

US EPA ARCHIVE DOCUMENT



Preliminary Remediation Goals (PRGs) and Remedial Goals (RGs)





PRGs and RGs

- PRGs - Health-based (generally), Conservative, products (by extension) of the Risk Characterization
- Not a Component of the Risk Assessment
- Generic Consideration for Risk Management



● ● ● | PRGs and RGs

- RGs - Varied Basis Including:
 - Health
 - Incremental Lifetime Cancer Risk (NCP: 10-6 to 10-4)
 - Non-cancer Hazard (Typically, 1.0)
 - Aesthetics
 - Odors, Taste, Appearance (turbidity - 5 nephelometric turbidity units (NTU))



● ● ● | PRGs and RGs

- RGs - Varied Basis Including (cont'd):
 - Legal/Regulatory
 - Risk-based Values versus Enforceable Standards
 - SWDA MCLs - Health Basis, Economics, Treatment Technology-mediated.
 - OSHA PELs - Anecdotal Health Basis





PRGs

- Generic PRGs - e.g., USEPA Region 9 PRGs
 - Conservative, consistent health basis (exceptions: Csat or “max”)
- Site-Specific PRGs -
 - Incorporate Site-Specific Exposure Parameter Values
 - Daily ingestion rates
 - Exposure frequencies
 - Mitigating factors
 - Based on goals and agreements with PRPs



Based on goals and agreements with PRPs, any generic PRG may be considered as an RG (as most are - for effective screening of COPCs) as long as exposure parameter values and complete exposure routes match up with the PRG defaults.



PRGs

- Exceedance suggests the need for further evaluation. Many PRG exceedances will trigger need for a risk assessment or removal action based on a cost-benefit analysis.



● ● ● Example Generic PRGs

- USEPA Region 9 PRGs (highly recommended - transparent, consistent, widespread usage, regularly updated - almost constant peer-review, focuses on driving pathways, and easy to use)
 - Target Cancer Risk of 10⁻⁶; Target Hazard of 1.0
 - Soil, Groundwater as Drinking Water (Tap Water), Ambient Air
 - Industrial Land Use
 - Soil: Incidental ingestion; inhalation of particulates; inhalation of volatiles; dermal absorption



● ● ● Example Generic PRGs

- USEPA Region 9 PRGs (cont'd)
 - Soil, Groundwater as Drinking Water (Tap Water), Ambient Air (cont'd)
 - Residential Land Use
 - Groundwater: Ingestion from drinking; inhalation of volatiles
 - Surface Water: Ingestion from drinking; inhalation of volatiles
 - Soil: Incidental ingestion; inhalation of particulates/volatiles; dermal absorption



● ● ● Example Generic PRGs

- USEPA Region 9 PRGs: Streamline and standardize decision making
- PRGs consider human health toxicity criteria with standard exposure factor values to estimate chemical concentrations in soil, air and water that are protective of human exposures (incl. Sensitive sub pops) over a lifetime
 - Exceeding these levels?



Exceeding these levels should not designate a site as “dirty” or trigger a response action.

Exceeding a PRG suggests a need for further evaluation (sampling, background/ambient levels, review of underlying assumptions, applicability of route-to-route extrapolations, use of chronic tox factors in assessing childhood exposures).

● ● ● Example Generic PRGs

- Can be used as screening criteria or initial clean-up goals, if:
 - Site-related exposure assumptions match up with default based PRG assumptions
 - PRGs not always indicative of the maximally exposed individual
 - Yes: Residential adult and child; Generic IC Adult Worker
 - No: Construction Worker, Recreational Users, Subsistence Fisher, Agricultural Family, etc.
 - There are no ecological considerations



EXHIBIT 1-1
 TYPICAL EXPOSURE PATHWAYS BY MEDIUM
 FOR RESIDENTIAL AND INDUSTRIAL LAND USES*

EXPOSURE PATHWAYS, ASSUMING:

MEDIUM	RESIDENTIAL LAND USE	INDUSTRIAL LAND USE
Ground Water	<i>Ingestion from drinking</i>	Ingestion from drinking
	<i>Inhalation of volatiles</i>	Inhalation of volatiles
	Dermal absorption from bathing	Dermal absorption
Surface Water	<i>Ingestion from drinking</i>	Ingestion from drinking
	<i>Inhalation of volatiles</i>	Inhalation of volatiles
	Dermal absorption from bathing	Dermal absorption
	Ingestion during swimming	
	Ingestion of contaminated fish	
Soil	<i>Ingestion</i>	<i>Ingestion</i>
	<i>Inhalation of particulates</i>	<i>Inhalation of particulates</i>
	<i>Inhalation of volatiles</i>	<i>Inhalation of volatiles</i>
	Exposure to indoor air from soil gas	Exposure to indoor air from soil gas
	Exposure to ground water contaminated by soil leachate	Exposure to ground water contaminated by soil leachate
	Ingestion via plant, meat, or dairy products	Inhalation of particulates from trucks and heavy equipment
	<i>Dermal absorption</i>	<i>Dermal absorption</i>

Footnote:
 *Exposure pathways considered in the PRG calculations are indicated in boldface italics.



