



U.S. ENVIRONMENTAL PROTECTION AGENCY, REGION 2

March 17, 2020

BY ELECTRONIC MAIL

Robert Law, Ph.D.
de maximis, inc.
186 Center Street, Suite 290
Clinton, New Jersey 08809

Re: Re: Draft Upper 9-Mile Source Control Interim Remedy Feasibility Study (FS) –
Administrative Settlement Agreement and Order on Consent for Remedial
Investigation/Feasibility Study (Agreement) CERCLA Docket No. 02-2007-2009

Dear Dr. Law:

The U.S. Environmental Protection Agency (EPA) has reviewed *Appendix H (the Interim Remedy Completion Evaluation Framework) of the draft Interim Remedy (IR) Feasibility Study (FS) Report*, prepared by Integral Consulting, Inc. (Integral) on behalf of the Cooperating Parties Group (CPG) for the Lower Passaic River Study Area (LPRSA) Remedial Investigation (RI)/FS. The draft *Appendix H* was received from the CPG on October 22, 2019. Comments from partner agency, New Jersey Department of Environmental Protection (NJDEP) were incorporated. In addition, modifications were made according to the January 31, 2020, Contaminated Sediments Technical Advisory Group (CSTAG) recommendations. In accordance with Section X, Paragraph 44(d) of the Agreement, EPA has enclosed an evaluation of CPG's *Draft FS* with this letter.

Please proceed with revisions to the *Appendix H* of the *Draft FS* within 30 calendar days consistent with the enclosed comment evaluations. If there are any questions or clarifications needed on EPA's enclosed comment evaluations, please contact me to discuss.

Sincerely,

A handwritten signature in black ink, appearing to read "Diane Salkie".

Diane Salkie, Remedial Project Manager
Lower Passaic River Study Area RI/FS

Enclosure

CC: Zizila, F. (EPA)
Sivak, M. (EPA)
Hyatt, B. (CPG)
Potter, W. (CPG)
Nickerson, J. (NJDEP)

**Draft Upper 9-Mile Source Control Interim Remedy Feasibility Study Appendix H
Lower Passaic River Study Area Remedial Investigation/Feasibility Study**

