Correcting Some Misconceptions about EPA's Superfund Approach for Radiation Risk Assessment

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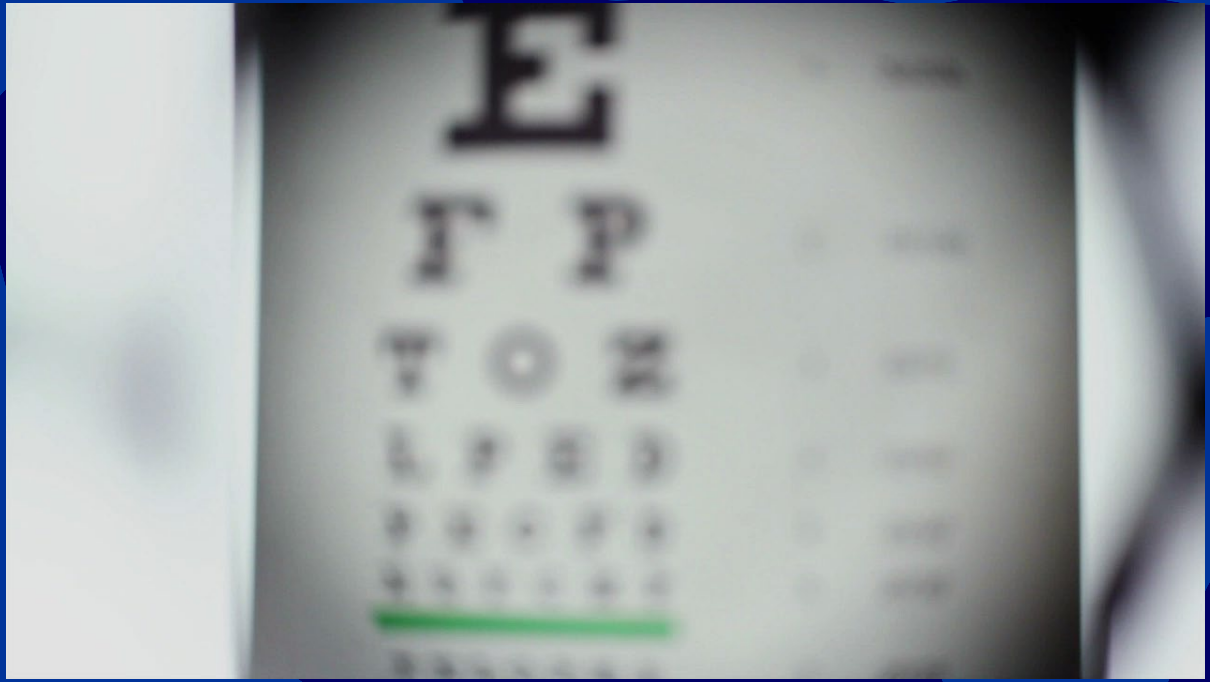
DISCLAIMER

- The views of the author of this presentation are those of the author and do not represent Agency policy or endorsement.
- Mention of trade names of commercial products should not be interpreted as an endorsement by the U.S. Environmental Protection Agency.

Purpose

- Provide clarification of some of the misunderstandings about the approach used by the EPA Superfund site remediation program by focusing on misstatements about the Superfund approach that the author has encountered from radiation professionals.



Brief Overview of Superfund Approach to Radiation

- Superfund program selects cleanup levels for radioactive contamination at sites generally using cancer risk (e.g., 10^{-4} to 10^{-6}), rather than millirem or millisieverts. Superfund uses:
  - slope factors when estimating cancer risk from radioactive contaminants, instead of converting from millirem. Current slope factors are based on risk coefficients in Federal Guidance 13 using ICRP107 data.
  - 10^{-6} as a point of departure and establishes Preliminary Remediation Goals (PRGs) at 1×10^{-6}. PRGs, not based on other environmental standards known as Applicable or Relevant and Appropriate Requirements (ARARs), are risk-based.

How to Address Radiation in a Chemical Program?

- With only approximately 66 radioactively contaminated NPL sites out of 1,789 total, the focus of the Superfund remedial program has been on chemicals.
- **Question:** How best address radiation?
- **Answer:** Address radiation in a consistent manner with chemicals, except to account for the technical differences posed by radiation.
  - » Radiation easily fits within Superfund framework
  - » Improves public confidence by taking mystery out of radiation
  - » Radioactively contaminated NPL sites also have chemical contamination

CERCLA Risk and Dose Online Calculators

Human Health - Radiological

Cancer risk (1×10^{-6})

- PRG (soil, water and air) 2002
- BPRG (inside buildings) 2007
- SPRG (outside surfaces) 2009

Dose (millirem per year)

- DCC (soil, water and air) 2004
- BDCC (inside buildings) 2010
- SDCC (outside surfaces) 2010

- RVISL (radon intrusion) 2021

Human Health - Chemical

- RSL (soil, water, and air) 2008
- WTC *document* (inside buildings) 2003
- VISL (vapor intrusion) 2018

Incorrect Assertions About EPA Superfund Program's Approach for Radiation

- But often I encounter incorrect assertions about EPA's approach for addressing radioactively contaminated sites. Similar incorrect assertions:
  - » Appear in journal articles
  - » Are told to EPA personnel (from regional staff to senior management) or said in public meetings

Incorrect Assertions

1. EPA's approach of addressing radiation and chemicals in a similar approach has not received any outside high- level review, either:
   » Risk management/policy review
   » Scientific review
2. EPA risk assessment models have not been peer reviewed
3. EPA is not using sound science
4. EPA's risk models result in dramatically different results from other models assessing the same scenario

Incorrect Assertions, continued.

5. EPA is using population risk modelling incorrectly
6. EPA's risk models are only for screening
7. EPA's cleanup level is 12 or 15 mrem/yr [0.12 or 0.15 mSv/yr]

- On the remaining slides I will briefly refute these incorrect assertions that continue to be made.
- Hopefully, this will clear up some of the continuing confusion.

First Incorrect Assertion

The EPA Superfund approach of addressing Chemical and Radioactive contamination in a consistent manner has not received high level review

Summary of Response to Incorrect Assertion

- This misconception is usually made from individuals not aware of various high-level reports from:
  - » Presidential/Congressional Blue-Ribbon committee
  - » National Academy of Science (NAS)
  - » Science Advisory Board (SAB)
  - » ISCORS (federal agency consensus group)

Blue-ribbon committee

- The Presidential/Congressional Commission on Risk Assessment and Risk Management developed a 1997 report to Congress on the appropriate uses of risk assessment and risk management in Federal regulatory programs.
- Final Report Volume 2 issued 1997, Risk Assessment and Risk Management In Regulatory Decision-Making recommended:
  - Radiation and chemicals should be addressed consistently, particularly when co-located.
  - Superfund should continue to use the 10^{-4} to 10^{-6} cancer risk range and reasonably anticipated land use

Blue-ribbon committee screen shots (pp 82, 122)

RISK ASSESSMENT AND
RISK MANAGEMENT IN
REGULATORY DECISION-MAKING

THE PRESIDENTIAL/CONGRESSIONAL
COMMISSION ON RISK ASSESSMENT
AND RISK MANAGEMENT

FINAL REPORT
VOLUME 2
1997

Recommendation

A concerted effort should be made to evaluate and relate the methods, assumptions, mechanisms, and standards for radiation risks to those for chemicals to clarify and enhance the comparability of risk management decisions and investments, especially when both types of hazards are present.

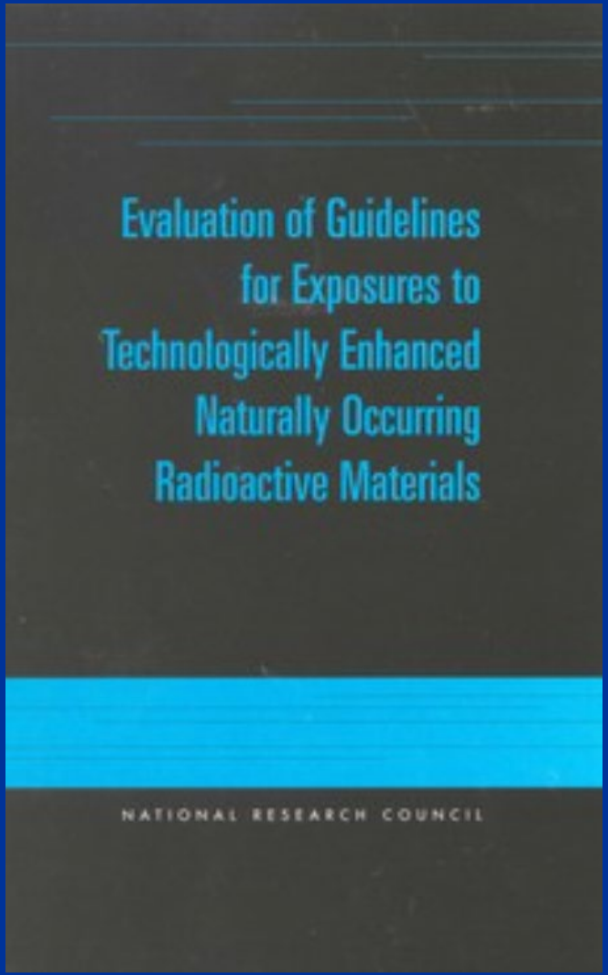
Recommendation

EPA should continue to use its 10^{-6} to 10^{-4} risk range as a guide for site-specific risk-based cleanup goals, related to future land use. Site-

National Academy of Science (NAS)

- 1999 NAS report "Evaluation of Guidelines for Exposures to Technologically Enhanced Naturally Occurring Radioactive Materials."
  - » NAS compared EPA's approach for risk assessment (slope factors) and NRC's approach (use EDE then convert to risk)
    - —NAS found EPA's approach methodologically more rigorous for assessing risks from chronic exposure to radionuclides.
  - » Compared EPA and NRC risk management approaches and determined differences were a matter of policy and not science, and should reflect societal values

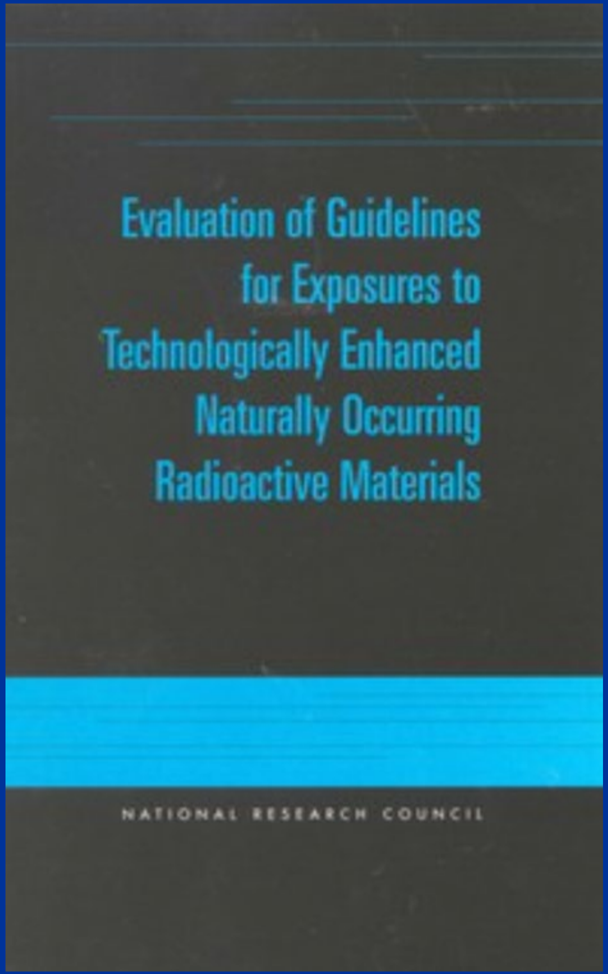
NAS screenshots on comparison of NRC/EPA risk assessment approach (pg 222)



The Nuclear Regulatory Commission's approach to estimating risk posed by chronic radiation exposure of the public normally is based on ICRP recommendations on estimating doses per unit exposure and the risk per unit dose. The Nuclear Regulatory Commission estimates lifetime risks on the basis

EPA has developed a methodologically more rigorous approach to assessing risk posed by chronic lifetime exposure to radionuclides, which is particularly important for internal exposure and differs in several respects from the simple approach described above.