● ● ● Example Generic PRGs

- CSM is Fundamental
 - Exposure pathways of concern must match (or assumed of a lesser degree) than underlying assumption in PRGs
 - Consider contaminant sources areas, exposure pathways, potential receptors



● ● ● Example Generic PRGs

- CSM is Fundamental (cont'd)
 - The CSM should answer the following questions
 - Are there ecological concerns?
 - Land uses other than those considered in PRGs?
 - Additional pathways: impact to groundwater, fish ingestion, dairy, beef, livestock?
 - Unusual site conditions (large areas of contamination, high fugitive dust, indoor air?)



**EXHIBIT 3-1
SUGGESTED WEBSITES FOR EVALUATING EXPOSURE
PATHWAYS NOT CURRENTLY ADDRESSED BY REGION 9 PRGs**

EXPOSURE PATHWAY	WEBSITE
Migration of contaminants to an underlying potable aquifer	EPA Soil Screening Guidance: http://www.epa.gov/superfund/resources/soil/index.htm California Water Board Guidance: http://www.swrcb.ca.gov/rwqcb2/rbsl.htm
Ingestion via plant uptake	EPA Soil Screening Guidance: http://www.epa.gov/superfund/resources/soil/index.htm EPA Fertilizer Risk Assessment: http://www.epa.gov/epaoswer/hazwaste/recycle/fertiliz/risk/
Ingestion via meat, dairy products, human milk	EPA Protocol for Combustion Facilities: http://www.epa.gov/epaoswer/hazwaste/combust/riskvol.htm#volume1 California "Hot Spots" Risk Guidelines: http://www.oshha.ca.gov/air/hot_spots/HRSGuide.html
Inhalation of volatiles that have migrated into basements or other enclosed spaces.	EPA's draft Subsurface Vapor Intrusion Guidance: http://www.epa.gov/correctiveaction/eis/vapor.htm EPA's Version of Johnson & Ettinger Model: http://www.epa.gov/oerpage/superfund/programs/risk/aimodel/johnson_ettinger.htm
Ecological pathways	EPA Ecological Soil Screening Guidance: http://www.epa.gov/superfund/programs/risk/ecorisk/ecosl.htm NOAA Sediment Screening Table: http://response.restoration.noaa.gov/cpr/sediment/squirt/squirt.html



● ● ● Example Generic PRGs

- PRGs correspond to fixed levels of carcinogenic risk (risk) and noncarcinogenic hazard (hazard)
 - ILCR (Target Risk): 1E-06 or 1×10^{-6} or One-in-One Million
 - Target Hazard Quotient: 1.0



● ● ● Example Generic PRGs

- Contaminants can have both CAN and NC effects, but carcinogenic response usually results in the lower (more stringent value)
 - PRG Table: Carcinogenic contaminants are accompanied by a “ca” designation. For noncarcinogenic hazard, a designation of “nc” is used.



Within the PRG table, those contaminants administered on the basis of their carcinogenic potential are accompanied by a “ca” designation. For noncarcinogenic hazard, a designation of “nc” is used.

● ● ● Example Generic PRGs

- Residential Soil PRGs:
 - Carcinogens
 - PRGs use an age-adjusted intake approach
 - Noncarcinogens
 - NC PRGs based on childhood exposures
- With a Relative Risk Range of 10^{-6} to 10^{-4} , options for PRGs to trigger or set less stringent cleanup levels for a specific site



Carcinogens:

PRGs use an age-adjusted intake approach that takes into account daily soil ingestion rates, body weights, and exposure durations for children from 1 to 6 years of age and older age groups aged 7 to 31 years of age. This approach was chosen to be able to account for the higher intake rates relative to body weight under childhood exposures as well as the longer exposure durations associated with a long-term resident.

