

CERTIFIED ENVIRONMENTAL CONTRACTORS, LLC
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Laboratory Quality Manual

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Approved:

		08/16/2021
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Quality Assurance Officer ("QAO")	Doreen Carone	Date

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1. Primary Control Document – Retained in Laboratory

Revision Record

Annual Review:	2020	_____
	2021	_____
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	2024	_____

Training Record: The following staff members have read this Manual, been instructed in following the standards contained herein, and agree to follow its requirements

Jason Elliott, Maria E. Miller, Doreen Carone, Angelo Spalluto.

Training Record

The following laboratory staff has read this Manual.

<u>Jason Elliott</u> Name	<u>Lab Analyst</u> Title	<u>08/16/2021</u> Date
<u>Maria E Miller</u> Name	<u>Lab Tech/TD</u> Title	<u>08/16/2021</u> Date
<u>Doreen Carone</u> Name	<u>Lab Tech/OAO</u> Title	<u>08/16/2021</u> Date
<u>Angelo Spalluto</u> Name	<u>Lab Analyst</u> Title	<u>08/16/2021</u> Date
_____ Name	_____ Title	_____ Date

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Accredited Test Method

Test
Radon in Air by Charcoal Canister

Method
EPA Method 402-R92-004

Quality System

The quality system defined in the quality manual applies to all personnel who perform activities related to the testing of radon in air using charcoal canisters. All employees are responsible for implementing the quality system. The individual documents define specific employee responsibilities.

Through a formal documented system of planned activities, the quality system meets the requirements of the New Jersey environmental laboratory accreditation program.

- The quality manual is maintained current and up to date by the Quality Assurance Officer (QAO) to reflect changes to the system.
- The laboratory defines its policy for each applicable standard element in the quality manual.
- For each element, as appropriate, the laboratory has documented procedures that further describe how the specific policy objectives and goals are met.
- The quality manual references these documented procedures.
- Where applicable, work instructions are referenced in the documented procedures and the quality manual.

Quality procedures and instructions are implemented as written. The procedures explain how the laboratory implements the standard requirements in accordance with its quality policy. They are revised, as necessary, to reflect the actual objectives, flow of tasks, and staff responsibilities. Quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions.

Standard Operating Procedures (SOPs) are maintained in the laboratory methods manual.

They specify the equipment and fixtures required, the resources and skills required, what tests and verifications are performed to measure process and product quality, the records and written documentation used by personnel, and standards of acceptability. SOPs are approved by the managerial staff and are maintained in the document control system.

Job Descriptions of Staff

Technical Director –

The technical director (“TD”), Maria Miller, has overall responsibility for the technical operation of the lab. The TD is also responsible for arranging and overseeing all support services including instrument service contracts, subcontracting sample analyses, and physical maintenance of the laboratory. The TD also interacts with departmental, interdepartmental and government officials to participate in coordination of lab participation in projects. The TD is part of the management team and reports directly to the owners of the company.

The TD is responsible for providing supervision to all laboratory personnel to ensure adherence to documented procedures. When the TD is not present in the lab, an employee who is familiar with test procedures, the objective of the testing and the assessment of results are appointed by the technical director to supervise the activities during his absence. If the absence is longer than 45 days, the accreditation body will be notified of the absence. The TD issues a memo to all staff on the personnel performing the duties of the technical director.

Quality Assurance Officer –

The quality assurance officer (“QAO”), Doreen Carone, has responsibility for the quality system and its implementation. The QAO has direct access to the highest level of management at which decisions are taken on lab policy and/or resources, and to the TD. When the QAO is not present, a deputy shall be appointed by issuing a memo to the staff.

Laboratory Analyst –

The laboratory analysts (Jason Elliott and Angelo Spalluto) are trained by the TD and by the QAO. The laboratory analyst job is to review all of the laboratory results looking for typographical errors and inconsistencies between the lab data and the final analytical result. Discrepancies or anomalies are brought to the QAO for review and action by documenting these on SOP Corrective Action forms.

Laboratory Technician –

The laboratory technicians (Maria Miller, and Doreen Carone) were trained by the QAO and supervised by the Lab Analyst. The laboratory technician job is processing the incoming samples, identifying any abnormalities, recording them, and processing the lab analysis and recording and printing the final reports. Discrepancies or anomalies are brought to the QAO for review and action by documenting these on corrective action forms.