No.	Section	General or Specific	Page No.	Comment
1.	N/A	General	N/A	<p>Appendix H requires additional framework detail for EPA to approve the IR FS. EPA, NJDEP, and the CPG have previously discussed the IR Completion Evaluation Framework in more detailed terms than is expressed by the draft appendix, including through EPA's memorandum "Lower Passaic River Study Area – Determination of Successful Completion of an Upper 9 Mile Source Control Interim Remedy" (last revised July 24, 2019) and related conversations that are memorialized in minutes from FS meetings and conference calls. The July 24th EPA memorandum and the related conversations capture the essence of the anticipated IR Completion Evaluation Framework. In addition, EPA, NJDEP, and the CPG have discussed the statistical testing framework to evaluate compliance with RAO 1 SWAC goals on multiple occasions, including through conference calls and FS-related meetings for which minutes have been developed.</p> <p>Specific comments below describe the portions of Appendix H where additional detail is appropriate. EPA acknowledges that certain specifics and details may not be determined until after pre-design data have been collected and the IR Completion Evaluation Framework is further expanded and finalized in the IR design. However, update the appendix to provide more detail where possible, including per the specific comments below.</p>
2.	N/A	General	N/A	<p>The IR Completion Evaluation Framework should be structured around an initial step to determine IR success and a separate and distinct process to determine IR completion if the initial step does not result in a determination of IR success. IR success would be evaluated by calculating post-IR SWACs for 2,3,7,8-TCDD and total PCBs, using the data generated through the post-IR sediment sampling program, and comparing those post-IR SWACs to the RAO 1 SWAC goals within a reverse null hypothesis statistical testing framework. This evaluation of IR success may ultimately incorporate data from more than one post-IR sediment sampling event, if additional sampling data are determined to be necessary or of value in improving statistical power within the statistical testing framework. If the IR is determined to be successful through statistical demonstration of RAO attainment, it would also be determined to be complete. If IR success is not demonstrated through statistical attainment of the RAO 1 SWAC goals when applying the reverse null hypothesis statistical testing framework, a determination of IR completion may still be possible through the application of a weight of evidence (WOE) assessment, incorporating various pre-IR, IR, and post-IR lines of evidence (LOEs). Revise the appendix to clearly describe the initial evaluation of IR success through statistical comparison of post-IR SWACs to RAO 1 SWAC goals, and then the separate and distinct possibility of evaluating IR completion through WOE analysis. This is well represented by the decision flow captured in Figure 2, but is not well described in the narrative of Appendix H as currently written.</p>
3.	N/A	General	N/A	<p>If statistical testing does not demonstrate successful attainment of RAO 1 SWAC goals, the individual LOEs will need to be appropriately considered in the WOE analysis for decision-making. EPA expects to discuss the specific components of each LOE and the possible approach to combining and weighting the LOEs with NJDEP and the CPG to arrive at an appropriate WOE scheme that values each LOE in a manner proportional and commensurate to the insights it provides. Critically, the metrics, endpoints, standards, and weighting for the LOEs must be in place prior to the IR Completion Evaluation Framework being employed. As examples, for the Remedy Implementation LOE, the performance monitoring plan (see Comment #18 below) must be in place prior to IR construction, and for the SWAC Attainment and Post-IR Confirmation Data Source Assessment LOEs, all salient details must be in place prior to collecting post-IR data (see various comments below including #s 20 through 26, 37, and 38 as pertains to the SWAC Attainment LOE, and Comment #28 below as pertains to the Post-IR Confirmation Data Source Assessment LOE). While EPA understands that the IR Completion Evaluation Framework will be finalized in the IR design to achieve this end, Appendix H should include all possible detail and otherwise the methods that will allow framework components to be finalized.</p>
4.	Section 1.1, Paragraph 1	Specific	1	<p>Revise the text to describe that the RAO 1 SWAC goals are "no greater than" 85 ppt for 2,3,7,8-TCDD and 0.46 ppm for total PCBs.</p>
5.	Section 1.1, Paragraph 2	Specific	1	<p>The text in this paragraph indicates that control of internal sources will be accomplished by "...remediating sediments with total PCB concentrations of 1 mg/kg or higher or 2,3,7,8-TCDD concentrations at or above a threshold established to achieve the 85 ppt SWAC goal." Revise this text to instead indicate "...at or above a threshold established to achieve the selected remedy SWAC target."</p> <p>The text in this paragraph suggests that subsurface sediments potentially requiring remediation are those sediments vulnerable to erosion and with concentrations in excess of subsurface RALs occurring in the 0.5 to 1.5 foot interval below the bed surface. Revise the text to indicate that this depth is based on currently available data, but that relevant depths of interest for application of RAO 2 will ultimately be determined using additional pre-design bathymetric, sidescan sonar, and chemistry data.</p> <p>The text in this paragraph also suggests that the remediation of subsurface sediments will be based on a 2,3,7,8-TCDD threshold "...two times the threshold established to achieve the surface layer 85 ng/kg SWAC goal." Revise this text to instead indicate "...to achieve the selected remedy surface layer SWAC target" and also to indicate that while the two times multiplier for the subsurface threshold is currently being assumed, the actual multiplier will be established in the IR design (and will be between one and a maximum of two per prior agreement between EPA, NJDEP, and the CPG).</p>
6.	Section 1.1, Paragraph 2	Specific	1	<p>This paragraph refers to what is presumably the RALs as "thresholds". For consistency with the body of the IR FS Report and internal consistency within Appendix H, use RALs here and elsewhere in the appendix when describing the thresholds that dictate remediation.</p>
7.	Section 1.1, Paragraph 8	Specific	1	<p>The text states that the SWAC attainment LOE "...relies on interpreting post-remedy sediment data, which do not yield a precise estimate of SWAC." The precision of a post-IR SWAC estimate is a function of the size of the remedial footprint, the accuracy of the remedial action, and the type and number of samples collected for post-IR verification. Revise this statement to reflect that post-IR SWAC estimates based on current RI data may be uncertain, but that PDI data will likely reduce uncertainties and that a balance between SWAC precision and sample size can and will be sought. This balance will be judged to be adequate when the rates of false (i.e., false negative and false positive) post-IR decisions are suitably controlled.</p>

