Department of Energy
Savannah River Operations Office
P.O. Box A
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JUN - 7 2023

Ms. Susan B. Fulmer, P. G., Manager
Federal Remediation Section
Division of Site Assessment, Remediation and Revitalization
Bureau of Land and Waste Management
South Carolina Department of Health and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201

Mr. Jon Richards
Savannah River Remediation Project Manager
Superfund Division
U. S. Environmental Protection Agency, Region 4
61 Forsyth Street, SW
Atlanta, Georgia 30303

Dear Ms. Fulmer and Mr. Richards:

SUBJECT: Environmental Compliance and Regulatory Document Handbook (SRNS-RP-2022-00330, Revision 0, June 2023) and Savannah River Site's Responses to the Regulatory Comments on the Revision 0a Document

The U. S. Department of Energy (DOE) is submitting the subject information for your review and approval. The Savannah River Site (SRS) submitted the updated EC&ACP Regulatory Document Handbook (SRNS-RP-2022-00330, Revision 0a, November 2022) for your review on November 16, 2022. The SRS received comments from the South Carolina Department of Health and Environmental Control (SCDHEC) on March 1, 2023. The SRS received comments from the U.S. Environmental Protection Agency (EPA) on March 14, 2023 and March 28, 2023. The draft SRS' responses to the SCDHEC's and EPA's comments were submitted for review on May 3, 2023. The SCDHEC and EPA responded on May 16, 2023 and May 22, 2023, respectively, that the draft responses to their comments were acceptable. SRS has finalized the responses and incorporated them into the Revision 0 document.

Please review the enclosures and provide your response within thirty (30) days of receipt. The effort and time that the SCDHEC and EPA have given on the subject document are greatly appreciated.

JUN - 7 2023

Questions from you or your staff may be directed to me at (803) 952-8365.

Sincerely,

Brian T. Hennessey Digitally signed by Brian T. Hennessey
Date: 2023.06.07 09:38:26 -04'00'

Brian T. Hennessey
FFA Project Manager, DOE-Savannah River
Remediation and Deactivation & Decommissioning Division

RDDD-23-012

Enclosures:
1. Environmental Compliance and Regulatory Document Handbook (SRNS-RP-2022-00330, Revision 0, June 2023)
2. SRS Responses to South Carolina Department of Health and Environmental Control Comments on the EC&ACP Regulatory Document Handbook (SRNS-RP-2022-00330, Revision 0a, November 2022)
3. SRS Responses to U.S. Environmental Protection Agency Comments on the EC&ACP Regulatory Document Handbook (SRNS-RP-2022-00330, Revision 0a, November 2022)

cc w/o encl:
J. Blalock, SCDHEC-Columbia
G. K. Taylor, SCDHEC-Columbia
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SRS Responses to South Carolina Department of Health and Environmental Control Comments on the EC&ACP Regulatory Document Handbook, SRNS-RP-2022-00330, Revision 0a, November 2022 Savannah River Site, South Carolina

Comments Received: March 1, 2023

Responsible Party For All Comments: Dena Brett, (803) 952-6031, dena.brett@srs.gov, and/or Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

The Department has reviewed the EC&ACP Regulatory Document Handbook and has the following comments.

The following items/subsections are included in the documents but were omitted from the formats in the Rev. 0a handbook:

1. Module F-2 RFI/RI Work Plan, page 1. Section 1.2 Regulatory Background in recent documents contains a statement that addresses the applicable FFA appendix for the OU. This subsection in the proposed format does not.

   Response: Agree.

   The F-2 RFI/RI Work Plan Format, Section 1.2 Regulatory Background, will be revised to include a statement that addresses the applicable FFA appendix for the OU as shown below.

   " …of RCRA and CERCLA. The status of the OU as a RCRA/CERCLA OU or CERCLA-only OU and the applicable FFA appendix is identified."

2. Module F-2 RFI/RI Work Plan, page 4. Section 3.5 Exposure Media Characterization should include the exposure route(s) and receptor(s) in this subsection.

   Response: Clarification.

   A description of the exposure routes and receptors is provided in Section 3.2, Conceptual Site Model of the F-2 RFI/RI Work Plan Format. The discussion of the conceptual site model (CSM) was relocated before Section 3.3 Primary Source Characterization, Section 3.4 Secondary Source Characterization, and Section 3.5 Exposure Media Characterization, because these sections refer to the CSM. No change to the F-2 RFI/RI Work Plan Format for this comment is proposed.

3. Module F-2 RFI/RI Work Plan, page 9. Section 7.1 List of Sampling/Collection Equipment in recent documents includes a discussion of equipment decontamination procedures, sample documentation, chain-of-custody, sample management and shipping, and data validation and management. This subsection in the proposed format does not appear to address these items.

   Response: Agree.

The F-2 RFI/RI Work Plan Format, Section 7.1 List of Sampling/Collection Equipment, will be revised to include a more detailed discussion of applicable procedures as shown below.

"…with preservatives, and coolers. References to applicable SRS ~~sampling~~ procedures are provided in this section~~.~~ (i.e., equipment decontamination procedures, sample documentation, chain-of-custody, sample management and shipping, and data validation and management)."

4. Module F-4, CMS/FS Format, page 3. Section 2.1 Remedial Action Objectives in recent documents contains a statement addressing the contaminants of interest. This subsection in the proposed format does not.

Response: Agree with clarification.

Section 2.1 Remedial Action Objectives was streamlined in the proposed F-4 CMS/FS Format to not include a separate subsection for the description of the contaminants of interest. Section 4.1 in both the F-3 RFI/RI/BRA Format and the F-5 Combined RFI/RI/BRA/CMS/FS Format provides a clearer description of RAOs. For consistency, the RAO description in the F-3 and F-5 Formats, Section 4.1, will replace the text in the F-4 CMS/FS Format, Section 2.1, and a statement will be added to all three formats to address the contaminants of interest as shown below.

Text will be added to Section 4.1 in both the F-3 RFI/RI/BRA Format and the F-5 Combined RFI/RI/BRA/CMS/FS Format as follows:

"The purpose of this section is to present the problem statement(s) by OU subunit as presented in the OU-specific scoping summary document. A statement that addresses the contaminants of interest for the OU will be included in this section. The RAOs are defined specifically for the problem to which they apply. The RAOs will specify the exposure pathway to be mitigated and the receptor to be protected. Key uncertainties specific to the remedial decisions identified for each OU subunit will also be presented. RAOs are typically listed in bullet form."

The text in F-4 CMS/FS Format, Section 2.1, will be replaced with the revised text from Formats F-3 and F-5 as follows:

"~~This section briefly describes the remedial action objectives (RAOs) for the OU and how they mitigate site risks (e.g., prevent contamination from reaching the groundwater by treating the contaminated soils, etc.). The reasonably anticipated future land use (i.e., industrial, unrestricted, etc.) is identified with a description of how the RAOs support the future land use.~~

The purpose of this section is to present the problem statement(s) by OU subunit as presented in the OU-specific scoping summary document. A statement that addresses the contaminants of interest for the OU will be included in this section. The RAOs are defined specifically for the problem to which they apply. The RAOs will specify the exposure pathway to be mitigated and the receptor to be protected. Key uncertainties specific to the remedial decisions identified for each OU subunit will also be presented. RAOs are typically listed in bullet form."

5. Module F-10, CMIP/RAIP Format, page 2. Section 1.3 Nature and Extent of Contamination in recent documents contains a brief discussion of site-specific factors. This subsection in the proposed format does not.

   Response: Agree.

   Section 1.3 in the F-10 CMIP/RAIP Format will be revised to include a statement that site-specific factors will be discussed if applicable. It is proposed that a discussion of site-specific factors will be included in Section 1.3 and not in a separate subsection as shown below.

   "…targeted for RA are provided. A description of any key site-specific factors is also included if applicable."

6. Module F-15, Data Usability Report, page 7. Previous documents include a subsection 3.11 Split Samples Comparability and a corresponding Table 14 Split Samples. These do not appear to be included in the proposed format.

   Response: Agree.

   The F-15 Data Usability Report Format will be revised to include Subsection 3.11 Split Samples Comparability and a corresponding Table 14 Split Samples as shown below.

   "3.11 Split Samples Comparability

   This section discusses samples taken from the same locations and analyzed by similar methods at different laboratories. Identification of the split samples is presented in tabular format as shown in the example below.

Table 14. Split Samples"

Station ID	Sample ID	Sample Interval	Date/Time Collected	Sample Type	Media	Lab
A013-02	A013-0000006	1-4	01/20/22 0950	REG	SOIL	GEL
A013-02	A013-0000007	1-4	01/20/22 0950	SPL	SOIL	TAL

7. Module F-17, EMR, page 2. Previous documents include a discussion of any potential deviations from the monitoring plan. This does not appear to be addressed in the proposed format.

   Response: Clarification.

   The F-17 EMR Format, Section 2.0 Operable Unit Description and History, third bullet, provides a description that deviations from the monitoring plan may be included in this section. No change to the F-17 EMR Format is proposed.

8. Module F-20, RADP, page 2. Previous documents include the following subsections of Section 1.0 General Description: Nature and extent of contamination, remedial action (selected), and community relations. The proposed format does not appear to include these items.

   Response: Clarification.

   The proposed F-20 RADP Format is consistent with all RADP documents that have been submitted and approved (4 total) since 2014. This format was developed with tri-party approval prior to the submittal of the RADP for the 488-4D Ash Landfill and 488-2D Ash Basin (SRNS-RP-2014-00459, June 2014). Subsequent RADPs for the 484-1D Ash Basin and 489-D Coal Pile Runoff Basin (SRNS-RP-2015-00196, May 2016), C-Area Groundwater Operable Unit (SRNS-RP-2018-00807, October 2018), and P-Area Groundwater Operable Unit (SRNS-RP-2019-00195, July 2019) follow this format. The additional subsections noted in the comment - nature and extent of contamination, remedial action and community relations are included in the more detailed F-10 CMIP/RAIP Format. As part of the document scoping before the first RADP submittal in 2014, the Core Team agreed to a more abbreviated format (to not include these subsections) and simply refer to details in the RSER/EE/CA document. No change to F-20 RADP Format is proposed.

Also the following editorial comment were noted.

1. Executive Summary, page 1. The acronym for operable units (OUs) is defined in the first sentence of the first paragraph and is defined again in the third sentence of the first paragraph.

   Response: Agree.

The definition of the OU acronym will be removed from the third sentence.

2. Constituents of Concern (COC) Refinement Process, COC-1, Radioactive Decay, page 4. In the first sentence, the parentheses around "RFI/" appear to have been included in error.

   Response: Agree.

   The parentheses around "RFI" in the acronym RFI/RI/BRA will be deleted.

3. Constituents of Concern (COC) Refinement Process, COC-1, page 5. The second sentence of the last paragraph defines the acronym for Remedial Alternative Objectives as RAOs, but the acronym list defines RAO as remedial action objective.

   Response: Agree.

   Remedial Alternative Objectives (RAOs) will be corrected to Remedial Action Objectives (RAOs).

GENERAL COMMENTS

1. It is unclear why Part I (RCRA/CERCLA Document Formats) of the Handbook does not identify the supporting guidance document(s) associated with documents F-1 through F-24. For example, F-2 (Resource Conservation and Recovery Act Facility Investigation/Remedial Investigation Work Plan Format) and F-14 (Sampling and Analysis Plan Format) should identify EPA's *Guidance on Systematic Planning Using the Data Quality Objectives Process*, EPA/240/B-06/001, dated February 2006 (EPA QA/G-4), as the guidance document for developing data quality objectives (DQOs). As another example, F-6 (Statement of Basis/Proposed Plan Format) and F-7 (Statement of Basis/Proposed Plan Fact Sheet Format) should identify EPA's *A Guide to Preparing Superfund Proposed Plans, Records of Decision, and Other Remedy Selection Decision Documents*, EPA 540-R-98-31, dated July 1999, as the guidance document for preparing Proposed Plans and Fact Sheets. Identifying the supporting guidance documents would be useful in ensuring that the documents discussed in F-1 through F-24 include the level of detail required for each report. Please revise Part I to identify the supporting guidance document(s) associated with documents F-1 through F-24.

Response: Agree with clarification.

Guidance documents will be identified in individual document formats located in Part I (RCRA/CERCLA Document Formats) where appropriate. While the document formats generally include the level of detail identified in guidance materials, document templates in the EC&ACP Regulatory Document Handbook are tailored specifically for the SRS Federal Facility Agreement (FFA) program based on previous regulatory reviews/comments on SRS RCRA/CERCLA documents and Core Team (i.e., USEPA, SCDHEC, and USDOE) agreements. Specific language or formats requested by USEPA and SCDHEC from these regulatory reviews are incorporated where appropriate. In addition, some document formats were developed specifically for the SRS FFA program from historical regulatory reviews and are not associated with guidance documents.

