7. LABORATORY PROCEDURES AND QUALITY ASSURANCE

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7. A. Objectives and Requirements

The analytical laboratory provides both qualitative and quantitative information for determining the extent of permittee compliance with permit discharge requirements. To be valuable or useful, the data must be representative and accurately describe the characteristics and concentrations of constituents in the samples submitted to the laboratory. The objectives of laboratory Quality Assurance (QA) are to monitor and document the accuracy and precision of the results reported and to meet reliability requirements.

QA refers to a total program for ensuring the reliability of data by utilizing administrative and technical procedures and policies regarding personnel, resources, and facilities. QA is required for all functions bearing on environmental measurements and includes activities such as project/ study definition; sample collection and tracking; laboratory analysis; data validation, analysis, reduction, and reporting; documentation; and data storage systems. Thus, the QA program is designed to evaluate and maintain the desired quality of data. Quality Control (QC), a function of QA, is the routine application of procedures for controlling the accuracy and precision of the measurement process and includes the proper calibration of instruments and the use of the appropriate analytical procedures.

The 40 *Code of Federal Regulations* (*CFR*) Section 122.41(e) (conditions applicable to all permits), requires adequate laboratory and process controls, including appropriate QA procedures. Each permittee's laboratory must have a QA/QC program. The laboratory must document the QA program in a written QA/QC manual and the lab should make it available to all personnel responsible for sample analyses. The manual must clearly identify the individuals involved in the QA program and document their responsibilities. The laboratory's standard operating procedures must meet user requirements in terms of specificity, completeness, precision, accuracy, representativeness, and comparability of the required testing procedures . The laboratory should devote approximately 10 to 20 percent of their resources to their QA/QC program.

Guidance in this chapter is broad based and may not be applicable to every laboratory. This chapter includes a Laboratory Quality Assurance Checklist for the inspector's use at the end of the chapter. For detailed information concerning laboratory QA, refer to Environmental Protection Agency's (EPA's) *Handbook for Analytical Quality Control in Water and Wastewater Laboratories* (USEPA 1979a). Further information is also available in the U.S. Environmental Protection Agency's (EPA's) *NPDES Compliance Monitoring Inspector Training Laboratory Analysis Module* (April 1990). If a more detailed assessment of a laboratory is required, personnel with more extensive knowledge of the methodologies should perform the inspection.

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7. B. Sample Handling Procedures

Evaluation of Permittee Sample Handling Procedures

Proper sample handling procedures are necessary in the laboratory from the sample's receipt to its discard. Sample handling procedures for small permittees may differ from procedures for larger permittees because staff organizational structures and treatment facility designs vary from one facility to the next. However, proper sample handling procedures should be standardized, utilized and documented by all permittees. In evaluating laboratory sample handling procedures, the inspector should verify the following:

- The laboratory has a sample custodian.
- The laboratory area is secure and restricts entry to authorized personnel only.
- The laboratory has a sample security area that is dry, clean, and isolated, has sufficient refrigerated space, and can be locked securely.
- A minimum number of people handle the samples.
- The custodian receives all incoming samples, signs the chain-of-custody record sheet accompanying the samples and retains the sheet as a permanent record.
- The custodian performs or analyzes checks of proper preservation, container type, and holding times and documents results.
- The custodian ensures that samples are properly stored.
- Only the custodian distributes samples to personnel who are to perform analyses.
- Transfer of samples is usually document by the sample custodian.
- Care and custody records for handling samples are accurate and up-to-date.

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7. C. Laboratory Analyses Techniques Evaluation

Evaluation of Permittee Laboratory Analytical Procedures

The permittee's laboratories or its contract laboratories must use uniform methods, thus, eliminating methodology as a variable when data are compared or shared among laboratories. The permittee's laboratory must select by consulting 40 *CFR* Part 136 or EPA for approval of alternative methods. A permittee may only use alternative test procedures if the procedures have EPA approval, as specified by 40 *CFR* 136.4 and 136.5, and promulgated under Public Law (PL) 92-500.