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8.	Section 1.1, Paragraph 8	Specific	1	<p>The text states “the uncertainty inherent in the SWAC estimates is tolerable because the SWAC goals are not absolute thresholds for source control or acceleration of long-term recovery.” The uncertainty depicted in Figure 1 is primarily due to delineation errors (i.e., removing non-target material and leaving target material behind). These errors are controllable through expanding the footprint to reduce false-negative targeting, or by increasing pre-design sampling density to improve targeting accuracy. The determination of meeting the SWAC goals is accompanied with uncertainties because post-IR SWACs are by necessity to be estimated from a sample of sediment data values and cannot be determined exactly. This situation is not unique to the LPRSA IR, although the project team has focused on minimizing uncertainties in the post-IR decision framework in order to make the most accurate evaluation of attainment of RAOs as is reasonable without inordinate sampling effort to quantify post-IR SWACs.</p> <p>In addition, while not absolute values from the perspective of exposure or risk, and while also not necessarily absolute expressions of when sources would be adequately addressed and/or recovery adequately accelerated by an IR, the RAO 1 SWAC goals do represent concentrations that demonstrate RAO attainment, even if the ability to measure SWACs is imprecise. Revise the text to convey these concepts when describing the SWAC goals as “not absolute”. Specifically, revise the third sentence in this paragraph to read: “The uncertainty inherent in the SWAC estimates is tolerable because, while the SWAC goals do represent concentrations that demonstrate RAO attainment, the SWAC goals are do not represent absolute thresholds for when sources would be adequately controlled or when acceleration of long-term recovery would be adequately accelerated by an IR.”</p>
9.	Section 1.1, Paragraph 8	Specific	1 to 2	<p>The narrative in this paragraph discusses uncertainty in SWACs around a concentration of 2,3,7,8-TCDD at 300 ppt, suggesting that this 300 ppt level is specifically meaningful to defining source sediments. Revise this discussion in accordance with the definition of source sediments being incorporated into the IR FS based on conversations between EPA, NJDEP, and the CPG, and update the provided example (including Figure 1) to instead demonstrate uncertainty using the RAL associated with one of the alternatives described in the IR FS. Use Alternative 3 (i.e., 75 ppt SWAC alternative, with a central tendency RAL of 205 ppt) as this example, and explain in the text that this example represents the midpoint of the range of 2,3,7,8-TCDD SWAC targets associated with the active alternatives that are eligible for selection and is for illustrative purposes only.</p>
10	Section 2	Specific	3	<p>The text in this section states that “each of the LOEs will be evaluated independently and then considered in conjunction to determine whether the remedy has been completed”. Revise this language to read “each of the LOEs will be evaluated independently and then some will be considered in conjunction through a weight-of-evidence assessment to determine whether the remedy IR has been completed.” While true that each LOE should be evaluated independently, as noted in Comment #2 above, the IR Completion Determination Framework should be structured around an initial step to determine IR success (through statistical demonstration of RAO attainment) and a separate and distinct process to determine IR completion if the initial step does not result in a determination of IR success.</p> <p>In the initial step, only the SWAC Attainment LOE (Section 2.4) would be relevant. In the potential separate process that would evaluate IR completion after failure to demonstrate IR success, the other LOEs would be considered in a WOE assessment. Revise this section to more clearly convey this approach. Also, because Section 3 of the IR Completion Determination Framework is intended to describe how the LOEs would be applied in practice, reference Section 3 and its purpose in Section 2.</p> <p>Also, revise the introductory portion of Section 2 to describe the use of adaptive management during the remediation of the upper 9-mile reach and the relevant hypotheses that pertain to the information gathered in support of the IR completion determination (e.g., the adaptive management hypothesis associated with demonstrating attainment of IR RAOs and success/completion of the IR), and reference Appendix D of the IR FS Report (which itself will contain information pertaining to the IR Completion Evaluation Framework as a component of the adaptive management approach and will reference Appendix H).</p>
11	Sections 2.1 through 2.4	Specific	3 to 5	<p>As currently presented, the numbering of the various LOEs suggests a priority or an order of application that is not consistent with how the LOEs would be evaluated either singularly to evaluate IR success or in conjunction to evaluate IR completion. To avoid this connotation, reorder the subsections to instead be grouped as pre-IR LOEs (Mapping of Concentrations and Areas Vulnerable to Erosion; Remedy Design), IR LOEs (Remedy Implementation), and post-IR LOEs (SWAC Attainment; Post-IR Confirmation Data Source Assessment).</p>
12	Section 2.1, Paragraph 1	Specific	3	<p>The text suggests that the PDI sampling would only occur between RM 8.3 and RM 15. Even if the spatial sampling density is less above RM 15 than between RM 8.3 and RM 15, it is still expected that pre-design sediment sampling will be performed above RM 15. This sampling would determine if there are actionable source areas between RM 15 and Dundee Dam that would need to be incorporated into the IR. This is required per the final RAOs memo of December 2018. Revise the text accordingly. Also, the text indicates that the initial round of PDI data would be geostatistically interpolated, but does not provide any detail regarding the specific geostatistical interpolation approach. Revise the text to include additional detail regarding the specific nature of the geostatistical interpolation that would be performed.</p>
13	Section 2.1, Paragraph 2	Specific	3	<p>The text suggests that only the 2019 bathymetric survey and a subsequent bathymetric survey would be used to understand areas of erosion. As previously discussed between EPA, NJDEP, and the CPG, other prior bathymetric surveys will also be used (where there is survey overlap) to evaluate areas of erosion. To the extent that more specific lithologic information would be important to understand erosional characteristics and/or to facilitate decisions related to “dredging to clean”, sidescan sonar survey information collected in conjunction with the 2019 and subsequent bathymetry events would be appropriate to evaluate conditions in the upper 9-mile reach. Revise the text accordingly. Also, revise the text in this paragraph to more clearly describe the process of “bathymetric differencing” and to indicate the difference between surveys that will be considered to represent an area vulnerable to erosion.</p>

