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QUALITY ASSURANCE IN RADON TESTING: PRACTICE MEETS THEORY

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ABSTRACT

Quality assurance programs are an explicit or de facto requirement for anyone measuring radon as a business, and this paper describes the basic elements of a program that would meet the guidelines drafted by several Federal and State agencies. This description includes not only the mechanics of conducting quality control measurements, but also their analysis and interpretation. The necessity for and goals of a quality assurance program for radon and decay product measurements are described with an understanding of the limitations and needs of commercial radon measurement and diagnostics programs. The use of spikes, blanks, duplicates, and routine instrument performance checks are the foundation that maintains the validity of the entire measurement program. This paper includes analysis techniques for recording and digesting the results of quality control measurements that can help a user to better understand and improve their measurement system. These techniques include the use of control charts to plot the results of duplicate measurements (to monitor precision) and spikes to monitor bias). In addition, methods for estimating the lowest concentrations that can be reliably discriminated from background are reviewed.

INTRODUCTION

Quality assurance (QA) is defined by the American Society of Testing and Materials (ASTM) as the *activity of providing the evidence* needed to establish confidence that data provided are of the required precision and accuracy. ASTM defines quality control (QC) as the *process* through which an organization measures its performance, *compares* its performance with standards, and *acts* on any differences (ASTM 1988). *Quality control* consists of measurements and associated activities needed to *assess* measurement program quality, as measured by precision, relative bias, the lower limit of detection (as well as other factors, such as the rates of data entry error) on an ongoing basis and to revise procedures to improve quality if necessary. In other words, the intent of QA/QC is to maintain a good quality measurement program and to ascertain and document the quality.

QA/QC must be an integral part of any measurement program. Since the validity of each measurement rests upon the QA program, measurement results that were not obtained within a program that includes QA/QC are questionable. There are many experienced and knowledgeable measurement experts who perform fine work but who do not have the time or support from management to implement and document QA/QC practices. They may produce accurate results, or they may have incorporated an erroneous calibration factor or flow rate and not be aware of the error. Regardless of the accuracy of their result, the lack of adequate documentation makes it impossible for their measurement results to be as incontrovertible as they need to be.

In addition to substantiating the adequacy of each measurement result, there are other benefits of conducting a QA program. First, performing QC measurements will add greatly to an operator's understanding of the methods they use. For example, it is crucial to know how low a concentration can be reliably measured and the variability that is expected at low concentrations. Second, a QA/QC program will include procedures for monitoring equipment, supplies, and operators. Third, a QA program is often specified as a contractual requirement, and records of a QA/QC program may be critical in the advent of a legal dispute.

A measurement program cannot exist without QA activities. Measurement companies are providing results to clients that may become critical to the sale of a house. If the measurement result is questioned, the tester may be in a liable situation if QA records do not provide adequate documentation of conformance to recommended practices.

Although the costs may be significant and ultimately borne by clients, the measurement results will only have substantiated validity if appropriate QA practices are implemented.

This paper first reviews the definitions of QA and QC, various types of QC measurements, documentation, and audits. The central portion of the paper outlines guidance for QA management and QA plans. The final section reviews methods for analyzing QC measurements, including the preparation of control charts.

QUALITY CONTROL MEASUREMENTS

QA is an umbrella term that includes many activities that are designed to ensure the validity of measurements. The measurements that are made for the purpose of assessing and monitoring data quality are called QC measurements. Guidance for QA in radon measurements can be found in documents written by the EPA, (U.S. EPA 1992a; U.S. EPA 1993), the American Society of Testing and Materials (ASTM 1990a) and the National Council on Radiation Protection and Measurements (NCRP 1988).

Routine Instrument Performance Checks

This category or QC measurement includes any activity that can be performed to assess how well the equipment is operating in relation to a previous check or to a standard check source. Operators of continuous methods and electret readers will be able to perform such checks on their own equipment; users of passive devices must rely on the laboratory to perform such checks.

Regular monitoring of equipment and operators is vital to ensure consistently unbiased results. Performance checks of analysis equipment include the frequent use of an instrument check source. In addition, important components of the device should be checked prior to each measurement and the results noted in a log. Critical components, such as pump flow rate, should be checked prior to and following each measurement and the results noted.

