STANDARD OPERATING PROCEDURE[1]

Risk Assessment Preliminary Review Process

LAND RECYCLING PROGRAM

BUREAU OF ENVIRONMENTAL CLEANUP AND BROWNFIELDS

MAY 2020

[1] DISCLAIMER: Nothing in this Standard Operating Procedure (SOP) is intended to or affects any regulatory requirements. The process, procedures and interpretations (Statements) herein are not an adjudication or a regulation. There is no intent on the part of DEP to give the Statements in this SOP that weight or deference. This SOP establishes the framework within which DEP will exercise its discretion in the future. When appropriate, DEP may deviate from this SOP.

1. Purpose and Applicability

The Department of Environmental Protection's (DEP) Land Recycling Program (LRP) is decentralized meaning site-related documents and reports submitted to DEP are reviewed and maintained at the regional office to which they are submitted. When a risk assessment (RA) report is submitted to a regional office and the project officer does not have the technical expertise to review the report, the project officer can request the review be performed at central office (CO). CO staff provide RA report reviews as a service to the regional offices as time permits but the overall responsibility of report reviews and the transmission of decision letters lies with the regional office.

This Standard Operating Procedure (SOP) describes the procedures by which DEP regional office staff will preliminarily screen RA reports. This SOP is intended to establish procedures for DEP staff and to supplement related information in the Land Recycling Program Technical Guidance Manual (TGM).

Remediators selecting the site-specific standard (SSS) should submit an RA report for review and approval unless no present or future complete exposure pathways exist. An RA report should be able to successfully demonstrate that any post-remediation contamination associated with a release that remains in the environment will not cause an excess cumulative risk to human or ecological receptors. **The risk assessment preliminary review process is intended to be a quick and simple review of the presence or absence of the fundamental components of a risk assessment. It is not intended to be an in-depth review of the report.**

The RA report preliminary review process should be performed as soon as possible following receipt of the report to allow CO enough time for their detailed review. If questions or complications arise during the preliminary review, please call CO as soon as possible for clarification or guidance.

2. Receipt of Risk Assessment

When a report that may include an RA is received at a regional office, the assigned staff will implement the following steps:

a. Verify that an RA is included in the report. An RA can be part of the following reports.

   i. Act 2 (Chapter 250)

      1. Stand-alone baseline RA report.

      2. Baseline RA report combined with Remedial Investigation Report (RI), Cleanup Plan (CP), Final Report (FR)

      3. Residual RA (Combined with FR)

   ii. Storage Tanks (Chapter 245)

      1. Site Characterization Report (SCR) [RA is required per § 245.310(a)(31)]

      2. Remedial Action Completion Report (residual RA)

b. If an RA report is submitted as a stand-alone document, verify that the RI Report or SCR for the site has been approved prior to implementation of the RA report preliminary review process. If

an RA is received as part of a combined report that includes an RI or SCR, proceed with the preliminary review of the RA, and submit it to CO if necessary. If, after full review of the RI/SCR is initiated, it is discovered that there are problems with the site characterization, notify CO that a detailed review of the RA report is not necessary. The RA is not reviewable if there is additional characterization needed.

c. Verify that an RA is necessary.

An RA is not necessary when:

i. All constituents of concern (COC) attain the Statewide health standard (SHS)

ii. Pathway elimination is the selected remedy for attainment for all media and COCs under the SSS

Preliminary Risk Assessment Review Checklist

If you can answer "yes" to all these questions, please submit the RA to CO for further review. If the answer to any of these questions is "no," please refer to the section of this SOP (referenced) below for guidance.

Please remember that these are a presence/absence check. If there are any questions, please call CO or send the report to CO for further review.

