

EXHIBIT E
Data Verification and Validation Strategy

EXHIBIT E: DATA VERIFICATION AND VALIDATION STRATEGY

This document sets out the strategy for verifying and validating the data generated by the sediment sampling program. Verification and validation of the data will be performed to ensure that results are generated in accordance with the procedures defined in the Field Sampling Plan (FSP) and QAPP and, hence, meet the data quality objectives and are usable. This document specifies the frequency at which analytical results will be verified and validated and the rationale for that frequency. The QAPP will provide the details of the techniques that will be employed and the rationale for their use.

Electronic data verification and data validation (where necessary) are conducted after samples have been taken and analyzed. Verification and validation are the “report card” at the end of data collection and analysis; they provide an understanding of the data quality. The response to data verification and data validation is critical. If correctable data quality issues are discovered, the findings must be immediately provided to the appropriate data generator such as the field samplers or laboratories so that appropriate corrective action can be taken to prevent the problem from recurring. The data verification program utilizes the information contained in the laboratory Electronic Data Deliverables (EDDs) and can provide information on data quality very quickly after the data generation. The more traditional data validation occurs after the formal laboratory reports are submitted and, although important to document data validity, does not provide timely feed back to a program that generates thousands of results per week from field samples. In a program of this magnitude and duration, there is ample opportunity to correct problems by use of the QA program elements described in the QAPP, by providing real-time feed back, and by taking corrective action.

Sample analysis and batch quality control results will be delivered in an EDD (refer to QAPP Section A9) for batch loading into the project database. Analytical results for all samples will also be provided in a full data package (refer to QAPP Section A9) in a scanned electronic media (Adobe® Acrobat® .pdf).

The usability of the analytical data will be assessed by using a tiered approach. Data will initially undergo an electronic data verification, which provides the first test of the quality of the results. This automated process assesses data usability by evaluating batch quality control results. The term verification is used because criteria-based checking of the laboratory-reported QC results against the limits defined in the QAPP is used to qualify data. Full data validation, *i.e.*, manual qualitative and quantitative checking, will be performed on the PCB analytical results that are subject to question and on a subset of the other analytical results. This “tiered” data review strategy is consistent with several innovative validation approaches suggested by US EPA Regions for large-scale analytical programs (*“Region I, EPA-New England Data Validation Functional Guidelines for Evaluating Environmental Analyses,” (July 1996, revised December 1996); “Innovative Approaches to Data Validation,” (Region III June 1995)*).

Automated electronic data verification will be performed on 100% of the total PCB, homolog PCB, TCLP, total RCRA metals, TOC and dioxin/furan data using the batch quality control results provided by the laboratories in the EDD. The specific measures evaluated during verification and the associated criteria are discussed in QAPP Section D.2.2. They include

- Holding times;
- Accuracy (by evaluating laboratory control sample (LCS) recovery, matrix spike/matrix spike duplicate (MS/MSD) recoveries (except for PCBs), and Performance Evaluation (PE) sample results);
- Precision (by evaluating laboratory duplicate results);
- Field duplicate sample precision;
- Blank contamination (laboratory method blanks and field generated blanks);
- Surrogate compound recoveries; and
- Percent solids for solid matrices.

This electronic verification process will provide an understanding of the data quality based on those QC indicators that have the most influence on qualification of data. The electronic verification process will operate in an automated process so that the quality of

the data can be determined soon after the laboratory reports it. In contrast, manual validation findings will not be available for three to four weeks after the data package is submitted by the laboratory because of the length of time professional validation takes. The use of electronic verification process can ultimately be “truthed” against the full data validation findings.

Full data validation will be performed on the PCB analytical data whose accuracy is open to question and on a subset of the other analytical data in accordance with the procedures defined in the QAPP Section D2.1. As requested by USEPA, the validation strategy for the PCB Aroclor and PCB homolog analyses is linked to the laboratory results of on-going Performance Evaluation (PE) sample analysis. The validation strategy for the remaining analyses is linked to the project DQOs.