NAS screenshots on comparison of NRC/EPA risk assessment approach (pg 234)



This committee offers the following comments on the issue of a limit on acceptable risk and, therefore, acceptable dose. First, the determination of an acceptable risk for any exposure situation clearly is entirely a matter of judgment (risk-management policy) which presumably reflects societal values. Inasmuch as EPA and the Nuclear Regulatory Commission have used essentially the same assumptions about the risks posed by radiation exposure in establishing radiation standards, it is clear that the determination of a limit on acceptable dose for any exposure situation also is entirely a matter of judgment. Therefore, any differences between the views of EPA and the Nuclear Regulatory Commission on an acceptable dose have no scientific or technical basis.

EPA Science Advisory Board (SAB)

- In 1992 the EPA SAB sent a letter to the EPA Administrator "Commentary on Harmonizing Chemical and Radiation Risk-Reduction Strategies." The SAB:
  - » SAB acknowledged that EPA guidance for Superfund sites, including DOE sites under CERCLA, would use a consistent risk-based approach for addressing radiation and chemical contamination in both risk assessment methodology and cleanup levels (e.g., no more than 10^{-4} cancer risk).
  - » SAB viewed the harmonization of radionuclides to the chemical approach as scientifically valid.

SAB screenshots (pg 9)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 18, 1992

EPA-SAB-RAC-COM-92-007

OFFICE OF
THE ADMINISTRATOR

Honorable William K. Reilly
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Subject: Commentary on Harmonizing Chemical and Radiation Risk-Reduction Strategies

Dear Mr. Reilly:

The Science Advisory Board's Radiation Advisory Committee would like to bring to your attention the need for the Agency to develop a more coherent policy for making risk-reduction decisions with respect to radiation and chemical exposures. As detailed in the attached commentary, *Harmonizing Chemical and Radiation Risk-Reduction Strategies*, the regulation of radiation risks has developed under a different paradigm than for regulation of chemical risks, and a significant potential exists for EPA decisions on radiation risk reduction to be seen as unjustified by the health physics community, the chemical risk management community, or both. Our concern has been stimulated by three recent reviews that we have conducted: the Idaho Radionuclides Study (EPA-SAB-RAC-LTR-92-004), the Radionuclides in Drinking Water proposal (EPA-SAB-RAC-COM-92-003), and the Citizens' Guide to Radon (EPA-SAB-RAC-LTR-92-005). In the first two reviews, we observed that application of the chemical paradigm to radiation issues was questioned by many in the radiation protection community. The Agency's treatment of radon in indoor air has been more in line with traditional radiation risk management, but it is inconsistent with the Agency's proposals for control of radon in drinking water.

Although the reasons for the differences between the two paradigms are historical as well as scientific, an important feature of radiation risk assessment and reduction is the existence of a natural background of radiation in the range of about 70 to 250 millirem (mrem) per year exclusive of indoor radon. With current EPA risk assessment assumptions, the average background – say, 100 mrems per year – is estimated to produce a cancer risk of about 3 per thousand people over a lifetime

Printed on Recycled Paper

The facilities of the Department of Energy that are part of the nuclear weapons complex form another group of problem sites where radionuclides are a significant or even dominating part of the cancer risk equation. Whether these facilities are treated as Superfund (CERCLA) problems or current waste disposal sites under the Resource Conservation and Recovery Act (RCRA), the treatment of radioactive materials is seen as necessarily being subject to the same types of risk analyses and remedial responses that EPA has used for chemicals. The document "Risk Assessment Guidelines for Superfund" (RAGS), for example, contains a section on how to assess the cancer risks from exposure to radionuclides, but does not suggest any different risk-reduction strategies than for carcinogenic chemicals. The implication is that remediation is expected if the lifetime risks from radionuclides are calculated to exceed about 10^{-4} (or lower in some proposals for radiation sites).

SAB screenshots (pp 10, 12)

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Need for Harmonization

Clearly, EPA needs to adopt policies that will allow its staff, the regulated community, scientific consultants to both parties, and the general public all to know what to expect in EPA's regulation of residual radioactivity and other radiation issues. The Radiation Advisory Committee does not claim any special insight in how the resolution should be accomplished, but does emphasize the importance of achieving such harmonization. Interest in the comparative risks of radiation and chemicals has a substantial history (NCRP, 1989) and is now becoming more widespread (Kocher and Hoffman, 1991).

Clearly, the choice among these options -- and others that may exist -- is a policy choice that transcends scientific analysis. The leadership of the Environmental Protection Agency has the authority and the responsibility to make the choice. We urge the choice to be articulated clearly so that the scientists who assess the risks of radiation and chemicals can understand the basis for subsequent decisions about risk reduction.

Interagency Steering Committee on Radiation Standards (ISCORS) Report

- A 2002 report by ISCORS entitled “A Method for Estimating Radiation Risk from Total Effective Dose Equivalent (TEDE).” Report was approved by EPA, NRC, DOE, DOD, and other federal agencies.
- The ISCORS report stated:
  - » The simple method of converting dose to risk is insufficient for a complex risk assessment such as those for CERCLA sites.
  - » Recommendation to use slope factors when a complex risk assessment is needed for assessing radionuclides, such as at a CERCLA sites.

ISCORS screenshot (pg 1)

Interagency Steering Committee on
Radiation Standards

Final Report

A Method for Estimating Radiation Risk from Total Effective Dose Equivalent (TEDE)

ISCORS Technical Report 2002-02

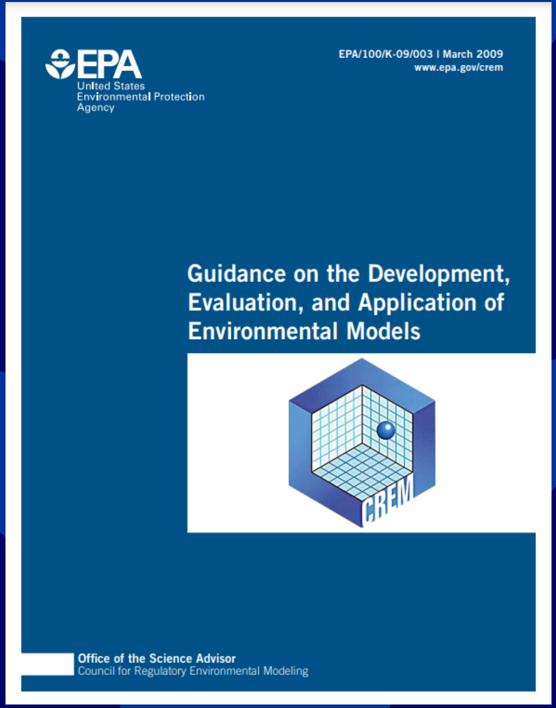
equivalent to cancer risk may be appropriate when radionuclide-specific data is missing. The conversion of dose to risk referred to in this document refers primarily to a conversion of total effective dose equivalent (TEDE, as defined by the Department of Energy in 10 CFR 835.2)[2] to lifetime cancer incidence and mortality risks. The conversion of TEDE to cancer risks using these conversion factors will not satisfy the requirements for a comprehensive radiation risk assessment, but may be of use for making less rigorous comparisons of risk. For situations in which a radiation risk assessment is required for making risk management decisions, the radionuclide-specific risk coefficients published in Federal Guidance Report No. 13 should be used.[3] For radiation risk assessments required by EPA's Superfund Program, the risk coefficients in EPA's Health Effects Assessment Summary Tables (HEAST)[4] should be used. Although

Second Incorrect Assertion

EPA Superfund Radiation Risk Assessment Models have not been peer reviewed

EPA Risk Assessment calculators (models) Peer and Verification Reviews

- Each of the 4 models for radiation risk assessment at Superfund sites (PRG, BPRG, SPRG, and RVISL) models for risk assessment have undergone independent external peer and verification review.
  - » Based on EPA document “Guidance on the Development, Evaluation, and Application of Environmental Models”
  - » Additional automatic computer verification occurs



Summary of Peer/Verification reviews and Nightly Computer checks for each EPA calculator

Type of Peer or Verification Review and Nightly Automatic Computer Verification Checks	Number of Peer and Verification Reviews and Type of Computer Checks for each Calculator				
	PRG	BRPG	SPRG	RVISL	Total
Independent External Peer Review	2	1	1	1	5
Non-Independent External Peer Review	4	1	2	2	9
Independent External Verification Review	3	1	0	1	5
Internal Verification Review	10	5	2	1	18
Auto check of default and site-specific runs	✓	✓			2
Auto check of default runs (since 2019)	✓	✓	✓	✓	4
Auto check of links	✓	✓	✓	✓	4

EPA Risk Assessment calculators (models) Peer and Verification review, continued.

- External reviews of each calculator are provided on “HOME” page, in “Welcome” section, third paragraph.
- See PRG calculator screenshots on the right and following pages as an example.


PRG Home

PRGs for Radionuclides

- Home Page
- User's Guide
- What's New
- Frequent Questions
- Equations
- PRG Calculator
- Generic Tables

Welcome

Welcome to the EPA's "Preliminary Remediation Goals for Radionuclide Contaminants at Superfund Sites" (PRG) Download and Calculator website. The recommended PRGs on this website are preliminary remediation goals (PRGs) for contaminated soil, water, and air. PRGs are addressed in the NCP and EPA CERCLA guidance. Typically PRGs are risk-based, conservative screening values to identify areas and contaminants of potential concern (COPCs) that may warrant further investigation.

This tool presents risk-based preliminary remediation goals (PRGs) calculated using default input parameters and the latest toxicity values. In addition, you are able to modify the input parameters to create site-specific PRGs to meet the needs of your site. To ensure proper application of the PRGs, please see further guidance on how to use the PRGs presented on this site located in the "PRG User's Guide", "PRG What's New", "PRG FAQ", and "PRG Download Area" links. The EPA has prepared a fact sheet for the general public that describes PRG uses, PRG calculator operation and land uses available for assessment. Additionally, this fact sheet describes the PRG and Dose Compliance Concentrations (DCC) calculators in greater detail for EPA staff. The Office of Solid Waste and Emergency Response (OSWER) Directive, Superfund Radiation Risk Assessment: A Community Toolkit was also developed by the EPA to help the public understand more about the risk assessment process used at Superfund sites with radioactive contamination.

The PRG calculator results were previously verified. The documentation from these may be seen on the Internal Verification and External Verification pages. The PRG calculator was previously peer reviewed and the documentation of those peer reviews may be seen here. The PRG calculator was previously part of several model comparison, and the documentation of one of those reviews may be seen in NCRP Report No. 146: Approaches to Risk Management in Remediation of Radioactively Contaminated Sites. This report examines EPA Superfund and NRC Decommissioning programs approach to radiation site cleanup. Section 3.3.3 is a "Comparison of EPA Preliminary Remediation Goals with NRC Screening Levels." It is part of a larger Section 3.3 "Methods of Site Characterization and Dose or Risk Assessment." Several other comparison reviews that focused on describing the default parameters in various models may be found here.

EPA Risk Assessment calculators (models) Peer and Verification review, continued.

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EPA Risk Assessment calculators (models) Peer review, continued.

External Peer Review Record

External peer review provides the main mechanism for independent evaluation and review of environmental models used by the Agency. For more general information on how EPA develops and evaluates models, see the EPA document Guidance on the Development, Evaluation, and Application of Environmental Models. The copy linked to includes some yellow highlighting of text used in this website for describing peer and verification reviews.

The purpose of peer review is two-fold:

1. To evaluate whether the assumptions, methods, and conclusions derived from environmental models are based on sound scientific principles.
2. To check the scientific appropriateness of a model for informing a specific regulatory decision. (The latter objective is particularly important for secondary applications of existing models.)

Peer review charge questions and corresponding records for peer reviewers those questions should be incorporated into the quality assurance project plan.

Mechanisms of external peer review include (but are not limited to):

- Using an ad hoc panel of scientists.
- Using an established external peer review mechanism such as the SAB.
- Holding a technical workshop.

When conducting an "independent external" scientific peer review of the PRG calculator model, EPA has used a peer review contractor to conduct the peer review process (e.g., select the peer reviewers, provide charge questions, summarize the peer review comments in a chart). EPA staff may provide comments on potential peer reviewers and charge questions. Later, EPA, with ORNL support, has developed responses to the peer review comments. See below material for the independent external scientific peer review of the PRG calculator.

