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Revision 0, 6/11/91

STATEMENT OF WORK

SOW # IC-INT-6/90

Nitrate Analysis of Ground-Water Samples

Impact Level II

Prepared by: E. J. Westergard 6-11-91  
E. J. Westergard Date

Reviewed by: B. L. Thomas 6-11-91  
B. L. Thomas, PQD Representative Date

Concurred by: J. M. Latkovich 6-12-91  
J. M. Latkovich Date

Approved by: S. C. Goheen 6/11/91  
S. C. Goheen Date

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A. SCOPE OF WORK

The purpose of this work is to provide nitrate analytical results by Ion Chromatography (IC) for ground water samples.

No work authorized by this SOW is to be performed by other organizations (i.e., subcontractors, internal or external) without prior approval of the Analytical Support Services Program (ASSP) Hazardous Chemistry Task Leader and Process Quality Department (PQD) representative. All work covered by this SOW shall be performed in accordance with requirements delineated in PNL QA Plan number SA-001.

No unauthorized work is to be performed unless this SOW is revised to cover such work by the ASSP Hazardous Chemistry Task Leader and PQD representative.

Processing of groundwater samples for nitrate analysis encompasses receipt, handling, and storage of samples, analytical testing, reporting of results, and disposal of sample residuals. All charges for processing of groundwater samples shall be made to the Battelle Test User Identification Number as identified on the Chain-of-Custody form and on the Sample Analysis Order (SAO).

A maximum of 50 samples for nitrate analysis will be delivered to the Analytical Laboratory each week. Samples will be contained in 125 mL Poly bottles and will be delivered to the laboratory during business hours accompanied by a Chain-of-Custody form and a SAO. Samples for nitrate analysis will contain no chemical preservative and shall be stored at 4 +/- 2 degrees C. The sample bottle label, Chain-of-Custody, and SAO will indicate the specific type of analyses to be performed (i.e., nitrate by IC). Each sample label will specify a unique sample identification, Test User Identifier and the analytical test ordered. The Chain-of-Custody form shall be signed as "relinquished" by the person delivering the sample and as "received" by the receiver of the sample. The date and time shall be entered where noted on the Chain-of-Custody. The bottom copy of the Chain-of-Custody shall be given to the person delivering the samples. The original Chain-of-Custody is to be maintained in the laboratory until data has been reported and the samples have been disposed. When retention of samples is no longer required, disposal of the samples shall be noted on the Chain-of-Custody in the required space along with initials of the person responsible for sample disposition and the date of disposition. The original Chain-of-Custody shall be returned to the PNL contact following sample disposition. The other Chain-of-Custody copy is to be retained as an Analytical Laboratory record.

The Analytical Laboratory shall assure the integrity and security of all samples (initial and unused portions), sample extracts and other preparations, and analytical data and results through the rigorous application of Chain-of-Custody procedures.

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The Analytical Laboratory shall store samples so that samples can be retrieved in a timely manner.

The Analytical Laboratory shall make its best effort to assure that any aliquots removed from a sample shall be representative of the entire sample. The laboratory shall store and preserve the integrity of the unused portions of samples, and any final analytical preparations with which measurements are made, for 30 business days following the final report of the analytical results.

Analysis of the groundwater samples shall be performed according to EPA Method 300.0. Analysis of samples for nitrate shall be completed within 48 hours following receipt of the samples by the Analytical Laboratory. The Contractually Required Quantitation Limit (CRQL) for nitrate analysis shall be 200 ug/L. Detection limits shall be at or below specified CRQL. Accuracy and precision shall be determined at concentrations within 3 to 5 times the specified CRQL. The laboratory shall be excused from attaining the CRQL when, due to the presence of interfering species in a sample to be processed, the specified CRQL cannot be attained utilizing the analytical method specified.

The Analytical Laboratory shall perform data Rechecks of previously reported results, if ordered. Data rechecks shall consist of a review of calculations, aliquot size, yield, and other data pertinent to the reported analytical result. The analytical laboratory shall also review the results of quality control samples as well as the results of other samples processed in the same batch. The quality control sample results and the results of the analytical laboratory's data recheck evaluations shall be delivered, in writing, within five (5) business days to the Battelle Technical Administrator for Battelle orders or the Test User for other orders. The Analytical Laboratory shall perform Reanalysis on the unused portions if ordered.