Supporting guidance documents will be referenced in individual document templates where appropriate as follows:

F-1 Remedial Site Evaluation Report Format

***Guidance for Performing Preliminary Assessments Under CERCLA*, OSWER Directive 9345.0-01A, Office of Emergency and Remedial Response, U.S. Environmental Protection Agency, Washington, D.C., September 1991.**

***Improving Site Assessment: Integrating Removal and Remedial Site Evaluations*, OSWER Directive 9360.0-39, Office of Emergency and Remedial Response, U.S. Environmental Protection Agency, Washington, D.C., April 2000.**

F-2 RCRA Facility Investigation/Remedial Investigation Work Plan Format

***Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA, Interim Final*, OSWER Directive 9355.3-01, Office of Emergency and Remedial Response, U.S. Environmental Protection Agency, Washington, D.C., October 1988.**

***Guidance on Systematic Planning Using the Data Quality Objectives Process*, EPA QA/G-4, EPA/240/B-06/001, Office of Environmental Information, U.S. Environmental Protection Agency, Washington, D.C., February 2006.**

***Area Completion Projects Programmatic Quality Assurance Project Plan for Environmental Data Collection and Management*, ERD-AG-2005-00001, Revision 5, Savannah River Site, Aiken, SC, 2012.**

F-3 RCRA Facility Investigation/Remedial Investigation/Baseline Risk Assessment Format

***Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA, Interim Final*, OSWER Directive 9355.3-01, Office of Emergency and Remedial Response, U.S. Environmental Protection Agency, Washington, D.C., October 1988.**

***Risk Assessment Guidance For Superfund, Volume 1, Human Health Evaluation Manual (Part A)*, Interim Final, EPA 540/1-89/002, Office of Emergency and Remedial Response, U.S. Environmental Protection Agency, Washington, D.C., December 1989.**

***Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments,* Interim Final, OSWER Directive 9285.7-25, Office of Solid Waste and Emergency Response, U.S. Environmental Protection Agency, Washington, D.C., June 1997.**

***Guidelines for Ecological Risk Assessment*. Risk Assessment Forum, EPA/630/R-95/002F, U.S. Environmental Protection Agency, Washington, D.C., April 1998.**

***Region 4 Ecological Risk Assessment Supplemental Guidance to ERAGS,* Scientific Support Section, Superfund Division, U.S. Environmental Protection Agency, Region 4, Atlanta, GA, March 2018.**

***Region 4 Human Health Risk Assessment Supplemental Guidance*, Scientific Support Section, Superfund Division, U.S. Environmental Protection Agency, Region 4, Atlanta, GA, March 2018.**

F-4 Corrective Measures Study/Feasibility Study Format

***Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA, Interim Final*, OSWER Directive 9355.3-01, Office of Emergency and Remedial Response, U.S. Environmental Protection Agency, Washington, D.C., October 1988.**

F-5 Combined RCRA Facility Investigation/Remedial Investigation/Baseline Risk Assessment/Corrective Measures Study/Feasibility Study Format

***Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA, Interim Final*, OSWER Directive 9355.3-01, Office of Emergency and Remedial Response, U.S. Environmental Protection Agency, Washington, D.C., October 1988.**

***Risk Assessment Guidance For Superfund, Volume 1, Human Health Evaluation Manual (Part A)*, Interim Final, EPA 540/1-89/002, Office of Emergency and Remedial Response, U.S. Environmental Protection Agency, Washington, D.C., December 1989.**

***Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments,* Interim Final, OSWER Directive 9285.7-25, Office of Solid Waste and Emergency Response, U.S. Environmental Protection Agency, Washington, D.C., June 1997.**

***Guidelines for Ecological Risk Assessment.* Risk Assessment Forum, EPA/630/R-95/002F, U.S. Environmental Protection Agency, Washington, D.C., April 1998.**

***Region 4 Ecological Risk Assessment Supplemental Guidance to ERAGS,* Scientific Support Section, Superfund Division, U.S. Environmental Protection Agency, Region 4, Atlanta, GA, March 2018.**

***Region 4 Human Health Risk Assessment Supplemental Guidance*, Scientific Support Section, Superfund Division, U.S. Environmental Protection Agency, Region 4, Atlanta, GA, March 2018.**

F-6 Statement of Basis/Proposed Plan Format

***A Guide to Preparing Superfund Proposed Plans, Records of Decision, and Other Remedy Selection Decision Documents*, OSWER Directive 9200.1-23P, Office of Solid Waste and Emergency Response, U.S. Environmental Protection Agency, Washington, D.C., July 1999.**

F-7 Statement of Basis/Proposed Plan Fact Sheet Format

***A Guide to Preparing Superfund Proposed Plans, Records of Decision, and Other Remedy Selection Decision Documents*, OSWER Directive 9200.1-23P, Office of Solid Waste and Emergency Response, U.S. Environmental Protection Agency, Washington, D.C., July 1999.**

F-8 Record of Decision Format

***A Guide to Preparing Superfund Proposed Plans, Records of Decision, and Other Remedy Selection Decision Documents*, OSWER Directive 9200.1-23P, Office of Solid Waste and Emergency Response, U.S. Environmental Protection Agency, Washington, D.C., July 1999.**

F-9 Land Use Control Implementation Plan Format

***Assuring Land Use Controls at Federal Facilities*, EPA Region IV Policy, U.S. Environmental Protection Agency, Region 4, Federal Facilities Branch, Atlanta GA, April 1998.**

F-10 Corrective Measures Implementation Plan/Remedial Action Implementation Plan Format

***Close Out Procedures for National Priorities List Sites*, USEPA OLEM Directive 9320.2-23, Office of Superfund Remediation and Technology Innovation, U.S. Environmental Protection Agency, Washington, D.C., June 2022.**

***Guidance for Management of Superfund Remedies in Post Construction*, USEPA OLEM Directive 9200.3-105, Office of Superfund Remediation and Technology Innovation, U.S. Environmental Protection Agency, Washington, D.C., February 2017.**

F-11 Post-Construction Report Format

***Close Out Procedures for National Priorities List Sites*, USEPA OLEM Directive 9320.2-23, Office of Superfund Remediation and Technology Innovation, U.S. Environmental Protection Agency, Washington, D.C., June 2022.**

***Guidance for Management of Superfund Remedies in Post Construction*, USEPA OLEM Directive 9200.3-105, Office of Superfund Remediation and Technology Innovation, U.S. Environmental Protection Agency, Washington, D.C., February 2017.**

F-12 Corrective Measures Implementation Report/Remedial Action Completion Report Format

***Close Out Procedures for National Priorities List Sites*, USEPA OLEM Directive 9320.2-23, Office of Superfund Remediation and Technology Innovation, U.S. Environmental Protection Agency, Washington, D.C., June 2022.**

***Guidance for Management of Superfund Remedies in Post Construction*, USEPA OLEM Directive 9200.3-105, Office of Superfund Remediation and Technology Innovation, U.S. Environmental Protection Agency, Washington, D.C., February 2017.**

F-13 Post-Construction Report/Corrective Measures Implementation Report/ Remedial Action Completion Report Format

***Close Out Procedures for National Priorities List Sites*, USEPA OLEM Directive 9320.2-23, Office of Superfund Remediation and Technology Innovation, U.S. Environmental Protection Agency, Washington, D.C., June 2022.**

***Guidance for Management of Superfund Remedies in Post Construction*, USEPA OLEM Directive 9200.3-105, Office of Superfund Remediation and Technology Innovation, U.S. Environmental Protection Agency, Washington, D.C., February 2017.**

F-14 Sampling and Analysis Plan Format

***Uniform Federal Policy for Quality Assurance Project Plans*, EPA-505-B-04-900A, DOD-DTIC-ADA-427785, Intergovernmental Data Quality Task Force (U.S. Environmental Protection Agency, U.S. Department of Defense, U.S. Department of Energy), Version 1 Final, March 2005.**

***Guidance on Systematic Planning Using the Data Quality Objectives Process*, EPA QA/G-4, EPA/240/B-06/001, Office of Environmental Information, U.S. Environmental Protection Agency, Washington, D.C., February 2006.**

***Area Completion Projects Programmatic Quality Assurance Project Plan for Environmental Data Collection and Management*, ERD-AG-2005-00001, Revision 5, Savannah River Site, Aiken, SC, April 2012.**

F-15 Data Usability Report Format

***Uniform Federal Policy for Quality Assurance Project Plans*, EPA-505-B-04-900A, DOD-DTIC-ADA-427785, Intergovernmental Data Quality Task Force (U.S.**

Environmental Protection Agency, U.S. Department of Defense, U.S. Department of Energy), Version 1 Final, March 2005.

***Area Completion Projects Programmatic Quality Assurance Project Plan for Environmental Data Collection and Management*, ERD-AG-2005-00001, Revision 5, Savannah River Site, Aiken, SC, April 2012.**

F-16 Performance Evaluation Report Format

This document template was developed specifically for the SRS FFA program and is not associated with a specific guidance document. No change to Document Format F-16 is proposed.

F-17 Effectiveness Monitoring Report Format

This document template was developed specifically for the SRS FFA program and is not associated with a specific guidance document. No change to Document Format F-17 is proposed.

F-18 Removal Site Evaluation Report Format

***Removal Actions Under CERCLA*, Office of Environmental Restoration Regulatory Integration Division (EM-431), Office of Environmental Guidance RCRA/CERCLA Division (EH-231), U.S. Department of Energy, Washington, D.C., September 1994.**

F-19 Removal Site Evaluation Report/Engineering Evaluation/Cost Analysis Format

***Conducting Non-Time Critical Removal Actions Under CERCLA*, OSWER Directive 9360.0-32, Office of Solid Waste and Emergency Response, U.S. Environmental Protection Agency, Washington, D.C., December 1993.**

***Removal Actions Under CERCLA*, Office of Environmental Restoration Regulatory Integration Division (EM-431), Office of Environmental Guidance RCRA/CERCLA Division (EH-231), U.S. Department of Energy, Washington, D.C., September 1994.**

F-20 Removal Action Design Plan Format

This document template was developed specifically for the SRS FFA program and is not associated with a specific guidance document. No change to Document Format F-20 is proposed.

F-21 Removal Action Report Format

This document template was developed specifically for the SRS FFA program and is not associated with a specific guidance document. No change to Document Format F-21 is proposed.

F-22 Comment Response Format

This document template was developed specifically for the SRS FFA program and is not associated with a specific guidance document. No change to Document Format F-22 is proposed.

F-23 Facility Decommissioning Evaluation Format

This document template was developed specifically for the SRS FFA program and is not associated with a specific guidance document. No change to Document Format F-23 is proposed.

F-24 Decommissioning Project Final Report Format

This document template was developed specifically for the SRS FFA program and is not associated with a specific guidance document. No change to Document Format F-24 is proposed.

For documents formats where guidance documents are referenced, the following footnote will be included:

"[1] Document formats included in the EC&ACP Regulatory Document Handbook are specific for the SRS Federal Facility Agreement (FFA) program and take into consideration available guidance materials and Core Team (i.e., USEPA, SCDHEC, and USDOE) agreements on regulatory documentation."

Responsible Party: Dena Brett, (803) 952-6031, dena.brett@srs.gov

2. Screening of groundwater or surface water constituents using comparisons to Applicable or Relevant and Appropriate Requirements (ARARs) deviates from current EPA policy. In particular, the use of Maximum Contaminant Levels (MCLs) may not be adequately conservative because they may not be risk-based. It is recommended that an MCL screen be conducted on groundwater/surface water analytes either in parallel with or after an initial screen with EPA's Regional Screening Levels (RSLs) to ensure that risk-based screening has been conducted.

Response: Clarification.

The methodology for screening of groundwater/surface water (GW/SW) is consistent with the streamlining agreements made with the Core Team (i.e., USEPA, SCDHEC, and USDOE) subject matter experts (SMEs) in the 2004/2005 timeframe during the SRS Area Completion Strategy scoping. The Core Team agreement is based on a graded approach that recognizes the MCL as an enforceable regulatory standard, i.e., ARAR under CERCLA. Risk-based screening was deemed unnecessary for constituents that have an MCL since the MCL takes precedence over the RSL in remedy selection. Per these agreements, risk-based screening was performed for GW/SW constituents only if there is no MCL.

The USEPA Core Team member expressed a concern regarding surface water screening at the Core Team Refresher Training held at the SREL Conference Center on December 8, 2022. The methodology currently described in draft Protocol HH-4 is consistent with previous agreements to screen against the MCL; in the absence of an MCL, screening is performed against the lower of the AWQC and the tap water RSL. USEPA expressed a concern that an AWQC screen was not performed for all surface water constituents and recommended an independent AWQC screen, whether an MCL is available or not.

The current description of the GW/SW in Protocol HH-4 does not distinguish between groundwater or surface water (which includes the AWQC screen). To address the USEPA concern in the framework of the Core Team streamlining agreements, the text and Table 2. Sample Surface Water Comparison in Protocol HH-4, Human Health Constituents of Potential Concern, will be revised as shown below.

"Data Screening for Groundwater or Surface Water Media

~~**Maximum detected concentrations of each constituent are compared to drinking water MCLs. In the absence of an MCL, the lowest value for the tap water PRG/RSL or promulgated ambient water quality criteria (AWQC, federal/state) is used as a screening threshold. Constituents that exceed the MCL/(PRG/RSL or AWQC) thresholds are further evaluated in the refinement of COCs step (i.e., *Constituents of Concern (COC) Refinement Process Protocol* [COC-1]). If no constituents exceed the MCL/(PRG/RSL or AWQC) comparison, then this part of the analysis is complete. Table 2 is a sample MCL comparison table for surface water media."**~~

For groundwater, the maximum detected concentrations of each constituent are compared to drinking water MCLs. In the absence of an MCL, the tap water RSL/PRG is used as a screening threshold. Constituents that 1) exceed the MCL screen, or 2) do not have a MCL and exceed the risk-based threshold are further evaluated in the refinement of COCs step (i.e., Constituents of Concern (COC) Refinement Process Protocol [COC-1]).

For surface water, the maximum detected concentration of each constituent is compared to

the drinking water MCL and ambient water quality criteria (AWQC, Consumption of Water plus Organism). In the absence of an MCL or AWQC, the tap water RSL/PRG is used as a screening threshold. Constituents that 1) exceed either the MCL or the AWQC screen, or 2) do not have an MCL or an AWQC and exceed the risk-based threshold are further evaluated in the refinement of COCs step (i.e., Constituents of Concern (COC) Refinement Process Protocol [COC-1]).

If no constituents exceed any of the screening comparisons, then this part of the analysis is complete. Table 2 is a sample comparison table for surface water media. (Note the groundwater table is similar to surface water but does not include an AWQC comparison)."

