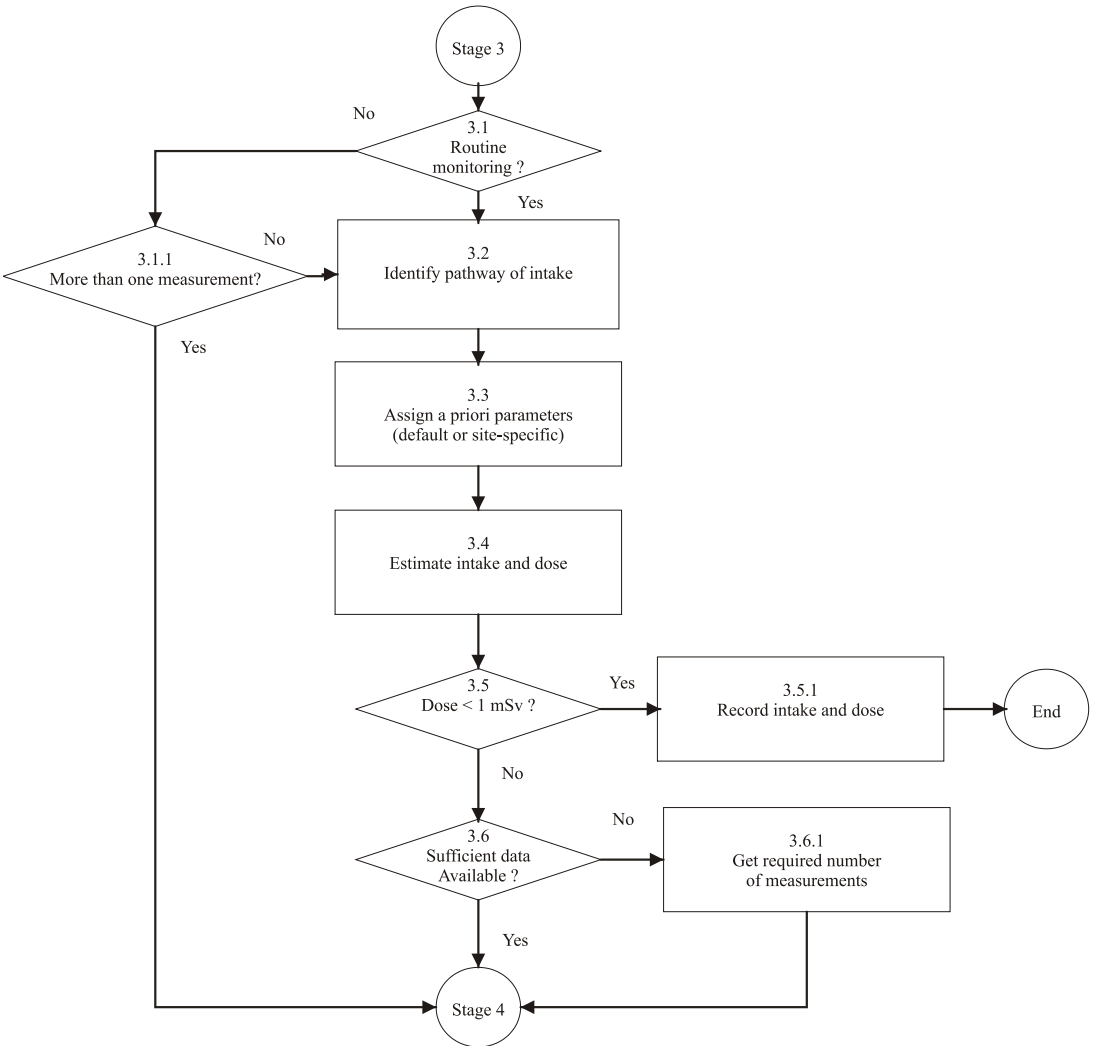


Figure 7.4: Stage 3. Standard evaluation procedure at Level 1.

7.5 Identification of pathway of intake for special evaluation above Level 1 (stage 4)

Special procedures are needed for the evaluation when there is evidence for an internal committed effective dose of more than 1 mSv or in all cases of special monitoring. In all these cases the evaluation procedures depend to some extent on the pathway of intake. Thus, in Stage 4 the pathway of intake has to be identified.

Step 4.1 : In many cases there is evidence for pure inhalation, as for example if room air contamination has been detected without detectable external contamination of the person under investigation. In those cases the special procedure for inhalation cases should be applied (Stage 5).

Step 4.2 : In a few cases there might be evidence for pure ingestion, as for example if contamination of the person or the working place has been detected, but not any contamination of the room air. In those cases the special procedure for ingestion cases should be applied (Stage 6).

Step 4.3: In cases where both contamination of the person or the working place and contamination of the room air is detected the pathway could be a combination of inhalation and ingestion. Such cases may be analysed as a mixture of inhalation and ingestion (Stage 7). However, a similar

pattern of contamination can arise from exposure to a large aerosol (AMAD more than about 10 μm). Unless the aerosol in the workplace has been well characterised it will be difficult to know which is more likely, or what fraction of the intake is due to ingestion. It is proposed here to assume pure inhalation as default unless there is information to justify that a part of the intake is ingestion.

Step 4.4 : In any case of a contaminated wound a special procedure have been developed to calculate the dose due to the intake via the wound. This pathway is considered by the guidelines at the Stage 8 (Step 4.4.1).

Step 4.5 : The revised guidelines do not consider the patterns of intake different from those indicated above (i.e. for injection or skin absorption). In case of injection, due to incident with syringe needle, the evaluation could follow the default assumption of the wound model with soluble weak category assumption, as this approach will be the most similar to the actual intake pattern.

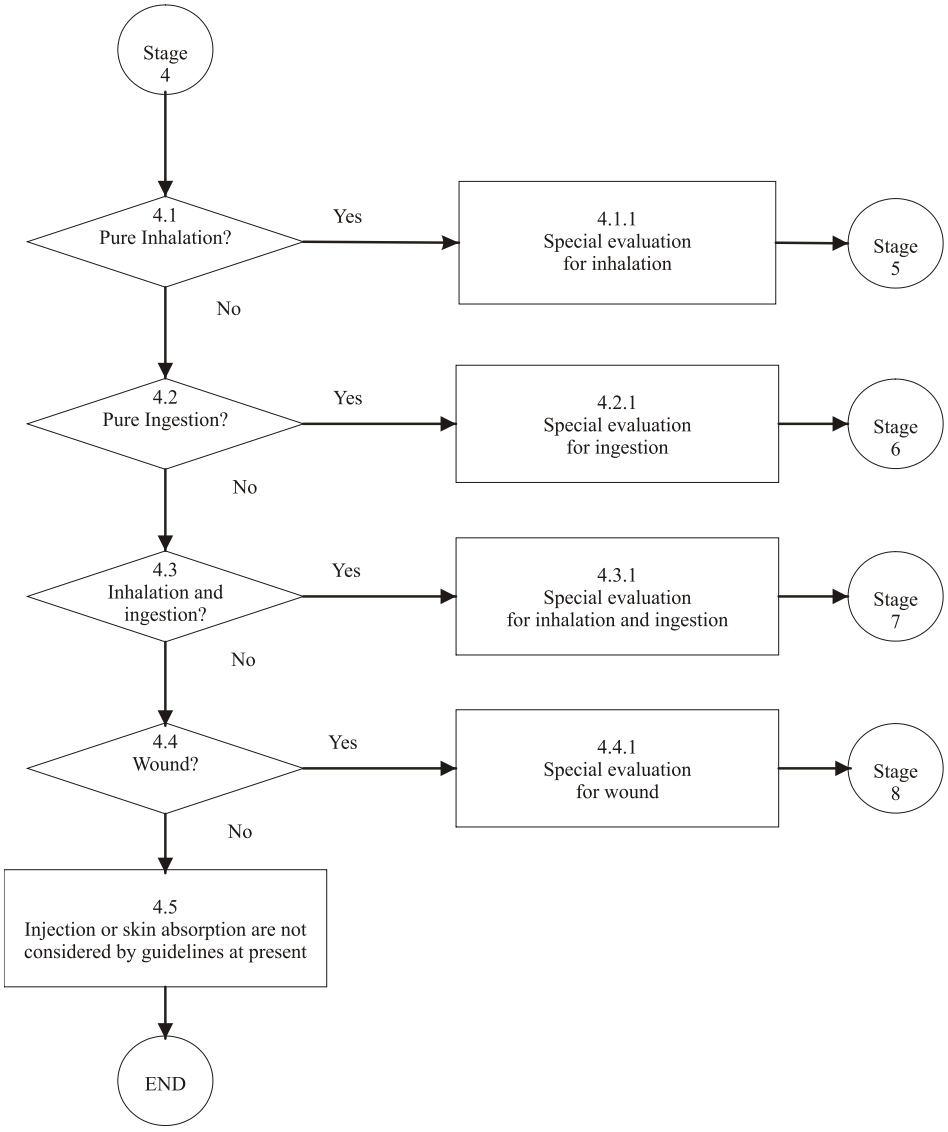


Figure 7.5 : Identification of pathway of intake for special evaluation above Level 1.

8.Inhalation (Stage 5)

8.1 Overview

The special procedure is grouped in three subsequent stages (seeFigure 8.1).

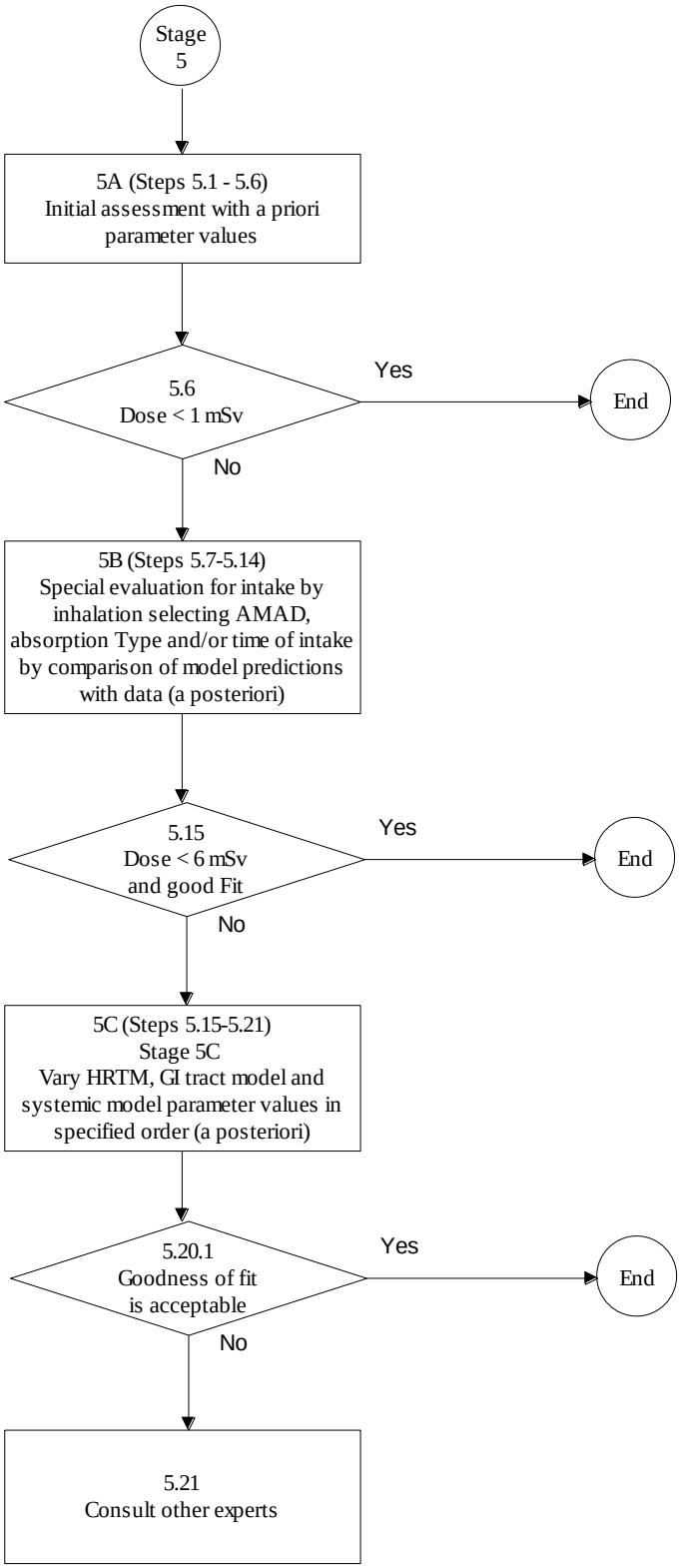


Figure 8.1: Stage 5. Special procedure for inhalation cases above Level 1 – Overview.

In the first stage (5A), a simple evaluation is carried out using parameter values chosen *a priori*: before the evaluation is carried out. The procedure is very similar to the "Standard procedure" (Stage 3). The main difference is that in a special procedure there should be more than one measurement.

In the second stage (5B), procedures are applied for varying the two main factors related to the inhaled material: the AMAD and absorption Type, and also the time of intake, if not known, using the measurement data (*a posteriori*).

In the third stage (5C), an advanced evaluation is carried out. It applies to cases where there are comprehensive data available. The fundamental approach of this stage is that the model parameter values are adjusted systematically, in a specific order, until the goodness of fit is acceptable (i.e. the fits obtained to all the data are not rejected by the specified criteria).

8.2 Simple evaluation (stage 5A)

Step 5.1: Identification and preparation of measurement data. It is expected that there will be more than one measurement available for a special assessment (M_i for i = 1 to n). It is therefore important that realistic uncertainties are assigned to the data ("scattering factor", SF, Step 2.1) There may be more than one type of measurement (urine, faeces, etc), and there may be measurements of more than one radionuclide involved in the exposure. If a specific incident (and hence time of intake) was not identified, the results of workplace monitoring, such as personal or room air sampling, should be checked to give guidance on the time course of intake.

Explore the possibility that certain measures are "rogue" by means of the procedure indicated in paragraph 6.1.

Step 5.2: (As Step 2.3 for a single measurement.) The contributions (P_i) from all previous intakes of the radionuclide considered are calculated, taking into account all pathways of intake, and all intakes of mixtures where the radionuclide was involved. The net values ($N_i = M_i - P_i$) of the radionuclide are calculated by subtracting P_i from the measured value M_i.

Step 5.3: (As Step 3.2 in the Standard Procedure, Stage 3, except for time of intake). Case or site specific parameter values should be assigned as far as they are available. Such *a priori* information needs to be well established and documented. Examples might include the Activity Median Aerodynamic Diameter, AMAD, (if it has been determined by appropriate air sampling, e.g., cascade impactor), specific absorption parameter values (if the inhaled material is sufficiently well characterised), or the time of intake (if potential exposure was limited, or an incident was known to occur). Otherwise the following default parameter values should be used:

- Mode of intake: Single intake
- Absorption Type and f_A value: default values as reported in the forthcoming ICRP OIR publication. In the meanwhile according to ICRP Publication 68, Annex F (ICRP 1994b) . If the compound is unknown, then for those elements where there is a choice of absorption types, the type for "unspecified compounds" should be used, if available. For uranium, in the absence of specific information, Type M is assumed, as reported in ICRP Publication 71 (ICRP 1995c).
- Particle size: 5 µm AMAD

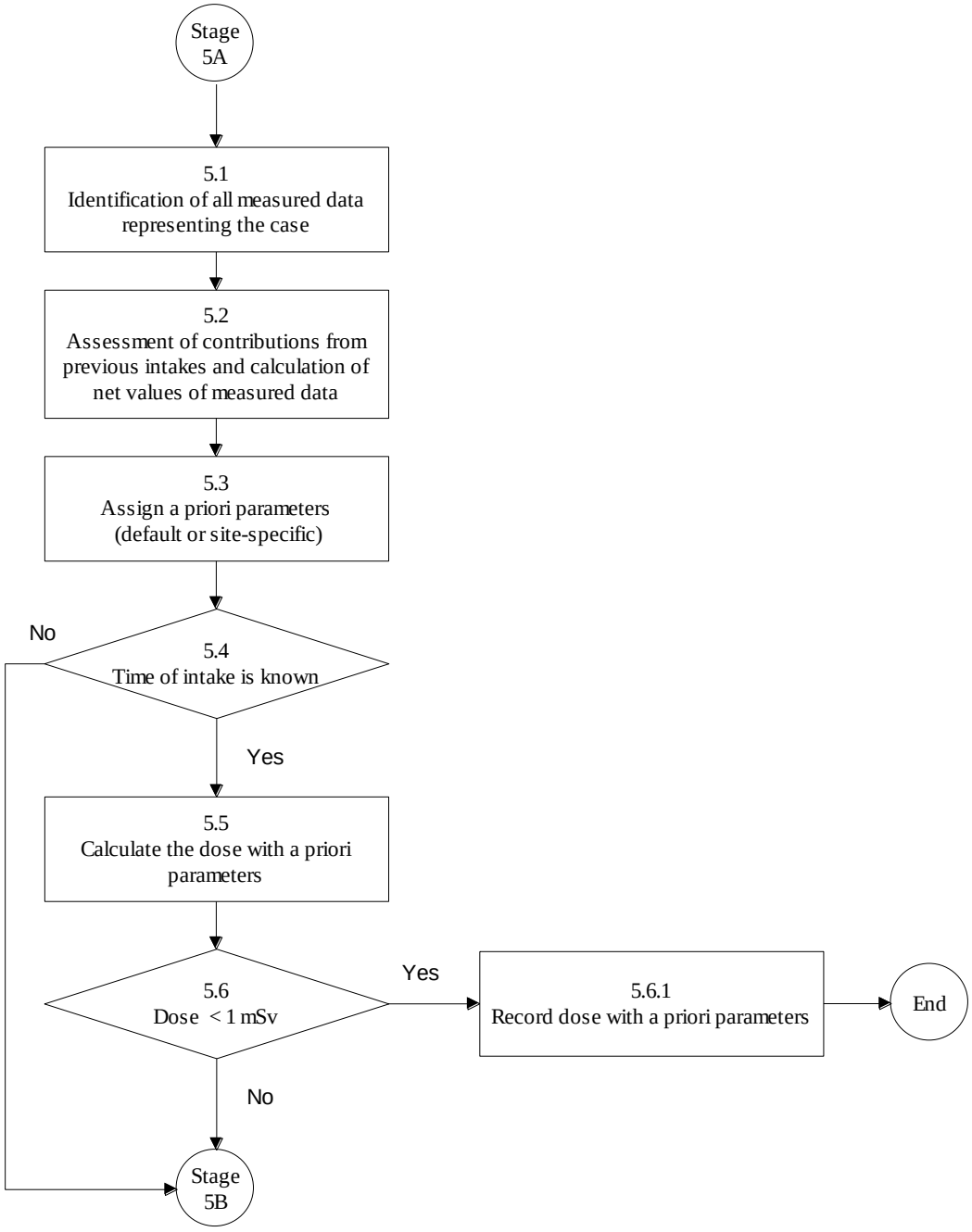


Figure 8.2: Stage 5A. Special procedure for inhalation cases above Level 1 – Part 1: simple evaluation using parameter values chosen *a priori.*

Step 5.4: Time of intake known/unknown. If the special procedure was initiated as a result of a known incident (and hence the time of intake is known) then a simple assessment (Step 5.5) should be carried out which is consistent with the Standard evaluation (Stage 3). If the special procedure was initiated as a result of a routine measurement being inconsistent with previous assessment (Step 2.6) or a dose >1 mSv resulting from the Standard evaluation (Step 3.4) where the time of intake is probably not known, then further special procedures (Stage 5B) are needed for more detailed evaluation of the case.

Step 5.5: (As step 3.3 in the Standard Procedure, Stage 3, but for more than one measurement). Using the assigned *a priori* parameter values, an estimate of intake I_i is obtained by dividing the net measured value $N_i = M_i - P_i$ by the appropriate retention or excretion function $m(t_i)$. The best estimate of intake can be calculated according to Chapter 5 with the equation:

$$\ln(I) = \frac{\sum_{i=1}^{n} \frac{\ln(N_i / m(t_i))}{[\ln(SF_i)]^2}}{\sum_{i=1}^{n} \frac{1}{[\ln(SF_i)]^2}} \qquad (8.1)$$

where SF_i is the scattering factor related to the net measured value N_i. If the scattering factor is the same for all measurements, the equation results in

$$I = \sqrt[n]{\prod_{i=1}^{n} \frac{N_i}{m(t_i)}}$$

i.e. the best estimate of the intake is the geometric mean of the intakes

$$I_i = \frac{N_i}{m(t_i)} \qquad (8.2)$$

calculated from the single measurements. Using the same assigned *a priori* parameter values the committed effective dose is calculated by multiplying the "best estimate" of intake by the appropriate dose coefficient (dose per unit intake).

In case of multiple data sets the calculation is performed according to the equation (5.5) or (5.6) where each intake estimate I_i or I_j is evaluated by means of eq. (8.2) i.e using N_i values instead of M_i values (see paragraph 5.3).

Step 5.6: If the effective dose estimated in step 5.5 (taking into account all available monitoring data) is less than 1 mSv, there is no need for further investigation (Step 5.6.1). In this particular case, the dose from the intake under consideration, rather than the "annual dose" as in Step 3.4, is the criterion, because intakes requiring special assessment procedures should be unusual for any individual worker. Otherwise further special procedures (Stage 5B) are needed for more detailed evaluation of the case.

Step 5.6.1: The results in terms of intake and committed effective dose from Step 5.6 are recorded together with the corresponding parameter values from Step 5.3.

8.3 Exposure related parameters (stage 5B)

In this stage, procedures are described for varying the three main factors related to the inhaled material: the AMAD and absorption Type, and also the time of intake, if not known, using the measurement data (*a posteriori*). Note, however, that if material specific absorption parameter values were assigned *a priori* (Step 5.3), default absorption Types should not be used (Steps 5.11, 5.12, 5.13 and 5.14): if an acceptable fit is not obtained with the assigned parameter values, they can be varied *a posteriori*, in Stage 5C.

In this Stage, and in Stage 5C that follows, parameter values are selected on the basis of the "fit" of the model predictions to the observations (data). Criteria for rejecting the fit have been already indicated in paragraph 6.3; this helps to decide whether to stop the evaluation, or to go on to further steps.

Step 5.7: Are there sufficient data ? As noted in the introduction, criteria for the "sufficient" number (and types) of relevant data, duration of monitoring etc., are proposed according to the dose. In this Step, the numbers for the range 1 mSv <Dose<6 mSv are appropriate, because a special

procedure is generally initiated on the assumption that the dose could exceed 1 mSv, and doses greater than 6 mSv are considered in Steps 5.11.2 and 5.12.2 below.

Step 5.7.1: Get additional dose relevant data. This assumes that the evaluation is being carried out in real time, so that the opportunity exists to obtain more measurements if those available are insufficient. (For historical cases, where it is not possible to obtain more measurements, it should be recorded that the data are insufficient, and therefore the result should be treated with caution.) When the additional data have been obtained, a simple re-evaluation going back to Stage 5A is made.

Step 5.8: Is the time of intake known? As noted in the introduction, there are two main alternative routes through this stage of the process, according to whether or not the time of intake is known. Generally, Special Procedures follow from an identified incident for which the time is known: Steps 5.9 to 5.11, and if necessary 5.13 are followed. However, previously unidentified intakes are sometimes found through e.g. routine monitoring, and so the time of intake is unknown, or known only to be within a certain interval. Step 5.12 and, if necessary, 5.14 are followed, but provide less opportunity for *a posteriori* characterisation of the material. If the early bioassay data are not decreasing with time then, in practice, it is difficult to estimate the time of intake. In such cases it is recommended to assume the time of intake as being the mid-point of the monitoring interval.

Step 5.9: Are early lung and faeces data available? During the first few days after an accidental inhalation intake of a relatively insoluble material (Type M or Type S) most of the activity will be in the respiratory tract, or cleared through the GI tract to the faeces. In the event of such an incident with potential for a significant intake it would therefore be expected that if feasible, measurements of lung and faeces would be made. If the cumulative faecal excretion over the first few days, and a measurement on which the initial lung deposit can be estimated are available, then an estimate can be made of the effective AMAD (Step 5.10). Alternatively, if whole body data is available then this can be used together with the early faecal data to estimate the effective AMAD (step 5.10) for relatively insoluble materials.

Step 5.10: Derive effective AMAD from early lung and faeces data. Although the reviews of reported measurements of AMAD in workplaces (e.g. Dorrian and Bailey 1995) support the ICRP publication 66/68 default value of 5 μm for occupational exposure, they also show that a wide range (about 1–20 μm) has been observed. If the airborne contamination in the workplace has been well characterised, it may be possible to use a more realistic value based on measurements of the activity size distribution. Alternatively, if there are suitable early measurement data available, an "effective" AMAD can be inferred *a posteriori* from the measurements. The main effect of the aerosol AMAD is to determine the relative amounts deposited (i) in the upper respiratory tract (extrathoracic airways, ET, bronchi, BB, and bronchioles, bb, in the HRTM), which (if not absorbed into blood) is mainly cleared rapidly to the GI tract and hence to faeces within a few days, and (ii) in the lower respiratory tract (alveolar-interstitial, AI, region in the HRTM), which is mainly cleared slowly from the lungs. ICRP Supporting Guidance 3 (ICRP 2002b) showed that for a relatively insoluble (Type M or S) material inhaled by a Reference Worker, the ratio of cumulative faecal excretion over the first 3 days ($F_{1\text{-}3}$) to lung activity on day 3 (L_3) increased almost linearly with AMAD over the range 1 to 10 μm (in Figure 8.3 the curves for ^{241}Am are plotted). Hence the observed ratio could be used to infer the "effective" AMAD. It is referred to as "effective", because the ratio will be determined not only by the aerosol size, but also by the subject's breathing pattern (especially if it involves mouth-breathing) and inter-subject variation in deposition under any given set of conditions.

This approach is preferable for dose assessment than *a priori* measurements of the AMAD, because it takes account of these particular aspects.

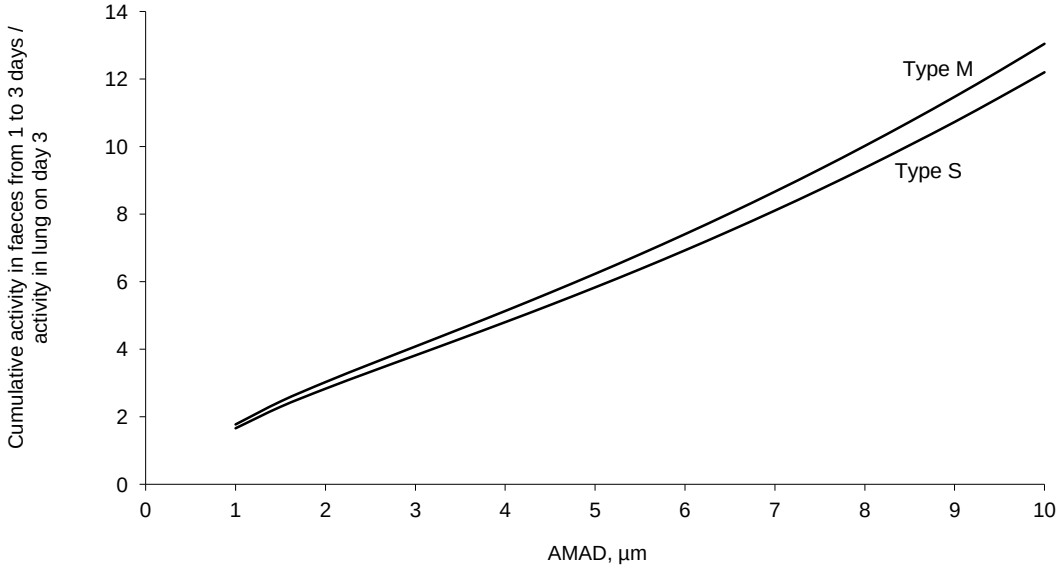


Figure 8.3: Variation with effective AMAD of the ratio of ^{241}Am cumulative activity in faeces from day 1 to day 3 to lung activity on day 3 after inhalation, predicted by the HRTM for a Reference Worker. (ICRP 2002b)

Such an evaluation has been performed also for ^{235}U (CONRAD, 2008). The behaviour of the ratio of cumulative activity in faeces from day 1 to day 3 to the lung activity on day 3 was found to be similar to that of ^{241}Am.

To help in the evaluation of the effective AMAD, a polynomial function was fitted to the calculated data of the ratio $F_{1\text{-}3}/L_3$ as a function of the effective AMAD for different radionuclides (Table 8.1). A third degree polynomial with the constraint that it passes through zero ($y=a\cdot x+b\cdot x^2+c\cdot x^3$) was used (CONRAD 2008). In the fitting y is the ratio $F_{1\text{-}3}/L_3$ and x is the effective AMAD value. The parameter values of the fitting as well as the overall correlation coefficient (R) are given in Table 8.1.

Table 8.1: Summary table of the fitting parameter values for the polynomial, $y=a\cdot x+b\cdot x^2+c\cdot x^3$ where y is the ratio $F_{1\text{-}3}/L_3$ and x is the effective AMAD value (CONRAD, 2008). The overall correlation coefficient (R) is also given.

Radio-nucide	Absorption Type	f_1	a	b	c	R
^{241}Am	M	0.0005	1.7665	-0.1567	0.0112	0.9995
^{241}Am	S	0.0005	1.6537	-0.1470	0.0105	0.9995
^{235}U	M	0.02	1.7321	-0.1536	0.0110	0.9995
^{235}U	S	0.002	1.6513	-0.1468	0.0105	0.9995

Marsh et al. 2008 extended this work to deal with ^{60}Co cases when there are no direct lung data but whole body data (CONRAD, 2008). In such cases the whole body measurement at day 10 (W_{10}) is used to infer the initial amount deposited in the lower respiratory tract for relatively insoluble materials. By the later time of 10 days almost all the material in ET_1 will have been cleared by nose blowing and most of the material in the alimentary tract will have been excreted and so most of the material measured in the whole body will be in the lower respiratory tract. Therefore, the ratio of $F_{1\text{-}3}/W_{10}$ can be used to estimate the effective AMAD for relatively insoluble materials. Figure 8.4 shows the variation of $F_{1\text{-}3}/W_{10}$ with the effective AMAD for Type M and S materials of ^{60}Co.

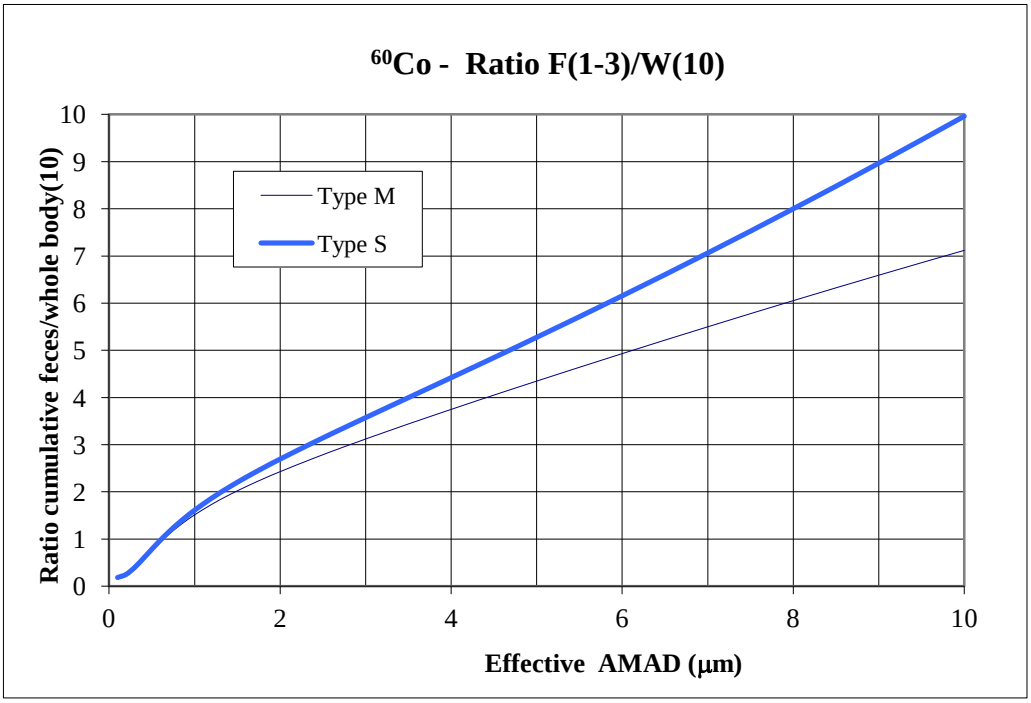


Figure 8.4 Ratio cumulative feces (F1-3) to whole body (W10) measurements for ^{60}Co at 10 days, absorption types M and S.

