

Using Risk Assessment to Guide Environmental Remediation Decisions: A Primer

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Amoret Bunn, PNNL Vicky Freedman, Sealaska Technical Services Laura Buelow, EPA Region 10







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- What is a risk?
- What is risk assessment?
- Why conduct a risk assessments?
- Risk assessment conceptual site models
- Dose vs. Risk



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Risk Defined for Human Health and the Environment

- Many definitions of "risk"
- For our purposes today:
 - \checkmark Risk is the chance of harmful effects to human health or to ecological systems resulting from exposure to an environmental "stressor".
 - \checkmark A stressor is any physical, chemical, or biological entity that can induce an adverse effect in humans or ecosystems.
 - ✓ Stressor = contaminant of concern = radionuclide
- Depends upon:
 - \checkmark How much of a contaminant is present in an environmental medium (e.g., soil, water, air) over what geographic area,
 - \checkmark How much contact (exposure) a person or ecological receptor has with the contaminated environmental medium, and
 - \checkmark How the contaminant affects the health of humans (e.g., toxicity) or ecological receptors (e.g., fish killed by lack of oxygen).









What is **Risk Assessment**?

Systematic process to determine if contaminants detected at a site are of concern to human health and the environment





Legend:

Human Health Risk Assessment Ecological Risk Assessment

Toxicity Assessment Characterization of Ecological Effects



Why conduct a risk assessment?

- A step within the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund)
 - Helps determine a need for action
 - Basis for determining levels of contaminants that can remain onsite while still adequately protecting public health
 - Basis for comparing potential health impacts of different future site uses and/or various remedial alternatives







Risk Assessment are Dependent on Conceptual Site Model

- Developed for both Human Health and Ecological Risk Assessments
- Exposure media: soil, water, air
- Exposures through variety of pathways: inhalation, ingestion, and direct exposure
- Considers both current and future land use







Ecological Risk Assessment Conceptual Site Model

Example: Conceptual Model for Ecological Risk Assessment, Hanford, <u>Risk Corridor Baseline</u> Risk Assessment

Assessment of Conditions:

- Community level
- Individual level
- Ρ **Population level**
- S Sub organism level (histology)
- Wildlife exposure analysis E
- Measurements of tissue concentrations



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Dose vs. Risk Endpoint in Radiation Risk Assessments

For radionuclides, concern is focused on health effects from radiation

- Dose is amount of energy absorbed by a person per unit mass
 - Biological dose or dose equivalent is a measure of biological damage to living tissue as a result of radiation exposure
 - Units are rems or sieverts (Sv)
 - ✓ 1 rem = 0.01 Sv
 - \checkmark 1 mrem = 0.00001 Sv = 10 µSv
 - \checkmark 1 µSv = 0.1 mrem





Source: https://www.imagewisely.org/Imaging-Modalities/Computed-Tomography/How-to-Understand-and-Communicate-Radiation-Risk

- Conversion of dose to risk for evaluation to regulation
 - Acceptable range 1 in 10,000 (10⁻⁴) to 1 in 1,000,000 (10⁻⁶)
 - For US Federal drinking water standards (40 CFR 141.16):
 - ✓ 4 mrem/yr (40 µSv)

e to risk for lation e 1 in 10,000 (10⁻⁴) (10⁻⁶) lrinking water FR 141.16): ISv)



Thank you



Technical Basis for Risk-Informed Decision-Making

A Historical Perspective on Radiation Protection Guidance

Vicky Freedman



GAO Report on Risk-Informed Decision-Making

- 2019 GAO report recommended that DOE adopt a risk-informed approach
- Facilitate decision-making approach that considers trade-offs
 - Risks to human health and the environment
 - Cost
 - Uncertainty
 - Diverse stakeholder perspectives



Risk Evaluation Approach for Low Beta Emitters

- Identify *risk-based factors* relevant for *remedy decisions for* five low-energy beta radioisotopes
 - Based on updated information on dosimetry, effective dose, and biokinetics, determine derived concentrations that correspond to a 4 mrem/yr (40 μSv) dose limit for using tap water scenario
 - Support management strategies where cleanup to drinking water standards (DWS) may not be attainable within a reasonable timeframe using currently available treatment technologies



Groundwater Risk Assessment

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Contaminant Fate & Transport

Contaminant concentrations are predicted at point(s) of compliance. For complex sites, this step may require the use of physically-based fate and transport models with high computational demands, which can limit the ability to assess uncertainty.