1. Are all parts of a risk assessment included? (section 3.a)
2. If screening is being done, are COC's screened properly? (RSL's) (3.b)
3. Are receptors identified? (3.c)
4. Are pathways identified? (3.d)
5. Are exposure factors discussed/identified? (3.e)
6. Is a toxicity discussion or table included? (3.f)
7. Are risk characterization and uncertainty present? (3.g)
8. Is there an ecological RA? (3.h)

*****This page can be removed and used as a guide during preliminary reviews.*****

3. Preliminary Review Process

Even if a disapproval would be issued from any of the steps in the review process, continue with the preliminary review so the preliminary review is comprehensive and includes all comments that may be necessary. This will prevent multiple rounds of preliminary review disapprovals.

a. The RA must include the following parts in order to be considered complete.

   i. Site characterization (§ 250.602(c)(1)) *

   ii. Exposure assessment (§ 250.602(c)(2)) *

   iii. Toxicity assessment (§ 250.602(c)(3))

   iv. Risk characterization (§ 250.602(c)(4))

   v. Uncertainty (§ 250.602(f))

   *Portions or all of these sections may be included in the RI/SCR report. If the RA contains a reference to the RI or SCR, that is sufficient.

   If sections i. through iii. are missing, disapprove the RA and include the comment, "This RA could not be reviewed in detail due to the lack of [missing section] which is required per § 250.602([regulatory citation for missing section])," in the disapproval letter along with any other comments resulting from the preliminary review.

   Note: Instructions for how to address submissions that are missing either the risk characterization section or the uncertainty section are discussed later in this SOP.

b. IF screening is being performed, make sure that soil and groundwater data for COC's are screened properly. Screening in an RA should be part of the site characterization section.

   i. If the media in question are attaining the site-specific standard ONLY, the data can only be screened using Environmental Protection Agency (EPA) Regional Screening Levels (RSL)

   If there are other screening values used in a RA submitted for SSS (for example, SHS MSCs), disapprove the RA and include the comment "This RA could not be reviewed in detail due to the improper screening procedure of COC's (§ 250.602(c)(1), § 250.602(b))" in the disapproval letter along with any other comments resulting from the preliminary review.

c. All receptors need to be identified. Receptor identification should be included in the site characterization or exposure assessment. The RA should include all possible receptors based on current and planned future land use.

   i. Receptors include all people who may access the site or area of contamination. There may be others, but some examples are:

      1. Adult/child/lifetime resident

2. Construction/utility worker
3. Indoor/outdoor worker
4. Trespasser

ii. Receptors are not, for example, water bodies (i.e. a pond or stream), soil, or groundwater.

If receptors are not identified, disapprove the RA and include the comment "This RA could not be reviewed in detail due to the lack of receptor identification (§ 250.402, § 250.602(b))" in the disapproval letter along with any other comments resulting from the preliminary review.

d. All potential exposure pathways need to be identified. Pathway identification should be included in the site characterization or exposure assessment. The RA should include all possible pathways to identified receptors based on current and planned future land use. These pathways may include (if applicable):

i. Inhalation - Vapor intrusion screening should be performed using the process defined in Section IV.K of the TGM.

1. 1/10th SHS screening values
2. Indoor air RSL's adjusted with appropriate attenuation factors

ii. Ingestion

iii. Dermal contact

If pathways are not identified, disapprove the RA and include the comment "This RA could not be reviewed in detail due to the lack of proper pathway identification (§ 250.404(a))" in the disapproval letter along with any other comments resulting from the preliminary review.

If the VI pathway is not screened properly, disapprove the RA and include the comment "This RA could not be reviewed in detail due to improper vapor intrusion pathway evaluation (§ 250.606(d)(3)(v))" in the disapproval letter along with any other comments resulting from the preliminary review.

e. Exposure factors must be discussed. Exposure factors should be included in the exposure assessment. These are based on identified receptors and pathways.

i. Defaults are listed in § 250.306 and § 250.307

ii. Must include justification and citation for variation from defaults § 250.603(b)