Step 5.11: Assessment of dose by fitting the absorption Type. Note, however, that if material specific absorption parameter values were assigned *a priori*, (Step 5.3) default absorption Types should not be used here or in Step 5.13: if an acceptable fit is not obtained with the assigned parameter values, they can be varied *a posteriori*, in Stage 5C.

At this step the AMAD has been determined according to the information available: default 5 µm AMAD, *a priori* characterisation, or *a posteriori* derivation. The other main characteristic of the inhaled material is the absorption type. An *a priori* assignment of the absorption Type has been made in Step 5.3 above according to the ICRP OIR Document or to the ICRP Publication 68 recommendations based on what is known of the chemical form of the inhaled material. A check is made on the Goodness of fit (Section 6.3) using this default absorption type. If it is acceptable, then the dose is calculated with the same model parameter values that were assumed in the assessment of intake and the process moves to Step 5.11.2 etc. If it is not, then other absorption types are tried, as follows.

The ICRP default absorption types for particulate materials: F (fast), M (moderate) and S (slow) each represent very wide ranges of absorption rates. There can be large differences between the actual absorption behaviour of a material and that assumed for the default to which it is assigned, which

can greatly affect lung retention and urinary excretion. Evaluations are therefore made assuming each of the other default types available for that element. In each case a check is made on the Goodness of fit (Section 6.3). If the fit is acceptable, then the dose is calculated with the same model parameter values that were assumed in the assessment of intake and the process moves to Step 5.11.2 etc. (If more than one absorption type fits, the one giving the best fit (i.e. that for which the p-value is greatest while the second "by eye" criterion is fulfilled) is chosen).

Step 5.11.1: Is the Goodness of fit acceptable? If the goodness of fit is acceptable (i.e. the fit obtained is not rejected by the specified criteria, see Section 6.3) then the estimated intake is taken as the best estimate. Otherwise further special procedures (Step 5.13 onwards) are needed for more detailed evaluation of the case.

Step 5.11.2: Is the dose less than 6 mSv? If the effective dose estimated in Step 5.11 is less than 6 mSv, there is no need for further investigation (Step 5.11.3). Otherwise further special procedures (Step 5.11.4 onwards) are needed for more detailed evaluation of the case.

Step 5.11.3: The results in terms of intake and committed effective dose from Step 5.11 are recorded together with the corresponding parameter values from Step 5.11.

Step 5.11.4: Check that there are sufficient data, and get more if necessary. This is similar to Steps 5.7 and 5.7.1. Criteria for the "sufficient" number (and types) of relevant data, duration of monitoring etc., are proposed according to the dose level (Section 6.5). In this Step, the numbers for Dose > 6 mSv are appropriate.

To get additional dose relevant data assumes that the evaluation is being carried out in real time, so that the opportunity exists to obtain more measurements if those available are insufficient. (For historical cases, where it is not possible to obtain more measurements, it should be recorded that the data are insufficient, and therefore the result should be treated with caution.) When the additional data have been obtained, further special procedures (Step 5.13 onwards) are needed for more detailed evaluation of the case.

Step 5.12: Assessment of dose by simultaneous fitting of the time of intake and the absorption Type.

As can be seen, this Step is reached through step 5.8 when the time of intake is unknown. At this step the AMAD has been determined according to the information available: default 5 µm AMAD or *a priori* characterisation. Note, however, that if material specific absorption parameter values were assigned *a priori*, (Step 5.3) default absorption types should not be used here: if an acceptable fit is not obtained with the assigned parameter values, they can be varied *a posteriori*, in Stage 5C.

The other main characteristic of the inhaled material is the absorption type. An *a priori* assignment of the absorption type has been made in Step 5.3 above according to the ICRP OIR Document or to the ICRP Publication 68 recommendations based on what is known of the chemical form of the inhaled material. A check is made on the Goodness of fit (Section 6.3) using this default absorption type and the default time of intake. (As in Step 3.2: Mid-point of the monitoring interval, i.e. the mid-point of the time range between the date of the measurement being considered and the date of either the previous measurement or the beginning of monitoring). If the fit is acceptable, then the dose is calculated with the same model parameter values that were assumed in the assessment of intake and the process moves to Step 5.12.2 etc. If it is not, then other absorption types and times of intake are tried, as described in the following paragraphs. However, if the early bioassay data are not decreasing with time then, in practice, it is difficult to estimate the time of intake. In

such cases it is recommended to assume the time of intake as being the mid-point of the monitoring interval.

The ICRP default absorption types for particulate materials: F (fast), M (moderate) and S (slow) each represent very wide ranges of absorption rates. There can be large differences between the actual absorption behaviour of a material and that assumed for the default to which it is assigned, which can greatly affect lung retention and urinary excretion. Evaluations are therefore made assuming each of the default types available for that element, for several times of intake spanning the period of possible intake. In each case a check is made on the Goodness of fit (Section 6.3).

If an acceptable fit is found, it is likely that acceptable fits will be found for a range of times of intake, and therefore the combination of absorption type and time of intake giving the best fit is chosen (that for which the p-value is greatest while the second "by eye" criterion is fulfilled). The dose is calculated with the same model parameter values that were assumed in the assessment of intake and the process moves to Step 5.12.2 etc.

Step 5.12.1: Is the Goodness of fit acceptable? If the goodness of fit is acceptable (i.e. the fit obtained is not rejected by the specified criteria, Section 6.3) then the estimated intake is taken as the best estimate. Otherwise further special procedures (Step 5.14 onwards) are needed for more detailed evaluation of the case.

Step 5.12.2: Is the dose less than 6 mSv? If the effective dose estimated in Step 5.12 is less than 6 mSv, there is no need for further investigation (Step 5.12.3). Otherwise further special procedures (Step 5.12.4 onwards) are needed for more detailed evaluation of the case.

Step 5.12.3: The results in terms of intake and committed effective dose from Step 5.12 are recorded together with the corresponding parameter values from Step 5.12.

Step 5.12.4: Check that there are sufficient data, and get more if necessary. This is similar to Steps 5.7 and 5.7.1. Criteria for the "sufficient" number (and types) of relevant data, duration of monitoring etc., are proposed according to the dose level (Section 6.5). In this Step, the numbers for Dose > 6 mSv are appropriate.

To get additional dose relevant data assumes that the evaluation is being carried out in real time, so that the opportunity exists to obtain more measurements if those available are insufficient. (For historical cases, where it is not possible to obtain more measurements, it should be recorded that the data are insufficient, and therefore the result should be treated with caution.) When the additional data have been obtained, further special procedures (Step 5.14 onwards) are needed for more detailed evaluation of the case.

Step 5.13: Assessment of dose by fitting a mixture of absorption Types. This is an extension of Step 5.11, to give greater flexibility in fitting by considering a mixture of absorption Types.

This step may have been reached through Step 5.11.1, because an acceptable fit was not obtained with any single absorption type. In that case combinations should be tried by inspection, trial and error, etc. If more than one fits (Stage 5C, Step 5.15), the mixture of absorption types giving the best fit is chosen (i.e. that for which the p-value is greatest while the second "by eye" criterion is fulfilled).

Alternatively, this step may have been reached through Steps 5.11.1 and 5.11.2, because the estimated dose is > 6 mSv, and more data may have been obtained. If so then as much of the procedure as necessary should be repeated: evaluate using in turn: the *a priori* default absorption

type; another absorption type; and a combination of absorption types, until an adequate fit is obtained.

Step 5.14: Assessment of dose by simultaneous fitting of the time of intake and a mixture of absorption types. This is an extension of Step 5.12, to give greater flexibility in fitting by consider a mixture of absorption types. Note, however, that if material specific absorption parameter values were assigned *a priori*, (Step 5.3) default absorption types should not be used here: if an acceptable fit is not obtained with the assigned parameter values, they can be varied *a posteriori*, in Stage 5C.

This step may have been reached through Step 5.12.1, because an acceptable fit was not obtained with any single absorption type and time of intake. In that case combinations of absorption Type should be tried. If more than one fits (Stage 5C, Step 5.15), the mixture of absorption types giving the best fit is chosen. If an acceptable fit is found, it is likely that acceptable fits will be found for a range of times of intake, and therefore the combination of the mixture of absorption types and time of intake giving the best fit is chosen (i.e. that for which the p-value is greatest while the second "by eye" criterion is fulfilled).

Alternatively, this step may have been reached through Steps 5.12.1 and 5.12.2, because the estimated dose is > 6 mSv, and more data may have been obtained. If so then as much of the procedure as necessary should be repeated: evaluate using in turn: the *a priori* default absorption type and default time of intake; all absorption types and variable time of intake; and a combination of absorption types and variable time of intake, until an adequate fit (i.e. that for which the p-value is greatest while the second "by eye" criterion is fulfilled) is obtained.

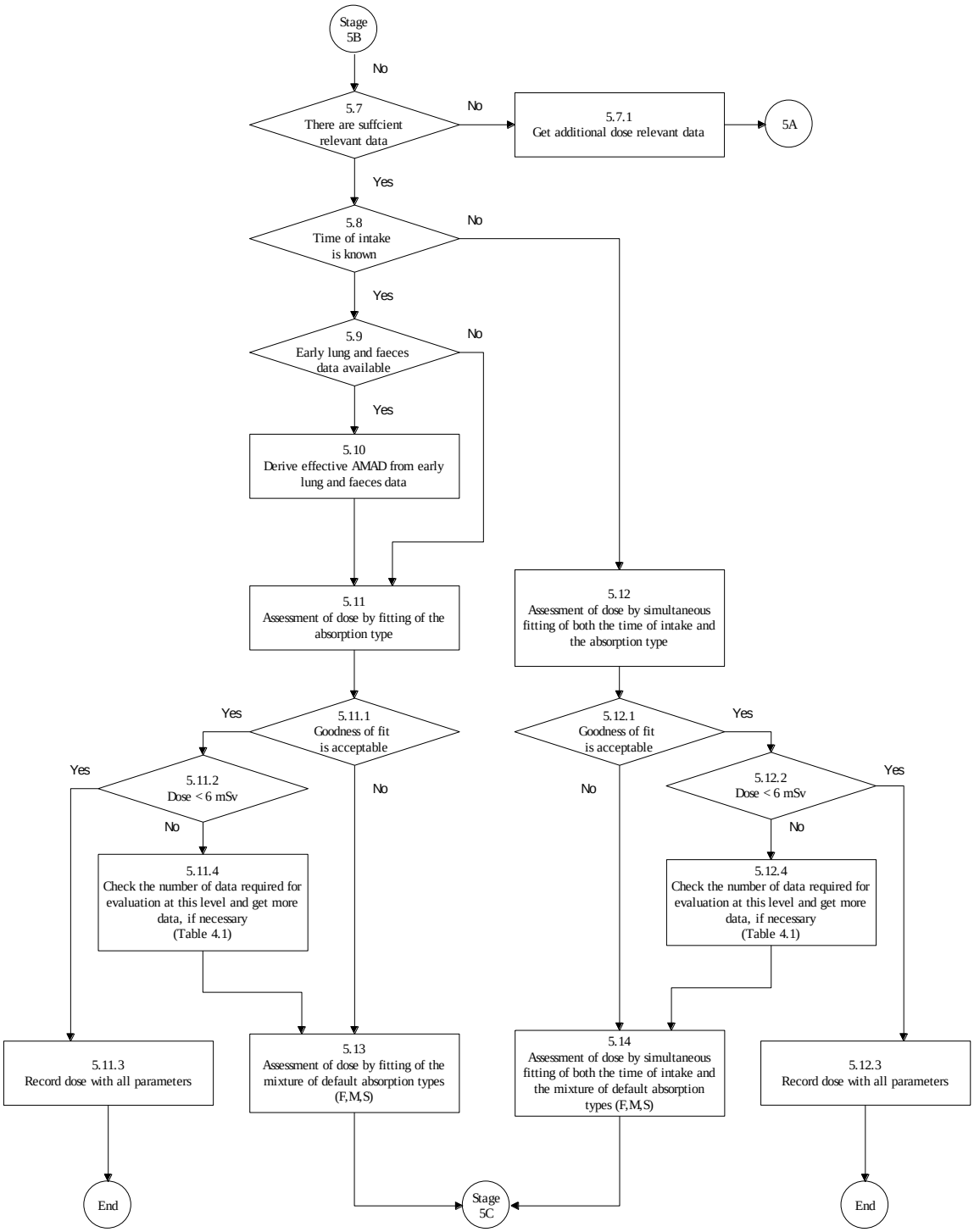


Figure 8.4: Stage 5B. Special procedure for inhalation cases above Level 1 – Part 2: Variation of the AMAD and absorption type, and also the time of intake, if not known.

8.3 Advanced evaluation (stage 5C)

In this stage, an advanced evaluation is carried out. It applies to cases where there are comprehensive data available. The fundamental approach is that the model parameter values are adjusted systematically, in a specific order, until the goodness of fit is acceptable (i.e. the fits obtained to all the data are not rejected by both specified criteria, see Section 6.3). If the fit is acceptable then the estimated intake is taken as the best estimate and the committed equivalent

doses to all organs and effective dose are calculated with the same model parameter values that were assumed for the assessment of intake.

These results (intake and committed equivalent and effective doses) are then recorded together with the corresponding parameter values (Step 5.15.1). If a subject specific parameter value has been changed then this should be noted and the quantity "committed effective dose " will no longer refer to Reference Person (see section 1.2.1).

Thus after each Step in which a parameter value is varied (5.17 to 5.22) there is a corresponding Step (5.17.1 to 5.22.1 respectively) to test the goodness of fit. Since these are all very similar to Step 5.15, explanatory text is not given.

If the time of intake is unknown, then by the start of this Stage it may have been assessed, based on simultaneous fitting of the model to the data with a mixture of absorption Types (Step 5.12). In that case, if any of the parameter values are changed in the Steps below, the time of intake should be re-assessed.

It is recommended, in cases where multiple types of bioassay data sets are available, that the intake and dose are assessed by fitting predicted values to the different types of data simultaneously.

Step 5.15: Is the goodness of fit acceptable? If the goodness of fit is acceptable (i.e. the fit obtained is not rejected by the specified criteria, Section 6.3) then the estimated intake is taken as the best estimate. The effective dose is then calculated with the same model parameter values that were assumed in the assessment of intake. However if the fit is rejected then proceed to next (step 5.16).

Step 5.16: Determine specific HRTM absorption parameter values: For materials that are moderately to very insoluble (typically absorption Types M or S), determine specific values for f_r and s_s by fitting f_r, s_s and intake to the data with s_r fixed at the value recommended in the ICRP OIR Document or in the ICRP Publication 68. For most materials there is no evidence for binding to the respiratory tract so the bound fraction f_b is taken to be zero. However, if relevant values of s_r and/or of f_b and s_b have been determined from *in vivo* experimental data then use these values.

Step 5.17: Determine specific f_A or, in absence of indication, f_1 value. Generally, it is not justifiable to change the f_1 value as well as the HRTM absorption parameter values. Occasionally, for inhaled materials that are relatively insoluble, it is necessary to reduce the value of f_1 so that the predicted systemic activities or urinary excretion rates are consistent with the data.

Step 5.18: Determine specific HRTM particle transport values: The parameter values that describe particle transport from the respiratory tract in the HRTM were based so far as possible on human experimental data, which enable typical lung clearance rates to be determined for a year or so after particle deposition in the lungs. However, the values were chosen to be average values for healthy non-smokers. The experimental data from which they were derived show considerable inter-subject variation even among healthy subjects, and indicate that clearance would generally be slower in smokers and patients with lung disease (ICRP Publication 66, 1994). If there are comprehensive lung and/or faecal excretion data available, it may be necessary to vary particle transport rates to improve the fits to the data.

It should be noted that adjusting particle transport rates also affects the amount absorbed into blood, because clearance from the lung is competitive between absorption into blood and particle transport to the GI tract. Thus in some cases it is necessary to readjust HRTM absorption parameter values (i.e. repeat step 5.16) after varying the particle transport rates.

Step 5.19: Determine specific alimentary tract model transit parameter values: The parameter values in the ICRP alimentary tract model – HATM (ICRP, 2006) again represent typical values, and there will be considerable inter- (and intra-) subject variations. The transit time through the alimentary tract affects the amount in the whole body and the amount excreted in the faeces within the first few days following inhalation or ingestion. If there are comprehensive early data it may be necessary to alter the alimentary tract model parameter values to obtain a reasonable fit to the data.

Step 5.20: Adjust systemic biokinetic model parameter values: Again, model parameters values were derived by ICRP to represent population averages, and there are likely to be individual variations, which will result in differences between predicted values and data, independently of the biokinetics of the respiratory or alimentary tract. This might well arise for very soluble materials, where particle transport rates have little effect. For example, whole body retention half-times vary between individuals for intakes of tritiated water or soluble forms of caesium (ICRP, 1989) and therefore in such cases differences between predicted values and whole body retention data may occur. Also for actinides, with sufficiently comprehensive data, individual differences from model predictions might be observed either for retention in liver and skeleton, or in the ratio between deposition in such organs and urinary excretion.

It is emphasised that this is the last step, so adjusting the systemic biokinetic model parameter values should only be considered after varying the HRTM and HATM parameter values (Steps 5.18 and 5.19). If the goodness of fit test results in the fit being rejected according to the specified criteria then consult other experts. Otherwise the results (intake and committed effective and equivalent doses to organs) are then recorded together with the corresponding parameter values (Step 5.15.1).

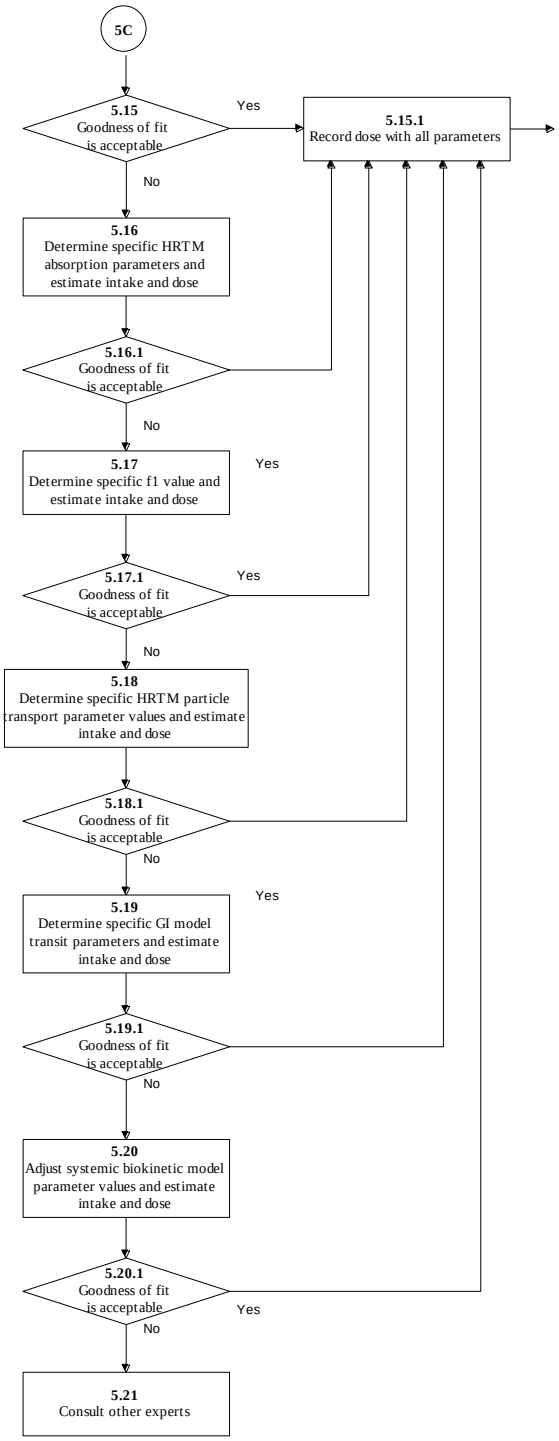


Figure 8.5: Stage 5C. Special procedure for inhalation cases above Level 1 – Part 3: More sophisticated evaluation with systematic adjustment of model parameter values.

9.Ingestion (Stage 6)

9.1 Overview

The special procedure is analogous to that for inhalation (Chapter 8) and there is, as a result a certain amount of repetition of that section here. It is grouped in three subsequent stages (see overview flowchart, Figure 9.1). In the first stage (6A), a simple evaluation is carried out using parameter values chosen *a priori*: before the evaluation is carried out. The procedure is very similar to the "Standard procedure" (Stage 3). The main difference is that in a special procedure there should be more than one measurement.

In the second stage (6B), procedures are applied for varying the main factor related to the ingested material: the fraction of material reaching body fluids following ingestion known as the f_A value (ICRP 2006). Generally the f_A value is a sum of different fractions (e.g. f_{ST} from stomach and f_{SI} from small intestine). In absence of indication of the f_A value, the f_1 value as reported in ICRP publication 68 (ICRP 1994b) is used. Moreover the time of intake, if not known, is fitted using the measurement data (*a posteriori*).

In the third stage (6C), an advanced evaluation is carried out. It applies to cases where there are comprehensive data available. The fundamental approach of this stage is that the model parameter values are adjusted systematically, in a specific order, until the goodness of fit is acceptable (i.e. the fits obtained to all the data are not rejected by the specified criteria).

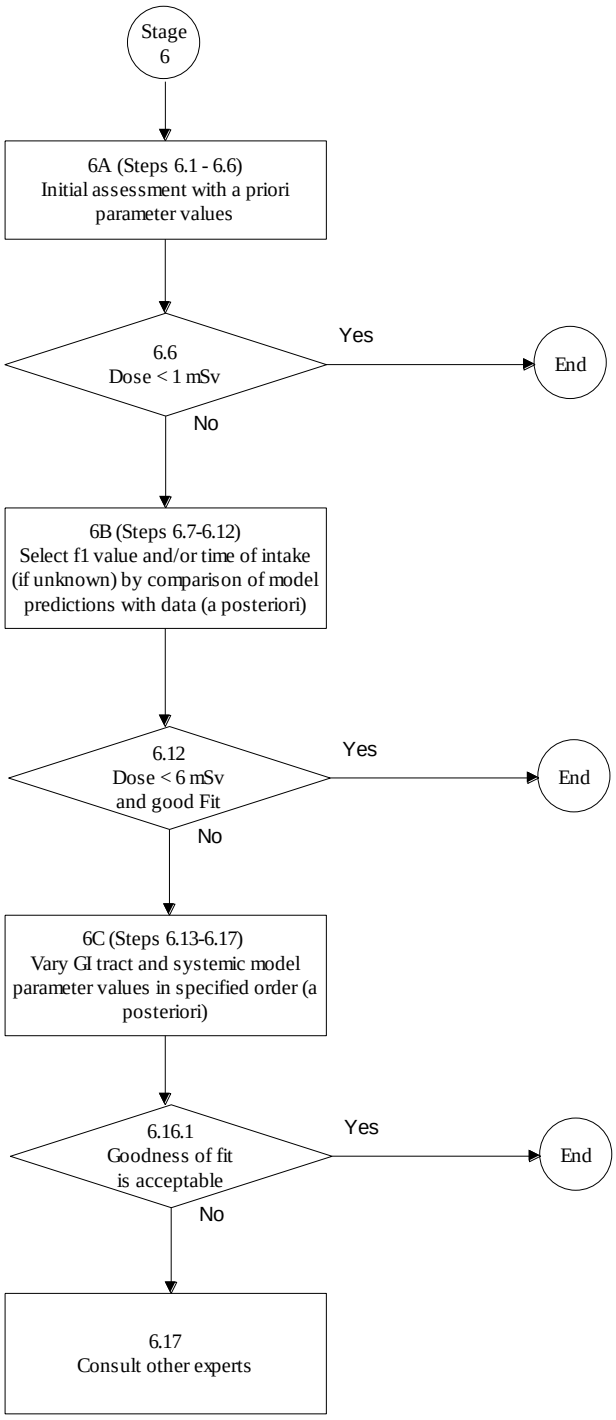


Figure 9.1: Stage 6. Special procedure for ingestion cases above Level 1 – Overview.

9.2 Simple evaluation (stage 6A)

In this stage, a simple evaluation is carried out using parameter values chosen *a priori*: before the evaluation is carried out. The procedure is very similar to the "Standard procedure" (Stage 3). The main difference is that in a special procedure there should be more than one measurement.

Step 6.1: Identification and preparation of measurement data. It is expected that there will be more than one measurement available for a special assessment (M_i for i = 1 to n). It is therefore important that realistic uncertainties are assigned to the data ("scattering factor", SF, Step 2.1)

There may be more than one type of measurement (urine, faeces, etc), and there may be measurements of more than one radionuclide involved in the exposure.

Explore the possibility that certain measures are "rogue" by means of the procedure indicated in paragraph 6.1.

Step 6.2: (As Step 2.3 for a single measurement.) The contributions (P_i) from all previous intakes of the radionuclide considered are calculated, taking into account all pathways of intake, and all intakes of mixtures where the radionuclide was involved. The net values ($N_i = M_i - P_i$) of the radionuclide are calculated by subtracting P_i from the measured value M_i.

Step 6.3: (As Step 3.2 in the Standard Procedure, Stage 3, except for time of intake).

Case or site specific parameter values should be assigned as far as they are available. Such *a priori* information needs to be well established and documented. Examples might include the fraction of the ingested activity that is absorbed into the systemic circulation: the "f_1 value" – if it has been determined by an appropriate in vivo experiment (although such experiments are uncommon), or the time of intake, if potential exposure was limited, or an incident was known to occur. Otherwise the following default parameter values should be used:

- Mode of intake: Single intake
- f_A / f_1 value: defaults according to the ICRP OIR Document or to the ICRP Publication 68, Annex E.

Step 6.4: Time of intake known/unknown. If the special procedure was initiated as a result of a known incident (and hence the time of intake is known) then a simple assessment (Step 6.5) should be carried out which is consistent with the Standard evaluation (Stage 3). If the special procedure was initiated as a result of a routine measurement being inconsistent with previous assessment (Step 2.6) or a dose >1 mSv resulting from the Standard evaluation (Step 3.4) where the time of intake is probably not known, then further special procedures (Stage 6B) are needed for more detailed evaluation of the case.

Step 6.5: (As step 3.3 in the Standard Procedure, Stage 3, but for more than one measurement). Using the assigned *a priori* parameter values, an estimate of intake I_i is obtained by dividing the net value $N_i = M_i - P_i$ by the appropriate retention or excretion function. The geometric mean of the value of I_i gives the "best estimate" of intake (see step 5.5). Using the same assigned *a priori* parameter values the committed effective dose is calculated by multiplying the "best estimate" of intake by the appropriate dose coefficient (dose per unit intake).

Step 6.6: If the effective dose estimated in Step 6.5 is less than 1 mSv, there is no need for further investigation (Step 6.6.1). (The dose from the intake under consideration, rather than the "annual dose" as in Step 3.4, is the criterion, because intakes requiring special assessment procedures should be unusual for any individual worker.) Otherwise further special procedures (Stage 6B) are needed for more detailed evaluation of the case.

Step 6.6.1: The results in terms of intake and committed effective dose from Step 6.6 are recorded together with the corresponding parameter values from Step 6.3.

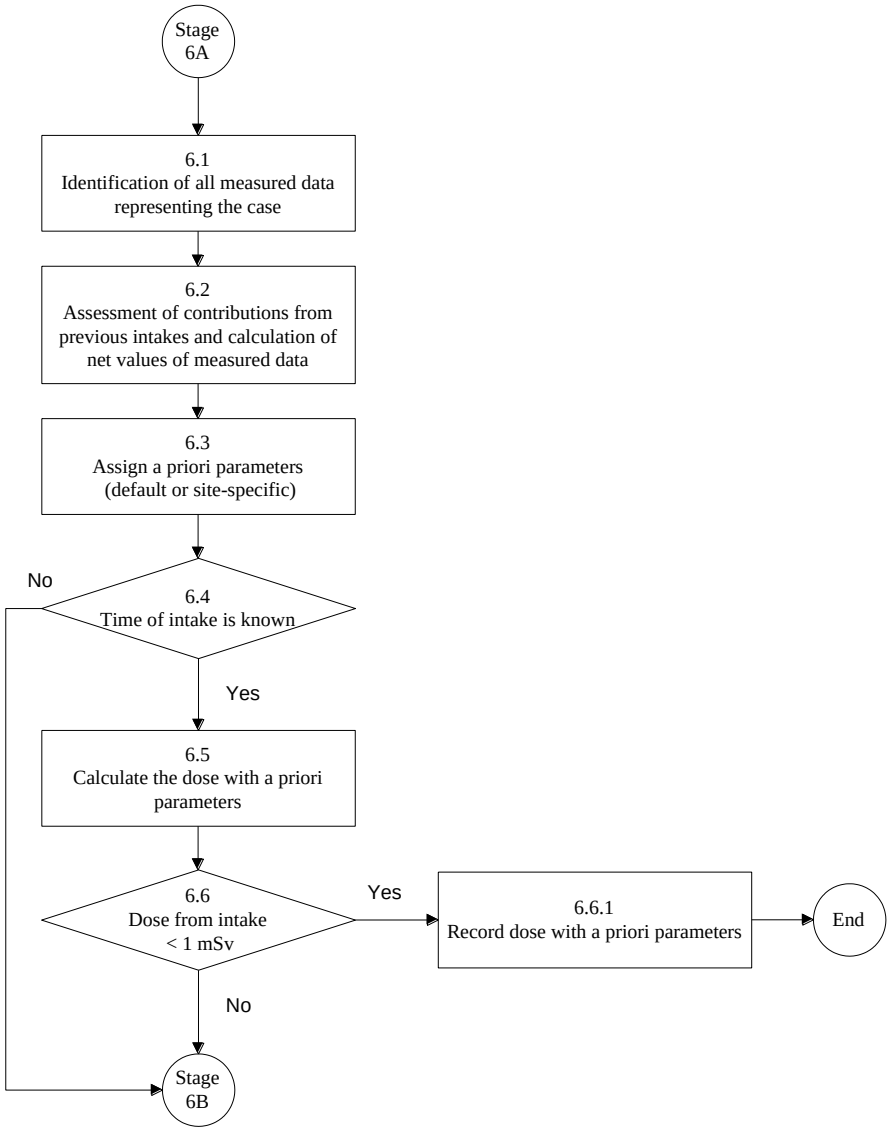


Figure 9.2: Stage 6A. Special procedure for ingestion cases above Level 1 – Part 1: simple evaluation using parameter values chosen *a priori.*

9.3 Exposure related parameters (stage 6B)

In this stage, procedures are described for varying the main factor related to the ingested material, the f_A / f_1 value, and also the time of intake, if not known, using the measurement data (*a posteriori*).

In this Stage, and in Stage 6C that follows, parameter values are selected on the basis of the "fit" of the model predictions to the observations (data). A check on whether the fit is adequate is used to decide whether to stop the evaluation, or to go on to further Steps. A measure of the "Goodness of fit" (GOF) and the criteria for deciding that the fit is good enough are therefore critical issues. There may be conflict between "harmonisation" and "accuracy". Generally the better the data (quality and quantity) the more likely it is that a statistical test will show that the data are inconsistent with the model. If the data are poor it is more likely that the model will fit – in the extreme case of a single measurement any model will fit. It is therefore important that there should be sufficient data available for assessment of a significant dose, and the higher the dose, the better the data should

be. Proposals are therefore made for the minimum amounts of data that would be acceptable ("sufficient", see Section 6.5).

As seen in the flow chart, there are two alternative routes through this stage of the process, according to whether or not the time of intake is known.

Step 6.7: Are there are sufficient data? As noted in the introduction, criteria for the "sufficient" number (and types) of relevant data, duration of monitoring etc, are proposed according to the dose (Section 6.5). In this Step, the numbers for the range 1 mSv <Dose <6 mSv are appropriate, because a Special procedure is generally initiated on the assumption that the dose could exceed 1 mSv, and doses greater than 6 mSv are considered in Steps 6.13 onwards.

Step 6.7.1: Get additional dose relevant data. This assumes that the evaluation is being carried out in real time, so that the opportunity exists to obtain more measurements if those available are insufficient. (For historical cases, where it is not possible to obtain more measurements, it should be recorded that the data are insufficient, and therefore the result should be treated with caution.) When the additional data have been obtained, a simple re-evaluation (Stage 6A) is made.

Step 6.8: Is the time of intake known? As noted in the introduction, there are two alternative routes through this stage of the process, according to whether or not the time of intake is known. Generally, Special Procedures follow from an identified incident for which the time is known (Step 6.9). However, previously unidentified intakes are sometimes found through e.g. routine monitoring, and so the time of intake is unknown, or known only to be within a certain interval. Step 6.10 is followed, but provides less opportunity for *a posteriori* characterisation of the material. If the early bioassay data are not decreasing with time then, in practice, it is difficult to estimate the time of intake. In such cases it is recommended to assume the time of intake as being the mid-point of the monitoring interval.

