

Appendix G

Tier 2b and Tier 2c Memoranda

Lower Duwamish Waterway Group

City of Seattle / King County / The Boeing Company

MEMORANDUM

To: Elly Hale, Nasrin Erdelyi, and Jaclyn Satira; USEPA
From: Lower Duwamish Waterway Group
(prepared by Anchor QEA and Windward Environmental LLC)
Subject: LDW Middle Reach – Archive PDI Sediment Samples to be Analyzed
Date: August 1, 2025

As described in the draft Data Evaluation Report (DER) for the Middle Reach (the draft final version of which was submitted to the U.S. Environmental Protection Agency [EPA] on July 24, 2025), some preliminary data gaps can be informed by analyzing archived Pre-Design Investigation (PDI) sediment samples (i.e., samples collected during Phase I or II of the PDI for the middle reach).¹ The results of these analyses will be used to provide information for design and to help inform the analysis of remaining data gaps to be filled by the Phase III PDI.

This memorandum documents the archived PDI samples identified for analysis. The data gaps addressed are related to data quality objectives (DQOs) 9, 10, and 12:

- **Further horizontal delineation (DQOs 9 and 10)** – Refine horizontal extent of remedial action level (RAL) exceedance areas (either polychlorinated biphenyl [PCB] interpolations or Thiessen polygons for other chemicals).
- **Further vertical delineation (DQO 12)** – Analyze vertical extent samples to provide additional information regarding the depth of contamination for remedial design (RD).

Based on these objectives, the archived Phase I and II samples were reviewed, and 48 samples from 24 locations have been identified for analysis (Table 1). Ten of these samples are RAL interval samples related to DQOs 9 and 10 and the other 38 are vertical extent samples related to DQO 12. Analytes include PCBs (41 samples), dioxins/furans (17 samples), and phthalates (11 samples). These locations are shown on the Map 1 series attached to this memorandum, which is a modified version of the Map 3-1 series of the DER. Sample analysis will be conducted as described in the EPA-approved PDI

¹ Additional archived samples may be identified for analysis as part of the Phase III PDI.

Quality Assurance Project Plan (QAPP) for the Middle Reach (Windward and Anchor QEA 2022), as well as PDI QAPP Addendum Nos. 1 and 2 for Phase II (Anchor QEA and Windward 2024a, b).

Samples will be submitted for analysis on August 15, 2025. Once samples have been submitted, it is anticipated that preliminary data will be received in about seven to eight weeks (mid-October), and that validation will take another four weeks to complete (mid-November). Data from these samples will be used to inform the evaluation of data gaps and the QAPP addendum for Phase III, a draft of which is due to EPA in January 2026, as well as to inform 60% RD. These data will be incorporated into the design dataset along with the data collected during the Phase III PDI.

Table 1
Archive Phase I and II PDI Samples to be Analyzed

RAL Exceedance Area	Location	Sample ID ¹	Count of Samples	Sample Type	Rationale for Analysis	Analytes
36	RM 1.75	SC1321 B	1	Vertical extent	Additional vertical information for RD	PCBs
32	RM 1.85	SS1821	1	0–10 cm	Refine surface PCB interpolation	PCBs
31	RM 1.9E	SS1349	1	0–10 cm	Refine surface dioxin/furan polygon	Dioxins/furans
30	RM 2.1E	SC1387 DE	2	Vertical extent	Additional vertical information for RD	PCBs
27	RM 2.2W	IT1411 D	1	Vertical extent	Additional vertical information for RD	PCBs
		IT1413 D	1	Vertical extent	Additional vertical information for RD	PCBs
		IT1418 D	1	Vertical extent	Additional vertical information for RD	PCBs
23	RM 2.2E	SC1433 DF	2	Vertical extent	Additional vertical information for RD	PCBs
22	RM 2.35	SC1460 KMN	3	Vertical extent	Additional vertical information for RD	PCBs
20	RM 2.4E	SC1468 A	1	0–60 cm	Refine subsurface phthalate polygon	Phthalates
		SC1468 BCDEF	5	Vertical extent	Additional vertical information for RD	PCBs, dioxins/furans, phthalates
		IT1469 BCDEF	5	Vertical extent	Additional vertical information for RD	
		IT1812 (Phase I)	1	0–45 cm	Refine subsurface dioxin/furan polygon	Dioxins/furans
17	RM 2.5W	IT1486 A	1	0–45 cm	Analyze 0–45-cm sample at location with 0–10-cm RAL exceedance where vertical was clean	PCBs, dioxins/furans
15	RM 2.5	SC1493 HI	2	Vertical extent	Additional vertical information for RD	PCBs
14	RM 2.5	SC1482 EGH	3	Vertical extent	Additional vertical information for RD	PCBs
		1488 FHJ	4	Vertical extent	Additional vertical information for RD	PCBs
Between areas 10 and 11	RM 2.65	SC1515 A	1	Shoal	Analyze shoal material in accordance with QAPP procedures (overdredge sample in shoaling core no longer exceeds RAL after Phase II validation)	PCBs
9	RM 2.7E	SC1521	1	0–60 cm	Refine subsurface dioxin/furan polygon	Dioxins/furans
		IT1216 (Phase I)	1	0–45 cm		Dioxins/furans