If there is no exposure factor discussion, disapprove the RA and include the comment "This RA could not be reviewed in detail due to the lack of an exposure discussion (§ 250.602(c)(2))" in the disapproval letter along with any other comments resulting from the preliminary review.

f. Toxicity must be discussed, and proper toxicity factors must be identified. A toxicity discussion is sometimes included in the exposure assessment or in its own section. These values are standard and are based on the COC's selected

   i. Should be a discussion about toxicity and how it works/what it means

   ii. Includes a table of toxicity values and sources

   If there is no toxicity discussion or table, disapprove the RA and include the comment "This RA could not be reviewed in detail due to improper toxicity discussion (§ 250.602(c)(3))" in the disapproval letter along with any other comments resulting from the preliminary review.

g. Risk characterization and uncertainty must be present. Risk characterization and uncertainty should be two separate sections of the document.

   If either or both sections are missing:

   i. If the remainder of the review resulted in no comments for disapproval, submit the RA for further review with a notation that the section(s) is (are) missing

   ii. If there are other comments resulting in disapproval, add the comment "A risk characterization discussion is a necessary portion of the risk assessment. (§ 250.602(c)(4))" or "An uncertainty discussion is a necessary portion of the risk assessment. (§ 250.602(f))" to the disapproval letter

h. An ecological RA is required under the SSS and should be included within the RA unless no complete exposure pathways to habitats or species of concern have been identified.

   An ecological RA may not be titled an "Ecological RA". It may have a title such as "ecological evaluation" or may just be a small section within the RI/SCR report. Please include ANY site-specific ecological evaluation information with the RA submission to CO for review.

   If the ecological RA is not present, do the following:

   i. If the remainder of the review resulted in no comments for disapproval, submit the RA for further review with a notation that the ecological risk assessment is missing

   ii. If there are other comments resulting in disapproval, add the comment "An ecological risk assessment is required within the site-specific standard. (§ 250.402(d))" to the disapproval letter

Appendix A
Preliminary Review Cover Sheet

Preliminary Review Cover Sheet

Facility Name	
Facility or Tanks ID No.	
Project Officer / Phone No.	
County and Municipality	
Report Title	
Report eFacts Due Date	
Date RA Comments Requested	

Are all parts of the risk assessment included? This includes: site characterization, exposure assessment, toxicity assessment, risk characterization, uncertainty.

Comments: [Yes] [No] [Maybe]

Are COC's screened? (NOT REQUIRED)

Comments: [Yes] [No] [Maybe]

Are receptors identified?

Comments: [Yes] [No] [Maybe]

Are pathways identified?

Comments: [Yes] [No] [Maybe]

Are exposure factors identified or discussed?

Comments: [Yes] [No] [Maybe]

Are toxicity factors identified or discussed?

Comments: [Yes] [No] [Maybe]

Are risk characterization and uncertainty present?

Comments: [Yes] [No] [Maybe]

