Necessity for Public Domain availability of Computing Software for Federal EEOICPA compensation for exposure to Nuclear Weapon Radiation

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Abstract

This research describes a computer program, called IREP, Interactive RadioEpidemiological Program which is used by Department of Labor in conjunction with other US agencies, CDC, NIOSH, to compute a probability that individual workers in specific groups developed cancer because they had been exposed to radiation during their work at facilities operated by the Federal government. This manuscript provides anonymized cancer results from one individual who developed cancer after exposure to radiation from work on the atomic bomb at a nuclear weapons facility. The central premise for this work is the request that the software source code is published in the public domain, accessible to anyone for download and inspection.

Key Words: Interactive RadioEpidemiological Program

1. EEOICPA

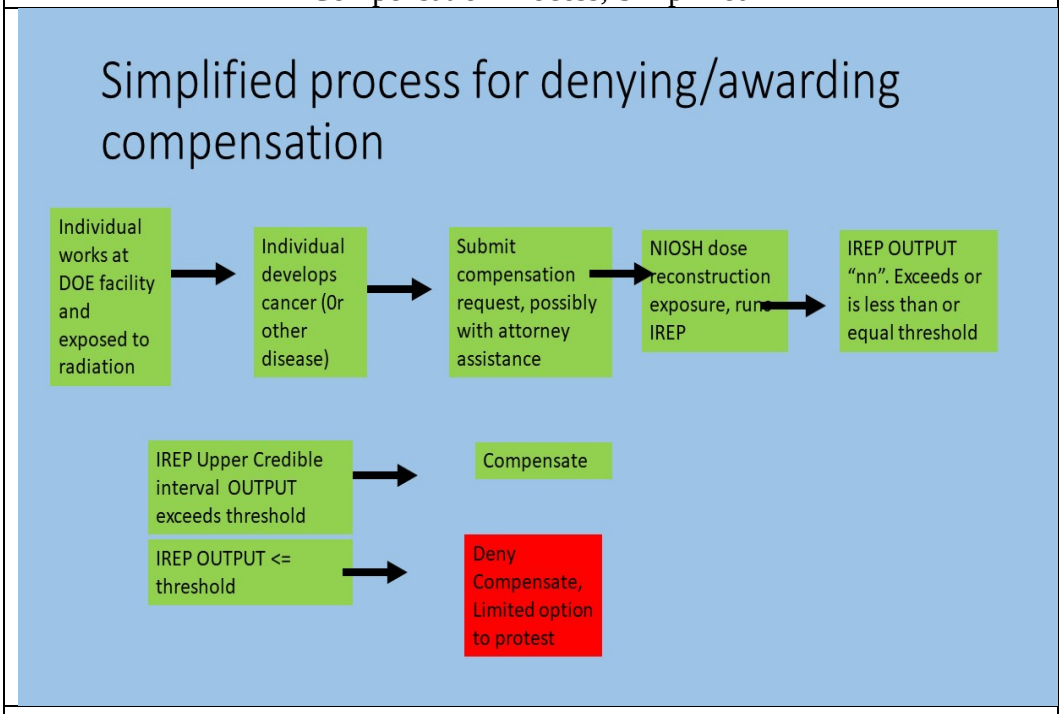
The Energy Employees Occupational Illness Compensation Program Act (EEOICPA) is a federal law the provides compensation for workers employed by the U.S. Department of Energy's (DOE) contractors or its predecessors who developed life threatening diseases due to their exposure to radiation and other toxic substances at DOE's nuclear weapons facilities. This includes workers employed at plutonium producing plants such as Hanford located in Washington, nuclear weapons production facilities, such as Oak Ridge located in Tennessee, as well as workers who were exposed during the above and underground testing of the nuclear arsenal at the Nevada Test Site.

Compensation under EEOICPA

1. EEOICPA program provides financial and medical compensation for DOL contract and subcontract workers exposed to radiation and other toxic substances who develop cancer or other diseases.
2. Decisions to award compensation under Part B of EEOICPA is based on estimated measurements of radiation exposure a worker may have received by reconstructing a worker's dose. The National Institute for Occupational Safety and Health (NIOSH) is responsible for the dose reconstruction process. These reconstructions utilize the Interactive Radio Epidemiological Program (IREP) computer program. IREP was developed and is managed by NIOSH to estimate if cancer due to radiation.
3. IREP source code is not publicly available. Despite the statute's explicit language that NIOSH "…shall …make available to researchers and the general public information on the

assumptions, methodology, and data used in establishing radiation doses under subsection…" NIOSH refuses to provide code. Source code level documentation needs to be publicly available.
4. Compensation decisions can have a life-or-death impact for the worker.
5. IREP source code, and source code level documentation should be in the public domain

Figure I
Compensation Process, Simplified



Motivating Example

The project arose when the anonymous individual had disputed a second computation of probability of causation and was given one final chance for a recalculation before a final decision was made. The two initial POCs had a value of the upper limit of the credible interval that was less than the threshold value.

1.1 Request of NIOSH, CDC and any agency with responsibility for IREP

NIOSH and any and every US government agency involved in the determination of benefits should, without exception provide publicly available source code and all related documentation of the IREP software program and related programs for the determination of compensation for the Patriotic contributions to government initiatives and exposure to lethal and life ending radiation exposures. The anonymous individual was exposed to radiation while working on plutonium triggers for the bomb.

1.2 Overview Of Process Of Calculation Of Probability Of Causation

1.2.1. Radiation Exposure History – film strips

Every individual who worked with radioactive materials recorded exposure with a film strip. The film strips were retained indefinitely. The exposure measurements were used as one critical input to the calculation of probability of cancer in the IREP program. As will be repeated below, the technical details and source code for these calculations is not in the public domain.

Under EEOICPA, individuals exposed to radiation during work with nuclear materials at US government facilities administered by DOL, including nuclear bomb testing were eligible for compensation. According to the DOL and NIOSH interpretation of the law, each claimant received a single numeric score (ranging from 0 to 100) from a computer program called "IREP". If the upper 99% credible limit of the score exceeded a threshold, claimant was reimbursed. If the upper 99% credible limit of the score did not exceed ("<") then claim was denied. I undertook a critical review of the public available information about the "compute program". Computer program called IREP for the calculation is not in the public domain and NIOSH would not release a copy for inspection

1.2.2 The IREP source code, source code documentation not publicly available
Despite my (CB) requests for the software to NIOSH through their website question feature, for the software, NIOSH refused to release the software, or its documentation in any form whatsoever, such as source code or a version for compiling on my own desktop
There does not appear to exist a standalone document describing and documenting in detail the program statements for IREP
There is no documentation of the supplementary software IMBAS.
NIOSH refers researchers to a publication in Health Physics (HP). The HP article does not give any of the detail clearly described in public documents

1.2.3 IMBA – Integrated Module for BioAssay Analysis

Excerpting from the CDC web page at (https://www.cdc.gov/niosh/ocas/imba.html) "Integrated Modules for Bioassay Analysis (IMBA) is a licensed computer software program that is used by NIOSH to calculate individual organ doses which result from the intake of radioactive material into the body. The program is based on internationally accepted models published by the International Commission on Radiological Protection (ICRP) and consists of several software modules created by the National Radiological Protection Board (NRPB) of the United Kingdom."

The IMBA statement is mis-leading. First, there are no actual measurements obtained of individual organ doses. The IMBA program is used to estimate or impute individual organ doses. The source code, source code documentation must be publicly available in order to verify the algorithms for imputing the individual doses. The CDC web page does not give the precise statement of the algorithms, and the user must guess the exact algorithms used.

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Material Errors, Questions, Concerns, Objections, False and Misleading Statements, Omissions, Gaps, Factual Mistakes, in NIOSH assigned share estimate, NIOSH models, NIOSH Process and Procedures and NIOSH documentation used for rejection of compensation under EEOICPA for <claimant > for cancers caused by Plutonium radiation exposure at <nuclear location>
Version 2.0

April 21, 2013

Chris Claimant , Ph.D.
Statistical Consultant and
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Statement

This letter is in response to the denial of compensation by NIOSH for a prostate and melanoma in situ cancers caused by radiation exposure from Plutonium of <claimant >, based on the assigned share model - mislabeled as a "probability of causation" - a false and misleading term. According to a <dates redacted> letter from NIOSH, Claimant was employed at <nuclear location>from <dates redacted> .The latter date is an error. Copies of the letters to Claimant and other relevant documents from NIOSH attached as scanned documents.

- It is not possible to replicate the dose reconstruction, or the NIOSH "POC" or assigned share calculations, due to numerous false and misleading statements in NIOSH documentations, and numerous gaps, omissions and errors..

<claimant >s assigned share using single cancer models is positive and is -not-zero. The NCI models are for single cancers not multiple cancers. Therefore this adds incontrovertible evidence that the cancer was caused by his prior Plutonium exposure.

We are further concerned that Claimant's assigned share is a gross underestimate of assigned share, due to the flaws, errors, omissions, inconsistencies, gaps, limitations and outright mistakes and false statements in the methods for assembling the data, reconstructing the dose, estimating the assigned share, incorrect use of statistical risk models, absence of uncertainties and numerous other errors. The flaws, gaps, omissions, inconsistencies, limitations, absence of uncertainties and outright mistakes are enumerated below. The list below is based on the incomplete documentation provided to date and we expect to have further comments upon receipt of the complete documentation.

The assigned share is claimant unfavorable and is falsely asserted as a measure of causality and has no known properties as a causal measure. There are numerous well studied valid causal methodologies in Statistics, Epidemiology and Econometrics.

Background

In reviewing the scanty public domain available documents we notice numerous claimant unfavorable limitations, shortcomings, gaps, and clear errors in the available documents and models.

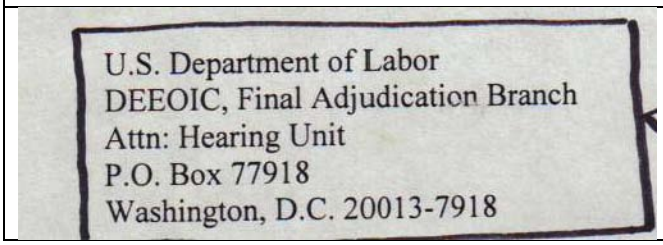
The scanty information provided in a variety of NIOSH documents and user manuals for IREP and IMBAS is not sufficient to reconstruct the analyses prepared by NIOSH, and insufficient to permit a scientific valid claimant favorable statistical sensitivity analysis.

Requests

We enumerate our requests below which are expected to permit replication of the dose reconstruction and simulation based analysis prepared by NIOSH and provide the definitive scientifically valid statistical analysis of the assigned share.

Error in NIOSH records on dates of <claimant>'s employment

Error in DEEOIC Mailing Address

Package mailed to DEEOIC returned


Claimant Unfavorable Assumption of Statistical Independence of Multiple Cancers.

The lack of details on the models and simulations leaves it unclear if or how the combined or Joint risk of two cancers, melanoma in situ and prostate cancer are modelled using the NCI and IREP equations. We request complete details on the method of combination of the assigned shares for the two cancers. The claimant -unfavorable and erroneous method is to model the marginal distribution of each cancer and combine in a naive manner, ignoring the statistical and biological relationship between the cancers and the common cancer causing radiation mechanism.

A claimant favorable distribution for a joint (bivariate) risk is that relative risks are multiplicative, or a power function.

