

3. Site-Specific Standard

a. Introduction

The objective of the site-specific standard is to develop and evaluate detailed site information using a rigorous scientific evaluation of a remedy to provide a protective cleanup standard unique to that site. Use of this standard requires the Department's review and approval (as required by statute) of the remedial investigation report, risk assessment report (if necessary), cleanup plan (if necessary) and final report. The relationship of these steps in the ~~risk-site specific~~ site assessment process is illustrated in Figure II-11. The remedial investigation report, risk assessment report, and cleanup plan may be submitted at the same time. In some cases, only a remedial investigation report and final report are required, and these can be combined (see Section ~~II.B.3.g~~ of this manual). In other cases (such as simple pathway elimination of all present and future exposure pathways), the risk assessment report and cleanup plan can be simplified.

All pathways of exposure are evaluated and the past, current and future use of the land is considered. The resulting cleanup remedy selected to meet site-specific soil and groundwater standards may be a combination of treatment/removal efforts, and engineering and institutional controls. The extent to which treatment and removal efforts are balanced with engineering and institutional controls is determined by the factors used in remedy selection. These factors are described in Section 304(j) of Act 2.

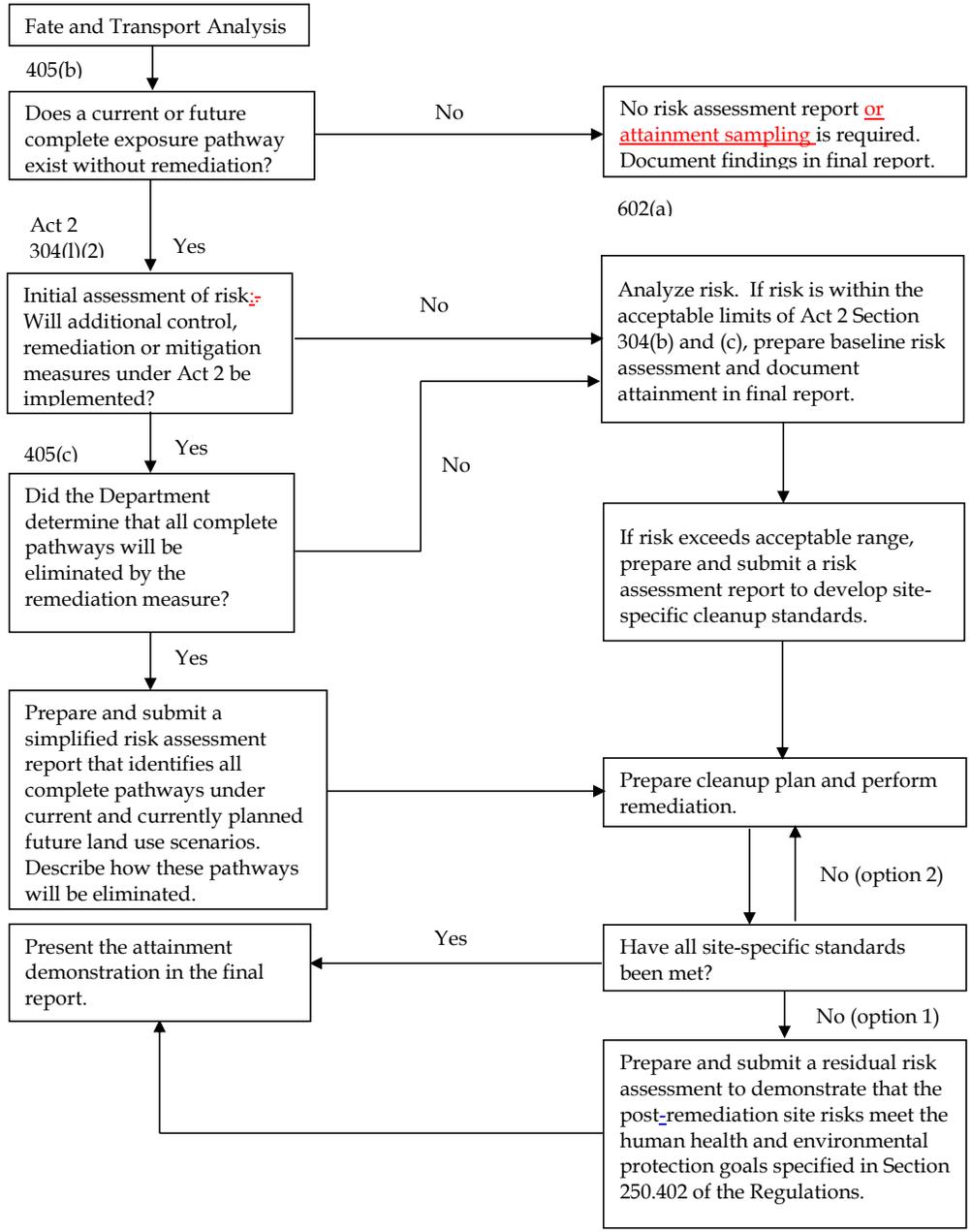
Persons utilizing the site-specific standards must comply with the applicable deed acknowledgment requirements under the SWMA or HSCA [Section 304 (m)], notice and review [Section 304 (n)], and community involvement requirements [Section 304 (o)] of Act 2.

The site-specific standard is a risk management approach. It offers more flexibility to the person than background or Statewide health standards because detailed site-specific information is collected for the evaluation. The guidance contained in Section II.A.4 of this manual provides a structure and process for this data collection or remedial investigation. The additional information does involve more time and effort to collect and additional reviews are required by the Department under Act 2. This approach differs in that full and total use of the site may not be possible to the extent that specific land uses were presumed and engineering and institutional controls are used in the final remedy. The site-specific standard approach addresses future use limitations by ~~deed~~ noti~~e~~environmental covenant. Also, use of the site-specific standard requires public involvement if the municipality requests to be involved in the remediation.

In determining soil and groundwater standards, consideration should be given to appropriate exposure factors to receptors based on land use of the site, the effectiveness of institutional or other controls placed on the future land use, potential pathways for human exposure, and appropriate statistical techniques.

Figure II-11

Risk-Site Specific Site Assessment Flowchart



b. Process Checklist for the Site-Specific Standard

A checklist for site-specific standard is provided below and can be used to ensure administrative completeness.

- Submit Notice of Intent to Remediate for the site-specific standard to the Department. Also send a copy of the NIR to the municipality, publish a summary of the notice in a newspaper of general circulation serving the area in which the site is located, and provide proof of publication to the Department. Procedures are in Section II.A.3 of this manual.
- Notify the municipality, publish a notice in a local newspaper, and provide proof of ~~publication-submittal~~ to the Department each time a remedial investigation report, risk assessment report, cleanup plan or final report is submitted to the Department. Procedures are in Section II.A.3 of this manual.
- Prepare and submit public involvement plan if requested by municipality. Procedures are in Section II.A.3 of this manual.
- Begin the remedial investigation. See Sections II.B.3 and II.A.4 of this manual for guidance.
- As an option, begin using the completeness list (See Section VI.C) to help verify that all requirements have been met.
- Prepare and submit a remedial investigation report which includes fate and transport analysis to determine if any exposure pathways exist at the site. A fee of \$250 is required. Reporting requirements are established by Sections 250.404 and 250.408 of the regulations and are described in Section II.B.3.g or III.A of this manual.
- Prepare and submit a risk assessment report (baseline risk assessment report and/or risk assessment report to develop site-specific standards) along with a fee of \$250 to the Department. A baseline risk assessment report is not required if the Department, in its remedial investigation report or cleanup plan approval, determines that a specific remediation measure that eliminates all pathways, ~~other than a no-action remedial alternative~~, can be implemented to attain the site-specific standard [Section 250.405(c) of the regulations]. This does not include a no-action remedial alternative. No risk assessment report is required if no present or future exposure pathways exist, as documented by a fate and transport analysis. Risk assessment requirements are established by Sections 250.402-407, 250.409 and Subchapter F of the regulations. Guidances are provided in Sections III.G and III.H of this manual. Reporting requirements are described in Section II.B.3.g.v of this manual.
- Prepare a cleanup plan. A cleanup plan is not required if no present or future exposure pathways exist. The cleanup plan is also not required if the approved baseline risk assessment report indicates that the site does not pose unacceptable risks to human health and the environment under current and planned future conditions. Cleanup plan requirements are established by

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Sections 304(j) and 304(l)(3) of the Act and Section 250.410 of the regulations. Guidance on the cleanup plan is provided in Section II.B.3.g. of this manual.

- Submit the cleanup plan, if required, and a fee of \$250.
- Remediate the site to the site-specific standard in accordance with the approved cleanup plan. No remedy is required if no present or future exposure pathways exist.
- Establish attainment of the site-specific standard in accordance with the requirements in Subchapter G of the regulations. Guidances are provided in Sections II.B.3.g. and III.B of this manual.
- Calculate the mass of contaminants remediated using the procedure in Section III.C of this manual.
- Complete the Final Report Summary ~~online~~ and submit electronically as instructed on the LRP web page.
- Submit final report, along with the optional completeness list (if used), and a fee of \$500 to the Department. Include information in Sections 250.411 and 250.204(f)(1)-(5) of the regulations. Include post-remediation care plan in accordance with Section 250.204(g) as appropriate. Document cooperation of third parties where access is needed for remediation or monitoring. Reporting requirements for the final report are described in Section II.B.3.g of this manual.
- Upon the Department's approval of the final report demonstrating compliance with substantive and procedural requirements of the site-specific standard, the site is automatically afforded the liability protection as outlined in Chapter 5 of Act 2.
- If engineering controls are used and ~~postremediation~~ post-remediation care is needed to maintain the standard, if fate and transport analysis indicates standard may be exceeded at the point of compliance in the future, if remediation relies on natural attenuation, or if mitigation measures are implemented in accordance with Section 250.311(f), continue with the ~~postremediation~~ post-remediation care program detailed in the final report. If areas of the source property were shown to have no current or probable future complete exposure pathway, the ~~postremediation~~ post-remediation controls described in Section III.D are needed.
- When the site-specific standard can be maintained without engineering controls operating and mitigation measures have been successfully sustained, document this to the Department and receive approval to end the ~~postremediation~~ post-remediation care program.

c. Site Investigation

The principal objectives of an investigation under the site-specific standard are to characterize the nature, extent, direction, volume and composition of regulated substances that have been released, and to obtain detailed site information,

including identification of exposure pathways, in order to develop a protective cleanup standard unique to that site.

Important tasks during the site investigation include site characterization, ~~ecological screening,~~ and pathway identification. The development of a site conceptual model and identification of contaminants of concern are also important steps in the site investigation process. This section provides specific information and procedures regarding site characterization, ~~ecological screening,~~ and pathway identification. At the conclusion of the site investigation, a remedial investigation report should be submitted to the Department for review and approval [Act 2, Section 304(l)(1)]. Section ~~H.B.3.g.i~~ of this manual describes specific information required to be included in the remedial investigation report.

i. Site Characterization

The site characterization must be conducted in accordance with scientifically recognized principles, standards, and procedures. The level of detail in the investigation and the methods selected shall sufficiently characterize the nature, present and future extent, direction, volume, and composition of regulated substances that have been released. The determination of the site conditions will be used to select the remedy ~~alternative~~ used to clean up the site. All interpretations of geologic and hydrogeologic data shall be prepared by a professional geologist licensed in Pennsylvania.

Methodologies presented in Section II.A.4 of this manual should be followed while conducting the site investigation. When evaluating the nonpoint source groundwater discharge to surface water, a person may consult EPA guidances in “A Review of Methods for Assessing Nonpoint Source Contaminated Groundwater Discharge to Surface Water, EPA 570/9-91-010, April 1991,” and “Handbook: Stream Sampling for Waste Load Allocation Application. EPA/625/6-80/013.” Section III.A.3 of this manual provides guidance to evaluate impacts on surface water from diffuse flow of contaminated groundwater.

As directed from specific knowledge of the subject property, including historic use ~~of the subject property,~~ or chemical usage information ~~regarding the subject property;~~ and based upon the guidance in Section II.A.4 of this manual, an appropriate number of sample locations should be investigated. These sample locations should be from the identified media of concern in order to characterize the nature and composition of the contaminants, including the characterization of the source of the regulated substances. and This will allow for development of a conceptual site model, taking into account the vertical and horizontal extent of contamination ~~with each medium of concern,~~ the direction, rate, extent and fate of contaminant movement within each medium of concern, and to identify the appropriate remedial technology options for each medium of concern.

When determining the relative location of soil or groundwater samples necessary to characterize the horizontal and vertical extent of contamination, factors such

as hydraulic conductivity of the soils, heterogeneity of the soils, and the nature of the contaminants should be considered.