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B. REPORTS AND COMMUNICATIONS

The Analytical Laboratory shall deliver reports not less than weekly to the Battelle Technical Administrator for Battelle orders or the Test Users for other orders. Analytical results shall be signed and dated by the analyst and reviewer.

Reported results shall contain the following information:

- a. Chain-of-Custody number
- b. Test User number
- c. ID/Sample number
- d. Analytical Laboratory sample number
- e. Identification of the analyst
- f. Date and time samples were analyzed
- g. Measuring and test equipment used for analysis
- h. Any deviation from procedure specified in SOW

Reports for all processed analytical tests shall be delivered within 25 business days from sample receipt.

C. QUALITY CONTROL

The Analytical Laboratory shall assure the integrity and validity of test results through implementation of an internal Quality Control program. The Program shall meet the Quality Control criteria of EPA Method 300.0.

Percent recovery shall be determined for matrix spikes according to the following equation:

$$\% \text{ Recovery} = (c-a)/b \times 100$$

Where:

a = average amount of the constituent found in the matrix prior to spiking

b = spike of a known amount of the constituent, and

c = average amount of the constituent found in matrix spike

Quality Control spiked standards and blanks shall be prepared and analyzed in accordance with EPA Method 300.0. Quality Control samples shall be analyzed on a minimum frequency of 1 QC sample for ten samples. All Quality Control data reported in the Quality Control reports shall be in the same units as that of sample results, that is ug/L (ppb)

D. RECORDS/QA REQUIREMENTS

Records requirements are contained in the Quality Assurance Requirements (Attachment 1)

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QUALITY ASSURANCE REQUIREMENTS  
for  
CONTRACT NO. 133690-A-M1

I. ORGANIZATIONAL STRUCTURE AND RESPONSIBILITIES

The organizational structure, functional responsibilities, level of authority, and lines of communication for the QA activities specified herein and for the activities affecting the quality of the services specified in the Statement of Work shall be documented. Those persons or organizations responsible for ensuring that an appropriate Quality Assurance program is established and for verifying that activities affecting the quality of the services specified in the Statement of Work have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom necessary to independently assess all activities affecting quality and to report the results of such assessments. Persons or organizations responsible for assessing quality-related activities shall have direct access to responsible management at a level where appropriate action can be effected, required authority and organizational freedom provided, including sufficient independence from cost and schedule considerations.

II. QUALITY ASSURANCE PROGRAM

The Quality Assurance program shall provide control of activities affecting quality of the services specified in the Statement of Work to an extent consistent with their importance. This program (including the requirements stated in Section III below) shall be documented by written policies, procedures, or instructions and shall be carried out in accordance with those policies, procedures, or instructions.

The identification, cause, and corrective action for significant conditions adverse to the quality of the services specified in the Statement of Work shall be documented and reported to appropriate levels of management as well as the Battelle Contract Representative; follow-up action shall be taken to track and verify implementation of corrective action.

Personnel performing services specified by the Statement of Work and personnel performing quality assurance activities shall be indoctrinated or trained in technical skills, standard QC and essential elements of the QA Program. Such indoctrination and training shall be commensurate with the scope, complexity, and nature of:

- (a) the services specified in the Statement of Work;
- (b) the quality assurance activities specified herein; and
- (c) the education, experience and proficiency of the person.

Records of the indoctrination and training shall take the form of:

- (a) attendance sheets;
- (b) training logs; or
- (c) personnel training records.