Sediment samples collected from the Hudson River are being used for preparing PE samples for use in both the inter-laboratory study and for on-going performance monitoring during the sediment sampling program. Table E-1 summarizes the analyses to be performed to set PE acceptance limits for each of the five (5) PE samples prior to the inter-laboratory study. Four (4) Hudson River PE samples have been developed with approximate concentrations of 1-3 ppm, 13 ppm, 169 ppm and 749 ppm. In order to develop initial acceptance criteria for each of the 4 PEs, 3 separate jars from each PE will be obtained during the sub-sampling step. One jar will be collected at the beginning, the middle and the end of the sub-sampling step. Additionally, the matrix-matched PE (a less than mesh size 70 clean soil spiked at approximately 30-40 ppm with 1221 and 1242 at a 3:1 ratio) will also be prepared and 3 separate jars sent for acceptance limit generation. This will produce 3 sample jars for each of the 4 Hudson River concentration levels (3 X 4 = 12 total jars) plus 3 sample jars of the matrix-matched PE. The 15 PE jars will be sent to Northeast Analytical (NEA) for extraction and analysis as follows. Each PE will be extracted by the methods included in Exhibits C or D. The extracts will be analyzed by the EPA-approved Total PCB as Aroclor Method GEHR8082 (Exhibit A) and EPA 680 GC/MS SIM method (Exhibit B). A laboratory other than NEA will further analyze the same extracts by the EPA 680 GC/MS SIM method (Exhibit B).

The specific number of analyses to be done by NEA on the 3 jars per PE level will be as follows. A single analysis will be done on each of the Jar 1 and Jar 2 samples. Three (3) analyses will be done on the Jar 3 sample. This will generate 5 analyses for each of the 5 PEs. The mean and variance of the results from the Jar 3 analyses will be compared to the Jar 1 and Jar 2 results using a *t* –Test. If the inter-analysis results are comparable at the 95% confidence interval, then the PE matrix will be considered homogeneous. The acceptance limits for each PE will be calculated using the 95% confidence interval of the five (5) results. If the inter-analysis results are not comparable at the 95% confidence interval, then the PE(s) will be re-homogenized and the process repeated.

Further, as previously mentioned, a laboratory independent of the GE SSAP will be selected to analyze each PE extract by the EPA 680 GC/MS SIM method (Exhibit B). The results of the five (5) analyses determined by NEA for each of the five (5) PEs will be compared to the five (5) analysis results determined by the independent laboratory for each of the five (5) PEs. An analysis of variance (ANOVA) test will be used to determine if the two sets of data are significantly different. If no significant difference is determined, then NEA's and the independent laboratory's results will be combined to account for inter-laboratory variability, and the combined results will be used to generate the initial PE acceptance limits as described above. If the two sets of data for any of the five (5) PEs are significantly different, then corrective action will be undertaken to determine if an analytical problem exists that has biased one set of data compared to the other. This investigation will primarily involve manual validation of both NEA's and the independent laboratory's GEHR680 analysis results to determine if quantitative or qualitative errors are present that explain the difference between the two sets of results. If errors are identified, then they will be corrected and the ANOVA test repeated. If errors are identified that can not be corrected, than an outlier test (Grubbs or Dixon) will be performed on the applicable PE set (5 NEA results and 5 independent laboratory results). Results that were identified as outliers will be discarded, and the remaining results combined to generate the acceptance limits at the 95% confidence interval. If no errors are identified or if the ANOVA test is repeated after correcting previously

identified errors, then the results from both NEA and the independent laboratory for the individual PE(s) in question will be combined to generate the acceptance limits at the 95% confidence interval. Again, this combination of results will account for inter-laboratory variability.

During the inter-laboratory study, 3 aliquots from each of the 4 PE concentrations and 1 aliquot of the matrix-matched PE will be analyzed by each laboratory participating in the program (current estimate is 10 laboratories). Table E-2 summarizes the analyses to be performed for each of the five (5) PE samples during the inter-laboratory study assuming 10 laboratories participate in the bidding process. These samples will be analyzed using the total PCB by Aroclor method (GEHR8082). PE acceptance criteria for on-going performance monitoring will be updated for the Aroclor PCB method (GEHR8082) using the results of the inter-laboratory comparison study. Each candidate laboratory's PE results will be compared to the acceptance limits at the 95% confidence intervals that were developed prior to the inter-laboratory comparison study. Results that do not meet this initial test will not be used in updating the PE acceptance limits. The remaining passing population of results which includes NEA's initial five (5) analyses used to set the acceptance limits prior to the inter-laboratory study will undergo an outlier test (Grubbs or Dixon). The results that survive the outlier test will be used to generate new acceptance limits at the 95% and 99% confidence intervals.