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14	Section 2.1, Paragraph 3	Specific	3	The text indicates that “an evaluation of the uncertainty of the delineation will be conducted to assess confidence that it accurately targets source areas.” Describe in the appendix what methods would be used in this uncertainty evaluation (e.g., an evaluation of targeting error rates, using cross-validation and/or geostatistical simulation techniques). Also, to the extent this represents a known uncertainty in the decision-making framework, ensure that the uncertainty and the means to reduce this uncertainty are adequately presented and addressed in the Adaptive Management Plan (Appendix D to the IR FS Report). Ensure the same for other specific uncertainties described in Appendix H.
15	Section 2.2	Specific	3 to 4	Currently, this section does not describe perhaps the most critical purpose of the Remedy Design LOE, which is to develop an IR footprint to meet the selected target SWACs and achieve the IR RAOs, incorporating the methods and principles that have previously been agreed to between EPA, NJDEP, and the CPG (e.g., by way of the March 8, 2019 agreement memorandum). Those previously agreed to methods and principles include establishing a multiplier for the subsurface RALs based on PDI data and comprehensive evaluation of bathymetric data, and sequentially applying RAO 1 followed by RAO 2 when developing the remediation footprint. Revise the text accordingly.
16	Section 2.2, Paragraph 1	Specific	3	The text describes that operational constraints will be considered during the IR design “to minimize concerns with undisturbed and generated residuals near structures and on potentially unstable slopes.” This language is not clear if the IR design footprint would be revised to account for areas that need to be avoided. Furthermore, the March 8, 2019 decision memorandum indicated that particular areas with potential operational constraints will be incorporated into the IR design footprint, and the IR FS Report (Section 7.1.1) indicates that alternative remedial approaches would be implemented in locations with operational constraints, if and as necessary. Revise this text to more clearly and consistently discuss operational constraints and the implications for the Remedy Design LOE.
17	Section 2.2, Paragraph 3	Specific	4	More clearly describe what the scope and purpose is of the value engineering step in the context of the Remedy Design LOE, and how a value engineering assessment might affect refinements to the IR design and/or assessment of this LOE. Note that the main body of the IR FS Report does not describe a value engineering step for the IR design, or what such an analysis would be intended to accomplish or what implications there might be for design. Upon review of additional details regarding the scope/purpose of the value engineering study, EPA will assess the utility of the study in the Remedial Design LOE.
18	Section 2.3	Specific	4	As written, this section contains almost no detail related to the performance monitoring program that would be in place during IR implementation and would inform the assessment of construction quality. Because this performance monitoring program will provide the information necessary for EPA to fulfill the intent of the construction certification process, it should be described first as the most critical consideration for remedy success. The performance monitoring program is anticipated to include the relevant construction controls and BMPs, the performance monitoring endpoints and metrics that define compliance and non-compliance, the performance data collection approach, and the construction contingency measures to address non-compliance. While selecting a qualified contractor is recognized to be important, this should be summarized after the performance monitoring approach and the construction certification process. It is always EPA’s expectation that qualified contractors would perform remediation work at a CERCLA site. EPA, NJDEP, and the CPG have previously discussed some expectations of the IR performance monitoring program. While EPA recognizes that the pre-design data will inform aspects of the performance monitoring program, and that the performance monitoring program will be finalized by way of the IR design based on consensus between EPA, NJDEP, and the CPG, Section 2.3 of Appendix H should be expanded to include more detail regarding the anticipated performance monitoring approach. It is critical to provide definition around the performance monitoring program in the IR FS, so that the program can be adequately captured in the IR decision document as an IR requirement. Current expectations for the performance monitoring approach include physical and chemical water quality monitoring to evaluate the potential for dredging releases and dredge-related contaminant releases, bathymetric data collection and analysis to evaluate dredging accuracy (and to specifically assess dredging accuracy from the perspective of contaminant mass removal), and monitoring to verify the lateral and vertical accuracy of cap placement. EPA expects that sediment sampling will be a component of the performance monitoring approach (e.g., to verify attainment of “dredge to clean” conditions that may not require the placement of a cap, pending consensus on the definition of clean in this context between EPA, NJDEP, and the CPG). Revise this section of Appendix H to include more detail on the expectations for the IR performance monitoring approach, and specify that the approach will be finalized in the IR design after pre-design data are available.
19	Section 2.4	Specific	4 to 5	Include in this section some discussion of the use of the post-IR sediment sampling data as a means to evaluate performance of the IR in terms of effectiveness of construction BMPs. EPA has previously discussed with the CPG the use of the post-IR sediment sampling data for this important purpose.
20	Section 2.4, Paragraph 1	Specific	4	Revise the text to indicate that “the post-IR sediment sampling program is anticipated to include not less than 400 individual sampling locations...” as opposed to “...on the order of 400 individual sampling locations...”. In addition, describe that a composite sampling scheme may be employed to improve the statistical power of the post-IR dataset while maintaining a reasonable number of sampling locations. This is consistent with the manner in which the post-IR sediment sampling program has been more recently described following additional assessment of current data, anticipated PDI data density, and expectations for post-IR sediment sampling program needs. Ultimately, the post-IR sample size will be determined by simultaneously evaluating sample size needs versus acceptable false outcome error rates and acceptable levels of equivalency. Also, revise the text to indicate that the probability-based sampling approach may include spatial stratification to account for important system characteristics. The potential value of incorporating spatial stratification in the post-IR sediment sampling program will be fully assessed during IR design.
21	Section 2.4, Paragraph 2	Specific	4	This section indicates that the value of Y embodies a degree of equivalence that would be reasonable in part because of the “non-absolute nature” of the RAO 1 SWAC goals. As noted above in Comment #8, while not absolute values from the perspective of exposure or risk, and while also not necessarily absolute expressions of when sources would be adequately addressed and/or recovery adequately accelerated following an IR, the RAO 1 SWAC goals do represent concentrations that demonstrate RAO attainment. Revise the text to

