

# Clarifying Misconceptions about the US EPA Superfund Remediation Program

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by

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## ABSTRACT

The U.S. Environmental Protection Agency (EPA) Office of Superfund Remediation and Technology Innovation (OSRTI) has primary responsibility for implementing the remedial long-term (non-emergency) portion of a key U.S. law regulating cleanup: the Comprehensive Environmental Response, Compensation and Liability Act, CERCLA, nicknamed “Superfund.” The Superfund program generally addresses radioactive contamination in a consistent manner as it addresses chemical contamination, except where there are technical differences between radionuclides and other chemicals. For example, when selecting cleanup levels for radioactively contaminated sites, they are generally expressed in terms of risk levels (e.g.,  $10^{-4}$ ), rather than millirem or millisieverts, as a unit of measure. Although EPA and other US agencies have issued millirem based regulations under other statutory authorities, under CERCLA EPA promulgated a risk range of  $10^{-4}$  to  $10^{-6}$  as a standard of protectiveness for all carcinogens including radionuclides. CERCLA guidance recommends the use of slope factors when estimating cancer risk from radioactive contaminants, rather than converting from millirem. Current slope factors are based on risk coefficients in Federal Guidance Report 13 using ICRP 107 data. The Superfund remedial program uses  $10^{-6}$  as a point of departure and establishes Preliminary Remediation Goals (PRGs) at  $1 \times 10^{-6}$ . PRGs, not based on other environmental standards known as Applicable or Relevant and Appropriate Requirements (ARARs), are risk-based concentrations, derived from standardized equations combining exposure information assumptions with EPA toxicity data. The policy rationale and technical underpinnings for this risk management approach, is often misunderstood by radiation professionals. This presentation will help clarify some of these misunderstandings by focusing on misstatements about the Superfund approach that the author has encountered from radiation professionals. Often, they are citing the wrong EPA documents or portions of documents incorrectly, or not reading sections of the correct Superfund guidance.

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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

## INTRODUCTION

To help meet the Superfund program’s mandate to protect human health and the environment from current and potential threats posed by uncontrolled hazardous substance (both radiological and non-

radiological pollutant or contaminant) releases, the Superfund program has developed a human health evaluation process as part of its remedial response program. The process of gathering and assessing human health risk information is adapted from well-established chemical risk assessment principles and procedures. The Superfund Baseline Risk Assessment provides an estimate of the likelihood and magnitude of health problems occurring if no cleanup action is taken at a site.

Cleanup levels for radioactive contamination at CERCLA sites are generally expressed in terms of risk levels (e.g.,  $10^{-4}$ ), rather than millirem or millisieverts, as a unit of measure. Although EPA and other US agencies have issued millirem based regulations under other statutory authorities, under CERCLA EPA promulgated a risk range of  $10^{-4}$  to  $10^{-6}$  as a standard of protectiveness for all carcinogens including radionuclides. CERCLA guidance recommends the use of slope factors when estimating cancer risk from radioactive contaminants, rather than converting from millirem. Current slope factors are based on risk coefficients in Federal Guidance Report 13 [1].

The  $10^{-4}$  to  $10^{-6}$  cancer risk range can be interpreted to mean that a highly exposed individual may have a one in 10,000 to one in 1,000,000 increased chance of developing cancer because of exposure to a site-related carcinogen. Once a decision has been made to take an action, the Superfund remedial program prefers cleanups achieving the more protective end of the range (i.e.,  $10^{-6}$ ). The Superfund remedial program uses  $10^{-6}$  as a point of departure and establishes Preliminary Remediation Goals (PRGs) at  $1 \times 10^{-6}$ .

Preliminary Remediation Goals (PRGs) are used for site "screening" and as initial cleanup goals if applicable. PRGs are not de facto cleanup standards and should not be applied as such. The PRG's role in site "screening" is to help identify areas, contaminants, and conditions that do not require further federal attention at a particular site.

PRGs not based on other environmental standards known as Applicable or Relevant and Appropriate Requirements (ARARs) are risk-based concentrations, derived from standardized equations combining exposure information assumptions with EPA toxicity data. PRGs based on cancer risk are established at  $1 \times 10^{-6}$ . PRGs are identified early in the CERCLA process. PRGs are modified as needed based on site-specific information.

Since 1997 the EPA Superfund program has had a continuing effort to provide updated guidance for addressing radioactively contaminated sites in a manner consistent with guidance for addressing chemically contaminated sites while accounting for radionuclides and chemicals' technical differences. The effort's intent is to facilitate NCP-consistent decisions at radioactively contaminated sites and to incorporate new information based on Superfund programmatic improvements. With only approximately 66 radioactively contaminated NPL sites out of 1,769 total sites, the focus of the Superfund remedial program has been on chemicals. Each of the radioactively contaminated NPL sites also has significant chemical contamination. To the policy issue of how best to address radiation contamination in a program with a chemical focus, EPA decided to address radiation in a consistent manner with chemicals, except to account for the technical differences posed by radiation. Radiation easily fits within Superfund framework of addressing carcinogens and the transport of inorganics. Addressing radiation in a similar manner also helps improve public confidence by taking mystery out of radiation, a contaminant which the public often fears more than chemicals. Also, all radioactively contaminated NPL sites also have chemical contamination.