Document Control

This manual and the SOPs are subject to document control. The latest approved versions are maintained in the QAO’s office and in the lab operating area. Other controlled documents include all of the lab’s recorded daily and periodical QA test results. These are listed and described in Appendix D.

The purpose of the document control system is to ensure that all applicable and current versions of the manual and the SOPs are maintained in the lab and in the QAO files. All SOPs and the LQM are reviewed once per year. If a document is revised during the year the revision record in the document will demonstrate the revision on Page 2. If a document has not been revised during the year, the review record shall bear the signature of the QAO and the date of the review. Amendment of documents is not allowed pending formal re-issue.

All data, including original observations, calculations and derived data, calibration records, QC records, and copies of the test reports, resulting from the analyses of samples will be kept for five years by the laboratory to allow historical reconstruction of the report result.

6. Traceability of Measurements

The laboratory analysis is performed using systems designed and made by The Nucleus firm in Oak Ridge, TN. This firm and its successor company no longer provide service on this equipment. The system uses sodium iodide scintillation counters, which require only daily performance checks. The daily performance checks and monthly external analysis provides assurance the equipment is calibrated and appropriate for use in making daily measurements.

All of the system parameters and instrument settings are determined by daily, monthly, and annual external and internal checks, which are described in Sections 8 and 13 below and in Appendix H. Our overall system accuracy is measured with monthly third-party “spikes” and with annual proficiency tests. These external tests are conducted by the Bowser-Morner company in Dayton, Ohio. Their standards are all NIST-traceable to the US EPA Radon Laboratory in Grand Junction, Colorado.

All RPP tests are carried out by one of the trained lab technicians on the Certified Environmental Contractors laboratory staff, and the results are reviewed by the QAO.

All records and documents are retained for five (5) years. All of the system parameters and the test data are preserved and are available for the 5-year period.

Observations are recorded at the time they are observed. Changes to observations or test records are made with a single line, and the date and initials of person making the change are recorded. Changes also include the reason the record was changed. Changes to records include both electronic and manual records. The maintenance logbook includes any changes or adjustments made to the software or measurement equipment. This helps to identify the reason any changes to instrument response are observed in the calibration logbook.

7. Review of All Requests, Tenders and Contracts

All new work is initiated by the technical director who delegates responsibilities for the new work according to available resources. Staff meets prior to initiation of new work in order to determine if appropriate facilities and resources are available. The plan for any

new testing will be reviewed and approved by the TD before commencing such work. If the review uncovers any potential conflicts, deficiencies, inappropriate accreditation status, and/or inability to perform the work, the laboratory will notify the client. In cases where differences exist between the request/tender and contract they will be resolved prior to starting work.

The review shall determine that facilities and resources are available to perform the work. The record of contract review includes pertinent discussions with the client regarding their requirements and results submitted during the contract period. For any new testing requirements, the TD or the QAO will ensure that standard operating procedures and demonstration of capability to perform those tests prior to reporting results are available. The SOP(s) will be under document control and a Demonstration of Capability statement(s) will be on file.

Clients are notified immediately in situations where the laboratory cannot conform to the contract and if there is a change in laboratory accreditation status.

8. Calibration/ Verification of Test Procedures.

General Inspections: Each piece of equipment is examined visually every day. Any defective item is clearly marked and removed from service until it has been shown to perform satisfactorily and is approved by the Technical Director or the QAO. Incidents of equipment malfunction or questionable function are logged into the Maintenance and Service File.

Calibration and/or verification procedures (daily and intra-daily tests, monthly Bowser Morner spike tests, and annual Radon Proficiency Program tests) are designed to ensure that the data are of known quality and are appropriate for a given regulation or decision. Details of instrument calibration and/or test verification procedures including calibration range, standardizations, calculations, and acceptance criteria are included or referenced in the SOPs. Sufficient raw data are retained to reconstruct the calibration used to calculate the sample result.

