

J-1822 ENVIRONMENTAL LABORATORY

**ENVIRONMENTAL SERVICE DEPARTMENT
PUBLIC WORKS CENTER, YOKOSUKA**

**QUALITY ASSURANCE & QUALITY CONTROL
(QA/QC)
MANAGEMENT PLAN**

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Sampling and Laboratory Testing

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1.0 INTRODUCTION

1.1 Purpose. To ensure that both routinely collected samples and generated analytical data are scientifically valid and defensible and are of known and acceptable precision and accuracy, a written set of standard procedures and practices for laboratory personnel is required. This Quality Assurance Plan establishes a framework for the conduct of all current procedures and those to be developed in the future.

1.2 Scope. The following items form elements of a successful QA/QC program. Each item below makes up a major section in this QA/QC Plan with detailed requirements listed under each.

- a. Qualified Staff
- b. Sample Control
- c. Documentation and Files
- d. Use of Good General Laboratory Practices
- e. Execution of SOPs
- f. Constant Improvement
- g. Calibration and Maintenance
- h. Internal and External Quality Control
- i. Internal Audit and Data Review
- j. Laboratory Material Management
- k. Customer Service
- l. Automation

1.3 Applicability. All PWC Yokosuka Environmental Laboratory Division personnel will adhere to these policies at all times. Deviations are allowed only with written approval of the Environmental Department Head, or Environmental Operations Director.

2.0 RESPONSIBILITIES

Proper command and control must be established to fix responsibilities for quality at appropriate levels while at the same time ensuring that undue influence and pressures are not exerted to circumvent established procedures.

2.1 Commanding Officer, PWC Yokosuka. The CO is ultimately responsible for quality assurance and will establish broad guidance for quality assurance.

2.2 PWC Yokosuka Environmental Department Head. The Department Head will provide a laboratory work place and procedures that minimize hazards to employees.

2.3 PWC Yokosuka Environmental Operations Director. The Operations Director is responsible for the execution of environmental laboratory operations and for ensuring that operations are done in accordance with all applicable safety and environmental regulations.

2.4 PWC Yokosuka Environmental Laboratory Division Manager (ELDM).

a. The ELDM will ensure that approved, standard procedures are in place and followed to produce a product of quality and value based upon industry standards and customer desires.

b. The ELDM will serve as the Quality Assurance Coordinator (QAC), overseeing the everyday functioning of the laboratory, including sample collection (where appropriate), and assisting chemists with any quality control problems.

c. The ELDM will assist and instruct chemists in proper quality techniques and will review chemists' procedures and data to ensure that the highest quality is maintained.

2.5 PWC Yokosuka Environmental Laboratory Division Chemists. Chemists will follow established procedures, take actions to solve quality problems, and attain the assistance of others as needed to produce a high quality product. Problems not solvable by the chemist shall be documented and brought to the attention of the PWC Yokosuka Environmental Laboratory Division Manager (ELDM).

3.0 DEFINITIONS

3.1 Accreditation. A formal recognition that an organization (laboratory) is competent to carry out specific tasks (tests) or specific types of tasks.

3.2 Calibration. The set of operations, which establish, under specified conditions, the relationship between values indicated by a measuring instrument, measuring system, or values represented by a material measure, and the corresponding known values of a measurand.

3.3 Certification. Procedure by which a regulatory agency or third party gives written assurance that a product, process or service conforms to specified requirements.

3.4 Data Quality Objectives (DQOs). Qualitative and quantitative statements which specify the study objectives, the most appropriate types of data to collect, and the levels of decision error that will be acceptable for the decision.

3.5 Laboratory. A body that calibrates and/or tests. The Navy defines an environmental laboratory as any fixed or mobile facility, in whole or in part, that performs testing for the purpose of environmental regulatory reporting and/or to determine compliance with federal, state, regional and/or local environmental laws and regulations. The PWC Environmental Laboratory is a multi-service laboratory in that it performs testing in support of multiple functions at an activity (e.g., hazardous waste disposal, drinking water monitoring, waste water treatment, etc.).