RAL Exceedance Area	Location	Sample ID ¹	Count of Samples	Sample Type	Rationale for Analysis	Analytes
8	RM 2.7W	SS1219 (Phase I)	1	0–10 cm	Refine surface dioxin/furan polygon	Dioxins/furans
		SS1220 (Phase I)	1	0–10 cm		Dioxins/furans
		IT1527 DF	2	Vertical extent	Additional vertical information for RD	PCBs
		IT1528 DF	2	Vertical extent	Additional vertical information for RD	PCBs
Between areas 1 and 2	RM 2.9	SC1579 CEF	4	Vertical extent	Additional vertical information for RD	PCBs

Notes:

1. For locations where multiple intervals were collected, letters after the location number (e.g., B, C, D, etc.) indicate the sample intervals to be analyzed.

ID: identification

PCBs: polychlorinated biphenyls

PDI: Pre-Design Investigation

QAPP: quality assurance project plan

RAL: remedial action level

RD: remedial design

RM: river mile

Lower Duwamish Waterway Group

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MEMORANDUM

To: Elly Hale, Nasrin Erdelyi, and Jaclyn Satira; USEPA
From: Lower Duwamish Waterway Group
(prepared by Anchor QEA and Windward Environmental LLC)
Subject: LDW Middle Reach – Archive PDI Sediment Samples to be Analyzed (Tier 2c) and
Response to EPA comments on the August 2025 Tier 2b Memorandum
Date: November 7, 2025

As described in the draft Data Evaluation Report (DER) for the Middle Reach (the final version of which was submitted to the U.S. Environmental Protection Agency [EPA] on September 30, 2025), some preliminary data gaps can be informed by analyzing archived Pre-Design Investigation (PDI) sediment samples (i.e., samples collected during Phase I or II of the PDI for the middle reach). The initial list of samples (referred to as the Tier 2b samples) was triggered for analysis in August 2025. This memorandum describes additional archived samples that will be submitted for analysis to inform RD (referred to as the Tier 2c samples).

This memorandum includes the following information:

- Table 1 – Tier 2c samples to be analyzed to fill data gaps identified during 30% RD
- Table 2 – Summary of preliminary Tier 2b results and response to EPA's specific comments on the Tier 2b sample list (note that the attached excel file provides more details regarding the preliminary Tier 2b results)
- Table 3 – Response to EPA's general comments on the Tier 2b memorandum

As with the Tier 2b samples, the Tier 2c samples identified for analysis are intended to address data gaps related to data quality objectives (DQOs) 9, 10, and 12:

- **Further horizontal delineation (DQOs 9 and 10)** – Refine horizontal extent of remedial action level (RAL) exceedance areas (either polychlorinated biphenyl [PCB] interpolations or Thiessen polygons for other chemicals).
- **Further vertical delineation (DQO 12)** – Analyze vertical extent samples to provide additional information regarding the depth of contamination for remedial design (RD).

Based on these objectives, the archived PDI samples were reviewed, and 31 samples from 20 locations have been identified for analysis (Table 1). Four of these samples are RAL interval samples related to DQOs 9 and 10 and the other 27 are vertical extent samples related to DQO 12. Analytes include PCBs (27 samples) and dioxins/furans (4 samples). These locations are shown on the Map 1 series attached to this memorandum, which is a modified version of the Map 3-1 series of the DER. Sample analysis will be conducted as described in the EPA-approved PDI Quality Assurance Project Plan (QAPP) for the Middle Reach (Windward and Anchor QEA 2022), as well as PDI QAPP Addendum Nos. 1 and 2 for Phase II (Anchor QEA and Windward 2024a, b).