Check sources can be sealed cells, electroplated disks, Ra-226 impregnated canisters, thoron or americium sources, or other sources that are used to test the counting system and ensure that the electronics are stable and that all is operating the same way it was the day before. Sealed radon cells are used routinely to monitor scintillation cell systems (continuous or grab). Sealed charcoal canisters containing radium can be used to monitor the responses of the sodium iodide counters, and the response of an electret reader can be tested with a reference electret. There are other checks that can be easily performed to check electronics or perform self-diagnostic procedures. Each user should develop methods for regularly (daily, or at least prior to each measurement) monitoring their measurement system, and for recording and reviewing results.

Duplicate Measurements

Duplicates are defined as collocated measurements, in which the detectors are placed side-by-side. The purpose of making duplicate measurements is to evaluate the variation that can be normally expected between two identical measurements of the same concentration. This allows the organization to monitor the component of measurement error caused by random differences in devices and/or the measurement process. Some degree of precision error is unavoidable, and may be caused by detector manufacture, improper data transcription or handling by suppliers, laboratories, or technicians performing placements. Since any one of these factors can change suddenly or gradually over time, continual monitoring of precision can serve to check on the continuity of the entire measurement system.

Duplicate measurements for both active and passive detectors should be side-by-side measurements made in *at least* 10 percent of the total number of measurement locations, or 50 each month, whichever is smaller. The locations selected for duplication should be distributed systematically throughout the entire population of samples. Groups selling measurements to homeowners can do this by providing two measurements, instead of one, to a random selection of purchasers, with the measurements made side-by-side. As with spiked samples introduced into the system as blind measurements, the precision of duplicate measurements should be monitored and recorded in the QA records. The methodology described later in this paper can be used to analyze data from duplicates. If the precision estimated by the user is not within the precision expected of the measurement method, the problem should be reported to the analysis laboratory and the cause investigated.

In addition to the minimum number of duplicates, a key procedure is that the measurement locations selected to receive duplicate detectors be *distributed among all measurement locations.* Although it will provide interesting data, it is not adequate to place all duplicate devices in your own basement. Some duplicate measurements must be made in locations that require all the different handling that are routine in the operation, such as mailing to various locations, travelling by car, handling by different technicians, counting by different equipment, and recording by different office personnel. This is the only way to estimate and monitor the *average* precision error shown by all the measurements. One way to implement this program is to target every tenth detector or house number to receive a duplicate.

An exception to this rule is when all the systematically-selected homes that receive duplicates have radon concentrations less than 150 Bq m^{-3}. In this case, a portion of the duplicates can be placed in homes where the concentration is known to be greater than 150 Bq m^{-3}.

Background Measurements

Background measurements are very important for some types of devices, including alpha track detectors, scintillation cell instruments, and electret ion chambers in areas of high gamma exposure. All radon or decay product measurement methods require some type of background measurements.

There are two categories of background measurements: *laboratory blanks*, made to assess the background counts of the instrumentation used to analyze the detectors, and *field blanks*, made to assess the background that accumulates during handling and shipping.

Laboratory Blanks: Laboratory blanks are used by a analysis laboratory to measure the counts or signal that should be subtracted from the results of field (in homes) detector analyses. For example, electret ion chambers are analyzed using an electret reader and the manufacturer provides instructions for monitoring the response of the reader to a blank.

Laboratory background measurements are interpreted as follows. First, the results of laboratory blanks are used to derive an average laboratory background level, which is subtracted from the results of the detectors used to measure radon in homes. This must be done by the analysis laboratory that processes the detectors and reports results. It is important for the distributor to ensure that the analysis laboratory they use is making laboratory background measurements and is subtracting them from the results before they receive their reports. The second interpretation of background measurements is to calculate the lower limit of detection, or LLD. The method and derivation of the LLD are described later in this paper.