Letters sent from NIOSH to <CLAIMANT> and documentation imply that <CLAIMANT>'s two cancers are separately modelled assuming statistical independence and the combined Assigned Share determined by an undocumented ad hoc combination of the marginal assigned share estimates. This ad hoc combination is statistically and scientifically impossible. We request that <CLAIMANT>'s cancers be modelled by an appropriate joint probability distribution, reflecting the probability of simultaneously having two cancers with a common cause radiation exposure using a claimant favorable prior joint distribution multiplicative in the relative risks.

a) Many sections of the dose reconstruction documents provided in spiral ring binders by NIOSH are illegible and unreadable. We request original, clear, readable copy in electronic format.

b) It appears that several pages of the data used for IREP may have equations embedded in the text, but these are unreadable - we request clear readable copy.

c) We request the full citations and copies of the National Cancer Institute models that apparently underlie the NIOSH IREP and IMBAS.

d) We request full access to the NIOSH IREP computer program source code and the associated documentation of the source code. We request all available documentation of the source code. The source code should be open-source, similar to well known statistical programs such as R.

e) We request relevant papers, computer program source code documentation, and unrestricted access to the bioassay program and its source code for IMBA.

f) We request full access to the POC calculations and de-identified dosing and cancer outcome data for all other employees evaluated under the NIOSH IREP model, in sufficient detail to prepare a valid statistical sensitivity analysis.

g) Based on the response from NIOSH, exhibit A, there is no single document that details the "equations" used in the model and no document that details exactly what was simulated and how. We request a single document with the complete documentation of the computer program IREP

h) We request the POC and all intermediate calculations from each of the 30 runs from Claimant data.

i) In the bioassay samples, we request the variance of the normal distribution be estimated from the available data, rather than assumed, or estimated in a Bayesian model using a normal distribution with a conjugate normal prior distribution.

j) We request the complete radiation badge raw data for <CLAIMANT> in an excel or .csv type format with clear hard copy of the badge data.

k) We request the details of the intermediate and final calculations resulting in the radiation exposure estimates and the missing data estimates

l) We request clarification as to whether or not the log transformed radiation exposure data was used in the estimation of the "POC" (attributable share).

m) We request the implementation of a Bayesian statistical model using a Markov Chain Monte Carlo (MCMC) to find an equilibrium distribution, with adequate burn-in with Gibbs sampler and adaptive rejection method - this method declassified and published in 1949 by Metropolis and 1953 by

Metropolis, Teller et al, subsequent publications by Ulam and Hastings etc. (cf References).

n) We request an evaluation of the existing NIOSH model operating characteristics by simulation, to estimate under a broad set of scenarios, the Type I and Type II error rates for probability of causation where Type I and II are based on the mathematical statistical theory of Neyman and Pearson and subsequent work.

o) We request that copies of the documents/manuals cited in the NIOSH materials provided to <CLAIMANT>, for "uncertainty assessment" be provided free of charge to <CLAIMANT>.

p) We request preparation of a full Bayesian probability model in conjunction with our itemized requests and to rectify errors noted below.

q) We request confirmation for each letter to <CLAIMANT> referring to POC whether the result was based on Probability of Causation (assigned share) or the xx% confidence intervals.

r) An additional personal statement from <CLAIMANT> "I recall wearing wrist badges on several occasions, but I have not been able to determine the frequency of use of the wrist badges in the documents sent to me from Atlanta. I have no way to determine if the data are complete, but I remember several occasions where multiple film badges were required during certain plutonium assembly operations. Assembly is what I did for several years. "

Claimant -unfavorable unknown statistical operating characteristics of the IREP, IMBAS models.

We request the preparation of statistical simulations to estimate the operating characteristics of the IREP software to estimate the Type I and Type II statistical error and false positive, true positive, false negative, true negative, operating characteristics.

Claimant -unfavorable Limitations and errors in current NIOSH formulation of "Probability of Causation"

A major concern with the NIOSH IREP model is that by design it "simulates to a claimant unfavorable foregone conclusion" using various unrealistic and inflexible assumptions. In a Bayesian statistical framework the NIOSH IREP inflexible distributions are an explicit example of the well known Bayesian theorem - Cromwell's rule. Under those circumstances it is appropriate to prepare a statistical analysis to assess sensitivity of the findings to the various and numerous assumptions.

Claimant unfavorable use of a Non-Causal assigned share model

The NIOSH IREP assigned share model uses a model which has no known properties for evaluating causation, when there are valid, deeply researched causal models in Statistics, Epidemiology and Econometrics.

Claimant Unfavorable IREP and IMBAS missing sources of uncertainty

The documentation of IMBAS and IREP has gaps, and omissions. The models miss the uncertainty in the reconstructed dose, uncertainty in imputation of missing values, uncertainty in coworker doses, and uncertainty in joint distribution of multiple cancers.

Claimant Favorable Full Bayesian Probability Model and Claimant Favorable Statistical Analysis using Markov Chain Monte Carlo (MCMC) methods

A Bayesian Statistical model is the most appropriate statistical methodology to examine and analyze and re-analyze the data and assigned share (falsely labelled as "probability of Causation") . A Bayesian statistical methodology includes -all- uncertainties, including distribution, distribution parameters and models.

Within the Bayesian framework, for example, the sensitivity of the NIOSH IREP model to assumption of a Log-Normal distribution should be examined using a claimant -favorable Gamma or Poisson function with appropriate claimant favorable prior distributions. Both Gamma and Poisson are counting distributions, consistent with the particle nature of radiation, and each produces a distribution of counts.

We request a Bayesian statistical assessment of the sensitivity of the Triangular distribution with an appropriately claimant favorable parameterized Beta Distribution. The triangular distribution is a special case of a beta distribution. Similarly we request an evaluation of the reasonableness or "uncertainty" of the normal distribution assumption using a conjugate normal prior distribution

The sensitivity of the NIOSH model to missing data needs to be explored in the context of well known statistical scenarios of "Missing Completely at Random", "Missing at Random" and "Not Missing at Random".

Particularly concerning is use of a single step imputation of missing dose which gives a claimant unfavorable bias.

- We request a claimant favorable imputation - either a multiple imputation or other plausible bayesian posterior predictive distribution of the missing data with a relevant prior distributions.

- We request implementation of a proper and full probability model for the relative risk and assigned share, that applies Bayes rule and the law of Total Probability to estimate probabilities of causation/assigned share with the available data using a Markov Chain Monte Carlo (MCMC) algorithm with adequate run-in on a modern Intel-type processor, such as an Intel Core 3 or

faster chip) and evaluation of the autocorrelation structure of the MCMC runs, and use of the Gibbs Sampler, and adaptive rejection in software such as WINBUGS.

Quantities of interest include the proper posterior predictive distribution of estimates, the 99% credible intervals and characterize the Type I, Type II, positive and negative predictive values, false positive and false negative rates, updating the model with <CLAIMANT>'s data.

The current models are at best poorly or not at all documented as per Exhibit A. As per the Exhibit A, below from NIOSH there is no single document that defines how the estimates are prepared but suggests looking at a publication in Health Physics. From the document http://dceg.cancer.gov/files/NIH_No_03-5387.pdf that does not explicitly state, Monte CArlo simulation is used to estimate uncertainty.

The paper in Health physics, does not provide adequate detail of a valid statistical method of POC estimation, for example, neither a full likelihood or a Bayesian probability model is adopted. The method in Health Physics appears to be completely ad hoc with no known statistical properties nor known operating characteristics for Type I or Type II error.

Frequentist statistical models of the risk and exposure may yield analytical closed form solutions based on the likelihood. Full probability -Bayesian- methods produce valid posterior (and other) estimates. Nowhere in the field of statistics is it -ever- appropriate to use a Monte CArlo simulation to determine uncertainty, when valid analytical methods are readily available..

The bias and inefficiency in this naive monte carlo estimation method is further worsened by the well known and proven biases in the estimation of assigned share (Greenland 19xx).

Greenland S. Relation of probability of causation to relative risk and doubling dose: A methodologic error that has become a social problem. *Am J Public Health* 1999;89:1166–169.

Greenland S, Robins JM. Conceptual problems in the definition and interpretation of attributable fractions. *Am J Epidemiol* 1988;128:1186–197.

There is no way to independently replicate the calculations nor is there a way to independently determine its statistical operating characteristics, specifically, the Type I and Type II error or the false positive, true positive or positive or negative predictive values.

The appropriate statistical methodology is to use a frequentist or Bayesian statistical solution, using either optimal methods of estimation producing confidence intervals from frequentist likelihoods or Bayesian solutions using modern Markov Chain Monte Carlo methods.

Aside from the bootstrap methodology, frequentist methodology uses analytical methods, but does not use simulation to estimate predictions and uncertainty.

The estimates as described in letters to Claimant , sometimes are "Probability of Causation" and other times "the upper 9x% uncertainty interval". Neither frequentist or Bayesian statistical methods define or report an uncertainty limit. Uncertainty must be expressed either with a 9x% confidence interval or a 9x% credible interval.

- We request confirmation in each letter to <CLAIMANT> whether the result was based on Probability of Causation (assigned share) or the xx% confidence intervals.

The most serious concern is that the results of the model are entirely artifactual. The radiation model does not include all the uncertainties, for example the uncertainties arising from the imputation of missing data, the uncertainties about the distributions of some exposures, e.g. triangular distribution. Essential analyses are missing for the sensitivity of the model to the distributions chosen, sensitivity to the imputation(s). Rather than triangular etc. distributions, alternative distributions are likely to be more valid, such as the Beta distribution, which can be parameterized to mimic a triangular distribution.

The choice of prior distributions swamp the results and the data does not inform or lead to the updating 'learning' of the prior distributions.

I. Miscellaneous Claimant Unfavorable Errors

Note the NIOSH report (http://dceg.cancer.gov/files/NIH_No_03-5387.pdf) notes that cancer of the prostate gland is not included in the IREP. Note there is no uncertainty parameter added for use of the bladder as a surrogate for the prostate.

Error in Dates of Employment

2. You were employed at the Rocky Flats Plant from September 2, 1958 to May 22, 1959 and from April 17, 1964 to April 17, 1964.

Exhibits and Claimant Unfavorable Omissions, Errors, Gaps and mistakes

The term "Probability of Causation" was never assessed by NIOSH and use of the term Probability is a false and misleading statement

Under Part E whether or not a condition is related to radiation, as a toxic substance, is based on the results of the dose reconstruction. If the dose reconstruction results yield a probability of causation that is less than 50%, then a finding is made under Part E of the Act that it is not as least as likely as not that radiation was a significant factor in causing, contributing to, or

Claimant Unfavorable incomplete or missing badge records

Claimant is concerned that he was supposed to have been wearing two film badges. We request the detailed information as to the number of film badges, as well as the details of the policy in place at <nuclear location>during Claimant employment and the number of film badges that employees were required to wear..

Exhibit A: Reply from NIOSH - documentation not available

----- Forwarded Message -----
From: NIOSH OCAS (CDC) <ocas@cdc.gov>
To: Chris <chrismclaimant @yahoo.com>
Sent: Tuesday, January 15, 2013 9:52 AM
Subject: RE: NIOSH IREP

Dr. Claimant :

Although there is no single document that describes the IREP algorithm in detail, I can point you to three documents that, when combined , provide a pretty good technical description of the models used in IREP. The first two, which are available on the web, can be found at:

http://dceg.cancer.gov/files/NIH_No_03-5387.pdf and
http://www.cdc.gov/niosh/ocas/pdfs/irep/irepfnl.pdf.

The first web address is a report of the NCI-CDC Working group that prepared the original IREP program and the second address is a document that essentially describes the modifications that NIOSH incorporated into the IREP program. A final source that describes how IREP works can be found in the following article that was published in the Health Physics Journal:

Kocher, D.C., Apostoaei, A.I., Henshaw, R.W., Hoffman, F.O., Schubauer-Berigan, M.K., Stancescu, D.O., Thomas, B.A., Trabalka, J.R., Gilbert, E.S., Land, C.E. Interactive Radioepidemiological Program (IREP): A web-based tool for estimating probability of causation/assigned share of radiogenic cancers. *Health Physics* 95(1):119-147; 2008.

James W. Neton, Ph.D., CHP

Associate Director for Science

Division of Compensation Analysis and Support

NIOSH

i. Claimant Unfavorable error - "probability of causation" and assigned share are not interchangeable terms.

Probability has a well defined meaning and a definition is available in the statistical literature.

employed the finalized version of the NCI update, with certain modifications important to claims under EEOICPA, as a basis for determining probability of causation for employees covered under EEOICPA.

share. The assigned share is a term recommended in the NCI update of the radioepidemiological tables, instead of probability of causation, to properly reflect that these estimates are properties of groups of similar people, not of the individual. In other words, it is not possible to determine, for a given individual, whether his or her cancer resulted from a workplace exposure to ionizing radiation. The assigned share is used to estimate the probability of causation needed for determining eligibility for an award under EEOICPA, and these terms are used interchangeably in this document. It should also be noted that this software does not predict an individual's chances of getting cancer from workplace radiation exposure. Rather, it estimates (from epidemiological models combined with information on the individual's past exposure) the likelihood that an existing cancer resulted from that exposure.

The model ..estimates ... the likelihood... is a false and misleading statement, the models estimate an assigned share and models do not estimate a "likelihood".

share. The assigned share is a term recommended in the NCI update of the radioepidemiological tables, instead of probability of causation, to properly reflect that these estimates are properties of groups of similar people, not of the individual. In other words, it is not possible to determine, for a given individual, whether his or her cancer resulted from a workplace exposure to ionizing radiation. The assigned share is used to estimate the probability of causation needed for determining eligibility for an award under EEOICPA, and these terms are used interchangeably in this document. It should also be noted that this software does not predict an individual's chances of getting cancer from workplace radiation exposure. Rather, it estimates (from epidemiological models combined with information on the individual's past exposure) the likelihood that an existing cancer resulted from that exposure.

Claimant Unfavorable use of Bladder as a Surrogate for Prostate

We request addition of uncertainty to the model that is favorable to the claimant , for the use of bladder as a surrogate for the prostate. We find it implausible, that there are no data sources for radiation as a cause of prostate cancer.

In addition, based on the DOE record and the guidance in the Technical Basis Document for the Rocky Flats Plant – Occupational Medical Dose,[8] dose for an anterior-posterior (AP) and lateral view (LAT) lumbar-spine examination was assigned. The X-ray dose was assigned using the bladder as a surrogate organ for the prostate.

Claimant Unfavorable assumptions for Variance Propagation

The correlation can be estimated from the data, and a client favorable interpretation may require assuming a correlation among the paramters in the model.