Unfortunately, in my role as the lead EPA staffer on Superfund radiation policies, I often encounter incorrect assertions about EPA's approach for addressing radioactively contaminated sites. Similar incorrect assertions often appear in journal articles, are told to EPA personnel (from the regional staff

level to senior management, including political appointees) or said in public meetings.

Below I will summarize some of the most common misconceptions that I will address further in subsequent sections of this paper.

1. EPA's approach of addressing radiation and chemicals in a similar approach has not received any outside high-level review, either:
  - a. Risk management/policy review
  - b. 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.
5. EPA is using population risk modelling incorrectly.
6. EPA's preferred models for conducting risk or dose assessments can only be used for screening, not risk assessments.
7. EPA's cleanup level is 12 or 15 millirem per year (mrem/yr) [0.12 or 0.15 mSv/yr].

## DISCUSSION

### First Misconception. EPA's Approach as not Received Outside High Level Review

The first common misconception to address is that EPA's approach of addressing radiation and chemicals in a similar approach has not received any outside high-level review: neither a risk management/policy review, nor a scientific review. This is incorrect on both counts.

#### *Blue Ribbon Commission*

In 1997 the Presidential/Congressional Commission on Risk Assessment and Risk Management developed a report to Congress on the appropriate uses of risk assessment and risk management in Federal regulatory programs. In "The Presidential/Congressional Commission on Risk Assessment and Risk Management Final Report Volume 1 1997" [2], the commission described their mandate on page i in the Executive Summary as "in the 1990 Clean Air Act Amendments, Congress mandated that a Commission on Risk Assessment and Risk Management be formed to: '...make a full investigation of the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws to prevent cancer and other chronic human health effects which may result from exposure to hazardous substances.'

In the Final Report Volume 2, "Risk Assessment and Risk Management In Regulatory Decision-Making" [3] the commission recommended that:

1. Radiation and chemicals should be addressed consistently, particularly when co-located, stating on page 82 "**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."
2. Superfund should continue to use the  $10^{-4}$  to  $10^{-6}$  cancer risk range and reasonably anticipated land use, stating on page 121 that for Superfund "**Recommendation** Risk assessments and remedy selection should be based on reasonably anticipated current and future uses of a site. As EPA's Land Use Directive of 1995 states, reasonable assumptions

about future land uses should be developed early in a process of seeking consensus with local officials and community representatives.”

*National Academy of Science*

In 1999 the National Academy of Science (NAS) issued a report “Evaluation of Guidelines for Exposures to Technologically Enhanced Naturally Occurring.” [4] NAS compared EPA’s approach for risk assessment (slope factors) and NRC’s approach (use EDE then convert to risk) and found NAS found EPA’s approach methodologically more rigorous for assessing risks from chronic exposure to radionuclides, stating on page 222 that:

“...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. ... Lifetime risk is estimated by multiplying the annual effective dose equivalent from external and internal exposure by the assumed exposure time (for example, 70 y) and the nominal risk of fatal cancers caused by uniform whole body irradiation of  $5 \times 10^{-2}$  per sievert... 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 further notes on page 224 that “aspects of EPA's approach to risk assessment for radionuclides described above have been used in several regulatory activities, including development of radionuclide-specific slope factors for use in risk assessments at contaminated sites subject to remediation under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).”

On page 225 NAS further states that:

“EPA's approach should provide more realistic estimates of risk than the approach used by the Nuclear Regulatory Commission. All the factors described in the previous section—the use of organ-specific risks for many organs instead of risks based on the effective dose equivalent and a nominal risk from uniform whole-body irradiation, the use of updated biokinetic models in estimating dose from ingrowth of decay products in the body, the use of organ specific RBEs for alpha particles, and the use of age-specific dose rates from internal exposure in conjunction with age-specific cancer risks—should result in more realistic estimates of risks associated with chronic lifetime exposure.”

NAS goes on to compare EPA and NRC risk management approaches and determined differences were a matter of policy and not science, and should reflect societal values by noting on pages 233-234 that:

“...this committee finds that the differences between EPA and other guidances for TENORM do not have a scientific and technical basis but, rather, result essentially from differences in policies for risk management. ...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.”

Although the focus of this report was on TENORM, NAS did state on page 221 that:

“...in general, there should be no difference between NORM and any other radioactive materials with regard to suitable approaches to estimating doses and risks related to external or internal exposure.”