EPA has also had more focused external "non-independent" external peer reviews on early drafts of the PRG calculator. EPA requested and received review by the Army Corps of Engineers Center for Excellence under an interagency agreement. See below material from these non-independent peer reviews

PRGs for Radionuclides

- Home Page
- User's Guide
- What's New
- Frequent Questions
- Equations
- PRG Calculator
- Generic Tables

June 22, 2021 to September 20, 2021 (Independent Peer Review)

Matrix of Peer Review Comments with EPA Resolution
EPA PRG Calculator Review Complete Package, which includes:

- Peer Review Charge Questions
- Matrix of Peer Review Comments
  - Dr. Christian Kunze (IAF Radionuclide Laboratory)
    - Review
    - Curriculum Vitae
    - Conflict of Interest Form
  - U.S. Nuclear Regulatory Commission (Joint Review)
    - Review
  - Dr. Boby Abu-Eid
    - Review
    - Curriculum Vitae
    - Conflict of Interest Form
  - Dr. Karen Pinkston
    - Review
    - Curriculum Vitae
    - Conflict of Interest Form
  - Dr. Rodolfo Avila (AF Consult AB Sweden)
    - Review
    - Curriculum Vitae
    - Conflict of Interest Form
  - Dr. Stephane Pepin (FANC - Belgium)
    - Review
    - Curriculum Vitae
    - Conflict of Interest Form
  - Carl Spreng (Retired. Former USDOE, former Colorado DPHE)
    - Review
    - Curriculum Vitae
    - Conflict of Interest Form
  - Brooke Stagich (Savannah National Laboratory)
    - Review
    - Curriculum Vitae
    - Conflict of Interest Form

October 30, 2014 to January 15, 2015 (Independent Peer Review)

Matrix of Peer Review Comments with EPA Resolution
EPA PRG Calculator Review Complete Package, which includes:

- Peer Review Charge Questions
- Matrix of Peer Review Comments
  - Thomas A. Schneider (Ohio Environmental Protection Agency)
    - Review
    - Curriculum Vitae
    - Conflict of Interest Form
  - U.S. Nuclear Regulatory Commission (Joint Review)
    - Review
  - Christepher A. McKenney
    - Review
    - Curriculum Vitae
    - Conflict of Interest Form
  - Leah S. Parks
    - Review
    - Curriculum Vitae
    - Conflict of Interest Form
  - Adam L. Schwartzman
    - Review
    - Curriculum Vitae
    - Conflict of Interest Form
  - Leo van Velzen (Nuclear Research and Consultancy Group)
    - Review
    - Curriculum Vitae
    - Conflict of Interest Form

May 5, 2021

Non-Independent Peer Review of EPA PRG Calculator draft revisions, which includes:

- Word document transmitted by email from:
  - Michael Filips (U.S. Army Corps of Engineers)

July 26, 2019

Non-Independent Peer Review of EPA PRG Calculator draft revisions, which includes:

- Email transmitting comments from:
  - David Hayes (U.S. Army Corps of Engineers)

August 24, 2016

Non-Independent Peer Review of EPA PRG Calculator draft revisions, which includes:

- Email transmitting comments from:
  - Julie Clements (U.S. Army Corps of Engineers)

July 29, 2004

Non-Independent Peer Review of EPA PRG Calculator User Guide, which includes:

- Email transmitting comments from:
  - Brian Hearty (U.S. Army Corps of Engineers)
  - Anita Meyer (U.S. Army Corps of Engineers)

EPA Risk Assessment calculators (models) External Verification review

PRG External Verification Record

External verification provides the main mechanism for independent evaluation and review of environmental models implemented by the Agency. It should include an examination of the numerical technique in the computer code for consistency with the conceptual model and governing equations. For more general information on how EPA develops and evaluates models, see the EPA document Guidance on the Development, Evaluation, and Application of Environmental Models. The linked copy includes some yellow highlighting of text used in this website for describing peer and verification reviews.

Independent testing of the code once it is fully developed can be useful as an additional check of integrity and quality. The purpose of external verification is verification that the code has no inherent numerical problems while obtaining a solution. Mechanisms of external verification includes code verification to make sure the code performs according to model design specifications.

The PRG calculator results were verified by external entities by conducting a numerical verification of calculator results.

PRGs for Radionuclides

- Home Page
- User's Guide
- What's New
- Frequent Questions
- Equations
- PRG Calculator
- Radionuclide Decay Chain
- Generic Tables

June 17, 2022 to August 8, 2022

EPA PRG Calculator Review Complete Package, which includes a Verification Study Charge by:

1. Dr. Boby Abu-Eid (Nuclear Regulatory Commission)
   - Review
   - Curriculum Vitae
   - Conflict of Interest Certification
2. Bart Eklund (Haley & Aldrich)
   - Review
   - Curriculum Vitae
   - Conflict of Interest Certification
3. Brooke Stagich (Savannah River National Laboratory)
   - Review
   - Curriculum Vitae
   - Conflict of Interest Certification

February 15, 2017 to April 3, 2017

EPA PRG Calculator Review Complete Package, which includes a Verification Study Charge by:

1. G Timothy Jannik (Savannah River National Laboratory)
   - Review
   - Curriculum Vitae
   - Conflict of Interest Certification
2. Mark Hogue (Savannah River Nuclear Solutions, LLC)
   - Review
   - Curriculum Vitae
   - Conflict of Interest Certification

April 24, 2015 to September 30, 2015

EPA PRG Calculator Review Complete Package, which includes a Verification Study Charge by:

1. G Timothy Jannik (Savannah River National Laboratory)
   - Review
     - Calculations for Resident Spreadsheet
     - Calculations for Recreator Spreadsheet
     - Calculations for Farmer Spreadsheet
     - Calculations for Indoor and Outdoor Workers Spreadsheet
     - Calculations for Composite Worker Spreadsheet
     - Calculations for Construction Spreadsheet
     - Calculations for Resident Groundwater Spreadsheet
   - Curriculum Vitae
   - Conflict of Interest Certification
2. Wm. Thomas Pentecost (Colorado Department of Public Health and Environment (Retired))
   - Review
   - Curriculum Vitae
   - Conflict of Interest Certification

EPA Risk Assessment calculators (models) Internal Verification review

PRG Internal Verification Record

Internal verification provides the main mechanism for non-independent evaluation and review of environmental models implemented by the Agency. It should include an examination of the numerical technique in the computer code for consistency with the conceptual model and governing equations. For more general information on how EPA develops and evaluates models, see the EPA document Guidance on the Development, Evaluation, and Application of Environmental Models. The linked copy includes some yellow highlighting of text used in this website for describing peer and verification reviews.

EPA guidance makes a distinction between multiple code verification by code developers and a potential independent testing of code, which is why this website make a distinction between internal and external verification. Independent testing of the code once it is fully developed can be useful as an additional check of integrity and quality.

PRGs for Radionuclides

- Home Page
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The purpose of internal verification is two-fold:

- Translation of mathematical equations that constitute model framework into functioning computer code.
- Verification that the code has no inherent numerical problems while obtaining a solution.

Mechanisms of internal verification include:

- Extensive model research and interpretation.
- Mind mapping new model functionality amongst our team of programmers and environmental scientists.
- Writing computer code the execute new model functionality.
- Maintain documentation of models, parameters, and equations.
- Code verification to make sure the code performs according to model design specifications.

The PRG calculator results were verified by Oak Ridge National Laboratory (ORNL) by conducting a comparison of calculator results to independent spreadsheets. Internal verification spreadsheets are presented below for workers and non-workers. Once the values are verified, the calculator is automatically checked every night for functionality and output verification using a python and selenium script that compares the new outputs for every decay output option with the previously verified outputs for the default, site-specific, and user provided options. The results of the most recent automatic verification can be found here. This automatic verification procedure has been used since October 2022. In addition, since May 2019, every default land use and media combination in the calculator is programmed to run nightly. The results are compared against the previous night, and any changes to PRGs are flagged for attention. Since August 2023, an automated link checking routine has been programmed to run nightly and flag any broken links. Additionally, independent manual link checking is performed on a quarterly basis to ensure comprehensive verification.

- **May 2022**

  The following spreadsheet provides peak PRGs at multiple timepoints for a few isotopes. The purpose of this spreadsheet is verify that the peak PRG variable time point output is following the expected trends for many different types of decay chains.

  Variable time peak verification.

- **June 2021**

  For June 2021, the spreadsheets are divided into results that use PRGs without decay applied, such as secular equilibrium and peak risk, and those that do use PRGs with decay. Each spreadsheet presents PRG outputs for default exposure parameters with default isotope-specific inputs, site-specific exposure parameters with default isotope-specific inputs, and site-specific exposure parameters with user-provided isotope-specific inputs. Outputs are presented below from the most recent calculator updates. Non-workers include: resident, farmer, recreator, and soil to groundwater land uses. Workers include: composite, indoor, outdoor, and construction land uses.

  June 2021 - Non Workers, uses PRGs with decay.
  June 2021 - Workers, uses PRGs with decay.
  June 2021 - Non Workers, uses PRGs without decay, such as secular equilibrium and peak risk.
  June 2021 - Workers, uses PRGs without decay, such as secular equilibrium and peak risk.

- **January 2019**

  For January 2019, the spreadsheets are divided into results that use secular equilibrium and those that do not use secular equilibrium. Each spreadsheet presents PRG outputs for default exposure parameters with default isotope-specific inputs, site-specific exposure parameters with default isotope-specific inputs, and site-specific exposure parameters with user-provided isotope-specific inputs. Outputs are presented below from the most recent calculator updates. Non-workers include: resident, farmer, recreator, and soil to groundwater land uses. Workers include: composite, indoor, outdoor, and construction land uses.

  January 2019 - Non Workers, does not assume secular equilibrium.
  January 2019 - Workers, does not assume secular equilibrium.
  January 2019 - Non Workers, assumes secular equilibrium.
  January 2019 - Workers, assumes secular equilibrium.

The following internal verification sheets are archived and cannot be altered.

- **January 2018**

  January 2018 - Non Workers, does not assume secular equilibrium.
  January 2018 - Workers, does not assume secular equilibrium.
  January 2018 - Non Workers, assumes secular equilibrium.
  January 2018 - Workers, assumes secular equilibrium.

- **July 2017**

  July 2017 - Non Workers, does not assume secular equilibrium.
  July 2017 - Workers, does not assume secular equilibrium.
  July 2017 - Non Workers, assumes secular equilibrium.
  July 2017 - Workers, assumes secular equilibrium.

- **December 2016**

  December 2016 - Non-Workers
  December 2016 - Workers

- **October 2015**

  October 2015 - All Output Options

- **September 2014**

  September 2014 - All Output Options

- **Quality assurance review spreadsheets prior to 2014 were often not kept. Those that were kept, have not been updated for ease of use and are provided below.**

  April 2012

  August 2010

Third Incorrect Assertion

EPA is not using Sound Science in its Superfund Radiation Risk Assessment Models

Sound Science - EPA working with DOE ORNL

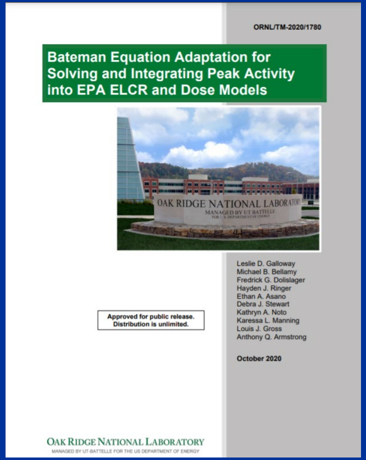
- EPA has an IAG with DOE's ORNL to develop, and to keep updated based on new science and EPA policies, EPA's risk (PRG, BPRG, SPRG), dose (DCC, BDCC, SDCC), and radon intrusion (RVISL which includes, risk, dose, and WL) assessment calculators.
  - The Center for Radiation Protection Knowledge, which is part of ORNL's Environmental Sciences Division, manages this work
  - During development of the PRG and DCC calculators, Keith Eckerman, recipient of the 12th Swedish Royal Academy Gold Medal, led this program

Sound Science - EPA working with DOE ORNL, continued.

- K. Z. Morgan, director of ORNL's Health Physics Division and an early recipient of the Swedish Royal Academy Gold Medal for Radiation Protection, started the ORNL Dosimetry Research Program in the 1950s.
  - Since its inception, the ORNL Dosimetry Research Program has provided the national and international scientific communities with models and data required to estimate radiation doses and risks establish exposure guidelines for radionuclides
- EPA works with ORNL to bring this knowledge of sound science on radiation to appropriately address radiation within the Superfund framework.

Sound Science - EPA working with DOE ORNL, continued.

- ORNL issues ORNL Technical Manuals and other publications in support of the EPA Superfund calculators.