Samples will be submitted for analysis after the data gaps meeting with EPA (scheduled for November 17, 2025). Once samples have been submitted, it is anticipated that preliminary data will be received in about six to eight weeks (mid-January), and that validation will take another four weeks to complete (mid-February). Data from these samples will be used to inform 60% RD. As with the Tier 2b samples, these data will be incorporated into the design dataset along with the data collected during the Phase III PDI.

Table 1
Archive Phase I and II PDI Samples to be Analyzed (Tier 2c Samples)

RAL Ex. Area	Location	Sample ID ¹	Count of Samples	Sample Type	Rationale for Analysis	Analytes
10/11	RM 2.6W	1515 C	1	Vertical extent	Side slope information for RD	PCBs
11	RM 2.6W	SC1509 FGH	3	Vertical extent	Side slope information for RD	PCBs
20	RM 2.4E	SS1812	1	0-10 cm	Evaluate dioxins/furans in area with subsurface exceedance	dioxins/furans
20	RM 2.4E	SS1813	1	0-10 cm	Evaluate dioxins/furans in area with subsurface exceedance	dioxins/furans
20	RM 2.4E	IT1813	1	0-45 cm	Refine dioxin/furan subsurface polygon	dioxins/furans
20	RM 2.4E	SC1159	1	0-60 cm	Refine dioxin/furan subsurface polygon	dioxins/furans
22	RM 2.1	1405 EF	2	Vertical extent	Side slope information for RD	PCBs
22	RM 2.1W	1408 C	1	Vertical extent	Side slope information for RD	PCBs
22	RM 2.2W	1420 CE	2	Vertical extent	Side slope information for RD	PCBs
22	RM 2.4W	1459 FGH	3	Vertical extent	Side slope information for RD	PCBs
23	RM 2.3E	1443 B	1	Vertical extent	Side slope information for RD	PCBs
30	RM 1.8E	1326 FG	2	Vertical extent	Side slope information for RD	PCBs
30	RM 1.9E	1334 JK	2	Vertical extent	Side slope information for RD	PCBs
30	RM 1.9E	1337 NP	2	Vertical extent	Side slope information for RD	PCBs
30	RM 1.9W	1338 JKL	3	Vertical extent	Side slope information for RD	PCBs
30	RM 1.9W	1339 H	1	Vertical extent	Vertical information for RD	PCBs
30	RM 1.9E	1340 K	1	Vertical extent	Vertical information for RD	PCBs
30	RM 1.9E	1341 K	1	Vertical extent	Vertical information for RD	PCBs
30	RM 1.9E	1344 L	1	Vertical extent	Vertical information for RD	PCBs
30	RM 2.0W	1346 G	1	Vertical extent	Vertical information for RD	PCBs

Notes:

1. For locations where multiple intervals were collected, letters after the location number (e.g., B, C, D, etc.) indicate the sample intervals to be analyzed.

ID: identification

PCBs: polychlorinated biphenyls

PDI: Pre-Design Investigation

QAPP: quality assurance project plan

RAL: remedial action level

RD: remedial design

Table 2
Summary of Preliminary Tier 2b results (unvalidated) and LDWG Response to EPA Comments on Specific Tier 2b Samples