Dose Calculations

Support the development of maximum concentrations through different exposure scenarios (e.g., farmer, resident, outdoor worker, etc.) to different media (e.g., soil, air, tap water) using tools such as PRG Calculator, RESRAD, GENII, etc.

Risk Estimates

Exposure scenarios are analyzed to produce guidelines for remediation and cleanup actions using different assumptions; Superfund requires that the selected remedy will meet the one in 10,000 to one in a million cancer (10⁻⁴ to 10⁻⁶) risk range for all carcinogens

Model Abstraction

Physically-based models may be abstracted to less complex models that can assess uncertainty associated with groundwater concentrations at points of compliance

Barriers to Cleanup

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I-129 Relatively mobile

- Complex speciation
- Presence of iodine-127 can interfere with treatment
- Long half-life limits natural attenuation
- Potential technologies likely species specific

Tc-99

- Highly mobile
- Long half-life limits natural attenuation
- Potential technologies need to be identified to limit flux to groundwater

H-3
Highly mobile

Standards Based on Radiation Protection Guidance

The Health Physics Society

Nonprofit scientific organization chartered in U.S. that develops position statements and recommendations on radiation protection

National Council on Radiation Protection and Measurements (NCRP)

National nonprofit chartered by Congress in 1964 to collect, analyze, and disseminate information on rad protection (Public Law 88-376) Different agencies rely on different sources for technical guidance published over the last 60 years The International Commission on Radiological Protection (ICRP)

Principal international, not-for-profit, independent organization concerned with radiation protection, providing recommendations and guidance on all aspects of protection against ionizing radiation

Other International Organizations

International Atomic Energy Agency (IAEA) and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) also provide unbiased international consensus on the risks of radiation exposure

Definitions and Terms



Technical Guidance and Regulations

ICRP Publication 2

radioactivity

dose coefficients in FGR-13 First major revision that is now inhalation, ingestion, **National Interim** used by the NRC, incorporating and external **Primary Drinking** Basis for EPA and NRC methods of ICRP Publication 26 exposure to soil **EPA Proposed Rule Water Regulations** with dose per unit intake published regulations, 4 mrem/y contamination Proposed rule never drinking water only, in multiple volumes (1979 – 1982) EPA establishes finalized due to concerns critical organ and total DWS for all public 1995 over the most effective way body approach water supplies to regulate radon and other 1979 considerations 1976 2000 1991 1960 1977 1999 **ICRP Publication 26** 1963 **ICRP** Publication 60 2011 Supplanted maximum DOE adopted the approach **National Bureau of** permissible body burden outlined in ICRP 60 (1991) for with the *effective dose* **Standards Handbook 69** worker exposure. Adopted DOE 1196-2011 "effective dose" term and Initial basis for dose updated weighting factors conversion factors for ingested

ICRP Publication 30

EPA Proposed Rule

Base regulatory limit on effective dose equivalent (ede) (ICRP 1977)

Derived concentrations based on effective dose limit of 100 mrem/y (all pathways), FGR-13 and ICRP Pubs 60 and 107

Federal

(FGR)-13

HEAST (EPA)

Included slope

factors for

Guidance Report

EPA document using gender specific dose

assessment based on ICRP Pub 72 (1996);

EPA Blue Book (2011) based on risk and

Advancements in Dosimetry and Biokinetics



Provided gender-specific physiological parameters for the Reference Man

EPA Blue Book

Revision of the EPA methodology for estimating cancer risks from radiation exposure based on the 2006 National Research Council report and EPA Science Advisory Board, providing basis for future updates to radiation protection rules and guidance.

ICRP Occupational Intakes of Radionuclides (OIR)

Provide updated information on chemical forms, decay parameters, biokinetics, and tables of committed effective dose for inhalation and ingestion [Parts 1 - 4 (2015 – 2019), and Part 5 (in preparation)].Organ equivalent doses is not yet available.



Regulation of Radiation Exposure



Federal Drinking Water Standards

Technical Basis

Dose factors in ICRP 2 (1960), methodology in NBS 69 (1963), DWS based on 4 mrem/y to most sensitive (critical) organ from ingestion of drinking water in an adult resulting in risk coefficients ranging from 10⁻⁴ to 10⁻⁶



Critical Organ Approach

Dose regulated based on the organ receiving the highest dose (considered as a point source) Not based on risk of cancer, but on minimizing immediate and hereditary effects.



