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Performance and System Audits

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5.1 Performance Audits

5.2 Data Quality Audits

5.3 Technical System Audits

5.4 Management System Audits

Audits will be conducted as a principal means to determine compliance with the QAPP. This approach will be used to review the actual performance of the project during its course and throughout all operations and levels of management. Specifically, audits will be conducted for both field and laboratory operations to assess the accuracy of the measurement systems and to determine the effectiveness of QC procedures. Several factors will be taken into consideration for determining the scope and frequency for audits as follows:

- Complexity of the activity;
- Duration and scope of activity;
- Degree of QC specified;
- Criteria to achieve QA objectives;
- Requirements for deliverables;
- Participation of subcontractors;
- Criticality of data collection; and
- Potential for or frequency of nonconformances.

The FPL PM (or their designee) will have responsibility for conducting FPL operated audits and the authority to delegate FPL audits functions, as necessary. For complex or highly specialized tasks, senior technical specialists may be assigned portions of an audit. Both the FPL PM (or their designee) and technical specialists will be familiar with the technical and procedural requirements of both field and laboratory operations, and the associated Monitoring Plan as well as this QAPP. In addition, auditors will not be directly involved with the actual tasks, themselves, so as not to introduce bias in the auditing process.

The audit process includes selecting an audit team, notifying the auditee , pre-audit planning, conducting the audit, identifying nonconformances (if applicable), reporting the audit results, and tracking closure of corrective actions. A process that does not meet the specifications in the QAPP is considered to be a non-conformance and must be resolved through the corrective action procedures described in Section 6. The term “nonconformance” is the same as a deficiency as referred to in F.A.C. 62-160.650. In circumstances where corrective actions have not been completed as planned or scheduled, the audit process provides for management intervention to resolve problems and for issuance of stop work orders, if necessary.

In addition to audits conducted by FPL, Agency personnel shall have access onsite to observe field activities, with annual field audits by the Agencies, and FPL shall provide copies of field-generated notes and logs upon request. If field events are delayed, notification shall be provided to the District and the FPL PM as soon as practical and include the revised field event schedule.. Laboratory audits performed by the Agencies or Agencies’ contractors shall be allowed for any facility analyzing samples from this monitoring program, however, all such audits will be coordinated, in advance, with FPL. All Agencies audits conducted pursuant to this QAPP and the Monitoring Plan will be coordinated by the District with the District being the point of contact for activities involving the subject Agencies audit. The District shall coordinate any agency field audits with the FPL PM.

The various types of audits to be conducted during the project are described in the following sections. These audits will be used for the following purposes:

- To verify that measurement systems are operating properly;
- To assess whether data quality is adequately documented;
- To confirm the adequacy of data collection systems; and
- To evaluate management effectiveness to meet QA guidelines.

All audits should be scheduled in advance. Audits should take place at or near the beginning of the project or task start to ensure sufficient time to implement corrective actions. The lead auditor will complete an audit plan and send the plan to the auditee approximately one week before the audit is scheduled. The audit plan should communicate all the requirements to auditee regarding the documents that will be reviewed and any materials or tasks that must be reviewed during the audit. The lead auditor should gather all relevant project documents including any documents referenced that are applicable to the task being audited. The QA officer from FPL or the District (depending on who is conducting the specific audit) shall review and approve the audit plan prior to submittal to the auditee.

The auditor will be responsible for preparing a findings report after completion of the audit and submitting this report to both the FPL PM (or their designee) and the District POC. The findings report will include a short summary of what was audited, copy of completed checklists, statements as to the conformity of the process with the QAPP, notable process improvements, and any deviations from the QAPP or other guidance that have not been fully

documented or approved. The FPL PM (or their designee) will be responsible for initiating corrective actions as described in Section 6. The FPL PM (or their designee) will perform follow-up audits as necessary to confirm the implementation of corrective actions.