Variance propagation is best demonstrated by a simple model that is a summation of terms:

$$R = k_o + \sum_{i=1}^{p} k_i x_i \qquad (3.1)$$

where

R = the quantity computed using the model
p = the number of uncertain parameters
k_o and k_i = coefficients
x_i = the i^{th} uncertain parameter

For an additive model like this, the mean value of the result, R, is equal to the sum of the mean values of the model parameters. The variance of the result, assuming statistical independence among the parameters, is equal to the sum of the variances of the parameters. Thus,

$$\bar{x}_R = k_o + \sum_{i=1}^{p} k_i \bar{x}_i \qquad (3.2)$$

and

$$s_R^2 = \sum_{i=1}^{p} k_i^2 s_i^2 \qquad (3.3)$$

Claimant Unfavorable Mis-interpretation and Misunderstanding of Goodness of Fit of cancer models

This is an explicit example of over-fitting of a model - the differences in deviances are trivial and unimportant. We request a Bayesian model averaging to include estimates from both models.

C: $f(e) = \min(\max(-15, e-30), 0)$, $g(a) = \min(\log(a/50), 0)$,

where "min" denotes "minimum" and "max" denotes "maximum."

The chosen specification (C) for $f(e)$ and $g(a)$ can also be written as follows:

$f(e) = -15$ for $e \leq 15$, $= e - 30$ for e between 15 and 30, and $= 0$ for $e > 30$;

$g(a) = \log(a/50)$ for $0 < a < 50$, and $= 0$ for $a \geq 50$. (IV.D.2)

When fitted to data for all solid cancers, the deviance values for models using the specifications A, B, and C were 3746.94, 3746.52, and 3743.15, respectively, with smaller deviance values indicating a closer fit of model to data. The nearly identical fits of models using A and B indicate that there is no direct evidence of modification of the ERR for exposure ages over 30 or attained ages over 50, and the somewhat better fit of model C indicates a lack of direct

Claimant - unfavorable availability of documents used by NIOSH for uncertainty assessment

The Guide for uncertainty analysis should be public domain documents for the benefit of claimant s. We request reimbursement for purchasing these documents -which should be public domain

Treatment of uncertainty in the updated report is guided by that in the original report and by more recent analyses, notably two publications of the National Council on Radiation Protection and Measurements (NCRP): Commentary 14 (NCRP 1996), *A Guide for Uncertainty Analysis and Dose and Risk Assessments Related to Environmental Contamination*, and Report 126 (NCRP 1997), *Uncertainties in Fatal Cancer Risk Estimates Used in Radiation*

Commentary No. 14 - A Guide for Uncertainty Analysis in Dose and Risk Assessments Related to Environmental Contamination

1

Report No. 126 - Uncertainties in Fatal Cancer Risk Estimates Used in Radiation Protection

Claimant Unfavorable Biased Dose estimates

The "total dose" and other doses are presented in the table below without claimant favorable standard deviations

Dose Categories		External*	On-Site Ambient	Medical X-Ray	Internal	Total
Prostate Adenocarcinoma 06/01/2004	Previous	13.343	0.752	1.520	4.005	19.620
	Revised	6.682	0.028	0.472	1.926	9.107
Melanoma *in-situ* skin 03/24/2010	Additional cancer	4.706	0.028	0.001	2.261	6.996

*External dose includes dosimeter, missed, and unmonitored dose. In the previous revision, the missed dose may have been reported at the 95% level. However, current reporting practices are to report the missed dose at the geometric mean.

Description	Diagnosis Date	Posterior-Anterior Chest	Anterior-Posterior/Lateral	Total X-ray
Prostate, adenocarcinoma	2004	0.200 rem	1.320 rem	1.520 rem

Claimant Unfavorable use of fixed and inflexible Radiation Effectiveness Factor distributions

these distributions can be modelled using normal, mixture or beta and other distributions with suitable prior distribution on the paraamters

NIOSH-IREP technical documentation June 18, 2002

Table 5A. Photons and electrons: Probability distributions of radiation effectiveness factors (REFs) to be used in estimating risks and probability of causation of cancers

Radiation type	Exposure	Probability distribution of radiation effectiveness factor (REF_L)	95% Confidence Interval		
Photons	Chronic or acute[a]		2.5th	50.0th	97.5th
E > 250 keV		Single-valued at 1.0 (higher-energy photons are assumed reference radiation)	----	1.0	----
E = 30-250 keV		Hybrid distribution with – 25% probability assigned to value 1.0; 75% probability assigned to lognormal distribution with 95% confidence interval between 1.0 and 5.0	1.0	1.9	4.7
E < 30 keV		Product of two distributions – (1) hybrid distribution for E_γ = 30-250 keV; and (2) triangular distribution with minimum of 1.0, mode of 1.3, and maximum of 1.6	1.1	2.4	6.1
Electrons	Chronic or acute[a]				
E > 15 keV		Single-valued at 1.0 (assumed to be same as value for reference higher-energy photons)	----	1.0	----
E < 15 keV		Lognormal distribution with 95% confidence interval between 1.2 and 5	1.2	2.4	5.0

[a]For solid tumors, DDREF is always applied under conditions of chronic exposure. At acute doses greater than 0.2 cGy, DDREF is assumed to be 1.0. At acute doses less than 0.2 cGy, a DDREF that can exceed 1.0 is applied, and the distribution of possible values approaches the probability distribution of DDREF that applies to all chronic exposures as the dose approaches zero.

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Table IV.H.3. Subjective uncertainty in radiation effectiveness factors: Neutrons. Factors to be applied in accordance with text equations (IV.H.2) and (IV.H.3).[a]

Cancer type	Exposure	Probability distribution of radiation effectiveness factor
Leukemia[b]	Chronic or acute[c]	
Neutron energies		
E = 0.1–2 MeV[d]		Lognormal distribution of REF_L with 2.5 and 97.5 percentiles at 2.0 and 60, respectively
E = 10–100 keV; E = 2–20 MeV		Stepwise uniform distribution of REF_L with— 30% probability assigned to values from 1.0 to 4.0; 50% probability assigned to values from 4.0 to 8.0; 20% probability assigned to values from 8.0 to 40
E < 10 keV; E > 20 MeV		Stepwise uniform distribution of REF_L with— 30% probability assigned to values from 1.0 to 2.3; 50% probability assigned to values from 2.3 to 3.5; 20% probability assigned to values from 3.5 to 25

Continued on page 68

Biased and Circular Reasoning in Completing Dose Reconstruction

The decision to "stop" dose reconstruction involves biased and circular reasoning, there is no definition of "evident that further research and analysis" - this requires that further research and analysis be prepared.

> Worst-case assumptions will be employed under condition in step 6.11.2 of this section to limit further research and analysis only for claims for which it is evident that further research and analysis will not produce a compensable level of radiation dose (a dose producing a probability of causation of 50% or greater), because using worst-case assumptions it can be determined that the employee could not have incurred a compensable level of radiation dose.

Claimant Unfavorable Computational Convenience

Computer speeds and ability to parallelize computations have increased sufficiently that computational speed is irrelevant.

However, compromises were made in the interests of computational efficiency. A possible approach for evaluating the uncertainty in the estimated ERR/Sv for each sex at various exposure and attained ages would have been to conduct joint analyses as described above, transforming the regression variables so that the parameter α reflected the ERR/Sv associated with a particular combination of sex, exposure age, and attained age, and obtain the profile likelihoods for the fitted α. However, this would have been extremely cumbersome (with slow computational speed) to implement in IREP, the interactive computer program for applying the algorithms developed by the Working Group.

Claimant Unfavorable inconsistency for uncertainty of Dosimeter readings, the 95% confidence dose is inconsistent with the 99% threshold for assigned share

with each dosimeter reading is assumed to be normally distributed, where the dosimeter reading is the mean and the upper 95% confidence dose is calculated by multiplying the uncertainty factor K(E) by each dosimeter reading using the following equations:

$$K(E) = 1 + 1.96\left[\frac{\sigma(E)}{E}\right]$$

$$\sigma(E) = \frac{\sigma^*}{D_\infty \gamma} e^{\gamma E}$$

where:
E = Exposure in roentgen
σ^* = Densitometer reading uncertainty typically 0.015 density units

D_∞ = Saturation Density of the Film (Dupont 502 = 2.8)
γ = film sensitivity (Dupont 502 ≈ 0.25)

Claimant Unfavorable Sensitivity of POC to low dose exposure

F. The uncertainty distribution of the adjustment factor for low-dose, low dose-rate exposure (i.e., the DDREF) used in NCI's and NIOSH's IREP currently has a large influence on the calculated probability of causation values. This factor merits further attention with respect

Claimant Unfavorable distributional assumptions

The use of a normal distribution for an annual dose and log-normal in missed dose are inconsistent and unnecessary

1.6 Uncertainty

The general approach to uncertainty in external dose reconstruction is to treat each variable as a distribution and then employ Monte Carlo sampling of each of the distributions to determine the overall uncertainty of the annual dose estimate. In general, the uncertainty in the measured dosimeter dose and the occupational medical dose is assumed to follow a normal distribution, while the uncertainty in the missed dose and the environmental dose is assumed to follow a log normal distribution. The uncertainty in the conversion of exposure or personal dose equivalent to organ dose is assumed to follow a triangular distribution with the upper and lower bounds determined by the most and least favorable geometry and energy.

Claimant Unfavorable Assumptions of Standard Deviation of Normal Distribution for X-rays

A claimant favorable methodology includes a prior distribution on the standard deviation that is claimant favorable.

Uncertainty

All internal dose, non-glovebox measured photon dose (1960–1965), and on-site ambient doses are assumed to have a constant distribution, whereas missed dose, measured photon dose with glovebox factor applied(1958, 1959), and lumbar-spine X-ray dose are applied as a lognormal distribution with a geometric standard deviation. Neutron doses evaluated by the NDR Project are assumed to be a normal distribution with a propagated uncertainty. Chest X-rays are assumed to have a normal distribution with a standard deviation of 30%.

Claimant Unfavorable Triangular Distribution

The triangular distribution is inflexibleThese can be modeled with a beta or normal distribution with a pertinent prior or conjugate distribution that is favorable to the client. "When properly performed" is not defined. The lowest and highest and most likely are data dependent and completely biased judgements when there are any missing data, and biased if the data was not measured exactly.

An acceptable approach, when feasible, is to determine the lowest possible, most likely, and highest possible doses given the data set used for the particular individual. Once these values are determined, a triangular distribution can be assumed using these three points as the parameters of the distribution. This approach gives credit for the parameters that are known while accounting for the parameters that are not well known. When properly performed, this method also inherently accounts for correlated parameters. Figure 5 shows a typical triangular distribution with a minimum value of zero, a maximum value of three and a most likely value of one.

Claimant unfavorable dose received assumed to be less than limit of detection.

"maximum dose being twice the mode dose" makes no sense.

The half the MDA is claimant unfavorable. a 99% confidence limit above the MDA would be claimant favorable.

The chronic intake rate was determined using half the minimum detection activity (MDA) for that radionuclide and assigned as the mode dose, with the maximum dose being twice the mode dose. The ICRP 66 lung model with default aerosol characteristics was assumed.[6]

Claimant Unfavorable chest dose not added

How may additional dose result in a reduction of dose?

with a minimum detectable activity for the period of 0.69 disintegration per minute (dpm) per day. For plutonium, Type Super S[19] was considered to be the most claimant-favorable solubility type based on urinalysis data (Types M, S, and Super S[19] were considered). Mr. Barker was also monitored during a medical recall chest count performed in 1994. However, for this assessment, the chest count data were not considered since this may result in a reduction of dose.

The chronic intake rate was determined using half the minimum detection activity (MDA) for

Claimant Unfavorable Reduction of Missed Dose Estimate

implementation Guideline. Based on limit of detection information provided in the Technical Basis Document for the Rocky Flats Plant – Occupational External Dose,[11] this results in a potential missed dose as shown in the table below.

Description	Diagnosis Date	Missed Photon (rem)	Missed Neutron (rem)
Prostate, Adenocarcinoma	06/01/2004	0.985	0.240
Melanoma *in-situ* skin	03/24/2010	0.855	0.113

The missed dose in this revision was reduced from the previously assigned missed dose based on changes in the application from an overestimating approach to a best estimate approach.

Claimant unfavorable reduction from previously assigned missed dose.

The missed dose in this revision was reduced from the previously assigned missed dose based on changes in the application from an overestimating approach to a best estimate approach.

Claimant unfavorable reduction of xray doses

The X-ray dose was revised from the overestimating assumption of annual X-rays to only the X-rays recorded in Mr. Barker's DOE record. This resulted in a reduction of the total occupational medical dose assigned.

Claimant Unfavorable - Neutron doses not reconstructed partial dose reconstruction.

We request additional sensitivity analysis using a prior distribution on neutron doses and request reconstruction of neutron doses, and reduction of the Assigned share to compensate for the decision to not include neutron doses.