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				convey these concepts when describing the SWAC goals as “non-absolute”, consistent with revisions made to Section 1.1 based on Comment #8.
22	Section 2.4, Paragraph 2	Specific	4 to 5	The text indicates that “the magnitude of Y will embody tolerance for the possibility that SWACs exceeding the RAO 1 SWAC goals could result from post-IR sampling data even though the IR has successfully addressed sediment sources in the Upper 9 Miles of the LPR.” While true, it should also be explicitly stated that Y embodies the possibility that a SWAC calculated from a data population with a true mean actually equal to or less than the RAO 1 SWAC goal may exceed the SWAC goal due to inherent uncertainty involved in estimating population means from sample data. Revise this sentence to read “the magnitude of Y will embody tolerance for the possibility that SWACs exceeding the RAO 1 SWAC goals could result from post-IR sampling data even though the true means are at or below the SWAC goals or otherwise the IR has successfully addressed sediment sources in the Upper 9 Miles of the LPR.”
23	Section 2.4, Paragraph 3	Specific	5	This paragraph indicates “if the 95% UCLs were to be less than or equal to Y times the SWAC goal of 0.46 ppm for total PCBs and Y times the SWAC goal of 85 ppt for 2,3,7,8-TCDD, the IR will be considered to have met the SWAC goals with an appropriate degree of statistical confidence and the IR is complete.” As indicated in Comment #2 above, the IR Completion Determination Framework should be framed around an initial determination of IR success based on comparison of post-IR SWACs to the RAO 1 SWAC goals within the reverse null statistical hypothesis testing framework. In the condition as described in this paragraph of Section 2.4, the IR would be determined to be successful, and because the IR would be concluded to be successful, it would also necessarily be considered complete (see Comments #30 and #31 below). Also note that this information that conveys application of and decision-making related to the LOE would be more suitable for Section 3, which describes the application and interpretation of the information resulting from the LOEs, including the IR successful and other outcomes from the statistical testing. Move this discussion to the beginning of Section 3, and otherwise revise the text as indicated in this comment.
24	Section 2.4, Paragraph 4	Specific	5	The first sentence in this paragraph states “the Y value will be established based on statistical simulations of post-remedy sampling data drawn from PDI data with non-remediated areas having the concentrations found in the PDI sampling, with some allowance for targeting error, and the remediated areas having a defined residual concentration informed by modeling of remedy implementation...”. This implies that definitively there would be only one Y value when in fact there could be different Y values for 2,3,7,8-TCDD and total PCBs. Revise this sentence to specify “the Y values will be established...”. Clarify in the text that measures would be taken to constrain variability in the PDI (e.g., in-fill sampling) and post-IR (e.g., compositing) datasets and that targeting errors are expected to be minimized by way of the PDI dataset, as compared to current assumptions about targeting errors based on available data. Also, for purposes of deriving the Y value, an assumption for the residual 2,3,7,8-TCDD concentration in remediated areas (i.e., 10 ppt) has already been agreed to between EPA, NJDEP, and the CPG for the IR FS Report. Revise the text to indicate this and to clarify what specifically is meant by “a defined residual concentration informed by modeling of remedy implementation” and how that modeling is expected to be performed.
25	Section 2.4, Paragraph 4	Specific	5	The second sentence in this paragraph states “the Y value will be set such that the expected frequency of false negatives (i.e., concluding that 85 ppt was not achieved when it was) derived from the statistical simulations is not more than 5%.” Revise the sentence to specify “the Y values will be set...” as there may be separate and distinct Y values for 2,3,7,8-TCDD and total PCBs, and revise the parenthetical in this sentence to read “(i.e., concluding that 85 ppt for 2,3,7,8-TCDD and/or 0.46 ppm for total PCBs were not achieved when the true means for the post-IR sediment surface interval are at or below the RAO 1 SWAC goals)”.
26	Section 2.4, Paragraph 4	Specific	5	The final sentence in this paragraph states “USEPA considers a level of 95% to be acceptable for the upper bound that will establish the Y value for the post-IR statistical testing.” To avoid any confusion between 95% as an appropriate level of statistical certainty for the confidence intervals around the post-IR SWACs and 95% confidence as an expression of control against a false negative declaration, restate this as “USEPA considers an error rate of 5% to be acceptable for the upper bound of a potential false negative outcome that will establish the Y values for the post-IR statistical testing. This corresponds to a 95% level of confidence that the IR would not be concluded to have not attained the RAO 1 SWAC goals when in fact it did. ” Also note that this portion of Appendix H should also describe the acceptable level of confidence around a potential false positive outcome, where the IR would be concluded to have been successful when the true post-IR 2,3,7,8-TCDD and/or total PCB SWAC(s) is/are actually not statistically equal to or less than the RAO 1 SWAC goal(s). False negative and false positive error rates are controllable through selection of Y values and the post-IR sample size. EPA, NJDEP, and the CPG have agreed on the maximum 5% error rate for a false negative outcome and have discussed the false positive error rate (i.e., 10% as most recently discussed). EPA recognizes that additional discussion may be necessary to arrive at consensus on this false positive error rate level.
27	Section 2.5	Specific	5	This section begins with a qualifier as to when this LOE might be relevant. The intent of Section 3 is to describe the implementation of the IR Completion Evaluation Framework and the application of the LOEs within the framework. Section 2.5 should describe the LOE without qualification, and information regarding the fit of this LOE within the overall decision-making framework should be included in Section 3. Notably, this LOE would be pertinent in at least some form in any outcome other than the IR successful outcome (see Comment #28 below). In addition, the last sentence in this section specifies that this LOE would be factored into a WOE evaluation. Similar statements are not made for each of the other LOEs, and this statement is redundant with information contained in Section 2 (see Comment #10 above) and Section 3; therefore, this language can be deleted. Revise the appendix accordingly.
28	Section 2.5	Specific	5	As draft Appendix H is currently written, the implication appears to be that this LOE would constitute two evaluations: <ul style="list-style-type: none"> ▪ an evaluation as a component of a WOE assessment following a statistically indeterminate outcome from the reverse null hypothesis statistical testing approach to determine if potential remaining source areas exist; and then, ▪ if the reverse null hypothesis statistical testing were to determine the IR was not conclusively complete after both an initial round of post-IR sediment sampling and additional follow-on sediment sampling, or if the WOE assessment following an indeterminate statistical outcome were to