Step 6.9: Assessment of dose by selecting the default f_A / f_1 value. An *a priori* assignment of the f_A / f_1 value has been made in Step 6.3 above according to the ICRP OIR Document or the ICRP Publication 68 recommendation based on what is known of the chemical form of the ingested material. A check is made on the Goodness of fit (Step 6.11) using this default f_A / f_1 value (Section 6.3). If it is acceptable, then the dose is calculated with the same model parameter values that were assumed in the assessment of intake and the process moves to Step 6.12 etc. If it is not, then other f_A / f_1 values are tried, as follows.

For some elements, the ICRP Publication 68 and the forthcoming ICRP OIR document give different f_1 / f_A values for different chemical forms. It is proposed that evaluations are made assuming each of the other default f_A / f_1 values available for that element. In each case a check is made on the Goodness of fit (Step 6.11). If the fit is acceptable, then the dose is calculated with the same model parameter values that were assumed in the assessment of intake and the process moves to Step 6.12 etc. (If more than one f_A / f_1 value fits, the one giving the best fit is chosen, i.e. that for which the p-value is greatest while the second "by-eye" criterion is fulfilled).

Step 6.10: Assessment of dose by simultaneous fitting of the time of intake and the f_A / f_1 value. As can be seen this Step is reached through Step 6.8 when the time of intake is unknown.

An *a priori* assignment of the f_A / f_1 value has been made in Step 6.3 above according to the ICRP OIR Document or the ICRP Publication 68 recommendation based on what is known of the chemical form of the ingested material. A check is made on the Goodness of fit (Step 6.11) using this default f_A / f_1 value and the default time of intake. (As in Step 3.2: Mid-point of the monitoring interval, i.e. the mid-point of the time range between the date of the measurement being

considered and the date of either the previous measurement or the beginning of monitoring). If the fit is acceptable, then the dose is calculated with the same model parameter values that were assumed in the assessment of intake and the process moves to Step 6.12 etc. If it is not, then other default f_A / f_1 values and times of intake are tried, as follows.

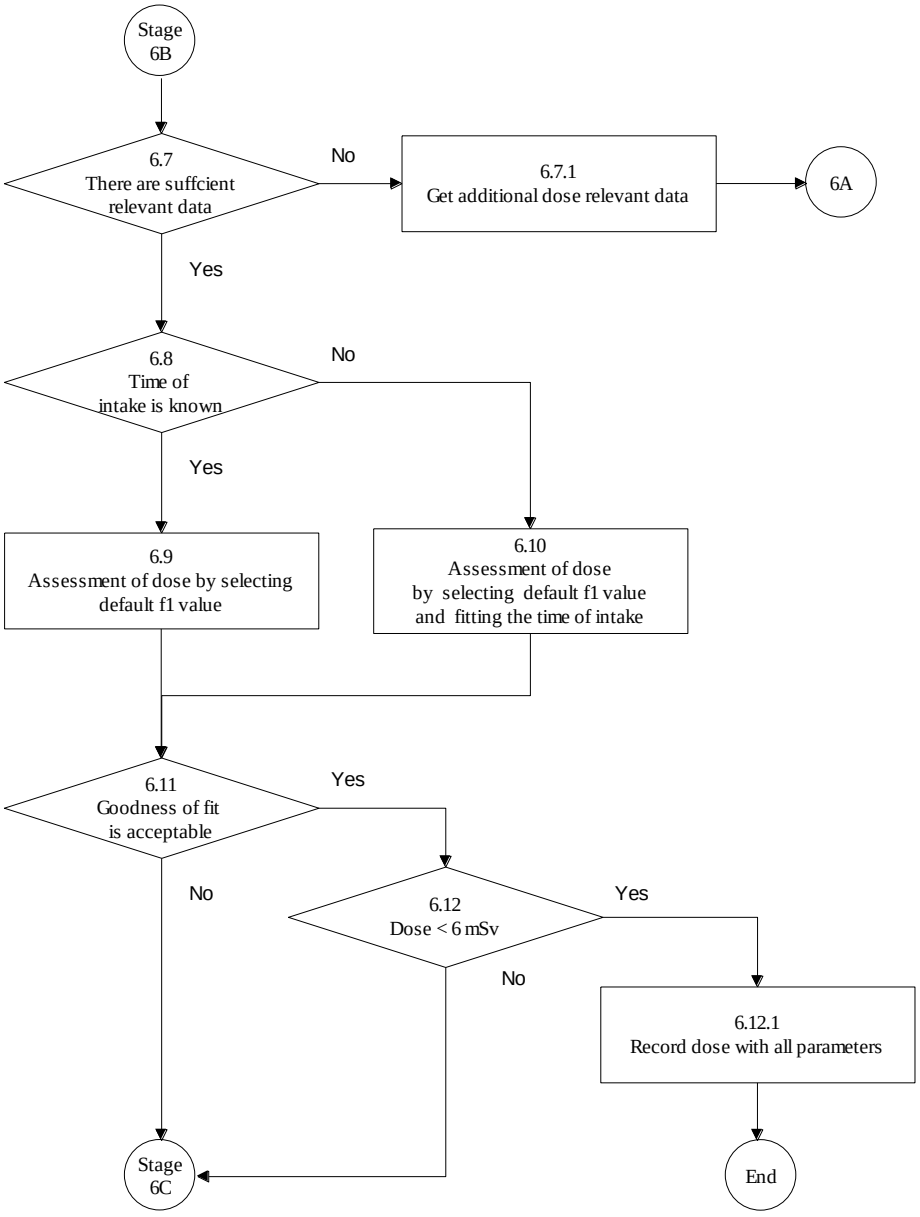


Figure 9.3: Stage 6B. Special procedure for ingestion cases above Level 1 – Part 2: Variation of the f_1 value, and also the time of intake, if not known

For some elements (e.g. cobalt, strontium, uranium, plutonium) it is expected that ICRP OIR Document will indicate specific f_A values. In the meanwhile ICRP Publication 68 gives different f_1 values for different chemical forms. It is proposed that evaluations are made assuming each of the other default values available for that element, for several times of intake spanning the period of possible intake. In each case a check is made on the Goodness of fit (Step 6.11).

If an acceptable fit is found, it is likely that acceptable fits will be found for a range of times of intake, and therefore the combination of f_A / f_1 value and time of intake giving the best fit is chosen, i.e. that for which the p-value is greatest while the second "by-eye" criterion is fulfilled. The dose is

calculated with the same model parameter values that were assumed in the assessment of intake and the process moves to Step 6.12 etc.

Step 6.11: Is the Goodness of fit acceptable? If the goodness of fit is acceptable (i.e. the fit obtained is not rejected by the specified criteria, Section 6.3) then the estimated intake is taken as the best estimate. Otherwise further special procedures (Step 6.13 onwards) are needed for more detailed evaluation of the case.

Step 6.12: Is the dose less than 6 mSv? If the effective dose estimated in Step 6.9 or 6.10 is less than 6 mSv, there is no need for further investigation (Step 6.12.1). Otherwise further special procedures (Step 6.13 onwards) are needed for more detailed evaluation of the case.

Step 6.12.1: The results in terms of intake and committed effective dose from Step 6.12 are recorded together with the corresponding parameter values from Step 6.9 or 6.10.

9.4 Advanced evaluation (stage 6C)

In this stage, an advanced evaluation is carried out. It applies to cases where there are comprehensive data available. The fundamental approach is that the model parameter values are adjusted systematically, in a specific order, until the goodness of fit is acceptable (i.e. the fits obtained to all the data are not rejected by the specified criteria). If the fit is acceptable, then the estimated intake is taken as the best estimate and the effective dose is calculated with the same model parameter values that were assumed in the assessment of intake. These results (intake and committed effective dose) are then recorded together with the corresponding parameter values (Step 6.12.1). Thus after each step in which a parameter value is varied (6.14 to 6.16) there is a corresponding step (6.14.1 to 6.16.1 respectively) to test the goodness of fit. Since these are all very similar, explanatory text is only given for Step 6.14.1.

If the time of intake is unknown, then by the start of this Stage it may have been assessed, based on simultaneous fitting of the model to the data with the f_A / f_1 value (Step 6.10). In that case, if any of the parameter values are changed in the Steps below, the time of intake should be re-assessed.

It is recommended, in cases where multiple types of bioassay data sets are available, that the intake and dose are assessed by fitting predicted values to the different types of data simultaneously.

Step 6.13**:** Check that there are sufficient data, and get more if necessary. This is similar to Steps 6.7 and 6.7.1 (Stage 6B). Criteria for the "sufficient" number (and types) of relevant data, duration of monitoring etc, are proposed according to the dose level. In this Step, the numbers for Dose > 6 mSv are appropriate.

To get additional dose relevant data assumes that the evaluation is being carried out in real time, so that the opportunity exists to obtain more measurements if those available are insufficient. (For historical cases, where it is not possible to obtain more measurements, it should be recorded that the data are insufficient, and therefore the result should be treated with caution.) When the additional data have been obtained, further special procedures (Step 6.14 onwards) are needed for more detailed evaluation of the case.

Step 6.14: Determine specific f_1 value. The f_1 value is the main variable related to the ingested material. The default values recommended by ICRP are generally typical values representing the wide ranges that might arise in practice, especially when a single value is given for all chemical forms of an element. GI tract absorption can also vary according to factors such as how recently a meal was taken. Hence it is reasonable to consider values different from the ICRP default. If

sufficiently comprehensive data are available, especially if it is possible to estimate both the intake and the total amount absorbed into blood (e.g. if early faecal and urine data are available), then it may be necessary to change the f_1 value to obtain a reasonable fit to the data.

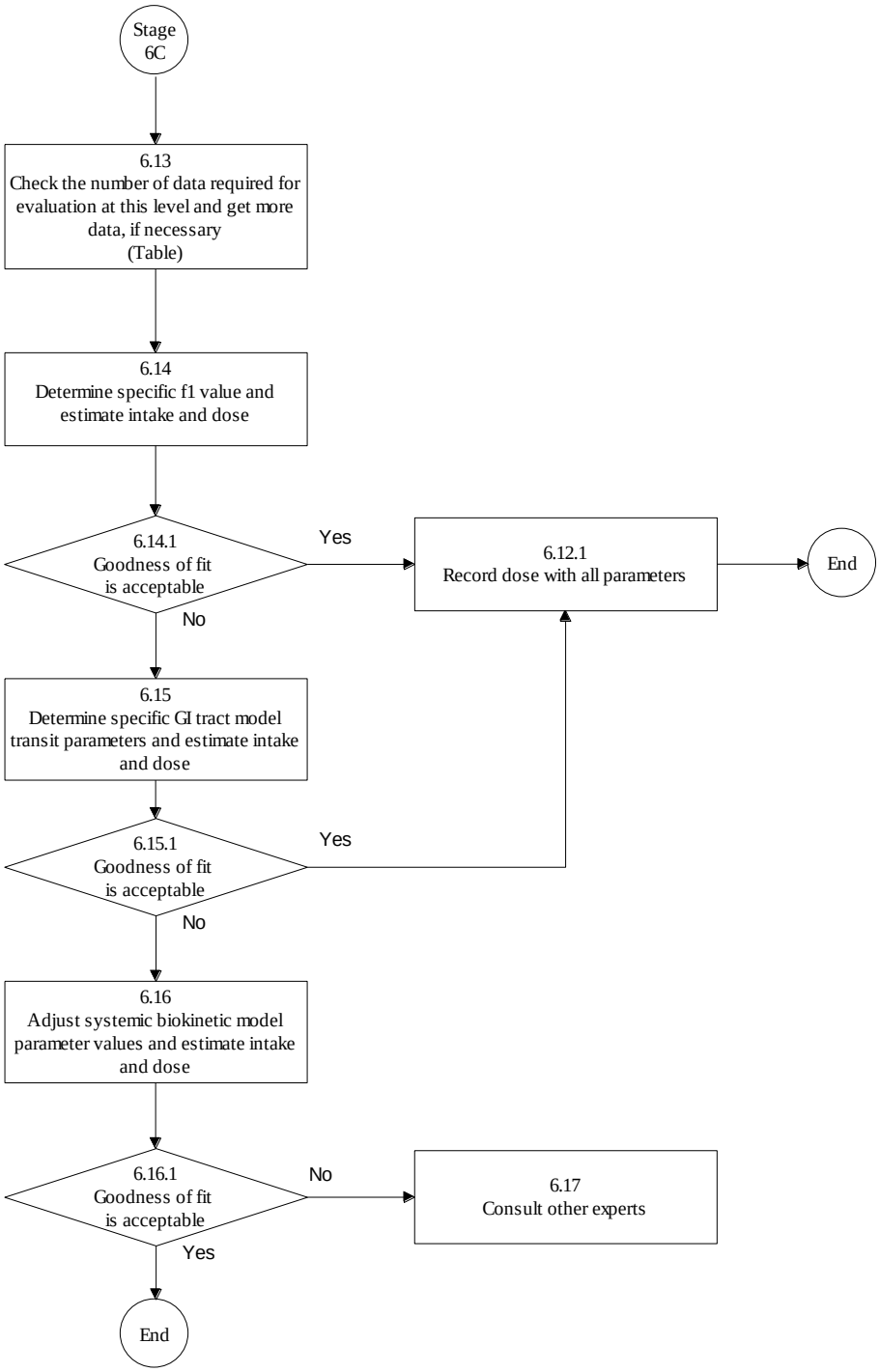


Figure 9.4: Stage 6C. More sophisticated evaluation for ingestion cases where there are comprehensive data available. Model parameters are adjusted systematically, in a specified order, until goodness of fit is acceptable.

Step 6.14.1**:** Is the goodness of fit acceptable? If the goodness of fit is acceptable (i.e. the fit obtained is not rejected by the specified criteria) then the estimated intake is taken as the best estimate. The effective dose is then calculated with the same model parameter values that were assumed in the assessment of intake. However if the fit is rejected then proceed to the next Step (6.15).

Step 6.15**:** Determine specific alimentary tract model transit parameter values. The parameter values in the ICRP alimentary tract model represent typical values, and there will be considerable inter- (and intra-) subject variations. Moreover, as noted in Step 6.1, while for ease of computation transit through the alimentary tract is represented by a series of compartments that clear exponentially, in practice, the movement is more like "slug" flow. It is therefore unlikely that individual daily faecal clearance measurements in the first few days after intake will follow the predicted pattern. The transit time through the alimentary tract affects the amount in the whole body and the amount excreted in the faeces within the first few days following inhalation or ingestion. If there are comprehensive early data it may be necessary to alter the alimentary tract transit parameter values to obtain a reasonable fit to the data.

Step 6.16: Adjust systemic biokinetic model parameter values. Systemic model parameter values were derived by ICRP to represent population averages, and there are likely to be individual variations, which will result in differences between predicted values and data, independently of the biokinetics in the alimentary tract. This might well arise for very soluble materials or for actinides where individual differences from model predictions might be observed either for retention in liver and skeleton, or in the ratio between deposition in such organs and urinary excretion.

It is emphasised that this is the last step, so adjusting the systemic biokinetic model parameter values should only be considered after varying the HATM parameter values, and f_A / f_1 value (Steps 6.14 and 6.15). If the goodness of fit test results in the fit being rejected according to the specified criteria then consult other experts. Otherwise the results (intake and committed effective dose) are then recorded together with the corresponding parameter values (Step 6.12.1).

10. Mixed Inhalation and Ingestion (Stage 7)

10.1 Overview

The special procedure is analogous to those for inhalation and ingestion (Sections 8.1 and 9.1) and there is, as a result a certain amount of repetition of that section here. It is grouped in three subsequent stages (see overview flowchart, Figure 10.1). In the first stage (7A), a simple evaluation is carried out using parameter values chosen *a priori*: before the evaluation is carried out. The procedure is very similar to the "Standard procedure" (Stage 3). The main difference is that in a special procedure there should be more than one measurement.

In the second stage (7B), procedures are applied for varying the main factor related to the scenario, the distribution of the intake between inhalation and ingestion and also the time of intake, if not known, using the measurement data (*a posteriori*).

In the third stage (7C), an advanced evaluation is carried out. It applies to cases where there are comprehensive data available. The fundamental approach of this stage is that the model parameter values are adjusted systematically, in a specific order, until the goodness of fit is acceptable (i.e. the fits obtained to all the data are not rejected by the specified criteria).

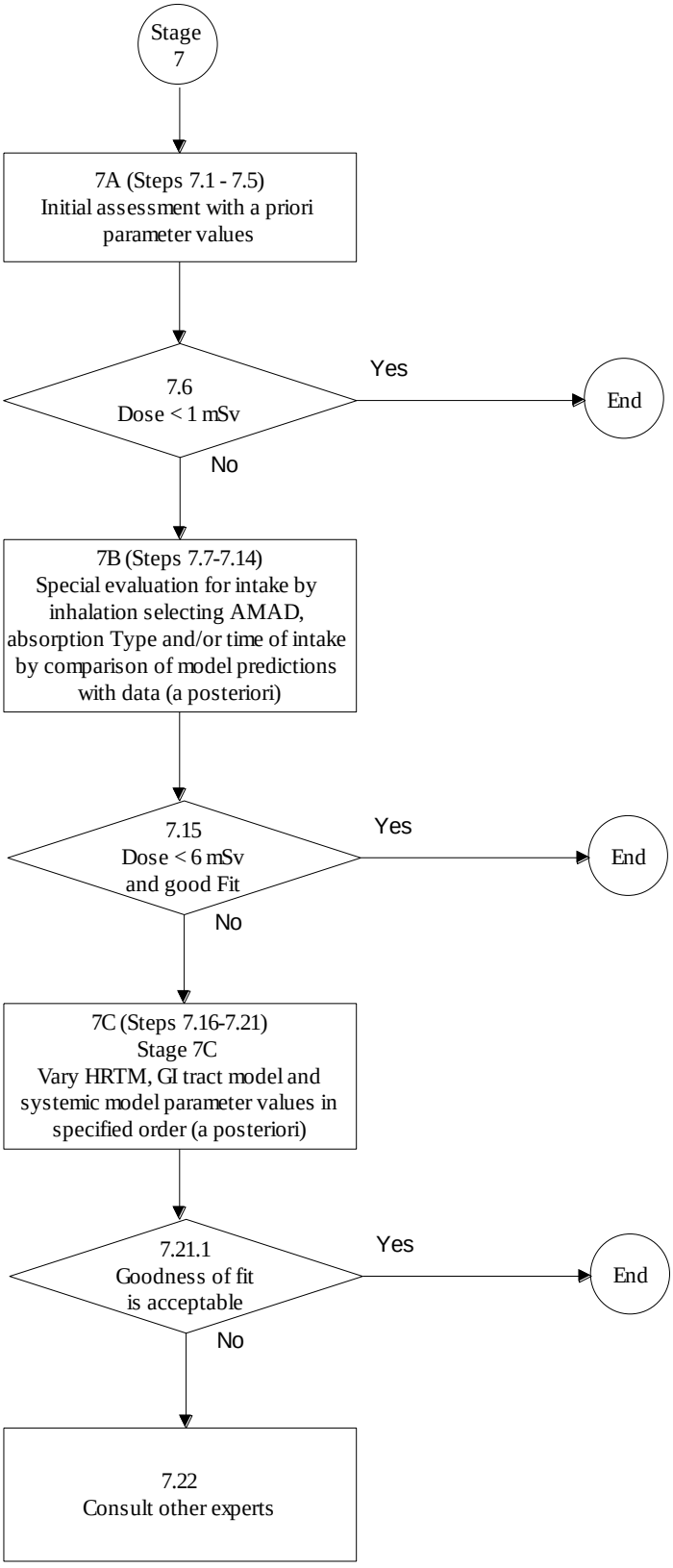


Figure 10.1: Stage 7. Special procedure for mixed inhalation and ingestion cases above Level 1 – Overview.

10.2 Simple evaluation (stage 7A)

In this Stage, a simple evaluation is carried out using parameter values chosen *a priori*: before the evaluation is carried out. The procedure is very similar to the "Standard procedure" (Stage 3). The main difference is that in a special procedure there should be more than one measurement.

Step 7.1: Identification and preparation of measurement data. It is expected that there will be more than one measurement available for a special assessment (M_i for i = 1 to n). It is therefore important that realistic uncertainties are assigned to the data ("scattering factor", SF, Step 2.1) There may be more than one type of measurement (urine, faeces, etc), and there may be measurements of more than one radionuclide involved in the exposure.

Explore the possibility that certain measures are "rogue" by means of the procedure indicated in paragraph 6.1.

Step 7.2: (As Step 2.3 for a single measurement.) The contributions (P_i) from all previous intakes of the radionuclide considered are calculated, taking into account all pathways of intake, and all intakes of mixtures where the radionuclide was involved. The net values ($N_i = M_i - P_i$) of the radionuclide are calculated by subtracting P_i from the measured value M_i.

Step 7.3: (As Step 3.2 in the Standard Procedure, Stage 3, except for time of intake). Case or site specific parameter values should be assigned as far as they are available. Such *a priori* information needs to be well established and documented. Examples might include the Activity Median Aerodynamic Diameter (AMAD) – if it has been determined by appropriate air sampling (e.g., cascade impactor), or the time of intake, if potential exposure was limited, or an incident was known to occur. Otherwise the following default parameter values should be used:

- Mode of intake: Single intake. By default 100% inhalation.
- Absorption Type and f_A / f_1 value for inhalation: defaults according to forthcoming ICRP OIR Document or ICRP Publication 68. If the compound is unknown, then for those elements where there is a choice of absorption types, the type for "unspecified compounds" should be used.
- f_A / f_1 value for ingestion: defaults according to forthcoming ICRP OIR Document or ICRP Publication 68.
- Particle size: 5 µm AMAD.

Step 7.4: Time of intake known/unknown. If the special procedure was initiated as a result of a known incident (and hence the time of intake is known) then a simple assessment (Step 7.5) should be carried out which is consistent with the Standard evaluation (Stage 3). If the special procedure was initiated as a result of a routine measurement being inconsistent with previous assessments (Step 2.6) or a dose >1 mSv resulting from the Standard evaluation (Step 3.4) where the time of intake is probably not known, then further special procedures (Stage 7B) are needed for more detailed evaluation of the case.

Step 7.5: (As Step 3.3 in the Standard Procedure, Stage 3, but for more than one measurement). Using the assigned *a priori* parameter values, an estimate of intake I_i is obtained by dividing the net value $N_i = M_i - P_i$ by the appropriate retention or excretion function. The geometric mean of the value of I_i gives the "best estimate" of intake (see step 5.5). Using the same assigned *a priori* parameter values the committed effective dose is calculated by multiplying the "best estimate" of intake by the appropriate dose coefficient (dose per unit intake).

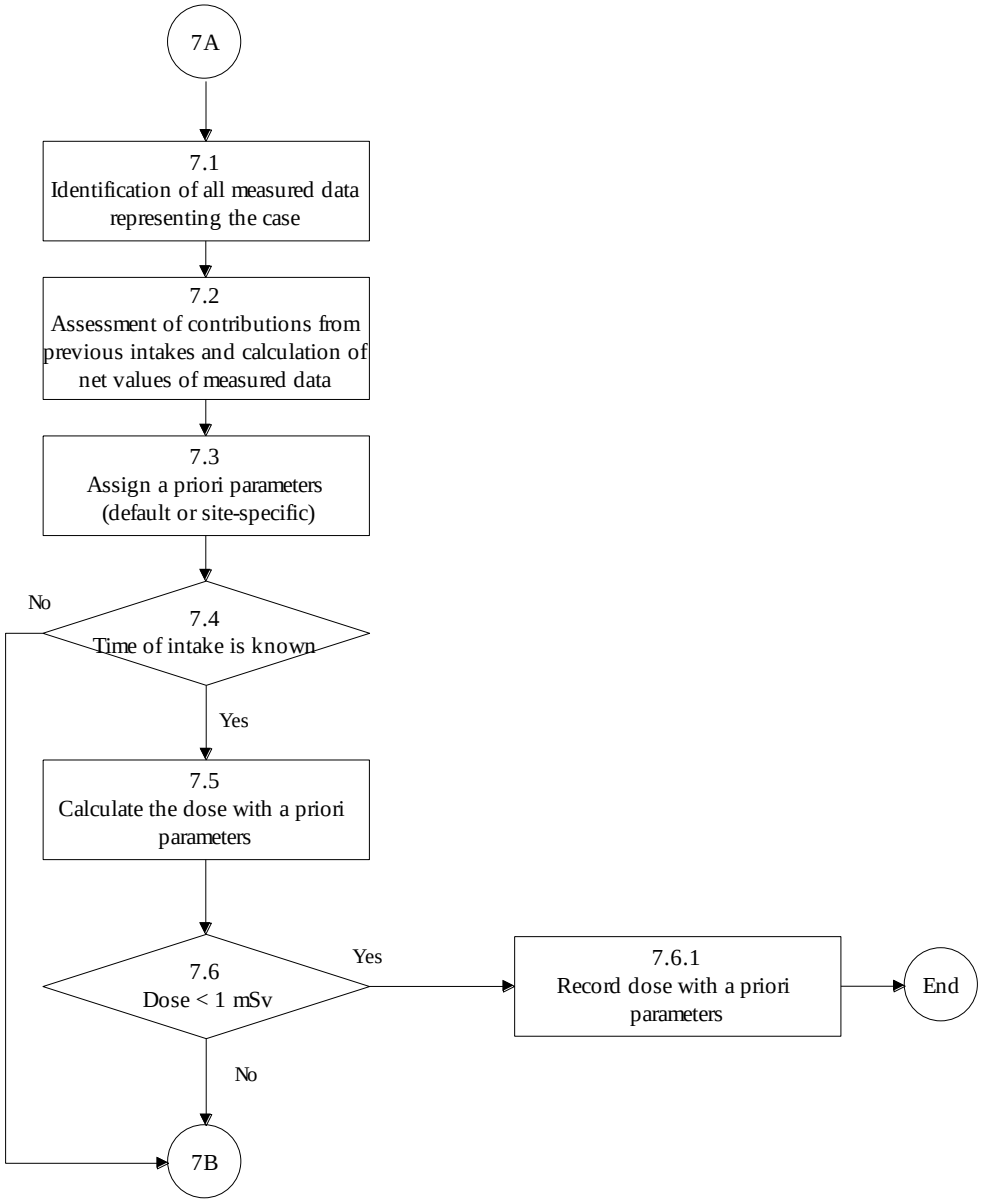


Figure 10.2: Stage 7A. Special procedure for mixed inhalation and ingestion cases above Level 1 – Part 1: simple evaluation using parameter values chosen *a priori.*

Step 7.6: If the effective dose estimated in Step 7.5 is less than 1 mSv, there is no need for further investigation (Step 7.6.1). (The dose from the intake under consideration, rather than the "annual dose" as in Step 3.4, is the criterion, because intakes requiring special assessment procedures should be unusual for any individual worker.) Otherwise further special procedures (Stage 7B) are needed for more detailed evaluation of the case.

Step 7.6.1: The results in terms of intake and committed effective dose from Step 7.6 are recorded together with the corresponding parameter values from Step 7.3.

10.3 Exposure related parameters (stage 7B)

In this Stage, procedures are described for varying (i) the pathway of intake (inhalation versus ingestion), (ii) the absorption Type of the inhaled material, and (iii) the time of intake (if not known), using the measurement data (*a posteriori*). The procedure is very similar to the corresponding

special procedure for mixed inhalation cases (Stage 5B), except that the pathway of intake is an additional variable, and it cannot be varied *a posteriori* as well as the aerosol AMAD (compare Step 7.10 with Step 5.10).

In this Stage, and in Stage 7C that follows, parameter values are selected on the basis of the "fit" of the model predictions to the observations (data). A check on whether the fit is adequate is used to decide whether to stop the evaluation, or to go on to further Steps. A measure of the "Goodness of fit" (GOF) and the criteria for deciding that the fit is good enough are therefore critical issues. There may be conflict between "harmonisation" and "accuracy". Generally the better the data (quality and quantity) the more likely it is that a statistical test will show that the data are inconsistent with the model. If the data are poor it is more likely that the model will fit – in the extreme case of a single measurement any model will fit. It is therefore important that there should be sufficient data available for assessment of a significant dose, and the higher the dose, the better the data should be. Proposals are therefore made for the minimum amounts of data that would be acceptable ("sufficient", see Section 6.5).

As seen in the flow chart, there are two main alternative routes through this Stage of the process, according to whether or not the time of intake is known.

Step 7.7: Are there are sufficient data? As noted in the introduction, criteria for the "sufficient" number (and types) of relevant data, duration of monitoring etc, are proposed according to the dose. In this Step, the numbers for the range 1 mSv <Dose <6 mSv are appropriate (Section 6.5), because a Special procedure is generally initiated on the assumption that the dose could exceed 1 mSv, and doses greater than 6 mSv are considered in Steps 7.11.2 and 7.12.2 below.

Step 7.7.1: Get additional dose relevant data. This assumes that the evaluation is being carried out in real time, so that the opportunity exists to obtain more measurements if those available are insufficient. (For historical cases, where it is not possible to obtain more measurements, it should be recorded that the data are insufficient, and therefore the result should be treated with caution.) When the additional data have been obtained, a simple re-evaluation as in Stage 7A is made.

Step 7.8**:** Is the time of intake known? As noted in the introduction, there are two main alternative routes through this Stage of the process, according to whether or not the time of intake is known. Generally, Special Procedures follow from an identified incident for which the time is known: Steps 7.9 to 7.11, and if necessary 7.13 are followed. However, previously unidentified intakes are sometimes found through e.g. routine monitoring, and so the time of intake is unknown, or known only to be within a certain interval. Step 7.12 and if necessary 7.14 are followed, but provide less opportunity for *a posteriori* characterisation of the material. If the early bioassay data are not decreasing with time then, in practice, it is difficult to estimate the time of intake. In such cases it is recommended to assume the time of intake as being the mid-point of the monitoring interval.

Step 7.9**:** Are early lung and faeces data available? During the first few days after an accidental inhalation intake of a relatively insoluble material (Type M or Type S) most of the activity will be in the respiratory tract, or cleared through the alimentary tract to the faeces. In the event of such an incident with potential for a significant intake it would therefore be expected that if feasible, measurements of lung and faeces would be made. If the AMAD is well known *a priori* for the exposure situation, and if both the cumulative faecal excretion over the first few days, and a measurement on which the initial lung deposit can be estimated are available, then an estimate can be made of the effective pathway of intake, i.e., the fractions of the intake via inhalation and ingestion (Step 7.10).

Step 7.10**:** Derive effective pathway of intake from early lung and faeces data. Suppose that the AMAD is well known from measurements of the activity-size distribution in the workplace, and it is considered that inhalation was accompanied by ingestion (e.g. from measurements of external contamination or high faecal excretion).

If early lung retention and faecal excretion data are available, it is possible to derive an "effective" fraction inhaled in the same way as the effective AMAD was derived in Stage 5B. If the fraction inhaled is F_{inh}, then the fraction ingested is 1 – F_{inh}. At 3 days after inhalation, the fractions of inhaled activity in lungs and cumulative faecal excretion are F_L and F_{finh}. At 3 days after ingestion, the fraction of ingested activity in cumulative faecal excretion is F_{fing}. Then the ratio of activity in lungs to that in cumulative faecal excretion is:

$$R\left(\frac{L}{F}\right) = \frac{F_{inh} \cdot F_L}{\left[F_{inh} \cdot F_{finh} + \left(1 - F_{inh}\right)F_{fing}\right]}$$

For example, for ^{241}Am, F_{fing} = 86.8% at 3 days. F_L and F_{finh} are as follows for 1 and 5 µm AMAD Types M and S:

Table 10.1: *Fraction of inhaled activity in lungs at 3 days and cumulative faecal excretion over 1 to 3 days for ^{241}Am. (Values of F_{finh} and F_L can be obtained from tables published by C. Potter [Potter 2002] or can be calculate with IMBA software [Birchall 2003]).*

AMAD, µm	Type	F_L (%)	F_{finh} (%)
1	M	10.5	18.6
1	S	11.8	19.6
5	M	5.5	34.4
5	S	6.2	36.1

Using these values, the dependence of the ratio of lung activity to faecal excretion on fraction inhaled is shown in Figure 10.3.