ORNL/TM-2020/1780

Bateman Equation Adaptation for Solving and Integrating Peak Activity into EPA ELCR and Dose Models

Leslie D. Galloway
Michael B. Bellamy
Fredrick G. Dolislager
Hayden J. Ringer
Ethan A. Asano
Debra J. Stewart
Kathryn A. Noto
Karessa L. Manning
Louis J. Gross
Anthony Q. Armstrong

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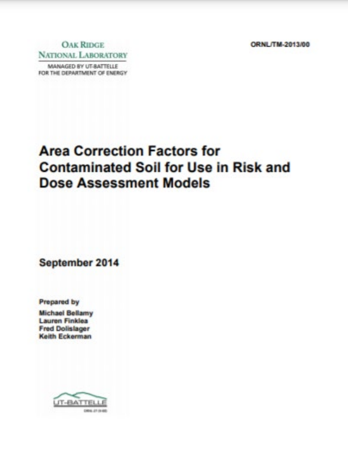
October 2020

Oak Ridge National Laboratory

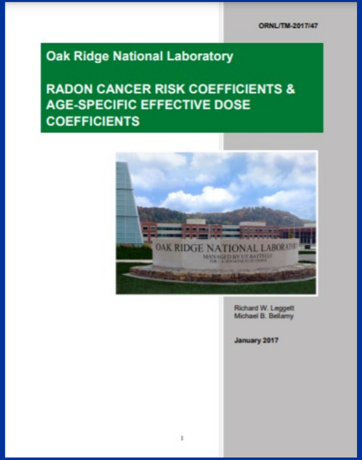

Oak Ridge National Laboratory

ORNL/TM-2013/00

Area Correction Factors for Contaminated Soil for Use in Risk and Dose Assessment Models

September 2014

Prepared by
Michael Bellamy
Lauren Finklea
Fred Dolislager
Keith Eckerman

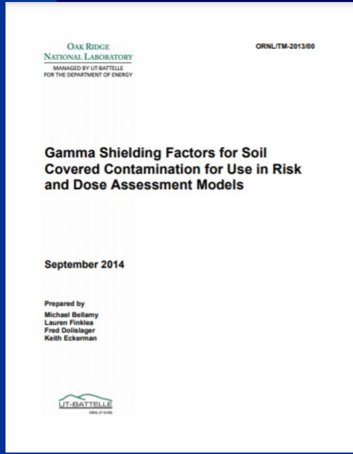

ORNL/TM-2017/47

Oak Ridge National Laboratory

RADON CANCER RISK COEFFICIENTS & AGE-SPECIFIC EFFECTIVE DOSE COEFFICIENTS

Richard W. Leggett
Michael B. Bellamy

January 2017

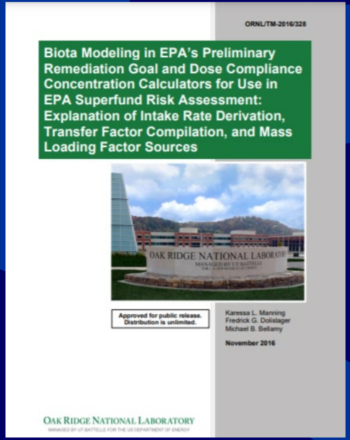

Oak Ridge National Laboratory

ORNL/TM-2013/00

Gamma Shielding Factors for Soil Covered Contamination for Use in Risk and Dose Assessment Models

September 2014

Prepared by
Michael Bellamy
Lauren Finklea
Fred Dolislager
Keith Eckerman


ORNL/TM-2016/328

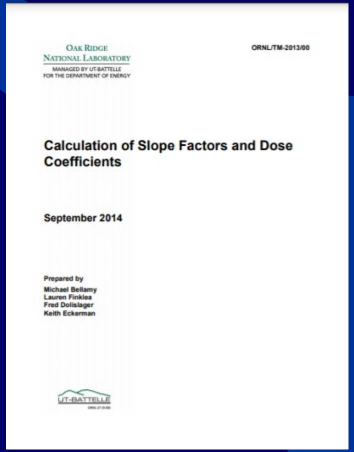
Biota Modeling in EPA's Preliminary Remediation Goal and Dose Compliance Concentration Calculators for Use in EPA Superfund Risk Assessment: Explanation of Intake Rate Derivation, Transfer Factor Compilation, and Mass Loading Factor Sources

Approved for public release. Distribution is unlimited.

Karessa L. Manning
Fredrick G. Dolislager
Michael B. Bellamy

November 2016

Oak Ridge National Laboratory

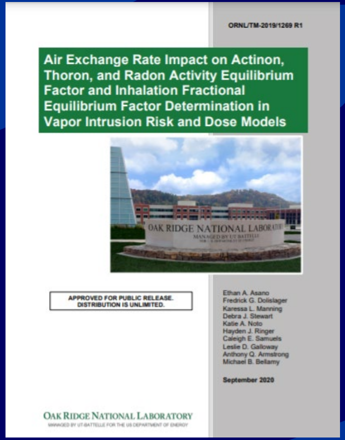

Oak Ridge National Laboratory

ORNL/TM-2013/00

Calculation of Slope Factors and Dose Coefficients

September 2014

Prepared by
Michael Bellamy
Lauren Finklea
Fred Dolislager
Keith Eckerman


ORNL/TM-2019/1269 R1

Air Exchange Rate Impact on Actinon, Thoron, and Radon Activity Equilibrium Factor and Inhalation Fractional Equilibrium Factor Determination in Vapor Intrusion Risk and Dose Models

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September 2020

Oak Ridge National Laboratory

Fourth Incorrect Assertion

EPA Superfund Radiation Risk Assessment models are very conservative compared to other models (particularly the United Kingdom's approach)

General Response to Incorrect Assertions

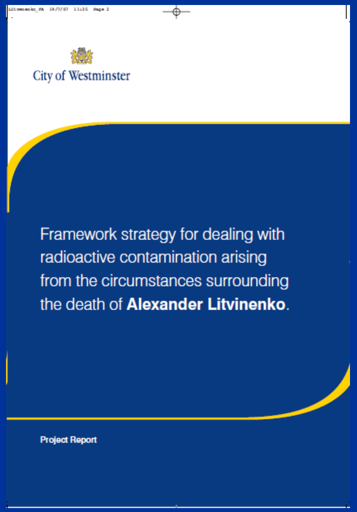
- Sometimes incorrect assertions are made that the EPA PRG calculators are ultra conservative compared to some other model.
- This misconception is often because users are not accounting for different risk management frameworks or conceptual site models.
  - » Default target risk in PRG calculators is 1×10^{-6}, not 25 mrem/yr (approximately 5×10^{-4}) or 100 mrem/yr (2×10^{-3})
  - » Defaults in PRG tools are intended for consistency with chemical models for CERCLA, not rad models for other laws or countries
    - —PRG calculator receptor is a highly exposed individual (Reasonable Maximum Exposure Scenario) not average individual (e.g., average member of the critical group)

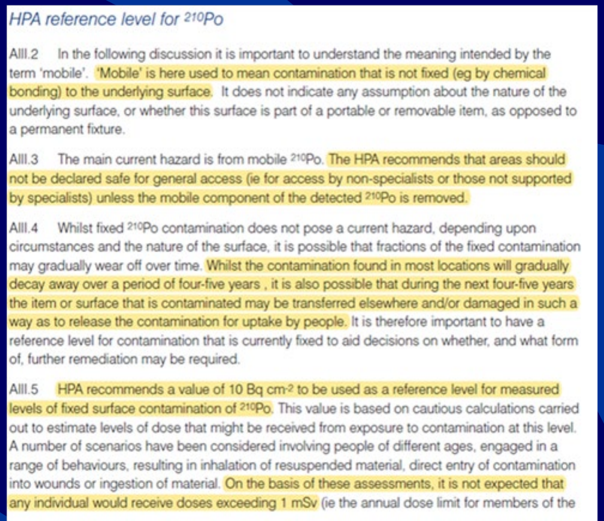
UK comparison -- An example of an incorrect comparison of PRG tools with another model

- It's been asserted that the UK cleanup of Po-210 after the Litvinenko poisoning incident allowed concentrations over **900,000** times higher than those allowed by EPA's PRG calculator. This was in a 2023 letter to editor of HPS journal. Similar recent claims:
  - » In 2022 ANS webinar and HPS letter, claim was UK allowed over **19,000** times higher than Superfund PRG calculators.
  - » At HPS 2021, it was claimed UK allowed **28,329** times higher
- There are several problems with these assertion that make them incorrect, which I will discuss over several slides.

UK comparison – issues with how UK cleanup concentrations were described

- These claims correctly cite **part** of the UK cleanup level for Po-210 of 10 Bq/cm2 to equate to 1 mSv (100 mrem). This was for fixed contamination. The other claim did not have supporting information.
- These claims do **not** include the UK cleanup level for P0-210 of removable contamination, which was non-detect or 0 Bq/cm2.





HPA reference level for ^{210}Po

AIII.2 In the following discussion it is important to understand the meaning intended by the term 'mobile'. 'Mobile' is here used to mean contamination that is not fixed (eg by chemical bonding) to the underlying surface. It does not indicate any assumption about the nature of the underlying surface, or whether this surface is part of a portable or removable item, as opposed to a permanent fixture.

AIII.3 The main current hazard is from mobile ^{210}Po. The HPA recommends that areas should not be declared safe for general access (ie for access by non-specialists or those not supported by specialists) unless the mobile component of the detected ^{210}Po is removed.

AIII.4 Whilst fixed ^{210}Po contamination does not pose a current hazard, depending upon circumstances and the nature of the surface, it is possible that fractions of the fixed contamination may gradually wear off over time. Whilst the contamination found in most locations will gradually decay away over a period of four-five years , it is also possible that during the next four-five years the item or surface that is contaminated may be transferred elsewhere and/or damaged in such a way as to release the contamination for uptake by people. It is therefore important to have a reference level for contamination that is currently fixed to aid decisions on whether, and what form of, further remediation may be required.

AIII.5 HPA recommends a value of 10 Bq cm^{-2} to be used as a reference level for measured levels of fixed surface contamination of ^{210}Po. This value is based on cautious calculations carried out to estimate levels of dose that might be received from exposure to contamination at this level. A number of scenarios have been considered involving people of different ages, engaged in a range of behaviours, resulting in inhalation of resuspended material, direct entry of contamination into wounds or ingestion of material. On the basis of these assessments, it is not expected that any individual would receive doses exceeding 1 mSv (ie the annual dose limit for members of the

UK comparison – Issues with how the EPA tools are used in these claims

- The letter-to-editor writer ran the wrong tool, the SPRG calculator for a scenario of dust on roadways.
- He also used only the results from eating the dust, and picked an output option (Secular Equilibrium) that does not account for decay as if the contamination were to be replenished.
- The writer also used as a target risk level, the more stringent end (1×10^{-6}) of the risk range rather than the more typical highest allowed (1×10^{-4}).

Default

Resident SPRGs for Settled Dust - Secular Equilibrium

Radionuclide	Ingestion SPRG TR=1E-06 (Bq/cm²)	Inhalation Mechanical SPRG TR=1E-06 (Bq/cm²)	Inhalation Wind SPRG TR=1E-06 (Bq/cm²)	External Exposure SPRG TR=1E-06 (Bq/cm²)	SPRG Wind TR=1E-06 (Bq/cm²)	SPRG Mechanical TR=1E-06 (Bq/cm²)
Secular Equilibrium SPRG for Po-210	*1.11E-05*	*5.84E-08*	*4.27E-05*	*4.92E+02*	*8.78E-06*	*5.81E-08*

Comparing our BPRG runs

- The letter-to-editor writer got a concentration of 0.000011 Bq/cm^2 for Po-210 at a risk level of 1×10^{-6} (which is a DeMinimus risk level).
- Using the typical upper bound target risk level of 1×10^{-4}, and a BPRG output option that accounts for decay, the Po-210 concentrations I got are:
  - » Settled dust 0.0172 Bq/cm^2
  - » 3D/Fixed 42,200,000,000 Bq/cm^2

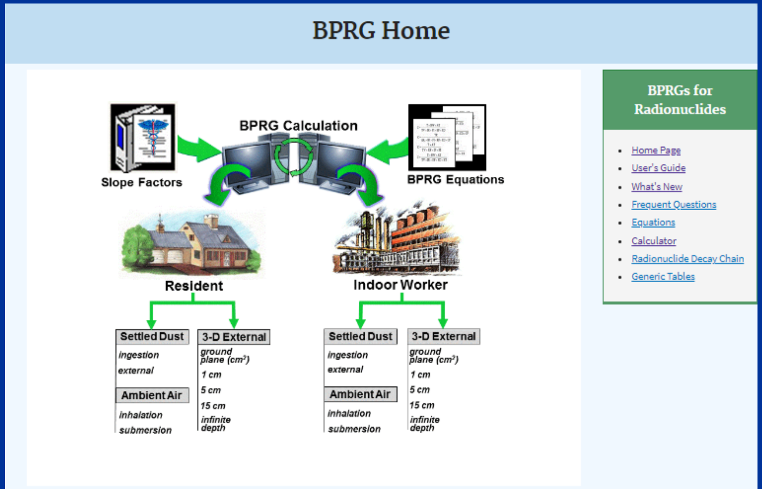
Comparing/Contrast My BPRG Run with UK EA cleanup concentration

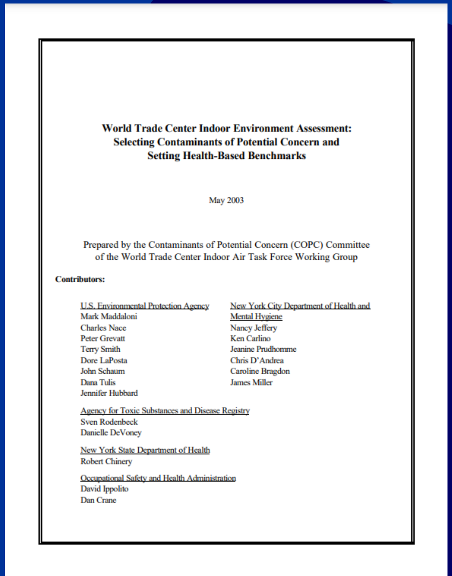
- A simple comparison between the UK and EPA approaches would indicate the UK is more stringent for both fixed/3D and mobile/dust contamination.