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				<p>demonstrate the IR was not complete, a more robust evaluation of potentially <u>actionable</u> remaining source areas as a final decision point in determining whether the IR could be concluded to be complete by overall WOE.</p> <p>If this is the case, this section of Appendix H should be revised to more clearly describe the underlying intent of this LOE.</p> <p>Specifically, this section indicates that “...the post-IR confirmation sediment sampling data will be evaluated for evidence of actionable source areas. Such evidence would be indications of a contiguous area at concentrations significantly above the RAL.” To meet the presumed intent of this LOE, revise the first sentence in this passage to read “...the post-IR confirmation sediment sampling data will be evaluated for evidence of actionable potentially remaining source areas that are the focus of the IR.” The second sentence of this passage is a highly simplified expression of an evaluation of potential remaining sources, and needs to be expanded to include more detail and to more accurately reflect discussions between EPA, NJDEP, and the CPG. Based on prior discussions, include the following as relevant factors in evaluating the existence of potential remaining sources:</p> <ul style="list-style-type: none"> • The relative magnitude of remaining surface sediment concentrations compared to RALs. • The distribution of RAL exceedances and the appearance of contiguous areas with such exceedances. • The occurrence of RAL exceedances in in-situ sediments versus deposited residuals and in remediated versus unremediated areas. <p>Also, delete the word “significantly” from this sentence. The concept that contiguous concentrations “significantly” above the RAL would constitute a remaining source area has not previously been discussed, and EPA does not consider this qualifier to be appropriate at this time.</p> <p>After this passage, include in the text a description of how this LOE would be expanded upon to inform an assessment of potentially actionable remaining sources. As discussed previously between EPA, NJDEP, and the CPG, information to be considered in determining if potentially remaining source areas are actionable includes:</p> <ul style="list-style-type: none"> • The relative magnitude of surface sediment concentrations compared to RALs. • The likely effect of removing additional sediment with respect to reducing contaminant migration and/or accelerating longer-term recovery in the system. • The feasibility of removing additional sediments. <p>EPA recognizes that additional discussion is needed between EPA, NJDEP, and the CPG to finalize a framework for evaluating remaining sources following review of the post-IR sediment data, including what relative magnitude of surface sediment concentrations in comparison to RALs would be meaningful and what specifically might constitute an actionable source. EPA expects this discussion to happen by way of ongoing FS-related meetings, such that yet more detail can be integrated into the IR Completion Determination Framework in the final IR FS Report and ultimately in the IR design. However, in the meantime, revise this portion of Appendix H in accordance with this comment.</p>
29	Section 3	Specific	6	<p>In accordance with Comment #2 above, revise this section to more clearly and explicitly structure the implementation of the evaluation framework around an initial step that assesses IR success through statistical comparison of post-IR SWACs to RAO 1 SWAC goals followed by, as necessary, a WOE analysis that might conclude IR completion even if RAO 1 SWAC goals are not attained. In addition, clearly describe and differentiate the meanings of “not conclusively complete” and “indeterminate”.</p>
30	Section 3, Paragraph 1	Specific	6	<p>The first sentence in this paragraph references Figure 2, which only represents 2,3,7,8-TCDD. While implied, the text does not state that an equivalent decision flow would represent total PCBs or that the decision framework in Figure 2 would be based on compliance for both chemicals (or non-compliance for either chemical). Revise the text to explicitly clarify this. Revise the second sentence to read “the first step is to compare the 95% UCLs of the SWACs calculated from the initial post-IR dataset to the limiting values established during remedial design (Y times the SWAC goal of 0.46 ppm for total PCBs and Y times the SWAC goal of 85 ppt for 2,3,7,8-TCDD, with Y potentially being different for total PCBs and 2,3,7,8-TCDD.” In addition, revise the last sentence in this paragraph to read “finding the 95% UCLs to be at or below the limiting values will demonstrate attainment of the RAO 1 SWAC goals and constitute remedy completion IR success (which will also necessarily constitute IR completion).”</p>
31	Section 3, Paragraph 2	Specific	6	<p>This paragraph currently reads “if the 95% UCLs for total PCBs or 2,3,7,8-TCDD exceed their limiting values, a second round of sediment sampling will be conducted to supplement the post-IR dataset and refined 95% UCLs will be estimated and compared to the limiting values. Finding them to be at or below the limiting values will constitute remedy completion.” Stating “a second round of sediment sampling” might imply that the post-IR sediment sampling that is performed immediately after IR construction would be repeated in scope, when in fact the specific approach to additional sediment sampling is not currently known. In addition, the second sentence in this paragraph is vague and should describe that 95% UCLs of the calculated post-IR SWACs would constitute a determination of IR success. Specifically revise this paragraph as follows: “If the 95% UCLs for total PCBs or 2,3,7,8-TCDD exceed their limiting values, a second round of additional post-IR sediment sampling will be conducted to supplement the initial post-IR dataset. The specific scope of additional post-IR sediment sampling would be developed based on assessment of the initial post-IR dataset. Post-IR SWACs will be recalculated and refined 95% UCLs will be estimated and compared to the limiting values. Finding them the 95% UCLs to be at or below the limiting values will demonstrate attainment of the RAO 1 SWAC goals and constitute remedy completion IR success (which will also necessarily constitute IR completion).”</p>
32	Section 3, Paragraph 3	Specific	6	<p>In the first sentence of this paragraph, specify that the SWAC goals are the RAO 1 SWAC goals to avoid any confusion. In addition, revise the second sentence of this paragraph to read “if either of the 95% LCLs exceed the RAO1 SWAC goals, the remedy IR will be deemed to not be conclusively complete.”</p>