#### *EPA Science Advisory Board*

In 1992 the EPA Science Advisory Board sent a letter to the EPA Administrator “Commentary on Harmonizing Chemical and Radiation Risk-Reduction Strategies.” [5] SAB viewed the harmonization of radionuclides to the chemical approach as scientifically valid, stating on page 11 that one set of:

“...alternative approaches would strive for clear consistency between the radiation and chemical risk reduction strategies”, including to “regulate radiation risks exactly as chemical risks are now regulated. Use 10<sup>-4</sup> as a standard criterion for remediation or regulation.”

NAS noted on page 12 after describing several alternatives, that:

“...clearly, all 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.”

In the letter the 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<sup>-4</sup> cancer risk), by stating on page 9 that:

“a second area of discordance grew out of the recognition of waste problems involving radioactive materials that were under the purview of EPA or state environmental agencies rather than the Nuclear Regulatory Commission or the nuclear/radiation safety agencies in agreement states. The most striking of these are the radioactive or mixed waste problems at sites that have been placed on the National Priority List for attention by the Superfund Program. ... 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<sup>-4</sup> (or lower in some proposals for radiation sites).”

#### *Interagency Steering Committee*

The Interagency Steering Committee on Radiation Standards (ISCORS), has federal agencies as members, including includes EPA, NRC, DOE, and DOD. In 2002 ISCORS issued entitled “A Method for Estimating Radiation Risk from Total Effective Dose Equivalent (TEDE).” [6] ISCORS noted that the simple method of converting dose to risk is insufficient for a complex risk assessment

such as those for CERCLA sites. ISCORS recommended that slope factors should be used when a complex risk assessment is needed for assessing radionuclides, such as at a CERCLA sites. The report stated on page 1 that:

“...for external sources of low linear energy transfer (LET) radiation that provide nearly uniform irradiation of the body, the risk of cancer incidence (morbidity) and mortality as a function of external dose can be closely approximated using the conversion factors of  $8 \times 10^{-2}$  risk per sievert and  $6 \times 10^{-2}$  risk per sievert respectively. The documentation for these conversion factors can be found in ‘Estimating Radiogenic Cancer Risks’ and its ‘Addendum: Uncertainty Analysis.’ These conversion factors can also provide a generally high-sided, but less accurate, estimation of risk from internal dose. A discussion of the sources and limits of this conservatism is presented in the discussion below. Using these factors to convert internal effective dose 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) 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. For radiation risk assessments required by EPA’s Superfund Program, the risk coefficients in EPA’s Health Effects Assessment Summary Tables (HEAST) should be used.”

### **Second Misconception. EPA’s Superfund Radiation Risk Assessment Models have not been Peer Reviewed**

EPA has developed an online model known as the PRG for radionuclides (Rad PRG) electronic calculator. This electronic calculator presents risk-based standardized exposure parameters and equations that should be used for calculating radionuclide PRGs for residential, commercial/industrial, and agricultural land use exposures, tap water and fish ingestion exposures. The calculator also presents soil PRGs to protect groundwater which are determined by calculating the concentration of radioactively contaminated soil leaching from soil to groundwater that will meet MCLs or risk-based concentrations. The Rad PRG calculator may be found at the EPA website (<http://epa-prgs.ornl.gov/radionuclides/>).

The EPA Superfund remedial program has two risk assessment tools that are particularly relevant to decommissioning activities conducted under CERCLA authority. The Preliminary Remediation Goals for Radionuclides in Buildings (BPRG) electronic calculator was developed to help standardize the evaluation and cleanup of radiologically contaminated buildings at which risk is being assessed for occupancy. BPRGs are radionuclide concentrations in dust, air and building materials that correspond to a specified level of human cancer risk. The BPRG calculator may be found at the EPA website (<http://epa-bprg.ornl.gov/>).

The Preliminary Remediation Goals for Radionuclides in Outside Surface (SPRG) calculator addresses hard outside surfaces such as building slabs, outside building walls, sidewalks and roads. SPRGs are radionuclide concentrations in dust and hard outside surface materials. The BPRG and SPRG calculators include both residential and industrial/commercial exposure scenarios. The SPRG calculator may be found at the EPA website (<http://epa-sprg.ornl.gov/>).

The Radon Vapor Intrusion Screening Level (RVISL) calculator addresses indoor radon. The RVISL calculates risk based PRGs, as well as dose-based concentrations and Working Levels. The RVISL calculator may be found at the EPA website (<https://epa-visl.ornl.gov/radionuclides/index.html>).

One common misconception that I encounter is that none of these models have been peer reviewed. Actually, each of the 3 Superfund Radiation PRG calculators and the RVISL calculator models for risk assessment have undergone external peer review based on EPA document “Guidance on the Development, Evaluation, and Application of Environmental Models.” [7] External peer review provides the main mechanism for independent evaluation and review of environmental models used by the Agency. 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.)

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 for one of the PRG or RVISL calculator models, 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 Oak Ridge National Laboratory (ORNL) support, has developed responses to the peer review comments.