Concentration Limits

Limits were established by the National Interim Primary Drinking Water Regulations (EPA 1976), becoming effective in 1977; public dose was set to a fraction of the worker dose limit because of the potential for enhanced effects in children or elderly



Final Rule

EPA intent was to review the 4 mrem/y dose limit for beta and photon emitters within 2 to 3 years of publication (EPA, 1976) to ensure that the MCL reflects the best available science, but review or changes to the standards have not been implemented to date

Health Physics Knowledge Updates

Method Updates

Updates based on methods published by the ICRP, the U.S. National Committee on Radiation Protection and Measurements and the National Council on Radiation Protection and Measurements (NCRP)

Biokinetic

Organ Specificity

Models

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Effective Dose

Use of effective dose uses weighted accumulation of internal doses that are "effectively" the same as an equivalent whole-body irradiation

Organ Specificity

Increased knowledge in the body following ingestion or inhalation, the irradiation of neighboring organs, and inclusion of organ-specific risks with organ/tissue weighting factors

Biokinetic Models

Refinements in biokinetic models has led to improvements in dosimetry and time factors (e.g., biological half-life)

Technical Basis for Exposure Limits



Summary

- Improved knowledge in health physics result in different concentration limits
 - Critical organ to Total Organ/Effective Dose
 - Age-specific, gender-specific parameters
 - More advanced biokinetic models, tissue weighting factors, etc.
- Derived concentrations (based on EPA exposure limit of 4 mrem/y [40 μSv]) resulted in higher concentration limits for all five low-beta emitters
- Risk-based concentration limits support risk-informed decision-making
 - Can include other exposure pathways (e.g., inhalation, food ingestion)
 - Does not necessarily result in higher concentration limits

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Thank you!



Risk-Informed Groundwater Cleanup Levels: Hanford Case Study for Low Energy Beta Emitters

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Amoret Bunn, PNNL







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Motivation: 200-UP-1 Interim ROD at Hanford

- Interim ROD (2012)
- Hydraulic control for ¹²⁹I plume
 - concentration range of 1 to 16 pCi/L [0.037 to 0.592 Bq/L])
- Three information gaps for ¹²⁹I
 - Geochemical conceptual model
 - Potential technologies
 - Applicability of Applicable or Relevant and Appropriate Requirements (ARARs) and Technical Impracticability (TI) waiver for final remedy





I-129 in groundwater at concentration exceeding Drinking Water Standard, 1 pCi/L (0.037 Bq/L)



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200 West Area Pump-and-Treat Remedy

- Network of extraction/injection wells to prevent spread of contaminants to Columbia River
- Ex-situ treatment technologies still under evaluation for **I**-129













Low Energy Beta Emitters

Half-Lives

Except for tritium, low energy beta emitters are long-lived radionuclides



Drinking Water Standard

Federal (DWS) based upon 4 mrem/y dose standard (NBS Handbook 69 1963



Hanford Max Groundwater Conc

Except for chlorine, maximum groundwater concentrations are 13-32 times higher than DWS



1 pCi = 0.037 Bq

All of the low energy beta emitter are relatively mobile in the environment

High

Medium

Low

Mobility





Risk-Based Concentration Calculations

 Calculate risk-based cleanup levels based on different technical guidance documents using

Resident Tap Water Scenario

- Drinking water ingestion
- Bathing
- Watering vegetable garden
- In-house use releases volatile components, leading to a subsequent inhalation pathway (for H-3 and C-14 only)
- Uses constant well-water concentration (1 pCi/L [0.037 Bq/L]) to quantify long-term radiation dose and risk
- Doses and risks are based on exposure parameters and factors that represent reasonable maximum exposure conditions



Exposure Pathways in the Risk Assessment Information System Resident Tap Water Scenario (https://rais.ornl.gov/tools/rais_rad_risk_guide.html)





Technical Basis Resident Tap Water Scenario

Based on 4 mrem/y (40 μ Sv/y)to any organ and basis for EPA DWS

ICRP Pub 2 (1960) NBS 69 (1963)



First major revision that is now used by the **NRC**, incorporating methods of ICRP Publication 26 with dose per unit intake



EPA Blue Book supports organ weighting factors and includes cancer risk coefficients, and different age groups