Tier 2b Samples and Preliminary Results							EPA Comments on Tier 2b Samples (August 15, 2025)	LDWG Response (November 7, 2025)
RAL Ex. Area	Location	Sample ID ¹	Sample Type	Rationale for Analysis	Analytes	Summary of Preliminary Tier 2b Results ²		
Between areas 1 and 2	RM 2.9	SC1579 CEFG	Vertical extent	Additional vertical information for RD	PCBs	C: < surface RAL E: < surface RAL F: < surface RAL G: > surface RAL	Analyze 1581 verticals given the exceedances at depth in nearby vertical 1582	Location 1581 is outside of the side slope for RAA 1B, and thus is not needed for RD.
8	RM 2.7W	SS1219 (Phase I)	0–10 cm	Refine surface dioxin/furan polygon	dioxins/furans	0-10 < RAL (dioxin/furan EF = 0.5)	None	--
		SS1220 (Phase I)	0–10 cm		dioxins/furans	0-10 < RAL (dioxin/furan EF = 0.3)	None	--
		IT1527 DF	Vertical extent	Additional vertical information for RD	PCBs, PAHs	D: > surface RAL (fluoranthene) F: < surface RAL	Add analysis for cPAHs given collocated PAH exceedances	As indicated to EPA in the August 21 email response, PAHs were added for these intervals as part of Tier 2b.
		IT1528 DF	Vertical extent	Additional vertical information for RD	PCBs, mercury, PAHs, dioxins/furans	D: > surface RAL (dioxins/furans) F: < surface RAL	Add PAH (nearby), D/F (collocated), and mercury (nearby) to ensure post-dredge surface meets RALs	As indicated to EPA in the August 21 email response, dioxins/furans, PAHs, and mercury were added for these intervals as part of Tier 2b
9	RM 2.7E	SC1521	0–60 cm	Refine subsurface dioxin/furan polygon	dioxins/furans	0-60 < RAL (dioxin/furan EF = 0.022)	None	--
		IT1216 (Phase I)	0–45 cm		dioxins/furans	0-45 < RAL (dioxin/furan EF = 0.044)	None	--
Between areas 10 and 11	RM 2.65	SC1515 A	Shoal	Analyze shoal material in accordance with QAPP procedures (overdredge sample in shoaling core no longer exceeds RAL after Phase II validation)	PCBs	shoal material < RAL (PCB EF = 0.42)	Add 1415C interval (z layer) in case A is below RALs. B overdredge is now clean, but D and deeper are all exceedances.	1515C will be added to Tier 2c to provide side slope information for RD (see Table 1).
14	RM 2.5	SC1482 EGH	Vertical extent	Additional vertical information for RD	PCBs	E: < surface RAL G: < surface RAL H: < surface RAL	See below comment for 1488	RAL interval samples at 1482 do not exceed RAL, and therefore this location is not included within the RAL exceedance area. The available vertical extent intervals provide sufficient information to inform PD&C.
		1488 FHIJ	Vertical extent	Additional vertical information for RD	PCBs	F: < surface RAL H: < surface RAL I: < surface RAL J: < surface RAL	1489 has very deep contamination and a prior hit in the overdredge interval. Why not include in RAL exceedance area? Is this area likely dredge and cap? If 1 more foot would get to clean, analyze deeper interval.	RAL interval samples at 1489 do not exceed RAL, and therefore this location is not included within the RAL exceedance area. The available vertical extent intervals for SC1488 provide sufficient information to inform PD&C.
15	RM 2.5	SC1493 HI	Vertical extent	Additional vertical information for RD	PCBs	H: > surface RAL I: > surface RAL	Add 1493J and K (RC1, should tag clean or support PD&C) if side slope of Area 15 or 14 will expose depths equivalent to D, F, or deeper at 1492, add these intervals for PCBs. 1489 has very deep contamination.	Intervals H and I (which were analyzed as part of Tier 2b) will provide information down to -29 ft MLLW. This provides sufficient information to inform PD&C adjacent to the FNC in this area where the authorized depth is -20 ft MLLW.
17	RM 2.5W	IT1486 A	0–45 cm	Analyze 0–45-cm sample at location with 0–10-cm RAL exceedance where vertical was clean	PCBs, dioxins/furans	0-45 < RAL (PCB EF = 0.029; dioxin/furan EF = 0.099)	None	--
20	RM 2.4E	SC1468 A	0–60 cm	Refine subsurface phthalate polygon	Phthalates	0-60 < RAL (phthalate EFs = 0.0097 to 0.15)	None	--