3.6 Method. (reference method) A sampling or measurement method which has been officially specified by an organization as meeting its data quality requirements.

3.7 Procedure. A set of systematic instructions for performing an operation.

3.8 Quality Assessment. The evaluation of data to determine if it meets the quality criteria required for a specific application.

3.9 Quality Assurance. An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that sampling and testing meet defined standards of quality with a stated level of confidence.

3.10 Quality Control. The activities whose purpose is to measure and control the quality of sampling and testing so that it meets the needs of users and provides assurance that the appropriate level of confidence is achieved.

3.11 Quality Control Check Samples. Any chemical substance, mixture, analytical standard, or material of a known chemical or biological measurement, other than a test substance (customer sample), that is administered for the purpose of establishing a basis of comparison with the test substance.

3.12 Quality Manual. A document stating the quality policy, quality system and quality practices of an organization. The quality manual, however named, may call up other documentation relating to the operation's quality arrangements.

3.13 Quality System. The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

3.14 Raw data. Any records, memoranda, or notes that are the result of original observations and/or activities of a study and are necessary for the reconstruction and evaluation of the report of that study. Raw data may include photographs, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.

3.15 Test. A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical

phenomenon, process or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate.

3.16 Traceability. The property of a sample or measurement whereby it can be related to appropriate international or national standards through an unbroken chain.

3.17 Verification. Confirmation by examination and provision of evidence that specified requirements have been met.

4.0 QUALIFIED STAFF

4.1 Position Descriptions (PDs). PDs will be in place for each staff member of the laboratory if his work has an impact on product quality. Copies of these PDs are maintained in the PWC Yokosuka Administration Department and COMNAVFORJAPAN Human Resource Office (HRO).

4.2 Qualifications. Qualifications for employees working in a career field are defined by the Master Labor Contract Office (for Japanese Nationals).

4.3 Training. Training will be accomplished both initially and on a continuous basis to maintain skills and to attain new ones. This will consist of a combination of formal training courses and on-the-job training. Training shall cover sample collection, laboratory analysis, and instrument calibration.

a. Training Plan. The ELDM will maintain a training plan for his chemists that will outline skills they must attain and procedures they must master. New employee orientations will cover the unit's mission and the command/supervisory structure.

b. Training Records. Records of training will be maintained in a training log.

c. Training Criteria. Employees learning a new procedure will be given written criteria for successfully learning that procedure. Both the instructor and trainee will document in a training log that key aspects of the procedure have been taught and understood.

d. Training Satisfied. Before a trainee is allowed to perform a procedure without supervision, the ELDM will certify that all criteria for performing the procedure have been successfully met. This will be done by checking the training log.

5.0 SAMPLE CONTROL

A system must be in place to account for all samples and to maintain the integrity of samples while in the control of the laboratory, whether from the point for sample collection or when the sample is received from the customer.

5.1 Sample Receiving

a. Documents. Samples are submitted to the laboratory by courier or by mail. Incoming shipments of samples will be accompanied by the necessary request forms or memorandums with all pertinent information.

b. Screening. All incoming samples will be carefully examined for any possible damage, signs of tampering, and to determine if they were properly sampled and preserved. The chemist is responsible for examining and accepting submitted samples.

5.2 Sample Log-In

a. ID# and Sample Holding. Each sample is assigned and labelled with a unique identification number, then stored in an appropriate holding area that maintains the required preservation.

b. Associated Documents. All pertinent correspondence (i.e. analysis request forms, memorandums, letters) submitted with the sample(s) are identified with the unique id number(s) and filed.

5.3 Sample Control by the Chemist. The chemist will ensure that the samples are maintained under proper storage conditions until the analyses are complete. Upon removing samples from the holding area, the chemist will verify that all pertinent information corresponds with the assigned sample.

5.4 Post-Analysis Disposal. Upon completion of sample analysis, the samples will be returned to their original sample containers and will be disposed of in accordance with The DoD Japan Environmental Governing Standards (JEGS).