DOE 1196-2011 derived concentration standards, gender-specific (not age-specific), with a single effective dose for each pathway



IAEA guidance supports radiation and tissue weighting factors, radiation detriment using latest available scientific information of the biology and physics of radiation exposure

ICRP Pub 103 (2007) IAEA (2014) ICRP OIR (2015 – 2019)

ICRP Pub 72 (1996) ICRP Pub 89 (2002) ICRP Pub 107 (2008) FGR-13 (1999)

ICRP Pub 60 (1991) ICRP Pub 72 (1996) FGR-13 (1999)

ICRP Pub 26 (1977) ICRP Pub 30 (1978)

Derived Concentration Limits Based on Exposure Limits

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 $\begin{array}{cccc} \mathbf{EPA} = 4 \ \mathrm{mrem/y} & \mathbf{WHO} = 10 \ \mathrm{mrem/y} & \mathbf{DOE-1196} = 100 \ \mathrm{mrem/y} & \mathbf{Effective \ Dose (updated \ dosimetry)} = 4 \ \mathrm{mrem/y} \\ (40 \ \mu \mathrm{Sv/yr}) & (100 \ \mu \mathrm{Sv/yr}) & (1000 \ \mu \mathrm{Sv/yr}) & (40 \ \mu \mathrm{Sv/yr}) \end{array}$

1 pCi = 0.037 Bq

Tritium (pCi/L)





Dose Calculations Resident Tap Water Scenario

- Calculated annual dose to organs and total body along four different pathways (mrem per pCi/L)
 - Drinking Water
 - Garden Crop Ingestion
 - Inhalation (C-14 and H only)
 - Bathing (estimated dose from immersion is negligible)
- Estimated dose varies due to differences in
 - Dose factors for each radionuclide
 - Radionuclide-specific parameters (e.g., solubility and soil to plant transfer)
- Need to understand pathways considered in dose/risk codes







Relative Pathway Contributions 3







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Based on Table 4.12 (Downs et al. 2020)

Effective Dose Resident Tap Water Scenario

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Dose to Risk Calculations Resident Tap Water Scenario

- Generally accepted value used for dose to risk conversion ~5x10⁻⁴ per rem (5% per Sv)
- Health Effects Assessment Summary Tables (HEAST) provides updated slope factors (risk per unit exposure factors) for:
 - Inhalation
 - Ingestion
 - External exposure to soil contamination
- FGR-13 (Eckerman et al. 1999) updated HEAST (EPA 1995)



Based on Table 4.14 (Downs et al. 2020)





Concentration Limits Tap Water Scenario

- Risk-based I-129 concentrations are up to 27 times higher than DWS
- **Risk-based Tc-99 concentrations** are up to 2.5 times lower than DWS

CENTER FOR 1 OF COMPLEX SITE @PNNL



1 pCi = 0.037 Bq

Low Beta Emitter DWS Relative to Risk-based and Derived Concentrations





Draft Manuscript: Intercomparison of Dose and Risk Models to Inform Groundwater Remediation Planning for Low Energy Beta-Emitting Radionuclides

- Radiation risk assessment models do not have identical assumptions, scenarios or calculations
 - Inputs are parameters for relevant exposure scenario
 - Output is risk or dose
 - Uncertainties in scenarios and parameters
- Codes can assist with answering initial questions:
 - Are remedial actions warranted?
 - What are the preliminary remediation goals (PRGs) for contaminants?
 - What exposure levels are protective of human health and the environment?
- Manuscript compares different radiation risk assessment models/codes that calculate dose and risk



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Draft Manuscript: Comparison of Radiation Risk Codes

Type of Code	ΤοοΙ	Sponsor; Developer	Calcula
Screening	Preliminary Remediation Goal (PRG) Calculator	EPA	Screening-level PRG correspondence of the second se
Screening	Risk Assessment and Information System (RAIS) Radionuclide Risk Calculator (RRC)	ORNL, University of Tennessee	Screening-level preliminary cle target risk
Screening	Dose Compliance Concentrations (DCC) Calculator	EPA	Screening-level preliminary cle target dose, by applying dose translate estimated exposure t
Cleanup decision levels	GENII (Generation II) Code (V 2.10.1)	DOE, EPA, NRC; PNNL	Cleanup level corresponding to radionuclide released; models including environmental accun surface water, groundwater, ar concentration in given medium
Cleanup decision levels	(RESidual RADioactivity) RESRAD-OFFSITE Code (V 4.0)	DOE, NRC; ANL	Cleanup level corresponding to integrated dose and risk from a code models release, transpor processes; can output and/or r concentrations in well and surf



tion Type

onding to target risk, by applying ate estimated exposure to risk

eanup level corresponding to

eanup level corresponding to conversion factor (DCF) to to dose

o target dose & target risk from fate and transport processes, nulation and removal from nd soil when radionuclide n is provided

o a dose limit and timespecified radionuclide inventory; rt, accumulation and exposure read in releases and face water