Tier 2b Samples and Preliminary Results							EPA Comments on Tier 2b Samples (August 15, 2025)	LDWG Response (November 7, 2025)
RAL Ex. Area	Location	Sample ID ¹	Sample Type	Rationale for Analysis	Analytes	Summary of Preliminary Tier 2b Results ²		
		SC1468 BCDEF (RAA 20B)	Vertical extent	Additional vertical information for RD	PCBs, dioxins/furans, phthalates	B: all < surface RAL C: all < surface RAL D: all < surface RAL E: all < surface RAL F: DF > surf RAL	Add intervals G, H, I and alternating after that (K, M, O). 1470 didn't tag clean at depth of 1468F.	The 30% RD for this area includes dredging (RAA 20B) and partial dredge and cap (RAA 20C). There is sufficient data at depth to complete design in these RAAs.
		IT1469 BCDEF (RAA 20C)	Vertical extent	Additional vertical information for RD		B: DF > surf RAL C: PCBs, DF > surf RAL D: PCBs, DF > surf RAL E: PCBs > surf RAL F: all < surface RAL	Add interval G. 1470 didn't tag clean at depth of G.	
		IT1812 (Phase I)	0–45 cm	Refine subsurface dioxin/furan polygon	dioxins/furans	0-45 > RAL (dioxin/furan EF = 2.8)	Add cPAHs. given nearby PAHs at 1813	As indicated to EPA in the August 21 email response, cPAHs already analyzed for IT1812 and SS1812.
22	RM 2.35	SC1460 KMN	Vertical extent	Additional vertical information for RD	PCBs	K: < surface RAL M: < surface RAL N: > surface RAL	None	--
23	RM 2.2E	SC1433 DF	Vertical extent	Additional vertical information for RD	PCBs	D: < surface RAL F: < surface RAL	None	--
27	RM 2.2W	IT1411 D	Vertical extent	Additional vertical information for RD	PCBs	D: < surface RAL	None	--
		IT1413 D	Vertical extent	Additional vertical information for RD	PCBs	D: < surface RAL	None	--
		IT1418 D	Vertical extent	Additional vertical information for RD	PCBs	D: < surface RAL	None	--
30	RM 2.1E	SC1387 DE	Vertical extent	Additional vertical information for RD	PCBs	D: > surface RAL E: < surface RAL	None	--
31	RM 1.9E	SS1349	0–10 cm	Refine surface dioxin/furan polygon	dioxins/furans	0-10 < RAL (dioxin/furan EF = 0.39)	If 1349 doesn't exceed RAL for d/f, then the extent of the d/f polygon will shrink. The PCB boundary of 31 appears driven by 1350, with 9 mg/kg OC (in RC2). V core at 1348 has no data. If the area between Area 31 and will NOT be included in SMA for side slope, analyze 1348 for 10 cm (if available) and 60 cm, d/f and PCBs.	SS1349 does not exceed RAL. Locations 1348 and 1349 are both within the side slope, so no additional analysis is needed for design.
32	RM 1.85	SS1821	0–10 cm	Refine surface PCB interpolation	PCBs	0-10 < RAL (PCB EF=0.55)	None	--
36	RM 1.75	SC1321 B	Vertical extent	Additional vertical information for RD	PCBs	B: < surface RAL	None	--

Notes:

1. For locations where multiple intervals were collected, letters after the location number (e.g., B, C, D, etc.) indicate the sample intervals to be analyzed.

2. Preliminary (unvalidated) Tier 2b results are summarized relative to RALs. **Green** indicates that concentrations are below RALs (or below surface sediment RALs for vertical extent samples), **red** indicates RAL interval samples with concentrations above RALs, and **purple** indicates vertical extent samples with concentrations above surface sediment RALs.