EPA has also had more focused external "non-independent" external peer reviews on early drafts of these calculators. EPA requested and received review by the Army Corps of Engineers Center for Excellence under an interagency agreement. To summarize for each of the 4 calculators:

1. the PRG calculator has undergone 2 independent peer reviews and 4 non-independent peer reviews which may be found at [https://epa-prgs.ornl.gov/radionuclides/prg\\_peer\\_review.html](https://epa-prgs.ornl.gov/radionuclides/prg_peer_review.html),
2. the BPRG calculator has 1 independent peer review and 1 non-independent peer review which may be found at [https://epa-bprg.ornl.gov/bprg\\_peer\\_review.html](https://epa-bprg.ornl.gov/bprg_peer_review.html),
3. the SPRG calculator has 1 independent peer review and 2 non-independent peer reviews, which may be found at [https://epa-sprg.ornl.gov/sprg\\_peer\\_review.html](https://epa-sprg.ornl.gov/sprg_peer_review.html),
4. and the RVISL calculator has 1 independent peer review and 2 non-independent peer reviews, which may be found at [https://epa-visl.ornl.gov/radionuclides/peer\\_review.html](https://epa-visl.ornl.gov/radionuclides/peer_review.html).

External reviews of each PRG calculator are provided on “HOME” page, in “Welcome” section, third paragraph, as illustrated for the PRG calculator in Figure 1 below.

## PRG Home

**PRG Calculation**

**PRGs for Radionuclides**

- [Home Page](#)
- [User's Guide](#)
- [What's New](#)
- [Frequent Questions](#)
- [Equations](#)
- [PRG Calculator](#)
- [Generic Tables](#)

**Resident**

<b>Soil</b>	<b>Tap Water</b>
• ingestion	• ingestion
• inhalation	• inhalation
• external	• immersion
• consumption of produce	• consumption of produce
<b>Fish</b>	<b>Air</b>
• consumption	• inhalation
	• submersion
<b>Soil Screening Levels</b> <small>(for protection of greenhouse)</small>	

**Construction Worker**

<b>Soil</b>
• ingestion
• inhalation
• external
<b>Air</b>
• inhalation
• submersion

**Outdoor Worker**

<b>Soil</b>
• ingestion
• inhalation
• external
<b>Air</b>
• inhalation
• submersion

**Indoor Worker**

<b>Soil</b>
• ingestion
• inhalation
• external
<b>Air</b>
• inhalation
• submersion

**Recreator**

<b>Soil/Sediment</b>	<b>Soil</b>	<b>Surface Water</b>
• ingestion	• ingestion	• ingestion
• inhalation	• inhalation	• immersion
• external	• external	• consumption of produce
<b>Air</b>	<b>Air</b>	<b>Biota</b>
• inhalation	• inhalation	• poultry
• submersion	• submersion	• eggs
		• beef
		• milk
		• swine
		• fish
		• goat
		• goat milk
		• sheep
		• sheep milk

**Farmer**

<b>Soil</b>	<b>Tap Water</b>
• ingestion	• ingestion
• inhalation	• inhalation
• external	• immersion
• consumption of produce	• consumption of produce
<b>Air</b>	<b>Biota</b>
• inhalation	• poultry
• submersion	• eggs
	• beef
	• milk
	• swine
	• fish
	• goat
	• goat milk
	• sheep
	• sheep milk

**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. 148: Approaches to Risk Management in Remediation of Radioactively Contaminated Sites](#). This report examines EPA Superfund and NRC Decommissioning programs approach to radionuclide 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](#).

Fig. 1. Screenshot depicting location of link to peer reviews PRG calculator Home webpage.

Each of the 4 calculators has undergone internal verification multiple times. Internal verification provides the main mechanism for non-independent evaluation and review of environmental models implemented by EPA. It should include an examination of the numerical technique in the computer code for consistency with the conceptual model and governing equations. EPA guidance [7] makes a distinction between multiple code verification by code developers and a potential independent testing of code. The PRG, BPRG, and RVISL have all had independent external verifications conducted.

In addition to the external and internal verification reports, two of the calculators are 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. This automatic verification procedure began in 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 the



default verified runs are flagged for attention. Since August 2023, an automated link checking routine has been programmed to run nightly and flag any broken links. Additionally, an independent manual link checking is performed on a quarterly basis to ensure comprehensive verification. Below in Figure 2 is a table summarizing the level of review and automatic checking of each of the risk calculators.

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

Fig. 2. Table Summarizing Peer and Verification Reviews and Automatic Checking of the Four Risk Assessment calculators

### Third Misconception. EPA’s Superfund Radiation Risk and Dose Assessment Models do not Use Sound Science

A third common misconception is that the EPA Superfund program is not using sound science while developing its risk and dose assessment models. EPA has an interagency agreement with the Department of Energy's Oak Ridge National Laboratory (ORNL) to develop the Superfund preliminary remediation goals (PRGs) and dose compliance concentration (DCC) calculators for CERCLA assessments, as well as risk and dose assessment tools, including developing geometrically challenging exposure factors. The Center for Radiation Protection Knowledge, which is part of ORNL's Environmental Sciences Division, manages this work. 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. Keith Eckerman, recipient of the most recent (12th) Swedish Royal Academy Gold Medal, led this program during the development of each PRG and DCC calculator. Since its inception, the ORNL Dosimetry Research Program has provided the national and international scientific communities with models and data required to estimate doses and risks from exposure to radionuclides and establish exposure guidelines for radionuclides.