Draft Manuscript: Conclusion

- Screening calculators:
 - Web-based calculators
 - Default parameters conservative to extremely conservative
- Cleanup decision level codes:
 - Mechanistic modeling codes
 - Provide site-specific preliminary goals for remediation
 - Clearly delineate the dose and risk drivers that inform cleanup priorities.
- Overall, tools for estimating dose and health risk play a crucial role in developing cleanup levels for radioactively contaminated sites
 - Crucial that assumptions inherent in default parameter values and code calculations be understood to support the technical basis for informing cleanup decisions.





Collaborators

- PNNL:
 - Bruce Napier
 - Janelle Downs
 - Mike Truex
 - Vicky Friedman
- Groundwater and Remedy **Options**:
 - Mark Rockhold
 - Jim Szecody
 - Carolyn Pearce



- Argonne National Laboratory:
 - Emmanuel Gnanapragasm
 - Jing-Jy Cheng
 - Sunita Kamboj
 - Margaret MacDonell



Thank you



₽EPA

Risk and ARARs at Superfund Sites, A Regulator's Perspective

RemPlex Seminar July 26, 2022

Laura Buelow, Ph.D. EPA Region 10 Hanford Project Office

The contents of this presentation do not necessarily reflect the views and policies of the Environmental Protection Agency. All opinions are my own.

Outline

- CERCLA Background
- What Triggers Remedial Action?
- Setting Cleanup Levels
- Applicable or Relevant and Appropriate Requirements (ARAR) Waivers



CERCLA Remedial Process



What Triggers Remedial Action at Superfund Sites?



Current and Future Land Use Tribal Use, Residential, Industrial, Recreational, etc.



St. Maries Creosote Site St. Maries, ID Within Coeur d'Alene Tribe Reservation



Upper Columbia River Residential Soil Cleanup

Henry Mine Idaho



Lower Duwamish Waterway, Seattle



Groundwater in CERCLA and the NCP

- 40 CFR §300.430(a)(1)(iii)(F) EPA expects to return usable ground waters to their beneficial uses wherever practicable, within a timeframe that is reasonable given the particular circumstances of the site. When restoration of ground water to beneficial uses is not practicable, EPA expects to prevent further migration of the plume, prevent exposure to the contaminated ground water, and evaluate further risk reduction.
- 40 CFR §300.430(e)(2)(i)(B) Maximum contaminant level goals (MCLGs), established under the Safe Drinking Water Act, that are set at levels above zero, shall be attained by remedial actions for ground or surface waters that are current or potential sources of drinking water, where the MCLGs are relevant and appropriate under the circumstances of the release based on the factors in § 300.400(g)(2). If an MCLG is determined not to be relevant and appropriate, the corresponding maximum contaminant level (MCL) shall be attained where relevant and appropriate to the circumstances of the release.

Groundwater Classification

- In states that have an EPA-endorsed Comprehensive State Ground Water Protection Program (CSGWPP), EPA will defer to the State's determination of current and future GW uses (with some exceptions)
- Class I- Special Groundwater
 - Highly vulnerable
 - Irreplaceable source of drinking water for a substantial population
 - Ecologically vital
- Class II- Current and Potential Sources of Drinking Water and Groundwater Having Other Beneficial Uses
- Class III- Groundwater Not a Potential Source of Drinking Water and/or Limited Beneficial Use
 - TDS concentration ≥ 10,000 mg/L
 - Contaminated by naturally occuring conditions or broad-scale human activity
 - Yields are insufficient to meet minimum needs to an average household (150 gal/day)

CERCLA Remedial Process



Threshold Criteria Under the NCP

- Overall protection of human health and the environment
 - Multiple contaminants can drive cleanup levels below MCLs
- Compliance with Applicable or Relevant and Appropriate Requirements (ARARs)
 - Other Federal environmental laws, as well as more stringent state environmental and siting laws
 - Unless invoking ARAR waiver

Record of Decision Cleanup Levels and Requirements

 State ARARs must be more protective than federal levels, they cannot be less protective.