5.5 Sample Shipping to Other Laboratories

a. Sample Handling. All samples that are to be forwarded to another installation or laboratory will be treated as stated in paragraphs 5.1 (Sample Receiving) and 5.2 (Sample Log-In). Include request forms or memoranda requesting analysis with the samples. Also include quality control check samples, where practical, to monitor quality.

b. Sample File. Keep the following on file for each sample or group of samples: analysis request, completed test results, and final analysis report.

6.0 DOCUMENTATION and FILES

All actions that impact quality will be documented and filed and become part of an audit trail.

6.1 Sampling and Testing Records. Such records should be kept on file in the PWC Environmental Laboratory. These records shall be kept for three years, or longer per contract requirements.

a. Sampling Records. If the sample(s) was/were collected by PWC Yokosuka Environmental Laboratory personnel, then the following should be included in the sampling record: (1) sampling date; (2) location sampled (include tables, graphs, sketches, and/or photographs, as appropriate); (3) name of individual(s) collecting sample; (4) reference to the sample collection procedures used.

b. Testing Records. The following should be included in the testing record: (1) unique identification number for the sample; (2) type of sample; (3) description of sample; (4) preservation used; (5) laboratory verification of preservation; (6) reference to the analytical method(s) used; (7) name of chemist(s) performing each test; (8) date of test; (9) measurements taken; (10) derived results; and (11) the instrument identification number for each instrument used in the analysis.

6.2 Final Result Reports. The final result report will be sent to the requestor. In addition, a copy should be kept on file in the PWC Environmental Laboratory.

a. Final Reports. The following should be included in the final report: (1) identification of the laboratory where the test was carried out; (2) unique identification of the test report and of each page; (3) name and address of the customer; (4) description and unambiguous identification of the sample tested; (5) date of receipt and date(s) of performance of the test; (6) identification of the test method used; (7) reference to sampling procedure (when applicable); (8) reported measurements and units of measure; and (9) signature and title of the person(s) accepting responsibility for the content of the report.

6.3 Sub-Contracting of Testing. If any part of the testing is sub-contracted, The PWC Yokosuka Environmental Laboratory shall ensure and be able to demonstrate that the contract laboratory performing the sampling or testing is able to comply with our Laboratory

QA/QC Plan as well as the DoD Japan Environmental Governing Standards (JEGS). Sub-contracting by private laboratories shall be approved in advance by The U.S. Navy.

6.4 SOPs. Procedural steps for actions that impact quality will be written as Standard Operating Procedures (SOPs).

a. Approval and Identification. All SOPs will be approved by the ELDM or Environmental Operations Director, and each SOP must have a unique number and be dated.

b. Current SOPs. A list of all current, approved SOPs will be maintained in a Laboratory Methods Manual and be made readily accessible for use.

c. SOP Modifications. Whenever a change to a method is approved, a revised SOP will be prepared, with the revision date indicated. All copies of the superseded SOP will be removed from circulation or use; however, copies of superseded SOPs will be maintained on file indefinitely.

6.4 Corrective Actions. Corrective actions for known deficiencies will be documented and maintained as a permanent record with a copy forwarded to the QAC.

7.0 USE OF GOOD GENERAL LABORATORY PRACTICES

Good general laboratory practices will be followed by all chemists to promote consistent quality work from one chemist to the next.

7.1 Reagent Water. Reagent water will be used by all chemists preparing standards, spikes, quality controls and reagents. Reagent water generated for use will be tested no less than once per week to ensure that quality is maintained. These checks will be recorded on the appropriate log sheet.

7.2 Glassware

a. Type. Class A glassware will be used by all chemists when making quantitative measurements and transfers of chemicals. An exception is metals analysis where the use of Class B plasticware is approved.

b. Cleaning. Glassware will be cleaned in a timely manner and stored in such a way to prevent and minimize contamination, damage and breakage. Mechanical or chemical cleaning materials that could scratch, etch or otherwise alter the calibrations of class A glassware will be avoided.