Below are some of the ORNL technical manuals specifically developed for the Superfund calculators:

1. “Area Correction Factors for Contaminated Soil for Use in Risk and Dose Assessment Model” Report and Appendix. ORNL/TM-2013/00  
[https://epa-prgs.ornl.gov/radionuclides/ACF\\_FINAL.pdf](https://epa-prgs.ornl.gov/radionuclides/ACF_FINAL.pdf)  
[https://epa-prgs.ornl.gov/radionuclides/ACF\\_FINAL\\_APPENDIX.pdf](https://epa-prgs.ornl.gov/radionuclides/ACF_FINAL_APPENDIX.pdf)
2. “Gamma Shielding Factors for Soil Covered Contamination for Use in Risk and Dose Assessment Models” Report and Appendix ORNL/TM-2013/00  
[https://epa-prgs.ornl.gov/radionuclides/GSF\\_FINAL.pdf](https://epa-prgs.ornl.gov/radionuclides/GSF_FINAL.pdf)  
[https://epa-prgs.ornl.gov/radionuclides/GSF\\_FINAL\\_APPENDIX.pdf](https://epa-prgs.ornl.gov/radionuclides/GSF_FINAL_APPENDIX.pdf)

3. “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: 2021 Revision” ORNL/TM-2016/328-R1  
[https://epa-prgs.ornl.gov/radionuclides/2021\\_Biota\\_TM\\_update\\_DRAFT\\_for\\_RADPRG\\_ug.pdf](https://epa-prgs.ornl.gov/radionuclides/2021_Biota_TM_update_DRAFT_for_RADPRG_ug.pdf)
4. “Bateman Equation Adaptation for Solving and Integrating Peak Activity into EPA ELCR and Dose Models” ORNL/TM-2020/1780  
<https://epa-prgs.ornl.gov/radionuclides/FINALPEAKTM.pdf>
5. “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” ORNL/TM-2019/1269 R1  
[https://epa-visl.ornl.gov/radionuclides/documents/RVISL\\_ORNLTM\\_R1.pdf](https://epa-visl.ornl.gov/radionuclides/documents/RVISL_ORNLTM_R1.pdf)

#### **Fourth Misconception. EPA’s Risk and Dose Assessment Models are Only for Screening**

The fourth common misconception to address is that EPA’s recommended models for risk and dose assessment are only suitable for screening purposes.

##### *EPA Approach*

In EPA’s Superfund guidance, “screening” refers to the process of identifying and defining areas, contaminants (chemicals or radionuclides), and conditions, at a particular site that do not require further Federal attention. Generally, at sites where contaminant concentrations fall below SLs, no further action or study is warranted under CERCLA. See page 1 of the relevant guidance documents for screening chemical and radiological soil contamination at Superfund sites, the “Soil Screening Guidance: User's Guide” [8] and “Soil Screening Guidance for Radionuclides: User's Guide.” [9] soil screening levels (SSLs) can be used as PRGs provided appropriate conditions are met (i.e., conditions found at a specific site are similar to conditions assumed in developing the SSLs). 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” [10] discusses the modification of PRGs to generate cleanup levels, stating that PRGs 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. These PRGs 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 PRGs.

These guidance documents built upon language in the regulations governing Superfund cleanups in 40 CFR Section 300.430(e)(2)(i). The regulatory language discusses how initially, PRGs are developed based on readily available information such as ARARs or other reliable information. PRGs should be modified, as necessary, as more information becomes available in the RI/FS. Final remediation goals will be determined when the remedy is selected.

Figure 3 illustrates the spectrum of soil contamination encountered at Superfund sites and the conceptual range of risk management responses. At one end are levels of contamination that clearly warrant a response action; at the other end are levels that warrant no further study under CERCLA. Screening levels identify the lower bound of the spectrum—levels below which EPA believes no further study is warranted under CERCLA, provided conditions associated with the SSLs are met. Appropriate cleanup goals for a

particular site may fall anywhere within this range depending on site-specific conditions.