Table 2. (Sample) Surface Water Comparison to MCLs, AWQC and RSLs/PRGs

Analyte	Detected Maximum Concentration	MCL	Result > MCL?	AWQC	Result > AWQC?	Tap Water RSL/PRG	Result > RSL/PRG?
Inorganics *(ug/L)*							
Constituent A	3.62E+00	6.0E+00	no	5.60E+00	no		
Constituent B	3.05E+00	1.0E+01	no	1.00E+01	no		
Constituent C	1.40E+00	4.0E+00	no	NA	---		
Constituent D	2.31E+01	5.0E+00	**YES**	NA	---		
Constituent E	1.47E+02	1.0E+02	**YES**	NA	---		
Constituent F	8.05E+02	NA	---	1.30E+03	no		
Constituent G	1.01E+00	2.0E+00	no	5.00E-02	**YES**		
Constituent H	5.80E+03	NA	---	NA	---	6.00E+03	no
Organics *(ug/L)*							
Constituent I	4.02E+00	2.0E-01	**YES**	3.80E-03	**YES**		
Constituent J	3.63E+01	5.0E+00	**YES**	2.50E+00	**YES**		
Constituent K	5.06E+02	1.0E+03	no	1.30E+03	no		
Pesticides/PCBs *(ug/L)*							
Constituent L	2.22E-01	2.0E+00	no	8.00E-04	**YES**		
Constituent M	1.16E-02	NA	---	NA	---	7.80E-03	**YES**
Radionuclides *(pCi/L)*							
Constituent N	2.30E+01	1.5E+01	**YES**	NA	---		
Constituent 0	1.37E+03	2.0E+04	no	NA	---		

MCL = Maximum Contaminant Level
AWQC - Ambient Water Quality Criteria (For Consumption of Water & Organism)
RSL = Tapwater Regional Screening Level
PRG = Tapwater Preliminary Remediation Goal
NA - Not available

Constituents to be carried forward for further evaluation are highlighted in bold **YES**.

In addition, Appendix C, Human Health Risk Assessment, C.2.2 Surface Water or Groundwater Media in Document Formats F-3 RFI/RI/BRA and F-5 Combined RFI/RI/BRA/CMS/FS will be revised to be consistent with the updated text in the HH-4 protocol.

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

3. The Human Health Receptors and Scenarios, PDF Page 335, does not include a construction worker as a potential future receptor. Given that construction workers, although short-term, may encounter greater exposure levels than other receptors, they should be included in a baseline human health risk assessment (BHHRA). Please revise the Handbook to include a construction worker as a future receptor of interest.

Response: Clarification.

As presented in the Protocol HH-2, Human Health Receptors and Scenarios, standard on-unit hypothetical exposure scenarios include the future industrial worker and the future resident. Protocol HH-2 further states that evaluation of other receptors in addition to the standard receptors will be assessed on a case-by-case basis if it is deemed appropriate by the project-specific Core Team.

The Core Team are the risk managers and decision makers for SRS OU cleanups. They decide upon the receptor scenarios to be evaluated before the investigation Work Plan is developed, based on reasonably anticipated future land use, consistent with OSWER Directive 9355.7-04, *Land Use in the CERCLA Remedy Selection Process*. This allows the Baseline Risk Assessment (BRA) and Feasibility Study to be focused on practicable and cost-effective remedial alternatives designed to meet appropriate remedial action objectives. The construction worker would not be considered a standard receptor at SRS, but if operable units (OUs) are located where future construction is likely or plausible, a construction worker may be considered for risk estimation in addition to the standard default industrial worker. This scenario would be discussed with the Core Team during the Post-Characterization Scoping Phase. The SRS Site Use/Site Clearance program precludes intrusive activities where there is known or potential contamination. No change to the EC&ACP Regulatory Document Handbook is proposed.

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

4. A vapor intrusion (VI) exposure scenario, with accompanying evaluation methodology, is not included in the Handbook. It is noted that inhalation of volatile contaminants is mentioned in the Human Health Receptors and Scenarios protocol (PDF Page 336) as a future residential exposure scenario, but it is unknown whether this refers to inhalation of vapors generated by domestic water use or VI. Please revise the Handbook to include a vapor intrusion scenario, and clarify what is meant by inhalation of volatile contaminants; vapor intrusion and inhalation of volatiles from domestic water use are two different exposure pathways and should be evaluated separately.

Response: Clarification.

SRS agrees that vapor intrusion and inhalation of volatiles from domestic water use are two different exposure pathways. Inhalation of vapors generated by domestic water use includes

activities such as showering, laundering, and dish washing.

In April 2003, SRS conducted an extensive vapor intrusion evaluation under Government Performance and Results Act (GPRA) for 241 buildings located over VOC contaminated groundwater plumes at SRS. The evaluation determined that these buildings did not pose a risk to human receptors via a vapor intrusion pathway. In 2005, SRS provided an updated vapor intrusion evaluation of three buildings at the request of SCDHEC. As documented in a September 30, 2005 memorandum from SCDHEC to USDOE (SCDHEC to USDOE/Savannah River Site Project File EPA ID#SC1 890 008 989), the 2005 evaluation demonstrated that vapor intrusion does not present a problem for existing buildings at SRS. In December 2007, USEPA provided a comment on the *SRS Third Five Year Remedy Review Report for the Savannah River Site* (WSRC-RP-2007-4063, Rev. 0, December 2007) to revise the document to indicate if land use controls (LUCs) address the prevention of unacceptable exposure to human receptors as a result of vapor intrusion. To manage this concern, USDOE agreed to include a LUC objective in future Records of Decision for those OUs located above VOC plumes that would prevent the construction of inhabitable buildings unless an evaluation of indoor air quality is performed. Because any potential exposure to human health from vapor intrusion is already managed by OU-specific LUCs, a vapor intrusion exposure scenario as a standard exposure pathway is not needed in the baseline human health risk assessment (HHRA). The LUC objective specific to vapor intrusion is documented in the EC&ACP Regulatory Document Handbook in Document Format F-8, Record of Decision Format, in Section XI. The USDOE does not anticipate the construction of new facilities over VOC plumes and will evaluate the need for a vapor intrusion evaluation on a case-by-case basis pending future needs.

Text in Protocol HH-2, Human Health Receptors and Scenarios, Future Resident Exposure Scenario, will be revised to clarify what is meant by inhalation of volatile contaminants in SRS risk assessments as shown below.

- **"Exposure to surface water or groundwater (for nonradionuclides – ingestion, inhalation of volatile contaminants (<u>i.e., vapors generated by domestic water use),</u> dermal contact; for radionuclides – ingestion, inhalation (<u>i.e., vapors generated by domestic water use</u>), immersion."**

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

5. The Handbook does not address data sensitivity (i.e., an evaluation of detection limits, reporting limits or, preferably, sample quantitation limits for constituents in media of interest in comparison to applicable health-based screening criteria). Elevated sample quantitation limits may result in some constituents not being identified as COPCs. To ensure that constituents are not overlooked in the risk assessment, please revise the Handbook to include a discussion of sample quantitation limits in comparison to the relevant screening levels.

COPCs predicated on non-detect results should be added to the COPC list and evaluated in the Uncertainty Analysis.

Response: Agree with clarification.

Laboratory contract detection limits/quantification limits are identified in an analytical specifications table in the RFI/RI Work Plan/Sampling and Analysis Plan that is reviewed and approved by the Core Team for each project. The laboratory contract detection limits must meet risk-based thresholds to the extent practical. When considering the detection limits for soil samples, there may be cases in which a given analyte has a detection limit in some samples that is greater than the reported value in other samples. Relatively high detection limits can occur as a result of moisture variations in the soil sample, matrix interferences, or from the need to dilute highly concentrated samples. However, outside of any special circumstances, it is unlikely that constituents are overlooked in the risk assessment based on elevated detection limits that are reported as non-detects. Typically, data groupings have a sufficient number of samples that meet the detection limit requirements and the potentially few samples that may not would not lessen the degree of confidence in the dataset as a whole. During the Post-Characterization Scoping Phase, the Core Team determines if data quantity and quality adequately meets the DQOs agreed to in the RFI/RI Work Plan/Sampling and Analysis Plan.

Document Format F-15, Data Usability Report, will be revised to include an assessment of data sensitivity. A new Section 2.6 Sensitivity and new Section 3.12 Summary of Data Sensitivity Evaluation will be added to discuss method detection limits (MDLs) and sample quantitation limits (SQLs) relative to the risk-based screening criteria as described in the response to Specific Comment #4.

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

6. There is no provision in the Human Health Protocols to address lead exposure in the event that the limits for lead in soil or groundwater are exceeded (i.e., concentrations greater than 400 milligrams per kilogram [mg/kg] or 15 micrograms per liter [µg/L], respectively). Arithmetic mean lead concentrations should be developed and used in biokinetic modeling using the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) Version 2.01 (2021) and the All Ages Lead Model (AALM; EPA 2021). Please revise the Handbook to include a discussion on the use of the most recent versions of the IEUBK and the AALM to evaluate potential risks from lead exposure.

Response: Clarification.

The lead screening values identified in the RSL table (resident soil = 400 mg/kg, industrial soil = 800 mg/kg, Tap Water = 15 µg/L, MCL = 15 µg/L) are based on the back-calculated

values using the IEUBK model, analysis of the NHANES III, and USEPA Action Level for water as quoted from the USEPA RSL website below.

"EPA has no consensus reference dose (RfD) or oral slope factor for inorganic lead, so it is not possible to calculate screening levels as done for other chemicals. EPA considers lead to be a special case because of the difficulty in identifying the classic "threshold" needed to develop an RfD. EPA therefore evaluates lead exposure by using blood-lead modeling, such as the Integrated Exposure-Uptake Biokinetic Model (IEUBK). The EPA Office of Solid Waste has also released a detailed directive on risk assessment and cleanup of residential soil lead. The directive recommends that soil lead levels less than 400 mg/kg are generally safe for residential use. Above that level, the document suggests collecting data and modeling blood-lead levels with the IEUBK model. For the purposes of screening, therefore, 400 mg/kg is recommended for residential soils. For water, we suggest 15 µg/L (the EPA Action Level in water), and for air, the National Ambient Air Quality Standard of 0.15 µg/m^3. An updated screening level for soil lead at commercial/industrial (i.e., non-residential) sites of 800 part per million (ppm) is based on a recent analysis of the combined phases of the National Health and Nutrition Examination Survey (NHANES III) that choose a cleanup goal protective for all subpopulations."

Per the USEPA description above, the lead screening values identified in the USEPA RSL table are considered conservative/protective thresholds. Lead is treated as a noncarcinogen in SRS risk assessments by performing a ratio of the 95% UCL exposure point concentration to the lead RSL, similar to an HQ calculation. Lead results with an HQ equal to or greater than 1 are carried forward as constituents of concern and further evaluated in the Protocol COC-1, Constituents of Concern (COC) Refinement Process. Using the 95% UCL is a conservative approach when compared to the IUEBK and AALM modeling that uses an arithmetic mean. Modeling using the IEUBK and AALM models based on the arithmetic mean may result in less conservative (higher) thresholds. In addition, the CERCLA value of 400 mg/kg was set by the USEPA Office of Solid Waste Emergency Response and adopted as a to-be-considered (TBC) for chemical-specific ARAR screening purposes.

The need to perform lead modeling should the 95% UCL exceed the screening levels will be discussed with the project Core Team in the Post-Characterization Scoping Phase when appropriate. No change to the EC&ACP Regulatory Document Handbook is proposed.

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

7. It is unclear whether protocol DG-3, Addressing the Combined Surficial Risks from Adjacent Units, applies to human health and ecological risk assessment activities since the decisions made regarding exposure units appear to be made by an undefined Core Team. Identification of exposure units is relevant to ecological risk in that respective data are usually pooled when developing exposure estimates, and ecological preliminary remedial goals (PRGs) are subject to the application of area or population area use factors (AUFs and PAUFs). The latter has the

potential to substantially increase PRGs when based on large home range wildlife receptors and smaller exposure units. Given that the SRS contains many exposure units in which large home range receptors can be exposed, expanding exposure profiles to units outside of the subunit or operable unit boundaries may be relevant. Additionally, institutional controls might also prevent some ecological receptors from accessing an exposure unit. These and other details should be evaluated when defining ecological exposure units, yet the protocol relies on a Core Team whose members are undefined and who may not have the appropriate experience in performing ecological risk assessments. Please revise protocol DG-3 of the Handbook to specifically identify exposure unit identification activities that apply to ecological risk, and provide details on how unit determinations will be made with respect to Core Team members and stated responsibilities.

Response: Clarification.

As explained in the Executive Summary of the EC&ACP Regulatory Document Handbook, Design Teams (SMEs) from the three agencies collaborated in developing the technical protocols and are proficient in their application and use. SMEs perform the technical operations using the protocols and provide information for the Core Team. Core Team members are defined as the designated risk managers and decision makers representing each agency (i.e., USEPA, SCDHEC, USDOE). Core Team members agree on exposure units, receptor scenarios, and all of the other factors considered in estimating human health and ecological risk, to define specific problems warranting response action and the objectives of those actions.

Protocol DG-3, Addressing the Combined Surficial Risks from Adjacent Units, was developed by Design Teams and approved by the Core Team to support the Area Completion Strategy in the 2004/2005 timeframe. It applies to human receptors only and describes how to address combined surficial risk from adjacent units over a large area (exposure area) in an industrial setting. The purpose of the protocol was to outline a strategy for evaluating an industrial area with multiple subunits that are interspersed with unimpacted areas using an area-weighted approach.

Ecological risk assessment was not considered in this effort because the industrial setting that this protocol pertains to does not provide suitable habitat for wildlife receptors. The discrete exposure areas to be considered in the risk assessment are agreed to by the project Core Team during the Post-Characterization Scoping Phase. No change to Protocol DG-3, Addressing Combined Surficial Risk from Adjacent Units, is proposed.