Many standardized test procedures promulgated under 40 *CFR* Part 136 are covered in *Methods for Chemical Analysis of Water and Wastes* (USEPA 1979b). Revisions and new additions to this publication are made whenever new analytical techniques or instruments are developed. These are considered accepted after final publication in the *Federal Register*. The latest accepted edition of *Standard Methods for the Examination of Water and Wastewater* [American Public Health Association (APHA), American Water Works Association (AWWA), and Water Environment Federation (WEF)]. (The most current 40 *CFR* Part 136 may supersede any method or technique cited in this manual.) Other approved methods from United States Geological Survey (USGS), American Society for Testing and Materials (ASTM), and several commercial vendor methods are also reference in 40 CFR 136.

In evaluating laboratory analytical procedures, the inspector should verify the following:

- The lab follows analytical methods specified in the most current 40 *CFR* Part 136 and properly performs any deviations allowed by 40 *CFR* Part 136.
- The lab uses a QC system that conforms to the system specified in the permit or to that detailed in published *Standard Methods* (APHA, AWWA, and WEF) (e.g., initial demonstration of capability for organic analyses).
- The lab maintains a QC record on reagent preparation, instrument calibration and maintenance, incubator temperature, and purchase of supplies.
- The lab conducts QC checks are made on materials, supplies, equipment, instrument calibration and maintenance, facilities, analyses, and standard solutions.
- The lab maintains documentation of any EPA-approved deviation from specified test procedures.

Evaluation of Permittee Laboratory Facilities and Equipment

To verify that the proper analytical procedures are being followed, the inspector should have the responsible analyst describe each of the procedures. The inspector should be alert to any deviation from the specified analytical method. Any questions regarding the proper procedures

can be resolved by referring to the cited methodology. Even simple analyses can yield invalid results if the methodology cited in 40 *CFR* Part 136 is not exactly followed. Certain required deviations from the approved method are cited in 40 CFR 136, notes.

Laboratory Services

The availability of laboratory services affects data reliability. The inspector should verify that the laboratory provides the following items:

- An adequate supply of laboratory pure water, free from chemical interferences and other undesirable contaminants. The lab should check water quality routinely and document it.
- Adequate bench, instrumentation, storage, and recordkeeping space.
- Clean and orderly work area to help avoid contamination.
- Adequate humidity and temperature control.
- Adequate lighting and ventilation.
- Dry, uncontaminated, compressed air when required.
- Efficient fume hood systems.
- Necessary equipment such as hot plate, incubator, water bath, refrigerator for samples, pH meter, thermometer, and balance.
- Electrical power for routine laboratory use and, if appropriate, voltage-regulated sources for delicate electronic instruments.
- Emergency equipment, fire extinguisher, eye wash station, shower, first aid kit, gloves, and goggles.
- Vibration-free area for accurate weighings.

The inspector should also check that the lab uses proper safety equipment (lab coats, gloves, safety glasses, goggles, and fume hoods) where necessary. The laboratory should have a fire extinguisher, eye wash station, shower, and first aid kit. The inspector should document any problems and refer to the proper authority [e.g., Occupational Safety and Health Administration (OSHA)].

Instruments and Equipment

Instrumentation is extremely important in the analytical laboratory. To a certain extent, analytical instrumentation is always developmental; manufacturers are continually redesigning and upgrading their products, striving for miniaturization, enhanced durability and sensitivity, and improved automation. In evaluating laboratory instruments and equipment, the inspector should verify the following:

- The lab follows standard and specific procedures for cleaning glassware and containers are followed. Chapter Two of EPA's *NPDES Compliance Monitoring Inspector Training Laboratory Analysis Module* (April 1990) contains detailed information on glassware cleaning.

- The lab has written requirements (e.g., standard operating procedures) for daily operation of instruments and equipment which are easily accessible and the staff follow them.

- Standards and appropriate blanks are available from suppliers to perform standard calibration procedures. The lab should use standard concentrations that closely bracket actual sample concentrations. Sources of standards are documented and where possible, traceable to a national standard [e.g., National Institute of Standards and Technology (NIST)].

- Records of each set of analysis performed including the order in which calibration, QA and samples were analyzed (i.e., analysis run logs or instrument run logs).