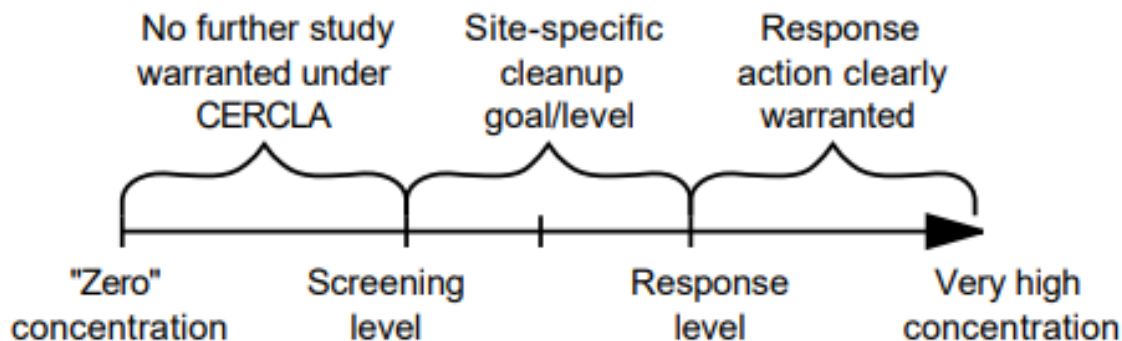


Fig 3. Conceptual Risk Management Spectrum for Contaminated Soil

Both the “Soil Screening Guidance: Technical Background Document” [11] and the “Soil Screening Guidance for Radionuclides: Technical Background Document” [12], include the evaluation of models that may be used for more detailed assessments. Both TBDs present information on the selection and use of more complex fate and transport models for calculating SSLs. The 1996 chemical TBD evaluates 9 soil to groundwater models, while the 2000 radiological TBD evaluates 5 soil to ground water models. The 1996 TBD also identifies several finite source volatilization models with potential applicability to SSL development.

In 2014, EPA further reiterated in the guidance document “Radiation Risk Assessment At CERCLA Sites: Q & A” [13] that the EPA’s 3 PRG calculators (PRG, BPRG, and SPRG), which are used to develop risk-based PRGs for radionuclides, are recommended by EPA for calculating risk in Superfund radiation risk assessment documents. EPA also recommended using the EPA’s 3 DCC calculators (DCC, BDCC, and SDCC) calculators to develop dose assessments for ARAR compliance purposes at Superfund sites. These risk and dose assessment models are similar to EPA’s methods for chemical risk assessment at CERCLA sites.

The Q & A guidance further recommends that 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 for some portion of the risk or dose assessment, then a 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/DCC model and the alternative model. Users are cautioned that they should have a thorough understanding of both the PRG/DCC 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/DCC inputs, which may be difficult since models tend to use different definitions for parameters. Any review of potential alternative models should include consultation with the Superfund remedial program’s National Radiation Expert (Stuart Walker of OSRTI).

It should be clear from the EPA guidance documents that the EPA PRG and DCC are recommended by EPA both for early screening and preliminary remediation goals, as well as risk calculations for risk assessment documents. But it appears some stakeholders are still confused and think the NRC’s approach

for dose assessment modeling is applicable at CERCLA sites, which it is not.

### *NRC Approach*

In the NRC document “Consolidated Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria”, [14] the Decontamination and Decommissioning (DandD) software package 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. A screening analysis by a licensee requires using either values from a look up table based on modeling runs from DandD, or a modelling run using the latest version of DandD. However, a site-specific dose analysis is considered to be any dose analysis that is done using other than the default screening tools. The guidance states that NRC staff had RESRAD and RESRAD-BUILD probabilistic models developed for such site-specific analyses. The guidance discusses the use by licensees of models other than DandD and RESRAD, but states these would likely require further review and verification by NRC staff.

### *Comparison of EPA and NRC Approach*

EPA for CERCLA uses the consistent models (e.g., PRG, RSL, DCC calculators) for chemical risk assessment and radiological risk and dose assessment. These models are used both for generic screening and site-specific assessments. Both generic and site-specific assessments are done using deterministic modeling. However, NRC uses two different models for generic screening (D&D) and site-specific (RESRAD) for dose assessments. NRC is also using deterministic modeling for screening and probabilistic modeling for site-specific assessments. Both EPA and NRC allow for other models other than their preferred models, but these alternative models are to be reviewed and approved by staff before use.

### **Fifth Misconception. EPA’s Risk Models are Much More Stringent than Other Models.**

The fifth misconception is 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 that are embedded in the defaults of each model. For example, the default target risk in PRG calculators is  $1 \times 10^{-6}$ , not 25 mrem/yr/0.25 msv/yr (approximately  $5 \times 10^{-4}$ ) or 100 mrem/yr/1msv/yr (approximately  $2 \times 10^{-3}$ ). The defaults input parameters in PRG tools are intended for consistency with chemical models for CERCLA, not radiation models that were developed for showing compliance with other laws in the US or for compliance with laws in other countries. The receptor that is being protected in the PRG calculator is a highly exposed individual (Reasonable Maximum Exposure, or RME Scenario) not average individual (e.g., average member of the critical group). The RME scenario as described in RAGs is a combination of high (95<sup>th</sup> or 90<sup>th</sup> percentile exposure parameters and central tendency 50<sup>th</sup> exposure parameters). To compare the results of models, one must ensure that the same conceptual site model is being addressed.