If groundwater is determined to be a medium of concern, adequate characterization of the effects of a release on groundwater will require a hydrogeologic study. ~~This study will determine~~ how naturally occurring physical and geochemical characteristics define the hydrostratigraphy (position of aquifers, aquitards, and aquicludes) ~~of the site, where appropriate,~~ which includes an assessment of the homogeneity and isotropy of aquifer materials based on hydraulic conductivity values (measured or published), and ~~an assessment of~~ local and regional groundwater flow directions ~~and as well as~~ any influence from pumping centers.

Characterizing the horizontal extent of contamination of regulated substance(s) will be defined by a minimum of two rounds of groundwater sampling from properly constructed and developed monitoring wells. The initial sampling event should be conducted no less than fourteen days from the date of the most recent well development, ~~or a~~ shorter time frame is permissible if it is demonstrated that, through development, pH and conductivity of the groundwater has stabilized. The second and subsequent sampling events should occur no less than fourteen days from the preceding sampling event.

When characterizing the vertical extent of groundwater contamination, consider the specific gravity of the regulated substances identified ~~in the site's groundwater,~~ and the potential for naturally occurring or induced downward vertical hydraulic gradients. If characterizing the vertical extent of groundwater contamination is necessary, properly constructed monitoring wells or nested monitoring wells should be utilized to focus groundwater sampling in zones of potential contaminant accumulation (*i.e.*, directly above a confining layer).

The determination of the use of groundwater is also an important task of site characterization. The uses of groundwater may include drinking water use, agricultural use, industrial uses, etc. As mandated by Act 2, groundwater will not be considered a current or potential source of drinking water where groundwater has a background total dissolved solid concentration greater than 2,500 milligrams per liter. Other than that mandate, current and probable future uses of groundwater must be determined on a site-specific basis. Current drinking water or agricultural uses of groundwater, at the time contamination was discovered, should be identified for protection. Additional requirements on the determination of the use of groundwater are in Section 250.403 of the regulations.

Development of a site conceptual model is an important step in identifying additional data needs ~~in site characterization~~ and ~~in~~ defining exposure. A site conceptual model identifies all potential or suspected sources of contamination, types and concentrations of contaminants detected at the site, potentially contaminated media, potential exposure pathways, and receptors. Many components of exposure (such as the source, receptors, migration pathways, and routes of exposure) are determined on a site-specific basis. The site conceptual

model provides a systematic way to identify and summarize this information to ensure that potential exposures at the site are accounted for accurately.

The conceptual model may be graphical, tabular or narrative but should provide an accurate understanding of complete exposure pathways for the site.

Examples of site conceptual models may be found in EPA or ASTM guidance documents, including Section 4.2 of *U.S. EPA Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (RAGS/HHEM), Part A*, *ASTM E-1739 RBCA, Tier 2 Guidance Manual*, and *ASTM E1689-95, Standard Guide for Developing Conceptual Site Models for Contaminated Sites*. It is suggested that the development of the site conceptual model be coordinated with the regulatory risk manager to ensure that potential pathways are adequately and appropriately addressed prior to performing the assessment.

ii. Preliminary Ecological Screening

Comment [B1]: Preliminary Eco Screening text moved to Section 3.d.

~~To ensure that any substantial present or probable future risk to the environment is eliminated, both human health and ecological risk evaluations are necessary. The objective of the Preliminary Ecological Screening is to quickly evaluate whether surface soil or sediments at a site have the potential to pose significant ecological impact or impacts requiring further evaluation. The site-specific initial screening procedure described in Section IV.H of this manual may be used during or immediately after the site characterization process to assess the potential for significant ecological impact. It should be noted that the ecological screening procedures under the Statewide health standard (in Section II.B.5 of this manual) should not be used to replace the site-specific initial screen procedure (Steps 1-2 in Section IV.H of this manual) when the site-specific standard is selected to protect human health and the environment. This is because the assumption to use the ecological screening procedures under the Statewide health standard is that the site has met Statewide health standards to protect human health. This underlying assumption cannot be made when the site-specific standard is selected to protect human health.~~

~~For sites that have met Statewide health standards to protect human health, but fail the ecological screening procedure under the Statewide health standard (in Section II.B.5 of this manual), and the remediator has elected to conduct a formal site-specific ecological risk assessment, the site-specific initial screen (Steps 1-2 in Section IV.H of this manual) can be ignored, because the site is beyond the decision point whether the site has the potential to pose significant ecological impact or not.~~

~~When conducting an ecological screening under the site-specific standard, the following should be performed:~~

- ~~• an ecological risk assessment to determine if an impact has occurred or will occur if the release of a regulated substance goes unabated;~~
- ~~• an ecological risk assessment conducted in accordance with Department-approved EPA or ASTM guidance to establish acceptable remediation levels~~

~~or alternative remedies based on current and future use that are protective of ecological receptors;~~

- ~~• implementation of the selected remedy, which may include mitigation measures under Section 250.311(f), that is protective of ecological receptors;~~

~~The results of the ecological screening should be provided in the remedial investigation report rather than in the final report when a person selects to comply with site specific standards.~~

~~iii.~~ **ii. Pathway Identification (Section 250.404 of the Regulations)**

Once the development of the site conceptual model is completed, current and future exposure pathways should be identified based on this site conceptual model. An exposure pathway describes the course a chemical or physical agent takes from the source to the exposed receptor. An exposure pathway analysis links the sources, locations, and types of environmental releases with population locations and activity patterns to determine the significant pathways of exposure.

A potentially complete exposure pathway generally consists of four elements:

- a source and mechanism of chemical release,
- a retention or transport medium (or media in cases involving media transfer of chemicals),
- a point of potential receptor contact with the contaminated medium (the exposure point), and
- an exposure route (e.g., ingestion) at the exposure point.

The person should consult the most recent U.S EPA or ASTM guidances to identify any potential current and future exposure pathways for both human receptors and environmental receptors. The pathway identification should take into account current pathways and the effects of engineering and institutional controls. Future exposure pathways should be based on currently planned and/or probable future land use. Guidance on land use considerations can be found in the USEPA OSWER Directive: *Land Use in The CERCLA Remedy Selection Process*. DEP guidance entitled *Site-Specific Human Health Risk Assessment Procedures* in Section III.G of this manual provides more information on pathway identification for human exposure. Guidance such as described in Sections 6.2 and 6.3 (relating to characterization of exposure setting and relating to identification of exposure pathways) of *U.S. EPA's Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (RAGS/HHEM), Part A*, provides a framework for pathway identification for human exposure. Subsection 6.3.2 of RAGS/HHEM, Part A particularly provides guidances to perform fate and transport analysis.

If no complete present or future exposure pathways exist, a risk assessment report and cleanup plan are not required and no remedy is required to be proposed or completed [Act 2, Section 304(l)(1)(v)]. When no complete present or future exposure pathways exist, a person only needs to follow the streamlined

reporting requirements in Section II.B.3.h of this manual instead of the reporting requirements in Section ~~H.B.3.g~~ of this manual. No attainment sampling is necessary if no current or future pathways exist.

~~The following is an example of no existence of complete exposure pathways: Contaminated soil is only detected beneath the concrete slab floor of an industrial building and the concrete slab is free from any contamination. The contaminant has very low mobility (low solubility in water, and is not volatile). The groundwater table is at a good distance from the contaminated soil and is not contaminated. In this case, the exposure to contaminated soil through direct contact, such as ingestion of soils, is very unlikely if a deed restriction regarding the contaminated soil is in place and the concrete cap is maintained. The low mobility of the contaminant and distance of contaminated soils from the groundwater table also make the contamination of groundwater unlikely. No groundwater exposure, such as ingestion of contaminated groundwater is expected. The nonvolatile characteristic of the contaminant and the absence of contaminated surface soil will also rule out inhalation pathways.~~

Comment [B2]: Confusing example

Prior to the identification of exposure routes, a person must identify sources and receiving media, evaluate fate and transport in release media, and identify exposure points and potential receptors. The following exposure scenarios contain examples of what should be considered:

i) Groundwater

The person-remediator shall identify routes of exposure for groundwater such as human exposure to groundwater by ingestion, human-inhalation, or dermal exposure routes. ~~of regulated substances from volatilization and migration of these substances into buildings or other areas where humans could be exposed or through indoor use of groundwater, human ingestion of regulated substances in surface water, or other site-specific surface water exposure pathways with respect to groundwater discharges or releases to surface water, human inhalation of regulated substances in air, such as via the use of industrial process water or via volatilization, or other site-specific air exposure pathways with respect to releases of regulated substances from groundwater to air.~~ The person-remediator should consider effects of discharge of groundwater into surface water and the effects on ecological receptors.

With respect to the groundwater ingestion pathway, the following guidance is provided. When determining whether groundwater on or off the source property must be protected under the site-specific standard for drinking water uses, the following will be applied [from Act 2, Section 304 (d)]:

- The *current and probable* future use of groundwater shall be identified and protected. Groundwater that has a background total dissolved solids content greater than 2,500 milligrams per liter or is not capable of transmitting water to a pumping well in usable and sustainable quantities shall not be considered a current or potential source of drinking water.

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- Site-specific sources of contaminants and potential receptors shall be identified.
- Natural environmental conditions affecting the fate and transport of contaminants, such as natural attenuation, shall be determined by appropriate scientific methods."

And from Section 250.403 the following apply:

- ~~Groundwater will not be considered a current or potential source of drinking water where groundwater has a background total dissolved solids concentration greater than 2,500 milligrams per liter.~~
- Except for groundwater excluded by the total dissolved solids limitation described above, current and probable future use of groundwater *shall be determined on a site-specific basis.*
- Drinking water use of groundwater shall be made suitable by at least meeting the primary and secondary MCLs at all points of exposure identified in 250.404 (relating to pathway identification and elimination).
- Current drinking water or agricultural uses of groundwater, *at the time contamination was discovered*, shall be protected." ~~[emphasis added]~~

Comment [B3]: Repetitive

~~In the As an~~ example; ~~of contamination~~ within a city with an established public water system and groundwater contamination ~~which extends~~ extending off-property, the complete exposure pathways ~~will~~ depend on volatilization potential of contamination ~~to receptors~~, and the current use or "probability" that future groundwater ingestion may occur. If surrounding properties are ~~currently~~ developed and have public water service, then it may be assumed that the probability is that those established patterns of water use ~~would will~~ continue into the future. Therefore, there are no current or probable future uses of groundwater as a drinking water source; and the groundwater ingestion pathway may (all other information supporting) be determined to be incomplete.

Note ~~however~~, that even in cases where the groundwater ingestion pathway is determined to be incomplete; the final report must include one or a combination of institutional controls or post-remedial measures which provide assurance that ~~the this~~ status of ~~no complete groundwater ingestion pathway~~ continues to exist in the future. See Section ~~H.C.9~~ under the site-specific standard for the range of institutional controls or post remedial measures available to a remediator. If a complete groundwater ingestion pathway is found to exist in the future, then the responsible person must demonstrate attainment of one of the three Act 2 standards.

ii) **Soil**

The person shall consider current and probable future exposure scenarios, such as human ingestion, ~~dermal contact, inhalation of volatiles and particulates and of soil when direct contact exposure to the soil may reasonably occur, exposure to groundwater by ingestion with respect to leaching of regulated substances~~

~~from soils to aquifer groundwater, human inhalation of regulated substances from volatilization and migration of these substances into buildings or other areas where humans could be exposed, human ingestion of regulated substances in surface water or other site-specific surface water exposure pathways with respect to regulated substances migration from soil to surface water, human inhalation of regulated substances in air or other site-specific air exposure pathways with respect to the release of regulated substances from soil to air.~~

Comment [B4]: Repetitive and extraneous

When evaluating the indoor exposure pathways, a person needs to address impacts of volatile organic compounds from soil only and groundwater, not extraneous sources.

~~iii) —~~ **Cases where there is no current groundwater ingestion route, but there is probable future exposure.**

~~An example of this situation would be where an open field is adjacent to the source property with no current users of groundwater. In general the Department will take the cautious position that undeveloped property has probable future exposure, since future development may include onsite groundwater use. Cases of probable future exposure would require actions to eliminate this probable exposure. A municipal ordinance prohibiting groundwater use would be one method of eliminating the pathway.~~

Comment [MSM5]: Repetitive.

~~iv)iii) —~~ **Cases where no complete current or future exposure pathway exists**

~~If, after completing the site characterization including exposure pathway identification described above,~~ no current or probable future complete exposure pathways exist without remediation, then no risk assessment report is required. Findings of no complete exposure pathway should be documented in the final report. When approved, the final report documents that the site meets the site-specific standard including meeting the allowable risk specified by Act 2, Sections 304 (b) and (c). Therefore no specific numeric concentration value (standard) is applied to the site and no attainment sampling is necessary.

In the specific and common case where no pathways exist because water users are being served by a public water system, then the final report must include one or a combination of institutional controls or post remedial measures which provide assurance that the status of no complete pathways continues to exist in the future. See Section III.D for the range of measures available to a remediator.