Noncarcinogens:

Age-adjusted approach is not used. NC PRGs based on childhood exposures and combines the higher childhood exposure with chronic toxicity criteria.

Toxicity-specific endpoints in children, dose-response curve is steep - marginal difference between NOAEL and LOAEL.

Because USEPA considers a Relative Risk Range of 10^{-6} to 10^{-4} , some people have begun employing an order-of-magnitude approach to use of the PRGs to trigger remediation levels or to set less stringent cleanup levels for a specific site.

● ● ● Example Generic PRGs

- By multiplying the PRGs by 10 or even 100, one can effectively adjust the target risk
 - This adjustment can lead one to overlook serious noncancer health threats



However: Because of the phenomenon discussed above for chemicals which can elicit cancer and noncancer effects (PRG generally reflective of cancer risk), this adjustment can lead one to overlook serious noncancer health threats.

● ● ● Example Generic PRGs

- By multiplying the PRGs by 10 or even 100, one can effectively adjust the target risk (cont'd)
 - For this reason, USEPA Region 4 has included indicators within the PRG table which warn the user against such order of magnitude adjustments
 - A designation of “ca*” indicates that the noncancer PRG will be exceeded if the cancer-based value is multiplied by 100 (10-4 risk)
 - A designation of “ca**” indicates that the noncancer PRG will be exceeded if the cancer-based value is multiplied by 10 (10-5 risk)



A designation of “ca*” indicates that the noncancer PRG will be exceeded if the cancer-based value that is presented is multiplied by a factor of 100 (to adjust to 10-4 risk).

A designation of “ca**” is used to indicate that the noncancer PRG will be exceeded if the cancer-based value that is presented in the table is multiplied by a factor of 10 (to adjust the TR to 10-5).

● ● ● Example Generic PRGs

- By multiplying the PRGs by 10 or even 100, one can effectively adjust the target risk (cont'd)
 - No range of “acceptable noncarcinogenic hazard” so noncancer PRGs should not be adjusted when setting final clean-up criteria
 - Back-of-the-envelope level of accuracy, consider verifying with your risk assessor or toxicologist



There is no range of “acceptable noncarcinogenic hazard” so that under no circumstances should noncancer PRGs be multiplied by 10 or 100 when setting final clean-up criteria.

You can do this for back-of-the-envelope type comparisons, but consider verifying any such adjustments with your risk assessor or toxicologist.

● ● ● Example Generic PRGs

- The PRG values are risk-based, with the following two exceptions which pertain solely to soil:
 - For several VOCs: PRG based on soil saturation (C_{sat}) “sat”
 - For relatively less toxic inorganic and SVOC contaminants: A non-risk based ceiling limit (“max”) given as 10⁺⁵ mg/kg (risk-based values are available in Inter-Calc Tables)



For several VOCs: PRGs based on soil saturation (C_{sat}) “sat” - concentrations above this level indicate the potential presence of free-phase product - NAPL - invalidates the VF

For relatively less toxic inorganic and SVOC contaminants: A non-risk based ceiling limit (“max”) given as 10⁺⁵ mg/kg (risk-based values are available in Inter-Calc Tables).

Risk-based values can exceed unity (> 1,000,000 mg/kg, which is not possible in reality).

10⁺⁵ is equivalent to 10% by weight of the soil sample - above this certain contact/exposure assumption may be violated.

PRGs do not address short-term exposures (e.g., pica behavior in children or construction exposures) and toxicological data used generally are not applicable at such high concentrations under acute exposures.



Example Generic PRGs

- PRG table may also include Cal-EPA PRGs (Cal-EPA-Modified PRG) where exposure parameter values or toxicity criteria deviate from federal approach. In these cases, the USEPA and Cal-EPA values are presented



CA DTSC - generally more protective - TCE notable exception
Noted when a factor of 4 difference occurs.

● ● ● **Example Generic PRGs**

- Clarification/Side-Bar - In case there is any confusion if you try to verify toxicity criteria in IRIS:
 - Inhalation Conversion Factors: RfCs (mg/m³) and URFs (m³/ug) in IRIS (>1991); RfDi (mg/kg/day) and SFi (mg/kg-day)⁻¹ in PRG table. Conversion based on body weight and inhalation rate.

$$RfDi \frac{mg}{(kg \cdot day)} = RfC (mg / m^3) \times \frac{20m^3}{day} \times \frac{1}{70kg}$$

$$SFi \frac{(kg \cdot day)}{(mg)} = URF (m^3 / ug) \times \frac{day}{20m^3} \times 70kg \times \frac{10^3 ug}{mg}$$



● ● ● Example Generic PRGs

- Route-to-Route Extrapolation of Toxicity Criteria
 - When no toxicity values available for a given route of exposure
 - SFo and RfDo frequently used for both oral and inhalation exposures for organics lacking inhalation (SFi, RfDi) values and reciprocal also true
 - Not typically advanced for inorganics based on portal-of-entry effects and significant differences in adsorption efficiency
 - Dermal exposure a larger issue



Dermal exposure a larger issue:

No dermal toxicity criteria in USEPA databases

Defensible data for use in adjustment not available - so SFo/RfDo often applied w/o adjustment.