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

8. The description of ecological PRG derivation, provided in protocol ECO-6 (Ecological Preliminary Remedial Goals), is ambiguous and does not incorporate exposure unit determination information that should be developed in DG-3, Addressing the Combined

Surficial Risks from Adjacent Units. These shortcomings are associated with use of AUFs versus PAUFs and the potential for excess exposure risks from contaminated areas within the SRS and adjacent exposure units. First, the description of PRG derivation includes identification of both AUFs and PAUFs without an explanation of how, when and/or where they will be used. If it is the intent to use PAUFs over AUFs, this should be specifically stated. In this case, there is little to no utility in including AUFs in the provided example tables. Notwithstanding this decision, it should be recognized that use of both AUF and PAUFs for operable units that are adjacent or near other units that have excess exposure risks can ultimately produce PRGs that are not protective. Given this uncertainty, it is recommended that a range of PRGs be derived using both AUFs and PAUFs so that agency stakeholders can assess protectiveness with respect to exposure risks from adjacent areas of concern and exposure units. In this sense, ecological PRG derivation should provide information on the connectivity of the site to adjacent areas of concern and exposure units. Note that this information is also germane to and should be described in protocol DG-3 as described in the previous general comment. Please revise protocol ECO-6 to include the recommendations described in this comment.

Response: Agree with clarification.

See response to General Comment #7 above. Protocol DG-3, Addressing the Combined Surficial Risks from Adjacent Units, applies to human receptors in an industrial setting. Exposure areas to be considered in the risk assessment are agreed to by the project Core Team during the Post-Characterization Scoping Phase. In general, the SRS cleanup program, as outlined in the FFA, identifies specific OUs for evaluation and makes final remedial decisions on an OU basis. Exceptions include units in an Area Closure which is in an industrial setting and not subject to a high level of rigor for the ecological evaluation. Another exception is the SRS Integrator Operable Unit (IOU) program which are large scale watershed-level evaluations for which area use factors are not applied.

The use of receptor-specific area use factors (AUFs)/population area use factors (PAUFs) is first presented in Protocol COC-1, Constituents of Concern Refinement Process, (i.e., uncertainty evaluation). Uncertainty tables/PAUF-adjusted HQs are provided for all receptors as an attachment to the ERA as identified in the Document Format F-3, RFI/RI/BRA Format, and Document Format F-5, Combined RFI/RI/BRA/CMS/FS Format.

As a protective assumption appropriate for ecological risk screening, the AUF is set to 1 when calculating the screening level and refinement level hazard quotients (HQs), making the conservative assumption that the animal receives all of its exposure from the contaminated site. The AUF will continue to be applied in this manner, per Core Team agreement, for units where this conservative assumption is deemed warranted. The PAUF-adjusted HQs are used to help determine whether an ecological COC should be carried forward for further remedial investigation, i.e., identified as a refined constituent

of concern (RCOC). Protocol ECO-6, Ecological Preliminary Remedial Goals, applies to these constituents.

Text will be added to Protocol ECO-6, Ecological Preliminary Remedial Goals, that recognizes that PRGs may be calculated using the receptor-specific AUFs as determined by the project Core Team as shown below.

"…The PAUF is calculated based on the ratio of the operable unit (OU) area to the known home range of the receptor to reflect the ~~fact that~~ receptor's ~~utilize~~ utilization of an area that extends beyond ~~just~~ the contaminated site.

Area of OU/ PAUF = OU specific PAUF

PRG = RSV / PAUF

Note that PRGs may also be calculated using the receptor-specific AUF as recommended by the project Core Team."

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

9. Statements made in protocol DP-3, Surrogates for Non-Detects, are incorrect and respective methodology should be revised to better utilize existing guidance on deriving exposure estimates for datasets which contain non-detection values. First, ProUCL software does have the ability to consider non-detects when calculating mean values and 95% upper confidence limits (95UCL). ProUCL uses the Kaplan-Meier (KM) method to estimate mean and 95UCL values in datasets that contain non-detects. Use of KM methods are preferred opposed to using half of the reported detection limit (surrogate values). In addition to DP-3, use of surrogate values is also described in protocol DP-1, Unit-Source Data Processing, in the context of deriving average values. Please revise protocols DP-1 and DP-3 to replace the surrogate value method with the ProUCL KM estimation method; note that this revision also includes removing the sentence in protocol DP-3 which states that ProUCL software does not consider non-detects.

Response: Agree with clarification.

Protocol DP-1, Unit Source Data Processing, will be revised to identify use of the ProUCL software to calculate the mean and clarify the reference to DP-3 as shown below.

"Calculate Unit-Source Average Values

For each constituent in each exposure group of unit-source samples, determine the ~~arithmetic~~ average value of all samples ~~using surrogate values for non-detected results~~. The *USEPA ProUCL for Environmental Applications for Data Sets With and Without Nondetect Observations* software package should be used to calculate the mean value. ProUCL uses the

Kaplan-Meier (KM) method to estimate the mean value for datasets with nondetects. If ProUCL is not able to process the data due to a low frequency of detects or limited number of samples, then calculate the mean using surrogate values for the non-detect results. Protocol DP-3, Surrogates for Non-Detects, provides further information on the methodology for determining surrogate values for non-detect results."

Protocol DP-3, Surrogate for Non-Detects, will be revised to indicate that the use of one half the MDL/MDA surrogates only applies to datasets that ProUCL is unable to process and calculate a mean as shown below.

"The *USEPA ProUCL for Environmental Applications for Data Sets With and Without Nondetect Observations* software package should be used to calculate the 95% UCL value[1]. Non-detected constituent concentrations should be processed in accordance with the ProUCL User's Guide for the 95% UCL calculation and the mean calculation. ~~However, the ProUCL software package does not consider non-detects to calculate a mean concentration, i.e., the mean concentration is based on the *detected results only*.~~ If ProUCL is not able to process the data due to a low frequency of detects or limited number of samples, then calculate the mean using surrogate values for the non-detect results as shown below. ~~This protocol applies to the calculation of a mean concentration that considers both detected results and non-detects (using surrogate values for the non-detects).~~"

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

10. It is unclear why ecological screening values (ESVs) and revised screening values (RSVs) are not provided in Protocol ECO-1, when all of the supporting sources are already known. Instead of reporting actual screening values, the protocol provides a series of generic tables to provide examples of how ESVs and RSVs are selected from cited sources. While this is helpful, it is not possible to validate whether cited sources contain values for contaminants found in the SRS. Please revise ECO-1 to provide a table of ESV and RSV selections and respective sources. Ideally, ESVs and RSVs from each cited source should be reported and the derivation steps shown.

Response: Clarification.

The purpose of Protocol ECO-1, Sources of Ecological Screening Values, is to establish the primary sources of the ESVs and RSVs used in the ERA process and identify references and weblinks to those sources. The protocol also describes how the site-specific screening values are derived and provides sample tables for each media type.

This approach is the same as the HHRA, i.e., RSL/PRG tables for the various receptors which are included as attachments for reference when preparing the BRA. This ensures that the most current thresholds are used when data processing for the risk assessment begins and eliminates the need to revise protocols every time thresholds are updated. The

references/thresholds are updated and provided in the project-specific ERA. No change to the EC&ACP Regulatory Document Handbook is proposed.

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

11. Protocol ECO-5, Ecological Site-Specific Data/Studies, states that site-specific ecological studies or other biological data collection activities may be needed but does not identify how this will be decided or who will determine whether they are needed. It is recommended that agency stakeholders are involved in the process of deciding whether ecological site-specific data/studies are needed and identifying site-specific investigations. It is also recommended that such studies are described in site-specific risk assessment work plans, as the descriptions of such studies provided in protocol ECO-5 are only examples of what could be done and may not be adequate in covering all possible site-specific data gaps. In addition, draft work plans can be reviewed and approved by agency stakeholders before data collection and risk assessment activities begin. Please revise protocol ECO-5 to include the above recommendations so that the decision management point to continue the ecological risk assessment process past COPC identification is clearly defined, and the opportunity for subsequent agency stakeholder input is documented.

Response: Agree.

The Core Team are the risk managers and decision makers for SRS OU cleanups and they, along with the project team SMEs, determine the adequacy of data and the need for additional data/studies as early as the Post-Characterization Scoping Phase. In application, the project team is directed by the Core Team to provide site-specific ecological studies or other biological data if it is needed to support a defensible risk decision.

Protocol ECO-5, Ecological Site Specific Data/Studies, will be revised to identify the project Core Team (i.e., agency stakeholders) involvement with determination of the need for additional site-specific sampling as shown below.

"Following identification of ecological (ECO) constituents of potential concern (COPCs), a determination is made if site-specific ecological studies or other biological data may be warranted to address critical uncertainties associated with using literature-based values only at this stage of the ecological risk assessment (ERA) process, and whether or not a remedial decision can be made from an ecological risk perspective. <u>As part of the operable unit scoping process, the project Core Team will consider any recommendation from the SMEs and determine whether ecological site-specific data/studies and/or additional investigations are warranted.</u> If deemed appropriate, a site-specific study plan is designed to ensure that adequate data are collected to support the ERA. <u>This study plan is reviewed and approved by the regulatory agencies before data collection begins</u>. There are a limited number of fundamental approaches for conducting site-specific investigations on ecological impacts of hazardous substances. Further soil/sediment/surface water sampling, tissue residue studies,

toxicity testing, and population or community evaluations are ~~four~~ examples of the most commonly used methodologies but are not exclusive of other site-specific approaches to address possible site-specific data gaps."

In terms of ecological site-specific studies, it is important to recognize that the Integrator Operable Unit (IOU) program encompasses large scale investigations that include the most ecologically sensitive environments at SRS. IOUs are defined as surface water bodies (e.g., site streams and Savannah River) and associated wetlands, including the water, sediment/ soil and related biota. The SRS IOU program includes bioassessment methods to determine the ability of a stream to support self-sustaining biological and ecological components of undisturbed, natural conditions to assess ecosystem health. The Bioassessment Program was initiated in 1996 and bioassessment monitoring was conducted periodically through 2017. The approach primarily utilizes surveys for fish and macroinvertebrate assemblages, and habitat surveys, and is supplemented by biota tissue collection, periodic trophic modeling of contaminants to wildlife receptors, and ecological studies conducted by the Savannah River Ecology Laboratory for evaluating IOU health. In 2019, the Core Team approved an Optimization of the IOU Program (Phase II) strategy which includes submittal of a Bioassessment of Savannah River Stream Systems report every 7 years focusing on fish and macroinvertebrate assemblages and habitat surveys.

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

12. Protocol COC-1, Constituents of Concern (COC) Refinement Process, should not include the provision for making recommendations to decide whether a COC should or should not be carried forward for further remedial evaluation. This represents a management decision point that should be discussed and made in consensus with agency stakeholders and not risk assessors. Stakeholder consensus should be made using all available information provided in risk assessments and from other information sources. As such, this information should be provided in a nonbiased fashion at the management decision point. Please revise Protocol COC-1 to specifically state that the decision to carry a COC forward for further remedial evaluation will be evaluated, discussed, and made in consensus with agency stakeholders using all available information.

Response: Agree with clarification.

The discussion of whether to carry a COC forward for further remedial evaluation is first presented at the Problem Identification Scoping meeting with the Core Team before submittal of the BRA. This process is outlined in the Handbook Appendix B, Five Phases of Project Scoping. SMEs propose refined COCs after using the appropriate technical protocols to transform environmental data into human health and environmental risk estimates, and after applying the uncertainty factors described in this protocol as appropriate. However, the Core Team makes the final determinations of refined COCs, receptors, exposure units, and all of the other factors considered in estimating human health and ecological risk, to

define specific problems warranting response action and remedial objectives. Review and subsequent approval of the BRA by the regulators ensures that comments are resolved, and the final agreement with the Core Team using all available information is documented.

Text will be added to the last paragraph of Protocol COC-1, Constituents of Concern (COC) Refinement Process, as shown below. Also note the correction to the last sentence per the response to a SCDHEC editorial (last) comment.

"Implementation of this protocol results in the identification of RCOCs that are recommended for further remedial evaluation. The decision to carry a COC forward for further remedial evaluation will be evaluated, discussed, and decided upon by the Core Team using all available information. Remedial Action~~Alternative~~ Objectives (RAOs) and Preliminary Remedial Goals (PRGs) will be developed for these RCOCs."

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

SPECIFIC COMMENTS

1. **Part I, RCRA/CERCLA Document Formats, F-2, Resource Conservation and Recovery Act Facility Investigation/Remedial Investigation Work Plan Format, PDF Page 30, and F-14, Sampling and Analysis Plan Format, PDF Page 226:** Section 4.1.6 (Specify the Limits on Decision Errors) of F-2 and Section 3.6 (Specify the Limits on Decision Errors) of F-14 do not specify that this step in the DQO process will include a discussion of the performance or acceptance criteria that the data will need to achieve in order to minimize the possibility of either making erroneous conclusions or failing to keep uncertainty in estimates to within acceptable levels, per EPA QA/G-4. Please revise F-2 and F-14 to clarify that performance or acceptance criteria will be specified in Step 6 of the DQO process.

Response: Agree.

The text in Section 4.1.6 of F-2 Resource Conservation and Recovery Act Facility Investigation/Remedial Investigation Work Plan Format will be updated as follows:

"This section presents the rationale for a biased sampling design if appropriate for the OU. If a statistical-based sample design is required, such as for confirmation sampling, then this section will specify the decision rule(s) as a statistical hypothesis test and determine the acceptable limits on decision errors. A discussion of the performance or acceptance criteria that the data will need to achieve in order to minimize the possibility of either making erroneous conclusions or failing to maintain uncertainty estimates within acceptable levels will be included in this section. The Project Quality Objectives (PQOs) are included in this section in order for the developers of the Data Usability Report to assess whether the sampling design has achieved its quality objectives for the collected data to be qualified for project decision-making."