For example, in recent years there have been several occurrences (e.g., at HPS annual meeting, HPS letter to the editor, ANS webinar etc.) where someone made the argument that the United Kingdom cleanup of Po-210 after the Litvinenko poisoning incident was 19,000, 28,329, or 900,00 times higher than allowed by EPA’s PRG calculator. There tend to be several issues with this comparison. The person making the allegation often will correctly cite part of the UK cleanup level for Po-210 of 10 Bq/cm<sup>2</sup> to equate to 1 mSv (100 mrem). This was for fixed contamination and assumed 2% of the material would flake off from damage. However, they do not include the UK cleanup level for Po-210 of removable contamination, which was non-detect or 0 Bq/cm<sup>2</sup>. This was described in the report “Framework strategy for dealing with

radioactive contamination arising from the circumstances surrounding the death of Alexander Litvinenko” [15] issued by the City of Westminster. The report states on pages 20-21:

“HPA reference level for  $^{210}\text{Po}$ . ... ‘Mobile’ is here used to mean contamination that is not fixed (eg by chemical bonding) to the underlying surface. ... The main current hazard is from mobile  $^{210}\text{Po}$ . 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  $^{210}\text{Po}$  is removed. AIII.4 Whilst fixed  $^{210}\text{Po}$  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  $10 \text{ Bq cm}^{-2}$  to be used as a reference level for measured levels of fixed surface contamination of  $^{210}\text{Po}$ . 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  $1 \text{ mSv}$  (ie the annual dose limit for members of the public) for a level of contamination of  $10 \text{ Bq cm}^{-2}$ , regardless of future treatment of that surface, if the contamination is currently fixed to a hard surface.”

Another common theme is that those making the incorrect allegation do not pick the appropriate model runs to compare with the UK cleanup values. In one instance a HPS conference presenter had run the correct EPA calculator for inside buildings, the BPRG but had incorrectly referred to it as the PRG calculator, which is for soil, water, and outside air. The presenter did pick an output option that I would not have recommended, secular equilibrium (SE) without decay. For a one-time release, choosing the option to account for decay would generally be more appropriate since there would not have been a continuing release of new Po-210. The presenter also ran the BPRG for settled dust which assumes a layer of contaminated dust over inside building surfaces. The presenter had gotten a concentration of  $0.000353 \text{ Bq/cm}^2$  for Po-210 at a risk level of  $1 \times 10^{-4}$ .

In another instance, the author of a response letter to the editors of the HPS Journal appeared when making his comparison to have used the ingestion only portion of a run of EPA’s SPRG calculator for dust on roadways. He came up with a value of  $0.000011 \text{ Bq/cm}^2$  using a target risk level of  $1 \times 10^{-6}$ .

To best compare the UK cleanup values to what might be allowed by the Superfund program, one should run the BPRG calculator, which is model that is intended to be used for establishing risk based cleanup levels for contamination inside buildings. The BPRG calculator would then be run using a residential scenario, with a target risk of  $1 \times 10^{-4}$  which is the typical upper end of the CERCLA  $10^{-4}$  to  $10^{-6}$  cancer risk range and compare the BPRG results for “dust” to the UK “removable” cleanup values and the BPRG results for “3D” to the UK “fixed” cleanup values. One should also use one of the BPRG output options that accounts for radioactive decay of Po-210 rather than assume it would be continually replenished. Using the target risk level of  $1 \times 10^{-4}$ , and the Peak Risk output option to account for Po-210 decay, the concentrations I had gotten are: for settled dust, or removable contamination, a concentration of 0.0168

Bq/cm<sup>2</sup> (compared to 0 Bq/cm<sup>2</sup> for the UK); and for 3D or fixed contamination a concentration of 42,200,000,000 Bq/cm<sup>2</sup> (compared to 10 Bq/cm<sup>2</sup> for the UK). A simple comparison between the UK and EPA approaches would indicate that the UK was more stringent for fixed contamination, but that is largely because the UK's risk assessment included an assumption of 2% of the material flaking off. There is not much difference between the two approaches for removable contamination but again the UK approach is more stringent than EPA's.

It should be noted the UK values are the result of a site-specific risk assessment, not a default run out of a model that the EPA values. Also, one should understand that the BPRG inputs for settled dust were intended for consistency with those inputs used during the World Trade Center cleanup of settled dust and a few subsequent updates in EPA's Exposure Factors Handbook and were not intended for consistency with any cleanups in the UK. This is because it has been EPA's policy for over 30 years that The Superfund program generally address radioactive contamination in a consistent manner as it addresses chemical contamination, except where there are technical differences between radionuclides and other chemicals. This approach to risk harmonization is vital since compliance with the 10<sup>-4</sup> to 10<sup>-6</sup> cancer risk range applies to all carcinogens, with the risks posed by radioactive and chemical carcinogens at the same site are summed together.

#### **Six Misconception, EPA Superfund is using population risk estimates incorrectly.**

The sixth misconception is that Superfund is using estimates of cancer cases across a population to select cleanup levels. It is claimed that Superfund's policy for risk-based cleanup is directly going against the UNSCEAR recommendation on not estimating population effects from low level exposure to radiation.