	Fixed/3D	Mobile/Dust
UK	10 Bq/cm2	non detect
EPA	42,200,000,000 Bq/cm^2	0.0172 Bq/cm^2

Comparing/Contrast My BPRG Run with UK EA cleanup concentration, continued

- My analysis is ***extremely*** superficial, since it is comparing results and not the underlying input parameters that are used.
  - » BPRG inputs were intended for consistency with World Trade Center cleanup and some updates in EPA's Exposure Factors Handbook, not consistency with UK.





World Trade Center Indoor Environment Assessment:
Selecting Contaminants of Potential Concern and
Setting Health-Based Benchmarks

May 2003

Prepared by the Contaminants of Potential Concern (COPC) Committee of the World Trade Center Indoor Air Task Force Working Group

Contributors:

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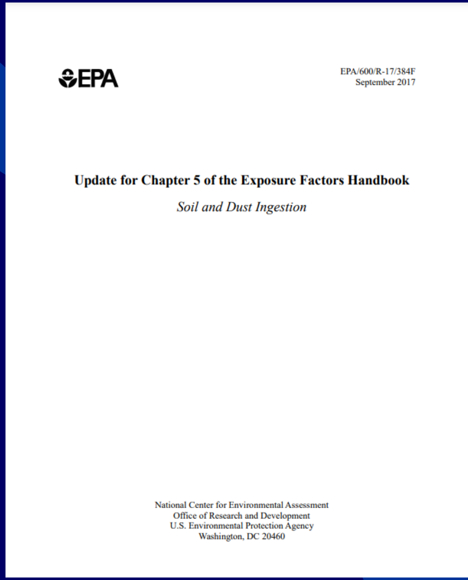


EPA

EPA/600/R-17/384F
September 2017

Update for Chapter 5 of the Exposure Factors Handbook

Soil and Dust Ingestion

National Center for Environmental Assessment
Office of Research and Development
U.S. Environmental Protection Agency
Washington, DC 20460

Conclusion on fourth incorrect assertion

- A lesson should you draw from these inaccurate Superfund/UK risk/dose Po-210 comparisons is to view such analyses skeptically when they are not conducted by the people in those programs since they may not understand either program.

Fifth Incorrect Assertion

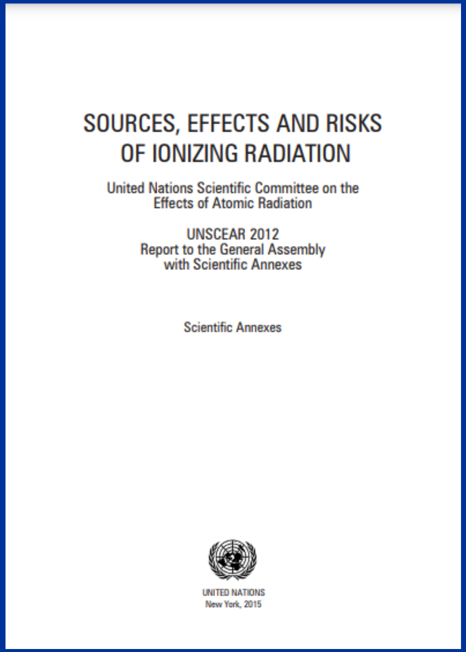
EPA Superfund Radiation Risk Assessment approach is incorrectly using population risk estimates

Background on Incorrect assertion

- Fifth misconception is that Superfund is using estimates of cancer cases across a population to select cleanup levels.
  - » It has been claimed that Superfund's policy for risk-based cleanup is directly going against the recommendation by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) to not estimate population effects from low level exposure to radiation

What UNSCEAR said

- 2012, UNSCEAR recommended against the practice of basing population risk from lower exposures in “Sources, Effects, and Risks of Ionizing Radiation.”


SOURCES, EFFECTS AND RISKS OF IONIZING RADIATION

United Nations Scientific Committee on the Effects of Atomic Radiation

UNSCEAR 2012
Report to the General Assembly
with Scientific Annexes

Scientific Annexes

UNITED NATIONS
New York, 2015

30. In general, increases in the frequency of occurrence of health effects in populations cannot be reliably attributed to chronic exposure to low-LET radiation at levels that are typical of the global average background levels of radiation. This is because of the uncertainties associated with the assessment of risks at low doses, the current absence of radiation-specific biomarkers for health effects and the insufficient statistical power of epidemiological studies. Therefore, the Scientific Committee does not recommend multiplying very low doses by large numbers of individuals to estimate numbers of radiation-induced health effects within a population exposed to incremental doses at levels equivalent to or lower than normal natural background levels.

What Superfund does – see Radiation Risk Assessment: Q&A (2014)

- Superfund RME scenario for establishing risk-based cleanup levels. This is a high-end estimate of individual risk.
- Population risk is generally not used in Superfund risk assessments or to establish cleanup levels.

Q30. How should risk characterization results for radionuclides be presented?

A. Results should be presented according to the standardized reporting format presented in *RAGS* Part D (U.S. EPA 1998a). EPA guidance for risk characterization (U.S. EPA 1995a, 1995b) indicates that four descriptors of risk are generally needed for a full characterization of risk: (1) central tendency (such as median, mean) estimate of individual risk; (2) high-end estimate (for example, the 95th percentile) of individual risk; (3) risk to important subgroups of the population, such as highly exposed or highly susceptible groups (such as children) or individuals, if known; and (4) population risk. The reasonable maximum exposure (RME) estimate of individual risk typically presented in Superfund risk assessments represents a measure of the high-end individual exposure and risk. While the RME estimate remains the primary scenario for Superfund risk management decisions, additional risk descriptors may be included to describe site risks more thoroughly (e.g., central tendency, sensitive subpopulations). Population risk is generally not used as part of Superfund risk assessments.

Q31. Is it necessary to present the collective risk to populations estimated along with that to individual receptors?

A. Generally, no. Risk to potential RME individual receptors generally is the primary measure of protectiveness under the CERCLA remedial process (the target range of 10^{-6} to 10^{-4} lifetime excess cancer risk to the RME receptor). As noted in Q30, however, Agency guidance (U.S. EPA 1995a, 1995b) also indicates that the central tendency risk to the potentially exposed population may be evaluated where possible. Consideration of central tendency risk may provide additional input to risk management decisions; such considerations may be either qualitative or quantitative, depending on the availability of data.

Many Federal Regulatory Process **Must** Evaluate Population Risk

- While Superfund decisions are based on RME not population risk, there are federal regulatory decisions made using population risk.
- Since 1970s, federal agencies consider the costs and benefits of most regulations under development that would be expected to have large economic effects.
  - » Evaluating number of cancer cases or deaths caused by cancer avoided by different proposed alternatives under consideration.
  - » This would require evaluating population health effects.

White House Executive Orders

- ◆Cost-benefit analysis of regulations is required by two Executive Orders (EO) issued by the White House.
  - » E.O. 12866 “Regulatory Planning and Review” (9/30/1993)
  - » E.O. 13563 “Improving Regulation and Regulatory Review” (1/18/2011)
- ◆An UNSCEAR recommendation does **NOT** overrule EO’s.

Federal Register
Vol. 58, No. 190
Monday, October 4, 1993

Presidential Documents

Title 3—
The President

Executive Order 12866 of September 30, 1993

Regulatory Planning and Review

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

With this Executive order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies.

Accordingly, by the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Statement of Regulatory Philosophy and Principles.*

(a) *The Regulatory Philosophy.* Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

(b) *The Principles of Regulation.* To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:

(1) Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.

(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is

EXECUTIVE ORDERS

Executive Order 13563 of January 18, 2011

Improving Regulation and Regulatory Review

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve regulation and regulatory review, it is hereby ordered as follows:

Section 1. *General Principles of Regulation.* (a) Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science. It must allow for public participation and an open exchange of ideas. It must promote predictability and reduce uncertainty. It must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative. It must ensure that regulations are accessible, consistent, written in plain language, and easy to understand. It must measure, and seek to improve, the actual results of regulatory requirements.

(b) This order is supplemental to and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866 of September 30, 1993. As stated in that Executive Order and to the extent permitted by law, each agency must, among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

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EPA

Sixth Incorrect Assertion

EPA Superfund Radiation Risk Assessment Models are only to be used for "Screening"

Response to the Incorrect Assertion that PRG calculators are only for "Screening"

- The misconception that EPA's PRG calculators are intended only for screening can occur when someone does not understand:
  - » the role of screening and preliminary remediation goals (PRGs) in risk and dose assessment for Superfund sites
  - » the role of the PRG calculator for radionuclides and RSL calculator for chemicals in screening and/or PRGs vs risk assessment
  - » how does this Superfund approach differ from "screening" in the NRC world

NCP (1990 Regulatory Language)

- 40 CFR Section 300.430(e)(2)(i).
  - » Develop PRGs based on readily available information
  - » Modify PRGs as necessary as more info becomes available
  - » Select final remediation goals in the ROD

federal register

Thursday
March 8, 1990

Part II

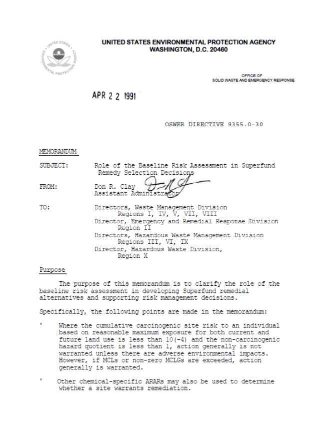
Environmental Protection Agency

40 CFR Part 300
National Oil and Hazardous Substances Pollution Contingency Plan; Final Rule

(i) Establish remedial action objectives specifying contaminants and media of concern, potential exposure pathways, and remediation goals. Initially, preliminary remediation goals are developed based on readily available information, such as chemical-specific ARARs or other reliable information. Preliminary remediation goals should be modified, as necessary, as more information becomes available during the RI/FS. Final remediation goals will be determined when the remedy is selected. Remediation goals shall establish acceptable exposure levels that are protective of human health and the environment and shall be developed by considering the following:

Role of the Baseline Risk Assessment in Superfund Remedy Decisions (1991 guidance)

- PRGs developed early in the process based on readily available information such as ARARs, 10^{-6} cancer risk or HI of 1.
- PRGs may be modified by the results of a baseline risk assessment by info such as clarifying exposure pathways or multiple contaminants or pathways.
- Final decision may modify PRGs based on waste management strategy.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

APR 22 1991

OSWER DIRECTIVE 9355.0-30

MEMORANDUM

SUBJECT: Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions

FROM: Don R. Clay
Assistant Administrator

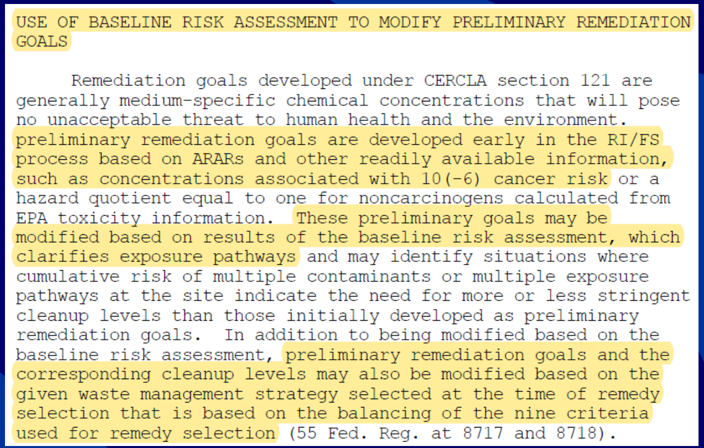
TO: Directors, Waste Management Division
Regions I, IV, V, VII, VIII
Director, Emergency and Remedial Response Division
Region II
Directors, Hazardous Waste Management Division
Regions III, VI, IX
Director, Hazardous Waste Division,
Region X

Purpose

The purpose of this memorandum is to clarify the role of the baseline risk assessment in developing Superfund remedial alternatives and supporting risk management decisions.