5.1 Performance Audits

A performance audit will be used to determine the status and effectiveness of both field and laboratory measurement systems. An independent check will be made to obtain a quantitative measure of the quality of data generated. For laboratories, this involves the use of performance evaluation samples analyzed for specific methods for accreditation by NELAC. Laboratories are required under NELAC to routinely analyze performance evaluation for parameters for which they are accredited. These samples have known concentrations of constituents that are analyzed as unknowns in the laboratory. Results of the laboratory analysis will be calculated for accuracy against the known concentrations and acceptance limits provided by the supplier or manufacturer. The FPL PM (or their designee) will audit the last three rounds of performance evaluation from the laboratory to verify compliance with the acceptance limits. For laboratories and/or laboratory parameters that are not accredited by NELAC, other method specific samples will be audited. Depending on the type of test, these samples could include initial demonstration of proficiency samples, secondary source calibration standards, and analysis of other standards with traceability to a certified standard, such as the IAEA VSMOW standard for certain isotope analyses. These results will be evaluated in relation to the QAPP objectives in Section 4.

Field performance will be evaluated using equipment decontamination blanks and field duplicate samples as described in Section 2.6.1, Field QC. Performance evaluation samples are not directly applicable to field samples. Other measures shall be used as a quality indicator of field performance including auditing of trends, review of actual results versus anticipated results, and direct observation of technical personnel performance.

5.2 Data Quality Audits

The data quality audit is an examination of data after they have been collected and verified by project personnel. It is conducted to determine how well the measurement system performed with respect to the performance goals specified in this QAPP and whether the data were accumulated, transferred, reduced, calculated, summarized, and reported correctly. It documents and evaluates the methods by which decisions were made during treatment of the data.

Data quality audits shall be conducted at least once per year during the project with an interval between audits of at least 6 months. Data quality audits entail tracing data through their processing steps and duplicating intermediate calculations. A representative set of the data is traced in detail from raw data and instrument readouts through data transcription or transference, through data manipulation (either manually or electronically by commercial or customized software), through data reduction to summary data, data calculations, and final reported data. The focus is on identifying a clear, logical connection between the steps. Particular attention is paid to the use of QC data in evaluating and reporting the data set.

The data quality audit report shall detail the results of custody tracing, a study of data transfer and intermediate calculations, a review of QA and QC data, and a study of project incidents that resulted in lost data. The audit report ends with conclusions about the quality of the data from the project with respect to the DQI goals and their fitness for their intended use.

5.3 Technical Systems Audits

A technical systems audit is used to confirm the adequacy of the data collection (field operation) and data generation (laboratory operation) systems. This is an on-site audit that will be conducted to determine whether the QAPP, Monitoring Plan, and SOPs are properly implemented. During the project, technical systems audits will be conducted for the laboratory operation as deemed necessary by the project team. Laboratory audits may be omitted or abbreviated if the laboratory is a current participant in a federal validation program or equivalent state certification program which requires assessments (such as NELAC). However, certification does not always replace an audit relative to project-specific requirements. Certification documentation must be provided for consideration prior to selection of the laboratory. If deemed necessary by the project team, laboratory audits will generally take place near the beginning of the project once samples have been initially analyzed.

Technical systems audits of field activities will be conducted at least once per year with an interval between audits of at least 6 months during the field operation. A systems audit of field procedures will evaluate and document, at a minimum, sampling methods (including collection, containers and preservation), equipment decontamination, chain of custody, sample tracking and shipment documentation, sample labeling, methodology, pre-field activities, equipment maintenance and calibration, post-field activities, sampling documentation and other field activity logs, field team debriefing, and equipment check-in and re-calibration. Table 5.3-1 details the checklist to be used during audits of field activities and/or documents, whether it requires an on-site inspection or if a review of the documentation is sufficient, and the frequency with which these audits are to be performed. These audits may be performed together or scheduled separately, but all shall be performed at least once per year.

Table 5.3-1. Field Technical Audit Checklists

Checklist	Description	Frequency
Health & Safety	Documentation audit	≥ once per year
Universal Documentation	Documentation audit	≥ once per year
COC	Documentation audit	≥ once per year
Decon	Documentation audit	≥ once per year
Field Cal	Documentation audit	≥ once per year
Field QC	Documentation audit	≥ once per year
Flow and Meteorological Audit	Documentation audit	≥ once per year
Maintenance	Documentation audit	≥ once per year
Groundwater	On-site audit	≥ once per year

Table 5.3-1. Field Technical Audit Checklists

Checklist	Description	Frequency
Surface Water	On-site audit	≥ once per year
Ecological	On-site audit	≥ once per year