ARAR Examples



Can Cleanup Levels Change?

- Pre-Record of Decision
 - MCLs go through Six-Year Review by EPA Drinking Water Program
 - EPA Regional Screening Levels can be updated
 - State ARARs updates
- Post-Record of Decision
 - Cleanup levels are "frozen" at time of signature
 - CERCLA Five-Year Reviews done to determine if remedy is "protective"
 - ARARs may need to be updated if remedy is no longer protective, usually requires a ROD Amendment

Example of RSL Change Pre-ROD



PROPOSED PLAN

OIL WATER SEPARATOR 17 (BUILDING 1347) AND OIL WATER SEPARATOR 19 (BUILDING 1354)

> ENVIRONMENTAL RESTORATION PROGRAM MOUNTAIN HOME AIR FORCE BASE, IDAHO

- Original Proposed Plan had dig and dispose in a landfill as the preferred alternative
- Before ROD was completed, updated benzo(a)pyrene toxicity values in IRIS increased screening levels and the site no longer exceeded screening levels
- New Proposed Plan issued that changed from dig and dispose in landfill to No Action

How are ARARs Waived?

40 CFR §300.430(f)(1)(ii)(B)(2) An alternative that does not meet an ARAR under federal environmental or state environmental or facility siting laws may be selected under the following circumstances:

- (1) The alternative is an **interim measure** and will become part of a total remedial action that will attain the applicable or relevant and appropriate federal or state requirement;
- (2) Compliance with the requirement will result in **greater risk** to human health and the environment than other alternatives;
- (3) Compliance with the requirement is **technically impracticable** from an engineering perspective;
- (4) The alternative will attain a **standard of performance that is equivalent** to that required under the otherwise applicable standard, requirement, or limitation through use of another method or approach;
- (5) With respect to a state requirement, **the state has not consistently applied**, or demonstrated the intention to consistently apply, the promulgated requirement in similar circumstances at other remedial actions within the state; or
- (6) For Fund-financed response actions only, an alternative that attains the ARAR will not provide a balance between the need for protection of human health and the environment at the site and the availability of Fund monies to respond to other sites that may present a threat to human health and the environment.

Interim Actions- Hanford Waste Sites

- No full baseline risk assessment
- WA State MTCA residential cleanup levels for chemicals
- 15 mrem (150 μSv)/year dose for radionuclides
- Following up with "final" Records of Decision, using risk for radionuclides (1x10⁻⁴)



Interim Actions- Hanford Groundwater

• 200-BP-5/PO-1

- Uranium and Tc-99 COCs
- Did not set cleanup levels for other co-contaminants that will be addressed in final ROD
- Still need to address source contamination (Central Plateau waste sites)

• 200-UP-1

- No technology to clean up I-129
- Not enough information for TI waiver at time of Interim ROD



Greater Risk ARAR Waiver at Hanford ERDF

- ARAR in ERDF ROD identifies 40 CFR 268, "Land Disposal Restrictions," which specifies that treatment standards must be met before these wastes can be placed (land disposed) within the ERDF trench
- The in-trench macroencapsulation treatment alternative was shown to significantly reduce worker risk
- Waiver was only for "placement", not for the treatment





Technical Impracticability Waiver (TI)

- As of 2012, 91 TI waivers have been issued, 81 of those are for groundwater
- Complex geology (fractured bedrock, karst terrain, heterogeneous soils with low permeability)
- Non-aqueous phase liquid (NAPL)
- Must still meet overall protectiveness of human health and the environment

TI Waivers Granted by EPA Nationwide (1988-2011)



Fiscal Year

Summary

- CERCLA action can be taken based on unacceptable risk **or** exceedance of MCLs
- Highest beneficial use for most aquifers is drinking water
- Cleanup levels are based on both risk-based concentrations and ARARs and are unique to each site
- ARARs must be met or waived



Questions?

Contact Info:Laura BuelowBuelow.Laura@epa.gov

Want to Learn More?

- <u>https://www.epa.gov/superfund</u>
- <u>https://trainex.org/</u>
- <u>https://clu-in.org/</u>