~~v) —~~ **Cases where complete pathways exist but the risk is within the allowable range**

~~Many times a pathway exposure analysis identifies complete exposure pathways, but upon analysis of the current and future risk *without remediation applied* (i.e. baseline risk assessment), it is found that the risk is below what is allowable by Act 2 and no remediation is required [Section 250.602(a)]. If this is the case, the remediator should prepare and submit a baseline risk assessment report documenting the current and future risk *without remediation applied* being~~

~~within the allowable levels as per Act 2, Section 304. When approved, the final report documents that the site meets the site-specific standard including meeting the allowable risk specified by Act 2, Sections 304 (b) and (c). Therefore no specific numeric concentration value (standard) is applied to the site.~~

~~If part of the exposure analysis found that some pathways were not complete because water users are being served by a public water system, then the final report must include one or a combination of institutional controls or post remedial measures which provide assurance that the status of no complete pathways continues to exist in the future. See Section II.C.9 for the range of measures available to a remediator.~~

~~In cases where the baseline risk assessment indicates that there are no unacceptable non-cancer hazards from systemic toxicants, and that the cumulative excess lifetime cancer risk is less than 1 in 10,000, the remediator may substitute the values that were used to demonstrate that the risk is within the statutory range [established by Section 304(b) and (c)], without performing a new calculation of a site-specific cleanup level. The person must also conduct a separate analysis of risk to ecological receptors.~~

Comment [MSM6]: Addressed in Section 3.d.

d. Risk Assessment and Development of Site-Specific Standards

This section provides general information on risk assessment, developing site-specific standards and pathway elimination. Sections III.G and H of this manual provide guidance on site-specific human health and ecological risk assessment procedures. This guidance should be followed to conduct a baseline risk assessment or to develop site-specific standards. During the development of site-specific cleanup levels with emphasis on the cumulative risks, a person should consider PQLs to ensure that the cleanup levels developed can be quantified.

Any person selecting the site-specific standard established by Section 304 of Act 2 should submit a risk assessment report to the Department for review and approval unless no present or future complete exposure pathways exist as demonstrated by a fate and transport analysis. If no such complete exposure pathways exist, a person only needs to follow ~~a the~~ streamlined reporting requirements in ~~Section II.B.3.h of this manual instead of the reporting requirements in Section II.B.3.g Table II-9~~ of this manual. If complete exposure pathways exist, the fate and transport analysis, which is a part of the exposure assessment, should be documented in the risk assessment report.

Although it might be helpful in some cases to establish the leaching potential of constituents in soil, passing the TCLP does not automatically indicate attainment of the site-specific standard. The TCLP is used for RCRA hazardous waste determinations. The risk associated with the regulated substances is considered in the site-specific risk assessment under Act 2.

To determine if a site-specific risk assessment is necessary, a site conceptual model should be developed that defines potential exposure scenarios and

pathways. The exposure scenario (*e.g.*, residential, industrial, recreational), which will define the exposure pathways, must be based on site-specific land use considerations. The pathways, which describe the mechanism by which receptors may be exposed to a source, are also site-specific. Engineering or institutional controls that are to be implemented which will eliminate exposure pathways must be incorporated into the conceptual model. Then, a risk assessment only needs to be performed if complete exposure pathways for humans and/or ecological receptors exist under current or future ~~planned~~ possible conditions.

A complete exposure pathway exists if there is a receptor to be exposed through an exposure route. For ecological receptors, a pathway is complete even if the current ecological receptors are not present as a result of the contamination. A pathway is not complete if there is no reasonable route; *i.e.*, the contaminant is not in an available form to affect the receptors.

However, before getting into the mechanics of performing the risk assessment, it is important to clearly define the problem that is to be addressed, the objectives of the study and how the results will be used to meet these objectives. This initial step is critical to ensure a successful outcome (accurate, protective, timely, cost-effective evaluation) and that the level of effort is commensurate with the scope of the problem.

Under Act 2, a risk assessment report may include the following:

- a baseline risk assessment report that describes the potential adverse effects, ~~including the evaluation of to both human and~~ ecological receptors, under both current and ~~planned~~ probable future conditions that are caused by the presence of regulated substances in the absence of any further control, remediation, or mitigation measures;
- a risk assessment report that documents which exposure pathways will be eliminated by a pathway elimination measure so that any substantial present or probable future risk to human health or the environment is eliminated;
- a risk assessment report that describes the methods used to develop a concentration level at which human health and the environment are protected; and
- the comments obtained as a result of a public comment period, if any, and the responses to those public comments.

If an unacceptable risk is identified at a site, a person may develop site-specific standards based on a site-specific risk assessment. A baseline risk assessment report is not required if the Department, in its remedial investigation report or cleanup plan approval, determines that a specific remediation measure, other than a no-action remedial alternative, can be implemented to attain the site-specific standard [Act 2, Section 304(l)(2) and Section 250.405(c) of the regulations]. A baseline risk assessment is that portion of a risk assessment that evaluates a risk in the absence of the proposed site-specific measure.

In developing site-specific standards, a person may either use the toxicological data presented in Tables 5a and 5b of [Appendix A](#), Chapter 250, or [refer to the toxicity database on the Land Recycling website for the most up-to-date values](#), ~~the procedure used by the Department to evaluate changes in those toxicity values based upon new or more appropriate information. The procedure for assessing the appropriateness of new or revised toxicity data is illustrated on [Figure II-12](#) and explained below.~~

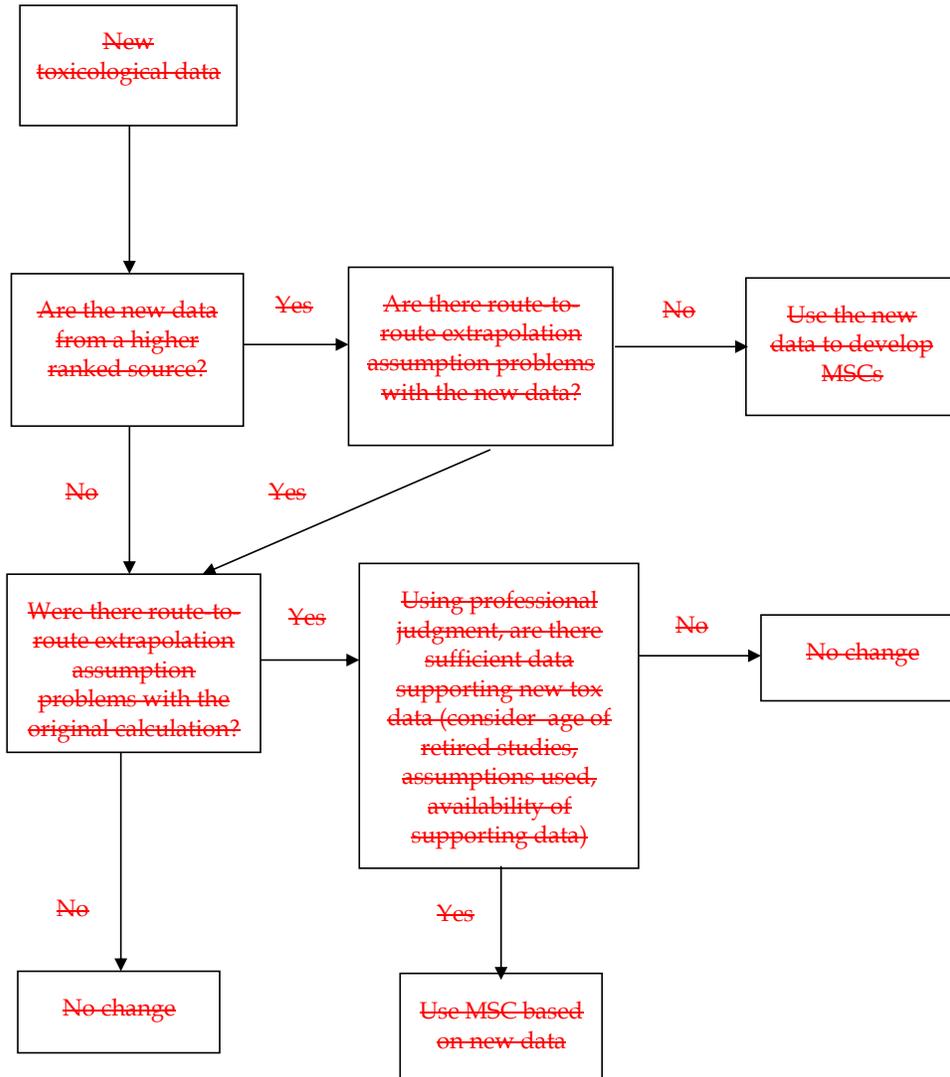
Comment [B7]: Deleted material below no longer accurate

~~When new toxicological data are available for any regulated substance, the first decision is whether the new source is from a "higher" ranked data source (according to [Section 250.605](#)). If yes, then a determination is made as to whether the new value is based on route-to-route extrapolation assumptions which are inappropriate. (e.g., port of entry effects). If appropriate, the new value is used. If not appropriate, or if the first decision point was answered "no", then a determination is made as to whether the original toxicity calculation was based on inappropriate route-to-route extrapolation assumptions, and if not then there would be no change in the toxicity value for that regulated substance. If this second determination finds that an inappropriate assumption was used, then professional judgment (by a person trained and experienced in the field of toxicology) is used to consider the change. Professional judgments would include consideration of the assumptions and the age of any retired study (e.g., retired NCEA provisional values). In cases where no data are available supporting the new toxicological value, no change would be proposed for use under Chapter 250.~~

Figure II-12

Process for Evaluating New Toxicological Data

Comment [B8]: Delete this entire figure, no longer relevant



As an alternative to developing site-specific numerical cleanup standards and remediation, individuals may choose to perform a combination of engineering and institutional controls to achieve pathway elimination for regulated substances of concern. Common methodologies used to eliminate exposure pathways include permanent capping of non-volatile contaminated soils with parking lots or building slab construction, ~~deed restrictions~~environmental covenants, slurry or cutoff walls, or liner systems.

~~Use of pathway elimination~~Remediation measures may require interface with the Solid Waste Management Act (see Section III.A), particularly for offsite removal of contaminated media or management of existing waste onsite.

To prepare the development of the site-specific standards risk assessment report, all current and probable future complete exposure pathways as identified in the fate and transport analysis should be addressed. When pathway elimination measures are planned and preapproved, the remaining pathways and the eliminated pathways under the post-remedial conditions should be identified in the site-specific standard risk assessment report. Site-specific cleanup levels should be developed to address the risks associated with these remaining pathways. Where all pathways have not been eliminated, a risk assessment report is required.

In addition to human health protection, the risk assessment must evaluate ecological receptors. An ecological risk assessment should be conducted with considerations of the site-specific ecological risk assessment procedure provided in Section III.H of this manual and the most recent U.S. EPA or ASTM guidances, including those listed in Table II-4.7. ~~To~~ determine whether an impact has occurred or will occur if a release goes unabated, to establish acceptable remediation levels or alternative remedies based on current or ~~intended~~probable future land use that are protective of the ecological receptors.

Ecological receptors include:

- individuals of threatened or endangered species as designated by the U.S. Fish and Wildlife Service under the Endangered Species Act;
- exceptional value wetlands as defined in 25 Pa. Code Section 105.17 (relating to wetlands);
- habitats of concern as defined in Section 250.1 of the regulations; and
- species of concern as identified in Section VI.E of this manual.

At the conclusion of the risk assessment, a risk assessment report should be submitted to the Department for review and approval. Section II.B.3.g of this manual describes specific information required to be included in the risk assessment report.

To ensure that any substantial present or probable future risk to the environment is eliminated, both human health and ecological risk evaluations are necessary. The objective of the Preliminary Ecological Screening is to quickly evaluate whether surface soil or sediments at a site have the potential to pose significant

Comment [B9]: Moved from Section 3.c.ii.

ecological impact or impacts requiring further evaluation. The site-specific initial screening procedure described in Section III.H of this manual may be used during or immediately after the site characterization process to assess the potential for significant ecological impact. It should be noted that the ecological screening procedures under the Statewide health standard (in Section II.B.2.e of this manual) should not be used to replace the site-specific initial screen procedure (Steps 1-2 in Section III.H of this manual) when the site-specific standard is selected to protect human health and the environment. This is because the assumption to use the ecological screening procedures under the Statewide health standard is that the site has met Statewide health standards to protect human health. This underlying assumption cannot be made when the site-specific standard is selected to protect human health.

When conducting an ecological screening under the site-specific standard, the following should be performed:

- an ecological risk assessment to determine if an impact has occurred or will occur if the release of a regulated substance goes unabated;
- an ecological risk assessment conducted in accordance with Department-approved EPA or ASTM guidance to establish acceptable remediation levels or alternative remedies based on current and future use that are protective of ecological receptors;
- implementation of the selected remedy, which may include mitigation measures under Section 250.311(f), that is protective of ecological receptors.