The PCB analyses will be subject to data validation in accordance with the following strategy:

- Total PCBs as Aroclors by SW-846 Method 8082 (SOP GEHR8082)
 1. PE samples for analysis of total PCBs as Aroclors by the SOP GEHR 8082 will be submitted to laboratories during the course of each sampling field season. For the laboratories running Aroclor analysis, the frequency of PE samples shall be one per day for the first two weeks (*e.g.*, 5 labs x 10 days = 50 PE samples). Thereafter, the frequency shall be one PE sample per laboratory per day for each laboratory performing satisfactorily. PE sample results will be compared to the

- acceptance criteria that will be based on the 95% confidence limit of the mean value of the PE results determined during the initial acceptance criteria generation. The 95% confidence acceptance limits for total PCBs as Aroclors will be updated after the inter-laboratory study is complete as described above. This more robust set of 95% confidence acceptance limits will be used for the on-going PE analysis during the SSAP.
2. Validation of total PCBs as Aroclor will be performed if the result of the PE sample analysis fails. If a PE result falls outside the 95% confidence acceptance limits, but inside the 99% confidence acceptance limits, then all samples will be validated that were analyzed in the SDG associated with the failing PE. If a PE result falls outside the 99% confidence acceptance limits, then all samples analyzed the day of the associated failing PE will be validated.
- PCB Homologs by EPA Method 680 (SOP GEHR680 – Exhibit B))
 1. Twelve PEs will be analyzed for PCB Homologs by EPA Method 680 (SOP GEHR8680 – Exhibit B) (three from each of the four Hudson River PE concentrations levels) during the first two weeks of the field season. For the remainder of the program, PE's for EPA Method 680 (SOP GEHR680 – Exhibit B) will be analyzed at a rate of one per SDG. PE sample results will be compared to the acceptance criteria that will be based on the 95% confidence limit of the mean value of the PE results determined during the initial acceptance criteria generation.
 2. Validation of PCB Homologs will be performed if the result of the PE sample analysis fails. If a PE result falls outside the 95% confidence acceptance limits, then all samples will be validated that were analyzed in the SDG associated with the failing PE.

For the other (non-PCB) analyses, data validation will be performed on a subset of the analytical results in accordance with the following frequencies:

- TOC by Lloyd Kahn
Validation of two (2) SDGs selected randomly from TOC data from each project laboratory will occur during each of the 2002 and 2003 field seasons in order to provide confirmation that the project laboratories are performing the analyses according to the requirements in the FSP and QAPP.

- Dioxins/Furans by EPA Method 1613B
Validation of one (1) SDG selected randomly from dioxin/furan data from each project laboratory will occur during each of the 2002 and 2003 field seasons in order to provide confirmation that the project laboratories are performing the analyses according to the requirements in the FSP and QAPP.

- RCRA Metals by SW-846 Method 6010B/7471A
Validation of one (1) SDG selected randomly of total RCRA metals data from each project laboratory will occur during each of the 2002 and 2003 field seasons in order to provide confirmation that the project laboratories are performing the analyses according to the requirements in the FSP and QAPP.

- TCLP Volatiles by SW-846 Method 1311/8260B
Validation of two (2) samples selected randomly from TCLP volatiles data from each River Section will be performed in order to provide confirmation that the project laboratories are performing the analyses according to the requirements in the FSP and QAPP.

- TCLP Semivolatiles SW-846 Method 1311/8270C
Validation of two (2) samples selected randomly from TCLP semivolatiles data from each River Section will be performed in order to provide confirmation that the project laboratories are performing the analyses according to the requirements in the FSP and QAPP.

- **TCLP Pesticides SW-846 Method 1311/8081A**
Validation of two (2) samples selected randomly from TCLP pesticides data from each River Section will occur in order to provide confirmation that the project laboratories are performing the analyses according to the requirements in the FSP and QAPP.
- **TCLP Herbicides SW-846 Method 1311/8151A**
Validation of two (2) samples selected randomly from TCLP herbicides data from each River Section will occur in order to provide confirmation that the project laboratories are performing the analyses according to the requirements in the FSP and QAPP.
- **TCLP Metals SW-846 Method 6010B/7470A**
Validation of two (2) samples selected randomly from TCLP metals data from each River Section will occur during each the 2002 and 2003 field seasons in order to provide confirmation that the project laboratories are performing the analyses according to the requirements in the FSP and QAPP.