Daily and other periodic tests include the following:

1. Background counts are measured for 6000 second runs twice a day. It is important that our system backgrounds be accurately known to minimize measurement uncertainties arising from laboratory backgrounds.
2. Lab blanks are measured on unexposed canisters for 600 second runs, once in the morning and again after every 20 sample runs on each counting station.
3. "Hot Can" runs (with radon content equivalent to 137-160 pCi/l) are run once a day in the morning and again after every 20 sample runs on each counting station. These runs confirm each station's calibration.
4. Laboratory Control Samples ("LCS") with radon content equivalent to about 4 pCi/l are run once a day in the morning and again after every 20 sample runs on each station.
5. In addition to the above, duplicate tests (Laboratory and/or Field) are to be made at 10% of the runs per station. Laboratory duplicates are to be run after every 20 runs per station.

Detailed SOPs for these calibration and QA tests and for routine sample assays are covered in Sections 9, 10, and 11 below.

Results of samples must be within the calibration range (bracketed by standards), or the results must be flagged as having less certainty. The QAO is notified if any calibration or test procedure result that is out of specification limits. Any station that is out of calibration is removed from service

The corrective action that is taken is determined by the QAO or by the TD.

A system discrepancy report will be generated whenever any station is out of specification. The report is retained in the System Maintenance file.

9. Sample Handling

- A. Sample Acceptance Policy – Samples may be collected by certified Radon Measurement Technicians or by individual property owners. The sample test kits are distributed either individually to single test purchasers or in bulk shipments to Home Inspectors or to other authorized group purchasers. The test canisters are serial-numbered, and the lab maintains a record of all purchases. Each test kit consists of a data sheet and a canister with a unique ID serial number.

After the exposure, the samples must be submitted to the laboratory with records of location, date and time of collection including beginning and ending exposure times, collector's name, and remarks. Complete preservation and handling instructions are furnished to the sample collectors. The number assigned to each canister also assures a unique ID is assigned to the sample. See SOP Number 4 for Sample Inspection SOP.

Samples collected by a certified radon measurement technicians or professional Home Inspectors must adhere to strict handling protocols. A small number of samples are sold to and handled by retail customers. In such cases the laboratory exercises reasonable diligence in monitoring the placement, retrieval and handling practices. Deficiencies in specified practice are noted in the test records and the analysis can be either rejected as invalid or qualified as an estimate by the technical director or the QAO. If the can is opened or severely damaged the sample is rejected. If the sample is received greater than 7 days after the end of exposure the sample is either rejected or qualified. If the exposure period is less than 46 hours the sample is measured and either qualified or rejected as decided by the QAO or TD.

- B. Sample Receipt Protocol - Upon receipt, the condition of the samples, including all items specified in the sample acceptance policy, are checked, and recorded.

Samples are almost always analyzed the same day they are received. If the

number received exceeds the laboratory's capacity, the samples which are not analyzed are stored overnight in the laboratory and entry is secured.

C. Sample Handling Protocols -

1. Each sample is uniquely identified using a durable label with a unique ID number.
2. The Lab maintains a register of all sample ID numbers, with specifics as to whom the sample was sold.
3. The sample acceptance policy is documented and available to the sample collectors. If any samples do not meet any requirements of the acceptance policy, the data is flagged in an unambiguous manner clearly defining the nature and substance of the variation.
4. The sample receipt protocol is documented. The condition of the sample, including any abnormalities or departures from standard condition as prescribed in the relevant test method, is recorded.
5. Sample records which are also available and linked to the sample ID include all required information specified by the sample acceptance policy.

10. Laboratory Environment

- A. Laboratory space is maintained with good housekeeping and is monitored to the specifications required for laboratory space and the testing performed. Electronic components are located away from drafts and doorways. Neighboring test areas of incompatible activities are effectively separated. Specific work areas are defined, and access is controlled. (Only authorized laboratory personnel and escorted visitors may enter the work area.) Good housekeeping measures are employed to avoid the possibility of contamination. Smoking is prohibited. Work areas include entries to the laboratory, sample receipt area, sample storage area, laboratory analysis area, data handling and storage area. Photographs of the test area are shown in Appendix E.
- B. All equipment and reference materials required for the accredited tests are available in the laboratory. Records are maintained for all equipment, reference measurement materials, and services used by the laboratory.