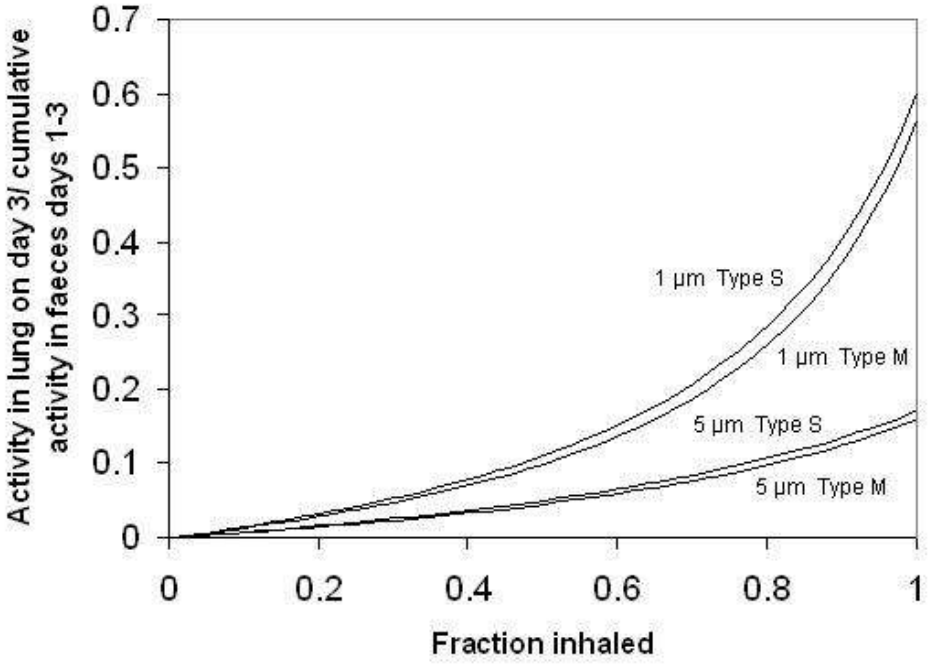


Figure 10.3: Variation with fraction inhaled of the ratio of ^{241}Am lung activity at 3 days after inhalation, to cumulative activity in faeces from 1 to 3 days predicted by the HRTM for a Reference Worker.

For example, when the ratio lung activity to cumulative faecal excretion amounts to 0.1, the fraction of ^{241}Am activity inhaled can be estimated at approximately 0.5 for material having particle size distribution with AMAD= 1 µm, independently from the absorption type, and at approximately 0.9 for material with AMAD = 5 µm.

Step 7.11: Assessment of dose by fitting the absorption type. At this step the AMAD has been determined (*a priori*) and fraction inhaled has either been chosen by default (Step 7.3) or derived *a posteriori* (Step 7.10). The other main characteristic of the inhaled material is the absorption type. An *a priori* assignment of the absorption type has been made in Step 7.3 above according to the ICRP OIR Document or to the ICRP Publication 68 recommendations based on what is known of the chemical form of the inhaled material. A check is made on the Goodness of fit (Step 7.11.1) using this default absorption type. If it is acceptable, then the dose is calculated with the same model parameter values that were assumed in the assessment of intake and the process moves to Step 7.11.2 etc. If it is not, then other absorption types are tried, as follows.

The ICRP default absorption types for particulate materials: F (fast), M (moderate) and S (slow) each represent very wide ranges of absorption rates. There can be large differences between the actual absorption behaviour of a material and that assumed for the default to which it is assigned, which can greatly affect lung retention and urinary excretion. Evaluations are therefore made assuming each of the other default types available for that element. In each case a check is made on the Goodness of fit (Step 7.11.1). If the fit is acceptable, then the dose is calculated with the same model parameter values that were assumed in the assessment of intake and the process moves to Step 7.11.2 etc. (If more than one absorption type fits, the one giving the best fit is chosen (i.e. that for which the p-value is greatest while the second "by eye" criterion is fulfilled).

Step 7.11.1: Is the Goodness of fit acceptable? If the goodness of fit is acceptable (i.e. the fit obtained is not rejected by the specified criteria) then the estimated intake is taken as the best estimate (Section 6.3). Otherwise further special procedures (Step 7.13 onwards) are needed for more detailed evaluation of the case.

Step 7.11.2: Is the dose less than 6 mSv? If the effective dose estimated in Step 7.11 is less than 6 mSv, there is no need for further investigation (Step 7.11.3). Otherwise further special procedures (Step 7.11.4 onwards) are needed for more detailed evaluation of the case.

Step 7.11.3: The results in terms of intake for each pathway and committed effective dose from Step 7.11 are recorded together with the corresponding parameter values from Step 7.11.

Step 7.11.4: Check that there are sufficient data, and get more if necessary. This is similar to Steps 7.7 and 7.7.1. Criteria for the "sufficient" number (and types) of relevant data, duration of monitoring etc, are proposed according to the dose. In this Step, the numbers for Dose > 6 mSv are appropriate (Section 6.5).

To get additional dose relevant data assumes that the evaluation is being carried out in real time, so that the opportunity exists to obtain more measurements if those available are insufficient. When the additional data have been obtained, further special procedures (Step 7.13 onwards) are needed for more detailed evaluation of the case. (For historical cases, where it is not possible to obtain more measurements, it should be recorded that the data are insufficient, and therefore the result should be treated with caution.)

Step 7.12: Assessment of dose by simultaneous fitting of the time of intake and the pathway of intake (fraction inhaled). As can be seen this Step is reached through Step 7.8 when the time of intake is unknown. At this Step the AMAD has been determined according to the information available: default 5 µm AMAD or *a priori* characterisation. Similarly, an *a priori* assignment of the absorption Type has been made in Step 7.3 above according to the ICRP OIR Document or to the ICRP Publication 68 recommendation based on what is known of the chemical form of the inhaled material.

A check is made on the Goodness of fit (Step 7.12.1) using this default absorption Type, default pathway of intake (Step 7.3) and the default time of intake. (As in Step 3.2: Mid-point of the monitoring interval, i.e. the mid-point of the time range between the date of the measurement being considered and the date of either the previous measurement or the beginning of monitoring). If the fit is acceptable, then the dose is calculated with the same model parameter values that were assumed in the assessment of intake and the process moves to Step 7.12.2 etc. If it is not, then other times of intake and values of fraction inhaled are tried, as follows.

Evaluations are made, for several times of intake spanning the period of possible intake, and for several values of the fraction inhaled. In each case a check is made on the Goodness of fit (Step 7.12.1).

If an acceptable fit is found, it is likely that acceptable fits will be found for a range of times of intake and a range of fractions inhaled. Therefore the combination of time of intake and fraction inhaled giving the best fit is chosen. The dose is calculated with the same model parameter values that were assumed in the assessment of intake and the process moves to Step 7.12.2 etc.

Step 7.12.1: Is the Goodness of fit acceptable? If the goodness of fit is acceptable (i.e. the fit obtained is not rejected by the specified criteria) then the estimated intake is taken as the best

estimate (Section 6.3). Otherwise further special procedures (Step 7.14 onwards) are needed for more detailed evaluation of the case.

Step 7.12.2: Is the dose less than 6 mSv? If the effective dose estimated in Step 7.12 is less than 6 mSv, there is no need for further investigation (Step 7.12.3). Otherwise further special procedures (Step 7.12.4 onwards) are needed for more detailed evaluation of the case. The same applies, if the effective dose estimated in Step 7.12 is more than 3 mSv and if there are other intakes in that year resulting in an effective dose of more than 3 mSv.

Step 7.12.3: The results in terms of intake and committed effective dose from Step 7.12 are recorded together with the corresponding parameter values from Step 7.12.

Step 7.12.4: Check that there are sufficient data, and get more if necessary. This is similar to Steps 7.7 and 7.7.1. Criteria for the "sufficient" number (and types) of relevant data, duration of monitoring etc, are proposed according to the dose (Section 6.5). In this Step, the numbers for Dose > 6 mSv are appropriate.

To get additional dose relevant data assumes that the evaluation is being carried out in real time, so that the opportunity exists to obtain more measurements if those available are insufficient. (For historical cases, where it is not possible to obtain more measurements, it should be recorded that the data are insufficient, and therefore the result should be treated with caution.) When the additional data have been obtained, further special procedures (Step 7.14 onwards) are needed for more detailed evaluation of the case.

Step 7.13: Assessment of dose by fitting a mixture of default absorption types (F, M, S) and the pathway of intake (fraction inhaled). This is an extension of Step 7.11, to give greater flexibility in fitting by considering a mixture of absorption types and by varying the fraction inhaled (unless it has been determined in Step 7.10).

This Step may have been reached through Step 7.11.1, because an acceptable fit was not obtained with any single absorption type. If the fraction inhaled was determined in Step 7.10 then mixtures of absorption Types should be tried by inspection, trial and error etc. If more than one fits (Stage 7C Step 7.15), the mixture of absorption types giving the best fit is chosen. (i.e. that for which the p-value is greatest while the second "by-eye" criterion is fulfilled)

Alternatively, this Step may have been reached through Steps 7.11.1 and 7.11.2, because the estimated dose is > 6 mSv, and more data may have been obtained. If so then as much of the procedure as necessary should be repeated: evaluate using in turn: the *a priori* default absorption type; another absorption type; and a combination of absorption types, until an adequate fit is obtained.

If the fraction inhaled was not determined in Step 7.10 because of insufficient relevant information, and an acceptable fit was not obtained with the default fraction inhaled (Step 7.3), evaluations are made for a range of mixtures of absorption types and for several values of the fraction inhaled. In each case a check is made on the Goodness of fit (Step 7.12.1). If an acceptable fit is found it is likely that acceptable fits will be found for a range of mixtures of absorption types and a range of fractions inhaled. Therefore the combination of the mixture of absorption types and fraction inhaled giving the best fit is chosen (i.e. that for which the p-value is greatest while the second "by-eye" criterion is fulfilled).

Figure 10.4: Stage 7B. Special procedure for mixed inhalation and ingestion cases above Level 1 – Part 2: Variation of the absorption Type and the ratio inhalation/ingestion, and also the time of intake, if not known.

Step 7.14: Assessment of dose by simultaneous fitting of the time of intake, a mixture of default absorption Types (F, M, S) and the pathway of intake (fraction inhaled). This is an extension of Step 7.12, to give greater flexibility in fitting by considering a mixture of absorption types as well.

This step may have been reached through Step 7.12.1, because an acceptable fit was not obtained with any time of intake and fraction inhaled. In that case other absorption types and combinations of absorption types should be tried.

Evaluations are made, for several times of intake spanning the period of possible intake, for several values of the fraction inhaled, and each of the other default types available for that element (as in Step 7.11). In each case a check is made on the Goodness of fit (Stage 7C Step 7.15). If an

acceptable fit is found, it is likely that acceptable fits will be found for a range of times of intake, and a range of fractions inhaled. Therefore the combination of the time of intake, the absorption type, and the fraction inhaled giving the best fit is chosen (i.e. that for which the p-value is greatest while the second "by-eye" criterion is fulfilled).

If no adequate fit is obtained then evaluations are made: for several times of intake spanning the period of possible intake, for several values of the fraction inhaled, and for mixtures of absorption type. In each case a check is made on the Goodness of fit (Stage 7C Step 7.15).

If an acceptable fit is found, it is likely that acceptable fits will be found for a range of times of intake, and a range of fractions inhaled. Therefore the combination of the time of intake, the mixture of absorption Types, and the fraction inhaled giving the best fit is chosen (i.e. that for which the p-value is greatest while the second "by eye" criterion is fulfilled).

Alternatively, this step may have been reached through Steps 7.12.1 and 7.12.2, because the estimated dose is > 6 mSv, and more data may have been obtained. If so then as much of the procedure as necessary should be repeated until an adequate fit is obtained. Evaluate using in turn: (i) the *a priori* default time of intake, default absorption type, and fraction inhaled; (ii) variable time of intake and fraction inhaled with default absorption type (repeat of Step 7.12); and (iii) variable time of intake, different absorption type, and fraction inhaled, (iv) variable time of intake, combination of absorption types, and fraction inhaled.

Step 7.15: Is the goodness of fit acceptable? If the goodness of fit is acceptable (i.e. the fit obtained is not rejected by the specified criteria) then the estimated intake is taken as the best estimate (Section 6.3). The effective dose is then calculated with the same model parameter values that were assumed in the assessment of intake. However if the fit is rejected then proceed to next (Step 7.16).

10.4 Advanced evaluation (stage 7C)

In this Stage, an advanced evaluation is carried out. It applies to cases where there are comprehensive data available. The fundamental approach is that the model parameter values are adjusted systematically, in a specific order, until the goodness of fit is acceptable (i.e. the fits obtained to all the data are not rejected by the specified criteria). If the fit is acceptable then the estimated intake is taken as the best estimate and the effective dose is calculated with the same model parameter values that were assumed in the assessment of intake. These results (intake and committed effective dose) are then recorded together with the corresponding parameter values (Step 7.15.1). Thus after each Step in which a parameter value is varied (7.17 to 7.22) there is a corresponding Step (7.17.1 to 7.22.1 respectively) to test the goodness of fit. Since these are all very similar to Step 7.15, explanatory text is not given.

By the start of this Stage the pathway of intake (fraction inhaled) might have been determined from early lung and faecal data (Step 7.10), in which case it should not be altered here. If not, it will have been assessed by simultaneous fitting of the model to the data with the time of intake and/or a mixture of absorption Types (Step 7.13 or 7.14). In that case, if any of the parameter values are changed in the Steps below, the fraction inhaled should be re-assessed.

Similarly, if the time of intake is unknown, then by the start of this Stage it may have been assessed, based on simultaneous fitting of the model to the data with the fraction inhaled and/or a mixture of absorption Types (Step 7.12 or 7.14). In that case, if any of the parameter values are changed in the Steps below, the time of intake should be re-assessed.

It is recommended, in cases where multiple types of bioassay data sets are available, that the intake and dose are assessed by fitting predicted values to the different types of data simultaneously.

Step 7.16: Determine specific HRTM absorption parameter values. For materials that are moderately to very insoluble (typically absorption Types M or S), determine specific values for f_r and s_s by fitting f_r, s_s and intake to the data with s_r fixed at the value recommended in the ICRP OIR Document or in the ICRP Publication 68. For most materials there is no evidence for binding to the respiratory tract so the bound fraction f_b is taken to be zero. However, if relevant values of s_r and/or of f_b and s_b have been determined from *in vivo* experimental data then use these values.

Step 7.17: Determine specific f_A or, in absence of indication; f_1 value. Bear in mind that it is possible to have different f_A / f_1 values for inhalation and ingestion of the same compound, e.g. default values for some uranium and plutonium compounds: compare the forthcoming ICRP OIR Document and/or the ICRP Publication 68, Annexes E and F.

Step 7.18: Determine specific HRTM particle transport values. The parameter values that describe particle transport from the respiratory tract in the HRTM were based so far as possible on human experimental data, which enable typical lung clearance rates to be determined for a year or so after particle deposition in the lungs. However, the values were chosen to be average values for healthy non-smokers. The experimental data from which they were derived show considerable inter-subject variation even among healthy subjects, and indicate that clearance would generally be slower in smokers and patients with lung disease ICRP Publication 66 (ICRP 1994). If there are comprehensive lung and/or faecal excretion data available, it may be necessary to vary particle transport rates to improve the fits to the data.

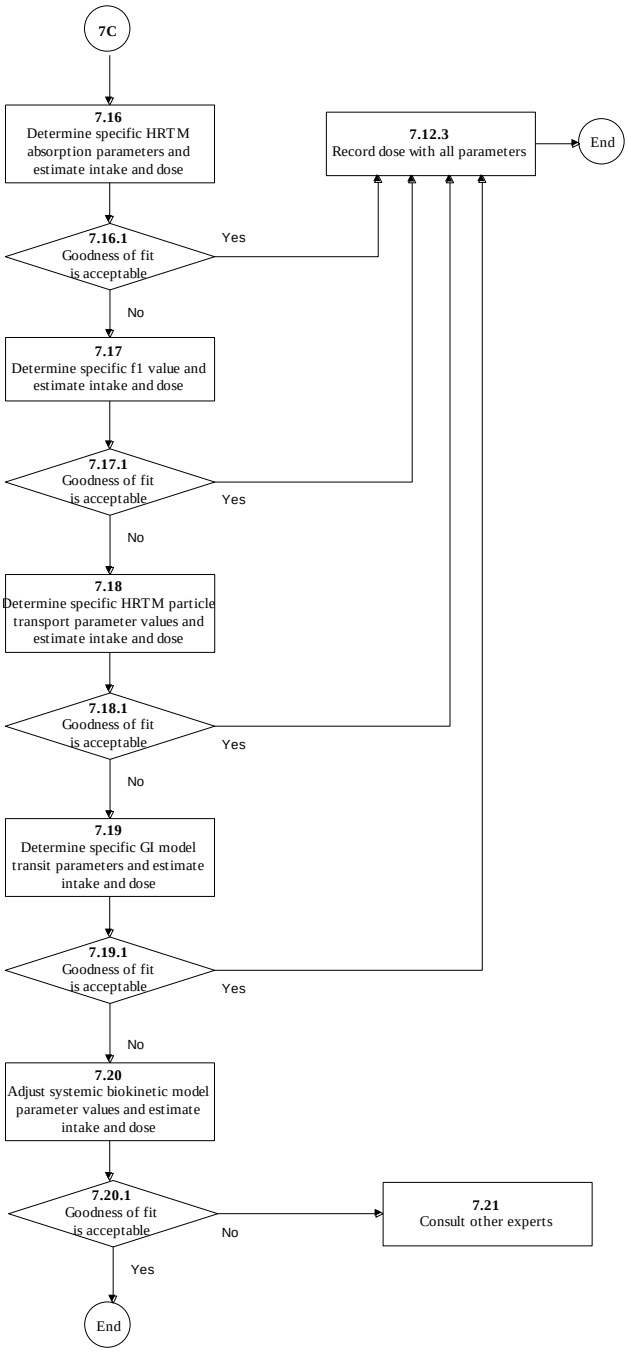


Figure 10.5: Stage 7C. Special procedure for mixed inhalation and ingestion cases above Level 1 – Part 3: More sophisticated evaluation with systematic adjustment of model parameter values.

It should be noted that adjusting particle transport rates also affects the amount absorbed into blood, because clearance from the lung is competitive between absorption into blood and particle transport to the alimentary tract. Thus in some cases it is necessary to readjust HRTM absorption parameter values (i.e. repeat Step 7.16) after varying the particle transport rates.

Step 7.19: Determine specific alimentary tract transit parameter values. The parameter values in the ICRP alimentary tract model – HATM again represent typical values, and there will be considerable inter- (and intra-) subject variations. The transit time through the GI tract affects the amount in the whole body and the amount excreted in the faeces within the first few days

following inhalation or ingestion. If there are comprehensive early data it may be necessary to alter the alimentary tract model parameter values to obtain a reasonable fit to the data.

Step 7.20: Adjust systemic biokinetic model parameter values. Again, model parameters values were derived by ICRP to represent population averages, and there are likely to be individual variations, which will result in differences between predicted values and data, independently of the biokinetics of the respiratory or alimentary tract. This might well arise for very soluble materials or for actinides where individual differences from model predictions might be observed either for retention in liver and skeleton, or in the ratio between deposition in such organs and urinary excretion.

It is emphasised that this is the last Step, so adjusting the systemic biokinetic model parameter values should only be considered after varying the HRTM and HATM parameter values, (Steps 7.16, 7.17, 7.18, and 7.19). If the goodness of fit test results in the fit being rejected according to the specified criteria then consult other experts. Otherwise the results (intake and committed effective dose) are then recorded together with the corresponding parameter values (Step 7.15.1).

11.Wound (Stage 8)

11.1 Introduction

The following flow charts are introduced inside the structured approach of the IDEAS Guidelines to account for the case when a wound contamination requires a special evaluation. Stage 8A relates to the evaluation using a default model category known *a priori*, stage 8B is related to the systematic search of a default category which best fits the excretion data, and stage 8C considers a mixture of two default retention categories which fits the excretion data.

Appropriate dose coefficients for intake through wound are not provided by the ICRP. They may be calculated applying both the wound model of NCRP (2006) and ICRP biokinetic and dosimetric models with the appropriate software. However, it can be shown that injection dose coefficients, corresponding to direct transfer through skin, provide a fairly good approximation of wound dose coefficients, except in the case of fragments (Ishigure 2007, Toohey 2011). Even in case of fragment, applying an injection dose coefficient to a wound intake would result in a conservative estimate of the committed effective dose. So the use of injection dose coefficients (NCRP 2006, IAEA 2004, and forthcoming ICRP OIR Document) is recommended when dedicated software is not available.

11.2 Assignment of one default category

Stage 8A

In this stage, a simple evaluation is carried out using parameter values chosen *a priori*: before the evaluation (see Figure 11.1). The procedure is very similar to the "Standard procedure" (Stage 3). The main difference is that in a special procedure there should be more than one measurement.

Step 8.1: Identification and preparation of measurement data representing the case. It is expected that there will be more than one measurement available for a special assessment (M_i for i = 1 to n). It is therefore important that realistic uncertainties are assigned to the data ("scattering factor", SF, Step 2.1). There may be more than one type of measurement (urine, faeces, etc), and there may be measurements of more than one radionuclide involved in the exposure. Usually for wound incident the time of intake is known.

Step 8.2: Assessment of contribution of previous intakes. The contributions (P_i) from all previous intakes of the radionuclide considered are calculated, taking into account all pathways of intake and all intakes of mixtures where the radionuclide was involved. The net values ($N_i = M_i - P_i$) of the radionuclide are calculated by subtracting P_i from the measured value M_i.

Step 8.3: Assign *a priori* parameters according to the suitable NCRP wound model category. A NCRP wound category should be assigned and the relative default parameter values should be assumed. Choose the NCRP category on the basis of the behaviour in time of the monitored quantity (e.g. daily urinary excretion). For example, for plutonium isotopes, choose "Soluble Strong" for decreasing urinary excretion behaviour; for nearly constant excretion behaviour use "Colloid". For daily urinary excretion increasing during time, use "Particles" or "Fragment" category.

Step 8.4: Calculate dose with a priori parameters. Using the assigned *a priori* parameter values, an estimate of wound deposited activity I_i is obtained by dividing the net value $N_i = M_i - P_i$ by the appropriate excretion function calculated by linking the NCRP wound model with the suitable

systemic model. Use the equations presented in Step 5.5 from Stage 5A. Using the same assigned *a priori* parameter values (both for wound and systemic models) the committed effective dose is calculated by multiplying the "best estimate" of the initial wound activity by the appropriate dose coefficient (dose per unit initial wound activity). For ^{239}Pu the dose coefficient for intravenous injection may be applied to every NCRP category with a fairly conservative approximation, except for the category "Fragments".

Step 8.5: If the committed effective dose estimated in Step 8.4 (from the intake under consideration and taking into account all available monitoring data) is less than 1 mSv, there is no need for further investigation (Step 8.5.1). Otherwise further special procedures (Stage 8B) are needed for more detailed evaluation of the case.

Step 8.5.1: The results in terms of wound deposited activity and committed effective dose from Step 8.4 are recorded together with the corresponding parameter values of the NCRP wound category (from Step 8.3).

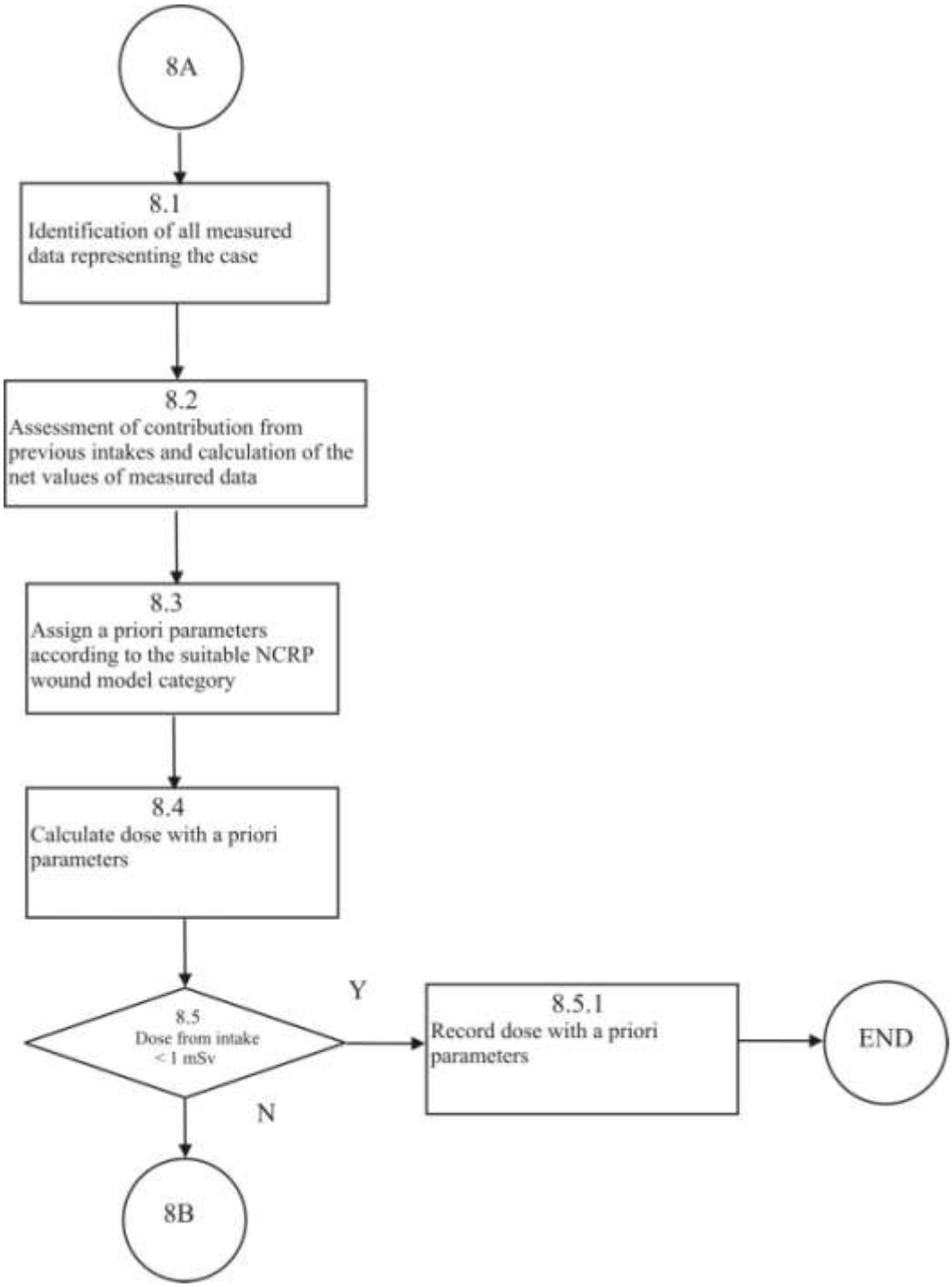


Figure 11.1: Stage 8A. Special procedure for wound cases above Level 1 – Part 1: simple evaluation using parameter values chosen *a priori*.

11.3 Fit of default categories

Stage 8B

In this stage, a procedure is described for trying to fit the data for different NCRP default categories and comparing them to the measured data (Figure 11.2). If an acceptable fit is not obtained with the assigned parameter values, a mix of default categories could be tried in Stage 8C (Figure 11.3).

In this Stage 8B, and in Stage 8C that follows, NCRP wound categories are selected or mixed, and the dose assessment is evaluated on the basis of the "fit" of the model predictions to the observations (data). A check on whether the fit is adequate is used to decide whether to stop the evaluation, or to go on to further steps. A measure of the "Goodness of fit" and the criteria for deciding that the fit is good enough are therefore critical issues. It is important that there should be sufficient data available for assessment of a significant dose, and the higher the dose, the better the data should be. Proposals are therefore made for the minimum amounts of data that would be acceptable (Section 6.5).

Step 8.6: Are there sufficient data? Criteria for the "sufficient" number (and types) of relevant data, duration of monitoring etc., are proposed according to the dose (Section 6.5). In this step, the numbers for the range 1 mSv < Dose < 6 mSv are appropriate.

Step 8.7: Get additional dose relevant data. This assumes that the evaluation is being carried out in real time, so that the opportunity exists to obtain more measurements if those available are insufficient. (For historical cases, where it is not possible to obtain more measurements, it should be recorded that the data are insufficient, and therefore the result should be treated with caution.) When the additional data have been obtained, a simple re-evaluation from Stage 8A is made.

Step 8.8: Assume NCRP "Soluble Weak" category. This is the first step for the systematic evaluation of the different default categories as indicated by NCRP. In this step the values of the measured quantity (e.g. daily urinary excretion) per unit deposited activity in wound, for the default NCRP category linked with the suitable systemic model, must be calculated.

Step 8.9: Calculate dose with NCRP default category parameter. By means of the values calculated in Step 8.8 an estimate of the deposited activity in wound is performed also using the equations presented in Step 5.5 from Stage 5A. The committed effective dose is evaluated via the dose coefficient. (see also note on ^{239}Pu on Step 8.4).

Step 8.10: Is the goodness of fit acceptable? If the goodness of fit is acceptable (i.e. the fit obtained is not rejected by the specified criteria, Section 6.3) go to Step 8.11. The estimated deposited activity is taken as the best estimate. Otherwise go to Step 8.12 to begin the iterative process to try other different NCRP wound categories.

Step 8.11: Is the dose less than 6 mSv? If the effective dose estimated in Step 8.9 is less than 6 mSv, there is no need for further investigation (Step 8.11.1). Otherwise further special procedures are needed (Stage 8C).

Step 8.11.1: Record dose with all parameters. The results in terms of wound deposited activity and committed effective dose from Step 8.9 are recorded together with the corresponding parameter values.

Step 8.12: Try another NCRP default category. Iteratively set the NCRP wound model to "Soluble Moderate", "Soluble Strong", "Soluble Avid", "Colloid", "Particle" and "Fragment". Use the default parameter values.

Step 8.13: Already tried all NCRP default categories? If no, go back to Step 8.9 to calculate dose with a new default category. Otherwise, when all the 7 categories have been already evaluated, go to Stage 8C.

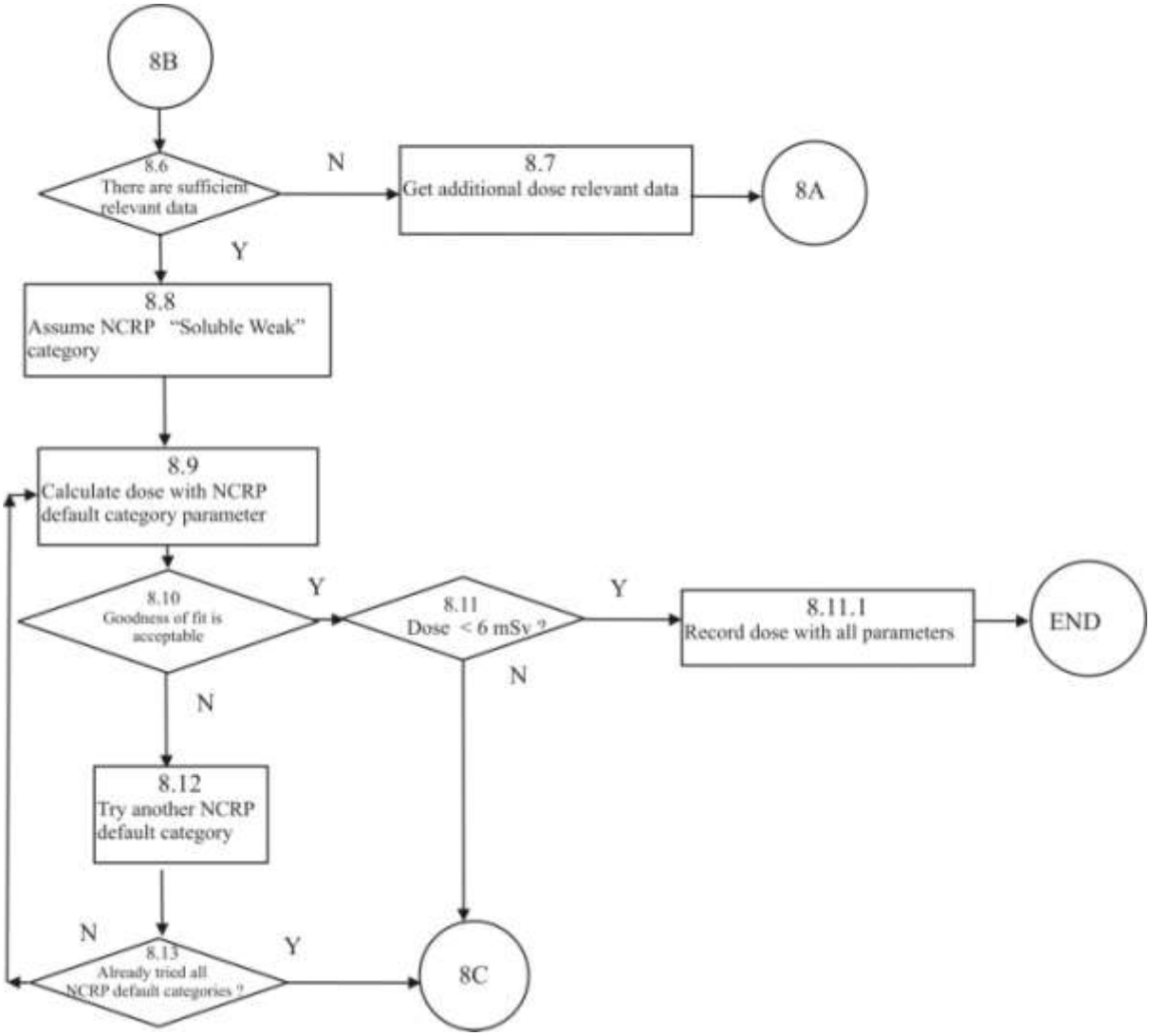


Figure 11.2: Stage 8B: Special procedure for wound cases above Level 1: Part 2 Evaluation by means of different NCRP default categories.