- Lab has written troubleshooting procedures are available to identify common equipment malfunctions.

- Lab follows written schedules for replacement, cleaning, checking, and/or adjustment by service personnel.

- Lab maintains documentation on equipment maintenance and service checks.

Commonly used analytical instruments include analytical balances, pH meters, dissolved oxygen meters, conductivity meters, turbidimeters, spectrophotometers, atomic absorption spectrophotometers, organic carbon analyzers, selective ion analyzers, gas-liquid chromatographs, titrimetric analyses, and temperature controls. Chapter Two of EPA's *NPDES Compliance Monitoring Inspector Training Laboratory Analysis Module*. (April 1990) includes a detailed discussions on these instruments.

Maintenance of laboratory facilities and equipment is an important factor in laboratory QA. Qualified service checks should be performed and documented.

Supplies

Chemical reagents, solvents, and gases are available in many grades of purity, ranging from technical grade to various ultrapure grades. The purity of the materials required in analytical chemistry varies with the type of analysis. The parameter being measured, the analytical method, and the sensitivity and specificity of the detection system determine the purity of the reagents required. Do not use reagents of lesser purity than that specified by the method. In evaluating laboratory supplies, the inspector should verify that the laboratory:

- Uses the required reagent purity for the specific analytical method.

- Stores standard reagents and solvents according to the manufacturer's directions.

- Checks working standards frequently to determine changes in concentration or composition.
- Verifies concentrations of stock solutions before being used to prepare new working standards.
- Date supplies with limited shelf life upon receipt and observe shelf-life recommendations, including the discard date on the container and the storage requirements.
- Prepare and standardize reagents against reliable primary standards.
- Label standards and reagents properly including the date of preparation, concentration and the analyst's identification.
- Store standards and reagents in appropriate containers and under required method conditions. If conditions are not specified, standards and reagents are stored according to 40 *CFR* Part 136, Table II. See Chapter Five, Sampling, Table 5-3.
- Check the accuracy of purchased solutions as per method requirements.
- Use clean containers of suitable composition with tight-fitting stoppers or caps for storage.
- Discard reagents when signs of discoloration, formation of precipitates, or significant changes in concentrations are observed.
- Prepare stock solutions and standards using volumetric glassware.

7. D. Quality Assurance and Quality Control

Evaluation of the Precision and Accuracy of the Permittee Laboratory

The purpose of laboratory control procedures is to ensure high-quality analyses by the use of control samples, control charts, reference materials, and instrument calibration. The laboratory must initiate and maintain controls throughout the analysis of samples. Specifically, each testing batch must contain at least one blank, standard, duplicate, and spiked (as applicable) sample analysis. When a batch contains more than 10 samples, every tenth sample should be followed by a duplicate and a spike (as applicable).

The precision of laboratory findings refers to the reproducibility or degree of agreement among replicate measurements of the same quantity. The closer the numerical values of the measurements come to each other, the more precise are the measurements. In a laboratory QC program, precision is determined by the analysis of actual samples in duplicate. These may represent a range of concentrations and a variety of interfering materials usually encountered during the analysis. Accuracy refers to the degree of difference between observed values and known or actual values. The closer the value of the measurement comes to the actual value, the more accurate the measurement is. The accuracy of a method can be determined by analyses of samples to which known amounts of reference standards have been added (spiked samples).

In evaluating the precision of the measurement process, the inspector should verify that:

- The lab introduces control samples into the train of actual samples to monitor the performance of the analytical system. Control samples include any digestions, extractions, distillations and other sample preparations as for sample analyses.

- Perform duplicate analyses with each batch of samples to determine precision. In general, 10 percent of the samples should be duplicated.

- Prepare and use precision control charts or other statistical techniques for each analytical procedure. Develop precision control charts by collecting data from a minimum of 15 to 20 duplicate samples (run in controlled conditions) over an extended period (e.g., 10 to 20 days). Statistical methods include calculation of mean, standard deviation, and variance to define the range and variability of the data.

- Take corrective actions when data fall outside the warning and control limits.

- Document out-of-control data, the situation, and the corrective action taken.