Independent validation of geotechnical parameters, ^{137}Cs , ^7Be , ignitability and reactivity analysis data will not occur.

The data validation strategy is based upon the fact that 100% verification of the key analytical data will occur, the quantity of samples to be collected, and the ruggedness of the overall QA program. The QA program incorporates many measures to monitor QA at various points during the course of the project including: pre-qualification of the laboratories (see QAPP Section C1.2.1), EDDs and data packages will be provided by project laboratories as part of the pre-sampling inter-laboratory evaluation so that these deliverables can be reviewed prior to initiation of sample collection to confirm adherence to project analytical and reporting protocols; PEs (see QAPP Section C1.2.1.2), common analytical SOPs for key parameters, field audits (see QAPP Section C1.1), laboratory audits (see QAPP Section C1.2.2) and electronic data verification (see QAPP Section

D2.2). These monitoring elements, together with the validation of analytical data (where necessary) as described above and in QAPP Section D2.1, will provide an overall assurance of the data quality.

The validation results will be compared to the results of the electronic verification for the same data set to provide an indication of the accuracy of the electronic verification process. If verification or validation identifies deficiencies in data quality, the source of the deficiencies will be investigated and corrective action will be taken (QAPP Section C1.3). Additional data may be validated if deemed necessary by the GE Project Manager and QA Program Manager as part of the corrective action process. However, no more than 200 samples will be validated per week.

Qualification of data resulting from the electronic verification or validation processes will be reflected by assigning the appropriate qualifier code to the sample result in the project database.

Due to the uncertainty of the ultimate validation volume for total PCBs as Aroclors and PCB homologs, the Data Summary Report to be provided to USEPA for each year of sampling will be submitted either 90 days following completion of field activities or 30 days following completion of any required PCB data validation, whichever is later, as provided in Exhibit F to the FSP.

TABLE E-1
Summary of Analyses for Initial PE Acceptance Criteria Development
GE Hudson River Design Support Sediment Sampling and Analysis Program

		Number of Analyses for Initial PE Acceptance Criteria Development								Total # to be Performed by Independent Lab*
		Jar 1		Jar 2		Jar 3		Total # Analyses		
PE Sample	Approx. Conc. (mg/Kg)	GEHR8082	GEHR680	GEHR8082	GEHR680	GEHR8082	GEHR680	GEHR8082	GEHR680	GEHR680
RFP_191.3B	1-3	1	1	1	1	3	3	5	5	5
RFP_191.3A	13	1	1	1	1	3	3	5	5	5
RFP_189.5	169	1	1	1	1	3	3	5	5	5
RFP_190.5	749	1	1	1	1	3	3	5	5	5
Wibby Aroclor Mix PE	30-40	1	1	1	1	3	3	5	5	5
Grand Total # of Analyses:								25	25	25

* - The independent laboratory will analyze the same extracts by GEHR680 as NEA analyzed.

TABLE E-2
Summary of Analyses for Inter-Laboratory Comparison Study
GE Hudson River Design Support Sediment Sampling and Analysis Program

Number of Total PCBs as Aroclor Analyses (GEHR8082) by Each Laboratory														
Laboratory Candidate	RFP_191.3B (approx. 1-3 mg/Kg)			RFP_191.3A (approx. 13 mg/Kg)			RFP_189.5 (approx. 169 mg/Kg)			RFP_190.5 (approx. 749 mg/Kg)			Wibby Aroclor Mix PE (approx. 30-40 mg/Kg)	
	Jar 1	Jar 2	Jar 3	Jar 1	Jar 2	Jar 3	Jar 1	Jar 2	Jar 3	Jar 1	Jar 2	Jar 3	Jar 1	
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
3	1	1	1	1	1	1	1	1	1	1	1	1	1	1
4	1	1	1	1	1	1	1	1	1	1	1	1	1	1
5	1	1	1	1	1	1	1	1	1	1	1	1	1	1
6	1	1	1	1	1	1	1	1	1	1	1	1	1	1
7	1	1	1	1	1	1	1	1	1	1	1	1	1	1
8	1	1	1	1	1	1	1	1	1	1	1	1	1	1
9	1	1	1	1	1	1	1	1	1	1	1	1	1	1
10	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Total # of Analyses:	30			30			30			30			10	