7.3 Chemicals

a. Purity. Chemicals of sufficient purity for the procedure being performed will be used. Typically this will be Reagent Grade or better.

b. Potency. Chemists will constantly check their reagents, standards and solutions to ensure that they are still fresh and fully potent. Outdated reagents and solutions will not be used, unless their integrity is verified by testing. Appropriate disposal practices must be followed, per The DoD Japan Environmental Governing Standards (JEGS).

7.4 Safety. Laboratory safety procedures will be followed at all times.

a. Department Head Responsibility. It is the responsibility of the Environmental Department Head to provide a work place and procedures that minimize hazards to employees.

b. Laboratory Employee Responsibility. It is the employees' responsibility to follow established procedures, use provided personal protective equipment (PPE), report accidents and to avoid unsafe acts. It is also the employees' responsibility to correct unsafe situations on-the-spot as noticed.

c. Unsafe Activities. Laboratory employees who suspect that they may have been asked to perform an unsafe act must immediately inform their supervisor.

7.5 Reporting Accidents. All accidents, regardless of how small, will be reported immediately. Safety is covered more extensively in the Chemical Hygiene Plan.

7.6 Housekeeping. Housekeeping involves keeping laboratory areas free from excess clutter. Adequate work space will allow chemists to complete work with minimal danger of confusing chemicals and samples, cross-contaminating samples, knocking over vessels of chemicals, or creating fire hazards.

7.7 Hoods. Hoods are especially prone to clutter and special effort must be made to keep these areas clear to allow the hood to operate as designed

7.8 Container Labelling Requirements. Labelling chemical containers is absolutely critical to quality and safety. Containers of reagents, standards, and other prepared media will be labelled with the following minimum information: (1) chemical name; (2) solvent; (3) concentration with units; (4) date prepared; (5) expiration date (as appropriate); and (6) the printed name of the preparer. Material Safety Data Sheet labelling will also be incorporated where appropriate.

8.0 EXECUTION OF SOPS

8.1 Approved SOPs. Approved SOPs will be followed for all work. No deviation from established procedure will be allowed without the written, signed approval of the Environmental Operations Director or the ELDM.

8.2 Deviation from SOPs. Approved procedure deviations will be documented by the chemist on the Test Results sheet and on the Analysis Report sheet.

9.0 CONSTANT IMPROVEMENT

It is not sufficient to attain, then maintain, what is minimally acceptable for a quality assurance program. Better ways to achieve a high quality product with maximum productivity must be sought and implemented; the staff must grow and develop in their careers; mistakes should be used as an opportunity to examine and improve the system.

9.1 Professional Development. All chemists will be provided the opportunity to achieve to their maximum potential consistent with the needs of the laboratory. This will be done through a combination of training and advanced assignments.

9.2 Corrective Action Reports. Corrective action reports will be written for any situation involving a failure in quality control. The report will detail what happened, why it happened, the changes that are required to prevent a recurrence and what corrections have been made.

9.3 Management Philosophy. A well-trained and informed staff serves as a good basis for constant improvement. Management must ensure that all members of the laboratory team understand that their ideas are welcomed to enhance the quality of their work and the analytical product. Management will objectively consider all ideas and evaluate them in terms of their ability to improve working conditions and product quality.

10.0 CALIBRATION AND MAINTENANCE

10.1 Requirements for Proper Functioning of Instruments

a. Calibration Frequency. Every instrument is checked and calibrated on each day of use. The function check/calibration procedure for each instrument shall be followed. Functions checks and calibration must be performed prior to running any sample for analysis.

b. Calibration Records. The ELDM will ensure that all calibration records, as well as any maintenance problems and corrective actions, are recorded on the Calibration & Maintenance Sheet, which is kept for each instrument in the PWC Yokosuka Environmental Laboratory.

c. Record Retention. The Calibration and Maintenance Sheets will be retained for the same period as the laboratory analytical data.

e. Instrument Service Contract. The most recent service contract will be kept on file for each instrument (include the instrument ID# on the contract).

