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APPENDICES

APPENDIX 31

1.0 OBJECTIVES

This Standard Operating Procedure (SOP) describes the procedures that the auditor will use for performing analytical laboratory audits and the reporting of the audit findings. Analytical laboratory audits will be performed to provide GE with an indication of the quality of the data that are being provided from the laboratories as part of the Hudson River Design Support Sediment Sampling and Analysis Program and to ensure that the laboratories are adhering to project requirements. This SOP applies to the laboratories and the auditor.

2.0 EQUIPMENT

Not applicable.

3.0 SUPPORTING SOPs and DOCUMENTS

Applicable Analytical SOPs.

Quality Assurance Project Plan (QAPP).

Applicable Field Sampling Plan (FSP).

Health and Safety Plan

Applicable Laboratory Quality Assurance Manual (LQAM)

4.0 PROCEDURE

4.1 SCHEDULING

The frequency of laboratory audits will be identified in the appropriate FSP and/or QAPP. When it has been determined that the performance of a laboratory audit is necessary, the auditor will initiate contact with the designated project laboratory. The auditor and the laboratory will mutually determine a date and time for the audit which is convenient for both parties and which

is within any deadline necessary to meet the needs of the FSP and/or QAPP. If necessary, unannounced audits may be performed.

4.2 PRE-AUDIT PREPARATION

At the time the laboratory audit is scheduled, the auditor will request any laboratory documents that would aid in the effectiveness of the audit if received prior to the audit. Such documents will include the LQAM, all analytical Standard Operating Procedures (SOPs) which are applicable to the analytical work being performed by the laboratory, and applicable recent Performance Evaluation (PE) sample analysis results.

Prior to the audit, the auditor will review all documents provided by the laboratory. In the laboratory audit report, a statement will be made as to the appropriateness and thoroughness of these documents in terms of the needs of the FSP and/or QAPP. In addition, the auditor will take notes upon this initial review that will aid in verifying that the laboratory is following the procedures described in the documents. Any deviations from the documents will also be noted in the laboratory audit report.

4.3 GENERAL AUDIT APPROACH

Upon arrival at the designated project laboratory, the auditor will initiate a meeting with the appropriate laboratory personnel (analytical laboratory supervisor(s) and quality assurance supervisor) to give a brief introduction of what they can expect to occur during the laboratory audit. This introduction focuses on several key points. The auditor(s) will identify that they will be performing the audit with the aid of a checklist that has been prepared by the auditor. The checklist will not be provided to the laboratory at any time.

This checklist guides the auditor(s) through the laboratory in the basic order that samples are processed through the laboratory starting with sample receipt and ending with data reporting. Another key point that will be made is that the auditor(s) will focus their questions toward the technicians and analysts who actually perform the work and **not** their supervisors. Laboratory supervisors may be present during the laboratory audit but may not answer the questions for the technicians/analysts unless the technicians/analysts cannot answer a given question. In addition, the auditor will ask questions regarding appropriate general laboratory information during this initial meeting.

The audit checklist is a proprietary document and has not been included with this SOP. It contains significant specific detail on the audit criteria and evaluation. The laboratory evaluation checklist includes the following eight sections. The laboratory audit will be performed in the basic order defined by the checklist, depending on the layout of the laboratory being audited. Subdivisions of the following sections will be necessary and will be dependent on the types of analytical work being performed for the FSP at the designated laboratory. The approach of the audit on the following topics is described in greater detail in the subsequent sections of this SOP. In addition to the following topics, the auditor(s) will also be evaluating the overall sample tracking throughout the audit and the communication between the various sections of the laboratory (with a special regard to how holding times are met). The narrative of the laboratory audit report will also follow the subject order of the checklist but will give the audit findings and recommendations in sufficient detail that the checklist will not be included with the report.

1. Organization and Personnel
2. Sample Receipt and Storage Area
3. Sample Preparation Area

4. Sample Analysis Instrumentation
5. Documentation
6. Quality Control Manual
7. Data Handling
8. Summary

Finally, following the audit, the auditor(s) will initiate another meeting with the appropriate laboratory personnel in order to debrief them on the audit findings. The debriefing meeting should accomplish several goals. First, the laboratory personnel must be made aware of the major points of the audit findings. This way, any statements made in the laboratory audit report will not be a surprise to the laboratory and the laboratory is given a chance to respond to the findings before the report is written. Their responses can then be incorporated into the laboratory audit report. Secondly, the auditor(s) should emphasize that recommendations will be made even to the best of laboratories. The major goal of a laboratory audit is to determine the quality of data which is currently being generated by the laboratory and to identify problems (or potential problems) so that appropriate corrective action can be initiated by the laboratory. However, laboratory audits are also attended to give all laboratories, no matter their level of quality, ideas on how to become a better laboratory. The extent of the impact of the recommendation(s) will be indicated in the report.

4.4 ORGANIZATION AND PERSONNEL

The auditor(s) must evaluate the size and experience of the organization and the number, working hours, experience, and education of the personnel in the context of the FSP analytical work which is being performed by the laboratory being audited. The general information about the organization and personnel should be addressed by the auditor(s) during the initial introduction meeting. The experience and education of the personnel are best evaluated at a later date by obtaining the staff's resumes during this introductory meeting. However, if the

resumes or some other similar summaries are not available, questions of this nature must be asked by the auditor(s) throughout the audit.