In 2012, UNSCEAR recommended against the practice of basing population risk from lower exposures in "Sources, Effects, and Risks of Ionizing Radiation" [16] on page 30 by stating:

"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."

However, the Superfund program uses the Reasonable Maximum Exposure (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. As stated in Superfund guidance "Radiation Risk Assessment at CERCLA sites: Q & A" [13], EPA's policy is:

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

- A. ...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).”

Although EPA is not basing cleanup decisions on population risk estimates, there are other federal programs that would look at such estimates. Since the 1970s, federal agencies have had to consider the costs and benefits of most regulations under development that would be expected to have large economic effects. The benefits of a regulation limiting a carcinogen such as radionuclides would likely include the number of cancer cases or deaths caused by cancer avoided by different proposed alternatives under consideration for the regulation. This would require evaluating population health effects. Such cost-benefit analysis of regulations under development is primarily required by Executive Order (EO) 12866 “Regulatory Planning and Review” (issued September 30, 1993, by President Clinton) [17]. E.O. 13563 “Improving Regulation and Regulatory Review” (issued January 18, 2011, by President Obama) [18] reaffirmed EO 12866 and provided more guidance on how cost-benefit analysis should be conducted. Neither of these Executive Orders is in conflict with UNSCEAR recommendations.

### **Seventh Misconception, EPA’s Superfund cleanup standard is 12 or 15 mrem/yr [0.12 or 0.15 mSv/yr].**

The last misconception I will address in this paper is that Superfund is using as a cleanup standard of either 12 or 15 millirem per year (mrem/yr), which corresponds to 0.12 or 0.15 millisievert per year (mSv/yr). This misconception started in the 1990’s, and EPA has been trying to correct this misconception even before this century began.

In the 1997 guidance document “Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination” [19], EPA had provided guidance that cleanup levels for radionuclides not based on an ARAR should use the  $10^{-4}$  to  $10^{-6}$  cancer risk range. EPA stated on page 2:

“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.”

On pages 3-4, EPA restated this guidance and added that the compliance with the risk range should be demonstrated using EPA Superfund guidance and developing risk assessments based on slope factors consistent with Superfund’s risk assessment methodology for chemical contamination:

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.<sup>6</sup> ...<sup>6</sup>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).<sup>7</sup> 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.”

In the 1997 guidance there was one paragraph that meant users could also conduct a dose assessment **in addition** to a risk assessment. Even in this sentence referring to 15 mrem/yr, the footnote states the cleanup level must still achieve  $10^{-4}$  to  $10^{-6}$  risk range. See on page 5 this language:

If a dose assessment is conducted at the site<sup>10</sup> 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  $3 \times 10^{-4}$  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.<sup>11</sup> ...<sup>10</sup>Cleanup levels not based on ARARs should be expressed as risk, although levels may at the same time be expressed in millirem.”

EPA noticed that the 1997 guidance document had been misread by some users, and in 1999 clarified its position in the guidance document “Radiation Risk Assessment At CERCLA Sites: Q & A” and its transmittal memo [20] to the EPA regions. On page 2 of the transmittal memo, EPA explains that 15 mrem/yr is not a cleanup standard for Superfund and that the  $10^{-4}$  to  $10^{-6}$  risk range should be used as the cleanup standard for radionuclides when an ARAR is not used to set the cleanup level:

“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.”

On page 13 of the 1999 guidance document, EPA further stated in the answer to question “32. When should a dose assessment be performed?” that:

OSWER Directive 9200.4-18 (US. 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 with  $10^{-6}$  as the point of departure and  $1 \times 10^{-6}$  used for PRGs) and expressed in terms of risk ( $\# \times 10^{\#}$ ). While the upper end of the risk range is not a discrete line at  $1 \times 10^{-4}$ , EPA generally uses  $1 \times 10^{-4}$  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 (US. 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).

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. On page 27 EPA states:

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  $1 \times 10^{-6}$  used for PRGs) and expressed in terms of risk ( $\# \times 10^{\#}$ ).**

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, rather than the previous 15

mrem/yr. However, this reference to 12 mrem/yr should only be used as an ARAR evaluation tool, not as a cleanup standard. On page 28 EPA stated:

**“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  $3 \times 10^{-4}$  excess lifetime cancer risk. ...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.”

Although there are some EPA regulatory programs that are dose-based, the Superfund program is not one of them. Cleanup levels for radioactive contamination at Superfund sites should continue to be based on the risk range when ARARs are not available or sufficiently protective as stated in EPA’s Superfund guidance.

## CONCLUSIONS

These examples of misconceptions of the Superfund approach to addressing radioactive contamination are illustrative of one’s I commonly encounter, and often seem to cause the most confusion with stakeholders. This is not intended to be a comprehensive list. Hopefully this paper and the subsequent presentation will help readers be more aware that these misconceptions are inaccurate when they hear them in the future.

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