Specifically, the following points are made in the memorandum:

- Where the cumulative carcinogenic site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 10(-4) and the non-carcinogenic hazard quotient is less than 1, action generally is not warranted unless there are adverse environmental impacts. However, if MCLs or non-zero MCLGs are exceeded, action generally is warranted.
- Other chemical-specific ARARs may also be used to determine whether a site warrants remediation.



USE OF BASELINE RISK ASSESSMENT TO MODIFY PRELIMINARY REMEDIATION GOALS

Remediation goals developed under CERCLA section 121 are generally medium-specific chemical concentrations that will pose no unacceptable threat to human health and the environment. preliminary remediation goals are developed early in the RI/FS process based on ARARs and other readily available information, such as concentrations associated with 10(-6) cancer risk or a hazard quotient equal to one for noncarcinogens calculated from EPA toxicity information. These preliminary goals may be modified based on results of the baseline risk assessment, which clarifies exposure pathways and may identify situations where cumulative risk of multiple contaminants or multiple exposure pathways at the site indicate the need for more or less stringent cleanup levels than those initially developed as preliminary remediation goals. In addition to being modified based on the baseline risk assessment, preliminary remediation goals and the corresponding cleanup levels may also be modified based on the given waste management strategy selected at the time of remedy selection that is based on the balancing of the nine criteria used for remedy selection (55 Fed. Reg. at 8717 and 8718).

Soil Screening Guidance User Guide (1996 for chemicals)

- Screening means identifying and defining areas, radionuclides, and conditions, at a particular site that do not require further Federal attention.
- Soil Screening Levels can be used as PRGs.

United States Environmental Protection Agency | Office of Solid Waste and Emergency Response Washington, DC 20460 | Publication 9355.4-23 July 1996

Superfund

EPA **Soil Screening Guidance: User's Guide**

Second Edition

SSLs are not national cleanup standards. SSLs alone do not trigger the need for response actions or define "unacceptable" levels of contaminants in soil. In this guidance, "screening" refers to the process of identifying and defining areas, contaminants, and conditions, at a particular site that do not require further Federal attention. Generally, at sites where contaminant concentrations fall below SSLs, no further action or study is warranted under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). (Some States have developed screening numbers that are more stringent than the generic SSLs presented here; therefore, further study may be warranted under State programs.) Generally, where contaminant concentrations equal or exceed SSLs, further study or investigation, but not necessarily cleanup, is warranted.

SSLs can be used as Preliminary Remediation Goals (PRGs) provided appropriate conditions are met (i.e., conditions found at a specific site are similar to conditions assumed in developing the SSLs). The concept of calculating risk-based contaminant levels in soils for use as PRGs (or "draft" cleanup levels) was introduced in the RAGS HHEM, *Part B, Development of Risk-Based Preliminary Remediation Goals.* (U.S. EPA, 1991c). The

PRGs may then be used as the basis for developing final cleanup levels based on the nine-criteria analysis described in the National Contingency Plan [Section 300.430 (3)(2)(I)(A)]. The directive entitled *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions* (U.S. EPA, 1991d) discusses the modification of PRGs to generate cleanup levels. The SSLs should only be

Soil Screening Guidance for Radionuclides: User Guide (2000)

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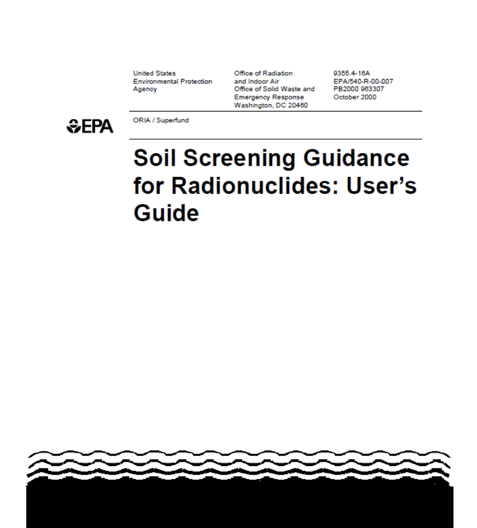
United States Environmental Protection Agency

Office of Radiation and Indoor Air
Office of Solid Waste and Emergency Response
Washington, DC 20460

9355.4-16A
EPA/540-R-00-007
PB2000 963307
October 2000

EPA

ORIA / Superfund

Soil Screening Guidance for Radionuclides: User's Guide

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EPA

Soil Screening Guidance Technical Background Document (1996 chem)

- Part 3 of the TBD included additional, more complicated models for more detailed assessments that include:
  - » 9 Soil to Groundwater models

Part 3: MODELS FOR DETAILED ASSESSMENT

The Soil Screening Guidance addresses the inhalation and migration to ground water exposure pathways with simple equations that require a small number of easily obtained soil parameters, meteorologic conditions, and hydrogeologic parameters. These equations incorporate a number of conservative simplifying assumptions—an infinite source, no fractionation between pathways, no biological or chemical degradation, no adsorption—conditions that can be addressed with more complicated models. Applying such models will more accurately define the risk of exposure via the inhalation or the migration to ground water pathway and, depending on site conditions, can lead to higher SSLs that are still protective. However, input data requirements and modeling costs make this option more expensive to implement than the SSL equations.

This part of the Technical Background Document presents information on the selection and use of more complex fate and transport models for calculating SSLs. Generally, the decision to use these models will involve balancing costs: if the models and assumptions used to develop simple site-specific SSLs are overly conservative with respect to site conditions (e.g., a thick unsaturated zone), the additional cost and time required to apply these models may be offset by the potential cost savings associated with higher, but still protective, SSLs.

Sections 3.1 and 3.2 include information on equations and models that can accommodate finite contaminant sources and fractionate contaminants between pathways (e.g., VLEACH and EMSOFT) and predict the subsequent impact on either ambient air or ground water. However, when using a finite source model, the site manager should recognize the uncertainties inherent in site-specific estimates of subsurface contaminant distributions and use conservative estimates of source size and concentrations to allow for such uncertainties. In addition, model predictions should be validated against actual site conditions to the extent possible.

3.2.2 Unsaturated Zone Models. In an effort to provide useful information for model application, EPA's ORD laboratories in Ada, Oklahoma, and Athens, Georgia, conducted an evaluation of nine unsaturated zone fate and transport models (Criscenti et al., 1994; Nofziger et al., 1994). The results of this effort are summarized here. The models reviewed are only a subset of the potentially appropriate models available to the public and are not meant to be construed as having received EPA approval. Other models also may be applicable to SSL development, depending on site-specific circumstances.

Each of the unsaturated zone models selected for evaluation are capable, to varying degrees, of simulating the transport and transformation of chemicals in the subsurface. Even the most unique site conditions can be simulated by either a single model or a combination of models. However, the intended uses and the required input parameters of these models vary. The models evaluated include:

- RITZ (Regulatory and Investigative Treatment Zone model)
- VIP (Vadose zone Interactive Process model)
- CMLS (Chemical Movement in Layered Soils model)
- HYDRUS
- SUMMERS (named after author)
- MULTIMED (MULTIMEDia exposure assessment model)
- VLEACH (Vadose zone LEACHing model)
- SESOIL (SEasonal SOIL compartment model)
- PRZM-2 (Pesticide Root Zone Model).

Soil Screening Guidance for Radionuclides Technical Background Document (2000)

- Part 3 of SSG for radionuclides TBD included additional more complicated models for more detailed assessments that include:
  - » 5 Soil to Groundwater models

Part 3: UNSATURATED ZONE MODELS FOR RADIONUCLIDE FATE AND TRANSPORT

In an effort to provide useful information for model application, EPA's NRMRL/SPRD in Ada, Oklahoma, conducted an evaluation of five unsaturated zone fate and transport models for radionuclides. The results of this effort follow. The models reviewed are only a subset of the potentially appropriate models available to the public and are not meant to be construed as having received EPA approval. Other models also may be applicable to SSL development, depending on site-specific circumstances.

Each of the unsaturated zone models selected for evaluation are capable, to varying degrees, of simulating the transport and transformation of chemicals in the subsurface. Even the most unique site conditions can be simulated by either a single model or a combination of models. However, the intended uses and the required input parameters of these models vary. The models evaluated include:

- HYDRUS
- MULTIMED_DP 1.0
- FECTUZ
- CHAIN
- CHAIN 2D

The applications, assumptions, and input requirements for the five models evaluated are described in this section. The model descriptions include model solution method (i.e., analytical, numerical), purpose of model, and methods used by the model to simulate water flow, decay reaction, and radionuclide transport. Each description is accompanied by a table of required input parameters. Input parameters discussed include soil properties, chemical properties, meteorological data, and other site information. In addition, certain input control parameters may be required, such as time stepping, grid discritization information, and output format. Information on determining the general applicability of the models to subsurface conditions is provided, followed by an assessment of each model's potential applicability to the soil screening process.

Radiation Risk Assessment at CERCLA Sites: Q&A (2014)

- Use PRG calculator for determining SSLs for screening purposes.
- For generic assessments use defaults in PRG and DCC calculators.

United States Environmental Protection Agency | Office of Superfund Remediation and Technology Innovation | Directive 9200.4-40 EPA 540-R-012-13 May 2014

Radiation Risk Assessment At CERCLA Sites: Q & A

NOTICE: The policies set out in this document are intended solely as guidance to U.S. Environmental Protection Agency (EPA) personnel; they are not final EPA actions and do not constitute rulemaking. These policies are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA officials may decide to follow the guidance provided in this document, or to act at variance with the guidance, based on analysis of specific-site circumstances. EPA also reserves the right to change the guidance at any time without public notice.

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Q3. What criteria should be used to determine areas of radioactive contamination or radioactivity releases?

During the site assessment phase, Section 7 of EPA's revised Hazard Ranking System (HRS) (see Appendix A to 40 Code of Federal Regulations [CFR] Part 300) outlines the methodology for evaluating radioactive releases and determining whether a radioactive release is a high priority for the CERCLA remedial program.

During risk assessments, guidance for the measurement and evaluation of radiological contaminants is provided in the *Soil Screening Guidance for Radionuclides* (Rad SSG) documents (U.S. EPA 2000a, 2000b). The Rad SSG also provides guidance on the determination of site-specific background levels for comparison to site measurements. The Soil Screening Levels (SSLs) are not cleanup standards, but may be used to inform further investigation at sites. The SSL risk assessment equations have been superseded by those in the PRGs calculator where applicable or relevant and appropriate requirements (ARARs) are not available or sufficiently protective; therefore, the PRG calculator should be used for determining SSL risk based concentrations rather than the Rad SSG documents.

Q14. To what extent should generic and site-specific factors and parameter values be used in exposure assessments?

A. For both radionuclide and chemical assessments in the Superfund remedial program, EPA recommends use of empirically-derived, site-specific factors and parameter values, where these values can be justified and documented. For generic assessments, EPA recommends use of the default parameter values provided in the PRG and DCC calculators (EPA 2002a, 2004a, 2007, 2009a, 2010a, and 2010b).

EPA

Radiation Risk Assessment at CERCLA Sites: Q&A (2014) continued

- Use PRG and DCC calculators for risk and dose assessments.
  - PRG/DCC consistent with how chemicals are assessed under CERCLA

Q16. What calculation methods or multimedia radionuclide transport and exposure models are recommended by EPA for Superfund risk assessments?

A. The PRG calculators (U.S. EPA 2002a, 2007, 2009a), which are used to develop risk-based PRGs for radionuclides, are recommended by EPA for Superfund remedial radiation risk assessments. These risk and dose assessment models are similar to EPA's methods for chemical risk assessment at CERCLA sites. Guidance on how to use each calculator, the default input parameters and their sources, is provided in the user guide for each calculator. In addition, a tutorial for using the PRG calculator is included in module 3 of the on-line training course *Radiation Risk Assessment: Update and Tools* (ITRC 2007), and a tutorial for the BPRG and SPRG calculators is provided in module 3 of the on-line training course *Decontamination and Decommissioning of Radiologically-Contaminated Facilities* (ITRC 2008b). The PRG calculator superseded the *Soil Screening Guidance for Radionuclides* (Rad SSG) calculator (U.S. EPA 2000e).