11. Procedures for Calibration, Verification, and Maintenance of Equipment

- A. Equipment is maintained, inspected, and cleaned daily. Any defective item of equipment is clearly marked and taken out of service until it has been shown to perform satisfactorily.
- B. The ASSAY SOP defines the equipment, software and details for handling the equipment. The reference standard used for daily calibration verification is milled uranium tailings sand.
- C. Equipment
Put into service in the late 1980's in new condition and moved to the current

location in 2001. Manufacturer's instructions are covered in the laboratory SOP, and the manufacturer's operating instruction manual is kept in the laboratory. A list of the instrument components is shown in Appendix F.

Daily performance checks are recorded, and historical limits are defined in the laboratory notebooks. All of the daily equipment calibration and operating parameter tests are described in Section 8.

Reference material is milled uranium tailings sand. It was started in use in the year 2000. It is local sand and there is therefore no certificate.

D. Calibration Samples:

Laboratory Control Samples ("LCS") are 3" canisters containing approximately 3 Grams of milled uranium tailings sand anchored in place by an over-layer of plaster of Paris. The sand appears to be entirely homogeneous in its radium content and is an excellent choice for these samples. This quantity of sand yields assays of approximately 4 pCi/l, which is in the range of commonly seen tests.

Hot Cans are standard 3" canisters containing 175 grams of milled uranium tailings sand. These samples yield an assay of between 137 and 160 pCi/l, which is high enough to produce good statistical readings in our standard 600-second running times.

E. Maintenance of the equipment by the technical staff on an as needed basis is documented in the maintenance folder.

F. Support equipment:

Canisters are weighed before and after exposure using Ohaus *Scout* balances. A staff technician checks the balances daily, and the balances and weights are calibrated once a year by Custom Calibration Solutions located in Hamilton, NJ.

Checks of the balance by Certified Environmental Contractors are made daily with four weights that bracket the range of use of the balance. Certified Environmental Contractors also makes annual checks with 10 weights from 1 gram to 200 grams. All of the daily and annual weight measurements must agree with the standard weights without any measurable error.

The Nucleus system used to measure our test samples is used to measure canister weights lying between 65.0 and 78.0 within +/- one tenth of one gram. The balance is used daily, so we have obtained a second set of weights that are used to inter-compare and verify their stability and non-drift.

G. Reference materials:

The reference materials consist of samples containing milled uranium tailings sand described in paragraph C. above. They are used only for internal calibration to maintain the validity of instrument performance. Reports of the inter-laboratory comparison with Bowser-Morner are maintained to demonstrate comparability of

test data with an EPA reference as required by the States of New Jersey. All Radon Proficiency tests, and all periodic Bowser-Morner inter-laboratory tests are traceable to the EPA facility in Grand Junction, CO.

12. Purchasing and Subcontracting

Materials and Supplies are purchased using the same quality of materials previously used for the testing. The quality of the equipment and materials used are defined in the Assay SOP. Orders are placed and when received the materials are checked against the orders. If acceptable this is noted on the packing slip and given to the TD for approval and payment.

Subcontracting – No subcontracting is performed for the scope of work.

13. Essential Quality Control Procedures

- A. The laboratory reports its participation in an accredited proficiency testing program for each category of approved testing. NJ RPP specifies its RPP requirement. We submit 5 samples annually to Bowser-Morner for this exercise. We also submit 10 samples per month to Bowser-Morner for our own quality control and spot calibration purposes. The results are used to evaluate the ability of the laboratory to produce accurate data. Proficiency test reports along with all raw data necessary to reconstruct the analyses are retained at the laboratory.
- B. The laboratory participates in inter-laboratory comparisons through its annual NJDEP program. The data acquired from quality control (QC) procedures are used to estimate the quality of analytical data, to determine the need for corrective action, and to interpret results after corrective actions are implemented. Each method standard operating procedure (SOP) includes detailed QC procedures and QC limits. QC limits are generated where no method limits exist. QC limits for laboratory control samples (LCS) are based on the historical mean recovery plus or minus three standard deviation units. Duplicate limits for precision range from zero to 3.27 times the mean of the historical differences or relative percent differences.
- C. In cases where historical data is not available, interim QC limits are used until 20 data points are available to calculate QC limits. Interim QC limits for LCS are 80% - 120% recovery. Interim QC limits for duplicates are 20% relative percent difference from the average.
- D. All quality control measures are assessed and evaluated on an on-going basis. Analytical data generated with QC samples that fall within prescribed acceptance limits indicate the test method was in control. Data generated with QC samples that fall outside QC limits indicate the test method was out of control. These data are considered suspect, and the corresponding samples are reanalyzed or reported with qualifiers if reanalysis is not possible.