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33	Section 3, Paragraph 4	Specific	6	<p>In accordance with Comment #11 above, instead of referencing the LOEs by numerical designation, reference the subsection in Section 2 where each LOE is described. Where this paragraph describes the application of the Post-IR Confirmation Data Source Assessment in the context of an initial evaluation of potentially remaining sources following an indeterminate statistical outcome, ensure that the discussion is consistent with Comment #28 above. Where this paragraph indicates that the initial and follow-on post-IR sediment sampling will likely yield a density of multiple samples per acre, provide the underlying information that supports this presumption and also describe that sidescan sonar data would be valuable in the assessment (see Comment #13 above). Also, this portion of the paragraph suggests that a density of multiple samples per acre defines the sufficiency of the post-IR dataset as adequate for evaluating spatial structure in the data (e.g., a contiguous area of elevated concentrations) to determine the existence of potential remaining source areas. Specify the measures that would be taken to support assessment of the data for this purpose if the spatial density is not multiple samples per acre.</p> <p>The second to last sentence of this paragraph states “if the LOE examination supports that the remedy has been successfully implemented, the conclusion will be that although the statistics are indeterminate, the IR construction is considered complete.” Replace “remedy” with “IR” in this sentence. Also, revise the sentence to indicate that the possible conclusion that the IR is considered complete although the statistics are indeterminate is by WOE (as opposed to through “LOE examination”). Also, otherwise revise the language in this paragraph to provide additional detail related to what factors will determine if each LOE supports that the IR has been successfully implemented.</p>
34	Section 3, Paragraph 5	Specific	6	<p>The information conveyed in this paragraph is presumably relevant to the determination that the IR is not conclusively complete following a WOE analysis after a statistically indeterminate outcome (current paragraph 4) or the determination that the IR is not conclusively complete following the finding that the 95% UCL of the calculated post-IR SWAC for 2,3,7,8-TCDD and/or total PCBs exceeds the limiting value and the corresponding 95% LCL exceeds the RAO 1 SWAC goal (current paragraph 3). Ensure that the text in this paragraph is clear in this regard. Also, revise the text that describes the more robust evaluation of potentially actionable remaining source areas (as compared to a preliminary evaluation of potential remaining source areas) per Comment #28 above. In the bulleted list of factors in this paragraph, EPA, NJDEP, and the CPG have not previously discussed the concepts of “contaminant mass” or “potential for erosion” as considerations in evaluating the potential for actionable remaining source areas, whereas the “potential for natural recovery” would appear to align generally with “the likely effect of removing additional sediment with respect to reducing contaminant migration and/or accelerating longer-term recovery in the system” as noted above in Comment #28. Provide additional detail in this paragraph regarding how each factor that might be considered in evaluating the potential for actionable remaining source areas would be applied in the evaluation. .</p>
35	Figure 1	Specific	N/A	<p>As noted in Comment #9 above, update this figure to demonstrate uncertainty using the central tendency RAL (205 ppt) associated with FS alternative 3.</p>
36	Figure 2	Specific	N/A	<p>To improve consistency with the narrative in the appendix, make the following edits to Figure 2:</p> <ul style="list-style-type: none"> For all locations where “UCL” or “LCL” is indicated, instead use “95% UCL” or “95% LCL” For the green decision box connected to “is UCL ≤ Y*85?”, use “IR Successful (and Necessarily Complete)” instead of “IR Complete” For the blue activity box currently reading “Assess Potential Source Areas for Remediation”, instead use “Assess Potential Remaining Source Areas for Remediation” For the blue decision question diamond currently reading “Actionable Source Areas Found?”, instead use “Actionable Remaining Source Areas Found Identified?” Specifically identify the “indeterminate” statistical case (i.e., the “yes” pathway after the decision question diamond reading “Is LCL ≤ 85?”)
37	Attachment 1, Section 1	Specific	N/A	<p>Throughout this section, use “IR” instead of “remedy”.</p> <p>In the third bullet under Data Needs, also acknowledge the existing replacement value 10 ppt for 2,3,7,8-TCDD for the IR FS and that this value will be refined accordingly (see Comment #24 above).</p> <p>In the fourth bullet under Data Needs, revise the text to read “this is acreage of the natural recovery areas area outside the IR footprint assumed to have been incorrectly not remediated and to have...”.</p> <p>In the last bullet under Data Needs, revise the text to read “the number of samples collected in the post-IR sediment sampling program (anticipated to be on the order of not less than 400 individual sampling locations)” (see Comment #20 above).</p>
38	Attachment 1, Section 2	Specific	N/A	<p>Throughout this section, use “IR” instead of “remedy”.</p> <p>In the second bullet under Steps, revise the text to read “use PDI data to define the concentrations of total PCBs and 2,3,7,8-TCDD in the correctly unremediated (Natural Recovery) areas”.</p> <p>In the second bullet under Steps, revise the text to read “conduct 1,000 simulations of stratified random post-remedy sampling of the Natural Recovery correctly unremediated, Targeting Error and remediated areas”.</p> <p>In the fourth bullet under Steps, revise the text to read “compute the 95% upper confidence limits (UCLs) of the total PCB and 2,3,7,8-TCDD SWACs for each simulation”.</p> <p>The recipe for deriving Y values should be supported by the explicit need for the SWACs of the simulated dataset being at or below the design targets. The value of Y should not be artificially elevated by allowing</p>