Information Used

NIOSH has determined, with concurrence from the Secretary of Health and Human Services, that unmonitored neutron doses at the Rocky Flats Plant cannot be reconstructed from 1952 through 1966, inclusive.[11] For this reason, a class of Rocky Flats Plant employees has been added to the Special Exposure Cohort (SEC). Upon evaluation, Mr. Barker did not meet the criteria for compensation under the SEC. Therefore, NIOSH conducted a partial dose reconstruction for his claim.

Claimant Unfavorable Uncertainty for Missed Dose Estimation

When there is no other information on which to base a decision, the missed dose should be determined using the following protocol:

1. Determine the standard deviation of the bioassay method at the detection limit. If this cannot be readily determined, assume that it is 0.3 times the value of the detection limit. This factor is derived from the fact that the sample analysis probably consists of a gross sample result minus a blank result. It assumes that the standard deviation of the gross result is at least as high as the blank result and therefore propagating the error dictates that the standard deviation of the detection limit must be at least $\sqrt{2}$ times the standard deviation of the blank. The factor also assumes some variation of the standard Currie equation ($LD = 2.71 + 4.65\ \sigma_b$) (Currie, 1968) was used to determine the detection limit. If the 2.71 is ignored, σ_b (the standard deviation of the blank) becomes LD/4.65 (where LD is the detection limit) and the standard deviation of the detection limit then becomes $\sqrt{2}$*LD/4.65 or 0.3*LD. Even though this is not an exact value, this should provide a reasonable approximation in the situations when no other information is available.
2. Subtract 1.645 times the standard deviation from the detection limit to achieve a new target value. This provides a target value that 95% of the samples at this level will not exceed the detection limit.
3. Assume a constant chronic exposure over the entire period in question and determine that intake based on the highest bioassay sample equaling this target value from number 2 above.
4. The uncertainty of this estimate will be considered to be normally distributed with a relative error equal to the standard deviation determined in step number 1 divided by the detection limit times 100%.

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Claimant Unfavorable definition of Subjective Probability

equivalent dose. The approach used here is, first, to extract the absorbed tissue dose in Gy from the input value of radiation-specific, equivalent dose in Sv, using the appropriate ICRP radiation weighting factor; and second, to recompute equivalent dose using a different, and uncertain, weight as specified by Kocher et al. (2002) and summarized in Section IV.H of the present report. The value of the new equivalent dose differs from the starting value in that the weight used (called a "radiation effectiveness factor" or REF) is expressed as an uncertain quantity with a subjective probability distribution based on radiobiological data, as opposed to a point value of a standard quality factor or radiation weighting factor used in radiation protection. Thus, the calculation of AS specifically takes account of the (uncertain) biological effectiveness of each radiation type and energy of concern.

Claimant Unfavorable Inconsistency in Compensation
The DVA has subsequently used the screening doses (based on the upper 99% confidence limit) developed by CIRRPC. In practice, few cases who have passed the screening have failed to receive rewards. This policy has the advantage that it is highly unlikely to exclude persons with meritorious claims. However, it is likely to award many persons whose true PCs are very much less than 50%, a use of funds that some might question. It also has the anomaly that the more uncertain the PC estimate, the more likely that a claimant will be awarded. For example, as noted in the NAS review of this report (2000), a claimant with a precisely estimated PC of 44% (CI: 41%–47%) would fail to receive an award, while a claimant with an imprecisely estimated PC of 9% (CI: 0%–82%) would be awarded.

Claimant Unfavorable Uncertainty of Bioassay samples

In keeping with section 8.2 of this guide, the uncertainty of the bioassay samples is assumed to be normally distributed with a standard deviation equal to 0.3 times the detection limit. Therefore the standard deviation is assumed to be 0.03 pCi/day. Now the missed dose is estimated by assuming a chronic dose for the entire period that will predict a maximum urine concentration of 0.04 pCi/day. This process results in estimating a chronic intake of 23 pCi/day for a 702 day (approx. 2 year) period.

Claimant Unfavorable Assumptions of Independent factors

Treatment of uncertainty in the updated report is guided by that in the original report and by more recent analyses, notably two publications of the National Council on Radiation Protection and Measurements (NCRP): Commentary 14 (NCRP 1996), *A Guide for Uncertainty Analysis and Dose and Risk Assessments Related to Environmental Contamination*, and Report 126 (NCRP 1997), *Uncertainties in Fatal Cancer Risk Estimates Used in Radiation Protection*. Essentially, the method involves calculation of an uncertain excess relative risk (ERR = excess risk/baseline risk) for the cancer of interest, as a function of radiation dose for each exposure. Other factors, represented by a series of randomly distributed factors which are assumed to be statistically independent, depend on informed but nevertheless subjective judgments from published reports of expert committees or by the authors of this report. They

Claimant Unfavorable Average of 30 Runs

http://www.cdc.gov/niosh/ocas/ocasirep.html#comprates

Your POC is estimated between 45 and 50.

One of your estimates was 47.41%

Based on the attached we will be requesting the output of each of the 30 runs (bullet point (2)) and (I'll) argue that

the use of the -mean- of the 99% CL of POC is -not claimant favorable- and instead the -maximum- of the runs should be used because that is the most claimant favorable -or- the 99% upper confidence limit of

7.0 PROCEDURE FOR CLAIMS WITH A PROBABILITY OF CAUSATION EQUAL TO OR GREATER THAN 45% BUT LESS THAN 52%

New procedure (adopted June 6, 2006) for resolving claims in which the upper 99th percentile credibility limit of probability of causation is equal to or greater than 45% but less than 52% using the default simulation sample size of 2000 and default random number seed of "99"

Previously, each claim with an initial probability of causation (PC) value falling between 45% and 50% at the upper 99th percentile credibility limit (C.L.) was processed by increasing the simulation sample size to 10,000, choosing a new random number seed, and rerunning the claim in NIOSH-IREP. The resulting upper 99% C.L. of PC obtained with a sample size of 10,000 determined the claim outcome, supplanting the initial PC value that had been obtained with a sample size of 2000. This procedure was adopted in order to provide better statistical precision for claims approaching the compensation threshold of 50%.

To achieve even greater statistical precision for claims close to the compensation threshold, the following procedure was adopted on June 6, 2006 and replaced the procedure described above.

For claims in which the initial PC is equal to or greater than 45% but less than 52% using the default sample size of 2000:

(1) The simulation sample size will be increased to 10,000.

(2) 30 additional IREP runs will be performed, using a new random number seed for each run.

(3) The average value (arithmetic mean) of the upper 99% C.L. of PC of the 30 runs will determine the claim outcome.

(4) For claims with more than one primary cancer in which the initial PC calculated from the "multiple primary" equation is equal to or greater than 45% but less than 52%, 30 runs will be performed for each primary cancer per steps 1 and 2 above. The arithmetic mean of the upper 99% C.L. of PC of the 30 runs for each cancer will then be entered into the multiple primary equation. The newly calculated PC, based upon the arithmetic mean PC value of each cancer as entered into the multiple primary equation, will determine the claim outcome.

Claimant Unfavorable definition of statistical significance

Section D. is not a standard definition of statistical significance.

D. New attention to cancer sites less strongly associated with radiation exposure

The cancers covered by the 1985 NIH report were those for which a statistically significant radiation dose response had been demonstrated in one or more major analyses. Statistical significance is equivalent to having a positive lower confidence limit, at a certain confidence level, for dose-specific excess relative risk, and therefore also for the AS. The list of cancers fitting this criterion is not greatly different today, but it is clearly possible for an upper uncertainty limit for the ERR to be greater than 1, and hence for the corresponding AS limit to be greater than 50%, even when the estimated ERR is not significantly greater than 0. Thus a wider range of cancer sites is of interest than that covered by the 1985 report.

Claimant unfavorable Reference and use of Monte Carlo Simulation

These monte carlo simulations do not reflect any uncertainty in the parameters. Only A Bayesian statistical analysis would reflect uncertainty in the distributions.

The above modifications drew heavily on developments in uncertainty analysis that have occurred since 1985. The BEIR V report used Monte Carlo simulations to evaluate statistical uncertainty in lifetime risks, but relied on lognormal propagation of errors for evaluating several other uncertainty sources. More recently, both NCRP and EPA have used Monte Carlo simulations, including flexible choice of distributions to describe uncertainties from individual sources. However, NCRP and EPA were primarily concerned with uncertainties in lifetime risks for general populations rather than uncertainties in age-specific risks for population subgroups with certain characteristics. Furthermore, NCRP provided a distribution only for the lifetime risk of all fatal cancers, although the report contains discussion of specific cancer types. To our knowledge, the work reported here is the first to evaluate uncertainty distributions for specific ERR (and therefore AS) values associated with any of a wide range of specific cancer types, individual characteristics, and exposure scenarios.

Claimant Favorable Definition of Probability - "reasonable expectation of an event in a single trial"

Probability is recognized also as providing a measure of the reasonable expectation of an event in a single trial. That the probability of drawing a white ball is $\frac{2}{3}$ and of drawing a black ball is $\frac{1}{3}$ means that a white ball is a more likely result of a trial than a black ball, and the numbers $\frac{2}{3}$ and $\frac{1}{3}$ serve to compare the likelihoods of the two results. According to the second main school of probability, this measure of reasonable expectation, rather than the frequency in an ensemble, is the primary meaning of probability.

If it could be shown that every measure of reasonable expectation is also a frequency in some ensemble and that every frequency in an ensemble measures a reasonable expectation, then the choice of one or the other as the primary meaning of probability would not be very important. I shall not attempt to discuss whether there are frequencies in an ensemble that are not measures of reasonable expectation. It is enough for my present purpose to show that the two interpretations are not always identical. For this it will suffice to point out that there are probabilities in the sense of reasonable expectations for which no ensemble exists and for which, if one is conceived, it is clearly no more than a convenient mental artifice. Thus, when the probability is calculated that more than one planetary system exists in the universe, it is barely tenable even as an artifice that this refers to the number of universes having more than one planetary system among an indefinitely large number of universes, all resembling in some way *the* universe, which by definition is all-inclusive.

CF.

^ R. T. Cox, "Probability, Frequency, and Reasonable Expectation," *Am. Jour. Phys.*, 14, 1–13, (1946).

R. T. Cox, *The Algebra of Probable Inference*, Johns Hopkins University Press, Baltimore, MD, (1961).

Chapter I. Appendices

Claimant Unfavorable Uncertainty in Missed Dose Estimation- Currie equation

Normal distribution 1.65 is 90% interval (one sided) 95% two sided

http://www.oswego.edu/~srp/stats/z.htm

When there is no other information on which to base a decision, the missed dose should be determined using the following protocol:

1. Determine the standard deviation of the bioassay method at the detection limit. If this cannot be readily determined, assume that it is 0.3 times the value of the detection limit. This factor is derived from the fact that the sample analysis probably consists of a gross sample result minus a blank result. It assumes that the standard deviation of the gross result is at least as high as the blank result and therefore propagating the error dictates that the standard deviation of the detection limit must be at least $\sqrt{2}$ times the standard deviation of the blank. The factor also assumes some variation of the standard Currie equation ($LD = 2.71 + 4.65\ \sigma_b$) (Currie, 1968) was used to determine the detection limit. If the 2.71 is ignored, σ_b (the standard deviation of the blank) becomes LD/4.65 (where LD is the detection limit) and the standard deviation of the detection limit then becomes $\sqrt{2}$*LD/4.65 or 0.3*LD. Even though this is not an exact value, this should provide a reasonable approximation in the situations when no other information is available.
2. Subtract 1.645 times the standard deviation from the detection limit to achieve a new target value. This provides a target value that 95% of the samples at this level will not exceed the detection limit.
3. Assume a constant chronic exposure over the entire period in question and determine that intake based on the highest bioassay sample equaling this target value from number 2 above.
4. The uncertainty of this estimate will be considered to be normally distributed with a relative error equal to the standard deviation determined in step number 1 divided by the detection limit times 100%.

Claimant Unfavorable Unmonitored neutron doses can't be estimated

Because limited neutron dose monitoring data were available for [redacted] between 1958 and 1964, and no estimation techniques can be employed to calculate an unmonitored neutron dose, the external doses assigned in this dose reconstruction include monitored and missed photon and neutron doses, dose received from occupationally-required medical X-rays, and dose resulting from exposure to on-site ambient external radiation. External coworker dose was applied to the dose reconstruction for periods where gaps appeared in the dosimeter records or the records were found to be incomplete.

However, all other doses are estimated by using coworker data

Claimant Unfavorable Estimates from CoWorker Data

We request that this imputation of missing data use a probability density or an established statistically valid method of imputation such as "nearest neigbor" or a multiple imputation method.

Coworker/Unmonitored Dose Assignment
During the periods th[redacted] was on site and not monitored or dosimetry results were unavailable, external dose was assigned in accordance with the Technical Basis Document for the Rocky Flats Plant – Occupational External Dose.[11]

Claimant Unfavorable use of Best estimate vs. over-estimate

Missed Dose
A potential missed dose was assigned to each actual or potential dosimeter cycle where a zero was reported to provide a claimant-favorable estimate of the potential external doses received by [redacted] A missed dose represents the dose that could have been received but may not have been recorded due to the dosimeter detection limits or site reporting practices.