The laboratory does a set of QC samples in the morning and a second set mid-day. During a typical day no more than 280 samples are counted. Seven (7) analysis stations are in service. The QC sample set is performed in the morning and afternoon. This ensures that one full set of QC samples is performed for every 20 samples on each station. Each QC sample set consists of one Method Blank, one LCS Standard, and one Hot Can, for 600 seconds each. The mid-day set also includes one Lab Duplicate test measurement for each counting station. If the daily workload exceeds 280 tests the Lab will conduct an additional full set of QC samples at the end of the day.

Laboratory control samples (LCS) are performed at a frequency of one per batch of twenty or fewer samples. The results are used to determine batch acceptance.

Laboratory duplicates are performed at a frequency of once per day if the total daily workload is less than 280 samples, or 20 per test station. If the daily load exceeds 280 samples, a second set of duplicate tests will be run on each counting station. Duplicates are a measure of precision. If a duplicate result falls outside QC limits the original sample and the duplicate sample data is regarded as unreliable. Field and/or Laboratory Duplicates to be run at 10% per station.

14. Control of Non-Conforming Test Results

Specific corrective action protocols for handling out-of control QC are in each method SOP. In addition, general procedures are followed to determine when departures from quality control have occurred. Provision is made for such deviations and documentation is determined by the Corrective Action Procedure. Because of the sampling schedule and the time frame of the analysis, it is not always possible to repeat the analyses if all quality control measures are not found acceptable. Therefore, if a quality control measure is found to be out-of-control, and the data is to be reported, all samples associated with the failed quality control measure are reported with the appropriate data qualifier. The data qualifier is a statement related to the specific QC failure and any information on the usability of the data.

All employees have the authority to stop work on samples when any aspect of the testing and reporting process does not conform to the laboratory's SOPs or client's requirements. The employee who stopped work shall immediately notify the QAO and TD. The QAO evaluates the significance of the non-conforming work. Corrective action is established for significant non-conforming work. If necessary, the client is notified, and defective reports are recalled. The QAO (or the Technical Director in the QAO's absence) is responsible for authorizing the resumption of work.

15. Corrective Action Procedure

Deficiencies cited in the external assessments, internal quality audits, complaints, and managerial reviews are documented. Records will be available to show that the root cause(s) of the deficiencies are investigated, including the results of the investigation. Records shall be available to document the intended corrective action. Records shall be available to show that the implemented corrective action is monitored for effectiveness. The Quality Assurance Officer maintains these records. The Technical Director ensures that the corrective actions are discharged within the agreed upon time frame. When non-conformances as well as departures from SOPs cause doubt about the laboratory's operations, the affected areas are promptly audited. The Corrective Action Form is used to record this information. If non-conformances cause doubt about sample results, the client is promptly notified.

Method SOPs provide QC acceptance criteria and specific protocols for routine corrective actions. Any QC measure result that falls outside of acceptance limits requires corrective action. When testing discrepancies are detected such as out-of-control QC, the analyst follows the specific protocol for corrective action as stated in the method SOP located in the Methods Manual. In addition, any discrepancies are documented on the Corrective Action form maintained in the laboratory. The discrepancy is identified, and the sample data associated with the discrepancy are flagged. The TD or QAO specifies corrective actions to be initiated by the analyst and ensure implementation and documentation of the corrective action. Each corrective action form is reviewed, signed, and dated by the QAO and the TD. Any client results associated with corrective actions must be reported back to the client, with the appropriate statement such as departures from procedures or QC failures.

16. Exceptionally Permitted Departures from Documented Policies and Procedures or From Standard Specifications.

The Technical Director will ensure the lab's policies and procedures are implemented. Arrangements for known and controlled departures from documented policies and procedures are allowed. Planned departures do not require audits; however, the departure must fully be documented by the analyst, TD or QAO. The documentation must include the reason for the departure, the affected SOP(s), the intended results of the departure and the actual results. If the data reported to the authority or client is affected adversely, the client must be notified in writing. The corrective action procedure is used for documenting this process. Typical departures from standards include under- or over-exposure times, delay in returning samples to the lab for assay, damaged canisters, improperly resealed canisters. In all such cases, the QAO describes the response he determines, and the client is notified in writing.