EF: exceedance factor

ID: identification

PCBs: polychlorinated biphenyls

PDI: Pre-Design Investigation

QAPP: quality assurance project plan

RAL: remedial action level

RD: remedial design

RM: river mile

Table 3
LDWG Response to EPA General Comments on Tier 2b Memorandum

Area	EPA General Comment (August 15, 2025)	LDWG Response (November 7, 2025)
Northern part of Area 8	The north part of Area 8 is in intertidal Recovery Category 2, and in most locations a 10 cm sample and a 45 cm sample are collocated. It seems that in two locations we have 10 cm RAL exceedances that were below the ENR upper limit, more or less collocated with 45 cm samples that are below RALs. For that reason, LDWG elected not to analyze the V core at 1524. But in a nearby part of Area 8, surface COC concentrations will require dredging, and V Cores 1527 and 1528 indicate COCs at considerable depth. Are these areas really different, in terms of history? Where will the line be drawn between dredging and ENR, and what will be exposed on the side slope of the dredge prism? What contamination will be below the ENR, and will knowing the answer help design a better long-term monitoring approach? EPA recommends that several intervals of 1524 be analyzed for PCBs and dioxins/furans to provide greater understanding of conditions here	Please review the approach presented in 30% RD for this area and we can discuss potential data gaps during the meeting on November 17, 2025.
FNC	Also, while only a few z-layer samples from the navigation channel remain on archive without analysis, EPA recommends analyzing all such samples. Could information help initiate planning for eventual maintenance dredging? Given evidence that in many locations the z-layer exceeds the PCB RAL, we think information about the extent of z-layer channel contamination in the shoaled material would help facilitate discussions with the Corps. This discussion will likely be difficult, and we think it would help to have LDWG initiate a conversation with the Corps sooner rather than when maintenance dredging is urgently needed	These z-layer sample data are not required to complete RD. LDWG is open to discussing this topic further with the Corps prior to any future maintenance dredging.
Between areas 9, 10, 11, 14, 18	Will the design be able to exclude all shoaled areas of the FNC that don't exceed RALs (such as between 9, 10, 11, 14, 18?). In Areas 18 and 14, for example, V core intervals 1162C, 1169D, and 1177D should all be analyzed for PCBs. Nearby sample 1185 had a concentration that was just under the PCB RAL (0.94EF) and this core may be in the side slope. Core 1502 (shoaling core) had a near RAL PCB concentration in one shoal interval. Given variability and near RAL concentrations, more information seems warranted to support SMA boundary development and coordinate around future maintenance dredging needs.	Please review the approach for these areas presented in 30% RD and we can discuss potential data gaps during the meeting on November 17, 2025.
South of area 21/22	Sample 1465 is not proposed for additional analyses, though the 60 cm sample at this location is barely below the RAL (it has a 0.99EF for the PCB RAL). Would analysis of other intervals provide confidence that this area doesn't warrant cleanup?	Location 1465 is beyond the interpolation uncertainty bands surrounding RAL exceedance area 22. Data is not required to complete RD.
Area 21/22	1408 is not proposed for additional analyses, but the concentrations of PCBs are particularly high in this core. It's near 1409, which will be dredged. Does the 10' buffer or the need for stable side slopes warrant including some dredging at 1408?	Additional intervals will be analyzed as part of Tier 2c to support RD (see Table 1).

Area	EPA General Comment (August 15, 2025)	LDWG Response (November 7, 2025)
Area 22/23	Between RAA 22 and 23 the mudline is below the authorized navigation and vessel scour depths. Surface analysis shows no RAL exceedances, but cores to the east and west in RAAs 22 and 23 show contamination at depth. There are some verticals in the area – 1422, 1440, etc. that are archived. EPA believes it would be prudent to assess contamination at depth in these areas, even though there are no applicable RALs, to support analysis of the potential for breakthrough or exposure through erosion.	This information is not needed for RD. Please review the approach for these areas presented in 30% RD and we can discuss additional questions during meeting on November 17, 2025.
Berth areas	Berths warrant specific attention. It's unclear what the operating depths is for individual berths in the Middle Reach. LDWG indicated in the RTCs for the Phase 2 DER that they are collecting this information for the 30% design (comment 5.c of Phase 2 DER). Would it be worth reviewing archived samples in berth areas and analyzing deeper intervals, based on information available to date?	See DER RTC for comment 5b. Please review the approach for these areas presented in 30% RD and we can discuss potential data gaps during the meeting on November 17, 2025.
Buried contamination	There are some samples where we will have contamination at depth below clean material (possible examples: 1479, 1489, 1534, 1559). The Phase II DER RTCs state that "The 30% RD will evaluate buried contamination using methods similar to those used in the upper reach, and results will be summarized in the 30% BODR" (comment 5). Please consider whether deeper intervals from these locations should be analyzed to validate the conservatism of such as evaluation.	See DER RTC for comment 5d. Please review the buried contamination evaluation presented in 30% RD and we can discuss additional questions during meeting on November 17, 2025.
Armoring adjacent to nearshore EAAs	Finally, there are nearshore RAAs with armoring that may cover uncharacterized sediment. As we have noted before, where a RAL exceedance is near an armored slope and the sediment under the armoring has not been characterized, EPA assumes the sediment under the rip rap is contaminated and expects it to be addressed in design. The current memorandum can't address this issue, as there are no archived samples. EPA recommends that LDWG identify such areas and be prepared to propose characterization in Phase III PDI.	Please review the approach for this area presented in 30% RD and we can discuss potential data gaps during the meeting on November 17, 2025.