Table II-4

List of Ecological Risk Assessment Guidances

U.S. EPA. 1997. Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments. EPA/540-R-97-006. PB97-963211. June 16, 1997.

U.S. EPA. 1989. Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference Document. EPA/600/3-89/013. PB89205967. March, 1989.

U.S. EPA. 1993a. Wildlife Exposure Factors Handbook, Volume I of II. EPA/600/R-93/187a. PB94-174778. December, 1993.

U.S. EPA. 1993b. Wildlife Exposure Factors Handbook, Volume II of II, Appendix: Literature Review Database. EPA/600/R-93/187b. PB94-177789. December, 1993.

U.S. EPA. 1992. Guidelines for Exposure Assessment; 57 FR, 22888-22938, May 29, 1992

ASTM, E 1739, Standard Guide for Risk-Based Corrective Action Applied at Petroleum Release Sites.

[Refer to the EPA website for the Region 3 BTAG \(Biological Technical Assistance Group\) screening tables and the SSL \(Soil Screening Levels\) tables as well as the NOAA website for the SQuiRT \(Screening Quick Reference Tables\) ecological screening values.](#)

e. Cleanup Plan

Section II.B.3.g ~~and Table II-7~~ of this manual describes information required to be included in the cleanup plan. A cleanup plan is not required and no remedy is required to be proposed or completed if neither current nor future exposure pathways exist. ~~The future exposure pathways should be based on currently planned future land use.~~ Subject to the Department’s approval of the baseline risk assessment report, a cleanup plan is also not required if the baseline risk assessment indicates the site is within the human health and environmental protection goals specified in Section 250.402 of the regulations under both current and currently planned future site conditions. After the site has been characterized using the suggested guidelines (or some equivalent technique) and a risk assessment performed ~~using equivalent or recommended guidelines~~ to develop site-specific standards for soil and groundwater, a remediation (cleanup) plan should be developed, which consists of identification and evaluation of remedial alternatives, ~~including risk assessment of the selected remedy,~~ selection of a proposed remedy, and plans for the development, construction, and initial operation of the proposed remedy. A number of factors required by Act 2 for consideration in selecting the remedy are set forth in Section 304 (j) of Act 2. As described in Section 304 (i) of Act 2, remediation to site-specific standards may include treatment, removal, engineering or institutional controls and may include innovative or other demonstrated measures. However, institutional controls such as fences, warning signs or future land use restriction may not be the sole remedy unless based upon exposure scenarios applicable at the time the contamination was discovered.

To evaluate the short-term and long-term effectiveness of a remedial alternative, the potential risk associated with implementation of the alternative and the risk associated with exposure to the remediated media must be evaluated. The ~~algorithms~~ pathways and exposure factors that were defined in the exposure assessment should be used to characterize these potential risks.

The risk characterization associated with short-term effectiveness considers the exposure of workers at the site and exposure of receptors in the vicinity surrounding the site to migrating media during the implementation of the remedial alternative. A comparison of a focused list of remedial alternatives may help predict the risks associated with the implementation of the remedial alternative or whether the implementation of alternatives may have any significant impact to human health and the environment.

The risk characterization associated with long-term effectiveness evaluates whether the remedial alternative may attain the remedial objectives (site-specific standards) and whether postremedial risks may achieve the acceptable levels of risk. There may be times when a specific cleanup goal for one constituent may not be attained, but the overall postremedial risk may be within acceptable levels. Evaluation of the postremedial risk is based on a prediction of what the postremedial exposure concentration would be. ~~For example, a cap would eliminate exposure to surface soils, thus rendering the risk to surface soils to be~~

~~negligible~~ If bioremediation is considered, the remedial objective would be the concentration that provides the basis for characterization of the postremedial risk. If the calculated postremedial risk is within the acceptable range, the remedial alternative would be considered a viable solution.

A person evaluating long-term and short-term risks of remedial alternatives should consider EPA's *Risk Assessment Guidance for Superfund* (RAGS), Volume 1, Part C, Chapter 2 for additional guidance. It should be noted that a quantitative risk assessment of remedial alternatives will not need to be conducted for all sites. In most cases, a qualitative rather than a detailed quantitative evaluation of both long-term and short-term risks is all that is needed to select the most appropriate alternative. However, the Department may require a quantitative risk assessment of the selected remedy if a quantitative risk assessment is needed to select the most appropriate remedy or a perceived risk of a selected remedy is high. No matter whether the risk evaluation is qualitative or quantitative, the cleanup plan should always discuss the degree of uncertainty associated with the risk assessment of the selected remedy.

Where there are imminent or immediate threats to human health or the environment, such as waste releasing from corroding tanks or drums, mitigating measures should be undertaken to prevent releases and further exposure as soon as these threats are identified.

The cleanup plan must document the evaluation of the factors listed in Section 304(j) of Act 2. The Department will review the alternative evaluated, the evaluation of the selected remedy in terms of the Section 304(j) criteria, public comments and response of the responsible person to the comments in the cleanup plan. The Section 304(j) criteria address a few general areas, such as the effectiveness of the remedy (long/short term) to manage risk; the extent to which the risks are being reduced; the ability to implement the remedy; reduction of toxicity, mobility, or volume of regulated substances; reliability and ~~postremediation~~ post-remediation care; and cost-benefit considerations.

The Department may require further evaluation of the selected remedy or of one or more alternative remedies on its own analysis of 304(j) factors in Act 2 or in response to comments received from the community surrounding the site as a result of the implementation of the community involvement plan or as a result of the Department's review of the cleanup plan. Persons shall submit to the Department, upon request, such additional information as may reasonably be required to complete the evaluation.

f. Remediation and Demonstration of Attainment

Remediation to the site-specific standards should be implemented in accordance with the approved cleanup plan.

The point of compliance for demonstration of the attainment of site-specific standards is described in Section 250.407 of the regulations. Site-specific standards shall be attained at and beyond the point of compliance, where the plume has migrated beyond the property boundary. For groundwater, the point

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of compliance is the property boundary that existed at the time the contamination was discovered. The remediator may request the movement of the point of compliance in certain circumstances described in Section 250.407(a). If any of those conditions exist, the remediator must request in writing prior to or at the time of submission of the cleanup plan to move the point of compliance. The Department will respond in writing to the request. The written approval must be obtained before using the adjusted point of compliance.

Except if an NPDES permit is required for purposes of complying with surface water quality in a spring, the point of compliance is the point of first designated or existing use as defined in 25 Pa Code 93.1, 93.4, and 93.9. This could mean right by the spring itself or some point downstream from the spring discharge. Determining the point of first designated use is required because it establishes the point where Chapter 93 water quality standards apply.

Technical guidance to determine point of first use is found in Implementation Guidance for Evaluating Wastewater Discharges to Drainage Ditches and Swales, revised ~~August, 1997~~ April 2008. In essence this guidance relies on biological techniques to determine the first downstream point where aquatic life can be documented. It applies to both perennial and intermittent streams with definable bed and banks, but not to ephemeral streams, that is, areas of overland runoff which occur only during or immediately following rainfall events and where there is no defined stream channel and stream substrate.

The site characterization will be the basis on which the vertical and horizontal extent of contamination above the standard is determined. Once this volume of the site is determined and remediation, if necessary, has been performed, then attainment of the standard will focus on the environmental media contained within that volume of the site. Where multiple releases occur on a property which produce distinctly separate zones of contamination, the characterization and subsequent attainment demonstrations will apply individually to the separate releases.

The three methods to demonstrate that the site-specific standard has been met are pathway elimination using an engineering/geologic evaluation, the 95% upper confidence limit of the arithmetic mean or other appropriate statistical methods to show that the site meets numerical site-specific standards, ~~and or~~ a residual risk assessment following implementation of the remedy to demonstrate that the risk associated with the site following remediation falls within the allowable risk range in Act 2. The residual risk assessment will be based on resampling and a reassessment of the cumulative risks associated with concentrations occurring following remediation.

In demonstrating attainment of the site-specific standard, concentrations of regulated substances are not required to be less than the limit related to the Practical Quantitation Limit (PQL) for that substance as provided for in Section 250.701(c), and as listed in Section III.F of this manual.

In demonstrating attainment of the site-specific standard, the removal of separate phase liquids is not required if attainment can be demonstrated in accordance with the requirements of Section 250.702(b)(3) of the regulations.

If the site-specific standard is numerically less than the background standard, the remediator may select the background standard, and attainment of the background standard should be demonstrated according to Section 303 of Act 2.

To ensure that contaminant concentration at the point of compliance will not exceed the selected standard in the future, a statistical time trend analysis, knowledge of the plume stability, or other acceptable method must be provided in the final report to the Department for review and approval.

Guidance on applying statistical methods to demonstrate attainment can be found in Section III.B of this manual. A person should consider the general guidelines of risk assessment in Sections III.G and III.H of this manual to perform the residual risk assessment. When submitting the final report, a person should ensure that the items identified in Section II.B.3.g and Table II-8 of this manual are included.

g. General Reporting Requirements Guidelines for the Site-Specific Standard

The remedial investigation report, risk assessment report, cleanup plan, and final report detailed below are not to be submitted to the Department until the 30-day public and municipal comment period has expired.

Comment [B10]: Former Sections were combined to simplify and remove repetitious language

i. Remedial Investigation Report (Section 250.408 of the Regulations)

The site characterization shall be conducted in accordance with scientifically recognized principles, standards and procedures. The level of detail in the investigation and the selected methods and analyses, that may include models, shall sufficiently define the rate of movement and the present and future extent and fate of contaminants, to ensure continued attainment of the remediation standard. All interpretations of geologic and hydrogeologic data shall be prepared by a professional geologist licensed in Pennsylvania. A suggested outline for a remedial investigation report is provided in Table II-5. ~~The remedial investigation report should include the following information:~~

ii. Cleanup Plan (Section 250.410 of the regulations)

The cleanup plan is not required if no current and probable future exposure pathways exist. The cleanup plan is also not required if the approved baseline risk assessment report indicates that the site does not pose unacceptable risks to human health and the environment under current and planned future conditions. A suggested outline for a cleanup plan is provided in Table II-7.

Comment [B11]: Moved from II.C.7.c

iii. Final Report [Section 250.411 of the Regulations]

A suggested outline for a final report under the site-specific standard is provided in Table II-8.

Comment [B12]: Moved from ILC.7.d

iv. Combined Remedial Investigation Report/Final Report

The site characterization shall be conducted in accordance with scientifically recognized principles, standards and procedures. The level of detail in the investigation and the selected methods and analyses, that may include models, shall sufficiently define the rate of movement and the present and future extent and fate of contaminants, to ensure continued attainment of the remediation standard. All interpretations of geologic and hydrogeologic data shall be prepared by a professional geologist licensed in Pennsylvania. A suggested outline for the combined remedial investigation report/final report under the site-specific standard is provided in Table II-9.

Comment [B13]: Moved from ILC.8.a

v. Risk Assessment Report (Section 250.409 of the Regulations)

A baseline risk assessment report is not required if the Department, in its remedial investigation report or cleanup plan approval, ~~determines~~ concurs that a specific remediation measure that eliminates all pathways, other than a no-action remedial alternative, can be implemented to attain the site-specific standard [Section 250.405(c)Section 250.405(c) of the regulations]. No risk assessment report is required if no present or future exposure pathways exist, as documented in the remedial investigation report by a fate and transport analysis.

A suggested outline for a risk assessment report is provided in Table II-6. The items in the outline are suggested as minimum requirements for inclusion in the report; the order and titles are not mandatory. If a baseline risk assessment is not required and a person submits the development of site-specific standard numerical values as a stand-alone document, more detailed risk assessment information should be provided in the development of site-specific standard numerical values document.

TABLE II-6

Suggested Outline for a Risk Assessment Report under the Site-Specific Standard

EXECUTIVE SUMMARY

PART 1 - Human Health Risk Assessment

I. Introduction

- Objectives of Risk Assessment
- Organization of Report

II. SITE Characterization

- Site history (brief)
- Site location/map
- Description of sources
- Nature and extent of contamination
- Identification of constituents of concern
- Site conceptual model

III. Exposure Assessment

- Exposure scenarios based on land use (current and future)
- Potential receptors based on land use (current and future)
- Summary of complete pathways (including fate and transport considerations)
- Quantification of exposure (not required, if all exposure pathways will be eliminated through pathway elimination measures.)

IV. Toxicity Assessment

(Not required if all exposure pathways will be eliminated through pathway elimination measures.)

- Toxicity values for constituents of concern
- Derivation of chemical-specific toxicity criteria (if applicable)
- Supporting data listing all relevant information on toxicity

TABLE II-6 (cont'd)

Suggested Outline for a Risk Assessment Report under the Site-Specific Standard

V. Risk Characterization

- Algorithms (not required if all exposure pathways will be eliminated through pathway elimination measures.)
- Calculations and Results. (not required if all exposure pathways will be eliminated through pathway elimination measures.)
- Description and fulfillment of risk assessment objectives
- Discussion of uncertainty for all sections of report, including uncertainties associated with site characterization, toxicity assessment, exposure assessment and risk characterization.