Field Blanks: The purpose of field background measurements, or field blanks, is to measure any effect due to exposure *other than in the house or environment being measured.* The detectors used for blanks must therefore be treated identically to the detectors deployed in homes except that they are not opened or brought into the environment to be measured. Blanks can, however, be carried around with other detectors, and this may be very important in cases where detectors to be calibrated are brought to a radon calibration facility. If there is any extraneous background added to the detectors used to calculate the calibration factor, it is important that it be measured so that it can be subtracted before calibration factors are calculated.

The EPA recommends that providers of passive detectors should place field blanks (unopened detectors) in locations numbering approximately five percent of the total number of detectors deployed, or 25 each month, whichever is smaller (U.S. EPA 1992a; U.S. EPA 1993).

The results of the field blanks should be monitored and compared with the value of LLD calculated using the analysis laboratory blanks. If the field blank results are consistently greater than the LLD, then the average result of the field blanks should be subtracted from the results of the other detectors in that exposure group.

Many laboratories use means control charts for monitoring both laboratory and field background; this is discussed later in this paper.

Known Exposure Measurements, or Spikes

The type of QC measurements that are made to determine the relative bias inherent in the measurements are termed known exposure measurements, or spikes.

Spikes consist of detectors that have been exposed to known concentrations in a radon calibration chamber. These detectors are labeled and submitted to the laboratory in the same manner as ordinary samples to preclude special processing. Suppliers and analysis laboratories should provide for the blind introduction of spiked samples into their measurement processes and the monitoring of the results in their QA programs.

The EPA requires that all participants in the Radon Measurement Proficiency program (including both analysis laboratories and service organizations) using passive devices conduct spiked measurements at a rate of three per 100 measurements, with a minimum of three per year and a maximum required of six per month (U.S. EPA 1991; U.S. EPA 1992a). Providers of measurements with active devices are required to recalibrate their instruments *at least* once every 12 months and perform cross-checks with RMP-listed devices at least once every six months.

The results of spikes can be plotted on a means control chart, as described later in this paper.

OTHER QUALITY ASSURANCE ISSUES

Documentation

Standard Operating Procedures: Organizations should assure that all work affecting quality of results (such as handling, storing, and analyzing devices) be prescribed in clear and complete written instructions. These work instructions, known as Standard Operating Procedures (SOPs), provide the criteria for performing the work, particularly the analytical and testing functions, and should prescribe the chain-of-custody procedures that are necessary to assure that analytical results can be used as evidence. The preparation and maintenance of, and compliance with, SOPs should be monitored by the organization's QA Officer.

Recordkeeping: There are other sources of error besides those inherent in the measurement process. Inadequate recordkeeping can lead to errors such as transposing results from different locations, or misplacing results or detectors. When planning procedures for data entry, the following factors are important. First, ensure that the proper forms and labels are available and can be easily understood by the homeowner, technician, data entry operator, or whoever must use and read them. Second, anyone recording data must receive adequate instructions that are documented and updated in the SOP for easy reference. Third, the data recording process should be monitored for errors. Many organizations use a double-entry method, wherein each field is entered by two different operators (or entered at two different times by the same operator) and checked automatically by the computer for differences. If this is not feasible, organizations should hand-check at least a portion of the day's entries for errors. In general, less involvement of human operators ensures fewer opportunities for error.

Chain-of-custody procedures to track detectors and placement/analysis dates should be established and documented in the SOP. These may be as simple as labeling large boxes or shelves for unexposed detectors ready to be used, detectors ready to be shipped/analyzed, and detector custody sign in/out sheets. Identical, printed, peel-off sample identification numbers placed on detectors, information sheets, result letters, and shipping containers can help reduce mix-ups. For detector types that need to be analyzed as soon as possible following exposure, the times and dates between the end of exposure and shipment/analysis is critical, so a daily check that all detectors in have been shipped/analyzed may be appropriate.

Logbooks are extremely useful tools for maintaining records of QA practices and QC measurements, including calibration results, background measurements results, and any changes in operators, materials, or procedures. Logbooks should be bound, and records made in pen. Every entry should include the name of the person making the entry and the date. Any relevant print-outs or plots can be photocopied and pasted into the logbook. Such a log can serve as an invaluable record, with all relevant information in one place.