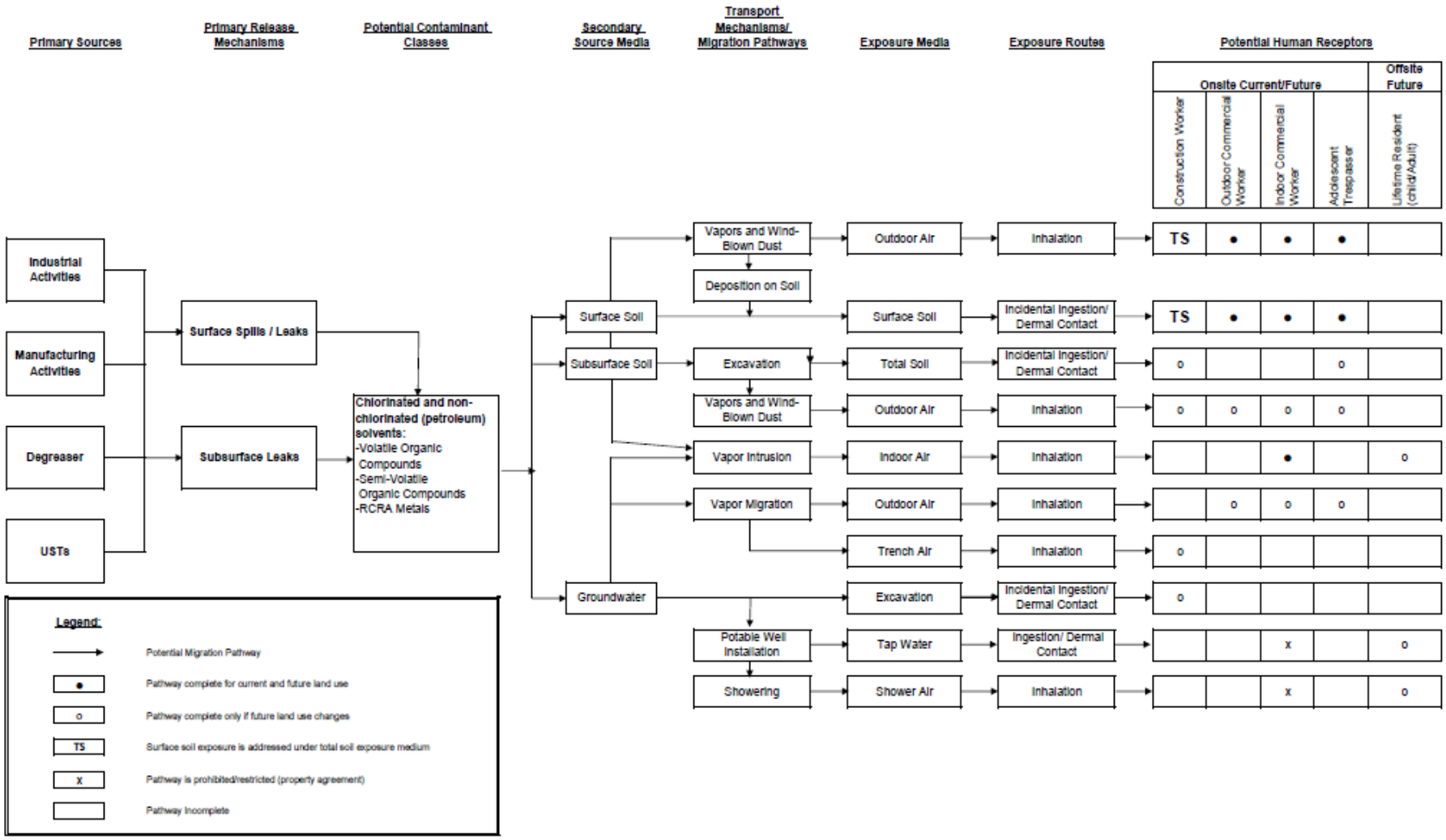
Is there an ecological RA?

Comments: [Yes] [No] [Maybe]

Appendix B
Examples

The examples provided below are not meant to be a guideline of what a section is "supposed to" look like, nor are they necessarily "correct". These are just some examples of what may be seen in a report. If there is any question either call CO or send the report in to CO for review.

Graphical CSM example:



COC Screening examples:

Text:

The screening process to identify soil COCs consists of a comparison of the maximum concentration of the detected chemical to the appropriate health-based screening value which, as stipulated by the DEP, is the EPA RSLs for Residential Soil, which represent target cancer risk (CR) of 1E-06, and a target hazard quotient (HQ) of 0.1.