VI. References

PART 2 - Ecological Risk Assessment

This section reports the results of the ecological risk assessment conducted using the guidance in Section III.H and, as applicable, EPA guidance.

Public Comments

Include the comments obtained as a result of a public involvement plan, if any, and the responses to those public comments.

Signatures

If any portions of the submitted report were prepared or reviewed by or under the responsible charge of a registered professional geologist or engineer, the professional geologist or engineer in charge must sign the report.

Comment [B14]: Moved from II.C.7.b

h. Detailed Report Requirements for the Site Specific Standard

i. Summary

Provide a summary paragraph(s) which will provide the reviewer with an overview of the site. This will serve to highlight the important issues and conclusion which will be presented in the report.

The Final Report Summary form is to be filled in and submitted to the Department electronically. The summary submitted with the final report should be a copy of that form.

Comment [B15]: Moved from ILC.7.d.i

ii. Introduction

Provide a summary of the investigation report(s) and risk assessment report and an interpretation of the conditions at the site (refined conceptual site model). Discuss the chosen method(s) of remediation. The remedy should be evaluated in accordance with the requirements of Section 304 (j) of Act 2.

Comment [B16]: Moved from ILC.7.c.i

iii. Site description

Provide a description of the site in sufficient detail as to give the reviewer an idea of the site location, and the types of operations that are currently and/or were formerly conducted on the site. As appropriate to the site, the description should include location, physical description of the property, ownership history, site use history, and regulatory action history (past cleanups).

TABLE II-5

Suggested Outline for Remedial Investigation Report under the Site-Specific Standard

Summary

(Section II.C.7.a.i)

Site Description

Provide a description of the site in sufficient detail to give an overall view of the site. (Section II.C.7.a.ii)

Site Characterization

Document current conditions at the site. (Sections II.C.7.a.iii-v)

Fate and Transport Analysis

Description of Fate and Transport analyses used and results and conclusions. (Sections II.C.7.a.vi and IV.A)

Other Information Required under the Site-Specific Standard

Provide the results of ecological receptor evaluation. Describe the public benefits of the use or reuse of the property. Identify complete exposure pathways. (Section II.C.7.a.vi)

Conclusions and Recommendations

Draw conclusions regarding the existence of exposure pathways and the potential effectiveness of institutional or engineering controls for pathway elimination. Identify the appropriate remedial technology options. (Section II.C.7.a.vii)

References

Attachments

(Section II.C.7.a.viii)

Public Comments

Include the comments obtained as a result of a public involvement plan, if any, and the responses to those public comments. (Section II.C.7.a.viii)

Signatures

(Section II.C.7.a.ix)

Comment [B17]: Moved to the end of the section

~~iii-iv.~~ **Site characterization**

The site characterization provides important information documenting the current conditions at the site. Information developed during the site characterization is primarily intended to describe the nature, concentrations, extent, and potential for movement of all contaminants present on the site, or that may have migrated from the site. For sites where there are multiple distinct areas of contamination, the site characterization process should be applied to each area individually.

~~iv-v.~~ **Source and identification of constituents of concern.**

For the area being investigated, include description of source characterization which may be in the form of a conceptual site model.

~~v-vi.~~ **Nature and extent of contamination**

Information needed to meet the requirements below should be included here.

~~For soils, include information on samples and measurements used to characterize the horizontal and vertical, present and future extent and fate of contamination and direction and rate of contaminant movement based on factors in the soil and the contaminant which affect migration. Soil and boring descriptions should be included as an attachment.~~

For soil and groundwater, include information on samples and measurements used to characterize the horizontal and vertical, present and future extent and fate of contamination, ~~and d~~Direction and velocity of contaminant movement should be based on factors of the groundwater and soil and as well as the contaminant(s) which affect migration. ~~Geologic boring descriptions and as built drawings of wells should be included as an attachment.~~

Text, tables, graphics, figures, maps and cross sections should be used to describe the nature, location, and composition of the regulated substances at the site. Providing the data in an appropriate format will expedite the review of the report.

~~vi-vii.~~ **Other information required under the site specific standard**

~~The results of the evaluation of ecological receptors discussed in Section II.C.3.b of this manual.~~

Description of the existing or potential public benefits of the use or reuse of the property for employment opportunities, housing, open space, recreation or other uses. Describe the past, present, and future use of the site.

Information obtained from attempts to comply with the background or Statewide health standards, such as background concentrations for constituents of concern.

~~A fate and transport analysis to identify all existing and potential migration pathways, if applicable. This part of the report should document the pathway identification process and provide justification if a pathway has been excluded~~

and summarize pathways for current land use and any probable future land use separately.

Modeling (optional) – Data Interpretation.

- Identify any programs or modeling used to interpret site conditions or predict plume migration. Identify codes used and any modifications made.
- Models should be developed from site-specific data.
- Identify limitations/assumptions used in the model(s).
Models should be validated to reproduce conditions measured in the field.
- Submit modeling files (input and output files).

Comment [B18]: Moved to fate and transport section (II.B.3.g.xiv).

viii. List of contacts

Name, address, and telephone number of project manager responsible for submittal of the cleanup plan.

Names, addresses, and telephone numbers of consultants or other persons responsible for preparing the cleanup plan.

Comment [B19]: Moved from II.C.7.c.ii

ix. Remedial alternative

Identify remediation alternatives considered and evaluate the ability and effectiveness of the selected remedy to achieve the site-specific standards, based on the factors set forth in Section 304 (j) of Act 2. The cleanup plan must document how each of the factors set forth in Section 304 (j) of Act 2 was evaluated. The evaluation should include an evaluation of the short-term and long-term risks and effectiveness assessment of the proposed remedy. In evaluating the other alternatives, no risk assessment/evaluation is required; rather a narrative describing the consideration of Section 304(j) factors relative to the proposed remedy should be included.

Comment [B20]: Moved from II.C.7.c.iv

x. Treatability studies

Provide results of any treatability, bench scale, or pilot scale studies or other data collected to support the remedial action(s).

All other site information relevant to the conceptual design, construction, or operation of the remedial action.

Specific characteristics of the site that may affect the implementation or effectiveness of the remedial action including such characteristics as topography, geology, depth of bedrock, potentiometric surfaces, and the existence of utilities.

Comment [B21]: Moved from II.C.7.c.v

xi. Design plans and specifications

Consists of adequate design plans and specifications sufficient to evaluate the proposed remedy including, but not limited to:

- Detailed description of the remedial action (treatment and/or removal) and remedial technology to be implemented. Adequate design plans and

specifications for all remedial activities, including remedial design, onsite treatment, storage, removal and disposal activities.

- Estimated volume of each medium to be treated and/or removed. Provide methodology and calculations used to estimate contaminant mass.
- Remedial Action Status Plan - To evaluate the short-term and long-term effectiveness of the remedial action to include, but not limited to, the following:
 - Location and construction details of all monitoring points.
 - Sampling and Analysis Plan, including QA/OC plan.
 - Other site specific monitoring as appropriate.
- Construction QA/OC Plan including engineering certification.
- Locations, telephone numbers, and contacts of offsite disposal facilities, including names, addresses, and telephone numbers of waste transportation companies.
- Site specific Health & Safety Plan which includes adherence to all applicable OSHA and NIOSH regulations and recommendation.
- Erosion and Sedimentation Control Plan Consistent with Chapter 102 (Erosion Control) relating to earth disturbance during remedial activities.
- Site Security Plan.
- A schedule for implementation of the proposed remedial action.
- Operation and Maintenance Plan which shall describe:
 - Startup testing, inspection and maintenance over the first year and subsequent years of operation.
 - Identification of equipment necessary for operation and maintenance.
 - Specification of the type, frequency, and duration of testing or maintenance to verify optimal remedial system performance.
- All federal, State and local permits and approvals and any agreements necessary for the construction and operation of the approved remedial action shall be identified.

Comment [B22]: Moved from ILC.7.c.vi

xii. Remediation

Documentation of the methodologies used to attain the site-specific standard. Includes removal and/or treatment technologies used, and any engineering and/or institutional controls used to attain or maintain the selected standard. This section should also include the calculation of the mass of contaminants addressed during the remediation of soil and/or groundwater, using the methodology in Section III.C.

Comment [B23]: Moved from ILC.7.d.ii

xiii. Attainment

Documentation that the remedy has been completed in accordance with an approved cleanup plan.

- Descriptions of treatment, removal, or decontamination procedures performed in remediation. Documentation of handling of remediation wastes in accordance with applicable regulations.
- Descriptions of the sampling methodology and analytical results.
- All sampling data, including QA/QC data.

The demonstration of attainment should be applied separately for each distinct area of contamination. Demonstration of attainment in a final report should include one or more of the following three types of information:

- Demonstration attainment of a numerical standard

The information includes demonstration that the calculated numerical site-specific standards have been met through the application of appropriate statistical tests, and demonstration that shows contaminant concentration at the point of compliance will not exceed the selected standard. The following information shall be documented in a final report when a statistical method is applied:

- A description of the statistical method;
- A clear statement of the applicable decision rule in the form of statistical hypothesis for each spatial unit and temporal boundary including the applicable statistical parameter of interest and the cleanup standard;
- A description of the underlying assumptions of the method;
- Documentation showing that the sample data set meets the underlying assumptions of the method and demonstrate that the method is appropriate to apply to the data;
- Specification of false positive rates;
- Documentation of input and output data for the statistical test, presented in tables, figures or both, as appropriate; and
- An interpretation and conclusion of the statistical test.

Demonstration that contaminant concentration at the point of compliance will not exceed the selected standard should be based on a statistical time trend analysis, knowledge of the plume stability or other acceptable method.

- Demonstration of pathway elimination

This demonstration should be based on either an engineering or hydrogeologic analysis, or both, which includes fate and transport analysis that some or all of the exposure pathways have been eliminated. The eliminated pathways and the remaining pathways should be clearly

identified. The pathway elimination demonstration should include the following:

- Identifying all exposure pathways prior to the implementation of pathway elimination technology, based on fate and transport analysis; and
- Identifying all exposure pathways after the implementation of pathway elimination technology, based on fate and transport analysis.

- **Residual Risk Assessment**

As an alternative to demonstrating the attainment of numerical standards, a person may perform a residual risk assessment to show that the risk which remains at a site following remediation is within the acceptable risk range specified in Act 2. The residual risk assessment will be based on resampling and a reassessment of the cumulative risks associated with concentrations occurring following remediation.

Comment [B24]: Moved from I.I.C.7.d.iii

xiv. Fate and transport analysis

The Fate and Transport Section (Section III.A of this manual) provides a discussion on fate and transport analysis. The amount of detail in the fate and transport analysis may vary from a basic description to a very extensive detailed model with quantitative modeling. Whenever a model is used the Department must be provided with the assumptions, data, and information on the model necessary for Department staff to evaluate and run the model. Any parameters used in the analysis or models used should use data from the site obtained during the site characterization. This includes identified ecological receptors.

Comment [B25]: Moved from I.I.C.7.d.iv

Modeling (optional) - Data Interpretation:

- Identify any programs or modeling used to interpret site conditions or predict plume migration. Identify codes used and any modifications made.
- Models should be developed from site-specific data.
- Identify limitations/assumptions used in the model(s).
- Models should be validated to reproduce conditions measured in the field.

Comment [B26]: Moved from I.I.C.7.a.vi

vii.xv. Conclusions and recommendations

In addition to documenting the items listed above, the remedial investigation report should draw conclusions regarding the existence of exposure pathways and the potential effectiveness of institutional or engineering controls in eliminating some or all of these pathways. The report also should identify the appropriate remedial technology options for each medium of concern.

xvi. ~~Postremediation~~Post-remediation care plan (if applicable) and other postremedial obligations (such as monitoring or institutional controls).

If engineering or institutional controls are needed to maintain a standard, if the fate and transport analysis indicates that the remediation standard may be exceeded at the point of compliance in the future, or, if the remediation relies on natural attenuation, a ~~postremediation~~post-remediation care plan must be documented in the final report. The plan should include:

- Reporting of any instance of nonattainment;
- Reporting of any measures to correct nonattainment conditions;
- Monitoring on a quarterly basis, or as otherwise approved by the Department, that demonstrates the effectiveness of the remedy and periodic reporting of monitoring results and analysis;
- Maintenance of records at the property where the remediation is being conducted for monitoring, sampling and analysis;
- A schedule for operation and maintenance of the controls and submission of any proposed changes; and
- If requested by the Department, documentation of financial ability to implement the remedy and the ~~postremediation~~post-remediation care plan.

