

## PROTOCOL

### Human Health Constituents of Concern

#### Introduction

This protocol has been developed in order to support the Savannah River Site environmental remediation program. It provides instructions for the identification of Human Health Constituents of Concern (HH COCs). The protocol instructions are based on the latest available USEPA guidance and agreement from the staff of USEPA, SCDHEC, and USDOE as members of the Risk Assessment Design Team (RADT).

This protocol is to be applied to constituents when a risk (hazard) estimate is needed. Ideally it is implemented after Human Health Constituents of Potential Concern (HH COPCs) have been identified; however it can be used on the entire list of detected analytes if the formal COPC screening has not been performed.

Preliminary remediation goals (PRGs) are risk-based tools used to evaluate potentially contaminated waste sites. They are derived in accordance with the methodologies described in the Risk Assessment Guidance documents published by USEPA. PRGs concentrations (activities) are based on pathways for which generally accepted methods, models, and assumptions have been developed. PRGs are concentrations (activities) that correspond to fixed levels of risk (i.e., either one-in-one million [ $1 \times 10^{-6}$ ] cancer risk or noncarcinogenic hazard quotient (HQ) of 1. If a substance causes both cancer and noncancer (systemic) effects, the most stringent criteria shall take precedence.

The most current USEPA Region 9 table is the source of the PRGs described in this protocol for nonradiological constituents; it combines current USEPA toxicity values with standard exposure factors to estimate contaminant concentrations in environmental media that the agency considers protective of humans. More detailed information on input parameters, exposure assumptions and calculation methods can be found at the USEPA Region 9 website: [www.epa.gov/region09/waste/sfund/prg/index.htm](http://www.epa.gov/region09/waste/sfund/prg/index.htm).

USEPA does not publish values for radiological constituents in a standardized table as they do for nonradiological PRGs. However, the USEPA Radionuclide PRGs for Superfund Electronic Calculator website provides a database tool with which to derive risk-based PRGs using standard default parameters and the latest toxicity values; it also allows the user to modify input parameters to create site specific PRGs. More detailed information can also be found at the USEPA Radcalculator website: <http://epa-prgs.ornl.gov/radionuclides/>.

Standardized reference tables that contain PRGs can be used in all stages of the risk decision-making process. The SRS risk assessment technical staff maintains and controls the PRG tables for use by Soil and Groundwater Closure Projects (SGCP).

### Details

1. Segregate carcinogenic (risk) and non-carcinogenic (hazard) constituents.
2. For carcinogens, calculate the risk based on the following equation:

$$\text{risk estimate} = ([\text{EPC}] / [\text{PRG}]) \times 1\text{E-}06$$

EPC = exposure point concentration

PRG = for radiological constituents: SRS-specific value for soil, concrete or groundwater (residential) media; or unit-specific value for sediment, surface water, or groundwater (industrial worker) media.

= for non-radiological constituents: USEPA Region 9 soil or tapwater value for soil or groundwater (residential); or 10X USEPA Region 9 soil value for concrete; or unit-specific values for sediment, surface water, and groundwater (industrial worker).

(Note that a risk estimate for volatile organic compounds (VOCs) in concrete media is not required since the pathways for exposure from concrete are not considered significant).

Sum the risk estimates of the chemical constituents to obtain a Total Chemical Risk estimate. Sum the risk estimates of the radiological constituents to obtain a Total Radiological Risk estimate. Sum the Total Chemical Risk estimate and the Total Radiological Risk estimate to obtain a Total Media Risk estimate. Constituents with an individual cancer risk greater than 1E-06 are identified as HH COCs.

Table 1 is a sample table for providing the human health carcinogenic risk estimate.

3. For noncarcinogens, calculate the hazard based on the following equation:

$$\text{HQ} = ([\text{EPC}] / [\text{PRG}])$$

HQ = hazard quotient

EPC = exposure point concentration

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PRG = USEPA Region 9 soil or tapwater value (for soil or groundwater), or 10X EPA Region 9 soil value (for concrete)

(Note that a hazard estimate for volatile organic compounds (VOCs) in concrete media is not required since the pathways for exposure from concrete are not considered significant).

Sum the HQs to obtain a Total Media Hazard Index (HI). If the Total Media HI is less than one, then no COCs are identified. If the Total Media HI is greater than one, then the constituents are segregated based on relevant target organs. Sum the HQs according to target organs. Constituents are identified as COCs if the Total Organ HQ is greater than 0.1 and the Total Organ HI is greater than one. If the Total Organ HI is less than one, then the constituents are not identified as HH COCs.

Table 2 is a sample table for providing the human health noncarcinogenic risk estimate.

4. Constituents retained to this point in the process are identified as HH COCs. They will be carried forward to an uncertainty discussion (i.e., Constituents of Concern Refinement Process Protocol). If no HH COCs have been identified at this point, then this part of the analysis is considered complete.