Control charts containing the results of any QC measurements can be kept in the QA notebook or posted for easy reference.

Data Validation

Each step in the process between obtaining the original counts, tracks, or voltage loss and the final results reported to clients should receive some data validation. Checking *at least* five percent of each phase of the data may be sufficient. Handchecking is adequate if it is done conscientiously. There should be a record of which records were

checked, by whom, the date, and how any errors found were resolved. Dates and initials in the records may be sufficient if the procedure used is documented.

Quality Assurance Audits

States may audit companies as part of State certification. Clients such as school districts, federal agencies, or private companies may conduct audits of the measurement organizations they are using or are considering using. Organizations may or may not be notified of the audits in advance, which is one reason why all logbooks and QA records should be on-hand on company premises when not actually in use in the field. Both laboratory and service organizations should maintain records appropriate for their activities in the event of an audit.

Quality Assurance Reporting

Periodic reports to management describing the results of QC measurements, problems that were encountered, and solutions or proposed solutions will keep management abreast of performance. These reports may be included in the QA logbooks and be available
during audits.

CALIBRATION

The term calibration is used describe the process to determine a conversion factor relating instrument or system response (in counts, voltage loss, or track density per time) to radon or decay product concentration. The term is also used to indicate that the instrument or system's response has been compared with national or international standards, and adjusted if necessary. (Calibration is *different from* routine measurements made to assess relative bias or check the calibration factor of the system; these are called spiked or known exposure measurements.) Useful definitions and nomenclature can be found in American National Standards Institute (ANSI) documents (ANSI 1978, ANSI 1987).

Calibration, as referred to in this paper, means that the response of the instrument or system can be related, or traced, to a radon or decay product concentration that was derived from a certified National Institute of Standards and Technology (NIST) radium-226 standard. These working standards of radon are usually constructed by bubbling nitrogen or other gas through a vial containing certified radium solution (solutions of Ra-226 in weak acid). By strict definition, any vial that is opened is no longer a NIST standard. With careful handling, however, a vial can be opened and transferred to another vessel while retaining its quality. If the empty vial and glassware are checked for residual radium, a laboratory standard that is "NIST-traceable" can be produced.

At present, NIST produces Standard Reference Material (SRM) Ra-226 solutions that may be used to produce working laboratory standards for radon-222 (Rn-222). There is no SRM for radon. General procedures for producing these working standards are described by the NCRP, (NCRP 1988), and EPA and NIST (NIST 1990).

QUALITY ASSURANCE MANAGEMENT

The responsibility for, and commitment to, a quality policy belongs to the highest level of management. If upper management does not provide an environment which supports a complete QA program and in which concerns and suggestions for improving quality can be raised, the quality of the measurements will suffer. QA management is that aspect of the overall management that determines and implements quality policy. The direct and ultimate responsibility for assuring data quality rests with the laboratory or field managers. These people have the primary responsibility for developing QA policies, procedures, and criteria, and delegating QA authority and responsibility.

Accountability is also an important part of QA management. Each person in the organization needs to understand and be accountable for, their own QA responsibilities.

Quality Assurance Officer

The establishment of a QA program requires a QA Officer within the organization to supervise and, as appropriate, carry out the monitoring, recordkeeping, statistical techniques, and other functions required to maintain good quality data. This person may have these duties as their sole responsibility, or may have other responsibilities as well. The QA Officer should be assimilated into the organization, reporting to the lowest level at which he/she

can be effective and unbiased in objectively serving the needs of the organization. In no case, however, should the QA Officer's functions be subordinate to an individual responsible for direct conduct of analyses.

In implementing his or her responsibilities, the QA Officer should have a reporting relationship with the top managers of the organization to assure that the appropriate laboratory or field managers are aware of their responsibilities for prescribing any needed corrective actions. For example, the QA Officer should be included in regular staff meetings or conference calls, and receive all organization memoranda and bulletins regarding staffing, training, equipment, recordkeeping, and changes in business practice and procedures.