11.0 INTERNAL QUALITY CONTROL

11.1 Internal Quality Control (IQC). IQC includes actions performed within the laboratory that help ensure product quality.

a. IQC Activities. IQC actions include performing calibrations and function checks as well as running reference samples for quality control. Quality control check samples include prepared samples of known value, blanks, duplicates and matrix spikes.

b. QC Check Sample Preparation. The chemist is to prepare and analyze quality control check samples, in accordance with the QA requirements for each test method.

c. QC Check Sample Results. Chemists will record all quality control check sample results on the instrument calibration and maintenance sheet.

11.2 Laboratory Certification. The PWC c940 Environmental Laboratory participates in the on-going asbestos testing certification program.

12.0 INTERNAL AUDIT AND DATA REVIEW

Periodic reviews of the quality system and review of all data will help to ensure that a quality product is delivered.

12.1 Internal Audits

a. Frequency. Internal audits of sample collection, analytical testing, and administrative procedures will be conducted annually by either the Environmental Operations Director or the ELDM.

b. These reviews will cover items such as: proper sample collection, sample accountability, retention of raw data, SOPs, documentation of QC actions, instrument QC, and the ability of the system to deliver a quality product on a consistent basis.

- c. Findings will be documented, as will any required corrective actions.

12.2 Data Review

- a. Reasonable Data. The chemist will ensure that all data falls within linear limits of the instrument and analytical method, and that the data is recorded with sufficient digits to be statistically significant.

- b. Data Review Requirements. Sample result data will receive two levels of review before being released to the client. Factors to be checked include technical correctness, completeness, and disclosure of qualified data.

- c. Documentation of Data Review. Reviews will be documented by the signature of the QAC/ELDM on the test report. If modifications or amendments are made, the following will be noted: the date, the person making the change, and the reason for the change.

13.0 LABORATORY MATERIAL MANAGEMENT

Having the proper kinds and quantities of supplies on-hand needed to support laboratory work will help ensure that quality work is performed. Therefore, proper management of supplies is crucial for quality control in a laboratory. Due to Japan's geographic location, supplies must be ordered farther in advance.

- 13.1 Laboratory Material Procurement. The ELDM, with assistance from the chemists, will place supply orders, track status, receive and store supplies. PWC Yokosuka material procurement procedures will be followed.

13.2 Incoming Materials

- a. Receiving Procedures. The PWC Materials Department checks the material and receiving slip against the purchase order/document register. Discrepancies are resolved by the Materials Department. Once supplies are accepted and received the document register and inventory lists are updated by the Materials Department. The PWC Yokosuka Environmental Laboratory also maintains inventory for the Laboratory and updates it annually.

- b. Labelling Requirements. All chemicals will be labeled with the following: date prepared or received, identity, concentration (where applicable), quality, and shelf life. Prepared solutions should also be labelled with the lot or batch # of the stock solution, the supplier, and the printed name of the preparer.

14.0 CUSTOMER SERVICE

This is very much a quality issue since quality of the product is defined by the customer. A commitment to excellent customer service on behalf of all laboratory employees will help ensure that a quality product is delivered.

14.1 Data Quality Objectives (DQOs). Customer/Client needs will be determined through direct contact, both verbal and written. Because clients are not always able to define their needs, laboratory chemists will work with them to arrive at reasonable criteria. These needs/criteria are often referred to as Data Quality Objectives (DQOs).

a. DQO Requirements. DQOs will be established based upon how the customer will use the data. This will define sample handling requirements, the tests to be performed, the time frame for completion, work documentation, and format reporting.

14.2 Customer Complaints. All complaints/ inquiries will be investigated. A summary report of findings, conclusions/ recommendations and actions taken will be written and filed. The customer will be contacted with resolutions or findings in a timely manner.

15.0 AUTOMATION

Tremendous gains in productivity can be realized through automation and every effort will be made to make maximum use of computer systems. Highly automated systems carry with them the risk of abuse, tampering, and the loss of a true data audit trail. To minimize these and other problems, laboratory automation will be in compliance with the US EPA Good Automated Laboratory Practices.