Table 1. (Sample) Human Health Carcinogenic Risk Estimate  
 Exposure Group Surface Soil, 0.0 to 0.3 m (0.0 to 1.0 ft)

Analyte <sup>1</sup>	Exposure Point Concentration <sup>2</sup>	Residential PRG <sup>3</sup>	Residential Risk Estimate <sup>4</sup>	Industrial PRG <sup>3</sup>	Industrial Risk Estimate <sup>4</sup>	COC? <sup>5</sup>
<b>Inorganics (mg/kg)</b>						
Constituent A	2.01E+00	3.90E-01	<b>5.15E-06</b>	1.59E+00	<b>1.26E-06</b>	<b>COC</b>
<b>Organics (mg/kg)</b>						
Constituent B	7.85E-02	6.21E-01	1.26E-07	2.11E+00	3.72E-08	no
Constituent C	1.03E-01	6.21E-02	<b>1.66E-06</b>	2.11E-01	4.88E-07	<b>COC</b>
Constituent D	1.74E-01	6.21E-01	2.80E-07	2.11E+00	8.25E-08	no
<b>Total Chemical Risk</b>			<b>7.22E-06</b>		<b>1.87E-06</b>	
<b>Radionuclides (pCi/g)</b>						
Constituent E	2.57E-01	6.05E-02	<b>4.25E-06</b>	1.12E-01	<b>2.29E-06</b>	<b>COC</b>
Constituent F	3.48E-01	1.97E-01	<b>1.77E-06</b>	3.94E-01	8.83E-07	<b>COC</b>
Constituent G	2.31E+01	7.77E-01	<b>2.97E-05</b>	1.79E+00	<b>1.29E-05</b>	<b>COC</b>
<b>Total Radionuclide Risk</b>			<b>3.57E-05</b>		<b>1.61E-05</b>	
<b>Total Media Risk</b>			<b>4.30E-05</b>		<b>1.80E-05</b>	

<sup>1</sup>Analytes that are identified as COPCs.

<sup>2</sup>Exposure Point Concentration (EPC) = Lesser of 95<sup>th</sup>% UCL of the mean concentration and the maximum concentration

<sup>3</sup>Nonradiological PRGs from the EPA Region 9 PRG table; Radiological PRGs from Engineering Calculation K-CLC-XXX

<sup>4</sup>Risk estimate = ([EPC] / [PRG]) x 1E-06.

<sup>5</sup>Constituent is a COC if risk estimate > 1E-06.

Table 2. (Sample) Human Health Noncarcinogenic Hazard Estimate  
Exposure Group Surface Soil, 0.0 to 0.3 m (0.0 to 1.0 ft)

Analyte <sup>1</sup>	Exposure Point Concentration <sup>2</sup>	Residential PRG <sup>3</sup>	Residential Hazard (HQ) Estimate <sup>4</sup>	Industrial PRG <sup>3</sup>	Industrial Hazard (HQ) Estimate <sup>4</sup>	COC? <sup>5</sup>
<b>Inorganics (mg/kg)</b>						
Constituent A	9.08E+03	7.61E+04	1.19E-01	1.00E+05	9.08E-02	no
Constituent B	2.01E+00	2.16E+01	9.31E-02	2.56E+02	7.85E-03	no
Constituent C	9.40E+03	2.35E+04	4.00E-01	1.00E+05	9.40E-02	no
Constituent D	1.93E+01	4.00E+02	4.83E-02	7.50E+02	2.57E-02	no
Constituent E	8.04E+02	1.76E+03	4.57E-01	1.95E+04	4.12E-02	no
Constituent F	9.51E-01	2.35E+01	4.05E-02	3.07E+02	3.10E-03	no
Constituent G	1.07E+00	5.16E+00	2.07E-01	6.75E+01	1.59E-02	no
<b>Total Media Hazard Index</b>			<b>1.37E+00</b>	<b>2.79E-01</b>		

<sup>1</sup>Analytes that are identified as COPCs.

<sup>2</sup>Exposure Point Concentration (EPC) = lesser of 95th% UCL of the mean concentration and the maximum concentration

<sup>3</sup>PRGs from the EPA Region 9 PRG table

<sup>3</sup>Hazard estimate = [EPC] / [PRG].

<sup>4</sup>If the total media hazard index is less than 1, then no COCs are identified. If the total media hazard index is greater than 1, then the constituents are segregated based on relevant target organs. HQs are summed according to target organs. Constituents are identified as COCs (based on land use) if the HQ is greater than 0.1 and the total organ hazard index is greater than 1.

Analyte	Target Organ	Source <sup>1</sup>	HQ (residential)	
Constituent A	CNS	NCEA	1.19E-01	<i>Total CNS Target Organ Hazard Index</i>
Constituent E	CNS	IRIS	4.57E-01	
Constituent F	CNS	IRIS	4.05E-02	
			<b>6.17E-01</b>	
Constituent B	Skin	IRIS	9.31E-02	<i>Total Skin Target Organ Hazard Index</i>
			<b>9.31E-02</b>	
Constituent C	Liver	NCEA / ATSDR	4.00E-01	<i>Total Liver Target Organ Hazard index</i>
			<b>4.00E-01</b>	
Constituent D	Blood	IRIS	4.83E-02	<i>Total Blood Target Organ Hazard Index</i>
Constituent G	Blood	IRIS	2.07E-01	
			<b>2.55E-01</b>	

<sup>1</sup>IRIS = Integrated Risk Management System

<sup>1</sup>NCEA = National Center for Environmental Assessment

<sup>1</sup>ATSDR = Agency for Toxic Substances and Disease Registry