### III. SPECIFIC QUALITY ASSURANCE PROGRAM REQUIREMENTS

#### A. Control of Software

1. Software Documentation - Each computer program that is a part of a software system affecting the quality of analytical tests and capable of being tested and evaluated independently of that system, shall be separately documented prior to release for use. The point in the development of the software at which documentation is required and the minimum documentation requirements shall be documented.
2. Software Testing - Verification of computer programs affecting the quality of analytical tests shall be determined and documented using data for which the correct result is known. The verification process shall be documented as proof it was performed.
3. Software Control - Methods shall be established to ensure that changes to computer software which affect the quality of analytical tests are properly controlled and approved. Such computer programs shall be identified using unique sequential revision numbers. Data resulting from analytical tests shall be traceable to the version(s) of software used in the analysis, data collection and evaluation and/or reporting of the test results.
4. Security of Software - Methods shall be established to help ensure the security of the software affecting the quality of analytical tests (i.e., help avoid unauthorized use and changes).
5. Error Control - Methods shall be established to evaluate, control, and correct data-entry errors or program problems that could affect the quality of analytical test results.

#### B. Control of Subcontracted Items and Services

The term "subcontract" as used herein has the same meaning as in the "Approval of Subcontracts" General Provision.

Subcontract documents shall require that subcontractors of all tiers comply with all applicable quality assurance and control requirements, including but not limited to those applicable to standards, measuring and test equipment, calibration services, and analytical test activities. Subcontracted items and services that have the potential to affect the quality of analytical tests shall be controlled to ensure conformance with subcontract requirements.

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Such control shall include one or more of the following: Source evaluation and selection (pre-performance/pre-award survey), source verification, audit, and examination of items or services before use.

Provision shall be made in all subcontract documents for audit of subcontractor quality systems by Battelle.

C. Written Procedures

Written procedures shall be developed, implemented and maintained to control activities that affect the accuracy or validity of analytical tests and the reports specified in the Statement of Work.

Procedures shall identify required calculation methods or provide for the documentation of such calculations. Procedures shall be reviewed at least annually and revised as needed. Such review shall be documented.

Procedures shall include the steps (precautions) taken to recognize and avoid or to minimize the effect of interferences to obtaining analytical test results that conform to the requirements of the Statement of Work.

Analytical or technical procedures shall address the use of internal quality control (QC) measures such as blank and standard samples and the use of control charts. In addition, the methods or techniques for determining analytical process or machine accuracy and precision shall be specified.

D. Document Control

The preparation and issue of, and changes to, documents that specify quality requirements and activities affecting the quality of analytical tests shall be controlled to assure that correct documents are being utilized. Such documents, including changes thereto, shall be reviewed for adequacy and appropriateness and shall be approved by management and quality assurance personnel prior to release to authorized personnel for use.

E. Identification and Control of Items

Positive identification and control measures shall be used to assure that test samples and other quality-affecting items are identifiable at all stages of the performance of analytical tests and are traceable from their source to the resultant report or to an outside laboratory.

F. Control of Measuring and Test Equipment

Measuring and test equipment used for activities affecting the quality of analytical tests shall be calibrated, adjusted, and maintained at prescribed intervals or prior to use, against certified equipment or standards having known and valid

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relationships to nationally recognized standards. If no nationally recognized standards exist, the bases for calibration shall be documented.

Each calibration procedure shall specify the standard to be used, the required frequency of calibration, any special instructions necessary for obtaining reliable calibration data, calibration control limits and the required treatment of data.

The calibration and control of standards required for any analytical test shall be specified in the analytical test procedure and in the calibration and control procedures if they are separate from the analytical procedure.

Tolerances for all measurements made during performance of an analytical test shall be specified. A tolerance limit can be stated with a measurement value given in a procedure; for example:  $15 \pm 0.1$  ml. If a tolerance limit is not stated with a measurement value, then a system of tolerances shall be specified.

The method and interval of calibration for equipment shall be defined based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting measurement control. When measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of the validity of any previous analytical test results obtained using that equipment during the period that the equipment was out of calibration. The results of such evaluation shall be promptly reported to the Battelle Contract Representative. Out-of-calibration equipment shall be tagged or segregated and not used until it has been recalibrated. If any measuring or test equipment is consistently found to be out of calibration, it shall be repaired or replaced. A calibration shall be performed when the accuracy of equipment is suspect.

Measuring and test equipment shall be properly handled and stored to maintain accuracy.