The text in Section 3.6 of Document Format F-14 will be updated as follows:

"This section presents the rationale for a biased sampling design if appropriate for the OU. If a statistical-based sample design is required, such as for confirmation sampling, then this section will specify the decision rule(s) as a statistical hypothesis test and determine the acceptable limits on decision errors. A discussion of the performance or acceptance criteria that the data will need to achieve in order to minimize the possibility of either making erroneous conclusions or failing to maintain uncertainty estimates within acceptable levels will be included in this section. The Project Quality Objectives (PQOs) are included in this section in order for the developers of the Data Usability Report to assess whether the sampling design has achieved its quality objectives for the collected data to be qualified for project decision-making."

The text in Section 3.7 of F-14 Sampling and Analysis Plan Format will be updated as follow:

"This section will summarize all the information from the previous steps, apply this information to identify alternative sampling designs that are appropriate for use, and document a sampling design that will yield the data that best addresses the study objectives while ensuring sufficient data quality. ~~The Project Quality Objectives are included in this section in order for the developers of the Data Usability Report to assess whether the sampling design has achieved its quality objectives for the collected data to be qualified for project decision-making.~~"

Responsible Party: Justin Steadman, (803) 952-7346, justin.steadman@srs.gov

2. **Part I, RCRA/CERCLA Document Formats, F-2, Resource Conservation and Recovery Act Facility Investigation/Remedial Investigation Work Plan Format, PDF Page 31:** Section 6.0 (Analytical Plan) refers to the program-level *Quality Assessment Program Plan for Environmental Data Collection and Management*; however, the correct reference is the program-level *Quality Assurance Project Plan for Environmental Data Collection and Management*. Please revise Section 6.0 to resolve this discrepancy.

Response: Agree.

Text in Section 6.0, Analytical Plan, of F-2 Resource Conservation and Recovery Act Facility Investigation/Remedial Investigation Work Plan Format will be revised as follows:

"This section describes the data quality levels for each type of data collected. All data collected under the work plan will follow the SRS program level Quality ~~Assessment Program~~ Assurance Project Plan for Environmental Data Collection and Management for the program level quality objectives, standard operating procedures, and quality assurance/quality control procedures."

Responsible Party: Justin Steadman, (803) 952-7346, justin.steadman@srs.gov

3. **Part I, RCRA/CERCLA Document Formats, F-14, Sampling and Analysis Plan Format, PDF Page 223:** Section 1.0 (Introduction) indicates that sampling and analysis plans (SAPs) are prepared in accordance with the Uniform Federal Policy for Quality Assurance Project Plans Manual, dated March 2005 (the UFP-QAPP Manual); however, several required elements of the UFP-QAPP Manual are missing from F-14. Examples of missing elements include, but may not be limited to, the following: project management and project organization, data management, assessments and corrective actions, and data verification and validation. In addition, it is unclear why F-14 does not discuss preparing SAPs using the UFP-QAPP format (i.e., worksheets). Please revise F-14 to include all required elements of the UFP-QAPP Manual, and clarify why the UFP-QAPP is not discussed.

Response: Clarification.

A Sampling and Analysis Plan Design Team (SAPDT), with representatives from the USDOE, USEPA, and SCDHEC, was formed in 2010 to reach agreement on the information and level of detail required in SRS Sampling and Analysis Plans (SAPs), Data Usability Reports (DURs), and the program level Quality Assurance Project Plan (QAPP) for Environmental Data Collection and Management. The SAPDT agreed that many of the elements in USEPA guidance (i.e., UFP-QAPP Manual) were repetitive between the SAP, DUR, and QAPP documents. To promote consistency and streamlining, the SAPDT reached agreement that the information in SAPs and DURs would be project specific and these documents would reference or summarize the program level checklist items contained in the program QAPP. A *Cross Walk of Final UFP QAPP Checklist 2008 to SRS SAP, QAPP, and DUR Documents* was prepared to identify the SRS equivalent procedures or Standard Operating Procedures for each UFP checklist criteria and the document this information was presented in (i.e., SAP, DUR, QAPP) and to provide the rationale if an item was not included. Agreement was reached with the USEPA and SCDHEC in July 2011 that program-related information contained in the approved program level QAPP would be referenced but not duplicated in the SAP and DUR templates. The SRS SAP and DUR templates and the SRS QAPP reflect these streamlining Core Team agreements, and no change to Document Format F-14 is proposed.

The approved SRS *Area Completion Projects Programmatic Quality Assurance Project Plan for Environmental Data Collection and Management* (ERD-AG-2005-00001, Revision 5, April 2012) and the *Scoping Summary for the Development of Area Completion Projects Sampling and Analysis Plans (U)* (ERD-EN-2010-0090, April 2012) including the *Cross Walk of Final UFP QAPP Checklist 2008 to SRS SAP, QAPP, and DUR Documents* was transmitted to the USEPA and SCDHEC in May 2012 and is available for reference upon request.

Responsible Party: Terry Killeen, (803) 952-6850, terry.killeen@srs.gov

4. **Part I, RCRA/CERCLA Document Formats, F-15, Data Usability Report Format, PDF Pages 232 to 238:** It is unclear why Section 2.0 (Assessment of Precision, Accuracy, Representativeness, Comparability, and Completeness Data Quality Indicators and Measurement Performance Criteria) does not include an assessment of sensitivity, which is also a data quality indicator (DQI). In addition, Section 2.0 states, "Completeness measures the amount of data resulting from the data collection activity;" however, this statement should clarify that completeness measures the amount of *valid* [emphasis added] data obtained. Further, Section 3.0 (Validation Findings) should specify that the discussions of quality control (QC) exceedances will include all QC parameters evaluated, the acceptance criteria used to evaluate each QC parameter, a list of all QC exceedances, as well as the extent of the exceedance, the samples associated with each exceedance, and the qualifiers applied. Please revise F-15 to include this information.

Response: Agree with clarification.

Document Format F-15, Data Usability Report Format, will be revised to include a new Section 2.6 Sensitivity to discuss the MDLs and SQLs relative to the limit of interest (e.g., Primary Drinking Water MCLs, etc.) for each matrix and constituent identified in the project-specific SAP. To accommodate this change, the title of Section 2.0 will be revised as follows:

"ASSESSMENT OF PRECISION, ACCURACY, REPRESENTATIVENESS, COMPARABILITY, ~~AND~~COMPLETENESS, AND SENSITIVITY DATA QUALITY INDICATORS AND MEASUREMENT PERFORMANCE CRITERIA".

The first sentence in Section 2.5 Completeness will be revised to state the following:

"This section discusses the completeness of the data measured as the amount of valid data (excluding missing or rejected samples/results) obtained from a measurement process that achieves the project goals, as compared to the amount of data planned to be obtained by the project."

A new Section 2.6 will be added to address the sensitivity evaluation as follows:

"Section 2.6 Sensitivity

"Sensitivity is the ability of the method or instrument to detect the target analytes at the level of interest (e.g., Regional Screening Levels [RSL] or Primary Drinking Water Maximum Contaminant Levels [MCL]). The sample quantitation limit (SQL) is the minimum concentration of an analyte that can be routinely identified and quantified above the method detection limit (MDL) by a laboratory. Sensitivity can be determined by comparing the MDLs and SQLs for each analyte and for each matrix (e.g., soil or groundwater). The project

team should document the project-required MDLs and SQLs for each matrix and analyte, which will be compared against the criteria of interest to ensure data usability."

Section 3.1 through Section 3.10 specify the acceptance criteria determined for each QA/QC criteria which are typically from SW-846 method QA/QC criteria and the SRS validation procedure. Section 3.11 provides a discussion of the comparability of split sample analysis. A new Section 3.12 will be added to the DUR format to summarize the sensitivity evaluation as follows:

"3.12 Summary of Data Sensitivity Evaluation

This section summarizes the results of the data sensitivity evaluation. It applies to constituents that have a high percentage of non-detects (i.e., greater than 95% non-detect) to identify if the MDL exceeds the threshold screening criteria. The review of MDLs by matrix, method, and analyte relative to criteria of interest is presented in tabular format in Appendix A. Non-detected results that have MDLs greater than the threshold criteria are identified below."

Table 15. Data Sensitivity Summary

Method Code	Analyte	Total # of Records with MDL Exceeding Screening Threshold
EPA 6010D	Antimony	3
	Silver	11

In addition, a List of Appendices will be added to the DUR format to reference a new Appendix A to include a table for the Comparison of MDLs for Non-Detects to Risk-Based Screening Criteria.

Responsible Party: Terry Killeen, (803) 952-6850, terry.killeen@srs.gov

5. **Part II, Technical Protocols, DP-1, Unit Source Data Processing, Reasonable Maximum Exposure (RME Values), PDF Page 315:** The statement at No. 1 (Determine the UCL 95 value) should be expanded to note that the 95 UCL on the arithmetic mean should be used as the RME value and that EPA's ProUCL software determines the most appropriate UCL based on best fit of the data; please revise this section accordingly.

Response: Agree with clarification.

Several improvements have been made to the decision logic for the recommendation of UCLs in ProUCL version 5.2 (2022). In general, the 95% UCL is used as the RME exposure point concentration; however, there may be instances that the 95% UCL either cannot be calculated or the calculated value is greater than the unit maximum concentration. In those

instances, the maximum concentration is designated as the RME concentration as described in No. 2 in the same section.

Protocol DP-1, Unit Source Data Processing, Reasonable Maximum Exposure (RME) Values will be revised as shown below.

> **"1. Determine the 95% UCL value[1]. The USEPA ProUCL for Environmental Applications for Data Sets With and Without Nondetect Observations software package should be used to calculate the 95% UCL value. <u>The ProUCL software recommends the most appropriate UCL based on the best fit of the data.</u>**
>
> **2. For each constituent in each exposure group for the unit-source samples, compare the 95% UCL value and the maximum value. Designate the lower of these two as the unit-source reasonable maximum exposure (RME) concentration for that constituent in that EG."**

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

6. **Part II, Technical Protocols, HH-3, Human Health RME Exposure Parameters, PDF Page 340:** The bullets under "Non-radiological Constituents" state that Future Resident and Future Industrial Worker exposures will be screened using EPA's RSLs; however, the specific RSL tables are not noted (i.e., Target Hazard Quotient (HQ) = 0.1 or 1). Please revise this bulleted list to include the reference to the specific RSL table that will be used for screening purposes.

Response: Agree with clarification.

The purpose of the Protocol HH-3, Human Health RME Exposure Parameters, is to generically describe the exposure assumptions that are used to derive RSLs/PRGs for the standard receptors evaluated in the risk assessment. Protocols HH-4, Human Health Constituents of Potential Concern and HH-5, Human Health Constituents of Concern, include a reference to the specific RSL table (i.e., target hazard quotient [HQ] = 0.1 or 1) to be used at that particular stage of the process. For clarification, text will be added to the Protocol HH-3, Human Health RME Exposure Parameters, as shown below.

<u>"Non-radiological Constituents</u>

The standard default parameters and input assumptions are used in the derivation of nonradiological RSLs for the future resident and future industrial worker scenarios unless otherwise noted. Details of the exposure assumptions are provided in the tables identified below and the USEPA RSL website. <u>The specific RSL table (i.e., target hazard quotient [HQ] = 0.1 or 1) to be used in the data screening process is identified in the Human Health Constituents of Potential Concern Protocol (HH-4) and Human Health Constituents of Concern Protocol (HH-5), as appropriate."</u>

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

7. **Part II, Technical Protocols, HH-3, Human Health RME Exposure Parameters, Other Site-Specific Human Health Receptor Examples, PDF Page 341:** References for the exposure parameters shown for onsite worker, adolescent trespasser, and recreational fisher are not provided for the bulleted list in this section. Please revise this bulleted list to include the references for the cited exposure parameters for these receptors.

Response: Clarification.

The other site-specific receptors described in Protocol HH-2, Human Health Receptors and Scenarios, and Protocol HH-3, Human Health RME Exposure Parameters, have been developed for and used in the SRS Integrator Operable Unit (IOU) program for the evaluation of watersheds. The Core Team, with support from their respective SMEs, makes the final determination on the site-specific receptors and exposure parameters based on the conceptual site model for the release. Because this information may vary between projects, the exposure parameters and references are provided in the respective BRAs rather than identified as standard exposure parameters in Protocol HH-3. No change to the EC&ACP Regulatory Document Handbook is proposed.

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

8. **Part II, Technical Protocols, HH-4, Human Health Constituents of Potential Concern, PDF Page 351:** There is a discrepancy between the screening RSLs noted on this page (i.e., HQ of 1 for noncarcinogens) vs. the RSLs cited on PDF Page 353 (HQ = 0.1 for noncarcinogens). Please revise this section to address this discrepancy.

Response: Agree.

The text in the Introduction section of Protocol HH-4, Human Health Constituents of Potential Concern, (pdf page 351) will be revised to acknowledge use of the HQ = 0.1 in the screening process described in Step 2 of the Protocol HH-4 (pdf page 353) as shown below.

- **"RSLs are concentrations that correspond to either a $1x10^{-6}$ risk level for carcinogens or a hazard quotient (HQ) <u>of 0.1</u> or 1 for noncarcinogens. If a substance causes both cancer and noncancer (systemic) effects, the more stringent criteria shall take precedence."**

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

9. **Part II, Technical Protocols, ECO-1, Sources of Ecological Screening Values, PDF Page 369:** The last bullet on this page incorrectly states that soil ESVs address toxicity through

direct exposure to wildlife. Wildlife ESVs do not typically account for direct exposure but are based on ingestion/dietary exposure. Please revise this sentence to correctly describe the basis of exposure for wildlife ESVs.