A systems audit of laboratory procedures will evaluate and document, at a minimum, methods for: data qualification, analytical data generation, COC documentation and protocol, instrument calibration, data reporting, and QC methods. Systems audits also will evaluate laboratory procedures for procurement of supplies and standards as well as disposal of samples. Table 5.3-2 details the checklist to be used during laboratory audits of NELAC labs, whether it requires an on-site inspection or if a review of the documentation is sufficient, and the frequency with which these audits are to be performed. Audits of laboratories supplying data for the project using non-standard methods (not certified by NELAC) shall be performed at the discretion of FPL and the District. During the data assessment process, if the PM or QA officer identify items requiring an audit, then the audit team will develop the appropriate checklists to employ depending on the specifics of the laboratory.

Table 5.3-2. Laboratory Technical Audit Checklists

Checklist	Description	Frequency
Laboratory (NELAC)	Documentation audit/ on-site audit; PE samples reviewed; validation monitors performance and signals possible need for on-site audit.	Optional; if validation identifies systemic errors; PM and QA officers discretion

A systems audit of data management will evaluate and document, at a minimum, methods for data storage, access, custody, security, and archiving of project data. Systems audits will also evaluate data management procedures for tracking changes and access to the data and ensuring only current or the latest versions of data are available for access. Audits conducted by the QA officer or designee shall follow the “FPL Audit Checklist_Data Management” checklist provided in Appendix G when conducting systems audits. Technical systems audits of data management will be conducted at least once per year during the field operation.

Subcontractors will be used to collect and/or generate certain data for the project. These may fall under field or laboratory operations. Subcontractor audits may be performed on new sources or existing sources of services that have had significant changes in personnel, ownership, or quality systems. Audits may be performed to assess a subcontractor’s QA program or verify the supplier’s capability to supply an item or service in a manner that satisfies the project quality requirements. In addition to the subcontractor’s QA program, the audit may include, as appropriate, the subcontractor’s facilities, production capabilities, personnel capabilities, process and inspection capabilities, and organization.

5.4 Management System Audits

A management systems audit will be used to evaluate the ability of the project management team to meet specified data collection and QA objectives. This type of audit will

not be scheduled. However, if substantial nonconformances are identified from the other scheduled audits, or if programmatic concerns exist for the quality of data and related documentation, then this form of auditing will be employed under the guidance and direction of the FPL PM (or their designee).

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Corrective Action

Corrective Action

6.1 Field Situations

6.2 Laboratory Situations

6.3 Short-Term Corrective Actions

6.4 Long-Term Corrective Actions

Provisions for establishing and maintaining QA reporting to the appropriate management authority will be instituted to assure that early and effective corrective action will be taken when data quality falls outside of established acceptance criteria described or referenced in this QAPP. In this context, corrective action involves the following steps:

- Discovery of a nonconformance;
- Identification of the responsible party;
- Plan and schedule of corrective/preventive action;
- Review of the corrective action taken;
- Confirmation that the desired results were produced; and
- Reporting/documentation of nonconformance, required corrective actions and verification of corrective actions taken.

The FPL PM (or their designee) is responsible for implementing all corrective actions pertaining to the field activities, and the laboratory director is responsible for implementing all corrective actions pertaining to the laboratory. It is their combined responsibility to see that all sampling and analytical procedures are followed, as specified, that the data generated meet the prescribed acceptance criteria and confirm that all corrective actions are implemented and the results are documented and reported to the District.

It is the intent of the QA process to minimize corrective actions through the development and implementation of effective internal controls. To accomplish this, procedures will be implemented, as described in this section, to activate a corrective action for each measurement system when acceptance criteria have been exceeded. In addition, reviews and assessments will be conducted on a periodic basis to check this implementation.

Results of QA reviews and assessments typically identify the requirement for corrective action.

The discovery of a nonconformance either from observations, data review or from an audit conducted by FPL, laboratory QA officer/director or by the District, shall be documented in writing and promptly sent to the FPL PM. A corrective action plan (CAP) will be prepared by FPL within 45 days of receipt of the documented nonconformance which will include: identification of the nonconformance and the associated corrective action taken; organizational level responsible for the action taken; steps to be taken to implement the corrective action; approval for the corrective action by the FPL PM; verification of the corrective action taken including confirmation that the desired results were achieved; corrections to all prior findings/data impacted by the nonconformance; and transmittal of documentation of these steps to the District.