In evaluating accuracy, the inspector should verify that the laboratory:

- The lab introduces spiked samples into the train of actual samples at least 10 percent of the time to monitor the performance of the analytical system.
- The lab uses spiked samples to monitor accuracy in each sample batch.
  - The amount of additive is appropriate to the detection limit and sample concentration.
- Prepare and use accuracy control charts for each analytical procedure. The lab should develop accuracy control charts by collecting data for a minimum of 15 to 20 samples over an extended period of time.
  - Establish accuracy limits (as % recovery) based on standard deviations whose upper and lower control limits are established at three times the standard deviation above and below the central line.
  - Establish the upper and lower warning limits at twice the standard deviation above and below the central line. Note: Some parameters have a defined warning limit required by 40 *CFR* Part 136.
  - Take corrective actions when data fall outside the warning and control limits.
  - Document out-of-control data or situation and the corrective action taken.

Evaluation of Permittee Data Handling and Reporting

An analytical laboratory must have a system for uniformly recording, correcting, processing, and reporting data. The inspector should verify that the laboratory:

- Uses correct formulas to calculate the final results.
- Applies round-off rules are uniformly.
- Establishes significant figures for each analysis.
- Cross-checking calculations provisions are available.
- Determine control chart approaches and statistical calculations for the purposes of QC and reporting.
- The laboratory report forms provide complete data documentation and permanent recording, and they facilitate data processing.
- The program for data handling provides data in the form/units required for reporting.
- Maintain laboratory records for a minimum of 3 years (or longer and made available if requested by EPA or the State).

- Keeps laboratory notebooks or pre-printed data forms that are bound permanently to provide good documentation, including the procedures performed and the details of the analysis, such as the original value recorded, correction factors applied, blanks used, and the reported data values. The dated notes indicate who performed the tests and include any abnormalities that occurred during the testing procedure. Laboratory maintains the notes as a permanent laboratory record.

- Procedures for correction of data entry errors are defined. Original data entries can be read and the individual(s) making the corrections are clearly identified.

- Back up computer data with duplicate copies (i.e., electronic and hardcopy).

- Proper data handling and reporting procedures are implemented by all contract laboratories performing sample analyses.

- Maintain data records that allow the recalculation of all results reported by the laboratory(ies) from the original unprocessed results (i.e., raw data) to the final results sent to EPA and the regulatory authority for a minimum of three (3) years.

Evaluation of Permittee Laboratory Personnel

Analytical operations in the laboratory vary in complexity. Consequently, laboratory should clearly define work assignments in the laboratory. All analysts should be thoroughly instructed in basic laboratory operations. Those persons performing complex analytical tasks should be qualified and properly trained. All analysts must follow specified laboratory procedures and be skilled in using the laboratory equipment and techniques required for the analyses assigned to them. In evaluating laboratory personnel, the inspector should consider the following factors:

- Adequacy of training

- Skill and diligence in following procedures

- Skill and knowledge of staff in using equipment and analytical methods (particularly for complex equipment such as gas chromatography)

- Precision and accuracy in performing analytical tasks

- Assignment of clearly defined tasks and responsibilities.

Evaluation of Contract Laboratories

When the permittee contracts with the laboratory to analyze samples, the inspector may need to evaluate the laboratory practices at the contracted laboratory. The practices can also be evaluated by other designated EPA inspectors. If a deficiency is identified at a contract laboratory, the permittee is responsible for the deficiency and will be notified.

Overview of the Discharge Monitoring Report Quality Assurance Program and How It Relates to the Inspection Program

The validity of the National Pollutant Discharge Elimination System (NPDES) program depends on the quality of the self-monitoring program. The Discharge Monitoring Report Quality Assurance (DMR QA) program is an important tool used to ensure the quality of NPDES self-monitoring data. The program is designed to evaluate and improve the ability of laboratories serving NPDES permittees to analyze and report accurate self-monitoring data.

Majors must purchase under NPDES performance evaluation samples containing constituents normally found in industrial and municipal wastewaters from accredited providers . They must analyze these samples using the analytical methods and laboratory normally employed for their reporting of NPDES self-monitoring data. The supplier of the performance evaluation sample will evaluate the results and respond to the permittee.