Table:

Target Analyte	EPA RSL Residential Soil (ug/kg)	C* or N*	Minimum Detected Concentration (ug/kg)	Maximum Detected Concentration (ug/kg)	Location of Maximum Detected Concentration	Minimum Nondetected Concentration (ug/kg)	Maximum Nondetected Concentration (ug/kg)	Frequency of Detection	Retained as a COC
Benzene	1,200	C	5.0	13.0	MW-8, MW-9	1.8	234	3 / 17	No
Cumene	190,000	N	9.8	9.8	SB-2	4.3	1,300	1 / 17	No
Ethylbenzene	5,800	C	ND	ND	NA	4.3	1,300	0 / 17	No
MTBE	47,000	C	ND	ND	NA	4.3	234	0 / 6	No
Naphthalene	3,800	C	7.2	23.0	MW-8	4.3	1,300	2 / 23	No
Toluene	490,000	N	ND	ND	NA	4.3	1,300	0 / 17	No
1,2,4-TMB	30,000	N	94.0	94.0	MW-8	4.3	6.0	1 / 6	No
1,3,5-TMB	27,000	N	30.0	30.0	MW-9	4.3	6.0	1 / 6	No

Receptor Identification example text:

The property is located in a primarily rural area. However, future use scenarios of the property are based on residential use, to assess the most conservative and accurate current and future land use conditions.

Based on this determination, it was determined that the following potential receptors were appropriate:

- *on-property/ off-property resident;*
- *on-property/ off-property construction/utility worker;*
- *on-property/ off-property commercial workers;*
- *surface water receptors (invertebrates and fish/amphibians); and,*
- *ecological receptors (sensitive habitats).*

A graphical representation of receptor identification can be found in the graphical CSM above.

Pathway Identification example text:

Because of the following factors, all other potential source, receptor-exposure pathway combinations are incomplete or eliminated as discussed below:

- *Surficial and Subsurface Soil – Inhalation of Ambient and Indoor Air: All target analyte concentrations in surficial and subsurface soil are below EPA RSLs and DEP SHS VI Screening Values. Therefore, there are no COCs in soil.*
- *Surficial and Subsurface Soil – Ingestion/ Dermal Contact: All target analyte concentrations in surficial and subsurface soil are below EPA RSLs, and there are no COCs in soil.*

A graphical representation of pathway identification can be found in the graphical CSM above.

Exposure Parameters examples:

Text:

The ingestion rate of 0.05 liter per day (L/day) for groundwater was used for construction/ utility worker. Typically, less than ten percent of total construction time involves excavation of building foundations or subsurface utility work. As a result, the conservative exposure frequency value used for this analysis was 24-days/ year and is based on professional judgment. The 24-days/ year exposure frequency assumes that the worker would be in contact with contaminated groundwater every working day for more than a month. Since the provisions contained in 29 CFR 1926 (Sub-Part P – Excavations) dictate that workers are not permitted to enter or work in excavations where standing water is visible, unless adequate protection is used, the assumed exposure time is two hours per day. This exposure time is based on professional judgment as to the length of time a construction worker would be exposed to contaminated groundwater before it is removed. A summary of exposure parameters for construction and commercial workers is presented in Table 10.

Table:

Parameter		Construction Worker / Utility Worker	Units	Source[a]
All Pathways				
Exposure Duration	ED	1	years	Site-specific assumption
Exposure Frequency Groundwater	EFgw	20	days/year	Site-specific assumption
Exposure Frequency Soil	EFsoil	20	days/year	Site-specific assumption
Averaging Time (carcinogens)	AT-C	25,550	days	70 year lifetime x 365 days/year
Averaging Time (noncarcinogens)	AT-NC	365	days	To correspond with ED
Body Weight	BW	80	kg	USEPA SDEF, RSL Calculator
Incidental Ingestion				
Ingestion Rate of Groundwater	IRgw	0.02	L/day	VDEQ, 2017
Ingestion Rate of Soil	IRsoil	330	mg/day	USEPA SSL
Inhalation				
Exposure Time Outdoor Air	ET	8	hr/day	USEPA RSL Calculator
Exposure Time in trench	ET	4	hr/day	VDEQ, 2017
Volatilization Factor - groundwater to trench air	VF	chemical-specific	L/m^3	Calculated
Transport Factor - volatilization from soil	VF	chemical-specific	$(mg/kg)/(mg/m^3)$	§250.307(d)
Transport Factor - soil particulate	PEF	1×10^{10}	$(mg/kg)/(mg/m^3)$	§250.307(d)
Dermal Absorption				
Exposure Time in trench	ET	4	hours/event	VDEQ, 2017
Events per day	EV	1	event/day	VDEQ, 2017
Skin Surface Area - groundwater contact	SA	2,100	cm^2	SA of forearms and hands
Soil Adherence Factor	AF	0.3	mg/cm^2	USEPA SSL, RSL Calculator
Skin Surface Area - soil contact	SA	3,527	cm^2	RSL Calculator