Response: Agree.

Text in Protocol ECO-1, Sources of Ecological Screening Values, last bullet will be revised to indicate that direct exposure applies to soil invertebrates and plants, and ingestion/dietary exposure applies to wildlife as shown below.

- **"The soil screening values typically address toxicity through direct exposure (i.e., toxicity to soil invertebrates such as earthworms, and plants~~, and wildlife~~) and/or ingestion/dietary exposure to wildlife receptors. The hierarchy for soil benchmarks…"**

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

10. **Part II, Technical Protocols, ECO-1, Sources of Ecological Screening Values, PDF Page 371:** The weblink to the SCDHEC water standards at the top of this page does not work. It appears that it contains an unnecessary space. Please correct the inoperable link.

Response: Agree.

The weblink to the SCDHEC water standards that is provided in Protocol ECO-1, Sources of Ecological Screening Values will be checked to ensure that the link is working appropriately as shown below.

https://scdhec.gov/sites/default/files/media/document/R.61-68_0.pdf

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

11. **Part II, Technical Protocols, ECO-2, Ecological Receptors and Measurement/Assessment Endpoints, PDF 377:** The last full sentence in the last bullet on this page is confusing and appears to state that plants are only included as an ecological receptor when threatened and endangered species (T&E) are present in the exposure area. Plants are the basis of terrestrial food webs, are ecologically important at most sites, and should be included as a receptor regardless of the T&E species present. Please revise this sentence to decouple T&E presence with plant community receptor status.

Response: Clarification.

Per previous agreements dating as far back as 1998 with the initial Risk Assessment Design Team (RADT), plants have not been included as a generic receptor niche that is evaluated in

SRS ecological risk assessments. The RADT determined that exceedance of plant toxicity thresholds (i.e., HQ > 1) is not a significant risk driver for a formal remedial decision at SRS OUs. Population/community level impacts to generic plants at a particular OU is not likely and should only be considered in the ecological risk assessment if T&E species are present (to protect the population/community). No change to the EC&ACP Regulatory Document Handbook is proposed.

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

12. Part II, Technical Protocols, ECO-3, Constituents of Potential Ecological Concern, PDF 381: The fourth sentence in the third paragraph on this page incorrectly states that screening level ESVs are derived from No Observed Adverse Effect Levels (NOAELs). This statement does not consider surface water ESVs that are based on aquatic life criteria or ambient water quality criteria (AWQC). AWQCs are based on chronic criteria where toxicity may occur in sensitive aquatic organisms after a prescribed exposure period. Please revise this paragraph to correctly describe the basis for surface water screening level ESVs that are based on AWQCs.

Response: Agree.

Text in Protocol ECO-3, Constituents of Potential Ecological Concern, third paragraph will be revised to clarify that ESVs for surface water are derived from AWQC as shown below.

"…The thresholds are derived from several sources and are used to evaluate conservative (protective) thresholds such as No Observed Adverse Effect Levels (NOAELs) and Lowest Observed Adverse Effect Levels (LOAELs). The ecological screening values (ESVs) are used in the initial screening level effects evaluation and are derived from NOAEL-based thresholds <u>for soil and sediment, and chronic ambient water quality criteria (AWQC) for surface water.</u> For constituents that exceed ESVs…"

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

13. Part II, Technical Protocols, ECO-3, Constituents of Potential Ecological Concern, PDF 382: The description of data preparation does not include information on how hardness- and pH-normalized AWQC will be processed. Hardness is often used to normalize AWQC for metals according to site- or sample-specific conditions and pH is used to calculate the chronic aluminum criterion using EPA recommended AWQC. Please revise this section to specifically identify whether hardness and pH will be used to generate AWQC based surface water ESVs.

Response: Agree.

Text will be added to Protocol ECO-3, Constituents of Potential Ecological Concern, to clarify that the surface water ESVs should be adjusted based on hardness or pH as shown below.

- **"SCDHEC R.61.68 Water Classification and Standards Table for Protection of Freshwater Aquatic Life, Water Quality Numeric Criteria for the Protection of Aquatic Life and Human Health appendix, continuous concentration criterion (CCC) thresholds that represent the highest instream concentration of a toxicant or an effluent to which the organisms can be exposed to protect against chronic (long-term) effects. USEPA derives chronic criteria from longer term (often greater than 28 days) tests that measure survival, growth, reproduction, and in some cases bioconcentration. ESVs should be adjusted for hardness- and pH- dependent analytes as described in the regulation."**

In addition, Protocol ECO-4, Ecological Constituents of Potential Concern/Constituents of Concern, will be similarly edited as shown below.

- **"…cases bioconcentration. RSVs should be adjusted for hardness- and pH-dependent analytes as described in the regulation."**

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

14. **Part II, Technical Protocols, ECO-3, Constituents of Potential Ecological Concern, PDF 383:** The second paragraph on this page states that constituents will be determined to be naturally occurring or anthropogenic without a description of how this will be evaluated. Please revise this paragraph to provide a clear explanation of how constituents will be identified as naturally occurring versus anthropogenic.

Response: Agree.

Text will be added to Protocol ECO-3, Constituents of Potential Ecological Concern, last paragraph under Surface Water to clarify naturally occurring and anthropogenic as shown below.

"Determine if the constituent is naturally occurring or anthropogenic. Naturally occurring constituents are the result of geologic source materials and geochemical processes that have not been influenced by human activity. Anthropogenic constituents are synthetic or natural substances that have been released to the environment as a result of human activities (e.g., atmospheric deposition of mercury, etc.). Anthropogenic constituents…"

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

15. **Part II, Technical Protocols, ECO-3, Constituents of Potential Ecological Concern, Figure 1, Flowchart of the COPEC Selection Process, PDF 385:** The first green box in this chart does not provide an evaluation step to identify whether detection limits are above an ESV. Simply removing a possible COPEC because it was not detected fails to recognize that analytical sensitivity may not be fine enough to measure a constituent above its ESV. This is

particularly relevant for soil and sediment analytical data where matrix interferences could result in higher-than-expected detection limits. In such cases, it is important to identify respective constituents and discuss as an uncertainty with related bias on risk characterization outcomes. Note that this same issue also occurs with the flowchart in protocol HH-4, Human Health Constituents of Potential Concern (PDF Page 355). Please revise the ECO-3 and HH-4 charts to include a screen of detection limits against screening values.

Response: Agree with clarification.

See response to General Comment #5. Document Format F-15, Data Usability Format, will be revised to include an assessment of data sensitivity. A new Section 2.6 Sensitivity and new Section 3.12 Summary of Data Sensitivity Evaluation will be added to discuss MDLs and SQLs relative to the risk-based screening criteria.

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

16. **Part II, Technical Protocols, ECO-4, Ecological Constituents of Potential Concern / Constituents of Concern, PDF 387:** The first bullet on this page identifies Region 4 Soil Screening Values as a source of RSVs, but this document does not provide Lowest Observed Adverse Effect Levels (LOAEL)-based screening values. Please revise this bullet to describe how LOAEL based RSVs will be obtained from this source or remove it.

Response: Agree.

The reference to USEPA Region 4 ERA Guidance, Table 3 will be deleted from Protocol ECO-4, Ecological Constituents of Potential Concern, as shown below.

"For soil, RSVs are based on the minimum value from the following:

- ~~**Region 4 Soil Screening Values for Hazardous Waste Sites, Table 3 provides NOAEL-based ESVs only and does not identify LOAEL-based RSVs for refinement level screening (EPA 2018).**~~
- **Los Alamos National Laboratory Receptor-specific Ecological Screening Level (ESL), Low Effect ESL (LANL 2017)."**

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

17. **Part II, Technical Protocols, ECO-4, Ecological Constituents of Potential Concern / Constituents of Concern, PDF 388:** The same two sources of AWQC surface water RSVs are used for screening level ESVs and RSVs. Therefore, there are no refinement steps for aquatic community COPECs. For the sake of transparency, please revise the description of surface water RSV selection to clarify what will be used for aquatic community surface water RSVs.

Response: Clarification.

The same sources of AWQC are used to identify both the ESVs and RSVs for surface water and there is no refinement to the threshold values used in the screening processes (i.e., ESVs = RSVs). However, there is a difference in the exposure point concentration that is used in the HQ calculation. Per Protocol ECO-3, Constituents of Potential Ecological Concern, ESV Comparison for surface water, the Screening HQ = Maximum Detected Concentration / ESV. Per Protocol ECO-4, Constituents of Potential Concern/Constituents of Concern, the Refinement HQ = 95% UCL / RSV. No change to the EC&ACP Regulatory Document is proposed.

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

18. **Part II, Technical Protocols, ECO-4, Ecological Constituents of Potential Concern / Constituents of Concern, PDF 388:** The last subsection on this page, Soil and Sediment, does not identify that the lowest of the soil or sediment RSVs from cited sources for each constituent among all receptors will be used to identify COPCs. This information is provided when describing ESV selection in protocol ECO-3 (bottom of PDF page 381). Please revise this subsection to specifically state that the RSV for each constituent will be identified as the lowest value among all receptors obtained from cited sources.

Response: Clarification.

The same text noted in the comment when describing ESV selection in Protocol ECO-3 is provided when describing RSV selection in Protocol ECO-4 as shown below.

- **"Los Alamos National Laboratory Receptor-specific ESL, Low Effect ESL (LANL 2017).**

For sediment/soil, (wetland soils, floodplain sediment), the thresholds are based on the lowest of the soil or sediment values for each constituent."

No change to the EC&ACP Regulatory Document Handbook is proposed.

Responsible Party: Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

19. **Part II, Technical Protocols, GW-2, Developing the Hydrogeological Conceptual Model, Physical Framework, Hydrogeologic Framework, PDF Page 408:** The text does not specify that the maps and cross sections that will be used to develop the hydrogeological conceptual model (HCM) will be scaled. Please revise the text to state the scaled maps and cross sections will be prepared.

Response: Agree.

Protocol GW-2, Developing the Hydrogeological Conceptual Model, Physical Framework, Hydrogeologic Framework will be revised to clarify that scaled maps and cross sections will be used to develop the HCM as follows:

Protocol GW-2, Physical Framework, Bullet #1:

"Geologic/lithologic map and cross sections showing the horizontal and vertical extent and boundaries of the system. Maps and cross sections may be scaled as appropriate for specific modeling tasks to aid in viewing and interpretation."

Responsible Party: Adam Willey, (803) 952-8738, adam.willey@srs.gov

20. **Part II, Technical Protocols, GW-3, Groundwater Model Selection, Design, and Application, Step 9, Model Documentation, PDF Page 424:** The Model Documentation is missing a discussion of the supporting figures that will be presented. For example, for presenting flow model calibration, it is important to include figures that depict both statistical (e.g., a scatter plot), spatial calibration (e.g., a residual head map), and to present how the model is calibrated over time (e.g., using hydrographs comparing actual versus modeled head). At a minimum, elements of the modeling report Items 2 and 4 through 8 should be accompanied by sufficient figures to document the model. Furthermore, it does not appear that the discussion of the nine steps of the modeling process workflow in the protocol discusses figures. Finally, it is noted that a list of the specific figures should/could be presented and included for each stage/step. Please revise the text to discuss the figures that will be included in modelling reports.

Response: Agree.

Protocol GW-3, Groundwater Model Selection, Design, and Application, will be revised to clarify the figures that will typically be included in a modeling report. The revised text involves identifying the figures within the description of each of the nine steps of the modeling process and providing a general statement within Step 9 Model Documentation regarding the need for sufficient figures to illustrate geographical, numerical, and statistical data that cannot be conveyed via text as follows:

Protocol GW-3, Step 2 - Develop a Conceptual Model:

"A hydrogeologic conceptual model (HCM) broadly describes the approximate direction of groundwater flow, the groundwater sources and sinks, the hydrostratigraphy, and other factors that affect the hydrogeologic system. A simplified geological cross-section or block diagram is often developed during this step to illustrate the elements of the HCM and their interactions with one another."

Protocol GW-3, Step 4 - Construct the Groundwater Model, *Discretization*:

"It is important to note that increases in the spatial (vertical and horizontal) and temporal discretization often lead to increases in the time required to execute the model, and trade-offs between discretization and computational requirements may need to be considered. The model discretization is often shown as a figure with the horizontal (areal) grid overlain on a base map of the study area. Similarly, the vertical discretization or model layering is shown as the vertical grid overlain onto a typical geological cross section covering the model area."

Protocol GW-3, Step 4 - Construct the Groundwater Model, *Groundwater Transport Boundaries:*

"Additional tools and analyses (e.g., vadose zone flow and transport modeling, external mass balance calculations, or geochemical modeling) may be required to reduce uncertainty and increase credibility of the way(s) in which contaminant mass sources are represented in the groundwater transport model.

Groundwater flow and transport model boundaries may be shown on figures similar to those describing model discretization; in this case with symbols or color coding within cells to identify the type of boundary condition used."

Protocol GW-3, Step 5 - Model Calibration, *Pre-calibration Analysis*:

"Qualitative and visual comparisons can also be useful in assessing model fit prior to calibration and in documenting the results: "scattergrams"[6], simulated and observed hydrographs and/or concentration versus time plots for individual wells, spatial error correlation maps, and temporal error correlation plots are all useful comparisons that can inform the calibration process."

Protocol GW-3, Step 6 - Model Sensitivity Analysis:

"Conversely, if changing the value of a parameter to any value within the reasonable range has no substantial effect on calibration quality, then the value of this parameter has not been constrained through calibration. The results of a sensitivity analysis are often assessed and illustrated using multiple plots, one for each parameter tested, which show the response of a calibration statistic to a range of parameter perturbations."