Records of calibration activities shall be maintained and all calibrated equipment shall be suitably marked to indicate calibration status.

A schedule of preventive maintenance activities shall be developed and the performance of preventative maintenance shall be documented. A documented inventory of critical spare parts and/or equipment necessary to minimize the downtime of measurement systems related to analytical test samples that have a holding time of 48 hours or less shall be maintained. A documented evaluation of the usage of such inventory shall be performed at least annually.

#### G. Handling, Storage and Shipping

Handling, storage, cleaning, packaging, shipping, and preservation of test samples shall be controlled to prevent damage, contamination or loss, and to minimize deterioration.

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The Contractor shall, throughout processing and performance of analytical tests, use appropriate containers, handling procedures, and preservation or treatment methods to prevent loss, degradation, or contamination of samples.

#### H. Status Indicators

The status of test samples and equipment shall be maintained through indicators, such as markings, shop travelers, analysis requests, log books, data records, analytical reports, calibration labels, deficiency tags, or other suitable means. The authority for application and removal of tags, markings and labels shall be documented.

#### I. Control of Nonconformances/Deficiencies and Corrective Action

Nonconforming items, test samples and analytical test results shall be controlled in accordance with written procedures. Controls shall provide for identification, documentation, evaluation, segregation (when practical), disposition, and for notification to affected contractor organizations. Procedural deficiencies shall be documented and the effect of the deficiency on resulting data shall be assessed and documented. A procedure shall identify the method(s) to be used to assure that the cause(s) of a nonconforming item or analytical test results, or deficient condition is identified and that corrective action is taken.

#### J. Data Reduction, Validation and Reporting

Written procedures shall be developed in accordance with Section C to control the reduction, validation and reporting of data to Battelle and its Designated Service Clients. All equations utilized to reduce data or to develop analytical precisions or accuracies shall be described. Key individuals or positions responsible for the review and validation of data, as well as the flow of data through the reduction, validation and reporting process shall be documented. Flow chart descriptive may be used.

#### K. Surveillance

Surveillances shall be planned and executed to verify compliance to the quality program required by this "Quality Assurance Requirements" document and the quality control requirements of the Statement of Work. Surveillance activities shall be performed by persons (1) other than those who performed or directly supervised the work being inspected and (2) independent of cost and schedule considerations. Surveillance results shall be documented and reported to management.

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## L. Audits

Audits shall be planned, scheduled and performed to verify compliance with all aspects of the quality assurance program and to determine its effectiveness. Internal audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing or supervising the activities being audited, but who have a good working knowledge of the organization's operation. Audits of suppliers shall be conducted periodically to assure continued conformance to contractual requirements. Audit results shall be documented and reported to and reviewed by the level of management with authority to affect any necessary corrective action. Corrective action shall be taken promptly when indicated. A method shall be established whereby management periodically assesses the adequacy of the quality assurance program. The method shall include provisions for reporting the results of assessments, including the distribution of those reports. The Battelle Contract Representative shall be notified whenever an audit or a management assessment of the adequacy of the quality assurance program results in a conclusion that contract technical, quality control or quality assurance requirements have not been met.

## IV. RECORDS

Records that furnish documentary evidence of the quality of the analytical test services specified in the Statement of Work and the QA activities specified herein shall be identified, prepared, and maintained. Records shall include, but not be limited to all those pieces of documentation which provide, or would have provided if generated, a complete traceability of a test sample from receipt, through the analytical test process to the reporting of the resultant data. Records include, but are not limited to logbooks, forms, laboratory record books, data sheets, calibration records, training records, and procurement documents.

All records shall be legible and traceable to the originator and the date originated. All records shall be protected against damage, deterioration, or loss. The record copy of all documents must be signed/initialled and dated. Changes to document entries shall be made by lining through the entry to be changed, signing or initialling and dating the change. If the reason for the change is unclear, a brief explanation shall be provided. A reproduced copy of an original record may be furnished to Battelle if such copy is signed, dated and stated to be "true and correct".

Records shall be readily retrievable and shall be made available for inspection by Battelle.

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