If mitigation measures are implemented to restore or replace equivalent ecological resources in the local area of the site, a ~~postremediation~~post-remediation care plan to maintain the mitigated ecological resources is documented in the final report. The plan should include:

- reporting of the ongoing success or failure of the mitigation measure implemented;
- mitigation measures instituted at the time of the final report shall be successfully accomplished and sustained up to five years from final report approval.
- In some cases, postremedial obligations described in Section could require documentation in a ~~postremediation~~post-remediation care plan.

Comment [B27]: Moved from II.C.7.d.viii

xvii. Cooperation or agreement of third party

When a person proposes a remedy that relies on access to properties owned by third parties, for remediation or monitoring, documentation of cooperation or agreement shall be submitted.

Comment [B28]: Moved from II.C.7.c.viii

xviii. Public comments

Include the comments obtained during the public and municipal comment period and the public involvement plan, if any, and the responses to those public comments.

Comment [B29]: Moved from II.C.7.c.ix

xix. References

~~viii,xx.~~ **Attachments**

Should include (but not limited to): Laboratory sheets for all data, applicable laboratory quality control results, historical sampling data results, and data eliminated from consideration based on data validation protocols. All data should be presented in tabular form.

Quality Assurance Plan

Health and Safety Plan

Sampling and Analysis Plan

Site map(s) which indicate(s):

- The boundaries of the site and all adjacent/contiguous properties.
- The location of all proposed and existing utilities, structures, and roads.
- All areas in which remedial action activities will be conducted.
- Horizontal and vertical boundaries and respective concentrations of contamination in the soils and groundwater.

Comment [B30]: Moved from ILC.7.c.iii

~~Maps and cross~~Cross sections used which present information on site characterization

Boring logs and as-built drawings

Proofs required, such as municipal notice, newspaper notice proof of publication.

Physical/chemical properties or toxicological/exposure factors including, but not limited to water solubility, vapor pressure, Henry's Law constant, compound density, octanol/water partition coefficient (K_{ow}), organic carbon partitioning coefficient (K_{oc}), and soil/water partitioning coefficient (K_d) needed for determining performance of remedial equipment and/or fate and transport analysis.

Photographs

Modeling files (input and output files).

~~The comments obtained as a result of a public involvement plan, if any, and the responses to those public comments~~

~~ix,xxi.~~ **Signatures:**

All those who participated in the remediation who are seeking relief from liability. If any portions of the submitted report were prepared or reviewed by or under the responsible charge of a registered professional geologist or engineer, the professional geologist or engineer in charge must sign the report.

TABLE II-5

Suggested Outline for Remedial Investigation Report under the Site-Specific Standard

I. Summary

(Section II.B.3.h.i)

II. Site Description

Provide a description of the site in sufficient detail to give an overall view of the site. (Section II.B.3.h.iii)

III. Site Characterization

Document current conditions at the site. (Sections II.B.3.h.iv - vi)

IV. Fate and Transport Analysis

Description of Fate and Transport analyses used and results and conclusions. (Sections II.B.3.h.xiv and III.A)

V. Other Information Required under the Site-Specific Standard

Provide the results of ecological receptor evaluation. Describe the public benefits of the use or reuse of the property. Identify complete exposure pathways. (Section II.B.3.h.vii)

VI. Conclusions and Recommendations

Draw conclusions regarding the existence of exposure pathways and the potential effectiveness of institutional or engineering controls for pathway elimination. Identify the appropriate remedial technology options. (Section II.B.3.h.xv)

VII. References

VIII. Attachments

(Section II.B.3.h.xx)

IX. Public Comments

Include the comments obtained as a result of a public involvement plan, if any, and the responses to those public comments. (Section II.B.3.h.xviii)

X. Signatures

(Section II.B.3.h.xxi)

TABLE II-7

Suggested Outline for a Cleanup Plan under the Site-Specific Standard

I. Introduction

(Section II.B.3.h.ii)

II. List of Contacts

(Section II.B.3.h.viii)

III. Site Maps

(Section II.B.3.h.xx)

IV. Remedial Alternative

Identify remediation alternatives considered and evaluate the ability and effectiveness of the selected remedy to achieve the site-specific standards, based on the factors set forth in Section 304 (j) of Act 2. (Section II.B.3.h.ix)

V. Treatability Studies

Provide results of any treatability, bench scale, or pilot scale studies or other data collected to support the remedial action(s). (Section II.B.3.h.x)

VI. Design Plans and Specifications

Consists of adequate design plans and specifications sufficient to evaluate the proposed remedy. (Section II.B.3.h.xi)

VII. ~~Postremediation~~Post-remediation Care Plan

(Section II.B.3.h.xvi)

VIII. Cooperation or Agreement of Third Party

(Section II.B.3.h.xvii)

IX. Public Comments

(Section II.B.3.h.xviii)

X. Signatures

(Section II.B.3.h.xxi)

TABLE II-8

Suggested Outline for a Final Report under the Site-Specific Standard

I. Summary

The final report summary should be a copy of the electronic form submitted to the Department. (Section II.B.3.h.i)

II. Remediation

Description of the remedial methodologies used to attain the selected standard. (Section II.B.3.h.xii)

III. Attainment

(Section II.B.3.h.xiii)

Demonstration of attainment of a numerical standard

- Soil site-specific standard
- Groundwater site-specific standard
- Surface water site-specific standard, and/or
- Sediment site-specific standard

Describe the statistical methods used to demonstrate attainment of the standard.

Demonstration of Pathway Elimination

Residual Risk Assessment

IV. Fate and Transport Analysis

Description of Fate and Transport analyses used and results and conclusions. (Section II.B.3.h.xiv and III.A)

V. ~~Postremediation~~Post-remediation Care Plan (if applicable)

This section is included only if necessary. It describes the engineering and institutional controls necessary to maintain the standard. (Section II.B.3.h.xvi)

VI. References

VII. Attachments

(Section II.B.3.h.xx)

VIII. Public Comments

(Section II.B.3.h.xviii)

IX. Signatures

(Section II.B.3.h.xxi)

TABLE II-9

Suggested Outline for the Combined Remedial Investigation Report/Final Report under the Site-Specific Standard When No Current and Future Complete Exposure Pathways Exist

I. Final Report Summary

The final report summary should be a copy of the electronic form submitted to the Department. (Section II.B.3.h.i)

II. Site Description

Provide a description of the site in sufficient detail to give an overall view of the site. (Section II.B.3.h.iii)

III. Site Characterization

Document current conditions at the site. (Sections II.B.3.h.iv-vi)

IV. Fate and Transport Analysis

Description of fate and transport analyses used and results and conclusions. (Sections II.B.3.h.xiv and III.A)

V. Other Information Required under the Site-Specific Standard

Provide the results of ecological receptor evaluation. Describe the public benefits of the use or reuse of the property. Identify complete exposure pathways. (Section II.B.3.h.vii)

VI. Conclusions and Recommendations

Draw conclusions regarding the existence of exposure pathways and the potential effectiveness of institutional or engineering controls for pathway elimination. Identify the appropriate remedial technology options. (Section II.B.3.h.xv)

VII. ~~Postremediation~~Post-remediation Care Plan (if applicable)

This section is included only if necessary. It describes the engineering and institutional controls necessary to maintain the standard. (Section II.B.3.h.xvi)

VIII. References

IX. Attachments

(Section II.B.3.h.xx)

X. Public Comments

(Section II.B.3.h.xviii)

XI. Signatures

(Section II.B.3.h.xxi)

x. **Risk Assessment Report (Section 250.409 of the Regulations)**

A baseline risk assessment report is not required if the Department, in its remedial investigation report or cleanup plan approval, determines that a specific remediation measure that eliminates all pathways, other than a no-action remedial alternative, can be implemented to attain the site-specific standard [Section 250.405(c)Section 250.405(c) of the regulations]. No risk assessment report is required if no present or future exposure pathways exist, as documented in the remedial investigation report by a fate and transport analysis.

A suggested outline for a risk assessment report is provided in Table II-6. The items in the outline are suggested as minimum requirements for inclusion in the report; the order and titles are not mandatory. If a baseline risk assessment is not required and a person submits the development of site-specific standard risk assessment report as a stand-alone document, more detailed risk assessment information should be provided in the development of site-specific standard risk assessment report.

TABLE II-6

Suggested Outline for a Risk Assessment Report under the Site Specific Standard

EXECUTIVE SUMMARY

PART 1— Human Health Risk Assessment

I. Introduction

(See Site Specific Human Health Risk Assessment Procedures, pages 1-2)

- Objectives of Risk Assessment
- Organization of Report

II. SITE Characterization

(See Site Specific Human Health Risk Assessment Procedures, pages 2-3)

- Site history (brief)
- Site location/ map
- Description of sources
- Nature and extent of contamination
- Identification of constituents of concern
- Site conceptual model

III. Exposure Assessment

(See Site Specific Human Health Risk Assessment Procedures, pages 3-8)

- Exposure scenarios based on land use (current and future)
- Potential receptors based on land use (current and future)
- Summary of complete pathways (including fate and transport considerations)
- Quantification of exposure (not required, if all exposure pathways will be eliminated through pathway elimination measures.)

IV. Toxicity Assessment

(See Site Specific Human Health Risk Assessment Procedures, pages 9-10. Not required if all exposure pathways will be eliminated through pathway elimination measures.)

- Toxicity values for constituents of concern
- Derivation of chemical specific toxicity criteria (if applicable)
- Supporting data listing all relevant information on toxicity

TABLE II-6 (cont'd)

Suggested Outline for a Risk Assessment Report under the Site Specific Standard

V. Risk Characterization

(See Site Specific Human Health Risk Assessment Procedures, pages 10-12)

- Algorithms (not required if all exposure pathways will be eliminated through pathway elimination measures.)
- Calculations and Results. (not required if all exposure pathways will be eliminated through pathway elimination measures.)
- Description and fulfillment of risk assessment objectives
- Discussion of uncertainty for all sections of report, including uncertainties associated with site characterization, toxicity assessment, exposure assessment and risk characterization.

VI. References

PART 2— Ecological Risk Assessment

This section reports the results of the ecological risk assessment conducted using the guidance in Section III.H and, as applicable, EPA guidance.

Public Comments

Include the comments obtained as a result of a public involvement plan, if any, and the responses to those public comments.

Signatures

Comment [B31]: Moved to II.3.g.v

xi. Cleanup Plan (Section 250.410 of the regulations)

The cleanup plan is not required if no current and probable future exposure pathways exist. The cleanup plan is also not required if the approved baseline risk assessment report indicates that the site does not pose unacceptable risks to human health and the environment under current and planned future conditions. A suggested outline for a cleanup plan is provided in Table II-7. The cleanup plan should include the following items:

i) Introduction

Provide a summary of the investigation report(s) and risk assessment report and an interpretation of the conditions at the site (refined conceptual site model). Discuss the chosen method(s) of remediation. The remedy should be evaluated in accordance with the requirements of Section 304 (j) of Act 2. The groundwater portions of the cleanup plan should be prepared and certified by a Registered Professional Geologist licensed in Pennsylvania and any drawings and designs of engineered systems should be prepared by a Professional Engineer licensed in Pennsylvania.

ii) List of contacts

Name, address, and telephone number of project manager responsible for submittal of the cleanup plan.

Names, addresses, and telephone numbers of consultants or other persons responsible for preparing the cleanup plan.

iii) Site map(s) which indicate(s):

The boundaries of the site and all adjacent/contiguous properties.

The location of all proposed and existing utilities, structures, and roads.

All areas in which remedial action activities will be conducted.

Horizontal and vertical boundaries and respective concentrations of contamination in the soils and groundwater.

iv) Remedial alternative

Identify remediation alternatives considered and evaluate the ability and effectiveness of the selected remedy to achieve the site specific standards, based on the factors set forth in Section 304 (j) of Act 2. The cleanup plan must document how each of the factors set forth in Section 304 (j) of Act 2 was evaluated. The evaluation should include a risk assessment of the proposed remedy. In evaluating the other alternatives, no risk assessment is required; rather a narrative describing the consideration of Section 304(j) factors relative to the proposed remedy should be included.

Comment [B32]: Moved to II.B.3.g

TABLE II-7

Suggested Outline for a Cleanup Plan under the Site-Specific Standard

I. Introduction

(Section II.C.7.c.i)

II. List of Contacts

(Section II.C.7.c.ii)

III. Site Maps

(Section II.C.7.c.iii)

IV. Remedial Alternative

Identify remediation alternatives considered and evaluate the ability and effectiveness of the selected remedy to achieve the site-specific standards, based on the factors set forth in Section 304 (j) of Act 2. (Section II.C.7.c.iv)

V. Treatability Studies

Provide results of any treatability, bench scale, or pilot scale studies or other data collected to support the remedial action(s). (Section II.C.7.c.v)

VI. Design Plans and Specifications

Consists of adequate design plans and specifications sufficient to evaluate the proposed remedy. (Section II.C.7.c.vi)

VII. Postremediation Care Plan

(Section II.C.7.c.vii)

VIII. Cooperation or Agreement of Third Party

(Section II.C.7.c.viii)

IX. Public Comments

(Section II.C.7.c.ix)

X. Signatures

(Section II.C.7.c.x)

Comment [B33]: Moved to the end of the section

v) — Treatability studies

Provide results of any treatability, bench scale, or pilot scale studies or other data collected to support the remedial action(s).