Protocol GW-3, Step 7 - Predictive Simulations:

"Results of the predictive simulations are often the most important model results—they meet a practical purpose and were the motivation for developing the model. The results may be assessed and illustrated using, as examples: drawdown or plume maps for key time periods,

plots of mass removal versus time, or water diversion from streams versus time. The specific illustration(s) will depend on the focus of the model."

Protocol GW-3, Step 8 - Predictive Uncertainty Analysis:

"An uncertainty analysis of the model predictions should be performed during or after execution of the predictive simulations. Uncertainty in model results may be illustrated with plots of the range of outcomes of a particular occurrence (e.g., a drawdown limitation or concentration limit) for specific probabilities of occurrence."

Protocol GW-3, Step 9 - Model Documentation:

"The model documentation should be detailed enough to enable a thorough, critical review of the model's conceptual basis and numerical implementation. The model documentation should also contain sufficient figures to illustrate geographical, numerical, and statistical data that cannot be conveyed via text. Typical figures that are used for each step of the modeling process were identified in the previous eight sections."

Responsible Party: Adam Willey, (803) 952-8738, adam.willey@srs.gov

21. **Part II, Technical Protocols, GW-4, Sensitivity and Uncertainty Analysis for Resource Conservation and Recovery Act/Comprehensive Environmental Response, Compensation, and Liability Act Groundwater Modeling, PDF Page 427, and GW-5, Process for Use of Monitored Natural Attenuation and Groundwater Mixing Zone Application, PDF Page 433:** The protocols do not discuss figures that should be presented to support the sensitivity and uncertainty analysis and to support the mixing zone application. Please revise the text in each protocol to list the specific figures that should be presented.

Response: Agree.

Protocol GW-4, Sensitivity and Uncertainty Analysis for Resource Conservation and Recovery Act/Comprehensive Environmental Response, Compensation, and Liability Act Groundwater Modeling, will be revised to clarify the figures that will typically be included to support the sensitivity and uncertainty analysis and to support the mixing zone application. The revised text involves identifying the figures within appropriate parts of each protocol as follows:

Protocol GW-4, Sensitivity Analysis, *Assess Parameter Sensitivities*:

"One common way of visualizing sensitivity simulation results is to plot changes to some model output (y-axis) as a function of the specified parameter value (x-axis). Examples of model outputs that could be evaluated and plotted include goodness of fit metrics such as ME, MAE, or RMSE (defined in protocol GW-3) or key predicted outputs such as water

levels, concentrations, stream flows, or mass flux at specific locations. These figures are often included in the model report."

Protocol GW-4, Uncertainty Analysis, *Quantifying Uncertainty for Predictions of Interest*:

"Using the same example, the probability of discharge concentrations being greater than a particular value (e.g., a contaminant regulatory limit) can be estimated at any time during the predictive simulation period based on the statistical distribution of concentrations through time. In this case, the probability of exceedance versus time would be plotted."

Protocol GW-4, Uncertainty Analysis, *Scenario Uncertainty Analysis*:

"Upon concluding the scenario uncertainty analysis/analyses, the uncertainties of model predictions should be summarized and documented in the model report (ASTM Standard D5718). Figures should be used to illustrate the uncertainty identified in the analysis. The types of figures will be problem specific but could include potentiometric surfaces and contaminant plume maps, or time series plots that illustrate the effect of uncertainty on the magnitude of key parameters (concentrations, heads, flows, mass flux, etc.)."

Responsible Party: Adam Willey, (803) 952-8738, adam.willey@srs.gov

Region 4 GW Comments

22. Part II, Technical Protocols, GW-2, Developing the Hydrogeological Conceptual Model, Contaminant Transport Framework, PDF page 408: Recommend including more data to the contaminant transport framework, such as the location, concentration, and depth of contaminant source, and more geochemical parameters, such as the half-life of the contaminant of concern (COC) and retardation factor.

Response: Agree with clarification.

More detail for the identification of contaminant source(s) is warranted in the data needed for the Contaminant Transport Framework. The example geochemical parameters in the Contaminant Transport Framework data needs is not intended to be comprehensive in the protocol as the required geochemical parameters will differ for each modeling task based on the complexity of the system and how robust the model is intended to be. The half-life of the contaminant is included, and the retardation factor will be added. The text in Protocol GW-2, Developing the Hydrogeological Conceptual Model, will be revised as follows:

Protocol GW-2, Contaminant Transport Framework, Bullet #1:

"Identification of the contaminant source(s). Data needs for contaminant source(s) include, but are not limited to, source dimensions and location, source depth, and concentrations of contaminant(s) of concern."

Protocol GW-2, Contaminant Transport Framework, Bullet #3:

"Identification of geochemical data needed for contaminants of concern (e.g., Kd's, f_{oc}, half-lives, retardation factors, etc.)"

Responsible Party: Adam Willey, (803) 952-8738, adam.willey@srs.gov

23. **Part II, Technical Protocols, GW-3, Groundwater Model Selection, Design, and Application, Boundary Conditions, PDF page 417:** Recommend having a figure and explain the type of the flow and transport boundary, the model domain for the flow and transport model, with an explanation of cell size and scale. For example, explain the location of a specific type of boundary.

Response: Agree.

Protocol GW-3, Groundwater Model Selection, Design, and Application, Boundary Conditions, will be revised to clarify the type of the flow and transport boundary and where it lies within the model domain and relative to cell size as follows:

Protocol GW-3, Step 4 - Construct the Groundwater Model, *Groundwater Transport Boundaries*:

"Additional tools and analyses (e.g., vadose zone flow and transport modeling, external mass balance calculations, or geochemical modeling) may be required to reduce uncertainty and increase credibility of the way(s) in which contaminant mass sources are represented in the groundwater transport model.

Groundwater flow and transport model boundaries may be shown on figures similar to those describing model discretization; in this case with symbols or color coding within cells to identify the type of boundary condition used."

Responsible Party: Adam Willey, (803) 952-8738, adam.willey@srs.gov

24. **Part II, Technical Protocols, GW-3, Groundwater Model Selection, Design, and Application, Step 5 – Model Calibration, PDF page 418:** Recommend defining how to evaluate what data sets and monitoring periods will be used to calibrate. The handbook only mentioned the calibration period, targets, and parameters, but didn't include how to evaluate what monitoring data sets, monitoring periods or literature data sets are applicable for calibration purposes. It is good to have the ratio of the groundwater head MAE (or RMSE) to

the range in head target values less than 0.05 (5%), but the range of the calculated groundwater head target should be focused on the appropriate model area.

Response: Agree.

Protocol GW-3, Groundwater Model Selection, Design, and Application, will be revised to clarify how to evaluate what data sets and monitoring periods will be used to calibrate the model as follows:

Protocol GW-3, Step 5 - Model Calibration:

"Transport parameters should generally be calibrated whenever solute transport is simulated if previous site-specific estimates do not exist.

Data Sets

High quality data are important for model calibration. Site-specific data should be used when available; however, literature-based data may be substituted for some parameters that are difficult to obtain (e.g., dispersivity) or are common to a specific constituent (e.g., radioactive decay rate) or hydrogeological environment (e.g., maximum evapotranspiration rate). For temporally varying quantities such as water levels, concentrations, recharge, and streamflows, data based on a routine (monthly, quarterly, annual) monitoring plan are generally preferable. Data for calibration targets should be checked and/or validated prior to their use."

Protocol GW-3 will be revised to clarify the area to which the ratio of groundwater head MAE (or RMSE) to the range in head target values applies as follows:

Protocol GW-3, Step 5 Model Calibration, Pre-calibration Analysis:

"For example, a model is generally considered to be well-calibrated if the ratio of the groundwater head MAE (or RMSE) to the range in head target values is less than 0.05 (5%) within an appropriate model area (e.g., the area of interest)."

Responsible Party: Adam Willey, (803) 952-8738, adam.willey@srs.gov

25. **Part II, Technical Protocols, GW-4, Sensitivity and Uncertainty Analysis for RCRA/CERCLA Groundwater Modeling, parameter Uncertainty Analysis, PDF page 428:** Recommend defining how to evaluate the parameter ranges are reasonable, and the requirement of the parameter data source, e.g., from field testing, or from the literature review as well. In addition, recommend including the explanation of the selection of the respective type of uncertainty analysis, e.g., Calibrated Parameter Ensembles. Given the model

calibration, it is recommended to test how the parameter sensitivity can affect the overall objective of the modeling goal.

Response: Agree.

Protocol GW-4, Sensitivity and Uncertainty Analysis for RCRA/CERCLA Groundwater Modeling, parameter Uncertainty Analysis, will be revised to define how to evaluate that the parameter ranges are reasonable and the requirement of the parameter data source, e.g., from field testing or from the literature review as follows:

Protocol GW-4, Uncertainty Analysis, Option 1 Monte Carlo Method:

"1. Define reasonable ranges for each uncertain parameter. Reasonable ranges may be determined from statistical evaluation of site-specific field data or literature values that are based on similar physical conditions as the site or modeled area. Reasonable ranges encompass the possible values that a reasonable professional could assign to a subset of or entire model; it does not encompass outliers."

Protocol GW-4 will be revised to provide an explanation of the selection of the respective type of uncertainty analysis, e.g., Calibrated Parameter Ensembles as follows:

Protocol GW-4, Uncertainty Analysis, Parameter Uncertainty Analysis:

"The selection of which type of uncertainty analysis to perform in practice will depend on the modeling objectives and prior decisions made during the model development process.

The Monte Carlo method is ideally suited to the evaluation of model predictions that result from an investigation of the full range in plausible model parameter values. Such an investigation into parameter uncertainty can lead to the definition and inclusion of poorly calibrated models. Poorly calibrated models can be reviewed and potentially eliminated from the analysis, as long as doing so does not limit an evaluation of a robust spectrum of parameter values.

Conversely, an uncertainty analysis that is predicated upon calibrated parameter ensembles places greater importance on predictions made with reasonably well-calibrated models. In most cases, limiting the analysis to well-calibrated models precludes culling the ensemble of poorly calibrated models. However, this approach limits the investigation into ranges of model parameter values that are narrower than the ranges of plausible values. Accordingly, the calculated uncertainty in resulting model predictions may be lower than that produced by the Monte Carlo method. The stepwise guidance for each method is explained below."

Protocol GW-4 will be revised to recommend testing how the parameter sensitivity can affect the overall objective of the modeling goal as follows:

Protocol GW-4, Sensitivity Analysis:

"Results evaluated are associated with the simulation of the historical (e.g., calibration) period simulated. Ideally the sensitivity analysis will inform how parameter sensitivity and variations in parameter values can affect the model results and overall objective of the modeling goal."

Responsible Party: Adam Willey, (803) 952-8738, adam.willey@srs.gov

EPA Additional Comments TECHNICAL REVIEW OF THE ENVIRONMENTAL COMPLIANCE AND AREA COMPLETION PROJECTS REGULATORY DOCUMENT HANDBOOK, SRNS-RP-2022-00330, REVISION 0A, NOVEMBER 2022, received March 28, 2023.

Response To All General and Specific Comments Received March 28, 2023: Clarification.

SRS appreciates the USEPA Region 4 review of the ecological risk assessment protocols located in the EC&ACP Regulatory Document Handbook, Revision 0a, November 2022, and the list of USEPA guidance. During development of the Regulatory Document Handbook in 1999, the USEPA, SCDHEC, and USDOE representatives to the SRS Federal Facility Agreement (FFA) recognized that a key factor to determine the technical direction of SRS RI/FS projects and acceptance of the technical results is agreement on the technical processes employed. A description of the process used for development of the protocols is provided in the Executive Summary of the Regulatory Document Handbook as follows:

"The USEPA publishes guidance for data processing, human health and ecological risk assessments, fate and transport modeling, groundwater modeling, etc., in addition to guidance for the content and format of regulatory documentation. However, the USDOE, USEPA, and SCDHEC recognized that subject matter experts (SMEs) may differ on how published guidance is applied to individual OUs and/or facilities for decommissioning.

"During the FFA program 'time-out,' the USDOE, USEPA, and SCDHEC agreed to promote consistency in application of published guidance in the preparation and review of RI/FS documents. The three agencies formed technical Design Teams represented by SMEs from their respective agencies. Each Design Team developed technical protocols to support consistent execution of the technical scope in SRS RI/FS projects. These technical protocols are not intended to replace or contradict federal or state regulations or published guidance materials. Rather, the technical protocols provide program-level agreement on standard processes so that baseline steps do not require renegotiation for each RI/FS project unless there is an identified need to deviate from the agreed-upon protocols (i.e., site-specific conditions, regulatory driver, etc.). The Design Teams also developed regulatory document formats to promote consistency in the preparation and review of RI/FS and remedial decision documents. The development and use of approved technical protocols and document formats to standardize many of the tasks involved in waste site investigation, assessment and cleanup, and facility decommissioning is recognized by all three agencies to be a vital and powerful tool for building Core Team consensus at all project phases and streamlining the efficient implementation of the FFA."