The total number of dosimeter cycles where a zero was assigned is shown in the table below.

Description	Diagnosis Date	Photon Zeros	Neutron Zeros
Prostate, Adenocarcinoma	06/01/2004	43	1
Melanoma *in-situ* skin	03/24/2010	43	1

These numbers used the methodology described as follows. In cases where the number of actual zeros could be determined from the records, the reported zeros were applied. For the years where dosimetry information was provided in quarterly or annual summary form, a best estimate of zeros to calculate missed dose was perfomed.[11] The best estimate of the number of zeros assigned was equal to the average of the maximum potential badge cycles and the number of reported zero badge cycles. The maximum potential badge cycles are equal to the maximum exchange frequency minus the number of reported positive badge cycles. The maximum exchange frequency was determined using that of a site support person as indicated in the Technical Basis Document for the Rocky Flats Plant – Occupational External Dose,[11] or the exchange frequency in the dosimetry reports.

Claimant Unfavorable Reduction in ambient dose

Description	Diagnosis Date	On-Site Ambient Dose (rem)
Prostate, Adenocarcinoma	06/01/2004	0.028
Melanoma *in-situ* skin	03/24/2010	0.028

Maximum on-site ambient doses were applied for each year of employment in the previous dose reconstruction. The application of best estimate ambient dose in the revised assessment follows guidance from the procedure, Occupational On-Site Ambient Dose Reconstruction for DOE Sites,[17] and the Technical Basis Document for the Rocky Flats Plant – Occupational Environmental Dose.[9] This resulted in a reduction of the total on-site ambient dose assigned.

Claimant Unfavorable use of undocumented non-open source Computer program IMBA

We request the IMBA source code, documentation, relevant papers, be provided for use in Bayesian sensitivity analysis

A computer code, the Integrated Modules for Bioassay Analysis (IMBA), was used to estimate intakes of radioactive material and the subsequent annual organ doses. The IMBA Expert ORAU-Edition was used for this dose reconstruction. The ICRP 66 lung model with default aerosol characteristics was assumed, in conjunction with ICRP 68 metabolic models. It should be emphasized that intake dates, scenarios, and intake levels were based upon mathematical models and do not necessarily prove that such intakes occurred on the given dates. These dates and scenarios provide an acceptable explanation of exposure and dose based upon the bioassay data provided. This approach is in accordance with the provisions of the Radiation Dose Reconstruction Rule (42 CFR 82)[1] and guidance in the Internal Dose Reconstruction Implementation Guideline.[6]

Claimant Unfavorable - Software is not validated
Verification of the NIOSH-IREP Computer Code Version 5.5.3 Report (July 2009) PDF 5 MB (512 pages) This report presents the results of a formal verification effort organized to ensure that the most current version of NIOSH-IREP software (version 5.5.3) calculates risk and probability of causation (PC) according to the methodology agreed upon by NCI and NIOSH. This verification process was performed by individuals of SENES Oak Ridge, Inc. who were not involved in the initial development of the code. It is important to note that this effort has not attempted to "validate" or question the models and procedures developed by NCI and NIOSH; this effort "verifies" that each part of the NIOSH-IREP code operates according to its intended use described in its technical documentation.

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Confidence limits - analytical CIRRPC Use of 1.645 for confidence limit is inconsistent with the 99% credible limit of probability of causation.
Science Panel Report No. 6 Use of Probability of Causation by the Veterans Administration in the Adjudication of Claims of Injury Due to Exposure to Ionizing Radiation

APPENDIX B[1]

DETERMINATION OF SCREENING DOSES

Derivation of Screening Dose Model

The PC is calculated as R/(1+R) where R is the relative excess risk and is defined as the ratio of the risk due to radiation and the baseline risk. R can be written as the product of two factors, F(D) and G. F(D) is a function of dose (D) in rad and is taken to be $D+D^2/116$ in the NIH Report, except for breast and thyroid cancer following low LET radiation. Note that F(1) is approximately equal to one, so that G can be regarded as the relative excess risk for a one rad exposure and will sometimes be referred to in this manner.

For the purpose of evaluating uncertainties, G can be assumed to be the product of several factors G(i). G(1) is taken to be the overall risk coefficient (for a particular type of cancer), and the remaining G(i) indicate possible modifying effects of various factors as follows: G(2), baseline values; G(3), age at exposure; G(4), time response; G(5), dose-response relationship; and G(6), Japanese dosimetry.

$\hat{G}(i)$ denotes the estimate of G(i) that is used in the NIH report, and it is assumed (as in section O of Chapter VII of the NIH Report) that the $\hat{G}(i)$ follow independent lognormal distributions, with geometric means given by G(i)/B(i) and geometric standard deviations S(i), where B(i) denotes bias. Note that if B(i) = 1, the uncertainty is unbiased, and that if B(i) is greater than one, then B(i) is the factor by which G(i) is underestimated. Specifically, the above model is based on the assumption that log $\hat{G}(i)$ is normally distributed with mean (log G(i) - log B(i)) and standard deviation log S(i). [Note: log means the natural logarithm, i.e. $\log_e$.]

Since $\hat{G}(i)$ are assumed independent, an upper 95 percent credibility limit for log $\hat{G}$ is given by

$$\sum_i [\log \hat{G}(i) + \log B(i)] + 1.645 * [\sum_i \log^2 S(i)]^{1/2}$$

---

[1] This Appendix was prepared by Dr. Ethel S. Gilbert, Battelle, Pacific Northwest Laboratories, at the request of the Subpanel on Radioepidemiological Tables, in order to provide the scientific basis and mathematical methodology for the determination of screening doses. Minor editorial changes were made by the Subpanel which, however, did not affect the scientific content of the Appendix. It assumes familiarity with the NIH Report, particularly Chapter VII, Section O. The Appendix is intended for the reader who is interested in the technical details of the procedure used to determine screening doses.

and the upper 95-percent credibility limit, which will be denoted by R95, for $\hat{G}$ is given by

$$\{\prod_i B(i)*\hat{G}(i)\}*\exp\{1.645*[\sum_i \log^2 S(i)]^{1/2}\}$$

$$= \hat{G} * X95, \text{ where } X95 = \{\prod_i B(i)\}*\exp\{1.645*[\sum_i \log^2 S(i)]^{1/2}\} \quad (1).$$

More generally, to obtain a Z percent upper credibility limit, the upper Z percentile of a standard normal distribution would be substituted for 1.645.

Once the B(i) and S(i) are specified, the factor X95 can be calculated. $\hat{G}$ may be calculated as $PC_1/(1-PC_1)$ where PC_1 is the probability of causation given in the NIH Report for a one rad exposure.

The upper limit for G, the relative excess risk for a one rad (0.01 Sv) exposure, is given by $R95=\hat{G}*X95$ where R95 is the relative excess risk at the upper 95 percent credibility level. The upper limit for the relative excess risk for a dose D is given by R95 * F(D), and the corresponding upper limit for the PC for dose D is given by

$$R95 * F(D)/[1 + R95 * F(D)] \quad (2)$$

To calculate the dose corresponding to an upper credibility limit on the PC of 50 percent, the expression in (2) is set equal to 0.50, and solved for D. This leads to the following quadratic equation:

$$R95 * D^2/116 + R95 * D - 1 = 0$$

It remains to determine the specific B(i) and S(i) needed to evaluate the factor X95. This is done in the discussion that follows on evaluating sources of uncertainty with S(i) referred to as the GSD (geometric standard deviation), and B(i) as bias. The values of B(i) and S(i) used to determine the screening doses are presented in Table A.

Treatment of Uncertainties

a. Baseline Values

When the individual characteristics of a claimant are examined, it is possible that in some cases it will be determined that the person's baseline risk is different from the average, leading to possible adjustment of the PC. It is important that a screening procedure allow for this possibility.

If it is determined that an individual has been exposed to other substances associated with the type of cancer at issue, or if it is determined that the individual has a

B-2

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$$= \hat{G} * X95, \text{ where } X95 = \{\prod_i B(i)\}*\exp\{1.645*[\sum_i \log^2 S(i)]^{1/2}\} \quad (1).$$

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Treatment of Uncertainties

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If it is determined that an individual has been exposed to other substances associated with the type of cancer at issue, or if it is determined that the individual has a

B-2

Definition and Parameters of Log-normal distribution

We request the definition of the log-normal distribution and correction of the error that parameter 3 is reported as 0.000

ATTACHMENT A
Photons 30-250 keV, $H_p(10)$

Bladder				
Percent error	**Dose distribution**	**Parameter 1**	**Parameter 2**	**Parameter 3**
5	Normal	0.740	0.115	0.000
10	Normal	0.739	0.132	0.000
20	Normal	0.739	0.186	0.000
30	Normal	0.738	0.250	0.000
40	Normal	0.738	0.312	0.000
50	Normal	0.757	0.371	0.000
60	Normal	0.780	0.419	0.000
70	Normal	0.825	0.470	0.000
80	Normal	0.862	0.520	0.000
90	Normal	0.896	0.564	0.000
100	Normal	0.950	0.611	0.000

Claimant Unfavorable Error in Use of normal distribution for dosimetry errors. The normal distribution is appropriate for values that range from negative infinity to infinity ($-\infty, \infty$) . The dosimetry errors are positive values. The choice of the normal distribution is an error and a positive valued distribution should be used instead of the normal distribution

Figures 1 and 2 illustrate examples of the distributions used in these simulations. The normal distribution (Figure 1 describing dosimetry error) is defined with a standard deviation of 32% (matching the data shown in Table 1). The triangular distribution (Figure 2 describing DCF error) is defined for the 30 to 250 keV photon *Hp(10)* DCF for the colon. Figure 3 shows the product of these two distributions. The outcome is a normal distribution with a mean of 0.59 and a standard deviation of 0.14 (the distribution type and associated parameters were determined using the Batch Fit feature of Crystal Ball®).

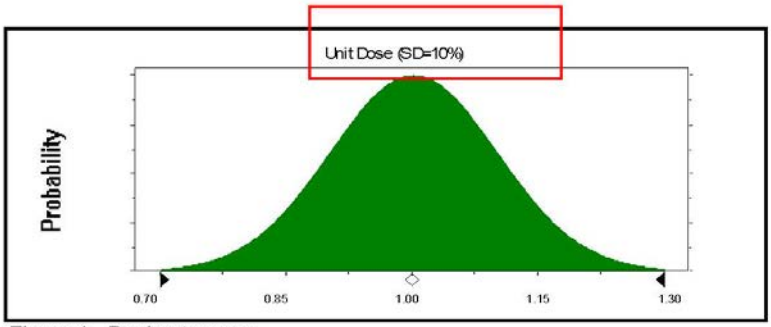

Figure 1. Dosimetry error.

Claimant Unfavorable Error in Use of Normal Distribution for Neutron dose

Presumably the Neutron dose is a positive number, however the normal distribution is appropriate for values ranging from negative infinity to positive infinity ($-\infty, \infty$)

Example 1 – Measured Photon/Neutron Dose
Interactive RadioEpidemiological Program (IREP) distribution choice: Normal.
IREP Parameter 1: 1.125 (total dose in cSv) × 0.59 (unit dose uncertainty mean) = 0.664 cSv.
IREP Parameter 2: 1.125 (total dose in cSv) × 0.14 (unit dose uncertainty standard deviation) = 0.158 cSv.

Using the data in Table 1, the unit dose distribution shown in Figure 3 would be chosen.

Claimant Unfavorable review of unspecified photon and neutron dose for the year.

There is no definition of what data was reviewed and who reviewed the data nor how the percentiles were constructed

Coworker doses were applied to ensure that a best estimate external dose was assigned. The percentile coworker distributions were chosen based on a review of the reported photon and neutron dose for that year.

NIOSH EEOICPA 99% credibility limit

Accounting for uncertainty is important because it can have a large effect on the probability of causation estimates. DVA, in its use of the 1985 radioepidemiological tables, employs the value found in the tables at the upper 99 percentile of the probability of causation estimate. Similarly, as required by EEOICPA, the U.S. Department of Labor (DOL) will use the upper 99 percent credibility limit to determine whether the cancers of employees are at least as likely as not caused by their radiation doses. This will help minimize the possibility of denying compensation to claimants under EEOICPA for those employees with cancers likely to have been caused by radiation exposures.

Claimant Unfavorable details not provided for Risk Models Developed by NCI

The risk models developed by NCI and CDC for IREP (NCI 2002) provide the primary basis for developing guidelines for estimating probability of causation under EEOICPA. They directly address most cancers and most types of radiation exposure relevant to employees covered by EEOICPA. These models take into account the employee's cancer type, year of birth, year of cancer diagnosis, and exposure information such as years of exposure, as well as the dose received from gamma radiation, x rays, alpha radiation, beta radiation, and neutrons during each year. The risk model

Claimant Unfavorable details and documentation of ICRP modelling not provided

The organ/tissue associated with this cancer is not included in the ICRP modeling of internal doses; so in accordance with NIOSH documentation, the largest dose to an exposed organ that is not described by the ICRP metabolic models was assigned as the appropriate internal dose.