All other site information relevant to the conceptual design, construction, or operation of the remedial action.

Specific characteristics of the site that may affect the implementation or effectiveness of the remedial action including such characteristics as topography, geology, depth of bedrock, potentiometric surfaces, and the existence of utilities.

vi) — Design plans and specifications

Consists of adequate design plans and specifications sufficient to evaluate the proposed remedy including, but not limited to:

- Detailed description of the remedial action (treatment and/or removal) and remedial technology to be implemented. Adequate design plans and specifications for all remedial activities, including remedial design, onsite treatment, storage, removal and disposal activities.
- Estimated volume of each medium to be treated and/or removed. Provide methodology and calculations used to estimate contaminant mass.
- Remedial Action Status Plan — To evaluate the short term and long term effectiveness of the remedial action to include, but not limited to, the following:
 - Location and construction details of all monitoring points.
 - Sampling and Analysis Plan, including QA/QC plan.
 - Other site specific monitoring as appropriate.
- Construction QA/QC Plan including engineering certification.
- Locations, telephone numbers, and contacts of offsite disposal facilities, including names, addresses, and telephone numbers of waste transportation companies.
- Site specific Health & Safety Plan which includes adherence to all applicable OSHA and NIOSH regulations and recommendation.
- Erosion and Sedimentation Control Plan Consistent with Chapter 102 (Erosion Control) relating to earth disturbance during remedial activities.
- Site Security Plan.
- A schedule for implementation of the proposed remedial action.
- Operation and Maintenance Plan which shall describe:
 - Startup testing, inspection and maintenance over the first year and subsequent years of operation.

- ~~— Identification of equipment necessary for operation and maintenance.~~
- ~~— Specification of the type, frequency, and duration of testing or maintenance to verify optimal remedial system performance.~~
- ~~• All federal, State and local permits and approvals and any agreements necessary for the construction and operation of the approved remedial action shall be identified.~~

~~vii) — **Postremediation care Plan**~~

~~Document proposed **postremediation care** requirements in a plan if they are needed to maintain the standards.~~

~~viii) — **Cooperation or agreement of third party**~~

~~When a person proposes a remedy that relies on access to properties owned by third parties, for remediation or monitoring, documentation of cooperation or agreement shall be submitted.~~

~~ix) — **Public comments**~~

~~Include the comments obtained during the public and municipal comment period and the public involvement plan, if any, and the responses to those public comments.~~

~~x) — **Signatures**~~

~~All those who participated in the remediation who are seeking relief from liability.~~

~~xii. — **Final Report [Section 250.411 of the Regulations]**~~

~~A suggested outline for a final report under the site-specific standard is provided in Table II-8.~~

~~i) — **Summary**~~

~~The Final Report Summary form is to be filled in and submitted to the Department electronically. The summary submitted with the final report should be a copy of that form: _____~~

Comment [B34]: Moved to II.B.3.g

TABLE II-8

Suggested Outline for a Final Report under the Site-Specific Standard

I. Summary

The final report summary should be a copy of the electronic form submitted to the Department.

II. Remediation

Description of the remedial methodologies used to attain the selected standard. (Sections II.C.7.d.i and II.C.7.d.ii)

III. Attainment

Demonstration of attainment of a numerical standard

- Soil site specific standard
- Groundwater site specific standard
- Surface water site specific standard, and/or
- Sediment site specific standard

Describe the statistical methods used to demonstrate attainment of the standard.

Demonstration of Pathway Elimination

Residual Risk Assessment

IV. Fate and Transport Analysis

Description of Fate and Transport analyses used and results and conclusions. (Section IV.A)

V. Postremediation Care Plan (if applicable)

This section is included only if necessary. It describes the engineering and institutional controls necessary to maintain the standard. (Section II.C.7.d.v)

VI. References

VII. Attachments

(Section II.C.7.d.vii)

VIII. Public Comments

(Section II.C.7.d.vii)

IX. Signatures

(Section II.C.7.d.viii)

Comment [B35]: Moved to the end of the section

ii) Remediation

Documentation of the methodologies used to attain the site-specific standard. Includes removal and/or treatment technologies used, and any engineering and/or institutional controls used to attain or maintain the selected standard. This section should also include the calculation of the mass of contaminants addressed during the remediation of soil and/or groundwater, using the methodology in Section IV.C.

iii) Attainment

Documentation that the remedy has been completed in accordance with an approved cleanup plan.

- Descriptions of treatment, removal, or decontamination procedures performed in remediation. Documentation of handling of remediation wastes in accordance with applicable regulations.
- Descriptions of the sampling methodology and analytical results.
- All sampling data, including QA/QC data.

The demonstration of attainment should be applied separately for each distinct area of contamination. Demonstration of attainment in a final report should include one or more of the following three types of information:

- Demonstration attainment of a numerical standard

The information includes demonstration that the calculated numerical site-specific standards have been met through the application of appropriate statistical tests, and demonstration that shows contaminant concentration at the point of compliance will not exceed the selected standard. The following information shall be documented in a final report when a statistical method is applied:

- A description of the statistical method;
- A clear statement of the applicable decision rule in the form of statistical hypothesis for each spatial unit and temporal boundary including the applicable statistical parameter of interest and the cleanup standard;
- A description of the underlying assumptions of the method;
- Documentation showing that the sample data set meets the underlying assumptions of the method and demonstrate that the method is appropriate to apply to the data;
- Specification of false positive rates;
- Documentation of input and output data for the statistical test, presented in tables, figures or both, as appropriate; and
- An interpretation and conclusion of the statistical test.

— Demonstration that contaminant concentration at the point of compliance will not exceed the selected standard should be based on a statistical time trend analysis, knowledge of the plume stability or other acceptable method.

- **Demonstration of pathway elimination**

This demonstration should be based on either an engineering or hydrogeologic analysis, or both, which includes fate and transport analysis that some or all of the exposure pathways have been eliminated. The eliminated pathways and the remaining pathways should be clearly identified. The pathway elimination demonstration should include the following:

- Identifying all exposure pathways prior to the implementation of pathway elimination technology, based on fate and transport analysis; and

- Identifying all exposure pathways after the implementation of pathway elimination technology, based on fate and transport analysis.

- **Residual Risk Assessment**

As an alternative to demonstrating the attainment of numerical standards, a person may perform a residual risk assessment to show that the risk which remains at a site following remediation is within the acceptable risk range specified in Act 2. The residual risk assessment will be based on resampling and a reassessment of the cumulative risks associated with concentrations occurring following remediation.

iv) — Fate and transport analysis

The Fate and Transport Section (Section IV.A of this manual) provides a discussion on fate and transport analysis. The amount of detail in the fate and transport analysis may vary from a description to a very extensive detailed model with quantitative modeling. Whenever a model is used the Department must be provided with the assumptions, data, and information on the model necessary for Department staff to evaluate and run the model. Any parameters used in the analysis or models used should use data from the site obtained during the site characterization.

v) — Postremediation care plan (if applicable) and other postremedial obligations (such as monitoring or institutional controls).

If engineering or institutional controls are needed to maintain a standard, if the fate and transport analysis indicates that the remediation standard may be exceeded at the point of compliance in the future, or, if the remediation relies on natural attenuation, a **postremediation** care plan must be documented in the final report. The plan should include:

- **Reporting of any instance of nonattainment;**

- ~~Reporting of any measures to correct nonattainment conditions;~~
- ~~Monitoring on a quarterly basis, or as otherwise approved by the Department, that demonstrates the effectiveness of the remedy and periodic reporting of monitoring results and analysis;~~
- ~~Maintenance of records at the property where the remediation is being conducted for monitoring, sampling and analysis;~~
- ~~A schedule for operation and maintenance of the controls and submission of any proposed changes; and~~
- ~~If requested by the Department, documentation of financial ability to implement the remedy and the **postremediation** care plan.~~

~~If mitigation measures are implemented to restore or replace equivalent ecological resources in the local area of the site, a **postremediation** care plan to maintain the mitigated ecological resources is documented in the final report. The plan should include:~~

- ~~reporting of the ongoing success or failure of the mitigation measure implemented;~~
- ~~mitigation measures instituted at the time of the final report shall be successfully accomplished and sustained up to five years from final report approval.~~
- ~~In some cases, postremedial obligations described in Section II.C.9 could require documentation in a **postremediation** care plan.~~

References

vi) — Attachments

~~Laboratory Sheets~~

~~Quality Assurance and Quality Control Plan~~

~~Health and Safety Plan~~

~~Sampling and Analysis Plan~~

~~Public comments include the comments obtained during the public and municipal comment period and as a result of a public involvement program, if any, and the responses to those public comments.~~

~~Before and after photographs~~

vii) — Signatures

~~All those who participated in the remediation who are seeking relief from liability.~~

i. Streamlined Reporting Requirements for Site-Specific Standard when No Current and Future Complete Exposure Pathways Exist

The combined remedial investigation report and final report detailed below are not to be submitted to the Department until the 30-day public and municipal comment period has expired. A suggested outline for the combined remedial investigation report/final report under the site-specific standard is provided in Table II-9.

i. Combined Remedial Investigation Report/Final Report

The site characterization shall be conducted in accordance with scientifically recognized principles, standards and procedures. The level of detail in the investigation and the selected methods and analyses, that may include models, shall sufficiently define the rate of movement and the present and future extent and fate of contaminants, to ensure continued attainment of the remediation standard. All interpretations of geologic and hydrogeologic data shall be prepared by a professional geologist licensed in Pennsylvania. The combined remedial investigation report/final report should include the following information:

Comment [B36]: Moved to II.B.3.g

TABLE II-9

Suggested Outline for the Combined Remedial Investigation Report/Final Report under the Site-Specific Standard When No Current and Future Complete Exposure Pathways Exist

I. Final Report Summary

The final report summary should be a copy of the electronic form submitted to the Department.

II. Site Description

Provide a description of the site in sufficient detail to give an overall view of the site. (Section II.C.8.a.ii)

III. Site Characterization

Document current conditions at the site. (Sections II.C.8.a.iii-v)

IV. Fate and Transport Analysis

Description of fate and transport analyses used and results and conclusions. (Sections II.C.8.a.vi and IV.A)

V. Other Information Required under the Site-Specific Standard

Provide the results of ecological receptor evaluation. Describe the public benefits of the use or reuse of the property. Identify complete exposure pathways. (Section II.C.8.a.vi)

VI. Conclusions and Recommendations

Draw conclusions regarding the existence of exposure pathways and the potential effectiveness of institutional or engineering controls for pathway elimination. Identify the appropriate remedial technology options. (Section II.C.8.a.vii)

VII. Postremediation Care Plan (if applicable)

This section is included only if necessary. It describes the engineering and institutional controls necessary to maintain the standard. (Section II.C.8.a.viii)

VIII. References

IX. Attachments

(Section II.c.8.a.x)

X. Public Comments

(Section II.C.8.a.x)

XI. Signatures

(Section II.C.8.a.xi)

Comment [B37]: Moved to the end of the section

i) Summary

Provide a summary paragraph(s) which will provide the reviewer with an overview of the site. This will serve to highlight the important issues and conclusion which will be presented in the report.

ii) Site description

Provide a description of the site in sufficient detail as to give the reviewer an idea of the site location, and the types of operations that are currently and/or were formerly conducted on the site. As appropriate to the site, the description should include: location, physical description of property, ownership history, site use history, and regulatory action history (past cleanups).

iii) Site characterization

The site characterization provides important information documenting the current conditions at the site. Information developed during the site characterization is primarily intended to describe the nature, concentrations, extent, and potential for movement of all contaminants present on the site, or that may have migrated from the site. For sites where there are multiple distinct areas of contamination, the site characterization process should be applied to each area individually.

iv) Source and identification of constituents of concern.

For the area being investigated, include description of source characterization which may be in the form of a conceptual site model.

v) Nature and extent of contamination

Information needed to meet the requirements below should be included here.

- For soils, include information on samples and measurements used to characterize the horizontal and vertical, present and future extent and fate of contamination and direction and rate of contaminant movement based on factors in the soil and the contaminant which affect migration. Soil and boring descriptions should be included as an attachment
- For groundwater, include information on samples and measurements used to characterize the horizontal and vertical, present and future extent and fate of contamination and direction and velocity of contaminant movement based on factors of the groundwater and the contaminant (s) which affect migration. Geologic boring descriptions and as built drawings of wells should be included as an attachment.