17. Preventive Action

Preventive action is the pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

All employees have the authority to recommend preventive action. Recommendations are made to the QAO in writing. After review with the TD, the QAO develops an action plan to design, implement and monitor the action. The plan must include controls that enable objective evaluation of its suitability. The preventive action is audited under the

direction of the QAO.

18. Service to Clients and Complaints

The laboratory provides controlled and limited access to the facilities and records for all clients. The review of the facilities and client records is limited to those records applicable to the given client. All laboratory data and information are maintained in a confidential manner. Clients are not admitted to the laboratory analysis area but will be given access to their specific test data on the premises if requested. Specific test results may be discussed in person or by phone, fax, or e-mail.

19. Internal Audit and Data Review

- A. Data Review - All original observations and calculations are reviewed and evaluated by the analyst or the QC Officer before they are reported. The data is reviewed, per the relevant SOPs, to ensure that calculations are correct, including any manual or electronic changes to the data. The reviewer will sign and date the space provided for review. The results of all quality control measures are reviewed and evaluated by the QC Officer before data are reported. Errors detected in the review process are referred to the analyst for corrective action. The QC Officer assures that all errors found in the review process are documented along with the corrective action. The QAO records this review on the data sheet or in the logbook.

Once per year, the QAO audits a random set of 10 data packages selected from the current year. The purpose of the review is to verify that all data integrity requirements are met.

- B. Internal Quality System Audits - The QAO performs or arranges for an internal quality system review annually. The audit is carried out by trained personnel who are independent (if possible) of the activity being audited. The QA Officer reviews the requirements of the EPA method and State program requirements against laboratory operations, and the laboratory Quality Manual and SOPs. The results of the audits are documented in writing. If audit findings cast doubt on the validity or correctness of the data, the lab takes immediate corrective action. Any corrective actions are documented. Any Authority/client whose work was possibly adversely affected shall be notified in writing. Documented reviews are performed with respect to any evidence of inappropriate actions or vulnerabilities related to data integrity. Allegations are confidentially investigated. All investigations that result in findings of inappropriate activity are documented and shall include any disciplinary actions involved, corrective actions taken, and all appropriate notifications to clients. Documentation is maintained for five years.
- C. Managerial Review - The Technical Director shall review the laboratory quality system and its testing and calibration activities annually to introduce any necessary changes or improvements. The review takes into account the outcome of recent internal audits, reports from managerial and supervisory personnel, suitability of policies and procedures, assessments by external bodies, the results of proficiency tests, any changes in the volume and type of work undertaken,

feedback from clients or Authorities, corrective and preventive actions and complaints, and other factors such as quality control activities, resources and staff training.

20. Training and Review of Personnel Qualifications

Laboratory management (the TD or QAO) reviews each applicant's level of qualification, experience, and skills against the laboratory's job description requirements before assigning an employee to the laboratory. Each analyst and technician have adequate experience and education to demonstrate general knowledge of the operation of the laboratory, of test methods, QC procedures, and records management. The Technical Director keeps the following personnel records:

A. The laboratory training file which contains:

1. Statements from each employee that they have read, understood, and are using the latest version of the laboratory Quality Manual and SOPs. The statements must be signed and dated.
2. A statement from each employee that they have read, acknowledged and understood their personal ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions. The statements must be signed and dated. See Appendix A.
3. A Demonstration of Capability (DOC) for each employee for each accredited method.
4. Documentation of any training courses, seminars, and/or workshops.
5. Documentation of each employee's continued proficiency to perform each test method by one of the following annually:
 - i. acceptable performance of a blind sample (single blind to the analyst).
 - ii. another Demonstration of Capability.
 - iii. at least four consecutive Laboratory Control Samples with acceptable levels of precision and accuracy.

B. Demonstration of Capability (DOC) - A DOC must be performed prior to using any test method, and any time there is a change in instrument type, personnel, or method. The initial demonstration is performed by analysis of 4 LCS samples and obtaining acceptable results for precision and recovery.