11.4 Mix of two categories

Stage 8C

The stage 8C may have been reached through Step 8.11 for an accepted fit with committed effective dose greater than 6 mSv or after having tried all the 7 default categories for the NCRP wound model. In this stage the bioassay calculated values per unit deposited activity are calculated by linearly combining the different bioassay values related to the different NCRP wound categories using the same systemic model.

Step 8.14: Check the number of data required for evaluation at this level and get more data, if necessary. This is similar to Step 8.7. Criteria for the "sufficient" number (and types) of relevant data,

duration of monitoring etc., are proposed according to the dose level (Section 6.5). In this step, the numbers for Dose > 6 mSv are appropriate.

To get additional dose relevant data assumes that the evaluation is being carried out in real time, so that the opportunity exists to obtain more measurements if those available are insufficient. (For historical cases, where it is not possible to obtain more measurements, it should be recorded that the data are insufficient, and therefore the result should be treated with caution.) When the additional data have been obtained, further special procedures (Step 8.15 onwards) are needed for more detailed evaluation of the case.

Step 8.15: Assessment of dose by fitting a mixture of two "Soluble" categories. This is an extension of Step 8.9, to give greater flexibility in fitting by considering a mixture of NCRP soluble categories. This step may have been reached through Step 8.13, because an acceptable fit was not obtained with any NCRP default category. In that case combinations of NCRP categories should be tried by inspection, trial and error etc. Use at a turn a mixture of "Soluble" categories: "Weak + Moderate", "Moderate + Strong", "Strong + Avid". If more than one mixture of NCRP categories fits the data, the mixture which gives the best fit is chosen (i.e. that for which the P-value is greatest while the second "by eye" criterion is fulfilled).

Alternatively, this step may have been reached through Step 8.11 because the estimated dose is > 6 mSv. In that case begin the evaluation using the NCRP category which provides the good fit in Step 8.10 and increase the relative fraction of another category, beginning with no contribution.

Step 8.16: Is the Goodness of fit acceptable? If the goodness of fit related to a certain mixture of categories is acceptable (i.e. the fit obtained is not rejected by the specified criteria) go to Step 8.16.1, for the record of the dose with all parameters. Otherwise go to Step 8.17. If more fitting are accepted by the indicated criteria use as best estimate that which provides the highest P-value based on χ_0^2, while the second "by eye" criterion is fulfilled.

Step 8.16.1: Record dose with all parameters. The results in terms of wound deposited activity and committed effective dose from Step 8.15 are recorded together with the corresponding parameter values.

Step 8.17: Assessment of dose by fitting a mixture of other NCRP categories as indicated. This is an extension of Step 8.15, to give greater flexibility in fitting by considering a mixture of NCRP insoluble categories. Use at a turn a mixture of these categories: "Soluble strong + Colloid", "Colloid + Particle", "Particle + Fragment". If more than one mixture of NCRP categories fits the data, the mixture which gives the best fit is chosen.

Step 8.18: Is the Goodness of fit acceptable? If the goodness of fit related to a certain mixture of categories is acceptable (i.e. the fit obtained is not rejected by the specified criteria) go to Step 8.18.1 for the record of the dose with all parameters. Otherwise go to Step 8.19.

Step 8.18.1: Record dose with all parameters. The results in terms of wound deposited activity and committed effective dose from Step 8.15 are recorded together with the corresponding parameter values.

Step 8.19: Consult other experts. If it is not possible to fit the data, also by means of mixtures of NCRP default categories, consult other experts.

The flow chart of Stage 8C is reported in Figure 11.3.

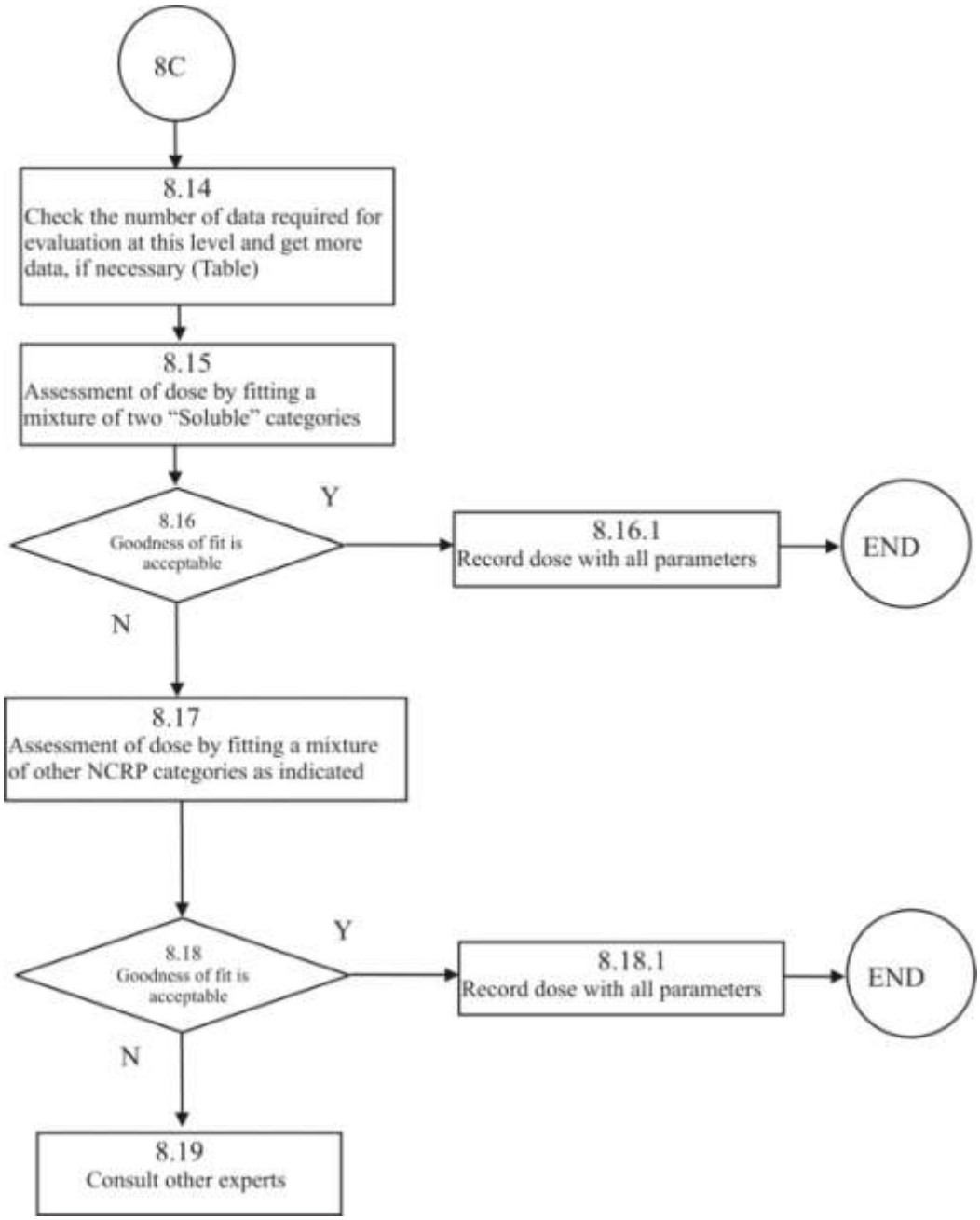


Figure 11.3: Stage 8C: special procedure for wound cases above Level 1 – Part 3: Evaluation performed by means of mixture of default NCRP categories.

12. Special case with direct dose assessment

12.1 Theory

Intakes, equivalent doses and effective doses are calculated with biokinetic and dosimetric models. Specifically, biokinetic models are used to predict bioassay quantities and to calculate the values of $U_S(50)^{(*)}$, i.e. the number of nuclear transformations in 50 years in source region S. The units of $U_S(50)$ are Bq s.

The equivalent dose to a target tissue, T of the Reference Male, H_T^M can be calculated as follows:

$$H_T^M(50) = \sum_S SEE^M(T \leftarrow S)\ U_S(50) \qquad (12.1)$$

where,

$SEE^M(T \leftarrow S)$ is the Specific Effective Energy for the Reference Male, which is the equivalent dose in T per disintegration in source region, S. Units are: Sv per disintegration = Sv $(Bq\ s)^{-1}$.

Knowing the equivalent dose to each of the target tissues of the reference male and reference female the effective dose can be calculated by applying equation 1.1 of Section 1.1.

In special cases, $U_S(50)$ can be determined directly from the measurement data without the use of a biokinetic model, and this is referred to as the direct dose assessment method. In other words, individual biokinetics are taken into account by calculating $U_S(50)$ directly from the measurement data. According to ICRP Publication 103 (ICRP, 2007), the direct dose assessment method should not be used to calculate effective dose as effective dose applies to a reference person and individual reference parameters should not be changed. However, the direct dose assessment is described here, as in some cases it may be seen as an appropriate method for the calculation of dose.

The direct dose assessment method is applicable only if:

- the distribution of activity is uniformly distributed throughout the body as is the case for tritiated water (HTO), or if the activity can be measured in an organ which is the main contributor to effective dose (for example, thyroid for iodine isotopes), and if
- the dose contribution from the decay products is negligible or if the decay products are in equilibrium with the parent nuclide.

If the retention function in the source region S (which may be the total body) can be approximated from measurement results, then $U_S(50)$ can be determined by integration of the retention function:

(*) Although the authors are aware of the new notation introduced by the publication MIRD Pamphlet 21 (MIRD 2009), the notation in the present chapter is based on the indications of ICRP Publication 78. Here the equivalences are reported: $S_w(r_T \leftarrow r_S,t)$ for $SEE(T \leftarrow S)$ and $\tilde{A}(r_S,T_D)$ for $U_S(50)$.

$$U_s(50) = \int_{t_B}^{t_E} A_S(t)\,dt \qquad (12.2)$$

where

t_B, t_E begin and end of the period for which the committed dose is to be calculated

$A_S(t)$ retention function in source region S in Bq

To apply this method, it is necessary to have a sufficient number of measurement results to be able to approximate the retention function A_S. Errors occur in interpolating the data and in extrapolating the data to earlier or later times. If the measurements are frequent then linear interpolation, i.e. using the trapezoidal method, is suggested. Thus, in such cases, the area under the measurement data is approximated by:

$$\int_{t_B}^{t_E} A_S(t)\,dt = \frac{b}{2} \cdot \sum_{i=0}^{n-1} (M_i + M_{i+1}) \cdot (t_{i+1} - t_i) \qquad (12.3)$$

where

M_i is the measured activity (Bq) in source region S at time t_i

t_i is the corresponding measurement time in units of days, ($t_o = t_B$ and $t_n = t_E$)

n is the total number of measurements, and

b is numerical constant converting days to seconds: 86400 s/d

If the dose before the first and after the last measurement is not negligible, these parts of the retention function must be estimated by some assumptions. The retention after the last measurement may be estimated by considering the effective half-time in the source region, if known. Alternatively, a conservative assumption might be to assume only physical decay (and no biokinetic removal from the body) after the last measurement.

In general, this method can only be applied for radionuclides which can be measured by external measurements, for example by a total body counter. However, for some radionuclides the total activity in the body can be assessed by excretion measurement results. Such an example is tritiated water (HTO) for which it is assumed that the activity concentration in total body water is the same as that in urine. In practice, the method is generally only applied to (i) HTO by urine monitoring (ii) soluble forms of caesium by total body monitoring, and to iodine isotopes by thyroid monitoring. However, it is not possible to assess lung doses from lung measurements. This is because the equivalent dose to lung calculated with the HRTM is a weighted mean of the doses to several regions of the respiratory tract and the activity content of these regions cannot be assessed separately by external measurements. In other words, the effective dose cannot be determined directly if the effective dose is dominated by the lung dose.

12.2 Application of direct dose assessment to intakes of tritiated water

Following intakes of tritiated water (HTO), most monitoring programmes consist of measuring the activity concentration of ^{3}H in urine samples. The resulting effective dose from intakes of HTO can be assessed using the direct dose assessment method. This method involves calculating the area under the urine activity concentration data to determine the number of nuclear transformations.

ICRP assumes that HTO is instantaneously translocated to blood following inhalation or ingestion. HTO is assumed to mix rapidly and completely with total body water after its entry to blood. Human studies using deuterium or HTO have confirmed that equilibration of HTO throughout the body water pool is essentially complete within 1 h after intake. For dosimetry purposes, it can be assumed that the activity concentration in urine (Bq/l) equals that of total body water. Thus, the activity in total body equals the activity concentration in urine multiplied by the total volume of body water, which is 42 l for reference man (ICRP, 1975)(†). Finding the area under the activity total body curve then gives the number of nuclear transformations in the total body.

If A_u is the area under the urine activity concentration data (Bq l^{-1} d) from the time of the first intake (t=0) to infinity then the total number of nuclear transformations, U_s is given by:

$$U_s = A_u\ 42\ b \qquad (12.4)$$

where b is a numerical constant converting days to seconds: 86400 s d^{-1}.

The total intake, I can be determined by calculating the total amount of activity lost from the body. The ICRP Publication on the revised reference man (ICRP Publication 89, Table 2.30, ICRP 2002a), gives the total water loss per day as 2.9 l d^{-1} for an adult male. Thus, the total activity lost from the body, which gives the total intake is given by:

$$I = 2.9\ A_u\ Bq \qquad (12.5)$$

The direct dose method does not depend upon a systemic biokinetic model, as U_s is obtained directly by calculating A_u from urine activity concentration data. If the measurements are frequent then linear interpolation, i.e. using the trapezoidal method, is suggested. Thus, in such cases, the area under the measurement data is approximated by:

(†) It is noted that a values of 42.6 l can be calculated for the total volume of body water for reference man based on the values given in ICRP Publication 89 (ICRP, 2002a). The reference value for water content of lean body mass (LBM) in adults is 73% and it is assumed that almost all the body water is contained in the LBM. Typically, LBM represents 80% of total body mass in males by early adulthood. The reference value for the total body mass of adult males is 73 k.g. Therefore, assuming unit density (1 k.g/l) for water, the total volume of body water for reference man is calculated as 73 k.g × 0.8 × 0.73 ÷ 1 k.g/l = 42.6 l. See sections 4.3.1 and 4.3.2 of ICRP Publication 89 (ICRP,2002).

$$\sum_{i=1}^{n-1} \frac{(C_{i+1} + C_i)(t_{i+1} - t_i)}{2} \quad \text{Bq l}^{-1} \text{ d}$$

where:

C_i is the activity concentration of HTO (Bq/l) in urine sample i

t_i is the corresponding measurement time (d) for urine sample i

n is the total number of urine samples.

Generally, if the data cover a time period much greater than the effective half time of HTO in the body (4-18 d) (ICRP,1989) and the last data value is relatively low then the error caused by not extrapolating the data to later times is insignificant. Otherwise, the retention after the last measurement can be estimated by considering a half-time of 10 d in the whole body. The extrapolated area is given by

$C_n \times 10/\ln(2)$ Bq l^{-1} d. (12.6)

In such cases where extrapolation is necessary, the extra dose arising from the intermediated and long term components due to HTO becoming organically bound in the body can also be accounted for. Taylor (2003) proposed a three-component exponential model for retention of HTO with half-times of 10 days (99%), 40 days (0.98%) and 350 days (0.02%). In this model, the extra dose from the bound tritium is only about 5% of that due to circulating HTO. Therefore, to account for the organically bound tritium, the equivalent dose is increased by 5% (i.e. multiplied by 1.05).

Single acute intake

For an acute intake of HTO at a known time, improved estimates of A_u can be obtained by fitting a sum of exponential terms, f(t), to the urine activity concentration data (Bq l^{-1}). However, care must be taken to ensure that the half-times and the coefficients of f(t) are reasonable. For example, the short term component is expected to have a half-time of about 10 days (range from 4-18 days), which accounts for more than about 90% of the effective dose (ICRP,1989).

If the fitted function f(t) is defined as follows:

$$f(t) = \sum_{i=1}^{n} a_i e^{-\lambda_i t} \quad Bq\, l^{-1}$$

where t is time after the acute intake in days, then the intake is given by:

$$I = 42\sum_{i=1}^{n} a_i \quad Bq$$

A_u can be calculated by integrating f(t) between zero and infinity:

$$A_u = \sum_{i=1}^{n} \frac{a_i}{\lambda_i} \quad Bq\,l^{-1}\,d \qquad (12.7)$$

The total number of nuclear transformations, U_s can be determined by substituting A_u into equation (12.4).

Specific Effective Energy for the Reference Male

The values of SEE(T ← WB) for HTO can be calculated for Reference Male assuming ^{3}H is uniformly distributed through the whole body (WB) source region. The value of SEE(T ← WB) for HTO is identical for each target organ and can be calculated as follows:

The average β energy of ^{3}H per nuclear transformation is 5.68 keV = $9.1 \cdot 10^{-16}$ J.

The reference value for the total body mass for adult male is 73 kg (ICRP, 2002a). The mass of the WB source organ is calculate by subtracting the masses of contents of the stomach, small intestine, large intestine, right colon, left colon, rectosigmoid and gall bladder from the total body mass. Using the values in ICRP Publication 89 (ICRP, 2002a) gives WB source organ mass of 72.042 kg for adult male. Taking a value of 1 for the radiation weighting factor for beta radiation gives:

$$\mathrm{SEE}^{\mathrm{M}}(\mathrm{T} \leftarrow \mathrm{WB}) = \frac{9.1\ \ 10^{-16}\ J}{72.042\ kg} = 1.26\ 10^{-17}\ Sv$$

Calculation of equivalent dose and 'effective dose'

For intakes of HTO the equivalent dose to each target organ for an adult male is identical and is obtained by multiplying the number of nuclear transformations, U_s with the SEE^M(T ← WB). This value can also be taken as equal to the 'effective dose' for the individual. In such cases where the urinary activity concentration of HTO is used to assess the dose, the estimated dose is relatively insensitive to the mass of the subject. This arises because the total volume of body water is proportional to the mass of the subject and the SEE^M(T ← WB) is inversely proportional to the mass of the subject. So the product of these quantities is relatively insensitive to the mass of the subject.

13. Examples of case studies

The following examples cases from EURADOS/IAEA Advanced Training COURSE – Prague – 2nd-6th February 2009, have been evaluated using ICRP publication 68 and 78 for numerical values of dose coefficients and bioassay quantities. The aim of these examples is to demonstrate the application of these guidelines for dose assessment. These bioassay quantities and dose coefficients are being revised by ICRP and new values will be published in the Occupational Intakes of Radionuclides (OIR) document series. National regulations will indicate the source of the numerical values that have to be used for internal dose assessment.

13.1 Chronic inhalation of ^{125}I (case ELP1)

Description of the working area

Plant for the production of kit for radioimmunoassay.

Characteristics of work

Production of kit for radioimmunoassay.

Reasons for monitoring; initiating event

Routine monitoring: personnel are monitored by means of thyroid monitoring every 3 months (approx.).

Actions taken

One person begins his work with radioactive material (^{125}I) on 4th May 2006. Throughout this work, no anomalous events were registered.

Additional information

Chemical form

Iodine gas.

Physical characteristics, particle size

Vapours. Air monitoring has been done only for the particulate phase. The data are normally below the limit of detection.

Nose swab, bronchial slime or similar

None

Any intervention used (blocking, chelating, etc.)

None

Body monitoring data

Organ monitoring data

Thyroid activity measurements

Date	Activity of ^{125}I in thyroid (Bq)	Uncertainty due to counting statistics, 1 ☒ (Bq)
31st Jul 2006	4410	± 290
4th Nov 2006	830	± 70
9th Feb 2007	7510	± 540
9th May 2007	5780	± 380
2nd Aug 2007	1900	± 150

Excretion monitoring data

Urine activity measurements

None

Faeces activity measurements

None

Personal Data

Sex

Male

Age

32 years

Weight

67 kg

Other comments relevant for intake and dose estimation

Estimate the intake and the committed effective dose E(50), performing an evaluation only using spread sheets, for the five periods of exposure of the worker.

Moreover, assess the case with the use of at least one of three available software tools.

Provide the evaluation that you consider to be the final one by filling in the following table.

	Period 4th May 2006 – 31st Jul 2006	Period 31st Jul 2006 – 4th Nov 2006	Period 4th Nov 2006 – 9th Feb 2007	Period 9th Feb 2007 – 9th May 2007	Period 9th May 2007 – 2nd Aug 2007
Value of contribution from previous intakes, P (Bq)					
P * SF^2 (Bq)					
P / SF^2 (Bq)					
Date of intake (dd/mm/yy) [if present an intake]					
Intake (Bq)					
E(50) (mSv)					
Final Step of IDEAS Guidelines					

Reference solution of Case ELP1

The case is assessed following the IDEAS Guidelines (GLs). The following tables present, for each flow chart, the description of the items and the indications related to the application of the guidelines to ELP1. The tables provide the relevant step number, the comment and reasons why this step was used and the action performed during the evaluation. The description is responsibility of the reviewer of the evaluation.

Evaluation of 1st monitoring measurement

Step	Indication	Comment	Action performed
1.1	Identify monitoring value	The person begins his work with radioactive material (^{125}I) on 4th May 2006. The first ^{125}I in thyroid measurement has been performed on 31st Jul 2006. The measured activity is 4410 Bq and the uncertainty is 290 Bq.	Go to 1.2
1.2	M < Mc ?	The Mc value has been calculated on the basis of a dose coefficient of 1.4 E-8 Sv/Bq and the retention function in thyroid for 90 days; it is equal to 203 Bq. So M is > Mc.	Go to 1.3

1.3	Above level 0.	Evaluation needed	Go to Stage 2 – Step 2.0
2.0	Understanding the case	On the basis of a m(t) value related to vapor retention of iodine in thyroid for the mid-point of the 1st monitoring period (88 days) and the related dose coefficient an intake of 40 kBq and a value of E(50) = to 0.52 mSv can be calculated.	Go to 2.1
2.1	Assessment of uncertainty on M	From Table 4.8 of GLs a value of 1.25 for SF_B component of the thyroid measurement of ^{125}I has been accepted. The uncertainty of measurement provides a value of SF_A =1.07, therefore the total SF = 1.26.	Go to 2.2
2.2	Contribution from previous intakes	There is no contribution from previous intake: P =0	Go to 2.3
2.3	$M > P * SF^2$?	Yes, as P = 0.	Go to 2.3.1
2.3.1	New intake	There is evidence of a new significant intake. As P =0, N=M.	Go to Stage 3 – Step 3.1
3.1	Routine monitoring ?	Yes.	Go to 3.2
3.2	Identify pathway of intake	Path is inhalation	Go to 3.3
3.3	Assign a priori parameters	Vapor, time of intake = midpoint inside the monitoring period .	Go to 3.4
3.4	Estimate intake and dose	Intake value = 37373 Bq; E(50) = 0.523 mSv.	Go to 3.5
3.5	Dose < 1 mSv	Yes	Go to 3.5.1
3.5.1	Record intake and dose	Intake date: 17/6/2006, Inhalation, vapor, intake = 37373 Bq; E(50) = 0.523 mSv.	End 1st monitoring period

Evaluation of 2nd monitoring measurement

Step	Indication	Comment	Action performed
1.1	Identify monitoring value	The second ^{125}I in thyroid measurement has been performed on 4th November 2006. The measured activity is 830 Bq and the uncertainty is 70 Bq.	Go to 1.2

1.2	M < Mc ?	The Mc value is equal to 207 Bq. So M is > Mc.	Go to 1.3
1.3	Above level 0.	Evaluation needed.	Go to Stage 2 – Step 2.0
2.0	Understanding the case	On the basis of a m(t) value related to vapor retention of iodine in thyroid for the mid point of the monitoring period (96 days) and the related dose coefficient, an intake of 8 kBq and a value of E(50) = 0.11 mSv can be calculated.	Go to 2.1
2.1	Assessment of uncertainty on M	From Table 4.8 of GLs a value of 1.25 for SF_B component of the thyroid measurement of ^{125}I has been accepted. The uncertainty of measurement provides a value of SF_A =1.09, therefore the total SF = 1.27.	Go to 2.2
2.2	Contribution from previous intakes	The contribution from the previous intake is equal to 792 Bq. The value of P * SF^2 =1277 Bq.	Go to 2.3
2.3	M > P * SF^2?	No.	Go to 2.4
2.4	P/SF^2<M< P* SF^2	The value of P/ SF^2 = 492. The condition is verified.	Go to 2.4.l
2.4.1	No new significant intake	There is non new significant intake: I = 0 Bq , E(50) = 0 mSv.	End of 2nd monitoring period

Evaluation of 3rd monitoring measurement

Step	Indication	Comment	Action performed
1.1	Identify monitoring value	The third ^{125}I in thyroid measurement has been performed on 9th Feb 2007. The measured activity is 7510 Bq and the uncertainty is 540 Bq.	Go to 1.2
1.2	M < Mc ?	The Mc value has been calculated on the basis of a dose coefficient of 1.4 E-8 Sv/Bq and the retention function in thyroid for 97 days, is equal to 209 Bq. So M is > Mc.	Go to 1.3
1.3	Above level 0.	Evaluation needed.	Go to Stage 2 – Step 2.0
2.0	Understanding the case	On the basis of a m(t) value related to vapor retention of iodine in thyroid for the mid point of the monitoring period (97 days) and the related dose coefficient an intake of 70 kBq and a value of E(50) = 0.97 mSv can be calculated.	Go to 2.1

2.1	Assessment of uncertainty on M	From Table 4.8 of GLs a value of 1.25 for SF_B component of the thyroid measurement of ^{125}I has been accepted. The uncertainty of measurement provides a value of SF_A =1.07, therefore the total SF = 1.26.	Go to 2.2
2.2	Contribution from previous intakes	The contribution from the previous intake is equal to 140 Bq. The value of P * SF^2 =224 Bq.	Go to 2.3
2.3	M > P * SF^2?	Yes.	Go to 2.3.1
2.3.1	New intake	There is evidence of a new significant intake. N = 7370 Bq.	Go to Stage 3 – Step 3.1
3.1	Routine monitoring ?	Yes.	Go to 3.2
3.2	Identify pathway of intake	Path is inhalation.	Go to 3.3
3.3	Assign a priori parameters	Vapor, time of intake = midpoint inside the monitoring period.	Go to 3.4
3.4	Estimate intake and dose	Intake value = 68239 Bq; E(50) = 0.955 mSv .	Go to 3.5
3.5	Dose < 1 mSv	Yes	Go to 3.5.1
3.5.1	Record intake and dose	Intake date: 22/12/2006, Inhalation, vapor, intake = 68239 Bq; E(50) = 0. 955 mSv.	End of 3rd monitoring period

Evaluation of 4th monitoring measurement

Step	Indication	Comment	Action performed
1.1	Identify monitoring value	The fourth ^{125}I in thyroid measurement has been performed on 9th May 2007. The measured activity is 5780 Bq and the uncertainty is 380 Bq.	Go to 1.2
1.2	M < Mc ?	The Mc value has been calculated on the basis of a dose coefficient of $1.4 \cdot 10^{-8}$ Sv/Bq and the retention function in thyroid for 89 days, is equal to 202 Bq. So M is > Mc.	Go to 1.3
1.3	Above level 0.	Evaluation needed.	Go to Stage 2 – Step 2.0

2.0	Understanding the case	On the basis of a m(t) value related to vapour retention of iodine in thyroid for the midpoint of the monitoring period (89 days) and the related dose coefficient an intake of 50 kBq and a value of E(50) = to 0.70 mSv can be calculated.	Go to 2.1
2.1	Assessment of uncertainty on M	From Table 4.8 of GLs a value of 1.25 for SF_B component of the thyroid measurement of ^{125}I has been accepted. The uncertainty of measurement provides a value of SF_A =1.07, therefore the total SF = 1.26.	Go to 2.2
2.2	Contribution from previous intakes	The contribution from both previous intakes is equal in total to 1530 Bq. The value of P * SF^2 =2436 Bq.	Go to 2.3
2.3	M > P * SF^2?	No.	Go to 2.3.1
2.3.1	New intake	There is evidence of a new significant intake. N = 4250 Bq.	Go to Stage 3 – Step 3.1
3.1	Routine monitoring ?	Yes.	Go to 3.2
3.2	Identify pathway of intake	Path is inhalation	Go to 3.3
3.3	Assign a priori parameters	Vapor, time of intake = midpoint inside the monitoring period.	Go to 3.4
3.4	Estimate intake and dose	Intake value = 36639 Bq; E(50) = 0.513 mSv .	Go to 3.5
3.5	Dose < 1 mSv	Yes	Go to 3.5.1
3.5.1	Record intake and dose	Intake date : 25/3/2007, Inhalation, vapour, intake = 36639 Bq; E(50) = 0.513 mSv	End 4^{th} monitoring period

Evaluation of 5^{th} monitoring measurement

Step	Indication	Comment	Action performed
1.1	Identify monitoring value	The fifth ^{125}I in thyroid measurement has been performed on 2^{nd} August 2007. The measured activity is 1900 Bq and the uncertainty is 150 Bq.	Go to 1.2
1.2	M < Mc ?	The Mc value is equal to 200 Bq. So M is > Mc.	Go to 1.3

1.3	Above level 0.	Evaluation needed	Go to Stage 2 – Step 2.0
2.0	Understanding the case	On the basis of a m(t) value related to vapor retention of iodine in thyroid for the midpoint of the monitoring period (85 days) and the related dose coefficient, an intake of 20 kBq and a value of E(50) = 0.22 mSv can be calculated.	Go to 2.1
2.1	Assessment of uncertainty on M	From Table 4.8 of GLs a value of 1.25 for SF_B component of the thyroid measurement of ^{125}I has been accepted. The uncertainty of measurement provides a value of SF_A =1.08, therefore the total SF = 1.27.	Go to 2.2
2.2	Contribution from previous intakes	The total contribution from the three previous intakes is equal to 1261 Bq. The value of P * SF^2 =2025 Bq.	Go to 2.3
2.3	M > P * SF^2?	No.	Go to 2.4
2.4	P/SF^2<M< P* SF^2	The value of P/SF^2 = 786 Bq. The condition is verified.	Go to 2.4.l
2.4.1	No new significant intake	There is non new significant intake. I = 0 Bq, E(50) = 0 mSv.	End

The final table of the reference evaluation is as follows.

	Period 4th May 2006 – 31st Jul 2006	Period 31st Jul 2006 – 4th Nov 2006	Period 4th Nov 2006 – 9th Feb 2007	Period 9th Feb 2007 – 9th May 2007	Period 9th May 2007 – 2nd Aug 2007
Value of contribution from previous intakes, P (Bq)	0	792	140	1530	1261
P * SF^2 (Bq)		1277	224	2436	2025
P / SF^2 (Bq)		492	88	961	786
Date of intake (dd/mm/yy) [if present an intake]	17/06/06		22/12/06	25/03/07	
Intake (Bq)	37373		68239	36639	

E(50) (mSv)	0.523		0.955	0.513	
Final Step of IDEAS Guidelines	Step 3.5.1.	Step 2.4.1	Step 3.5.1.	Step 3.5.1.	Step 2.4.1

13.2 Acute inhalation of Enriched Uranium (case ELP2)

The event

Characteristics of work

Changing filters on the ventilation system surrounding a foundry handling enriched uranium.

Reasons for monitoring; initiating event

Proper respiratory protection not worn.

Actions taken

A chest measurement was carried out 3 hours after the incident. A program of monitoring was set up that included in-vivo chest measurements and the collection of urine.

Additional information

Chemical form

U_3O_8

Physical characteristics, particle size

Aerosol

Nose swab, bronchial slime or similar

None.

Any intervention used (blocking, chelating, etc.)