Text, tables, graphics, figures, maps and cross sections need to be used to describe the nature, location, and composition of the regulated substances at the site. Providing the data in an appropriate format will expedite the review of the report.

vi) Other information required under the site-specific standard

The results of the evaluation of ecological receptors discussed in Section II.C.3.b of this manual.

Description of the existing or potential public benefits of the use or reuse of the property for employment opportunities, housing, open space, recreation or other uses.

Information obtained from attempts to comply with the background or Statewide health standards, such as background concentrations for constituents of concern.

A fate and transport analysis to demonstrate no current and probable future exposure pathways exist. This part of the report should document the pathway identification process and provide justification if a pathway has been excluded. The fate and transport analysis should be performed for current land use and any probable future land use separately.

Modeling (optional) Data Interpretation.

- Identify any programs or modeling used to interpret site conditions or predict plume migration. Identify codes used and any modifications made.
- Models should be developed from site specific data.
- Identify limitations/assumptions used in the model(s).
- Models should be validated to reproduce conditions measured in the field.
- Submit modeling files (input and output files).

vii) Conclusions and recommendations of remedial investigation

In addition to documenting the items listed above, the remedial investigation report should draw conclusions regarding the existence of exposure pathways and the potential effectiveness of institutional or engineering controls in eliminating some or all of these pathways. The report also should identify the appropriate remedial technology options for each medium of concern.

viii) Postremediation care plan (if applicable)

If engineering or institutional controls are needed to maintain a standard, if the fate and transport analysis indicates that the remediation standard may be exceeded at the point of compliance in the future, or if the remediation relies on natural attenuation, a postremediation care plan must be documented in the final report. In most cases, the plan should include:

- Reporting of any instance of nonattainment;
- Reporting of any measures to correct nonattainment conditions;

- Monitoring on a quarterly basis, or as otherwise approved by the Department, that demonstrates the effectiveness of the remedy and periodic reporting of monitoring results and analysis;
- Maintenance of records at the property where the remediation is being conducted for monitoring, sampling and analysis;
- A schedule for operation and maintenance of the controls and submission of any proposed changes; and
- If requested by the Department, documentation of financial ability to implement the remedy and the **postremediation** care plan.

If the **postremediation** care plan or an institutional control (See Section II.C.9) is being used to verify that a site continues to have incomplete exposure pathway status, the following are required in the **postremediation** care plan:

- Procedures and schedule for how the incomplete exposure pathway status will be reviewed.
- Reporting details and schedule for submittal to the Department.

If mitigation measures are implemented to restore or replace equivalent ecological resources in the local area of the site, a **postremediation** care plan to maintain the mitigated ecological resources is documented in the final report. The plan should include:

- reporting of the ongoing success or failure of the mitigation measure implemented;
- mitigation measures instituted at the time of the final report shall be successfully accomplished and sustained up to five years from final report approval.
- In some cases, postremedial obligations described in Section II.C.9 could require documentation in a **postremediation** care plan.

ix) — References

x) — Attachments

Laboratory sheets for all data, applicable laboratory quality control results, historical sampling data results, and data eliminated from consideration based on data validation protocols. All data should be presented in table form.

Quality Assurance Plan

Health and Safety Plan

Sampling and Analysis Plan

Maps and cross sections used which present information onsite characterization

Boring logs and as-built drawings

~~Proofs required, such as: municipal notice, newspaper notice, proof of publication;~~

~~Physical/chemical properties or toxicological/exposure factors including, but not limited to: water solubility, vapor pressure, Henry's Law constant, compound density, octanol/water partition coefficient (K_{ow}), organic carbon partitioning coefficient (K_{oc}), and soil/water partitioning coefficient (K_d) needed for determining performance of remedial equipment and/or fate and transport analysis;~~

~~The comments obtained as a result of a public involvement plan, if any, and the responses to those public comments;~~

~~photographs~~

xi) — Signatures

~~All those who participated in the remediation who are seeking relief from liability;~~

~~Institutional Controls and other Postremedial Measures~~

Comment [B38]: Moved to II.B.3.g

Comment [B39]: Moved to section III.D

ii. — Defining

~~An institutional control is a legal or administrative tool or action taken to reduce the potential for exposure to hazardous substances. There are some postremedial measures which, although they are not strictly institutional controls, can nonetheless be effective in providing assurance that an incomplete ingestion pathway continues to exist. Institutional controls and other post remedial obligations may include, but are not limited to, use restrictions, environmental monitoring requirements, and site access and security measures. **Postremediation** care is often required in conjunction with institutional controls, but by itself is not considered an institutional control measure.~~

~~The sole purpose of the institutional control is to provide human health protectiveness as part of a remediation under Act 2.~~

iii. — Implementing

~~Institutional controls are most commonly intended to be used in conjunction with a remedy that directly provides pathway elimination, or on sites where a risk analysis has determined that a current or probable future complete pathway for exposure does not exist. The other set of cases where institutional controls are used is when current or probable future exposure is present and the institutional control is effectively the only factor preventing exposure. Examples of this type of use are contaminated soil with NO physical cap, or where groundwater contamination exists on properties above drinking water levels and those properties are undeveloped (e.g. open field) and have a reasonable chance for future groundwater use for drinking or agricultural purposes.~~

~~The institutional control measures listed below can be chosen, at the option of the remediator, for the purpose of reducing the opportunity for future human exposure to regulated substances from the site. To the extent that the remediator~~

~~chooses to implement multiple or more substantive or restrictive controls, the less likely the chance that conditions will result in the loss of liability protection due to a successful reopener under Act 2, Section 505.~~

~~This concept of the remediator choosing the institutional controls can be thought of similarly to the incentive a remediator has to conduct a sound and complete site characterization (as discussed in Section I of this manual), namely the effectiveness of the institutional controls chosen affects the soundness of the liability protection provided for under Act 2, Chapter 5.~~

~~The Department may suggest and guide the remediator in selecting the combination of controls best suited to the site, but in the end the remediation method – including any institutional controls – is the choice of the remediator. The Department will base its approval or disapproval of the final report on whether the remedy, at present, has been shown to attain one of the three standards and, if remedies are to remain in place after the approval (e.g. caps, nonuse groundwater), that there is an adequate **postremediation** care plan in place to assure that those remedies remain effective in maintaining the chosen standard and that implementation actions and results are routinely reported to the Department.~~

~~The Department is developing a database of information to track all sites with institutional controls applied as a part of an Act 2 remediation. The purpose of this listing is to allow the Department to have continued monitoring of those institutional controls and when fully functional, for the benefit of the public having access to the information in the Department's eFacts system.~~

iv. — Listing

~~Potential controls are listed below. Keep in mind that sometimes it may be most appropriate to use more than one of these controls on a single Act 2 site.~~

i) — Routine and periodic assessments

~~This type of postremedial obligation should be used in areas determined in the final report to have no exposure and no probable future exposure, to assure that conditions have not changed from those exposure assumptions. The details of these would be specified in the approved final report.~~

~~This **postremediation** management approach is appropriate for groundwater areas in which an approved final report documents the area as either having present contamination or the likelihood of future contamination above the applicable drinking water standard, and where it has been demonstrated (as part of the final report) and accepted by the Department that there is *no current or probable future use* of the groundwater. Such demonstrations would in most cases involve documenting that all the properties overlain by the plume or areas where it is expected to migrate at concentrations above the applicable drinking water standard, are fully developed and supplied by a public water system. There are exceptions to this rule however. Take for example the case of a source property which has adjacent to it a railroad property followed by a major river. The~~

~~downgradient property where the contamination could migrate may not have public water or buildings, but is developed in a way that it is more than reasonable to assume there would be no future groundwater supply wells for drinking or agricultural use.~~

~~The conditions for carrying out these assessments are to be incorporated into a postremediation care plan, which includes regular reporting to the Department. There are several benefits to this approach:~~

- ~~• the Department directly receives routine status reports on the effectiveness of the control,~~
- ~~• the Department has clear authority to enforce the controls if they prove ineffective in protecting human health and the environment, and~~
- ~~• the Department can more easily allow termination of this approach when it is determined that it is not necessary to protect human health and the environment. Such cases would be typical when groundwater contamination naturally attenuates over time.~~

ii) ~~Equitable servitude and easements~~

~~Commonly called deed restrictions, these are conditions placed on the deed which restrict use of or access to the property to some degree. Sites where equitable servitude and easements are particularly effective would be cases where the Department has not agreed that no current or probable future use of the groundwater for drinking or agricultural purposes exists, and would include:~~

- ~~• source properties, as a pathway elimination measure,~~
- ~~• properties containing, or adjacent to, contamination sources which are not fully developed (e.g. open fields),~~
- ~~• properties which do not currently have connection to a public water supply, and~~
- ~~• properties where probable future development of the groundwater for drinking purposes may take place.~~

~~These controls have the advantage of being effective in maintaining themselves over multiple transfers of property ownership and there is not as much need for continued monitoring of the presence of the deed restriction once it is in place.~~

~~Disadvantages include:~~

- ~~• the ability to enforce these restrictions is not under the direct control of the Department~~
- ~~• it essentially remains on the deed for perpetuity, even beyond the point of its usefulness in protecting human health (although the Department may~~

~~provide a future letter terminating its interest in the need for the restriction);
and~~

- ~~• the inability (in some cases) to implement it in off source properties (e.g. groundwater contamination extending off the source property). This is particularly significant in cases of groundwater contamination in urban areas where plumes can extend to dozens, or even hundreds, of properties, obliterating the effectiveness of this form of control unless ALL of the deeds for the extensive number of properties can be modified at the same time.~~

~~The use of these deed restrictions in cases where groundwater contamination above drinking water levels has migrated, or may migrate, off the source property may be considered by the Department to be a requirement where it has determined that current or probable future groundwater use will occur. At this time, the Department considers determinations of probable future use to be subjective and believes that there is a lack of a foundation of individual site determinations across the Commonwealth upon which written guidance for regional use can be based. Therefore, the Department will require both regional and central offices to approve, in each case, the requirement for deed restrictions on such sites. The Department believes this approval procedure will help maintain consistency in the implementation of Act 2. In addition to the documentation of the deed restriction, the Department will require documentation of the agreement with the property owner to place said restriction(s). These documentations will be recorded in the Department tracking database of institutional controls.~~

~~The Department is concerned about the perpetual stigma placed on properties that have deed restrictions after they have served their function for public health protection purposes. Persons with properties having deed restrictions may at any future time propose, through the Act 2 NIR process, to attain a standard not requiring a deed restriction. This may be used in cases where future owners may want to conduct further remediation on the property, or far into the future when natural attenuation may effectively result in a site meeting a Statewide health standard. Upon approval of attaining an appropriate Act 2 standard (i.e., one to which a deed restriction is not integral), the use restriction may be removed from the deed.~~

iii) — Environmental notice

~~These are controls such as the deed acknowledgements required under HSCA, Act 108, section 512(b). The area and contaminants present are documented in the deed as notice. This has some of the same advantages as the equitable servitude and easements. Owners could modify the area and change use at their own caution.~~

iv) — Local ordinance

~~This type of control includes zoning, which is a control put on by local government. It has the advantage of being under the control and enforcement of~~

~~the local government level. This is consistent with Commonwealth and Department initiatives to encourage involvement of local governments in land and water use planning. The Department anticipates that one use of the local ordinance method will be to eliminate the groundwater ingestion pathway under the site-specific standard and the nonuse aquifer Statewide health standard. An ordinance used to satisfy Section 250.303(c)(1), 2) and (3) (relating to documenting no groundwater ingestion and community water connections) must meet the following performance criteria:~~

- ~~• Establish a specific geographic area to which the ordinance relates. This may be part of a political subdivision or multiple subdivisions.~~
- ~~• Establish prohibition of use of groundwater for the following:
 - ~~i) Drinking water use~~
 - ~~ii) Agricultural purposes, as defined by Section 250.5 (definitions).~~~~
- ~~• Require that all properties in the specified area connect to community water supply for uses described above.~~
- ~~• Notification to water suppliers servicing the area of the conditions of the ordinance.~~
- ~~• Provide for notification to the Department if and when the ordinance is modified or eliminated.~~

~~**v) Groundwater use restriction zone.**~~

~~Provided for in Section 250.303(f), nonuse aquifer certification areas are zones in which local governments have identified groundwater as not being used for potable purposes. Under Section 250.303(b) of the regulations, all groundwater in aquifers is presumed to be used or currently planned for use, unless criteria outlined in Section 250.303(c) are met. The revision to Section 250.303(f) provides for areas meeting the criteria in Section 250.303(c) to be certified by the Department as areas of groundwater nonuse. This application for areal certification may be made by a municipality, redevelopment or economic development authority, or other governmental or quasi-governmental agency. Upon certification by the Department, these areas are overlain by local controls restricting future groundwater use.~~