C. On-going Demonstration of Proficiency: This laboratory, through QC charting, has historical data adequately demonstrating analyst's capability to meet the laboratory-generated acceptance criteria. Where the analyst has demonstrated capability through analysis and QC charting of Laboratory Control Samples with acceptable results, the procedure for demonstrating continued proficiency to

perform the test method (above) is used for the DOC Certification Statement.

21. Data Integrity

Data Integrity/Ethics training shall occur for each employee required to perform laboratory testing or handle samples at the initial hiring orientation or within two weeks after assignment to laboratory functions. Annual training is also required for all employees. Training is conducted either in-house or externally. A record of training and a signed attestation by the trained employee shall be placed in the employee's training file.

Topics covered are documented in writing and provided to all trainees. Key topics covered are the organizational mission and its relationship to the critical need for honesty and full disclosure in all analytical reporting, how and when to report data integrity issues and record keeping. Training includes discussion regarding all data integrity procedures, data integrity training documentation, in-depth data monitoring and data integrity procedure documentation.

Trainees are required to understand that any infractions of the laboratory data integrity procedures will result in a detailed investigation that could lead to very serious consequences including immediate termination, or civil/criminal prosecution.

The initial and annual refresher data integrity training shall have a signature attendance sheet that demonstrates that all staff has participated and understand their obligation related to data integrity/ethics. Specific examples of breaches of ethical behavior should be discussed including improper data manipulations, adjustments of instrument time clocks, and inappropriate changes in concentrations of standards. Data integrity training requires emphasis on the importance of proper written narration on the part of the analyst with respect to those cases where analytical data may be useful but are in one sense or another partially deficient.

Senior managers/department heads acknowledge their support of these procedures by upholding the spirit and intent of the laboratory's data integrity procedures and effectively implement the specific requirements of the procedures. See SOP DI-01, Data Integrity.

22. Reporting Analytical Results

The results of each test carried out unambiguously and objectively by the laboratory are reported accurately. The following is included on test reports or is available at the laboratory. The information for the client in the report of laboratory analysis is based on applicable regulatory requirements or client requests:

- 1.) Title.
- 2.) Name and address of laboratory, and phone number with name of contact person for

questions.

- 3.) Unique identification of report.
- 4.) Name and address of client and project name, if applicable
- 5.) Description and unambiguous identification of the tested sample including the client identification code.
- 6.) Identification of results derived from any sample that did not meet sample acceptance requirements, such as, improper container, or holding time.
- 7.) Date of receipt of sample, date and time of sample collection, date(s) of laboratory assay.
- 8.) Identification of test method used.
- 9.) Any deviations from (such as failed QC), additions to or exclusions from the test method (such as environmental conditions), and any non-standard conditions that may have affected the quality of the results, including the use and definitions of data qualifiers.
- 11.) Measurements, examinations, and derived results with any failures identified.
- 12.) A statement of the estimated uncertainty of the result (+/- 0.3 pCi/l for results less than 3 pCi/l, +/- 10% for results higher than 3 pCi/l.);
- 13.) A signature and title, or an equivalent electronic identification of the person(s) accepting responsibility for the content of the of the report, and date of issue.

Subcontracted laboratories are identified by accreditation number on the report for any accredited testing. A sample client report is shown in Appendix I.

If errors are detected in the report, a subsequent revised report is issued. The updated report is stamped with a, "A Revised Report" label.

If the laboratory discovers equipment used to derive results in any report casts doubt on the validity of the result it shall notify the client(s) in writing.

The laboratory shall, where clients require transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, ensure that the confidentiality requirements are met so that confidentiality is preserved. A statement is placed on all transmissions to notify the recipient that if the information is not for them, they should discard the information and notify the laboratory.

23. Confidentiality and Proprietary Rights

Reports of laboratory analysis are only released to the named contact person on the sample submittal form or job contract. All data and client information are considered confidential business information. Clients must identify any propriety rights that have been assigned to third parties related to the information supplied at the start of any contract. Under NJ regulations, laboratory results are also released to the owner of the property tested.

24. References

1. Indoor Radon and Radon Decay Product Measurement Device Protocols, EPA 402-R-92-004, July 1992.
3. New Jersey Administrative Code Chapter 7:18.