Example Toxicity factor section:

Text:

Chemical-specific oral and inhalation RfDs and CSFs are obtained from the integrated risk information system (IRIS). The IRIS is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to environmental contaminants. The RfD and reference concentration (RfC) provide quantitative information for use in RA for health effects known or assumed to be produced through a nonlinear (possibly threshold) mode of action. The RfD (expressed in units of mg of substance/kg body weight-day) is defined as an estimate of a daily exposure to the human population that is likely to be without an appreciable risk of deleterious effects during a lifetime. An RfD can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used.

Table:

Constituents of Interest	Dermal Reference Dose [1] (mg/kg-day)	Dermal Cancer Slope Factor [2] $(mg/kg\text{-}day)^{-1}$	Gastrointestinal Absorption Factor	Oral Reference Dose (mg/kg-day)		Oral Cancer Slope Factor $(mg/kg\text{-}day)^{-1}$		Inhalation Reference Conc. (mg/m^3)		Inhalation Unit Risk Factor $(ug/m^3)^{-1}$	
Semi-Volatile Organic Compounds											
Benzo(a)anthracene	NA	1.1E-01	0.89	NA		1.0E-01	E	NA		1.1E-04	C
Benzo(a)pyrene	2.7E-04	1.1E+00	0.89	3.0E-04	I	1.0E+00	I	2.0E-06	I	6.0E-04	I
Benzo(b)fluoranthene	NA	1.1E-01	0.89	NA		1.0E-01	E	NA		1.1E-04	C
Benzo(k)fluoranthene	NA	1.1E-02	0.89	NA		1.0E-02	E	NA		1.1E-04	C
Chrysene	NA	1.1E-03	0.89	NA		1.0E-03	E	NA		1.1E-05	C
Dibenz(a,h)anthracene	NA	1.1E+00	0.89	NA		1.0E+00	E	NA		1.2E-03	C
2,6-Dinitrotoluene	1.5E-04	3.0E+00	0.50	3.0E-04	X	1.5E+00	P	NA		NA	
Indeno(1,2,3-cd)pyrene	NA	1.1E-01	0.89	NA		1.0E-01	E	NA		1.1E-04	C
Naphthalene	1.8E-02	1.3E-01	0.89	2.0E-02	I	1.2E-01	C	3.0E-03	I	3.4E-05	C
Pentachlorophenol	2.5E-03	8.0E-01	0.50	5.0E-03	I	4.0E-01	I	NA		5.1E-06	C
Inorganics											
Arsenic	2.9E-04	1.6E+00	0.95	3.0E-04	I	1.5E+00	I	1.5E-05	C	4.3E-03	I
Cobalt	3.0E-04	NA	1	3.0E-04	P	NA		6.0E-06	P	9.0E-03	P
Iron	7.0E-01	NA	1	7.0E-01	P	NA		NA		NA	
Manganese	5.6E-03	NA	0.04	1.4E-01	I	NA		5.0E-05	I	NA	
Vanadium	1.3E-04	NA	0.026	5.0E-03	S	NA		1.0E-04	D	NA	
Zinc	3.0E-01	NA	1	3.0E-01	I	NA		NA		NA	