Highlights

- The DMR QA Program has been an excellent means of focusing on and improving the quality of laboratory results used in developing DMR data. Improvements in the DMR QA data have been significant.

- This program has helped major permittees identify and correct both analytical and data handling problems in their laboratories.

- In general, permittees are receptive to the program and recognize its value, including some who challenged EPA's authority to require participation.

- Regions and States are generally supportive and have made good use of the results of this program for targeting inspections and directing other follow-up activities. This ability to concentrate corrective actions on problem permittees results in an increased efficiency in improving the self-monitoring data of all NPDES permittees.

- The program is one of the least resource-intensive methods for maintaining direct and regular technical contact with NPDES permittees. It has been recognized as a cost-effective effort.

- Utilizing computer technology, the following ways of managing and analyzing DMR QA data were started in FY 1985: compiling tracking summaries, comparing performance of the major industries, tracking multiple permittees, and regenerating past performance evaluation reports.

The DMR QA Program and the NPDES inspection programs are interdependent in several areas. First, to target the inspections, the regulatory agency can use DMR QA evaluations of permittee performance can be used, since the evaluations identify potential problems in laboratory analysis or data handling and reporting. This targeting helps to direct limited resources to permittees who need them most. Non-reporting of DMR QA results is an important trigger for on-site inspections.

The results are provide to and tracked by EPA and the State DMR QA coordinator.

Finally, EPA uses the Performance Audit Inspection (PAI), to follow up the DMR QA. The DMR QA results should be cross-checked with the permit prior to the onsite visit, and parameters that were failed should be checked by the inspector during a laboratory inspection.

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7. E. References and Laboratory Quality Assurance Checklist

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U.S. Environmental Protection Agency. April 1990. *NPDES Compliance Monitoring Inspector Training Laboratory Analysis Module*.

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U.S. Environmental Protection Agency. July 1998. *EPA Quality Manual for Environmental Programs.*

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LABORATORY QUALITY ASSURANCE CHECKLIST

A. GENERAL

Yes	No	N/A	1. Written laboratory QA manual available.

B. SAMPLE HANDLING PROCEDURES

Yes	No	N/A	1. Laboratory has sample custodian and a back-up custodian.
Yes	No	N/A	2. Access to laboratory area restricted to authorized personnel only.
Yes	No	N/A	3. Sample security area available within laboratory that is dry, clean, and isolated; has sufficient refrigerated space; and can be locked securely.
Yes	No	N/A	4. Custodian receives and logs in all incoming samples.
Yes	No	N/A	5. Follows established chain-of-custody procedures.
Yes	No	N/A	6. Checks of proper preservation, container type, and holding times performed by the custodian or the analysts with the results fully documented.
Yes	No	N/A	7. Samples properly stored by custodian.
Yes	No	N/A	8. Samples distributed to analysts by custodian only.
Yes	No	N/A	9. Transfer of samples fully documented.
Yes	No	N/A	10. Accurate and up-to-date care and custody records for handling samples maintained.
Yes	No	N/A	11. Documentation and procedures for disposal of test samples and test standards.

C. LABORATORY PROCEDURES

Yes	No	N/A	1. EPA-approved written analytical testing procedures used and protocols are easily accessible by laboratory personnel.
Yes	No	N/A	2. If alternate analytical procedures used, proper written approval obtained.
Yes	No	N/A	3. Calibration and maintenance of instruments and equipment satisfactory.
Yes	No	N/A	4. QA procedures used.
Yes	No	N/A	5. QC procedures adequate.
			6. Duplicate samples are analyzed % of time.
			7. Spiked samples are used % of time.
Yes	No	N/A	8. Whole Effluent Toxicity (WET) testing is required by the permit and conducted by the laboratory. Culturing procedures are adequately documented for each organism tested.
Yes	No	N/A	9. WET testing protocols are clearly described.
Yes	No	N/A	10. Commercial laboratory used. Name _____ Address _____ Contact _____ Phone _____ Certification # _____

LABORATORY QUALITY ASSURANCE CHECKLIST (Continued)