In 2003, 2004, and 2005, the Risk Assessment Design Team (RADT), consisting of SMEs from the USEPA, SCDHEC, and USDOE, reconvened to review risk assessment methodology and risk protocols and to develop streamlining initiatives for the SRS Area Completion Strategy to support accelerated cleanup. Streamlining initiatives for human health and ecological risk assessments in support of the area completion strategy were recommended by the RADT and

approved by the Core Team (i.e., USEPA, SCDHEC, and USDOE risk managers) in 2005. Specifically for the ecological risk assessment, agreement was reached on the methodology for selection of exposure areas, ecological thresholds (ET), standard receptors and exposure assumptions, generation of standard lookup tables identifying NOAEL-based and LOAEL-based ETs, ecological screening values (ESV) screening steps, updated toxicity reference values (TRV), development of radiological ETs if necessary, and a streamlined document format for the presentation of human health and ecological risk assessments The 2005 agreements were modified during the scoping/development of the RI/BRA for the Lower Three Runs Integrator Operable Unit (IOU), beginning in October 2015. Additional scoping meetings were held and the ecological risk assessment approach was ultimately finalized/agreed to by the project Core Team in 2016. The primary difference between the 2005 agreements and LTR IOU approach is identification/use of the EPA Region 4 screening thresholds (ESVs and refinement screening values [RSV]) and the No-Effect and Low-Effect screening levels established by Los Alamos National Laboratory. These updated thresholds replaced the SRS-derived receptors and ETs from 2005 that were used in the initial data screening. The LTR IOU RI/BRA did implement the document format streamlining concepts and was approved in 2018. Subsequently it was used as a template for the RFI/RI/BRA/CMS/FS for the G-Area Oil Seepage Basin Operable Unit (OU) (approved in 2018) and the RFI/RI/BRA/CMS/FS for the ECODS N-1, Central Shops Scrap Lumber Pile, and Ford Building OU (approved in 2022). As noted above, streamlining steps are not intended to replace or contradict regulations or guidance materials or to minimize the estimated risk; they rely on the SMEs' professional judgement and experience to reduce or combine process steps where possible that do not substantially alter the final results of the risk assessment.

The Core Team has successfully applied the *Principles of Environmental Restoration* at SRS since 1999 to standardize and greatly streamline the process of collecting and interpreting complex environmental data and to create a collaborative environment among the regulatory agencies for making cleanup decisions. Fundamental to accelerated cleanup is Core Team agreement on the technical protocols and document formats to ensure program consistency. SRS OUs are scoped with the regulatory agencies throughout the life cycle of the RI/FS project, and Core Team agreement on key information is reached at each stage of the RI/FS process (refer to the Regulatory Document Handbook, Appendix B, Figure B-1 - The Five Scoping Phases). This includes review of characterization data and data quality objectives, data processing and screening, risk screening and assessment, modeling, etc., based on the approved technical protocols to support Core Team risk management decision making and remedy selection. The USDOE, USEPA, and SCDHEC have relied on the Core Team process and streamlining initiatives for over two decades to reach consistent, defensible remedial decisions on 412 of 515 SRS release sites to date (May 2023) without ever resorting to the dispute resolution process of the FFA to resolve process or policy disagreements.

Agreement on the continued implementation of technical protocols and regulatory document

content confirms the confidence of the SMEs and the Core Team that the collaboratively developed streamlining process remains protective of human health and the environment and facilitates remedial assessment. SRS is committed to ensuring that any new guidance is reviewed and considered, Design Teams are reconvened if appropriate, and technical protocols are updated as needed. As documented during the 2022 Core Team scoping meeting for the update of the Regulatory Document Handbook, there is now a need to perform a comprehensive handbook review and update to incorporate lessons learned by the Core Team from the past two decades. However, implementation of all aspects of applicable EPA guidance as suggested would be a significant impediment to the three party-approved streamlining process and would impact and delay future OU cleanups while not adding to the protectiveness of final cleanup decisions. For this reason, SRS does not believe a change to the streamlining approach and supporting technical protocols is warranted as suggested in the following comments, and no change to EC&ACP Regulatory Document Handbook is proposed.

Responsible Party: Dena Brett, (803) 952-6031, dena.brett@srs.gov, and/or Doug Martinson, (803) 952-6043, douglas.martinson@srs.gov

GENERAL ECOLOGICAL COMMENTS:

1. Provide Linkage to EPA Guidance. All applicable EPA guidance is to be followed. To the degree that the ERA protocols in the Handbook differ from EPA guidance the DOE should describe how a DOE approach that differs from the approach laid out in EPA guidance will result in a decision that is equally protective as if all aspects of the EPA guidance were followed. Relevant EPA guidance includes but is not limited to:

    a. Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments – Interim Final. EPA 540-R-97-006, OSWER 9285.7-25, PB97-963211, June 1997. https://www.epa.gov/risk/ecological-risk-assessment-guidance-superfund-process-designing-and-conducting-ecological-risk

    b. Region 4, Regional Ecological Risk Assessment Guidance. (March 2018 Update). https://www.epa.gov/risk/regional-ecological-risk-assessment-era-supplemental-guidance

    c. Region 4 Preferred Parameters for Conducting ERAs in Region 4.

    d. Allometric Scaling of Terrestrial Wildlife Oral Toxicity Measurements and Comparison of Ecological to Human Health Assessments Contexts. EPA/600/R-21/305. ERASC-017F. December 2021. https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=544142

    e. Determination of the Biologically Relevant Sampling Depth for Terrestrial and Aquatic Ecological Risk Assessment EPA/600/R-15/176. ERASC-015F. October 2015. https://cfpub.epa.gov/ncea/erasc/recordisplay.cfm?deid=310058

f. Ecological Revitalization and Attractive Nuisance Issues. https://www.epa.gov/remedytech/ecological-revitalization-and-attractive-nuisance-issues

g. EPA Eco Update: The Role of Screening-Level Risk Assessments and Refining Contaminants of Concern in Baseline Ecological Risk Assessments. Publication 9345.0-14. EPA 540/F-01/014. June 2001. https://www.epa.gov/sites/default/files/2015-09/documents/slera0601.pdf

h. Role of Background in the CERCLA Cleanup Program. https://www.epa.gov/risk/role-background-cercla-cleanup-program

i. Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites. https://www.epa.gov/risk/guidance-comparing-background-and-chemical-concentrations-soil-cercla-sites

j. EPA Supported Guidance for Radiation Protection: https://www.epa.gov/radiation

k. Science Policy Counsel Risk Characterization Handbook. https://www.epa.gov/sites/default/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf

2. Environmental Setting: Sections like Section 5.1 of F-1 and Section 2.1.1. of F-3 & F-5 on the ecological setting, hydrology and habitat should map and describe the boundaries of FEMA 100-year floodplains. Soils in floodplains are likely to be considered habitat for ecological receptors.

3. Documenting of Basis for Decisions: Sections like F-3, D.2.4 Screening and Refinement Level Ecological Effects Conclusion, should direct the user to document how agreement was reached between DOE and regulators on the preliminary chemicals of potential ecological concern, data gaps, and needs for site specific data collection or studies before DOE proceeds to the baseline ecological risk assessment (BERA). This comment pertains to SLERA Step 2, screening-level risk characterization. At the conclusion of the screening-level ecological risk assessment (SLERA) is a scientific and management decision point. Are there some constituents that exceed the ecological screening benchmarks but habitat at the site is limited? Is there potential for risk but risks are uncertain? Describe data gaps. The justification for collecting, or not collecting, site-specific data to support the ERA should be clearly presented. Discuss the process to receive input by risk assessors and risk managers with EPA and SCDHEC. This is requested to fulfill EPA requirements for transparency in risk characterization (USEPA 2000).

4. Refinement of Preliminary Chemicals of Potential Ecological Concern: Chemicals of potential ecological concern that exit the ERA process for reasons apart from having a maximum detected concentration less than (not less than or equal to) the ecological screening benchmark require more than one line of evidence. This includes chemicals that were not detected. These

non-detected chemicals should not be categorically dismissed as preliminary chemicals of potential concern. There should be a discussion of the chemicals used at the site or anticipated to be present at the site to support a decision to allow a non-detected chemical to exit the process.

5. Refinement of Preliminary Chemicals of Potential Ecological Concern: It should be clear to the reader that a chemical allowed to exit the ERA process because the maximum detected concentration was less than the background screening concentration (i.e., 2 x average background concentration) is exiting because of EPA's policy not to clean up contamination less than background not to be confused with the absence of potential risk. This comment describes a situation where the maximum detected concentration exceeds the screening ecological benchmark but is less than the background screening concentration.

6. Refinement of Preliminary Chemicals of Potential Ecological Concern (ECO-3, Page 1 of 6): The process to refine COPECs based on the lowest observable adverse effects concentration (LOAEL) is dependent on the absence of threatened or endangered species at the site. A Endangered Species Act Section 7 consultation will be necessary to document the absence of listed species to support the refinement process in ECO-3.

7. Sources of Ecological Screening Values (ECO-1): The Los Alamos National Laboratory (LANL) ECORISK database is a screening tool to evaluate impacts from chemicals and radionuclides in environmental media on ecological receptors at LANL. The database is an access database file with the ability to look up screening values by constituent and receptor. Supporting documentation is included. Screening ecological benchmark values are available for over 182 chemicals. The latest public release of the database was Release 4.1 in September 2017 by Los Alamos National Laboratory. Version 4.2 was released November 2020. It is available from Intellus New Mexico. https://www.intellusnm.com/documents/documents.cfm. The new version has values for perfluorinated substances. Please update to the most current version. Obtain the screening values directly from the primary sources. Please tables of the values for EPA review.

SPECIFIC COMMENTS:

1. Section 3.10 Applicable or Relevant and Appropriate Requirements Evaluation, F-3, Page 7 of 40: Revise section to include relevant location specific applicable or relevant and appropriate requirements (ARARs) like Clean Water Act Section 404 requirements for wetlands and Section 7 consultation for sites with habitat for threatened or endangered species.

2. Section D.2.4 Screening and Refinement Level Ecological Effects Conclusion, F-3, Page 28 of 40: A site-specific uncertainty section should be included to describe the adequacy of site characterization and uncertainties regarding:

   a. Analytical data,

b. Conceptual site model,

c. Habitat,

d. Exposure pathways and assumptions,

e. Toxicity information, and

f. Bioaccumulation.

An uncertainty section and a weight of evidence evaluation are not the same. Weight of evidence is used to support a decision to allow a chemical to exit the ERA process. Uncertainty sections discuss what is unknown that could potentially affect the decision to eliminate a COPEC or the characterization of risk in a more general sense than may affect more than one chemical, groups of chemical, or exposure pathways.

3. Section 1.2.5 Baseline Risk Assessment, F-4, Page 2 of 8: Please summarize ERA also in this section.

4. Section D.2.3 Results/Refinement of Constituents of Potential Concern, F-5, Page 31 of 46: The text refers to the population area use factors (PAUF) and mean concentration as the basis for refining COPECs. Region 4 has a file of food-chain model default exposure assumptions with the home ranges the Region supports for use in a calculation of the area use factor. Region 4 does not support the use of the PAUF and mean concentration. The region does not support the PAUF because sustainable populations is population fitness, which is not equivalent to species dispersal distances. The Region recommends that SRS characterize the boundaries of habitat within the spatial scale of effects for species for which the ecological risk will be assessed. The habitat amount and fragmentation will affect the ability of species to disperse. Ecological habitat that presents unacceptable ecological risk should be considered as contributing to habitat fragmentation. Habitat fragmentation can lead to decreases in abundance of species and ultimately to effects on populations and communities. Species that refuse to traverse patches of unsuitable habitat have a spatial scale of effect approximately the same as their home range (Jackson & Fahrig 2012). Species that disperse randomly, are larger bodied, and reproduce slowly will have a spatial scale of effects proportional to and larger than their average and maximum dispersal distance. Species with high population numbers, smaller bodies, and who reproduce rapidly will have a spatial scale of effects smaller than those in the other category, which could be less than the average dispersal distance (Jackson & Fahrig 2012). The dispersal distance can be important, but it should be applied judiciously depending on the movement patterns and populations sizes. The species selected as a model species for the ERA should be one that had a spatial scale of influence approximately the size of the site or smaller.

5. Section D.2.3 Results/Refinement of Constituents of Potential Concern, F-5, Page 31 of 46: The Region uses the 95% upper confidence level on the mean concentration as the exposure point concentration for ERA. The initial scoping of the ERA should establish habitat areas that

will be assessed for ecological risk that represent management decision units for which an ecological risk assessment will be conducted. Establishment of habitat units will determine the area over which a 95% upper confidence limit on the mean concentration will be computed.

6. Background Exposure Groups, DG-1, Page 2 of 4: Background data sets should ideally be in the same watershed and of the same soil type as the site.

7. Step 1: Data Preparation, ECO-3, Page 2 of 6: Do not screen out constituents for background until the BERA refinement of COPECs step in the ERA (USEPA 2001).

8. Flowchart of the COPEC Selection Process, ECO-3, Page 5 of 6: This comment refers to the first exit point in the COPEC screening process to consider detected constituents in the exposure group. If a constituent was not detected and the sample quantitation limit is greater than the screening benchmark, then discuss in the weight of evidence discussion for that constituents and uncertainty section whether the chemical was used at or is likely to be associated with the site. Use more than one line of evidence before allowing a constituent to exit the ERA process.

9. Flowchart of the COPEC Selection Process, ECO-3, Page 5 of 6: USEPA (2002) guidance recommends retaining COPECs having maximum detected concentrations less than background screening concentrations until the final risk characterization step. Constituents having maximum detected concentrations less than background, however, are not investigated further in the risk assessment. This step is for transparency to the public. For example, natural soil conditions could affect the species of vegetation growing. Naturally high levels of radon in soils could have health consequences unrelated to the site. One is not to drop constituents for background until Step 4 of the flowchart on final COPEC identification.

REFERENCES:

Jackson, H.B., and L. Fahrig. 2012. What size is a biologically relevant landscape? Landscape Ecol (2012) 27:929–941. DOI 10.1007/s10980-012-9757-9.

USEPA 2000. k. Science Policy Counsel Risk Characterization Handbook. https://www.epa.gov/sites/default/files/2015-10/documents/osp_risk_characterization_handbook_2000.pdf

USEPA 2001. g. EPA Eco Update: The Role of Screening-Level Risk Assessments and Refining Contaminants of Concern in Baseline Ecological Risk Assessments. Publication 9345.0-14. EPA 540/F-01/014. June 2001. https://www.epa.gov/sites/default/files/2015-09/documents/slera0601.pdf

USEPA 2002. Role of Background in the CERCLA Cleanup Program. https://www.epa.gov/risk/role-background-cercla-cleanup-program.