Claimant Unfavorable Currie Equation at 95% one-sided Type I error level for the confidence limit

The use of the one sided 95% confidence limit is not consistent with the use of a 99% confidence limit elsewhere in the model building.

When there is no other information on which to base a decision, the missed dose should be determined using the following protocol:

1. Determine the standard deviation of the bioassay method at the detection limit. If this cannot be readily determined, assume that it is 0.3 times the value of the detection limit. This factor is derived from the fact that the sample analysis probably consists of a gross sample result minus a blank result. It assumes that the standard deviation of the gross result is at least as high as the blank result and therefore propagating the error dictates that the standard deviation of the detection limit must be at least $\sqrt{2}$ times the standard deviation of the blank. The factor also assumes some variation of the standard Currie equation ($LD = 2.71 + 4.65\ \sigma_b$) (Currie, 1968) was used to determine the detection limit. If the 2.71 is ignored, σ_b (the standard deviation of the blank) becomes LD/4.65 (where LD is the detection limit) and the standard deviation of the detection limit then becomes $\sqrt{2}$*LD/4.65 or 0.3*LD. Even though this is not an exact value, this should provide a reasonable approximation in the situations when no other information is available.
2. Subtract 1.645 times the standard deviation from the detection limit to achieve a new target value. This provides a target value that 95% of the samples at this level will not exceed the detection limit.
3. Assume a constant chronic exposure over the entire period in question and determine that intake based on the highest bioassay sample equaling this target value from number 2 above.
4. The uncertainty of this estimate will be considered to be normally distributed with a relative error equal to the standard deviation determined in step number 1 divided by the detection limit times 100%.

Claimant Unfavorable Neutron Dose Cannot be reconstructed

This leads to an underestimate of <CLAIMANT>'s radiation dose and underestimate of the assigned share

Information Used

NIOSH has determined, with concurrence from the Secretary of Health and Human Services, that unmonitored neutron doses at the Rocky Flats Plant cannot be reconstructed from 1952 through 1966, inclusive.[11] For this reason, a class of Rocky Flats Plant employees has been added to the Special Exposure Cohort (SEC). Upon evaluation, Mr. Barker did not meet the criteria for compensation under the SEC. Therefore, NIOSH conducted a partial dose reconstruction for his claim.

Claimant Unfavorable best estimate vs. overestimate should not be based on "minimal effort"

5.1 **Overestimate**

5.1.1 The general philosophy for an Overestimate approach is to assign dose from all eligible X-ray procedures under EEOICPA for each site where the Energy Employee worked.

5.1.2 An Overestimate approach is typically applied to cases with a clear POC of less than 50%.

5.1.3 There is no need to request case-specific X-ray data if not immediately available.

5.2 **Best Estimate**

5.2.1 The general philosophy for a Best-Estimate approach is to assign dose from all eligible X-ray procedures under EEOICPA for each site where the Energy Employee worked. However, some X-rays should be excluded from a Best-Estimate approach. For example, prehire and rehire procedures more than 1 year before DOL-verified employment should not be included. However, if records provide documented extenuating circumstances for a delay in the start of employment, X-ray procedures up to 2 years before DOL-verified employment may be considered. Based on the possibility of physical changes over time, it is expected that prehire and rehire X-ray procedures more than 1 or 2 years before DOL-verified employment would have had to have been redone to verify the physical condition of the potential Energy Employee. If records indicate such additional X-ray procedures, all of the prehire and rehire procedures should be included in the dose reconstruction.

5.2.2 A Best-Estimate approach is typically applied to cases for which the POC exceeds 50% if the X-ray dose is maximized or to cases for which a best estimate can be obtained with minimal effort.

5.2.3 All available X-ray data should be requested from the site (if not already provided) if the compensability decision could be affected.

Claimant Unfavorable - dose reconstructor chooses approach- overestimates should be used first.

Dose Reconstructor

6.1 Reviews the information in the case file.

6.2 Determines the approach (Overestimate, Best Estimate, Minimizing, or Skin) to apply to reconstruct the dose. For Overestimate, proceeds to Section 6.2.1; for Best Estimate, proceeds to Section 6.2.2; for Minimizing, proceeds to Section 6.2.3; and for Skin, proceeds to Section 6.2.4.

6.2.1 Overestimate Approach

Claimant unfavorable papers need to be provided for free for claimant review

The papers cited in the NIOSH manuals and website need to be provided for free to claimant

2.1.1.3.2 TLD Uncertainty

The uncertainty of thermoluminescent dosimeters is generally lower than film badge dosimeters, however the uncertainty is still somewhat dependent on the dose. Several biases can occur that, when combined, contribute to the random error. The fading of the dosimeter, especially in high temperature environments, results in a slight decrease in the measured dose. Conversely, the annealing process can result in residual artificial dose and spurious luminescence from contaminants, thereby overestimating the true dose. A simple estimate of uncertainty based on Hirning (1992) is to divide exposure into two components with one part based on the limit of detection, which dominates in the low dose region, and the other based on a best estimate of overall dosimeter uncertainty (generally 5 - 10%). A key assumption is that the two components are uncorrelated. This is appropriate since the variance in the low dose region would be dominated by measurement or counting statistics (i.e. total counts above background on a photo multiplier tube (PMT)). Conversely, in the upper dose region, the variance from counting statistics plays a rather insignificant role, however the uncertainty associated with the calibration, energy response of the dosimeter, and fading begin to dominate. Generally the relative uncertainty associated with radiation monitoring has been less than 5 - 10% at relatively high dose levels. This uncertainty increases with decreasing dose from 10 - 15% in the hundreds of millirem (Hendee 1967; Wallace, Watkins 1968) to approximately 100% at the LOD

Claimant Unfavorable X ray data collected only if compensation is affected.

This is an error not a conditional option- the assigned share can only be estimated accurately when the full data are collected.

estimate can be obtained with minimal effort.

5.2.3 All available X-ray data should be requested from the site (if not already provided) if the compensability decision could be affected.

Claimant Unfavorable use of coworker doses.

No definition provided as to who reviewed the data, the coworkers included, nor how the percentile doses were estimated

Coworker doses were applied to ensure that a best estimate external dose was assigned. The percentile coworker distributions were chosen based on a review of the reported photon and neutron dose for that year.

Claimant unfavorable - Assigned share is defined as the same as probability of causation

This is a clear cut error and a misleading use of terminology

share. The assigned share is a term recommended in the NCI update of the radioepidemiological tables, instead of probability of causation, to properly reflect that these estimates are properties of groups of similar people, not of the individual. In other words, it is not possible to determine, for a given individual, whether his or her cancer resulted from a workplace exposure to ionizing radiation. The assigned share is used to estimate the probability of causation needed for determining eligibility for an award under EEOICPA, and these terms are used interchangeably in this document. It should also be noted that this software does not predict an individual's chances of getting cancer from workplace radiation exposure. Rather, it estimates (from epidemiological models combined with information on the individual's past exposure) the likelihood that an existing cancer resulted from that exposure.

Claimant Unfavorable - Uncertainty about dose response not included in model the uncertainty about dose response can be included in the estimates using a Bayesian Model Averaging

While many studies have found an association between ionizing radiation exposure and skin cancer, the appropriate form of dose-response model for skin cancer is highly uncertain (ICRP 1991a, p. 52). Some researchers advocate the use of a threshold model, on the basis of observations about dose-response relationships for such deterministic endpoints as skin dermatitis, desquamation and erythema, and upon evidence for a nonlinear dose-response relationship observed in some animal studies (reviewed in ICRP 1991a, pp 52-55). However, no evidence of a dose threshold was observed in a meta-analysis of twelve UV and ionizing radiation-exposed groups (Shore 1990, UNSCEAR 2000b). A recent study evaluated various forms of the dose-response relationship for the atomic bomb survivors, and concluded that the best-fitting model for non-melanoma skin cancer is proportional to the fourth power of dose (Little and Charles 1997). However, a more recent analysis found no significant model improvement (over linearity) using a linear-quadratic model (Ron et al. 1998). A linear dose-response relationship for non-melanoma skin cancer has been advocated by others as well

Claimant Unfavorable TLD uncertainty not included in the assigned share estimate
2.1.1.3.2 TLD Uncertainty The uncertainty of thermoluminescent dosimeters is generally lower than film badge dosimeters, however the uncertainty is still somewhat dependent on the dose. Several biases can occur that, when combined, contribute to the random error. The fading of the dosimeter, especially in high temperature environments, results in a slight decrease in the measured dose. Conversely, the annealing process can result in residual artificial dose and spurious luminescence from contaminants, thereby overestimating the true dose. A simple estimate of uncertainty based on Hirning (1992) is to divide exposure into two components with one part based on the limit of detection, which dominates in the low dose region, and the other based on a best estimate of overall dosimeter uncertainty (generally 5 - 10%). A key assumption is that the two components are uncorrelated. This is appropriate since the variance in the low dose region would be dominated by measurement or counting statistics (i.e. total counts above background on a photo multiplier tube (PMT)). Conversely, in the upper dose region, the variance from counting statistics plays a rather insignificant role, however the uncertainty associated with the calibration, energy response of the dosimeter, and fading begin to dominate. Generally the relative uncertainty associated with radiation monitoring has been less than 5 - 10% at relatively high dose levels. This uncertainty increases with decreasing dose from 10 - 15% in the hundreds of millirem (Hendee 1967; Wallace, Watkins 1968) to approximately 100% at the LOD

Claimant Unfavorable Uncertainty in assigned share ratio baseline risk not included in model	
of causation (PC) is calculated as the risk of cancer attributable to radiation exposure (RadRisk) divided by the sum of the baseline risk of cancer to the general population (BasRisk) plus the risk attributable to the radiation exposure, then multiplied by 100 percent, as follows: $\frac{\text{RadRisk}}{\text{RadRisk} + \text{BasRisk}} \times 100\% = \text{PC}$	

Claimant unfavorable inflexible definitions of distributions which do not include any uncertainty

The distributions other than single valued can be defined in a flexible way with a conjugate normal prior on a normal or log normal distribution. These distributions DO NOT include any uncertainty and a claimant favorable Bayesian model with a likelihood and prior distribution are appropriate

Table 5A. Photons and electrons: Probability distributions of radiation effectiveness factors (REFs) to be used in estimating risks and probability of causation of cancers

Radiation type	Exposure	Probability distribution of radiation effectiveness factor (REF_L)	95% Confidence Interval		
Photons	Chronic or acute[a]		2.5th	50.0th	97.5th
E > 250 keV		Single-valued at 1.0 (higher-energy photons are assumed reference radiation)	---	1.0	---
E = 30-250 keV		Hybrid distribution with – 25% probability assigned to value 1.0; 75% probability assigned to lognormal distribution with 95% confidence interval between 1.0 and 5.0	1.0	1.9	4.7
E < 30 keV		Product of two distributions – (1) hybrid distribution for E_γ = 30-250 keV; and (2) triangular distribution with minimum of 1.0, mode of 1.3, and maximum of 1.6	1.1	2.4	6.1
Electrons	Chronic or acute[a]				
E > 15 keV		Single-valued at 1.0 (assumed to be same as value for reference higher-energy photons)	---	1.0	---
E < 15 keV		Lognormal distribution with 95% confidence interval between 1.2 and 5	1.2	2.4	5.0

[a]For solid tumors, DDREF is always applied under conditions of chronic exposure. At acute doses greater than 0.2 cGy, DDREF is assumed to be 1.0. At acute doses less than 0.2 cGy, a DDREF that can exceed 1.0 is applied, and the distribution of possible values approaches the probability distribution of DDREF that applies to all chronic exposures as the dose approaches zero.

Claimant Unfavorable estimates of Transfer of Risk from Japanese to US

study. Because of this large uncertainty, the method of risk transfer from the Japanese to the U.S. racial/ethnic groups, built into the NIOSH-IREP program, should incorporate the possibility of an additive or multiplicative interaction (or a mixture of these). Given the conflicting evidence regarding the appropriateness of any specific interaction model between UV and ionizing radiation exposure, the IREP program uses the same uncertainty distribution for risk transfer as was used for all other solid cancers (except breast and stomach cancer). This distribution is trapezoidal, equally weighting the probabilities for an additive and multiplicative interaction, with slight probabilities of sub-additive or super-multiplicative interactions.

Claimant Unfavorable - simulations and "precalculated" are not defined

Tables 5 through 7 show a comparison of results for the efficiency method (precalculated) and custom Monte Carlo simulations for colon, bladder, and lung calculations respectively. Because these are Monte Carlo calculations, small differences between methods are expected. The relative error figure in these tables describes the difference between the efficient method and a custom Monte Carlo calculation.

