APPENDIX I

QUALITY ASSURANCE AND QUALITY CONTROL GUIDANCE

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QUALITY ASSURANCE(QA) AND QUALITY CONTROL (QC) GUIDANCE

I.1 GENERAL QA AND QC CONSIDERATIONS

The primary objective of the specific QA and QC guidance provided in this document is to ensure that

- Appropriate data quality objectives or requirements are established **prior** to sample collection and analysis.
- Samples are collected, processed, and analyzed according to scientifically valid, cost-effective, standardized procedures.
- The integrity and security of samples and data are maintained at all times.
- Recordkeeping and documentation procedures are adequate to ensure the traceability of all samples and data from initial sample collection through final reporting and archiving and to ensure the verifiability and defensibility of reported results.
- Data quality is assessed, documented, and reported properly.
- Reported results are complete, accurate, and comparable with those from other similar monitoring programs.

I.2 QA PLAN REQUIREMENTS

To ensure the quality, defensibility, and comparability of the data used to determine exposure assessments and fish consumption advisories, it is essential that an effective QA program be developed as part of the overall design for each monitoring program. The specific QA activities should be documented in a written QA Project Plan (QAPP) or in a combined Work/QA Plan and should be implemented strictly throughout all phases of the monitoring program.

The QAPP should follow the guidelines and requirements specified in *EPA Guidance for Quality Assurance Project Plans* (EPA QA/G-5) and *EPA Requirements for Quality Assurance Project Plans for Environmental Data* (EPA

QA/R-5), where applicable. To obtain the type and quality of environmental data needed for decision making or a specified end use, the QAPP needs to provide a project-specific strategy for applying QA and quality control (QC) procedures.

The QAPP should be composed of standardized, recognizable elements that cover the entire project. These elements should be organized under four general categories that correspond to the planning, implementation, assessment, and validation phases of the project. Although project-specific tailoring of the EPA guidance for developing QA plans is encouraged, all required information must be included either in full or by reference to appropriate standard operating procedures (SOPs). The following summarizes the pertinent elements of a QAPP for each phase of the project.

1. Project Management

    a. A historical and scientific perspective of the project including a description of the problem to be solved or the decision to be made

    b. A clear statement of the project goals and the approach to be used and an overview of the work to be performed and the schedule of implementation

    c. A description of the program organization and personnel roles and responsibilities, including responsibility for ensuring adherence to the QA plan

    d. Specification of data quality objectives in terms of accuracy, precision, representativeness, and completeness, for data generated from each type of measurement system

    e. Identification of special training for project personnel

    f. A description of the procedure for obtaining approval for substantive changes in the monitoring program

    g. Detailed description of health and safety procedures

2. Measurement and Data Acquisition

    a. Detailed descriptions of field sample collection and handling procedures, including documentation of

        - Target species and size (age) class
        - Sampling site locations
        - Target contaminants
        - Sampling times/schedules

- Numbers of samples and sample replication strategy
- Sample collection procedures
- Sample processing procedures, including sample identification, labeling, preservation, and storage conditions
- Sample shipping procedures

b. A detailed description of chain-of-custody procedures, including specification of standard chain-of-custody forms and clear assignment of field and laboratory personnel responsibilities for sample custody

c. Detailed descriptions of laboratory procedures for sample receipt, storage, and preparation, including specification of the kinds of samples to be prepared for analyses (e.g., composite vs. individual, whole body vs. fillet, replicates)

d. Detailed descriptions of the analytical methods used for quantitation of target contaminants and percent lipid determination

e. Detailed descriptions of methods routinely used to assess data accuracy, precision, and completeness, including

- Internal QC checks using field, reagent, or method blanks; spiked samples; split samples; QC samples prepared from standard reference materials; and replicate analyses
- Calibration checks
- Data quality assessments

f. Detailed descriptions of preventive maintenance procedures for sampling and analysis equipment

g. Detailed descriptions of calibration procedures for all measurement instruments, including specification of reference materials used for calibration standards and calibration schedules

h. Detailed descriptions of recordkeeping and documentation procedures, including requirements for

- Maintaining field and laboratory logs and notebooks
- Use of standard data collection and reporting forms
- Making changes to original records
- Number of significant figures to be recorded for each type of data
- Units of reporting
- Routine procedures to assess the accuracy and completeness of records

3. Assessment and Oversight

   a. Detailed descriptions of data management and reporting procedures, including requirements for

      - Technical reports
      - QA and QC reports
      - Data coding procedures
      - Database specifications
      - QA review of reported data
      - Data storage and archiving procedures

   b. Detailed descriptions of procedures for internal QC performance and/or systems audits for sampling and analysis programs

   c. Detailed descriptions of procedures for external QA performance and/or systems audits for sampling and analysis programs, including participation in certified QA proficiency testing or interlaboratory comparison programs

   d. Detailed descriptions of corrective action procedures in both sampling and analysis programs, including

      - Criteria and responsibility for determining the need for corrective action
      - Procedures for ensuring that effective corrective action has been taken
      - Procedures for documenting and reporting corrective actions

4. Data Validation and Usability

   a. Provide the criteria to be used in reviewing and validating the data and for deciding the degree to which each data item has met its quality specification

   b. Describe the process to be used for validating and verifying data, including the chain of custody for data throughout the project

   c. Include detailed descriptions of data analysis procedures, including

      - Statistical treatment of data
      - Data summary formats (e.g., plots, tables)

   d. Precisely define and interpret how validation issues differ from verification issues

Guidance for addressing each of the QA or QC elements outlined above, including a list of recommended standard reference materials and external QA or interlaboratory comparison programs for the analyses of target analytes, is incorporated in the appropriate sections of this guidance document. The EPA guidance and requirements documents (EPA QA/G-5 and EPA QA.R-5) should be referenced for more detailed discussions of the elements to be included in the QA plan (available at **http://es.epa.gov/ncerqa/qaqa_docs.html**).