To avoid unnecessary inconsistency between radiological and chemical risk assessment at the same site, users should generally use the same model for chemical and radionuclide risk assessment. If there is a reason on a site-specific basis for using another model justification for doing so should be developed. The justification should include specific supporting data and information in the administrative record. The justification normally would include the model runs using both the recommended EPA PRG model and the alternative model. Users are cautioned that they should have a thorough understanding of both the PRG recommended model and any alternative model when evaluating whether a different approach is appropriate. When alternative models are used, the user should adjust the default input parameters to be as close as possible to the PRG inputs, which may be difficult since models tend to use different definitions for parameters. Numerous computerized mathematical models have been developed by EPA

Q36. Should dose recommendations from other federal agencies be used to assess risk or establish cleanup levels?

A. Generally, no. **Dose assessments generally should only be performed to assess risks or to establish cleanup levels at CERCLA remedial sites** to show compliance with an ARAR that requires a dose assessment (for example 40 CFR 61 Subparts H and I, and 10 CFR 61.41). Dose level recommendations from international and other non-EPA organizations are not enforceable and therefore cannot be ARARs. The selection of

EPA recommends using the DCC, BDCC, and SDCC calculators (U.S. EPA 2004a, **2010a, and 2010b) to develop dose assessments for ARAR compliance purposes at Superfund remedial sites.** As indicated on page 2 of the memorandum transmitting the DCC calculator (U.S. EPA 2004c), that guidance superseded the dose assessment equations in Chapter 10 of *RAGs* Part A (U.S. EPA 1989a).

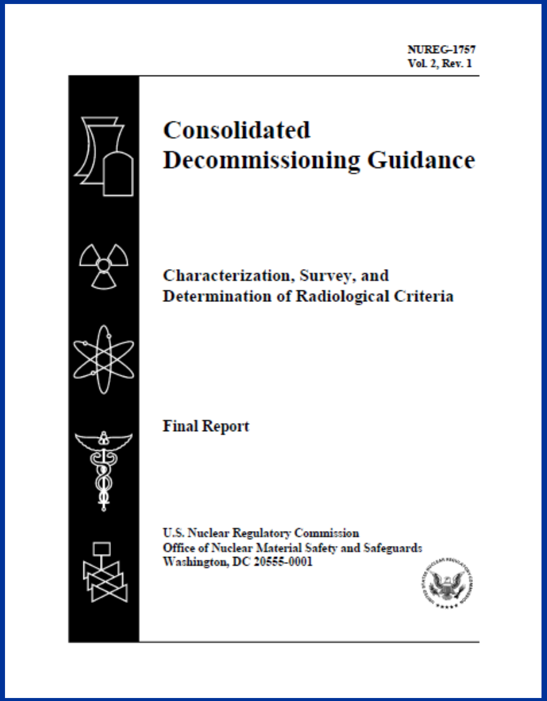
So Where is the Confusion???

- Probably some are more used to the NRC approach to modeling.
- Some users may think NRC approach to modeling is transferable over to CERCLA sites.
  - **IT IS NOT**
  - Next few slides quote some NRC policies

NRC Consolidated Decommissioning Guidance

Characterization, Survey, and Determination of Radiological Criteria

- NRC uses DandD code for screening dose assessments for soil and building surfaces.
- NRC does NOT use DandD for site-specific dose analysis.


NUREG-1757
Vol. 2, Rev. 1

Consolidated Decommissioning Guidance

Characterization, Survey, and Determination of Radiological Criteria

Final Report

U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Washington, DC 20555-0001

DandD code. The Decontamination and Decommissioning (DandD) software package, developed by NRC, that addresses compliance with the dose criteria of 10 CFR Part 20, Subpart E. Specifically, DandD embodies NRC's guidance on screening dose assessments to allow licensees to perform simple estimates of the annual dose from residual radioactivity in soils and on building surfaces.

Site-Specific Dose Analysis. Any dose analysis that is done other than by using the default screening tools.

NRC Consolidated Decommissioning Guidance continued

- ◆NRC accepts for screening, concentrations in tables for soil and buildings based on DandD, or a modelling run using DandD.

NRC staff should accept for a screening analyses the following currently available screening tools:

- A look-up table (Table H.1) for common beta- and gamma-emitting radionuclides for building-surface residual radioactivity (63 FR 64132, November 18, 1998).
- A look-up table (Table H.2) for common radionuclides for soil surface residual radioactivity (64 FR 68395, December 7, 1999).

A licensee may perform a screening analysis to demonstrate compliance with the radiological criteria for license termination specified in Part 20, Subpart E. The screening analysis described in Chapter 16 of this volume requires that the licensee either (a) refer to radionuclide-specific screening values listed in the *Federal Register* (63 FR 64132 and 64 FR 68395) or (b) use the latest DandD computer code. A licensee pursuing the screening option may find that implementation of the DandD code is necessary if radionuclides not included in the *Federal Register* listings should be considered.

Table H.1 Acceptable License Termination Screening Values of Common Radionuclides for Building-Surface Contamination

Radionuclide	Symbol	Acceptable Screening Levels[a] for Unrestricted Release (dpm/100 cm^2)[b]
Hydrogen-3 (Tritium)	^{3}H	120000000
Carbon-14	^{14}C	3700000
Sodium-22	^{22}Na	9500
Sulfur-35	^{35}S	13000000
Chlorine-36	^{36}Cl	500000
Manganese-54	^{54}Mn	32000
Iron-55	^{55}Fe	4500000
Cobalt-60	^{60}Co	7100
Nickel-63	^{63}Ni	1800000
Strontium-90	^{90}Sr	8700
Technetium-99	^{99}Tc	1300000
Iodine-129	^{129}I	35000
Cesium-137	^{137}Cs	28000
Iridium-192	^{192}Ir	74000

Notes:

a Screening levels are based on the assumption that the fraction of removable surface contamination is equal to 0.1. For cases when the fraction of removable contamination is undetermined or higher than 0.1, users may assume for screening purposes that 100 % of surface contamination is removable, and therefore the screening levels should be decreased by a factor of 10. Users may calculate site-specific levels using available data on the fraction of removable contamination and DandD Version 2.

b Units are disintegrations per minute (dpm) per 100 square centimeters (dpm/100 cm^2). One dpm is equivalent to 0.0167 becquerel (Bq). Therefore, to convert to units of Bq/m^2, multiply each value by 1.67. The screening values represent surface concentrations of individual radionuclides that would be deemed in compliance with the 0.25 mSv/y (25 mrem/y) unrestricted release dose limit in 10 CFR 20.1402. For radionuclides in a mixture, the "sum of fractions" rule applies (see Part 20, Appendix B, Note 4).

Table H.2 Screening Values[a] (pCi/g) of Common Radionuclides for Soil Surface Contamination Levels

Radionuclide	Symbol	Surface Soil Screening Values[b]
Hydrogen-3	^{3}H	110
Carbon-14	^{14}C	12
Sodium-22	^{22}Na	4.3
Sulfur-35	^{35}S	270
Chlorine-36	^{36}Cl	0.36
Calcium-45	^{45}Ca	57
Scandium-46	^{46}Sc	15
Manganese-54	^{54}Mn	15
Iron-55	^{55}Fe	10000
Cobalt-57	^{57}Co	150
Cobalt-60	^{60}Co	3.8
Nickel-59	^{59}Ni	5500
Nickel-63	^{63}Ni	2100
Strontium-90	^{90}Sr	1.7
Niobium-94	^{94}Nb	5.8
Technetium-99	^{99}Tc	19
Iodine-129	^{129}I	0.5
Cesium-134	^{134}Cs	5.7
Cesium-137	^{137}Cs	11
Europium-152	^{152}Eu	8.7
Europium-154	^{154}Eu	8
Iridium-192	^{192}Ir	41
Lead-210	^{210}Pb	0.9
Radium-226	^{226}Ra	0.7
Radium-226+C[c]	$^{226}Ra+C$	0.6
Actinium-227	^{227}Ac	0.5
Actinium-227+C	$^{227}Ac+C$	0.5
Thorium-228	^{228}Th	4.7

Table H.2 Screening Values[a] (pCi/g) of Common Radionuclides for Soil Screening Surface Contamination Levels (continued)

Radionuclide	Symbol	Surface Soil Screening Values[b]
Thorium-228+C[c]	$^{228}Th+C$	4.7
Thorium-230	^{230}Th	1.8
Thorium-230+C	$^{230}Th+C$	0.6
Thorium-232	^{232}Th	1.1
Thorium-232+C	$^{232}Th+C$	1.1
Protactinium-231	^{231}Pa	0.3
Protactinium-231+C	$^{231}Pa+C$	0.3
Uranium-234	^{234}U	13
Uranium-235	^{235}U	8
Uranium-235+C	$^{235}U+C$	0.29
Uranium-238	^{238}U	14
Uranium-238+C	$^{238}U+C$	0.5
Plutonium-238	^{238}Pu	2.5
Plutonium-239	^{239}Pu	2.3
Plutonium-241	^{241}Pu	72
Americium-241	^{241}Am	2.1
Curium-242	^{242}Cm	160
Curium-243	^{243}Cm	3.2

Notes:

a These values represent surficial surface soil concentrations of individual radionuclides that would be deemed in compliance with the 25 mrem/y (0.25 mSv/y) unrestricted release dose limit in 10 CFR 20.1402. For radionuclides in a mixture, the "sum of fractions" rule applies; see Section 2.7 of this volume.

b Screening values are in units of (pCi/g) equivalent to 25 mrem/y (0.25 mSv/y). To convert from pCi/g to units of becquerel per kilogram (Bq/kg), divide each value by 0.027. These values were derived using DandD screening methodology (NUREG/CR–5512, Volume 3 (NRC 1999)). They were derived based on selection of the 90th percentile of the output dose distribution *for each specific radionuclide* (or radionuclide with the specific decay chain). Behavioral parameters were set at the mean of the distribution of the assumed critical group. The metabolic parameters were set at "Reference Man" or at the mean of the distribution for an average human.

c "Plus Chain (+C)" indicates a value for a radionuclide with its decay progeny present in equilibrium. The values are concentrations of the parent radionuclide but account for contributions from the complete chain of progeny in equilibrium with the parent radionuclide (NUREG/CR–5512, Volumes 1, 2, and 3).

NRC Consolidated Decommissioning Guidance continued

- For site-specific analysis, RESRAD and RESRAD Build are recommended by NRC.

NRC staff developed RESRAD and RESRAD–BUILD probabilistic codes for site-specific analysis. Development of the probabilistic DandD and RESRAD/RESRAD–BUILD codes also

I.5.4 Use of Codes and Models Other than DandD and RESRAD

NRC staff should provide flexibility for possible use of other codes and models selected by licensees. However, less common codes, specifically those developed by users, may require more extensive NRC staff review and verifications. In this context, NRC staff may review the following pertinent aspects when using other less common codes:

The NRC approach is NOT relevant to CERCLA risk or dose assessment

- EPA, for CERCLA, uses the same models (e.g., PRG, RSL, DCC calculators) for chemical risk assessment and radiological risk and dose assessment.
  - » Both for generic screening and site-specific assessments
- NRC uses two different models for generic screening (D&D) and site-specific (RESRAD) for dose assessments.
- Both EPA and NRC allow for other models, but they must be reviewed and approved by staff.

What to Do?

- Use the CERCLA approach when conducting screening and risk assessments at CERCLA sites.

Conclusion for incorrect assertions 5 & 6

- Both incorrect assertions 5 and 6 seem to be based on people confusing Superfund with either:
  - » NRC's decommissioning program, or
  - » Other Federal government regulatory programs

Seventh Incorrect Assertion

EPA's Superfund cleanup standard is 12 or 15 mrem/yr [0.12 or 0.15 mSv/yr]

Response to the incorrect assertion that EPA's cleanup standard is 12 or 15 mrem/yr

- The misconception that the EPA's cleanup levels for radioactively contaminated sites began in the 1990's.
- In the 1997 guidance document "Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination"
  - EPA stated that cleanup levels for radionuclides not based on an ARAR should use the 10^{-4} to 10^{-6} cancer risk range.