A corrective action plan in some cases may not affectively address or correct a documented nonconformance. In such cases, a justification for the non-action will be noted along with a statement as to whether the subject data requires qualification. Nonconformance issues that have corrective actions procedures detailed in referenced FDEP SOP's and this QAPP (i.e. calibrations) shall not be required to submit a CAP.

Once the CAP has been received by the District, the Agencies shall have 14 days to provide written comments to the FPL PM pertaining to technical applicability and completeness of the CAP with the QAPP. Failure to complete a CAP shall result in a recommendation that the affected data be qualified and/or rejected.

If data rejected during validation is deemed critical by the FPL PM (or their designee) or the District to meeting the project objectives, reanalysis or resampling (if out of holding time) may be required to fill the data gaps in a manner that meet the project objectives and QAPP criteria.

The FPL PM (or their designee), or any project member who discovers or suspects a nonconformance is responsible for initiating a nonconformance report. The FPL PM (or their designee) will assure that no additional work, which is dependent on the nonconforming activity, is performed until a confirmed nonconformance is corrected.

The FPL PM (or their designee) will be responsible for reviewing all assessment and nonconformance reports to determine areas of poor quality or failure to adhere to established procedures. In addition, the FPL PM (or their designee) will be responsible for evaluating all reported nonconformances, deciding the steps to be taken for correction, and documenting/executing the corrective action plan as described above. Corrective action measures will be selected to prevent or reduce the likelihood of future nonconformances and address the causes to the extent identifiable. Selected measures will be appropriate to the seriousness of the nonconformance and realistic in terms of the resources required for implementation.

Upon completion of the corrective action, the FPL PM (or their designee) will evaluate the adequacy and completeness of the action taken. If the action is found inadequate, the PM will resolve the problem and determine any further actions. Implementation of any further action will be scheduled by the PM.

6.1 Field Situations

The need for corrective action in the field may be determined by field assessments or by more direct means such as equipment malfunction. Once a problem has been identified, it may be addressed immediately and the project management staff notified that corrective action is necessary. All corrective actions taken in the field will follow the procedures and comply with the documentation requirements for addressing nonconformance outlined above. In addition, corrective actions made immediately in the field will also be documented in the project logbook.

After a corrective action has been implemented, its effectiveness will be verified. If the action does not resolve the problem, appropriate personnel will be assigned to investigate and effectively remediate the problem.

6.2 Laboratory Situations

As described above, all nonconformance shall be documented in writing by the laboratory QA officer or director and sent to FPL's PM however, the need for corrective action as a result of laboratory assessments will be initiated by the laboratory QA officer or director and documented within the lab reports. Corrective actions may include, but are not limited to:

- Reanalyzing samples, if holding times permit;
- Correcting laboratory procedures;
- Recalibrating instruments using fresh standards;
- Replacing solvents or other reagents that give unacceptable blank values;

- Training additional laboratory personnel in correct sample preparation and analysis procedures; and
- Accepting data with an acknowledged level of uncertainty.

Whenever corrective action is deemed necessary, the laboratory director will ensure that the problem is defined, the cause is investigated and determined, an appropriate corrective action is determined, and the action is implemented and verified. The FPL PM will be responsible for working with the laboratory director to ensure that the procedures and documentation requirements for addressing any laboratory nonconformance are complied with.

6.3 Long-Term Corrective Actions

Long-term corrective actions refers to overall changes in the QA program or project made in response to any problems found after examination of field and/or laboratory QC samples, laboratory control charts, field and/or laboratory assessments, and/or validation. Long-term corrective actions target the overall systems of performance to help alleviate continual quality problems with instrumentation or sample analysis or to prevent recurrence of one-time incidents. When long-term corrective actions are implemented, the PM will evaluate the impact on previously generated data and determine whether appropriate qualification should be added to previous data sets. In addition, the FPL PM shall make an assessment of whether the long term corrective action is consistent with provisions of the approved QAPP and request revisions to the QAPP in writing to the District if necessary.