Claimant Unfavorable Dose Simulation errors

The methods for simulation are not clearly defined. The normal distribution has two parameters, the mean and variance. Why is "parameter 3" included?

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Skin				
Percent error	**Dose distribution**	**Parameter 1**	**Parameter 2**	**Parameter 3**
5	Normal	0.822	0.058	0.000
10	Normal	0.821	0.091	0.000
20	Normal	0.823	0.170	0.000
30	Normal	0.822	0.252	0.000
40	Normal	0.823	0.327	0.000
50	Normal	0.842	0.391	0.000
60	Normal	0.867	0.446	0.000
70	Normal	0.919	0.503	0.000
80	Normal	0.961	0.560	0.000
90	Normal	0.999	0.610	0.000
100	Normal	1.056	0.657	0.000

Claimant Unfavorable dose reported at 95% level and "may have been reported"

Claimant Unfavorable Revised doses change

What does "May have been reported" mean?

Why does dose decrease?

Missed Dose sections of this report).

These changes have resulted in the following changes in dose.

Dose Categories	Previous Dose (rem)	Revised Dose (rem)
External (Dosimeter measured, missed, and coworker)	21.425	13.343
On-Site Ambient	0.584	0.752
Medical X-ray	0.752	1.520
Internal	4.005	4.005
Total	**26.766**	**19.620**

* In the previous revision, the missed dose may have been reported at the 95% level. However, current reporting practices are to report the missed dose at the geometric mean.

Claimant Unfavorable estimation problems

The number of decimal digits gives a claimant unfavorable estimate and the fluctuation of "parameter 3" is consistent with an error in the estimation software

FEB-4-2013 21:26 FROM:CHRIS BARKER 222 TO:CHRIS P.5/6

Birth Year	Year of Diagnosis	Cancer Model	Should alt model be run?
1936	2004	All Male Genitalia	No

Secondary Cancer #2	Secondary Cancer #3
N/A	N/A
N/A	N/A

Parameter 1	Parameter 2	Parameter 3
0.286	0.077	0.000
1.045	1.503	0.000
0.357	0.182	0.000
0.155	0.080	0.000
0.267	1.678	0.000
0.082	1.496	0.000
2.014	1.378	0.000
0.714	1.399	0.000
0.019	0.007	0.000
0.018	0.008	0.000
0.010	0.004	0.000
0.001	0.001	0.000
0.056	2.416	0.000
0.182	1.767	0.000
0.354	1.628	0.000
0.166	1.629	0.000
0.021	1.629	0.000
0.082	1.620	0.000
0.125	1.624	0.000
0.022	1.733	0.000
0.006	1.738	0.000
0.157	1.684	0.000
0.055	1.684	0.000
0.019	0.054	0.066
0.309	1.460	0.000
0.029	0.083	0.101
0.004	0.004	0.005
0.013	1.340	0.000
0.024	0.000	0.000
0.004	0.000	0.000
0.004	0.000	0.000
0.004	0.000	0.000
0.004	0.000	0.000
0.004	0.000	0.000
0.004	0.000	0.000
0.004	0.000	0.000
0.025	0.008	0.000
0.025	0.008	0.000
0.050	0.015	0.000

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Claimant Unfavorable change in distribution for identical radiation level

The distribution of photons 30-250KEV changes from normal to lognormal

CLAIMANT CANCER DIAGNOSES

	Primary Cancer #1	Primary Cancer #2	Primary Cancer #3	Secondary Cancer #1
Cancer Type	ostate Adenocarcinor	N/A	N/A	N/A
Date of Diagnosis	2004	N/A	N/A	N/A

EXPOSURE INFORMATION

Number of exposures

89

Exposure #	Exposure Year	Exposure Rate	Radiation Type	Dose Distribution Type
1	1958	acute	hotons E=30-250ke	normal
2	1959	acute	hotons E=30-250ke	lognormal
3	1961	acute	hotons E=30-250ke	normal
4	1962	acute	hotons E=30-250ke	normal
5	1959	chronic	neutrons E<10keV	lognormal
6	1959	chronic	eutrons E=10-100ke	lognormal
7	1959	chronic	trons E=100keV-2M	lognormal
8	1959	chronic	eutrons E=2-20MeV	lognormal

General Exposure Information:

#	Exp. Year	Organ Dose (cSv)	Exp. Rate	Radiation Type
1	1958	Normal (0.286 , 0.0768)	acute	photons E=30-250keV
2	1959	Lognormal (1.05 , 1.5)	acute	photons E=30-250keV
3	1961	Normal (0.357 , 0.182)	acute	photons E=30-250keV
4	1962	Normal (0.155 , 0.0802)	acute	photons E=30-250keV
5	1959	Lognormal (0.267 , 1.68)	chronic	neutrons E<10keV
6	1959	Lognormal (0.0823 , 1.5)	chronic	neutrons E=10-100keV
7	1959	Lognormal (2.01 , 1.38)	chronic	neutrons E=100keV-2MeV
8	1959	Lognormal (0.714 , 1.4)	chronic	neutrons E=2-20MeV

Claimant Unfavorable data sorting order.

Dates should be sorted by calendar year. Numerical order of exposure # is not defined

PERSONAL INFORMATION

Claimant Name	NIOSH ID #	DOL Case No	DOL District Office
Robert Barrie Barker	020781	522524905	DE

CLAIMANT CANCER DIAGNOSES

	Primary Cancer #1	Primary Cancer #2	Primary Cancer #3	Se
Cancer Type	ostate Adenocarcinor	N/A	N/A	
Date of Diagnosis	2004	N/A	N/A	

EXPOSURE INFORMATION

Number of exposures
89

Exposure #	Exposure Year	Exposure Rate	Radiation Type	Dos
1	1958	acute	hotons E=30-250ke	
2	1959	acute	hotons E=30-250ke	
3	1961	acute	hotons E=30-250ke	
4	1962	acute	hotons E=30-250ke	
5	1959	chronic	neutrons E<10keV	
6	1959	chronic	eutrons E=10-100ke	
7	1959	chronic	trons E=100keV-2M	
8	1959	chronic	eutrons E=2-20Me	
9	1958	acute	photons E<30keV	
10	1959	acute	photons E<30keV	
11	1961	acute	photons E<30keV	
12	1962	acute	photons E<30keV	
13	1958	acute	hotons E=30-250ke	
14	1959	acute	hotons E=30-250ke	
15	1960	acute	hotons E=30-250ke	
16	1961	acute	hotons E=30-250ke	
17	1962	acute	hotons E=30-250ke	
18	1963	acute	hotons E=30-250ke	
19	1964	acute	hotons E=30-250ke	
20	1959	chronic	neutrons E<10keV	
21	1959	chronic	eutrons E=10-100ke	
22	1959	chronic	trons E=100keV-2M	
23	1959	chronic	eutrons E=2-20Me	
24	1958	acute	hotons E=30-250ke	
25	1959	acute	hotons E=30-250ke	
26	1960	acute	hotons E=30-250ke	
27	1958	acute	photons E<30keV	
28	1959	acute	photons E<30keV	
29	1960	acute	photons E<30keV	
30	1958	chronic	hotons E=30-250ke	
31	1959	chronic	hotons E=30-250ke	
32	1960	chronic	hotons E=30-250ke	
33	1961	chronic	hotons E=30-250ke	
34	1962	chronic	hotons E=30-250ke	
35	1963	chronic	hotons E=30-250ke	
36	1964	chronic	hotons E=30-250ke	
37	1958	acute	hotons E=30-250ke	
38	1960	acute	hotons E=30-250ke	
39	1961	acute	hotons E=30-250ke	

Claimant Unfavorable failure to define "expected"
expected by by whom, under what circumstances, by what criteria defined-in advance of looking at the data"

[redacted] participated in the routine internal (urine bioassays) and external monitoring programs over the course of most of his employment. These measurements are intended to determine if any intake of radionuclides (from inhalation or wounds) had occurred. None of those measurements showed any significant intake of radioactive material. The assigned internal dose to the prostate based on hypothetical intakes is expected to exceed any unmeasured or unrecorded dose from these incidents. Mr. Barker also participated in the routine external dose measurement program and any significant external dose from these incidents would be expected to have been recorded by the routine program. In addition, potential missed doses and coworker doses were assigned for all zeros or gaps in dosimetry badge readings and would be expected to exceed any potential unmeasured or unrecorded dose. No information was raised in the interview to suggest that the doses estimated in this dose reconstruction are ~~not~~ claimant favorable.

Claimant Unfavorable definition of "significant intake"
"significant intake" was never defined in advance of looking at the data

[redacted]icipated in the routine internal (urine bioassays) and external monitoring programs over the course of most of his employment. These measurements are intended to determine if any intake of radionuclides (from inhalation or wounds) had occurred. None of those measurements showed any significant intake of radioactive material. The assigned internal dose to the prostate based on hypothetical intakes is expected to exceed any unmeasured or unrecorded dose from these incidents. Mr. Barker also participated in the routine external dose measurement program and any significant external dose from these incidents would be expected to have been recorded by the routine program. In addition, potential missed doses and coworker doses were assigned for all zeros or gaps in dosimetry badge readings and would be expected to exceed any potential unmeasured or unrecorded dose. No information was raised in the interview to suggest that the doses estimated in this dose reconstruction are ~~not~~ claimant favorable.

Claimant Unfavorable urine bioassay data not provided to claimant

[redacted] participated in the routine internal (urine bioassays) and external monitoring programs over the course of most of his employment. These measurements are intended to determine if any intake of radionuclides (from inhalation or wounds) had occurred. None of those measurements showed any significant intake of radioactive material. The assigned internal dose to the prostate based on hypothetical intakes is expected to exceed any unmeasured or unrecorded dose from these incidents. Mr. Barker also participated in the routine external dose measurement program and any significant external dose from these incidents would be expected to have been recorded by the routine program. In addition, potential missed doses and coworker doses were assigned for all zeros or gaps in dosimetry badge readings and would be expected to exceed any potential unmeasured or unrecorded dose. No information was raised in the interview to suggest that the doses estimated in this dose reconstruction are ~~not~~ claimant favorable.

Claimant Unfavorable software estimation error, software not 21CFR Part II compliant

It is not clear if this is output of an iteration or some other result. The log-normal apparently used in the modelling has three parameter estimates and parameter 3 has -obvious- convergence plans.
We request use of 21CFR Part II compliant software such as SAS to estimate the log-normal.
For data that are log normal, taking logarithms provides data that is normally distributed. The output (nowhere defined in the manual) appears to show an unnecessary iterative estimation

Birth Year	Year of Diagnosis	Cancer Model	Should alt model be run?
1936	2004	All Male Genitalia	No

Secondary Cancer #2	Secondary Cancer #3
N/A	N/A
N/A	N/A

Parameter 1	Parameter 2	Parameter 3
0.286	0.077	0.000
1.045	1.503	0.000
0.357	0.182	0.000
0.155	0.080	0.000
0.267	1.678	0.000
0.082	1.496	0.000
2.014	1.378	0.000
0.714	1.399	0.000
0.019	0.007	0.000
0.018	0.008	0.000
0.010	0.004	0.000
0.001	0.001	0.000
0.056	2.416	0.000
0.182	1.767	0.000
0.354	1.628	0.000
0.166	1.629	0.000
0.021	1.629	0.000
0.082	1.620	0.000
0.125	1.624	0.000
0.022	1.733	0.000
0.006	1.738	0.000
0.157	1.684	0.000
0.055	1.684	0.000
0.019	0.054	0.066
0.309	1.460	0.000
0.029	0.083	0.101
0.004	0.004	0.005
0.013	1.340	0.000
0.024	0.000	0.000
0.004	0.000	0.000
0.004	0.000	0.000
0.004	0.000	0.000
0.004	0.000	0.000
0.004	0.000	0.000
0.004	0.000	0.000
0.004	0.000	0.000
0.025	0.008	0.000
0.025	0.008	0.000
0.050	0.015	0.000

Claimant Unfavorable Coworker Dose Assignment

A coworker dose estimate based on a 50th percentile , is unfavorable and a 99% quantile is consistent with other estimates used by NIOSH.

Coworker Dose Assignment
During the periods that [redacted] was on site and not monitored (i.e., 1960 Quarters 1 and 2; and 1964 Quarters 2, 3, and 4), external dose was assigned in accordance with the Technical Information Bulletin: External Coworker Dosimetry Data for the Rocky Flats Plant.[16] These doses were assigned at the 50th percentile of coworker distribution to ensure that the unmonitored external dose to the prostate was not underestimated. The 50th percentile was applied because it represents a reasonable overestimate of [redacted] exposure, based on his recorded measured dose history.