Although this is provided for carte blanche in the PRG tables, some contaminants are known to cause a direct toxic effect in the skin, contraindicating such an extrapolation: e.g., cPAHs (BaP) - mouse skin painting assays.

● ● ● Example Generic PRGs

- PRGs with Special Considerations
 - Cadmium: Separate RfDo for water and food - USEPA Region 9 uses RfDo for water
 - Chromium: Cr6:Cr3 assumed 1:6 ratio (total chromium) also, 100% Cr6



Cadmium

Separate RfDo for water and food - USEPA Region 9 uses RfDo for water (twice as conservative)

● ● ● Example Generic PRGs

- PRGs with Special Considerations (cont'd)
 - Lead: Calculate clean-up goals such that there is a less than 5% probability that children's (or fetal) blood-lead levels will exceed 10 ug/dL
 - USEPA - IEUBK pharmacokinetic model - Residential PRG - 400 mg/kg
 - Cal-EPA - LeadSpread pharmacokinetic model - similar - 150 mg/kg
 - Industrial PRG - ALM (1996 and 2003): Protective of a developing fetus. 800 mg/kg (780 - 1,235 ppm, can approach 2,000 mg/kg or higher in site-specific application)



● ● ● Example Generic PRGs

- PRGs with Special Considerations (cont'd)
 - TCDD and PCBs - TEF/TEQ (also, slope factor range for PCBs)
 - PAHs - Relative Potency Factors based on toxicity of B(a)P
 - Vinyl Chloride - childhood sensitivities



● ● ● Example Generic PRGs

- Soil Screening Levels - Provided for in USEPA Region 9 PRG Table.
 - Soil concentration protective of underlying groundwater
 - 100 of the most common contaminants at Superfund Sites
 - Dilution-Attenuation Factors of 1 (none: shallow water table, fractured media, karst topography, sources > 39 acres) and 20
 - We will chat more about these levels later





PRGs

- USEPA Region 6 Media-Specific Screening Levels (MSSLs)
- USEPA Region 3 Risk-Based Concentrations (RBCs): Limitations
 - RBCs do not consider transfers from soil to air
 - Cumulative risk from multiple contaminants (neither do the PRGs)
 - RBCs do not consider dermal risk



If we have time



PRGs

- RBCs are useful when:
 - A single medium is contaminated
 - a single contaminant contributes the vast majority of the health risk
 - Volatilization, dermal contact and other pathways that are not included in the RBCs are not expected to be significant





PRGs

- USEPA Soil Screening Levels:
 - Based on the potential for leaching and protection of groundwater
 - Focus is generally on the Dilution/Attenuation Factors (DAFs) of 1 and 20



Soil screening values based on the potential for leaching and protection of groundwater
Groundwater Protection SSLs account for a number of pathways, but focus is generally on the Dilution/Attenuation Factors (DAFs) of 1 and 20



PRGs

- USEPA Soil Screening Levels (cont'd):
 - Soil Direct Contact Tables provided to address residential exposures (1996) and specific pathway assessment methodology w/r/t industrial exposures (2002 version)
 - e.g., Particulate emissions factor (PEF) development for generic industrial worker and construction worker exposures (vehicular dust suspension).





PRGs

- National Primary Drinking Water Regulations:
 - Safe Drinking Water Act's Maximum Contaminant Level Goals (MCLGs)
 - A level below which there is no known or expected risk to human health
 - Maximum Contaminant Levels (MCLs)
 - Legally-enforceable standards that apply to public water systems





PRGs

- National Primary Drinking Water Regulations (cont'd):
 - MCLs (cont'd)
 - Set as close to the MCLG as is feasible - treatment technology and cost ---> Not consistently health-based
 - EPA may adjust the MCL such that it “maximizes health risk reduction ... at a cost that is justified by the benefits”
 - Treatment Technique (TT): No reliable method which is economically and technically feasible



Set as close to the MCLG as is feasible using the the best available treatment technology and taking cost into consideration (occurrence in the environment, human exposure and risks of adverse health effects in the general population analytical methods of detection, technical feasibility and impacts of regulation on water systems, the economy and public health) ---> Not consistently health-based

EPA may adjust the MCL for a particular class or group of systems to a level that “maximizes health risk reduction benefits at a cost that is justified by the benefits.”