1997 guidance - screenshots

ARARs are often the determining factor in establishing cleanup levels at CERCLA sites. However, where ARARs are not available or are not sufficiently protective, EPA generally sets site-specific remediation levels for: 1) carcinogens at a level that represents an excess upper bound lifetime cancer risk to an individual of between 10^{-4} to 10^{-6}; and for 2) non-carcinogens such that the cumulative risks from exposure will not result in adverse effects to human populations (including sensitive sub-populations) that may be exposed during a lifetime or part of a lifetime, incorporating an adequate margin of safety. (See 40 CFR 300.430(e)(2)(i)(A)(2).) Since all radionuclides are carcinogens, this guidance addresses carcinogenic risk. If non-carcinogenic risks are posed by specific radionuclides, those risks should be taken into account in establishing cleanup levels or suitable remedial actions. The site-specific level of cleanup is determined using the nine criteria specified in Section 300.430(e)(9)(iii) of the NCP.

OBJECTIVE

This guidance clarifies that cleanups of radionuclides are governed by the risk range for all carcinogens established in the NCP when ARARs are not available or are not sufficiently protective. This is to say, such cleanups should generally achieve risk levels in the 10^{-4} to 10^{-6} range. EPA has a consistent methodology for assessing cancer risks and determining PRGs at CERCLA sites no matter the type of contamination.[6]

[6] U.S. EPA, "Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A) Interim Final," EPA//540/1-89/002, December 1989. U.S. EPA, "Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals", EPA/540/R-92/003, December 1991.

Cancer risks for radionuclides should generally be estimated using the slope factor approach identified in this methodology. Slope factors were developed by EPA for more than 300 radionuclides in the *Health Effects Assessment Summary Tables* (HEAST).[7] Cleanup levels for radioactive contamination at CERCLA sites should be established as they would for any chemical that poses an unacceptable risk and the risks should be characterized in standard Agency risk language consistent with CERCLA guidance.

Cancer risk from both radiological and non-radiological contaminants should be summed to provide risk estimates for persons exposed to both types of carcinogenic contaminants. Although these risks initially may be tabulated separately, risk estimates contained in proposed and final site decision documents (e.g., proposed plans, Record of Decisions (RODs), Action Memos, ROD Amendments, Explanation of Significant Differences (ESDs)) should be summed to provide an estimate of the combined risk to individuals presented by **all** carcinogenic contaminants.

1997 guidance – screenshots, continued.

- There was one paragraph that meant users could also conduct a dose assessment **in addition** to a risk assessment
  - Even in the sentence referring to 15 mrem/yr, the footnote states the cleanup level must still achieve 10^{-4} to 10^{-6} risk range

If a dose assessment is conducted at the site[10] then 15 millirem per year (mrem/yr) effective dose equivalent (EDE) should generally be the maximum dose limit for humans. This level equates to approximately 3×10^{-4} increased lifetime risk and is consistent with levels generally considered protective in other governmental actions, particularly regulations and guidance developed by EPA in other radiation control programs.[11]

[10] Cleanup levels not based on ARARs should be expressed as risk, although levels may at the same time be expressed in millirem.

1999 Rad Risk Assessment Q&A clarifies policy

- The EPA 1999 guidance document “Radiation Risk Assessment At CERCLA Sites: Q & A”, provided guidance that:
  - » dose assessments should only be conducted under CERCLA where necessary to demonstrate ARAR compliance, and
  - » dose-based ARARs should be 15 millirems per year or less to be considered protective.

1999 transmittal memo and guidance - screenshots

Two issues addressed in this Risk Q & A should be noted here. First, the answer to question 32 in the Risk Q & A is intended to further clarify that 15 millirem per year is not a presumptive cleanup level under CERCLA, but rather site decision-makers should continue to use the risk range when ARARs are not used to set cleanup levels. There has been some confusion among stakeholders regarding this point because of language in the 1997 guidance. EPA is issuing further guidance today to site decision makers on this topic. This Risk Q&A clarifies that, in general, dose assessments should only be conducted under CERCLA where necessary to demonstrate ARAR compliance. Further, dose recommendations (e.g., guidance such as DOE Orders and NRC Regulatory Guides) should generally not be used as to-be-considered material (TBCs). Although in other statutes EPA has used dose as a surrogate for risk, the selection of cleanup levels for carcinogens for a CERCLA remedy is based on the risk range when ARARs are not available or are not sufficiently protective. Thus, in general, site decision-makers should not use dose-based guidance rather than the CERCLA risk range in developing cleanup levels. This is because for several reasons, using dose-based guidance would result in unnecessary inconsistency regarding how radiological and non-radiological (chemical) contaminants are addressed at CERCLA sites. These reasons include: (1) estimates of risk from a given dose estimate may vary by an order of magnitude or more for a particular radionuclide, and; (2) dose based guidance generally begins an analysis for determining a site-specific cleanup level at a minimally acceptable risk level rather than the 10^{-6} point of departure set out in the NCP.

1999 transmittal memo and guidance – screenshots, continued

Q32 . When should a dose assessment be performed?

OSWER Directive 9200.4-18 (U.S. EPA 1997a) specifies that cleanup levels for radioactive contamination at CERCLA sites should be established as they would for any chemical that poses an unacceptable risk and the risks should be characterized in standard Agency risk language consistent with CERCLA guidance. **Cleanup levels not based on an ARAR should be based on the carcinogenic risk range (generally 10^{-4} to 10^{-6}, with 10^{-6} as the point of departure and 1×10^{-6} used for PRGs) and expressed in terms of risk (# x $10^{-\#}$).** While the upper end of the risk range is not a discrete line at 1×10^{-4}, EPA generally uses 1×10^{-4} in making risk management decisions. A specific risk estimate around 10^{-4} may be considered acceptable if based on site-specific circumstances. For further discussion of how EPA uses the risk range, see OSWER Directive 9355.0-30, Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions (U.S. EPA 1991d). In general, dose assessment used as a method to assess risk is not recommended at CERCLA sites.

Please note that the references to 15 mrem/yr in OSWER Directive 9200.4-18 are intended as guidance for the

evaluation of potential ARARs and TBCs, and should not be used as a TBC for establishing 15 mrem/yr cleanup levels at CERCLA sites. **At CERCLA sites dose assessments should generally not be performed to assess risks or to establish cleanup levels** except to show compliance with an ARAR that requires a dose assessment (e.g., 40 CFR 61 Subparts H and I, and 10 CFR 61.41).

2014 guidance

- In 2014, EPA updated the guidance document "Radiation Risk Assessment At CERCLA Sites: Q & A." The 2014 version continued to provide guidance that dose assessments should only be conducted under CERCLA where necessary to demonstrate ARAR compliance

Q33. When should a dose assessment be performed?

A. Dose assessments should be conducted during CERCLA remedial responses only when considering compliance of clean up plans with dose-based ARARs. As discussed in OSWER Directive 9200.4-18 (U.S. EPA 1997a), cleanup levels for radioactive contamination at remedial sites should be established as they would for any chemical that poses an unacceptable risk and the risks should be characterized in standard Agency risk language consistent with CERCLA guidance for remedial sites. Thus, **cleanup levels not based on an ARAR should be based on the carcinogenic risk range (generally 10^{-4} to 10^{-6}, with 10^{-6} as the point of departure and 1×10^{-6} used for PRGs) and expressed in terms of risk (# x $10^{-\#}$).**

EPA

2014 guidance, continued

- The 2014 guidance made a revision that dose-based ARARs should now be 12 mrem/yr or less to be considered protective based on newer science in Federal Guidance 13.

Q35. Should the ARAR protectiveness criteria evaluation recommendation be changed from 15 mrem/yr to reflect the updates to radiation risk estimates contained in Federal Guidance Report 13?

A. **Yes, ARAR protectiveness criteria evaluation recommendation of 15 mrem/yr should be changed to 12 mrem/yr to reflect the current federal government position on the risks posed by radiation, which is contained in EPA's Federal Guidance Report 13 (U.S. EPA 1999c).** More recent scientific information reflected in EPA's Federal Guidance Report 13 risk estimates show that 12 mrem/yr is now considered to correspond approximately to 3×10^{-4} excess lifetime cancer risk. This *updated approach is based on FGR 13's assumption of a risk of cancer incidence* of 8.46×10^{-4} per rem of exposure (while still using the EPA CERCLA standard period of exposure of 30 years for residential land use, which also was the basis of the 15 mrem/yr determination in OSWER Directive 9200.4-18). Therefore, the ARAR evaluation guidance first discussed in OSWER Directive 9200.4-18 is being updated to 12 mrem/yr so that ARARs that are greater than 12 mrem/yr effective dose equivalent (EDE) are generally not considered sufficiently protective for developing cleanup levels under CERCLA at remedial sites. As before, this ARAR evaluation tool should not be used as a to be considered (TBC) as a basis for establishing 12 mrem/yr cleanup levels at CERCLA remedial sites.

Please note that the prior references to 15 mrem/yr in OSWER Directive 9200.4-18 were intended as guidance for the evaluation of potential ARARs and TBCs factors and **should not be used as a TBC for establishing 15 mrem/yr cleanup levels at CERCLA sites**. Consistent with that guidance, using 15 mrem/yr as an ARAR evaluation tool originally was based on three factors:

1. The CERCLA risk range for remedial sites. In 1997, 15 mrem/yr was estimated to correspond to approximately 3×10^{-4} under the then EPA practice of using the dose to risk estimate conversions assumption of a risk of cancer incidence of 7.6×10^{-4} per rem of exposure, found in ICRP 1991 and NAS 1990. This dose to risk estimate has been superseded by the assumption of a risk of cancer incidence of 8.46×10^{-4} per rem of exposure in FGR 13 (U.S. EPA 1999c).
2. Prior EPA radiation rulemakings, and
3. Prior EPA CERCLA site-specific decisions.

2014 guidance, continued

- The 2014 guidance made the following revisions:
  - » risk-based cleanup levels and risk assessments should now be developed using the PRG calculators, and
  - » a newly developed consultation process should now be followed if use of an alternative model was justified.

2014 guidance, continued screenshots

Q16. What calculation methods or multimedia radionuclide transport and exposure models are recommended by EPA for Superfund risk assessments?

A. The PRG calculators (U.S. EPA 2002a, 2007, 2009a), which are used to develop risk-based PRGs for radionuclides, are recommended by EPA for Superfund remedial radiation risk assessments. These risk and dose assessment models are similar to EPA's methods for chemical risk assessment at CERCLA sites. Guidance on how to use each calculator, the default input parameters and their sources, is provided in the user guide for each calculator. In addition, a tutorial for using the PRG calculator is included in module 3 of the on-line training course *Radiation Risk Assessment: Update and Tools* (ITRC 2007), and a tutorial for the BPRG and SPRG calculators is provided in module 3 of the on-line training course *Decontamination and Decommissioning of Radiologically-Contaminated Facilities* (ITRC 2008b). The PRG calculator superseded the *Soil Screening Guidance for Radionuclides* (Rad SSG) calculator (U.S. EPA 2000e).

To avoid unnecessary inconsistency between radiological and chemical risk assessment at the same site, users should generally use the same model for chemical and radionuclide risk assessment. If there is a reason on a site-specific basis for using another model justification for doing so should be developed. The justification should include specific supporting data and information in the administrative record. The justification normally would include the model runs using both the recommended EPA PRG model and the alternative model. Users are cautioned that they should have a thorough understanding of both the PRG recommended model and any alternative model when evaluating whether a different approach is appropriate. When alternative models are used, the user should adjust the default input parameters to be as close as possible to the PRG inputs, which may be difficult since models tend to use different definitions for parameters. Numerous computerized mathematical models have been developed by EPA

Q10. For CERCLA risk assessments at remedial sites, is it appropriate to use guidance or approaches developed by other Federal, State or Tribal Agencies or by International or National Organizations?

A. EPA has made the policy decision that risks from radionuclide exposures at remedial sites should be estimated in the same manner as chemical contaminants, which is consistent with EPA's remedial program implementing guidance (e.g., EPA 1997g, 1999d, 2000f). Consequently, approaches that do not follow the remedial program's policies and guidance should not be used at CERCLA remedial sites. Should regional staff have questions, they should consult with the Superfund remedial program's National Radiation Expert (Stuart Walker of OSRTI at the time this fact sheet was issued, at (703) 603-8748 or walker.stuart@epa.gov), before using guidance from other organizations that is not already incorporated into this and other EPA Superfund remedial program guidance. The

Conclusion for incorrect assertion 7

- Incorrect assertion 7 seems to be based on people continuing to misread a 1997 guidance document.
- To understand the EPA CERCLA approach users should read the 2014 guidance and the clarification in the 1999 transmittal memo.

For More Information

For further information or questions:

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Questions
Answers