None

Body monitoring data

Chest activity measurements

Time of measurement after intake (d)	Activity of ^{235}U in chest, (Bq)	Uncertainty due to counting statistics, (1 σ) (Bq)
0.125	43	±7
7	29	±6
18	26	±6
30	27	±6
60	22	±5

Excretion monitoring data

Urine activity measurements

Time of measurement after intake. (d)	Urinary excretion rate of ^{235}U (Bq/d)
2	1.2E+00
9	2.6E-01
16	3.7E-01
30	1.7E-01
58	1.3E-01

All urine excretion values are affected by a percentage uncertainty due to counting statistics of ±10% (1 σ).

Personal Data

Sex

Male

Age

35 years

Weight

70 kg

Other comments relevant for intake and dose estimation

The urine data are simulated 24 h urine measurements. The activity of ^{234}U and ^{238}U were also measured by alpha spectrometry but are not reported for this exercise. However, the data were consistent with enriched uranium (^{235}U: 3.5% in weight). Assume the isotopic composition given in Table 3.

Previous urinary excretion measurements indicated that uranium excretion due to dietary intakes is less than 0.1 μg d^{-1} of natural uranium.

Estimate the intake of all uranium isotopes and calculate the committed effective dose E(50) arising from each radionuclide and the total value, performing an evaluation only using spread sheets.

Please fill in Tables A and B:

Table A: Assumptions adopted in the evaluation.

AMAD (μm)	
Absorption Type	
f_1 value	
Final step of IDEAS guidelines	

Table B: Assessed intake and committed effective dose for inhalation of enriched uranium.

Isotope	% alpha activity	ratio to U-235	Intake (Bq)	Dose coefficient e(50), (Sv/Bq)	E(50), (mSv)
U-238	14.78	4.28			
U-235	3.45	1.00			
U-234	81.77	23.70			
Total	100	-	-	-	

Supporting tables (as provided to participants):

Table C: Isotopic composition of enriched (3.5 %) uranium

Isotope	% Isotopic composition[a]	% Alpha activity	Alpha activity[b] Bq/g
U-238	96.471	14.78	1.20E+04
U-235	3.5000	3.45	2.80E+03
U-234	0.02884	81.77	6.64E+04
Total alpha activity, Bq/g			8.12E+04
Alpha activity ratio U-234/U-238			5.53
Alpha activity ratio U-235/U-238			0.233

[a] Composition is given as weight % of total U isotopes

[b] Alpha activity per gram uranium

Table D: Isotopic composition of natural uranium

Isotope	% Isotopic composition [a]	% Alpha activity	Alpha activity[b] Bq/g
U-238	99.2745	48.26	1.23E+04
U-235	0.7200	2.25	5.76E+02
U-234	0.0055	49.49	1.27E+04
Total alpha activity, Bq/g			2.56E+04
Alpha activity ratio U-234/U-238			1.03
Alpha activity ratio U-235/U-238			0.047

[a] Composition is given as weight % of total U isotopes

[b] Alpha activity per gram uranium

Reference solution for case ELP2

The case is assessed following the IDEAS Guidelines (GLs). The following tables present, for each flow chart, the description of the items and the indications related to the application of the guidelines to ELP2. The tables provide the relevant step number, the comment and reasons why this step was used and the action performed during the evaluation. The description is responsibility of the reviewer of the evaluation.

Evaluation of Stage 1

Step	Indication	Comment	Action performed
1.1	Identify monitoring value	The first chest value at 0.125 d after intake has been considered (43 Bq, uncertainty ±7 Bq)	Go to 1.2
1.2	M < Mc ?	Also considering the greatest value reported in Table 3.9 of the GLs for ^{235}U, type S in lungs (0.3 Bq) the measured value is greater than Mc.	Go to 1.3
1.3	Above level 0.	Evaluation needed	Go to Stage 2

Evaluation of Stage 2

Step	Indication	Comment	Action performed
2.0	Understanding the case	On the base of the m(t) value for ^{235}U and the chosen absorption type S (as the compound is known to be U_3O_8) 0.074 Bq per Bq intake (related to 0.1 d) and the isotopic ratios related to the other U isotopes the following values of intake and E(50) have been preliminary evaluated. ^{235}U: Intake = 600 Bq , E(50) = 3.5 mSv ^{234}U: Intake = 10000 Bq , E(50) = 94 mSv ^{238}U: Intake = 2500 Bq , E(50) = 14 mSv A total value of E(50) of around 111 mSv has been evaluated. The value is well above the annual limit for occupational exposure (20 mSv/y).	Go to 2.1
2.1	Assessment of uncertainty on M	From table 4.8 of GLs, a value of 1.15 for SF_B component of the lung measurement of ^{235}U has been accepted. The uncertainty of measurement provides a value of SF_A =1.18: therefore the total SF = 1.24.	Go to 2.2
2.2	Contribution from previous intakes	There is no contribution from previous intakes: P = 0	Go to 2.3
2.3	$M > P * SF^2$?	Yes, as P = 0	Go to 2.3.1
2.3.1	New intake	There is evidence of a new significant intake. As P = 0, N = M.	Go to Stage 3

Evaluation of Stages 3 and 4

Step	Indication	Comment	Action performed
3.1	Routine monitoring ?	No	Go to Stage 4
4.1	Pure Inhalation ?	It is indicated in the case description that: “Proper respiratory protection not worn.“ So “pure inhalation” is considered.	Go to 4.1. 1 and Stage 5

Evaluation of Stage 5

Step	Indication	Comment	Action performe

			d
5.1	Identification of all measurement data	There are available 5 chest activity measurements spanning from 3 hours up to 60 days after intake and 5 urine measurements from 2 up to 58 days post incident, for the single radioactive isotope ^{235}U. For all measurements the correct SF value has been calculated using the indication of the uncertainty of both chest and urine measurements. For Chest measurements the SF values spans from 1.24 to 1.31. For urine measurements the value of SF, unique for all measures, is 1.62. At a glance one can consider that no outlier value is present. The isotopic ratios in mass and in activity are reported at the end of the case description. The ratios are deemed not to be affected by uncertainty.	Go to 5.2
5.2	Assessment of the contribution of previous intakes	No previous contribution has been evaluated as at the end of the case description it is reported that "Previous urinary excretion measurements indicated that uranium excretion due to dietary intakes is less than 0.1 µg d^{-1} of natural uranium". So no previous intake occurred.	Go to 5.3
5.3	Assign a priori parameters.	It has been assumed: single intake, absorption type indicated by ICRP Publication 78 for U_3O_8 compounds, i.e. Type S, AMAD = 5 µm. f_1 = 0.002 as related to type S.	Go to 5.4
5.4	Time of intake is known ?	Yes.	Go to 5.5
5.5	Calculate dose with a priori parameters.	The best estimate of the intake has been calculated using the equation $$\ln(I) = \frac{\sum_{i=1}^{n_c} \frac{\ln\left(\frac{N_{Ci}}{m_C(t_i)}\right)}{\left[\ln(SF_{Ci})\right]^2} + \sum_{j=1}^{n_U} \frac{\ln\left(\frac{N_{Uj}}{m_U(t_j)}\right)}{\left[\ln(SF_U)\right]^2}}{\sum_{i=1}^{n_c} \frac{1}{\left[\ln(SF_{Ci})\right]^2} + \sum_{j=1}^{n_U} \frac{1}{\left[\ln(SF_U)\right]^2}}$$ where the scattering factor of the urine measurement is unique for all available measurements. The following values of intake and E(50) have been evaluated. ^{235}U: Intake = 1184 Bq , E(50) = 7.2 mSv ^{234}U: Intake = 28069 Bq , E(50) = 190.9 mSv ^{238}U: Intake = 5073 Bq , E(50) = 28.9 mSv Therefore a total of 227 mSv has been evaluated.	Go to 5.6

5.6	Dose < 1 mSv ?	No, the dose either related to the single radionuclide ^{235}U or the total is well above 1 mSv.	Go to Stage 5B
5.7	Are there sufficient relevant data ?	From Table 6.2 of GLs 2 urine + 2 feces + 2 lung measurements are needed, in a 30 day period. Here 5 lung + 5 urine measurements are available, in a 60 d period. So we can conclude that there are sufficient relevant data.	Go to 5.8
5.8	Time of intake is known?	Yes	Go to 5.9
5.9	Early lung and faeces data are available?	Only chest (i.e. lung) measurements are available and not faeces. So, No.	Go to 5.11
5.11 and 5.11.1	Assess the dose by fitting the absorption type.	The first assessment has already been performed by means of the default absorption type S. The observed chi-square value has been evaluated using the equation $\chi_0^2 = \sum_{i=1}^{n_C}\left(\frac{\ln(N_{Ci}) - \ln(I \bullet m_C(t_i))}{\ln(SF_{Ci})}\right)^2 + \sum_{j=1}^{n_U}\left(\frac{\ln(N_{Uj}) - \ln(I \bullet m_U(t_j))}{\ln(SF_U)}\right)^2$ Its value is 247 with 9 degrees of freedom. This represents a P-value of 4E-46%: the fit is completely rejected. The second assessment has been performed assuming an absorption type M, always using the equation reported in Step 5.5. In this case the value for the chest retention function per unit intake at 0.125 d, has been linearly interpolated between the tabulated values of MONDAL/MONDES (Ishigure 2003) PC, respectively for 0.1 and 0.2 d (for 0.125 d the interpolate value is equal to 0.065875). In case of type M absorption (with relative f_1 value =0.02) the result of the best estimates of intake are: ^{235}U: Intake = 667 Bq , E(50) = 1.2 mSv ^{234}U: Intake = 15808 Bq , E(50) = 33.2 mSv ^{238}U: Intake = 2857 Bq , E(50) = 4.6 mSv Therefore a total of 39 mSv has been evaluated. The observed chi-square value is 3.3 with 9 degrees of freedom. This determines a P-value of 0.95. The second criterion is fulfilled: no systematic underestimation or overestimation of data is present. The fit is accepted.	Go to 5.11.2

		Although ICRP 68 recommends absorption Type S for U_3O_8, in ICRP Publication 71 (ICRP 1995c), §249 page 298, it is noted that considerable behavior for U_3O_8 was observed with some studies indicating Type M and others Type S. In this case the urine data indicates Type M material.	
5.11.2	Dose < 6 mSv ?	For the radioisotope under investigation i.e. ^{235}U: Yes	Go to 5.11.3
5.11.3	Record dose with all parameters	Those used in step 5.11, for type M.	End

In Figure 6 and in Figure 7 the measurement values, respectively for chest and urine daily excretion measurements, and the fitted curves, both for absorption type M and S, are reported.

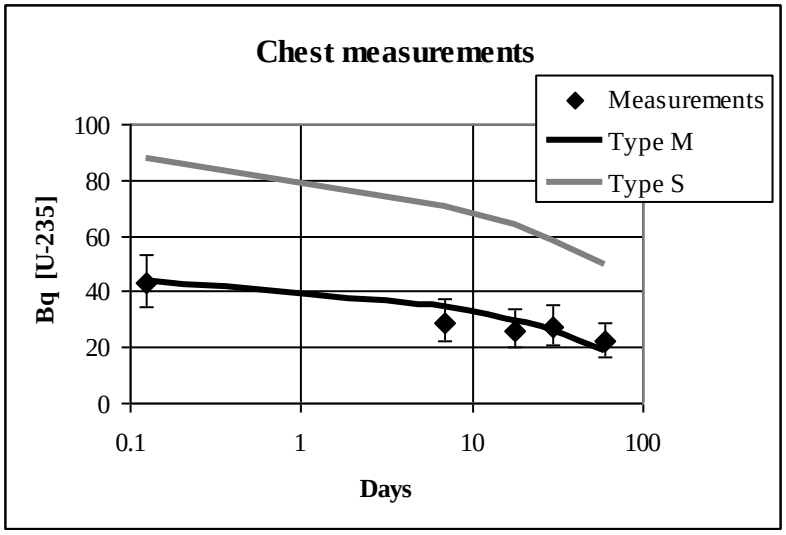


Figure 6: Chest measurements and fitted curves for absorption type M and S.

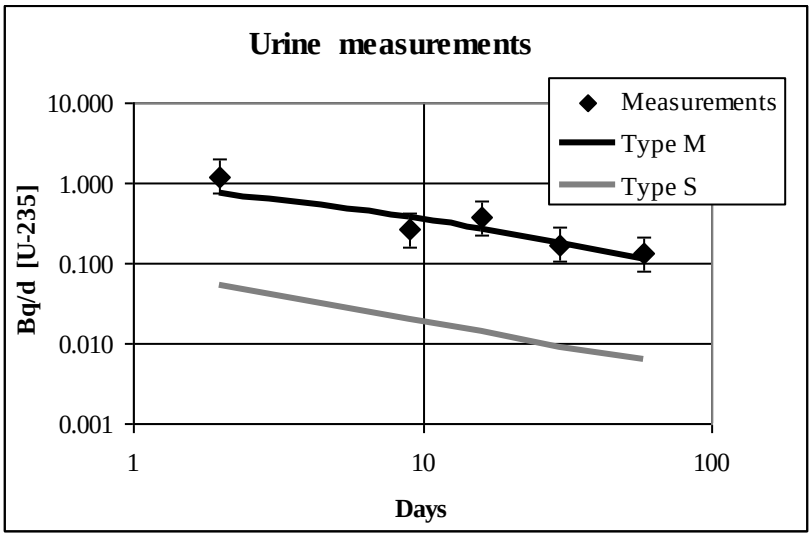


Figure 7: Urine daily excretion measurements and fitted curves for absorption type M and S

The final tables of the reference evaluation are as follows.

Assumptions adopted in the evaluation.

AMAD (µm)	5
Absorption Type	M
f_1 value	0.02
Final step of IDEAS guidelines	5.11.3

Assessed intake and committed effective dose for inhalation of enriched uranium.

Isotope	% alpha activity	ratio to U-235	Intake (Bq)	Dose coefficient e(50), (Sv/Bq)	E(50), (mSv)
U-238	14.78	4.28	2857	$1.6 \cdot 10^{-6}$	4.6
U-235	3.45	1.00	667	$1.8 \cdot 10^{-6}$	1.2
U-234	81.77	23.70	15808	$2.1 \cdot 10^{-6}$	33.2
Total	100	-	-	-	39.0

13.3 Acute inhalation of ^{241}Am (Case ELP3)

The event

Description of the working area

Laboratory.

Characteristics of work

The person was in charge with disposing an ^{241}Am source.

Reasons for monitoring; initiating event

While examining an old 370 MBq sealed ^{241}Am source, the subject discovered loose contamination in the immediate vicinity of the work area. Subsequent measurements revealed loose ^{241}Am contamination in the general work area.

Actions taken

A nose swab was taken and a chest measurement was carried out 3 hours after the incident. A program of monitoring was set up that included in-vivo chest measurements and the collection of urine and fecal samples.

Additional information

Chemical form

Believed to be in an oxide form.

Physical characteristics, particle size

Aerosol

Nose swab, bronchial slime or similar

Positive nose swap indicating inhalation.

Any intervention used (blocking, chelating, etc.)

None

Body monitoring data

Chest activity measurements

Time of measurement after intake (d)	Activity of ^{241}Am in chest, (Bq)
0.125	73
3	62

10	52
30	47
60	49
100	23
180	28

Excretion monitoring data

Urine activity measurements

Time of measurement after intake. (d)	Urinary excretion rate (Bq/d)
2	8.7E-03
9	4.0E-03
15	5.0E-03
25	3.0E-03
40	6.6E-03
60	1.2E-03

Faeces activity measurements

Time of measurement after intake. (d)	Faecal excretion rate, (Bq/d)
1	3.1E+01
2	9.1E+01
3	2.5E+00
9	1.1E+00
15	3.4E-01
25	1.1E+00
60	9.8E-02

Personal Data

Sex

Male

Age

35 years

Weight

70 kg

Other comments relevant for intake and dose estimation

The urine data are simulated 24 h urine measurements.

At the working place the process involves only one type of material (no possibility of mixtures of different chemical compounds).

Please estimate the intake and the committed effective dose E(50) using either IMBA professional or AIDE.

Consider the possibility of varying material specific parameters (e.g. AMAD, and the HRTM absorption parameters, f_r and s_s) to obtain a good fit to the data

Please, submit your final results by filling in the following table.

Quantity	**Value**
Effective AMAD (μm)	
Specific HRTM absorption parameters	-
▪ Fraction dissolved rapidily, f_r	
▪ Rapid dissolution rate, s_r (d^{-1})	
▪ Slow dissolution rate, s_s (d^{-1})	
f_1 value (fraction uptake from GI tract)	
Intake (Bq)	
Committed effective dose (mSv)	
Final step of IDEAS Guidelines	
Used software	

Reference solution of Case ELP3

The following tables describe the assessment of case ELP3 by following the IDEAS Guidelines (GLs). The tables give the relevant step number, a brief description of the step, the reasons why the step was carried out, and the results of the evaluation (Tables 6-10). The description is the responsibility of the reviewer of the evaluation.

The following assessment was carried out with IMBA Professional, although it can equally be assessed with AIDE.

Evaluation of Stage 1 for case ELP3

Step	Indication	Comment	Action performed
1.1	Identify monitoring value	Lung measurement at 0.125 d is 73 Bq of Am-241	Go to 1.2
1.2	M < Mc	Critical monitoring value M_c for lung with a monitoring interval of 360 d is 0.044 Bq. Therefore M> M_c.	Go to 1.3
1.3	Above level 0.	Evaluation needed	Go to Stage 2

Evaluation of Stage 2 for case ELP3

Step	Indication	Comment	Action performed
2.0	Understanding the case	Hand calculation: At t = 3 days, lung measurement, M = 62 Bq. ICRP Publication 78 (ICRP 1997) gives a predicted lung value of 0.055 Bq per Bq intake for inhalation of ^{241}Am (5 µm AMAD, Type M, special monitoring at t = 3 d). So intake = 62/0.055 = 1100 Bq. Dose coefficient, e(50) = $2.7 \cdot 10^{-5}$ Sv/Bq and therefore effective dose, E(50) = 30 mSv. The assessor should also plot the data.	Go to 2.1
2.1	Assessment of uncertainty on M	Lung: Assume SF = 1.4 as given in Table 4.8 of guidelines for in-vivo measurements of ^{241}Am, which emits a 60 keV photon.	Go to 2.2
2.2	Contribution from previous intakes	There is no contribution from previous intake : P =0	Go to 2.3
2.3	M > P * SF^2?	Yes, as P = 0	Go to 2.3.1
2.3.1	New intake	There is evidence of a new significant intake. As P =0, N=M.	Go to Stage 3

Evaluation of Stages 3 and 4 for case ELP3

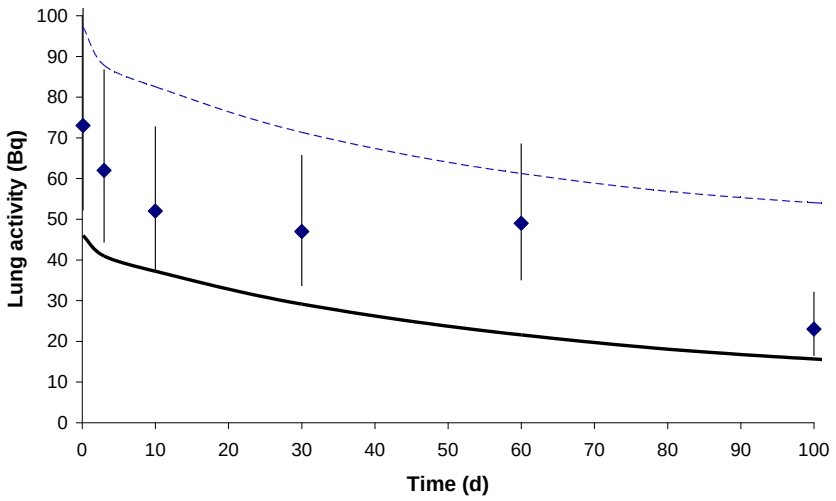
Step	Indication	Comment	Action performed
3.1	Routine monitoring ?	No.	Go to Stage 4
4.1	Pure Inhalation ?	The positive nose swap together with the chest data indicates inhalation. So assume pure inhalation.	Go to 4.1.1 and Stage 5

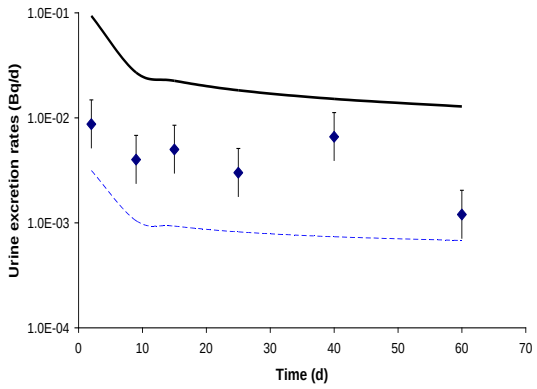
Evaluation of Stages 5A and 5B for case ELP3.

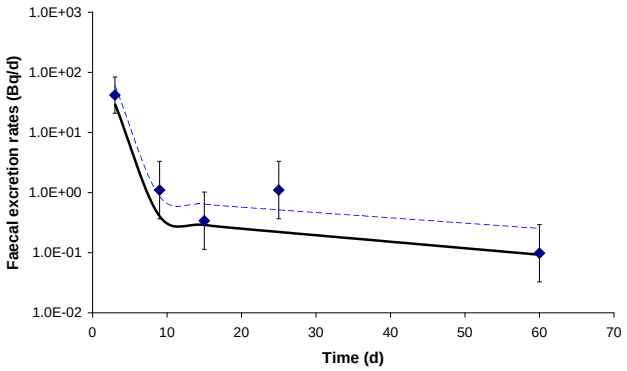
Step	Indication	Comment	Action performed
5.1	Identification of all measurement data	Use all measurement data available. However, for the early faecal data consider the cumulative faecal excretion over the first 3 days as suggested on section 4.1. The faecal excretion over the first 3 days is (31 + 91 + 2.5) Bq = 124.5 Bq. So instead of entering the first 3 data measurements into IMBA ™, this should be entered as one data point as 124.5/3 Bq/d = 41.5 Bq/d with a 3 day collection period. The corresponding SF value is 2.0 for 72 hour faecal excretion (Table 21). **Lung**: Assume SF= 1.4 as given in Table 20 for in-vivo measurements of ^{241}Am, which emits a 60 keV photon. **Urine:** SF_B= 1.6 (Table 21). Urinary excretion values range from 1.2 to 8.7 mBq/d and therefore the corresponding Type A errors range from about 12% to 25% (See Figure 9 of OMINEX report (Etherington 2004, Hurtgen 2003). Combining Type A and Type B errors gives overall SF values of 1.62 to 1.70. For simplicity, assume SF = 1.7 for all urine measurements. **Faeces, 24 –hour samples:** SF_B = 3 (Table 21). Measurement values range from 0.1 Bq to 90 Bq so the corresponding Type A error is less than 10% (See Figure 9 of OMINEX report, Etherington 2004, Hurtgen 2003) As the Type A errors are small compared with the Type B errors, assume SF = 3.0 for all 24-h faecal measurements By plotting the data it appears there are no outliers.	Go to 5.2

5.2	Assessment of the contribution of previous intakes	No previous intakes.	Go to 5.3
5.3	Assign a priori parameters.	Single intake, absorption Type M, 5 µm AMAD	Go to 5.4
5.4	Time of intake is known ?	Yes.	Go to 5.5
5.5	Calculate dose with *a priori* parameters.	Intakes were estimated by fitting simultaneously the predicted lung retention, urine and faecal excretion rates to the data with IMBA Professional™ PC. The fitting method is the maximum likelihood method, which is the recommended method in the IDEAS Guidelines. Results : Intake = 684 Bq , E(50) = 18.5 mSv Note: the fit to data is bad.	Go to 5.6
5.6	Dose < 1 mSv ?	No.	Go to Stage 5B
5.7	Are sufficient relevant data?	It can be seen from Table 6.2 of GLs, for the doses above 1 mSv and below 6 mSv the minimum number of data suggested is 2 lung data over a 30 d period, 2 faecal data over a 30 d period and 2 urine data over a 30 d period. In this case there are sufficient data as we have 4 lung data over a 30 d period, 6 faecal data over a 30 d period and 4 urine data over a 30 d period.	Go to 5.8
5.8	Time of intake is known?	Yes	Go to 5.9
5.9	Early lung and faeces data available?	Yes	Go to 5.10
5.10	Derive effective AMAD	Effective AMAD evaluation F(1-3)/L(3) = (31+ 91 + 2.5)/62 = 2.0. For americium Type M this gives an effective AMAD of 1.3 µm (see Figure 8.3 of GLs).	Go to 5.11
5.11 and 5.11.1	Assess the dose by fitting the absorption type.	Assuming AMAD = 1.3 µm , Type M the following estimate is obtained: Intake = 403 Bq , E(50) = 15.8 mSv Fit to data is bad; χ_0^2 = 103 with 17 degrees of freedom. Corresponding p-value < 0.05. Furthermore, by eye, the	Go to 5.13

		fits to the lung and urine data are poor (Figure 3). **Reject fit**. ICRP 68 recommends absorption Type M for all compounds of americium. However, with IMBA Professional™ a fit can be carried out assuming Type S. Assuming single intake, absorption Type S and 1.3 µm AMAD, the following estimate is obtained: Intake = 771 Bq , E(50) = 11.2 mSv Fit to data is bad; χ_0^2 = 60.7 with 17 degrees of freedom. Corresponding p-value < 0.05. Furthermore, by eye, the fits to the lung and urine data are poor (Figure 3). Reject fit.	
5.13	Fitting a mixture of absorption Types	For this exercise the participants were ask to determine specific absorption parameter values as described in Stage 5C.	Go to Stage 5C.





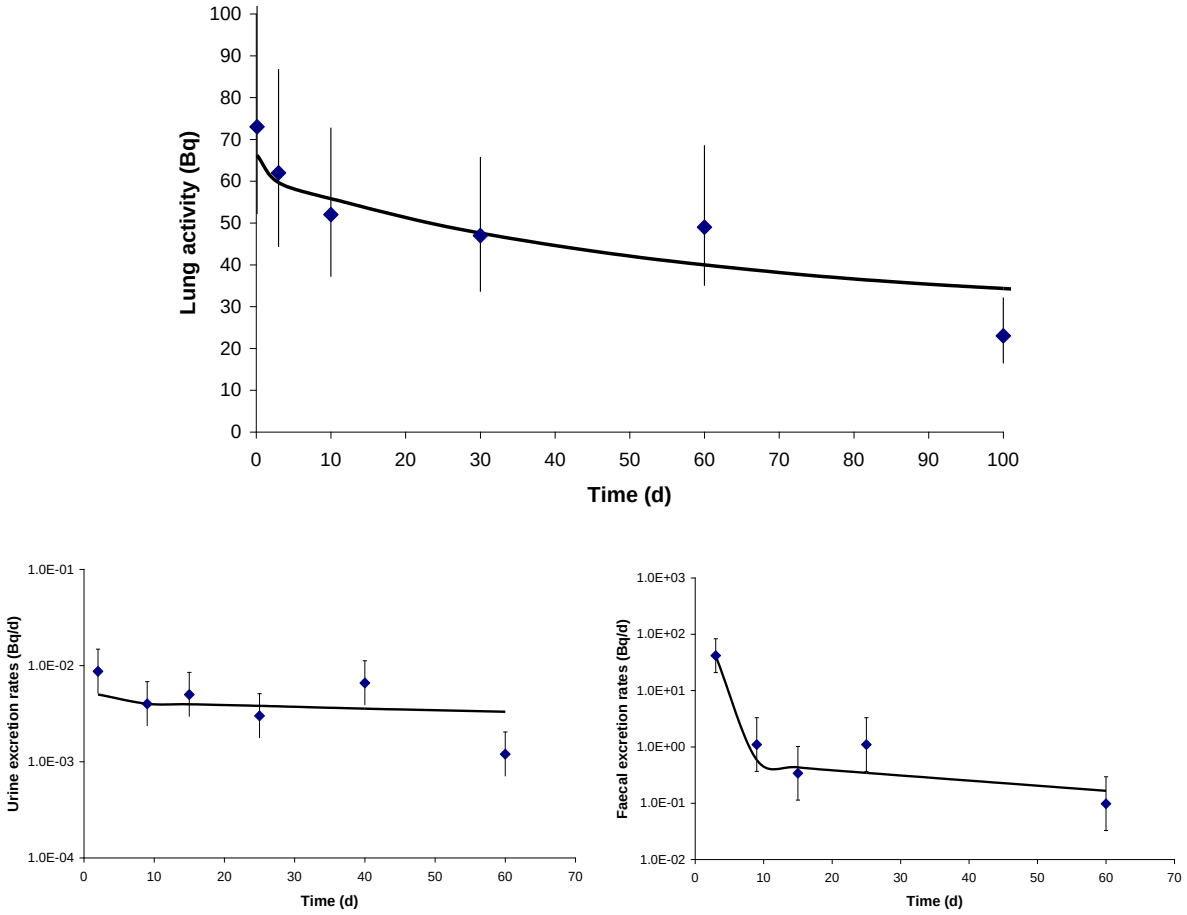


Model fits to lung urine and faecal data assuming absorption Type M (—) or absorption Type S (- - -).

Evaluation of Stage 5C for case ELP3

Step	Indication	Comment	Action performed
5.16 And 5.16.1	Determine specific HRTM absorption parameter values.	Starting with Type M absorption parameter values it can be seen that the model predictions over estimates the urine data and under-estimates the lung data. This indicates that the model assumes too much lung-to-blood absorption. So reduce the fraction dissolved rapidly, f_r and reduce the slow dissolution rate, s_s. First reduce f_r. Reducing f_r from 0.1 to 0.001 reduces the overall χ_0^2 value from 103 to 68. Then reduce s_s. Reducing s_s from $5 \cdot 10^{-3}$ d^{-1} to $8 \cdot 10^{-4}$ d^{-1} reduces the overall χ_0^2 from 68 to 10. This gives a good fit to the data. Results with specific absorption values of $f_r = 0.001$, $s_r = 100$ d^{-1}, $s_s = 8 \cdot 10^{-4}$ d^{-1} and $f_b = 0$ are as follows: Intake = 525 Bq , E(50) = 11.5 mSv. Fit to data is good (Figure 4); $\chi_0^2 = 10$ with 17 degrees of freedom. Corresponding p-value = 0.9. Fit not rejected. The fits are not rejected as the χ^2 test did not fail (p-value > 0.05). Furthermore, by eye, the fits to the lung, faecal and urine data are good (Figure 4).	Go to 5.15.1

5.15.1	Record dose with all parameters	Estimated intake and dose are recorded with all parameter values: Intake = 525 Bq of ^{241}Am Effective dose = 11.5 mSv AMAD = 1.3 µm Specific HRTM absorption parameter values: f_r = 0.001, s_r = 100 d^{-1}, s_s = 8 ·10^{-4} d^{-1} and f_b =0.	End



Model fits to lung, urine and faecal data assuming specific absorption parameter values.

A summary of the results are given in the following table

Summary of estimated intakes of ^{241}Am and resulting doses[(a)]

Assessment procedure step	AMAD (μm)	Absorption	Goodness of fit		Comment	Intake (Bq)	E(50) (mSv)
			χ_0^2 [(b)]	p-value [(c)]			
5.5	5	Type M	128	$< 10^{-10}$	Reject fit	684	18.5
5.11	1.3	Type M	103	$2.8 \cdot 10^{-14}$	Reject fit	405	15.8
5.11	1.3	Type S	61	$8.0 \cdot 10^{-7}$	Reject fit	771	11.2
5.13	1.3	Specific values	10	0.9	Good fit and end of assessment.	**525**	**11.5**

(a) Intake estimates were obtained by fitting the predicted bioassay values to the chest data, urine data and faecal data simultaneously with IMBA Professional™.

(b) The expected value of χ^2 is equal to the number of degrees of freedom; (i.e. the number of data points – 1 = 17, as the faecal data at days 1, 2 and 3 have been considered as a unique measurement with a collection period of 3 days.).

(c) The p- value is the probability that χ^2 is greater than χ_0^2 for 17 degrees of freedom.

The final table of the reference evaluation is as follows.

Quantity	**Value**
Effective AMAD (μm)	1.3
Specific HRTM absorption parameters	-
▪ Fraction dissolved rapidily, f_r	0.001
▪ Rapid dissolution rate, s_r (d^{-1})	100
▪ Slow dissolution rate, s_s (d^{-1})	$8 \cdot 10^{-4}$
f_1 value (fraction uptake from GI tract)	$5 \cdot 10^{-4}$
Intake (Bq)	525
Committed effective dose (mSv)	11.5
Final step of IDEAS Guidelines	5.16 – 5.16.1 – 5.15.1
Used software	As reported by evaluator

13.4 Ingestion of ^{137}Cs (case ELP4)

Case description

The event

Description of the working area

Research laboratory.

Reasons for monitoring; initiating event

The subject was removing some caesium chloride from a multidose vial. The vial contained 250 MBq of ^{137}Cs. When the subject put a hypodermic needle through the rubber septum, some liquid was ejected from the vial into his face.