Treatment Technique (TT): An enforceable level of performance for public water systems when there is no reliable method which is economically and technically feasible

Lead and copper are regulated by Treatment Technique that requires systems to control the corrosiveness of their water (Cu = 1.3 mg/L, Pb = 0.015 mg/L)



PRGs

- National Secondary Drinking Water Regulations:
 - Non-enforceable guidelines. Recommended to water supply systems, but not required for compliance.
- USEPA Vapor Intrusion Screening Criteria: *Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils* (2002):
 - Groundwater, shallow and deep soil gas and indoor air screening criteria
 - Variable target risk. Tiered approach



Non-enforceable guidelines regarding contaminants that may cause cosmetic effects such as ... Eew ... skin or tooth discoloration) or aesthetic effects (such as taste, odor and color ... Yum) in drinking water. Recommended to water supply systems, but not required for compliance. Many states adopt these standards

Groundwater, shallow and deep soil gas and indoor air screening criteria. The subsurface media screening values are based on attenuation factors, with the indoor air concentration as a target. Best for use with sub-slab soil gas data.

Variable target risk. Tiered approach. Need I say it? Only for VOCs



PRGs

- USEPA Vapor Intrusion Screening Criteria (cont'd):
 - Residential (home) exposure - or - commercial properties where public is routinely present
 - OSHA takes lead in assessing indoor air in the workplace (considers PPE, etc.)
 - C/I setting - indicator for add'l eval. - not compliance standard



Primarily for use in assessing residential (home) exposure - or commercial properties where public is routinely present (e.g., stores, hospitals, libraries, schools, hotels, etc.)

OSHA takes lead in assessing indoor air in the workplace (considers PPE, etc.).

Can be used to assess industrial setting - as an indicator for the need for additional evaluation - not as compliance standards.

Need to make adjustments for building-specific air volumes, air exchange rates, etc. To be used in tandem with USEPA's User's Guide for Evaluating Subsurface Vapor Intrusion into Buildings (2003)



PRGs

- *Soil Screening Levels Guidance for Radionuclides: User's Guide and Technical Background Document* (USEPA, 2000)
- National Ambient Water Quality Criteria:
 - Guidance (not regulation) for states and tribes in adopting water quality standards under section 303(c) of the Clean Water Act
 - Columns 8: Human Health for Consumption of Water + Organisms





PRGs

- National Ambient Water Quality Criteria (cont'd):
 - Column 9: Human Health for Consumption of Organisms Only
 - Consider when screening surface water concentrations
- Agency for Toxic Substances and Disease Registry
 - Inhalation Minimal Risk Levels



Considers new fish ingestion rate of 17 g/day



PRGs

- Occupational Health and Safety Administration
 - Permissible Exposure Limits
- Toxicity Criteria Databases
 - Integrated Risk Information System (IRIS)
 - Provisional Peer-Reviewed Toxicity Values (PPRTVs)
 - Health Effects Assessment Summary Tables (HEAST)
 - National Center for Environmental Assessment (NCEA) (request)





PRGs

- Appropriate Uses for PRGs (recap):
 - Initial screening, based on applicability of exposures, receptor groups at issue and exposure parameter values
 - Tentative or initial remedial goals, with reservations as outlined above
 - Back-of-the-Envelope estimates of risk or hazard - order of magnitude levels of specificity





PRGs

- Quick Overview: Exposure Parameter Values and Sources
 - Exposure Factors Handbook (USEPA, 1997)
 - Child-Specific Exposure Factors Handbook (USEPA, 2002)
 - Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities (HHRAP) (USEPA 1998 and 1999 errata)
 - Soil Screening Levels Guidances (USEPA, 1996, 2000, 2002)





PRGs

- Quick Overview: Exposure Parameter Values and Sources (cont'd)
 - Risk Assessment Guidance for Superfund, Part E (USEPA, 2004)
 - Subsurface Vapor Intrusion Guidance (USEPA, 2002)
 - Adult Lead Model (2003)
- Case Studies: Using the USEPA Region 9 PRG Table and InterCalc Tables