D. LABORATORY FACILITIES AND EQUIPMENT

Yes	No	N/A	1.	Proper grade laboratory pure water available for specific analysis.
Yes	No	N/A	2.	Adequate bench, instrumentation, storage, and recordkeeping space available.
Yes	No	N/A	3.	Clean and orderly work area available to help avoid contamination.
Yes	No	N/A	4.	Dry, uncontaminated compressed air available.
Yes	No	N/A	5.	Sufficiently ventilate fume hood.
Yes	No	N/A	6.	Laboratory sufficiently lighted and ventilated.
Yes	No	N/A	7.	Adequate electrical sources available.
Yes	No	N/A	8.	Instruments/equipment in good condition.
Yes	No	N/A	9.	Use proper safety equipment (lab coats, gloves, safety glasses, goggles, and fume hoods) when necessary.
Yes	No	N/A	10.	Written requirements for daily operation of instruments available.
Yes	No	N/A	11.	Standards and appropriate blanks available to perform daily check procedures.
Yes	No	N/A	12.	Sources of standards documented and where possible traceable to a national standard (e.g., NIST).
Yes	No	N/A	13.	Records of each set of analysis including order in which calibration, QC and samples were analyzed (i.e., analysis run logs or instrument run logs) available.
Yes	No	N/A	14.	Written troubleshooting procedures for instruments available.
Yes	No	N/A	15.	Schedule for required maintenance exists.
Yes	No	N/A	16.	Proper volumetric glassware used.
Yes	No	N/A	17.	Glassware properly cleaned.
Yes	No	N/A	18.	Properly store standard reagents and solvents with the expiration dates clearly displayed on the containers.
Yes	No	N/A	19.	Frequently checked working standards.
Yes	No	N/A	20.	Discard standards after recommended shelf-life has expired.
Yes	No	N/A	21.	Background reagents and solvents run with every series of samples.
Yes	No	N/A	22.	Written procedures exists for cleanup, hazard response methods, and applications of correction methods for reagents and solvents.
Yes	No	N/A	23.	Replace gas cylinders at 100-200 psi.

LABORATORY QUALITY ASSURANCE CHECKLIST (Continued)

E. LABORATORY'S PRECISION, ACCURACY, AND CONTROL PROCEDURES

Yes	No	N/A	1.	Analyzed multiple replicates (blanks, duplicates, spikes, and splits) for each type of control check and information recorded.
Yes	No	N/A	2.	Plotted precision and accuracy control methods used to determine whether valid, questionable, or invalid data are being generated from day to day.
Yes	No	N/A	3.	Generate control samples introduced into the train of actual samples to ensure that valid data.
Yes	No	N/A	4.	Precision and accuracy of the analyses are sufficient.

F. DATA HANDLING AND REPORTING

Yes	No	N/A	1.	Uniformly apply round-off rules.
Yes	No	N/A	2.	Establish significant figures for each analysis.
Yes	No	N/A	3.	Use provision for cross-checking calculation.
Yes	No	N/A	4.	Use correct formulas to calculate final results.
Yes	No	N/A	5.	Control chart approach and statistical calculations for QC and report available and followed.
Yes	No	N/A	6.	Report forms developed to provide complete data documentation and permanent records and to facilitate data processing.
Yes	No	N/A	7.	Data reported in proper form and units.
Yes	No	N/A	8.	Laboratory records readily available to regulatory agency for required time of 3 years.
Yes	No	N/A	9.	Laboratory notebook or pre-printed data forms bound permanently to provide good documentation.
Yes	No	N/A	10.	Computer data backed up with duplicate copies (i.e., electronic and hardcopy).
Yes	No	N/A	11.	Efficient filing system exists, enabling prompt retrieval of information and channeling of report copies.
Yes	No	N/A	12.	Data records allow recalculation of all results reported by the laboratory(ies) from the original unprocessed results (raw data) to the final results sent to EPA and the regulatory authority.

G. LABORATORY PERSONNEL

Yes	No	N/A	1.	Enough analysts present to perform the analyses necessary.
Yes	No	N/A	2.	Analysts have on hand the necessary references for EPA procedures being used.
Yes	No	N/A	3.	Analysts trained in procedures performed through formal or informal training or certification programs.

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