4.5 SAMPLE RECEIPT AND STORAGE AREA

The auditor(s) should interview the designated sample custodian in this area of the laboratory. If a sample custodian has not been designated by the laboratory, the auditor(s) must interview any personnel responsible for receiving and logging in samples upon receipt at the laboratory. The auditor(s) must determine whether the laboratory personnel do anything to compromise the integrity of the samples during the check-in process, such as subjecting samples to any procedures which might lead to contamination or allowing temperature-preserved samples to warm to room temperature. In addition, the auditor(s) must verify that the laboratory personnel check and record all appropriate information regarding the condition of the samples upon receipt (i.e., Chains-of-Custody, cooler temperature, preservation, etc.). Furthermore, the auditor(s) must determine whether the sample storage area(s) are kept at the proper well-documented temperatures without any possibility of cross-contamination of samples. Finally, the auditor(s) must verify that the laboratory properly documents the condition of the samples upon receipt and that the information is determined from the check-in procedure. It must also be determined whether the tracking system in which the samples have been logged is adequate to ensure that holding times are being met.

4.6 SAMPLE PREPARATION AREA

The auditor(s) must evaluate the overall appearance and appropriateness of the size of the sample preparation area and the condition of the facility and equipment in the sample preparation area. The auditor(s) must verify that the equipment, water, and standards used in sample preparation are appropriately calibrated, stored, and/or maintained and that all appropriate information regarding these issues is properly documented. While in this area, the auditor(s) must interview the sample preparation technicians responsible for the preparations for the analyses of concern for the FSP. During the interviews, the auditor(s) must determine whether the sample preparation technicians follow good laboratory practices as well as the required analytical preparation methods. The auditor(s) must evaluate whether the laboratory is introducing the appropriate type and number of quality control samples at this point and that the sample technicians' procedures or equipment do not introduce possible contamination (i.e., glassware is cleaned properly) or inaccuracies (i.e., proper glassware and standards are used correctly). The auditor(s) must also evaluate the laboratory's sample tracking system through this area to verify that holding times are properly tracked. Finally, the auditor(s) must verify whether all preparation procedures are appropriately documented.

4.7 SAMPLE ANALYSIS INSTRUMENTATION

In the various sample analysis instrumentation areas of the laboratory, the auditor(s) must interview the analyst(s) responsible for the analyses of concern for the FSP. When possible, analysts will also be observed performing assigned tasks. The auditor(s) must evaluate whether the instrumentation used for the analyses of concern for the FSP is appropriate and is properly maintained. Through the interviews with the analysts and observations of actual tasks, it must be determined if each instrument is calibrated (according to the associated analytical method) with well-documented calibration standards at the required frequency and that these instrument

calibrations are properly documented. The auditor(s) must determine if method detection limit studies have been performed on each instrument used for analysis. In addition, the auditor(s) must determine if standards and quality control samples are being analyzed at an appropriate frequency and whether appropriate quality control limits are being utilized for these analyses. The analysts' practices must be evaluated for their attention to the quality control results and to the possibility of instrument carryover. The auditor(s) must evaluate whether appropriate corrective actions are being taken when standard or quality control results are out of the method-required or laboratory-determined limits. Finally, the auditor(s) must determine whether all the analysis procedures and results are properly documented.

4.8 DOCUMENTATION

The auditor(s) must evaluate the laboratory's documentation procedures throughout the audit. It should be determined if well-labeled, neat, bound notebooks are being used to document and trace standards, calibrations, laboratory procedures, and any other routine quality control check. The auditor(s) must examine notebooks and observe whether they have been properly reviewed at the laboratory and that there are no obliterations.

The auditor(s) must also evaluate the data package preparation practices. Such practices include the system used for the collection of various hard copy data, validation of results prior to data package release, completeness checks, generation of cover letters or case narratives, and retention of data packages at the laboratory.

4.9 QUALITY CONTROL MANUAL

The appropriateness and thoroughness of the laboratory's quality control manual, as well as the LQAM and analytical SOPs, must be evaluated prior to the audit. However, throughout the audit, the auditor(s) must verify if the laboratory is actually following the practices defined in their documents. Any deviations from the documented procedures must be discussed in the laboratory audit report.

4.10 DATA HANDLING

The auditor(s) must determine whether the laboratory's data handling procedures are adequate. Proper data handling techniques include the checking of calculations by a second person, documenting calculations, recording all corrective actions taken on rejected data, and properly documenting detection limits and quality control results. In addition, data must be retained at the laboratory for an appropriate amount of time.

4.11 SUMMARY

The auditor(s) must summarize the major points of the laboratory audit findings and the overall impact on the quality of the data issued from the laboratory. The summary should also reflect the overall attitude that the laboratory has toward quality assurance and quality control.

4.12 REPORT FORMAT

The laboratory audit report must contain the following sections in the following order. It must also contain a completed checklist as an attachment.

1. Introduction
2. Executive Summary

3. Audit Findings

The introduction should summarize who performed the audit, when the audit was performed, the name and location of the laboratory, and the laboratory's role in the FSP. The Executive Summary should address the major findings of the laboratory audit along with the possible impact on the laboratory's data quality. The Audit Findings should follow the major headings of the checklist summarizing the findings presented on the checklist along with any recommendations for improvement or corrective action. The report will be signed by the auditor(s) who performed the audit.

5.0 TRAINING

The auditor's conducting the laboratory audit must have demonstrated knowledge in laboratory quality assurance/quality control practices. This knowledge will include experience in analytical data validation and having conducted at least two prior laboratory audits.