Claimant Unfavorable "reasonable"Coworker Dose Assignment

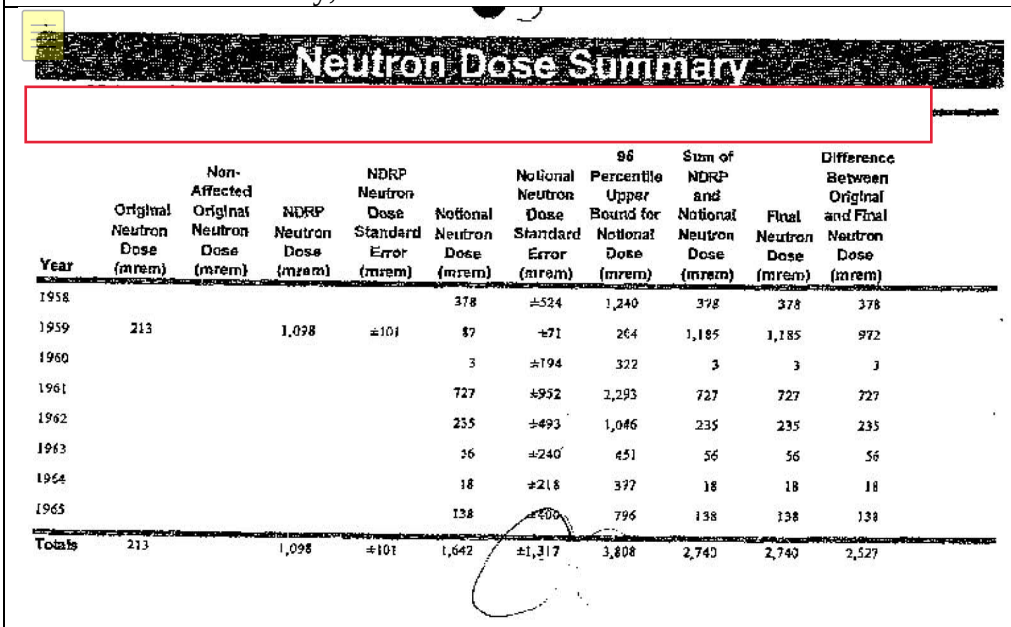
...Reasonable ...and overestimate... is not defined.

Coworker Dose Assignment
During the periods that Mr. [redacted] was on site and not monitored (i.e., 1960 Quarters 1 and 2; and 1964 Quarters 2, 3, and 4), external dose was assigned in accordance with the Technical Information Bulletin: External Coworker Dosimetry Data for the Rocky Flats Plant.[16] These doses were assigned at the 50th percentile of coworker distribution to ensure that the unmonitored external dose to the prostate was not underestimated. The 50th percentile was applied because it represents a reasonable overestimate of [redacted]'s exposure, based on his recorded measured dose history.

Claimant Unfavorable Use of Crystal Ball software for simulations - not 21 CFR Part 11 compliant software
The software is not 21 CFR part 11 compliant
Claimant Unfavorable Use of NIOSH IREP software for probability of causation estimates - not 21 CFR Part 11 compliant software
The software is not 21 CFR part 11 compliant
Claimant Unfavorable Use of NIOSH IMBAS software not 21 CFR Part 11 compliant software
The software is not 21 CFR part 11 compliant

Claimant Unfavorable Omissions and Undefined quantities on <CLAIMANT> NIOSH output

we request a mathematical definition of the calculation of all quantities in the Neutron Dose Summary, such as standard devation



Neutron Dose Summary

Year	Original Neutron Dose (mrem)	Non-Affected Original Neutron Dose (mrem)	NDRP Neutron Dose (mrem)	NDRP Neutron Dose Standard Error (mrem)	Notional Neutron Dose (mrem)	Notional Neutron Dose Standard Error (mrem)	96 Percentile Upper Bound for Notional Dose (mrem)	Sum of NDRP and Notional Neutron Dose (mrem)	Final Neutron Dose (mrem)	Difference Between Original and Final Neutron Dose (mrem)
1958					378	±524	1,240	378	378	378
1959	213		1,098	±101	87	±71	264	1,185	1,185	972
1960					3	±194	322	3	3	3
1961					727	±952	2,293	727	727	727
1962					235	±493	1,046	235	235	235
1963					56	±240	451	56	56	56
1964					18	±218	377	18	18	18
1965					138	±400	796	138	138	138
Totals	213		1,098	±101	1,642	±1,317	3,808	2,740	2,740	2,527

Claimant Unfavorable Neutron Doses May have been affected.

We request a definition of "may" and given the uncertainty why was any change made, and we request that any changes use the result most favorable to the claimant

The NDRP study re-evaluated neutron doses by re-reading films and glass plates used to monitor workers for neutron doses and by estimating neutron dose for periods of time when workers were not monitored for neutron exposure. The project identified that your neutron doses of record may have been affected.

Claimant unfavorable use of Cromwell's Law

The assumption of a fixed distribution is a claimant unfavorable application of Cromwell's law

Jackman, Simon (2009) Bayesian Analysis for the Social Sciences, Wiley.

Carlyle, Thomas, ed. (1855). Oliver Cromwell's Letters and Speeches 1. New York: Harper. p. 448.

Lindley, Dennis (1991). Making Decisions (2 ed.). Wiley. p. 104.

The magnitude of the bias associated with Approach 2 can be estimated, for sites computed using Approach 1 (Table IV.D.1), as follows: suppose that the 99% upper statistical uncertainty limit for AS is 50% if computed using lognormal assumptions for ERR_{1Sv} (i.e., the 99% limit for ERR is 1) for dose D. The corresponding upper limit for AS based on ERR, also computed using lognormal assumptions but with the Approach 2 assumption of zero covariance between $\log(\alpha)$ and $h(e, a; \gamma, \delta)$, is likely to be either higher or lower than 50%, thus indicating the direction and magnitude of bias using the decision rule selected by the DVA, and mandated by the Energy Employees Occupational Illness Compensation Program Act of 2000. The percentages of over- or underestimation of AS using Approach 2, for the five Approach 1 sites, are shown in Appendix Table C.1 (page 92) for exposure ages e = 18, 20, 25, and 30 (or over) and attained ages a = 25, 30, 35, 40, 45, and 50 (or over), where $a \geq e + 7$.

Claimant Unfavorable assumptions of an unknown, undefined constant distribution.

A proper Bayesian probability model with an appropriate claimant favorable prior should be applied. A "constant disribution" is not defined and is not - claimant favorable and an application of Cromwell's Rule

Uncertainty

All internal dose, non-glovebox measured photon dose (1960–1965), and on-site ambient doses are assumed to have a constant distribution, whereas missed dose, measured photon dose with glovebox factor applied(1958, 1959), and lumbar-spine X-ray dose are applied as a lognormal distribution with a geometric standard deviation. Neutron doses evaluated by the NDR Project are assumed to be a normal distribution with a propagated uncertainty. Chest X-rays are assumed to have a normal distribution with a standard deviation of 30%.

Radiation exposure due to Cracks in gloves not included in assigned share model

Dose from Radiological Incidents

The record of the telephone interview was evaluated carefully by the dose reconstructor. It was noted that Mr. Barker was once in an incident where he was struck with a hammer, but no contamination resulted from this incident. It was also noted that Mr. Barker observed that the gloves in the gloveboxes would frequently develop small tears. None of this information suggests that the doses estimated in this dose reconstruction are not claimant favorable.

Claimant Unfavorable estimate of twice the mode dose.

the internal mode, and triangular and constant distribution are not defined. the median or mean or upper 99% confidence limit is a superior estimate

Uncertainty

Uncertainties for all doses, except for medical X-ray and ambient external dose, were calculated using Monte Carlo methods,[20] as discussed above and applied as either a triangular, normal, or lognormal distribution. On-site ambient doses were assumed to have a constant distribution. Medical X-rays are assumed to have a normal distribution with a standard deviation of 30%.

Internal dose estimates based on missed dose were applied as a triangular distribution (minimum = zero, mode = dose calculated above, and maximum = twice the mode dose).

Claimant unfavorable statistical bias in assumptions on standard deviation, constant relative percentage, "on the order of" and "simple estimate"

The minimum detection level (*MDL*), sometimes called the critical limit (L_C), is generally defined as the point when the uncertainty of the reading at the 95% confidence level is ± 100%. The standard deviation at this level can be defined as:

$$\sigma_{MDL} = \frac{L_C}{k} = \frac{L_C}{1.96}$$

Assuming that $\sigma_{MDL} \approx \sigma_n$ (the standard deviation of the null readings) and that the standard deviation at the high dose level (σ_μ) is a constant relative percentage on the order of 10-20%, a simple estimate of uncertainty based on exposure level can be defined as:

$$\sigma(E) = \sqrt{\left(\frac{L_C}{1.96}\right)^2 + \left(\frac{\sigma^*}{100}(E)\right)^2}$$

where:

Claimant Unfavorable assumptions about correlation/covariances among dosimetry measurements

The assumptions are not clear. However, for separate dosimeters worn by Claimant , there is an -induced- correlation among the measurements not included here.

Figure 2.1 Comparison of film badge uncertainty to simplified uncertainty

2.1.1.3.4 Uncertainty Combination
The uncertainty from each film dosimeter should be calculated and the combined annual uncertainty should calculated using standard error propagation methodology (square root of the sum of the squares) as shown in the following equation.

$$\sigma_D^2 = \sigma_1^2 + \sigma_2^2 + \sigma_3^2 + ...\sigma_i^2$$

where
σ_D = Uncertainty of Annual dose
σ_i = Uncertainty of a Single Dosimeter

Claimant unfavorable coefficients without any uncertainty - an application of Cromwell's Law

There are no confidence limits or standard errors in numerous tables in NIOSH documents, following is an example

Appendix Table E.1. Comparison of CIRRPC and IREP: ERR values for site-specific cancers, exposure age 20, diagnosis at age 55 unless otherwise indicated. Tabular values are for a male (female in the case of breast cancer) with exposure at organ-specific equivalent dose of 1 cSv chronic photon radiation at > 250 keV.

(1) Type of Cancer	(2) ERR85[1] at 1 cSv, × 100	(3) Dose and linearity factor[2], FDL	(4) **FDL × ERR85 at 1 cSv, × 100**	(5) Baseline Factor[3], FB	(6) FDL × FB × ERR85 at 1 cSv, × 100	(7) **IREP ERR at 1 cSv[4], × 100**
Leukemia except CLL						
Peak[6]	6.13	2.43	**14.9**	1.2	17.9	**16.8**
15 years after exposure	2.05	2.43	**5.0**	1.2	6.0	**4.6**
30 years after exposure	0.23	2.43	**0.56**	1.2	0.68	**0.67**
Acute Myeloid Leuk.						
Peak[6]	5.96	2.43	**14.5**	1.2	17.4	**5.1**
15 years after exposure	1.87	2.43	**4.6**	1.2	5.5	**2.9**
30 years after exposure	0.15	2.43	**0.35**	1.2	0.42	**1.2**
Chronic Myeloid Leuk.						
Peak[6]	6.35	2.43	**15.4**	1.2	18.5	**26.9**
15 years after exposure	2.51	2.43	**6.1**	1.2	7.3	**2.3**
30 years after exposure	0.62	2.43	**1.5**	1.2	1.8	**0.06**
Esophagus	0.207	2.43	**0.50**	2.3	1.16	**0.34**
Stomach	0.569	2.43	**1.5**	1.9	2.6	**0.22**
Colon	0.167	2.43	**0.41**	2.4	0.97	**0.47**
Liver	2.81	2.43	**6.9**	2.6	17.9	**1.28**
Pancreas	0.446	2.43	**1.1**	1.9	2.1	**0.10**
Lung (Nonsmoker)	0.831	2.43	**2.0**	2.2	4.44	**0.40**
Lung (Smoker)	0.074	2.43	**0.18**	2.2	0.40	**0.09**
Urinary	0.124	2.43	**0.30**	4.1	1.24	**0.46 or 0.35[5]**
Female Breast	0.606	1.00	**0.61**	1.9	1.15	**0.38**
Thyroid	2.82	1.00	**2.8**	2.7	6.3	**1.2**

[1]The ERR at 1 cSv as given by NIH (1985).

[2]For nonlinear estimates based on the A-bomb survivor data, the factor includes 1.62 to correct for dosimetry-related bias and 1.5 to correct for a one-third probability of a linear dose-response.

[3]To calculate CIRRPC screening doses, ERRs were adjusted upward to consider the possibility that a subject might have an exceptionally low baseline risk. These factors were obtained as ratio of average U.S. rate divided by the 10th percentile of the distribution for all U.S. counties.

[4]These are ERRs based on 5000 iterations with IREP.

[5]The first value is that for all urinary cancers; the second is that for bladder cancer.

[6]This is the maximum ERR for all time periods after exposure. For the NIH tables, this occurred in the period 3–8 years following exposure. For IREP, the maximum occurred five years after exposure.

100 Report of the NCI-CDC Working Group to Revise the 1985 NIH Radioepidemiological Tables

i. Claimant Unfavorable non-existent ethical oversight due to absence of a Bioethicist, or member of clergy or claimant or claimant caretaker on

the the panel overseeing use of the NIOSH IREP or reviewing compensation decisions.

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Attachments - pages 1 to approximately 1011
These appendices were provided to NIOSH.