Actions taken

A program of whole body measurements was carried out.

Additional information

Chemical form

Caesium chloride.

Physical characteristics, particle size

Liquid.

Any intervention used (blocking, chelating, etc.)

None.

Body monitoring data

Whole body measurements

Time of measurement after intake (d)	Activity of ^{137}Cs in total body, (Bq)
1	8.8E+04
8	6.0E+04
15	3.0E+04
17	9.3E+04
30	8.3E+04
46	4.8E+05
50	4.6E+05
60	4.4E+05

Personal Data

Male, 35 years of age, and weight 75 kg.

Other comments relevant for intake and dose estimation

The data indicates the possibility of another intake between days 30 and 46. After questioning the subject a similar incident to the first one occurred, but he could not remember when it happened. For this exercise please assume ingestion for both intakes for simplicity.

Estimate the intake and the committed effective dose E(50) for each intake, performing an evaluation only using spread sheets.

Moreover, assess the case with the use of at least one of three available software tools.

Take care of identifying possible outliers in performing the evaluations.

Provide the evaluation that you consider to be the final one by filling in the following tables.

Estimation of first intake and resulting dose

Please estimate the first intake and calculate the resulting committed effective dose E(50) by considering the first 5 data points (i.e. data at times 1 d to 30 d). Please fill in Table 1.

Assessment of first intake and resulting dose

Quantity	Value
Time of first intake (d)	0
Route of intake	ingestion
Any outliers? If yes, how many ?	
Intake (Bq)	
Committed effective dose (mSv)	
Final step of IDEAS Guidelines	
Used software	

Estimation of second intake and resulting dose

Please estimate the second intake and calculate the resulting committed effective dose E(50) by considering all the data points. Please fill in the Table 2.

Assessment of second intake and resulting dose

Quantity	Value
Time of second intake (d)	
Route of intake	ingestion

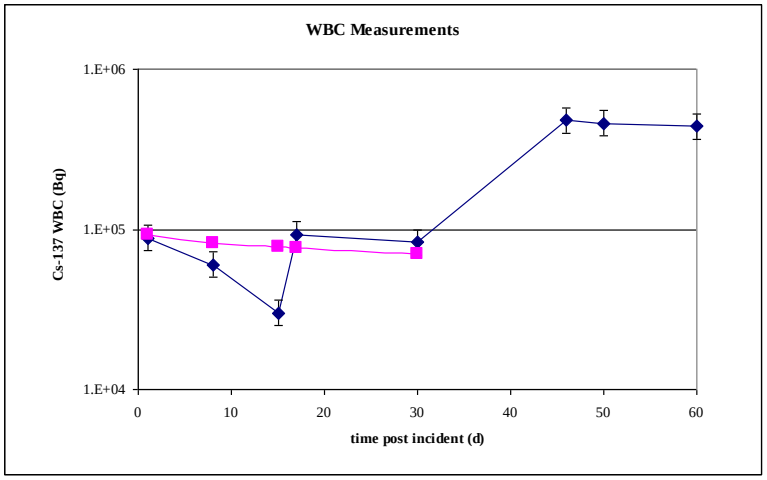
Any outliers? If yes, how many ?	
Intake (Bq)	
Committed effective dose (mSv)	
Final step of IDEAS Guidelines	
Used software	

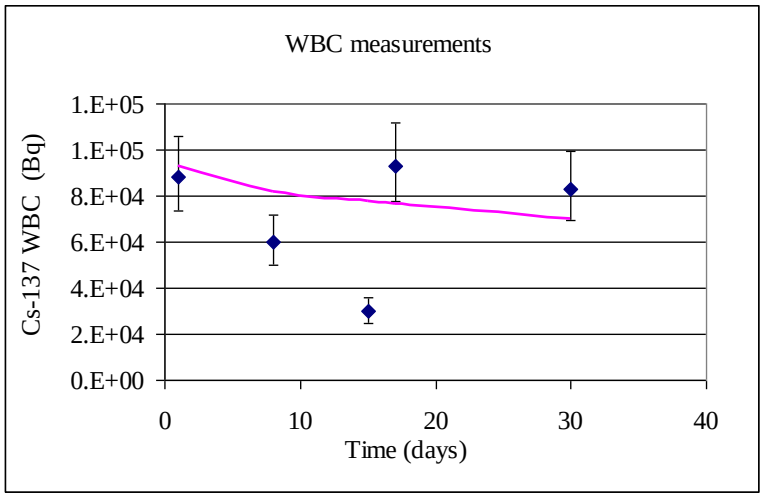
Reference solution for Case ELP4

The case is assessed following the IDEAS Guidelines (GLs). The following tables present, for each flow chart, the description of the items and the indications related to the application of the guidelines to ELP4. The tables provide the relevant step number, the comment and reasons why this step was used and the action performed during the evaluation. The description is responsibility of the reviewer of the evaluation.

Evaluation of 1st Intake

Step	Indication	Comment	Action performed
1.1	Identify monitoring value	Some liquid with ^{137}Cs was ejected from a vial to the subject's face. The first WBC measurement has been performed one day after the incident. The measured activity is 8800 Bq. Special Monitoring.	Go to 1.2
1.2	M < Mc ?	The Mc value has been calculated for ingestion, on the basis of a dose coefficient of $1.3 \cdot 10^{-8}$ Sv/Bq and the retention function for t = 1 day. Mc= 20.7 Bq, so M > Mc.	Go to 1.3
1.3	Above level 0.	Evaluation needed.	Go to Stage 2 – Step 2.0
2.0	Understanding the case	On the basis of a m(t) value related to ingestion of Caesium 1 day after the incident, an intake of 90 kBq and a value of E(50) = 1.17 mSv are calculated.	Go to 2.1
2.1	Assessment of uncertainty on M	From Table 4.8 of GLs a value of 1.15 for SF_B and 1.07 for SF_A of the WB measurement of ^{137}Cs have been accepted. Total SF = 1.2.	Go to 2.2
2.2	Contribution from previous intakes	There is no contribution from previous intake : P =0	Go to 2.3
2.3	M > P * SF^2?	Yes, as P = 0	Go to 2.3.1

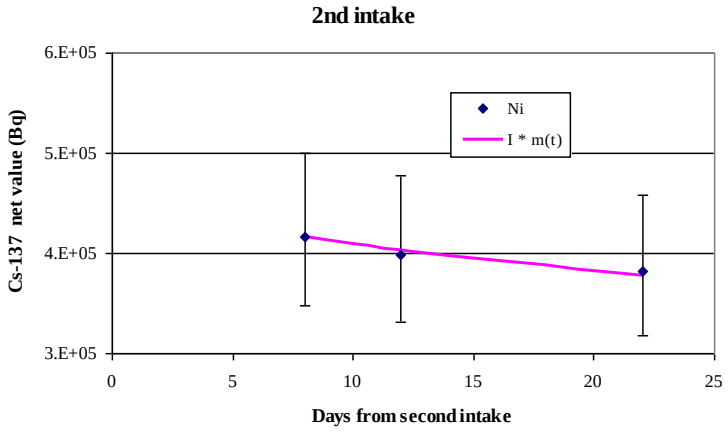
2.3.1	New intake	There is evidence of a new significant intake. As P=0, N=M.	Go to Stage 3 – step 3.1
3.1	Routine monitoring ?	No. This is Special Monitoring.	Go to Stage 4 - step 4.1
4.1	Identify pathway of intake	Path is NOT inhalation	Go to 4.2
4.2	Identify pathway of intake	Path is ingestion. Special evaluation for ingestion is needed.	Go to Stage 6A- Step 6.1
6.1	Identification and preparation of measurement data	Evaluation of an outlier: At 15 d, the M value seems to be too small. Check if the value is a factor of SF^3 away from the trend of the data: M (expected_trend) = $7.74 \cdot 10^4$ Bq as evaluated on the base of the intake evaluated using the other 4 measurements ($9.50 \cdot 10^4$ Bq) and the m(t) value for ingestion at 15 d = 0.815 Bq per Bq intake. M(actual value)= $3 \cdot 10^4$ Bq $SF^3 = 1.728$ M(expected_trend)/SF^3 = $4.48 \cdot 10^4$ Bq M(actual value) < M(expected_trend)/SF^3 Then, M (actual value, t = 15d) = is an outlier.  Possible second intake from day 31 to day 45.	Go to Step 6.2
6.2	Contribution from previous intakes	There is no contribution from previous intake : P = 0	Go to 6.3
6.3	Assign a priori parameters	Single intake; f_1= 1	Go to 6.4

6.4	Time of intake	Time of intake is known.	Go to 6.5
6.5	Evaluation of the first Intake and resulted Dose	Calculate dose with a priori parameters, for the 4 first WB measurements (from day 1 to day 30), SF= 1.2 and $e(50)_{ing}$=1.3 $\cdot 10^{-8}$ Sv/Bq I= 9.50 $\cdot 10^{4}$ Bq E(50)= 1.23 mSv	Go to 6.6
6.6	Dose < 1 mSv	No.	Go to Stage 6.B -Step 6.7
6.7	Check of sufficient data	From Table 6.2 of GL, as minimum: 3 data in 90 days are required. 4 data are here available: YES, there are sufficient data.	Go to 6.8
6.8	Time of intake	Time of intake is known.	Go to 6.9
6.9	Assessment of dose with default f_1 value	Same values as step 6.5 I= 9.50 $\cdot 10^{4}$ Bq E(50)= 1.23 mSv	Go to 6.11
6.11	Check the goodness of fit	Criterion 1: The observed chi-square value has been evaluated using the equation $\chi_0^2 = \sum_{i=1}^{n_{WBC}} \left(\frac{\ln(N_{WBCi}) - \ln(I \bullet m_{WBC}(t_i))}{\ln(SF_{WBC})} \right)^2$ The value of χ_0^2 is 4.96 with 3 degrees of freedom. This represents a P-value of 0.175 and the fit is NOT rejected. Criterion 2: fit "by-eye" fulfilled, with 2 data above and 2 data below the trend 	Go to 6.12
6.12	Dose < 6 mSv	Yes.	Go to 6.12.1
6.12.1	Record dose	Single Intake at day 0, f_1=1, $e(50)_{ing}$= 1.3 $\cdot 10^{-8}$ Sv/Bq	

	with all parameters	$I_1 = 9.495 \cdot 10^4$ Bq E(50)= 1.23 mSv. For IMBA™ software reference value: see the second intake evaluation.	

Evaluation of 2nd Intake

Step	Indication	Comment	Action performed
1.1	Identify monitoring value	A second ^{137}Cs intake is assumed after day 30, affecting the measurements at day 46: M = $4.8 \cdot 10^5$ Bq. Time of intake at the middle of the interval between both measurements.	Go to 1.2
1.2	M < Mc ?	The Mc value is 290 Bq, calculate by m(8) = 0.86 and e(50)= $1.3 \cdot 10^{-8}$ Sv/Bq. So M is > Mc.	Go to 1.3
1.3	Above level 0.	Evaluation needed.	Go to Stage 2 – Step 2.0
2.0	Understanding the case	On the basis of a m(t) value related to ^{137}Cs retention for the mid point of the monitoring period (8 days) and the related dose coefficient: I= $6 \cdot 10^5$ Bq and E(50) = 7.3 mSv.	Go to 2.1
2.1	Assessment of uncertainty on M	From Table 4.8 of GLs a value of 1.15 for SF_B component and 1.07 for SF_A component have been accepted. Total SF = 1.2.	Go to 2.2
2.2	Contribution from previous intakes	Calculation of contribution of previous intake: date = 0, days = 46, m(46) = 0.668 Bq per Bq intake. I_1 (Bq) = 94950 Bq P(Bq)= 63427 Bq.	Go to 2.3
2.3	M > P * SF^2?	SF^2 = 1.44; M= $4.8 \cdot 10^5$ Bq; P * SF^2= $9.1 \cdot 10^4$. M > P * SF^2 : Yes: there is a new significant intake.	Go to 2.3.1
2.3.1	N=M-P	N= $4.17 \cdot 10^5$Bq	Go to Stage 3
3.1	Routine monitoring?	No, Special monitoring	Go to Stage4
4.	Pathway of intake	Pure Ingestion. Special evaluation of ingestion.	Go to Stage 6
6.1	Identification and preparation of measurement data	Possible second intake from day 30 to day 46. Report of data: Day M_i (Bq) 46 $4.8 \cdot 10^5$ 50 $4.6 \cdot 10^5$ 60 $4.4 \cdot 10^5$	

6.2	Contribution from previous intakes	I_1 (Bq) = 94950 Day m(t) P_i (Bq) N_i (Bq) 46 0.668 63427 $4.17 \cdot 10^5$ 50 0.651 61813 $3.98 \cdot 10^5$ 60 0.611 58015 $3.82 \cdot 10^5$	Go to 6.3
6.3	Assign *a priori* parameters.	Single intake; f_1= 1.	Go to 6.4
6.4	Time of intake	Time of intake is unknown.	Go to Stage 6B
6.7	Check of sufficient data	From Table 6.2 of GL, as minimum: 3 WBC data in 90 days are required. 3 data are here available: Yes, there are sufficient data.	Go to 6.8
6.8	Time of intake	Time of intake is unknown.	Go to 6.10
6.10	Assessment of dose with default f_1 value and fitting time of intake	First trial of time of intake: mid point of the time interval (31 - 45) days: day 38. $e(50)_{ing} = 1.3 \cdot 10^{-8}$ Sv/Bq I_2= 484420 Bq E(50)= 6.30 mSv	Go to 6.11
6.11	Check goodness of fit	Criterion 1: The observed chi-square value has been evaluated using the equation $\chi_0^2 = \sum_{i=1}^{n_{WBC}} \left(\frac{\ln(N_{WBCi}) - \ln(I \bullet m_{WBC}(t_i))}{\ln(SF_{WBC})} \right)^2$ Its value is $8.9 \cdot 10^{-3}$ with 2 degrees of freedom. This represents a P-value of 0.9956 and the fit is not rejected. Criterion 2: the fit "by-eye" is fulfilled,  Sensitivity analysis on the date of the second intake	Go to 6.12

Day of second intake	Obs-chi-sq	P-Value	Intake (Bq)	
31	0.0087	0.9957	508429	
32	0.0092	0.9954	505430	
33	0.0087	0.9957	502041	
34	0.0082	0.9959	498698	
35	0.0087	0.9957	495196	
36	0.0080	0.9960	491748	best
37	0.0084	0.9958	488152	
38	0.0089	0.9956	484420	mid period
39	0.0097	0.9951	480561	
40	0.0122	0.9939	476396	
41	0.0173	0.9914	471774	
42	0.0271	0.9866	466721	
43	0.0464	0.9771	460942	
44	0.0850	0.9584	454188	
45	0.1435	0.9307	446367	

Best fit : day 36

Mid-period: day 38

Due to the not substantial difference in fitted values assumed best estimated intake that on mid period: day 38.

The evaluation can also been performed using the IMBA™ software.

The procedure to perform the evaluation is as follows.

- Select ^{137}Cs as indicator nuclide.
- Introduce the bioassay WBC values and dates in the "Bioassay Calculation" window.
- Introduce a SF viale = 1.2 for all measurmentes and as error distribution "LOGNORM".
- Exclude the value at 15 d.
- Input the defalt values for ingestion for the first intake set at day d = 0.
- Input a second intake regime at day d=38.

		- Select alo for this regime the default ingestion ICRP parameters. - Calulate the intakes : The reference results are 93988 Bq and 479110 Bq. - Calculate the respective E(50) values : 1.28 mSv and 6.51 mSv.	
6.12	Dose < 6 mSv?	E(50) = 6.30 mSv. No.	Go to Stage 6C
6.13	Sufficient data?	From Table 6.2 of GLs: 5 data in a 90 days period are required. No, there are not sufficient data. Result should be treated with caution!	Go to 6.14
6.14	Check f1	It was not possible without software to determine if the value of $f_1 = 1$ is useful or not. So maintain the $f_1 = 1$	Go to 6.14.1
6.14.1	Goodness of fit	Yes, as indicated in step 6.11.	Go to 6.12.1
6.12.1	Record of doses with all parameters	Day of intake: 38 Single Intake $f_1 = 1$ $e(50)_{ing}$ (Sv/Bq) = $1.3 \cdot 10^{-8}$ I(Bq) = 484420 E(50) (mSv) = 6.30 For IMBA™ software : I(Bq) = 479110 $e(50)_{ing}$ (Sv/Bq) = $1.36 \cdot 10^{-8}$ E(50) (mSv) = 6.51	END

The final tables of the reference evaluations are as follows.

Assessment of first intake and resulting dose

Quantity	Value
Time of first intake (d)	0
Route of intake	ingestion
Any outliers? If yes, how many ?	Yes, one outlier.
Intake (Bq)	93988

Committed effective dose (mSv)	1.28
Final step of IDEAS Guidelines	Step 6.12 - 6.12.1
Used software	IMBA™

Assessment of second intake and resulting dose

Quantity	Value
Time of second intake (d)	38
Route of intake	ingestion
Any outliers? If yes, how many ?	No.
Intake (Bq)	479110
Committed effective dose (mSv)	6.51
Final step of IDEAS Guidelines	Step 6.14.1 – 6.12.1
Used software	IMBA™

14. Annexes

14.1 Annex 1 – Isotopic composition of natural, enriched and depleted uranium and plutonium materials encountered in the nuclear industry.

The specific activities of radionuclides of Uranium are presented in Table 14.1

Table 14.1: Specific activities of radionuclides of uranium

Nuclide	Half-life[b,c] (y)	Atomic mass[d] (u)	Specific activity (Bq/g)
^{234}U	(2.455 ± 0.006) 10^5	234.0409521	2.3022E+08
^{235}U	(7.040± 0.010) 10^8	235.0439299	7.9939E+04
^{238}U	(4.468± 0.005) 10^9	238.0507882	1.2437E+04
^{236}U	(2.343± 0.006) 10^7	236.0455680	2.3917E+06

a) Avogadro's number **6.02214E+23** mol^{-1}
b) Atomic & Nuclear Data, Laboratoire National Henri Becquerel. http://www.nucleide.org/NucData.htm
c) 1 year = 365.2421988 days as stated in Note Technique DETECS/LNHB/2006-58. CEA/LNHB. (2006). http://www.nucleide.org/DDEP_WG/Periodes_2006.pdf
d) Reference (Audi 2003)

The following Tables 14.2- 14.4 show the composition of natural, enriched and depleted uranium in terms of activity. Note that the composition in terms of mass is completely different.

Table 14.2: **Isotopic composition of natural uranium**

Isotope	% Isotopic composition, [a]	% Alpha activity	Alpha activity, [b] Bq/g
U-238	99.2837	49.03	1.23E+04
U-236	0.0000	0.00	0.00E+00
U-235	0.7110	2.26	5.68E+02
U-234	0.005329	48.72	1.23E+04
U-233	0.0000	0.00	0.00E+00
U-232	0.0000	0.00	0.00E+00
Total alpha activity, Bq/g			2.51E+04
Alpha activity ratio U-234/U-238			0.994
Alpha activity ratio U-235/U-238			0.046

[a] Composition is given as weight % of total U isotopes

[b] Alpha activity per gram uranium

Berglund (2011) for isotopic composition

Table 14.3: **Isotopic composition of enriched (3.7 %) uranium**

Isotope	% Isotopic composition [a]	% Alpha activity	Alpha activity, [b] Bq/g
U-238	92.264	12.69	1.15E+04
U-236	0.002	0.05	4.78E+01
U-235	3.701	3.27	2.96E+03
U-234	0.033	83.99	7.60E+04
U-233	0.000	0.00	0.00E+00
U-232	0.000	0.00	0.00E+00
Total alpha activity, Bq/g			9.05E+04
Alpha activity ratio U-234/U-238			6.621
Alpha activity ratio U-235/U-238			0.258

[a] Composition is given as weight % of total U isotopes

[b] Alpha activity per gram uranium

Industrial oxide UO_2 , reference (Ansoborlo 1995)

Table 14.4: **Isotopic composition of 0.2% weight depleted uranium**

Isotope	% Isotopic composition, [a]	% Alpha activity	Alpha activity, [b] Bq/g
U-238	99.800	88.57	1.24E+04
U-236	0.0027	0.46	6.46E+01
U-235	0.1940	1.11	1.55E+02
U-234	0.0006	9.86	1.38E+03
U-233	0.0000	0.00	0.00E+00
U-232	0.0000	0.00	0.00E+00
Total alpha activity, Bq/g			1.40E+04
Alpha activity ratio U-234/U-238			0.111
Alpha activity ratio U-235/U-238			0.012

[a] Composition is given as weight % of total U isotopes

[b] Alpha activity per gram uranium

Example of depleted uranium taken from a smear sample in UNEP report (UNEP 2002)

Table 14.5 Specific activities of radionuclides of plutonium

Nuclide	Half-life[(b,c)] (y)	Atomic mass[(d)] (u)	Specific activity (Bq/g)
^{238}Pu	87.74 ± 0.03	238.0495599	6.3331E+11
^{239}Pu	(2.4100 ± 0.0011) 10^4	239.0521634	2.2960E+09
^{240}Pu	(6.561± 0.007) 10^3	240.0538135	8.3985E+09
^{241}Pu	14.33 ± 0.04	241.0568515	3.8293E+12
^{242}Pu	(3.73 ± 0.03) 10^5	242.0587426	1.4650E+08
^{241}Am	432.6 ± 0.6	241.0568291	1.2685E+11

(b) Atomic & Nuclear Data, Laboratoire National Henri Becquerel. http://www.nucleide.org/NucData.htm

(c) 1 year = 365.2421988 days as stated in Note Technique DETECS/LNHB/2006-58. CEA/LNHB. (2006). http://www.nucleide.org/DDEP_WG/Periodes_2006.pdf

(d) Reference (Audi 2003)

Table 14.6: **Composition of Weapon-Grade Plutonium**.

Isotope	% Isotopic composition, Pu+Am [b]	% Pu-Alpha activity	% Total-Alpha ☒ activity	% Total activity
Pu-238	0.05	10.70	10.70	0.94
Pu-239	93.0	72.26	72.26	6.36
Pu-240	6.1	17.03	17.03	1.50
Pu-241	0.8		-	91.19
Pu-242	0.05	0.00	0.00	0.00
Am-241	0.0	-	-	-
Pu-241 activity/Total Pu activity				**10**
Pu-241 /(Pu-239+Pu-240) activity				**12**
Am-241 activity/Pu-241 activity				**0.000**

Reference (DOE 1998)

Table 14.7: **Composition of Fuel-Grade Plutonium**.

Isotope	% Isotopic composition, Pu+Am [b]	% Pu-Alpha activity	% Total-Alpha ☒ activity	% Total activity
Pu-238	0.10	17.53	17.53	0.53
Pu-239	84.4	53.64	53.64	1.64
Pu-240	12.4	28.83	28.83	0.88
Pu-241	3.0			96.95
Pu-242	0.1	0.00	0.00	0.00
Am-241	0.0	-	-	-
Pu-241 activity/Total Pu activity				**32**
Pu-241 /(Pu-239+Pu-240) activity				**39**
Am-241 activity/Pu-241 activity				**0.000**

Reference (DOE 1998)

Table 14.8. **Composition of Pu from LWR just after unloading**.

Isotope	% Isotopic composition, Pu+Am	% Pu-Alpha activity	% Total-Alpha activity	% Total activity
Pu-238	1.26	71.04	68.33	1.47
Pu-239	56.62	11.57	11.13	0.24
Pu-240	23.18	17.33	16.67	0.36
Pu-241	13.86			97.85
Pu-242	4.73	0.06	0.06	0.00
Am-241	0.35	3.95	3.80	0.08
Pu-241 activity/Total Pu activity				**47**
Pu-241 /(Pu-239+Pu-240) activity				**163**
Am-241 activity/Pu-241 activity				**0.001**

Reference (OECD 1989)

Table 14.9. **Composition of Spent Commercial Fuel of Uranium, just after chemical separation**.

Isotope	% Isotopic composition, Pu+Am	% Pu-Alpha activity	% Total-Alpha activity	% Total activity
Pu-238	1.49	73.59		2.31
Pu-239	59.50	10.65		0.33
Pu-240	23.98	15.71		0.49
Pu-241	10.33			96.86
Pu-242	4.0	0.05		0.00
Am-241	0.0	-		-
Pu-241 activity/Total Pu activity				**31**
Pu-241 /(Pu-239+Pu-240) activity				**117**
Am-241 activity/Pu-241 activity				**0.002**

Reference (DOE 1998)

Table 14.10. **Composition of Low-exposure Pu 5 years after chemical separation**.

Isotope	% Isotopic composition, Pu+Am	% Pu-Alpha activity	% Total-Alpha activity	% Total activity
Pu-238	0.001	0.24	0.23	0.04
Pu-239	93.5	80.82	77.03	11.93
Pu-240	5.99	18.94	18.05	2.80
Pu-241	0.397			84.51
Pu-242	0.001	0.00	0.00	0.00
Am-241	0.103	4.92	4.69	0.73
Pu-241 activity/Total Pu activity				**5.7**
Pu-241 /(Pu-239+Pu-240) activity				**5.7**
Am-241 activity/Pu-241 activity				**0.009**

Reference (PNNL 2009)

Table 14.11. **Composition of High-exposure Pu 5 years after chemical separation**.

Isotope	% Isotopic composition, Pu+Am	% Pu-Alpha activity	% Total-Alpha activity	% Total activity
Pu-238	1.85	79.23	65.70	3.14
Pu-239	63.3	9.83	8.15	0.39
Pu-240	19.2	10.90	9.04	0.43
Pu-241	9.27			95.22
Pu-242	3.88	0.04	0.03	0.00
Am-241	2.4	20.59	17.07	0.82
Pu-241 activity/Total Pu ☒ activity				**24**
Pu-241 /(Pu-239+Pu-240) ☒ activity				**116**
Am-241 activity/Pu-241 activity				**0.009**

Reference (PNNL 2009)

Table 14.12. **Composition of Pu from LWR after 15 years after unloading**.

Isotope	% Isotopic composition, Pu+Am	% Pu-Alpha activity	% Total-Alpha activity	% Total activity
Pu-238	1.26	71.04	36.20	3.33
Pu-239	56.62	11.57	5.90	0.54
Pu-240	23.18	17.33	8.83	0.81
Pu-241	5.69			90.81
Pu-242	4.73	0.06	0.03	0.00
Am-241	8.52	96.21	49.03	4.50
Pu-241 activity/Total Pu ☒ activity				**19**
Pu-241 /(Pu-239+Pu-240) ☒ activity				**67**
Am-241 activity/Pu-241 activity				**0.050**

Reference (OECD 1989)

14.2 Annex 2 –- Data fitting

Usually for a special monitoring programme, the bioassay data for an intake estimate will consist of results for different measurements performed at different times, and even from different monitoring techniques, eg., direct and indirect measurements.

To determine the best estimate of a single intake, when the time of intake is known, it is first necessary to calculate the predicted values, $m(t_i)$, for unit intake of the measured quantities. It is then required to determine the best estimate of the intake, I, such that the product $I\,m(t_i)$ "best fits" the measurement data (t_i, M_i). In cases where multiple types of bioassay data sets are available, it is recommended to assess the intake and dose by fitting predicted values to the different types of measurement data simultaneously (Section 5.3). For example, if urine and faecal data sets are available then, the intake is assessed by fitting predicted values to both data sets simultaneously.

The two data fitting methods that are most widely applicable are the maximum likelihood method and the Bayesian approach. However, in these guidelines the Bayesian approach is not considered. The method recommended, here, is the maximum likelihood method (Section 5.3). As the likelihood function is the central statistical quantity for this method, it is discussed in detail. The following topics are discussed.

- Likelihood function
- Likelihood function for "less than" measurements
- Maximum likelihood method

The following sections assume that an acute intake, I has occurred at a known time. It is also assumed that no previous intakes have occurred. However, the last Section discusses how the maximum likelihood method can be extended to deal with previous intakes.

14.2.1 Likelihood function

A fundamental statistical quantity is the likelihood function $L_i(I)$, defined by

$$L_i(I) = P(M_i \mid I) \tag{14.1}$$

where $P(M_i|I)\,dM_i$ is the probability of observing measurement value M_i in the interval between M_i and $M_i + dM_i$ given that the true value of the intake is I.

As an example, $P(M_i|I)$ might be given by a lognormal distribution:

$$L_i(I) = \frac{1}{M_i \ln(SF_i)\sqrt{2\pi}} \exp\left[-\frac{\left[\ln(M_i) - \ln(I\ m(t_i))\right]^2}{2\left[\ln(SF_i)\right]^2} \right] \tag{14.2}$$

where SF_i is the geometric standard deviation.

The meaning of $L_i(I)$ is that if the intake was indeed, I and many measurements could, hypothetically, be repeated at the same time, t_i, then the distribution of the measurement results would be described by $L_i(I)$. The probability of a measurement result being in the interval between M_i and $M_i + dM_i$ would then be $P(M_i|I)\, dM_i$. The likelihood function can therefore be determined by measurement if the true measurement value remains relatively constant with time [Moss et al. 1969].

When there are n independent measurements, the combined likelihood function is the product of the likelihood functions for the individual measurements:

$$L(I) = \prod_{i=1}^{n} L_i(I) \qquad (14.3)$$

Therefore, $L(I)$ is associated with the probability of observing all the data given the intake.

In practice a counting measurement is converted to activity by a normalisation (or calibration) factor, C_{rn}. An important situation is where C_{rn}, has a large uncertainty, which is assumed to be lognormal with a geometric standard deviation of SF_B. As described in Section 4.2, the overall uncertainty on the activity consists of two parts:

- the uncertainty due to counting statistics described by Poisson statistics, referred to as a Type A uncertainty, and
- the more subjective normalisation uncertainty, referred to as a Type B uncertainty.

Miller *et al.* (2002) gives the exact likelihood function for measurements involving counting. The function describes uncertainties due to counting statistics (Type A uncertainties) with a Poisson distribution whereas all other uncertainties (Type B uncertainties) are described with a single lognormal distribution. The exact likelihood function is recommended for special cases involving low count rate. However, for cases where the counts are relatively high (i.e. Type A errors are relatively small) then the following simplifications can be made.

When the number of sample counts is large enough (greater than about 10 counts with small background), the normal approximation to the Poisson likelihood function is approximately lognormal, because the normal and log normal distributions approach each other as the uncertainty goes to zero (Miller 2007),

$$\frac{1}{\sqrt{2\pi}\,\sigma_{A_i}} \exp\left[-\frac{\left(M_i - I\,m(t_i)\right)^2}{2\sigma_{A_i}^2} \right] \rightarrow \frac{1}{\sqrt{2\pi}\;M_i \ln(SF_{A_i})} \exp\left[-\frac{\left[\ln(M_i) - \ln(I\,m(t_i))\right]^2}{2\left[\ln(SF_{A_i})\right]^2} \right]$$

where

$$\ln(SF_{A_i}) = \frac{\sigma_{A_i}}{M_i}$$

The convolution of this log normal distribution with the log normal distribution of C_{rn} (having a geometric standard deviation of SF_B) then leads to another log normal distribution:

$$L_i(I) = \frac{1}{M_i \ln(SF_i)\sqrt{2\pi}} \exp\left[-\frac{\left[\ln(M_i) - \ln(I\ m(t_i))\right]^2}{2\left[\ln(SF_i)\right]^2} \right] \qquad (14.4)$$

Where SF_i is the total scattering faction given as follows:

$$SF_i = \exp\sqrt{\left[\ln(SF_{A_i})\right]^2 + \left[\ln(SF_{B_i})\right]^2} \qquad (14.5)$$

This is the likelihood function recommended by the guidelines (Section 4.2) and is applicable to cases where the counts are relatively large (i.e. when $SF_A < 1.4$). Miller (2007) recommends this lognormal approximation if the ratio $\ln(SF_A) : \ln(SF_B)$ is less than 1/3. If this inequality is not satisfied then Miller, 2007 considers that the exact likelihood function, or one of the alterative expressions, they describe should be used.

The log normal distribution has an important qualitative property that *I=0* always has zero likelihood. The exact likelihood function, on the other hand, often has a significant nonzero value at *I=0*, and sometimes the maximum occurs at this point. Equation (14.4) should not be applied when the number of measured counts is small, since it rules out a small or zero intake in the interpretation of the data.

14.2.2 Likelihood function for 'less than' measurements

The maximum likelihood method can be applied to assess intakes from data sets consisting of positive values (i.e. values above a decision threshold, DT) and values reported as being below a detection limit (DL). The likelihood function for a 'less than' measurement gives the probability that a measured value is reported as <DL given the true intake is *I*.