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				<p>targeting errors to drive the SWACs of the simulated dataset above these targets. Revise this section accordingly.</p> <p>In this section, there is no mention of controlling the probability of incorrectly declaring success when in fact the RAO 1 SWAC goals have not been met (i.e., false positive error). The recipe should balance both Type I and Type II errors to ensure that the Y values and sample size are derived so that the probability of declaring success when the RAO 1 SWAC goals have been met would be 95% and the probability of falsely declaring success when the RAO 1 SWAC goals have not been met is at an appropriate level (i.e., 10% as suggested in prior discussions between EPA, NJDEP, and the CPG; see Comment #26 above). Revise this section accordingly.</p> <p>Also, as EPA, NJDEP, and the CPG have previously discussed, in the event that post-IR SWACs cannot be reliably measured and/or evaluated reasonably using the Y factor methodology outlined in Attachment 1, the overall framework for generating and assessing post-IR data and demonstrating attainment of the RAO 1 SWAC goals would need to be reconsidered between EPA Region 2, NJDEP, and the CPG. This outcome would become evident only after the PDI data are available. For instance, if variability in the PDI dataset is high enough to potentially require a post-IR sampling program equivalent in spatial density to the PDI and/or to support the use of a very high Y value as a basis of equivalence to demonstrate attainment of the ROA 1 SWAC goals, then it is likely that there is a fundamental lack of understanding of the system to support an IR and to implement the Y factor methodology. While the PDI data are anticipated to have the opposite effect (i.e., to constrain uncertainty), revise this section to acknowledge this possible outcome.</p>