The DL is an *a priori* calculated value which specifies the minimum activity that can be detected by a defined measurement procedure [Health Physics Society (1996)]. Associated with the *DL* is the decision threshold, DT, which is also referred to as the critical level or decision level. If the measured value is below DT , then a decision is made that the measured value is solely due to background and as a result the value is usually reported as being < *DL*. In such a case the likelihood function is given by an integral quantity:

$$L_j(I) = \int_{M=M_{\min}}^{DT_j} P(M|I)\, dM \qquad (14.6)$$

where:

$P(M|I)\,dM$ is the probability of observing a measurement value between M and $M + dM$ given that the true intake is I.

DT_j is the decision threshold for a measurement carried out at t_j.

M_{min} is the lower limit of integration and its value depends on the choice of the probability distribution. For example, if the probability distribution is lognormal then M_{min}=0 but if it is normal then M_{min}=-∞.

Given that the true intake is I, $L_j(I)$ is the probability of the measured value being below DT_j and therefore being reported as $<DL$.

If a data set, of independent measurements, consists of n data points that are not reported as $<DL$ (i.e. above DT) and p points reported as $<DL$, then the combined likelihood function for the data set is given by:

$$L(I) = \left(\prod_{i=1}^{n} P(M_i|I) \right) \left(\prod_{j=1}^{p} \int_{M=M_{min}}^{DT_j} P(M_i|I)\,dM \right) \qquad (14.7)$$

Therefore, L(I) is associated with the probability of observing the data set given the intake.

For example, if it is assumed that the measurements are lognormally distributed (i.e. given by equation 14.4) then the last parenthesis of equation 14.7, which gives the probability of observing p measurements reported as $<DL$, is given by:

$$\prod_{j=1}^{p} \int_{M=0}^{DT_j} \frac{1}{M\ \ln(SF_j)\sqrt{2\pi}} \exp\left[-\frac{\left[\ln(M) - \ln(I\,m(t_j))\right]^2}{2\left[\ln(SF_j)\right]^2} \right] dM$$

where SF_j is the total scattering factor (Section 4.2).

14.2.3 Maximum likelihood method

Using the maximum likelihood method, the "best fit" value of the intake, I, is that which maximises the likelihood function given by equation 14.3 or equation 14.7. In general, the maximum must be determined numerically. This can be accomplished by stepping I from 0 to some limit value and searching for the maximum of the likelihood function, or a more sophisticated numerical method may be employed.

If the likelihood functions for all individual measurements are given by lognormal distributions (i.e. given by equation 14.4) and none of the measurements are reported as $<DL$, then the combined likelihood function is obtained by substituting equation 14.4 into equation 14.3:

$$L(I) = Const \times \exp\left[-\frac{\chi^2(I)}{2}\right] \qquad (14.8)$$

where

$$Const = \prod_{i=1}^{n} \frac{1}{\sqrt{2\pi} \cdot M_i \cdot \ln(SF_i)}$$

and

$$\chi^2(I) = \sum_{i=1}^{n} \frac{[\ln(M_i) - \ln(I\, m(t_i))]^2}{[\ln(SF_i)]^2}$$

The maximum of the likelihood function occurs where $\chi^2(I)$ is a minimum. In order to minimise χ^2 this expression is differentiated with respect to ln(I) and set equal to zero. Re-arranging for I gives:

$$\ln(I) = \frac{\sum_{i=1}^{n} \frac{\ln(M_i / m(t_i))}{[\ln(SF_i)]^2}}{\sum_{i=1}^{n} \frac{1}{[\ln(SF_i)]^2}}$$

Substituting $I_i = \frac{M_i}{m(t_i)}$

where I_i is the intake calculated from the ith measurement gives:

$$\ln(I) = \frac{\sum_{i=1}^{n} \frac{\ln(I_i)}{[\ln(SF_i)]^2}}{\sum_{i=1}^{n} \frac{1}{[\ln(SF_i)]^2}} \qquad (14.9)$$

So ln(I) is a weighted average of ln(I_i), the log of the individual intake estimates calculated from a single bioassay measurement. Various methods of weighting the individual estimates of intake I_i to obtain an average "best fit" value of I look to the maximum likelihood method for their justification.

As an example, consider urine data where the scattering factor is dominated by Type B uncertainties (i.e. uncertainties other than counting errors such as calibration errors, and errors related to biological variability and sampling procedures). In this case, the SF can be assumed to be constant for each of the urine measurements, i.e. $SF_i = SF_u$ = constant. Therefore, the equation for the best estimate of intake (14.9) reduces to

$$\ln(I) = \frac{1}{n}\sum_{i=1}^{n} \ln(I_i) = \ln\left[\left(\prod_{i=1}^{n} I_i\right)^{\frac{1}{n}}\right]$$

That is

$$I = \sqrt[n]{\prod_{i=1}^{n} I_i}$$

Therefore, when the values of the SF of the individual measurements can be considered equal to one another, the best estimate of intake is the geometric mean of the individual intake estimates.

Equation 14.9 can also be applied to cases where data sets from different monitoring techniques are available. For example, if n_u urine and n_f faecal data are available and the scattering factors for the urine and faecal data are SF_u and SF_f respectively, then equation 14.9 becomes:

$$\ln(I) = \frac{\sum_{i=1}^{n_u} \frac{\ln(I_i)}{(\ln(SF_u))^2} + \sum_{j=1}^{n_f} \frac{\ln(I_j)}{(\ln(SF_f))^2}}{\sum_{i=1}^{n_u} \frac{1}{(\ln(SF_u))^2} + \sum_{j=1}^{n_f} \frac{1}{(\ln(SF_f))^2}}$$

Or, in a simpler way ,

$$\ln(I) = \frac{\frac{\sum_{i=1}^{n_u} \ln(I_i)}{(\ln(SF_u))^2} + \frac{\sum_{j=1}^{n_f} \ln(I_j)}{(\ln(SF_f))^2}}{\frac{n_u}{(\ln(SF_u))^2} + \frac{n_f}{(\ln(SF_f))^2}} \qquad (14.11)$$

where I_i refers to the individual intake estimates from the urine data and I_j refers to the individual intake estimates from the faecal data. It is assumed here that Type B uncertainties dominate so that for each urine data, SF_i is assumed to be constant (= SF_u) and for each faecal data, SF_j is also assumed to be constant (= SF_f).

14.2.4 Extension to multiple intakes

Any previous intakes that influence the actual measurement result need to be taken into account. The guidelines propose to calculate the net value of the activity of the radionuclide, N_i by subtracting the contributions from previous intakes, P_i from the measurement value (i.e. $N_i = M_i - P_i$). For simplicity, ignoring the uncertainty in P_i, equation 14.9 can be applied to determine the best estimate of intake but with:

$$I_i = \frac{N_i}{m(t_i)}$$

In applying equation 14.9 to such cases, it is assumed that the net values of the activity are lognormally distributed with a given *SF*. It is acknowledged that the actual distribution of the net values is not lognormal because subtracting a value (P_i) from lognormally distributed values (M_i) does not result in another lognormal distribution.

An alternative approach is to fit the previous intakes as well as the intake of interest to all the data simultaneously using the maximum likelihood method. The maximum likelihood methodology can easily be extended to deal with several intakes. For *k* intakes, the likelihood function becomes

k-dimensional, and the problem becomes of one of finding the set of *k* values of *I* (intake amounts) that maximises it. For example, equation 14.4 becomes:

$$L_i(I) = \frac{1}{M_i \ln(SF_i)\sqrt{2\pi}} \exp\left[- \frac{\left[\ln(M_i) - \{\ln(I_1\ m_1(t_i - \tau_1)) + \ln(I_2\ m_2(t_i - \tau_2)) + \ldots + \ln(I_k\ m_k(t_i - \tau_k))\}\right]^2}{2\left[\ln(SF_i)\right]^2} \right]$$

where τ_1, τ_2, … τ_k are the times of each intake.

14.3 Annex 3 – The autocorrelation test statistics

Intakes, equivalent doses and effective doses are calculated with biokinetic and dosimetric models.

The autocorrelation test statistic has been considered by Puncher et al. (2007) as a tool for assessing the 'Goodness of fit' after fitting biokinetic models to bioassay data. This test statistic considered by Puncher et al. (2007) is the so called lag-1 autocorrelation statistic and is defined as:

$$\rho = \frac{\sum_{i=1}^{n-1} R_i R_{i+1}}{\sum_{i=1}^{n} R_i^{\,2}} \qquad (-1 < \rho < 1) \qquad (14.12)$$

Where R_i is the ith residual in the sequence of n residuals (where $n \geq 6$). If the fitting procedure assumes that the measurement uncertainties are distributed log-normally, with the same scattering factor (SF) for each measurement, then each residual is calculated as follows:

$$R_i = \frac{\ln(M_i) - \ln(I \;\; m(t_i))}{\ln(SF)} \qquad (14.13)$$

Where:

M_i The ith measurement, made at time t_i after the intake.

I The estimated intake.

$m(t_i)$ The predicted value of the measured quantity for unit intake at time t_i after the intake.

SF The scattering factor defined as the geometric standard deviation of the log-normal distribution.

There are several things to note regarding Equation (14.11):

- The numerator provides a measure of "non-randomness".
- The numerator is normalized by the sum of the square of the residuals (χ^2). This has the effect that the value of ρ is completely independent of the magnitude of the variance, and the assumed uncertainty.
- Under totally random conditions one would expect ρ=0. However, as the sequence becomes less random, ρ approaches unity. Thus, values of ρ close to unity indicate a poor fitting model.

The above formula for the autocorrelation coefficient does not apply to data that are reported as below the DL (<DL). The calculated value for ρ is compared to its null distribution, corresponding to the null hypothesis that there is no correlation between pairs of consecutive elements in the series of residuals. When the number of data n is greater than, or equal to, six, the null distribution of ρ may be approximated by a normal distribution. The mean (μ) and standard deviation (σ) of this distribution are

$$\mu = -\frac{1}{n} \qquad (14.14)$$

and $$\sigma = \frac{n-2}{n\sqrt{n-1}}. \qquad (14.15)$$

Therefore, p-values can easily be obtained from Statistical Tables. The Monte Carlo simulations carried out by Puncher et al., 2007 indicated that the ρ-statistic should be applied using an upper one tail test: The fit is considered inadequate when the probability that ρ is larger than ρ_0 is less than a specified level of significance; e.g. a critical value at 95% can be set at μ+1.64 σ, in which case the fit is rejected if $\rho_0 >$ μ+1.64 σ where ρ_0 is the calculated autocorrelation coefficient.

In cases where data sets from different monitoring techniques are available it is possible to extend the autocorrelation test (Gregoratto, 2013) by defining the auto-correlation statistic ρ for the whole sequence of n residues obtained by joining the data sets in the following way. As an example, for the case of two data sets, e.g, if both urine and faecal measurements are available, $n=n_U+n_F$, where n_U and n_F are the number of urine and faecal measurements, the autocorrelation may be defined as:

$$\rho = \frac{\sum_{i=1}^{n_U-1} R_{U,i} R_{U,i+1} + \sum_{i=1}^{n_F-1} R_{Fi,} R_{F,i+1}}{\sum_{i=1}^{n_U} R_{Ui}{}^2 + \sum_{i=1}^{n_F} R_{Fi}{}^2} = \rho_U \frac{\chi_U^2}{\chi^2} + \rho_F \frac{\chi_F^2}{\chi^2} \qquad (14.16)$$

where ρ_U and ρ_F are the autocorrelations calculated for each data set according to (Eq. 14.12),

χ_U^2 and χ_F^2 are the chi-squared calculated for each data set and $\chi^2 = \chi_U^2 + \chi_F^2$ is the total chi-squared.

When the total number of data n is greater than, or equal to six, the ρ statistic (Eq. 14.16) follows approximately a Gaussian distribution with mean and standard deviation calculated by

$$\mu = -\frac{1}{n}\left(\frac{n-n_{bio}}{n-1}\right) \qquad (14.17)$$

and $$\sigma = \frac{n-2}{n\sqrt{n-1}}\sqrt{\frac{n-n_{bio}}{n-1}}. \qquad (14.18)$$

where n_{bio} is the number of bioassay data sets (Note that Eqs. 14.17 and 14.18 reduce to Eqs. 14.14 and 14.15 respectively when $n_{bio}=1$). However, in order to detect correlations in the time series of

residues in any of the different bioassay datasets it is recommended that the number of data to be at least four for each dataset (Gregoratto, 2013).

A major strength of the ρ-statistic, apart from its objectivity, is that it is insensitive to the assumed variance of the bioassay data. This is in stark contrast to the χ^2 test, which is wholly dependent on the assumed variance of the data. It is therefore clear, that the ρ-statistic can be used to quantify the fit by eye test. The question as to whether it should be used to replace the χ^2 test is not so easy to answer. It could be argued that the two statistics measure different things and are independent e.g. the χ^2 test measures the total deviation from the predicted fit, while the ρ test measures non-randomness in the series of residuals after fitting. For example, if one test didn't reject, and the other did, then the model should be rejected. It does, however, bring into question what is meant by the significance of the tests. If, for example, there were 20 different independent tests, all carried out at the 95% confidence level, then one might expect that on average, at least one of the tests would reject a model that was correct. The combined significance of the tests must therefore be considered if both are to be used simultaneously.

To avoid this problem, it might be suggested that the ρ test should replace both the χ^2 test and the 'by eye' test. An argument in favour of this approach is suggested by the observation that if the model is incorrect, then the ρ test is always better at rejecting, independently of any error assumption. However, one disadvantage of the ρ test is that it cannot be applied where the number of data in each dataset is less than four. In these cases an alternative test must be used.

One advantage of applying both statistics is that there might be situations in which the ρ test refutes the null hypothesis, and the χ^2 test doesn't. These situations indicate that the error on the measurements may have been overestimated, and a more realistic error might be inferred from the measurement data.

14.4 Annex 4 – Hand evaluation of the p-value

To help in the evaluation of the probability value

$$P\left(\chi^2 > \chi_0^2\right) = P\left(\tilde{\chi}^2 > \tilde{\chi}_0^2\right)$$

the probability values for an observed reduced chi-square value is reported in Table 14.17.

The p-value correspond to the following integral

$$p-value = \frac{2}{2^{d/2}\cdot\Gamma\left(d/2\right)}\int_{\chi_0}^{\infty} x^{d-1}e^{-x^2/2}dx$$

The use of the Table 14.17 is as follows.

First calculate the reduced observed chi-square

$$\tilde{\chi}_0^{\,2} = \frac{\chi_0^{\,2}}{n_d}$$

(where n_d =n-1 is the number of degrees of freedom, where n is the total number of used measurements), then look for its value in the table in the line corresponding to n_d.

For example, having an observed value of chi-square of 13 with 10 degrees of freedom, first calculate

$$\tilde{\chi}_0^{\,2} = \frac{13}{10} = 1.3$$

for 10 degrees of freedom, the probability for this value of reduced chi-square is 0.224; as this value is above 0.05, the fit is not rejected.

Alternatively the p-value can be evaluated by means of the Microsoft Excel™ function CHIDIST(x,deg_freedom) where "x" is the observed chi-square value and "deg_freedom" is the number of degrees of freedom = n-1).

Table 14.17 : Values of probability associated to $P\left(\tilde{\chi}^2 > \tilde{\chi}_0^2\right)$

	P value for observed reduced chi-square and degrees of freedom.																													
	Observed reduced chi-squared																													
DoF	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2	2.1	2.2	2.4	2.6	2.8	3	3.5	4	4.5	5
1	0.752	0.655	0.584	0.527	0.480	0.439	0.403	0.371	0.343	0.317	0.294	0.273	0.254	0.237	0.221	0.206	0.192	0.180	0.168	0.157	0.147	0.138	0.121	0.107	0.094	0.083	0.061	0.046	0.034	0.025
2	0.905	0.819	0.741	0.670	0.607	0.549	0.497	0.449	0.407	0.368	0.333	0.301	0.273	0.247	0.223	0.202	0.183	0.165	0.150	0.135	0.122	0.111	0.091	0.074	0.061	0.050	0.030	0.018	0.011	0.007
3	0.960	0.896	0.825	0.753	0.682	0.615	0.552	0.494	0.440	0.392	0.348	0.308	0.272	0.241	0.212	0.187	0.165	0.145	0.127	0.112	0.098	0.086	0.066	0.050	0.038	0.029	0.015	0.007	0.004	0.002
4	0.982	0.938	0.878	0.809	0.736	0.663	0.592	0.525	0.463	0.406	0.355	0.308	0.267	0.231	0.199	0.171	0.147	0.126	0.107	0.092	0.078	0.066	0.048	0.034	0.024	0.017	0.007	0.003	0.001	-
5	0.992	0.963	0.913	0.849	0.776	0.700	0.623	0.549	0.480	0.416	0.358	0.306	0.261	0.221	0.186	0.156	0.131	0.109	0.091	0.075	0.062	0.051	0.035	0.023	0.016	0.010	0.004	0.001	-	-
6	0.996	0.977	0.937	0.879	0.809	0.731	0.650	0.570	0.494	0.423	0.359	0.303	0.253	0.210	0.174	0.143	0.116	0.095	0.077	0.062	0.050	0.040	0.025	0.016	0.010	0.006	0.002	0.001	-	-
7	0.998	0.986	0.954	0.903	0.835	0.756	0.672	0.587	0.505	0.429	0.360	0.299	0.246	0.200	0.162	0.130	0.104	0.082	0.065	0.051	0.040	0.031	0.019	0.011	0.007	0.004	0.001	-	-	-
8	0.999	0.991	0.966	0.921	0.857	0.779	0.692	0.603	0.515	0.433	0.359	0.294	0.238	0.191	0.151	0.119	0.093	0.072	0.055	0.042	0.032	0.024	0.014	0.008	0.004	0.002	-	-	-	-
9	1.000	0.994	0.975	0.936	0.876	0.798	0.710	0.616	0.524	0.437	0.359	0.290	0.231	0.182	0.141	0.109	0.083	0.063	0.047	0.035	0.026	0.019	0.010	0.005	0.003	0.001	-	-	-	-
10	1.000	0.996	0.981	0.947	0.891	0.815	0.725	0.629	0.532	0.440	0.358	0.285	0.224	0.173	0.132	0.100	0.074	0.055	0.040	0.029	0.021	0.015	0.008	0.004	0.002	0.001	-	-	-	-
11	1.000	0.998	0.986	0.957	0.905	0.830	0.740	0.640	0.539	0.443	0.356	0.280	0.217	0.165	0.124	0.091	0.067	0.048	0.034	0.024	0.017	0.012	0.006	0.003	0.001	0.001	-	-	-	-
12	1.000	0.998	0.990	0.964	0.916	0.844	0.753	0.651	0.546	0.446	0.355	0.276	0.210	0.157	0.116	0.084	0.060	0.042	0.029	0.020	0.014	0.009	0.004	0.002	0.001	-	-	-	-	-
13	1.000	0.999	0.992	0.971	0.926	0.856	0.765	0.661	0.552	0.448	0.353	0.271	0.204	0.150	0.108	0.077	0.054	0.037	0.025	0.017	0.011	0.007	0.003	0.001	0.001	-	-	-	-	-
14	1.000	0.999	0.994	0.976	0.935	0.867	0.777	0.670	0.558	0.450	0.351	0.267	0.198	0.143	0.102	0.071	0.048	0.033	0.022	0.014	0.009	0.006	0.002	0.001	-	-	-	-	-	-
15	1.000	1.000	0.996	0.980	0.942	0.878	0.787	0.679	0.564	0.451	0.350	0.263	0.192	0.137	0.095	0.065	0.044	0.029	0.019	0.012	0.008	0.005	0.002	0.001	-	-	-	-	-	-
16	1.000	1.000	0.997	0.983	0.949	0.887	0.797	0.687	0.569	0.453	0.348	0.258	0.186	0.131	0.090	0.060	0.039	0.025	0.016	0.010	0.006	0.004	0.001	-	-	-	-	-	-	-
17	1.000	1.000	0.997	0.986	0.955	0.895	0.806	0.695	0.574	0.454	0.346	0.254	0.181	0.125	0.084	0.055	0.035	0.022	0.014	0.008	0.005	0.003	0.001	-	-	-	-	-	-	-
18	1.000	1.000	0.998	0.988	0.960	0.903	0.815	0.703	0.579	0.456	0.344	0.250	0.176	0.120	0.079	0.051	0.032	0.020	0.012	0.007	0.004	0.002	0.001	-	-	-	-	-	-	-
19	1.000	1.000	0.999	0.990	0.964	0.910	0.823	0.710	0.583	0.457	0.342	0.246	0.171	0.114	0.074	0.047	0.029	0.017	0.010	0.006	0.003	0.002	0.001	-	-	-	-	-	-	-
20	1.000	1.000	0.999	0.992	0.968	0.916	0.830	0.717	0.587	0.458	0.341	0.242	0.166	0.109	0.070	0.043	0.026	0.015	0.009	0.005	0.003	0.002	-	-	-	-	-	-	-	-
21	1.000	1.000	0.999	0.993	0.972	0.922	0.838	0.723	0.592	0.459	0.339	0.239	0.161	0.105	0.066	0.040	0.024	0.014	0.008	0.004	0.002	0.001	-	-	-	-	-	-	-	-
22	1.000	1.000	0.999	0.994	0.975	0.927	0.845	0.729	0.596	0.460	0.337	0.235	0.157	0.100	0.062	0.037	0.021	0.012	0.007	0.004	0.002	0.001	-	-	-	-	-	-	-	-
23	1.000	1.000	1.000	0.995	0.977	0.932	0.851	0.735	0.599	0.461	0.335	0.231	0.152	0.096	0.058	0.034	0.019	0.011	0.006	0.003	0.002	0.001	-	-	-	-	-	-	-	-
24	1.000	1.000	1.000	0.996	0.980	0.937	0.857	0.741	0.603	0.462	0.333	0.228	0.148	0.092	0.055	0.032	0.018	0.009	0.005	0.003	0.001	0.001	-	-	-	-	-	-	-	-
25	1.000	1.000	1.000	0.997	0.982	0.941	0.863	0.747	0.607	0.462	0.331	0.224	0.144	0.088	0.052	0.029	0.016	0.008	0.004	0.002	0.001	-	-	-	-	-	-	-	-	-
26	1.000	1.000	1.000	0.997	0.984	0.945	0.868	0.752	0.610	0.463	0.330	0.221	0.140	0.085	0.049	0.027	0.014	0.007	0.004	0.002	0.001	-	-	-	-	-	-	-	-	-
27	1.000	1.000	1.000	0.998	0.986	0.949	0.874	0.757	0.614	0.464	0.328	0.218	0.136	0.081	0.046	0.025	0.013	0.007	0.003	0.002	0.001	-	-	-	-	-	-	-	-	-
28	1.000	1.000	1.000	0.998	0.987	0.952	0.879	0.762	0.617	0.464	0.326	0.214	0.133	0.078	0.043	0.023	0.012	0.006	0.003	0.001	0.001	-	-	-	-	-	-	-	-	-
29	1.000	1.000	1.000	0.998	0.989	0.956	0.883	0.767	0.620	0.465	0.324	0.211	0.129	0.075	0.041	0.021	0.011	0.005	0.002	0.001	-	-	-	-	-	-	-	-	-	-
30	1.000	1.000	1.000	0.999	0.990	0.959	0.888	0.772	0.623	0.466	0.323	0.208	0.126	0.072	0.039	0.020	0.010	0.005	0.002	0.001	-	-	-	-	-	-	-	-	-	-
31	1.000	1.000	1.000	0.999	0.991	0.961	0.892	0.777	0.626	0.466	0.321	0.205	0.122	0.069	0.036	0.018	0.009	0.004	0.002	0.001	-	-	-	-	-	-	-	-	-	-
32	1.000	1.000	1.000	0.999	0.992	0.964	0.896	0.781	0.629	0.467	0.319	0.202	0.119	0.066	0.034	0.017	0.008	0.004	0.002	0.001	-	-	-	-	-	-	-	-	-	-
33	1.000	1.000	1.000	0.999	0.993	0.966	0.900	0.785	0.632	0.467	0.317	0.199	0.116	0.063	0.032	0.016	0.007	0.003	0.001	0.001	-	-	-	-	-	-	-	-	-	-
34	1.000	1.000	1.000	0.999	0.993	0.968	0.904	0.789	0.635	0.468	0.316	0.196	0.113	0.061	0.031	0.015	0.007	0.003	0.001	-	-	-	-	-	-	-	-	-	-	-
35	1.000	1.000	1.000	0.999	0.994	0.970	0.908	0.794	0.638	0.468	0.314	0.193	0.110	0.058	0.029	0.014	0.006	0.003	0.001	-	-	-	-	-	-	-	-	-	-	-
36	1.000	1.000	1.000	1.000	0.995	0.972	0.911	0.797	0.641	0.469	0.312	0.191	0.107	0.056	0.027	0.013	0.005	0.002	0.001	-	-	-	-	-	-	-	-	-	-	-
37	1.000	1.000	1.000	1.000	0.995	0.974	0.914	0.801	0.643	0.469	0.311	0.188	0.105	0.054	0.026	0.012	0.005	0.002	0.001	-	-	-	-	-	-	-	-	-	-	-
38	1.000	1.000	1.000	1.000	0.996	0.976	0.918	0.805	0.646	0.469	0.309	0.185	0.102	0.052	0.024	0.011	0.005	0.002	0.001	-	-	-	-	-	-	-	-	-	-	-
39	1.000	1.000	1.000	1.000	0.996	0.977	0.921	0.809	0.648	0.470	0.308	0.183	0.099	0.050	0.023	0.010	0.004	0.002	0.001	-	-	-	-	-	-	-	-	-	-	-
40	1.000	1.000	1.000	1.000	0.997	0.979	0.923	0.812	0.651	0.470	0.306	0.180	0.097	0.048	0.022	0.009	0.004	0.001	0.001	-	-	-	-	-	-	-	-	-	-	-
41	1.000	1.000	1.000	1.000	0.997	0.980	0.926	0.816	0.653	0.471	0.304	0.178	0.094	0.046	0.021	0.009	0.003	0.001	-	-	-	-	-	-	-	-	-	-	-	-
42	1.000	1.000	1.000	1.000	0.997	0.981	0.929	0.819	0.656	0.471	0.303	0.175	0.092	0.044	0.020	0.008	0.003	0.001	-	-	-	-	-	-	-	-	-	-	-	-
43	1.000	1.000	1.000	1.000	0.997	0.982	0.932	0.822	0.658	0.471	0.301	0.173	0.090	0.042	0.019	0.007	0.003	0.001	-	-	-	-	-	-	-	-	-	-	-	-
44	1.000	1.000	1.000	1.000	0.998	0.984	0.934	0.826	0.661	0.472	0.300	0.171	0.087	0.041	0.018	0.007	0.003	0.001	-	-	-	-	-	-	-	-	-	-	-	-
45	1.000	1.000	1.000	1.000	0.998	0.985	0.936	0.829	0.663	0.472	0.298	0.168	0.085	0.039	0.017	0.006	0.002	0.001	-	-	-	-	-	-	-	-	-	-	-	-
46	1.000	1.000	1.000	1.000	0.998	0.986	0.939	0.832	0.665	0.472	0.297	0.166	0.083	0.038	0.016	0.006	0.002	0.001	-	-	-	-	-	-	-	-	-	-	-	-
47	1.000	1.000	1.000	1.000	0.998	0.986	0.941	0.835	0.667	0.473	0.295	0.164	0.081	0.036	0.015	0.006	0.002	0.001	-	-	-	-	-	-	-	-	-	-	-	-
48	1.000	1.000	1.000	1.000	0.999	0.987	0.943	0.838	0.670	0.473	0.294	0.162	0.079	0.035	0.014	0.005	0.002	0.001	-	-	-	-	-	-	-	-	-	-	-	-
49	1.000	1.000	1.000	1.000	0.999	0.988	0.945	0.840	0.672	0.473	0.292	0.159	0.077	0.034	0.013	0.005	0.002	0.001	-	-	-	-	-	-	-	-	-	-	-	-
50	1.000	1.000	1.000	1.000	0.999	0.989	0.947	0.843	0.674	0.473	0.291	0.157	0.075	0.032	0.013	0.004	0.001	-	-	-	-	-	-	-	-	-	-	-	-	-

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Abbreviation and symbols

AMAD	Activity Median Aerodynamic Diameter
A_U	Area under the activity concentration data, eq. (12.4)
b	Numerical constant equal to 86400 s/d , eq. (12.2)
C_i	Activity concentration of tritiated water in urine sample i
CIS	Colloid and intermediate state
CONRAD	Coordinated Network for radiation dosimetry: project funded by European Commission within the 6th Framework Programme for research and training in nuclear energy (Jan. 2005 – May 2008).
C_m	Normalization factor in eq. (4.2)
D	Assessed committed effective dose in Table 6.1
D_T	Mean absorbed dose in organ or tissue T
DL	Detection limit
DT	Decision threshold
DTPA	Diethylene triamine pentaacetic acid
E(50)	Committed effective dose
E	Effective dose
ELP	Exercise Left to Participants
f_1	Fractional absorption as in ICRP 30 Gastro-intestinal model
f_A	Fraction of the material entering the alimentary tract that is absorbed in the absence of radioactive decay or endogenous input to the tract
$F_{1\text{-}3}$	Cumulative faecal excretion over the first 3 days after intake
F_{fing}	Fraction of ingested activity in cumulative faecal excretion (section 10.3)
F_{finh}	Fraction of inhaled activity in cumulative faecal excretion (section 10.3)
F_{inh}	Inhaled fraction in a mixed inhalation-ingestion intake (section 10.3)
F_L	Fraction of inhaled activity in lungs (section 10.3)
GLs	Guidelines
GOF	Goodness of fit
H_T^M	Equivalent dose for organ or tissue T of the Reference Male
H_T^F	Equivalent dose for organ or tissue T of the Reference Female
H_{rmd}^M	Equivalent dose for the remainder tissues of the Reference Male
H_{rmd}^F	Equivalent dose for the remainder tissues of the Reference Female
HATM	Human Alimentary Tract Model
HRTM	Human Respiratory Tract Model
HTO	Tritiated water
I	Intake
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection.
ICP-MS	Inductively coupled plasma mass spectrometry
IDEAS	General Guidelines for the Estimation of Committed Effective Dose from Incorporation Monitoring Data (IDEAS Guidelines)
IMIE	Individual Monitoring of Internal Exposure software
IMBA™	Integrated Modules for Bioassay Analysis software
ISO	International Organization for Standardization
l	Number of varying parameters for a linear model
k	Number of multiple intakes in section 14.2.4
$L_i(I)$	Likelihood function of observing a measurement value M_i, given the true value of intake is I.
L_3	Lung activity at day 3 after intake
LN	Lymph nodes

M	Measured quantity (e.g. whole body measured content or measured urinary daily excretion)
M_c	Critical monitoring quantity
m(t)	Retention or excretion function at time t per unit intake
m(T/2)	Retention or excretion function at mid time of monitoring period T, per unit intake
mSv	milli sievert
NCRP	National Council on Radiation Protection and Measurements
n	number of available measurements, eq (6.1), (12.3)
n_{bio}	number of bioassay data sets in eq (14.18)
N	Net value of the activity
N_B	Number of measured background counts in eq (4.2)
N_G	Number of measured counts in eq (4.2)
OIR	Occupational Intakes of Radionuclides
P	Contribution, to the measurement M, of all previous, already evaluated, intakes
PABS	Particles, Aggregates and Bound State
R	Correlation coefficient
R_B	Background count rate , eq. (4.2)
R_i	Normalized residual i, eq (6.1), (14.13)
$SEE^M(T \leftarrow S)$	Specific Effective Energy for the Reference Male (S = source region, T = target region)
SF	Scattering Factor
SF_A	Scattering Factor component due to counting statistics
SF_B	Scattering Factor component due to all other uncertainties
$SF_{u,i}$	Scattering Factor related to urinary measurement i
$SF_{f,j}$	Scattering Factor related to faecal measurement j
T	Monitoring period
T_B	Background count time , eq. (4.2)
T_S	Sample count time , eq. (4.2)
TIMS	Thermal Ionization Mass Spectrometry
TPA	Trapped particles and aggregates
Tr-KPA	Kinetic phosphorescence analysis
$U_S(50)$	Number of nuclear transformations in 50 years in source region S
WG7	Working Group 7 internal dosimetry within EURADOS
w_T	Tissue weighting factor
x_{50}	Median of all measured values at a certain time t after intake
χ_o^2	Observed chi-squared value
χ_U^2	Observed chi-squared value calculated for the urine dataset
χ_F^2	Observed chi-squared value calculated for the faeces dataset
$\tilde{\chi}_0^2$	Reduced observed chi-squared value
ρ	Autocorrelation test statistic
ρ_U	Autocorrelation value calculated for urine dataset
ρ_F	Autocorrelation value calculated for faeces dataset
σ_A	Type A uncertainty