QUALITY ASSURANCE PLANS

A Quality Assurance Plan (QAP) is a written document, which presents, in specific terms, the policies, organization, objectives, functional activities, and specific QA and QC activities that are designed to achieve the objectives of the project (U.S. EPA 1980). The QAP documents the program in terms of measurement methods used, calibration standards and frequencies planned, auditing planned, etc. It also provides management with a document that can be used to assess whether the planned QA activities are being implemented, and to examine the importance of these activities toward the goal of quality data in terms of relative bias and precision.

There are 16 elements of a QAP that are described in EPA's guidance for preparing such plans (U.S. EPA 1980, U.S. EPA 1989).

Signature Page (element 1)

The title page of the QAP should include the signatures of the organization's QA Officer and his/her supervisor. Other individuals who are also responsible for the quality of measurements should sign the completed QAP, indicating their approval.

Table of Contents (element 2)

The table of contents should include page numbers for each of the 16 elements of the QAP, and the "revision number," signifying the number of times and most current date that each element was revised.

Description of Operations (element 3)

This part of the QAP should provide a complete description of all the relevant organization operations, including different measurement methods, distribution activities, on-site visits, and transmittal of results to clients. The description must be sufficient so that someone unfamiliar with the operations can understand the numbers and types of measurements made by the organization.

Organization and Responsibilities (element 4)

This part of the QAP usually includes a detailed organizational chart showing management structure and lines of communication. The names of all key individuals in charge of every major activity in the project should be included. Telephone numbers should also be provided to facilitate communication between project officials. Both technical and QA/QC functions should also be listed.

The most important person to identify is the QA Officer, and the line of authority for their activities. It is important to employ a QA Officer who is not part of the financial or functional operation of the organization (for example, the vice president of the company would not be a good choice) to allow the QA Officer to act freely to ensure data quality.

Quality Assurance Objectives for Measurement Data in terms of Precision and Bias (element 5)

The quantitative QA objectives for precision and bias should be discussed and presented in a table. The table should list the quantitative goals for precision and relative bias for each measured value used to calculate radon concentration.

Precision: Precision is defined as the measure of the variability of a process used to make repeated measurements under carefully controlled (identical) conditions. Because variability is not usually constant at different

concentrations, estimates of precision must be made at different concentrations in the range of interest. Precision objectives for several concentrations or ranges (for example, greater than 150 Bq m^{-3}, may be specified. (Technical guidance for calculating and assessing relative bias and precision is provided later in this paper.)

Relative Bias: Relative Bias is defined as the degree of agreement of a measurement result with an accepted reference or true value. In this case, the reference value is the concentration in the radon calibration facility where the spiked measurements are performed. Bias may be expressed in terms of percent difference, or as

$$\%D = (MV-CV)/CV$$

where %D = percent difference;

MV = measured value of spiked measurement; and

CV = radon calibration chamber value.

Note that the definition of percent difference is similar to the definition of Individual Relative Error (IRE), as defined in the *RMP Program Handbook* (U.S. EPA 1991), except that the numerator of the IRE is the absolute value of the difference while %D can have positive or negative values. This formula is identical to the "relative bias" formula used by the Nuclear Regulatory Commission (U.S. NRC 1986, page 33).

It is advisable to specify ranges over which the relative bias goals are to be met. The quantitative goal for relative bias could be stated, for example, as a percent difference (or Individual Relative Error, IRE) of ±15 percent or less at radon concentrations greater than 150 Bq m^{-3} (for individual spiked results or as an average for a set of spikes).

Another expression of bias is percent recovery, which can be defined as the measured value divided by the chamber value. Note that the difference between percent bias and percent recovery is one, so that, for example, if percent difference is 0.25, percent recovery will be 1.25.

Sampling Procedures (element 6)

This section would include information on the method by which the radon or radon decay product concentrations are to be measured; the guidelines used to select the locations for detector deployment, including the procedures for choosing the exact sampling locations; the measurement conditions; the logbooks or recordkeeping procedures, with a list of the information to be gathered with each measurement; and the schedule and other relevant information about shipping detectors to the laboratory.

Detector Custody (element 7)

This section would describe the chain-of-custody procedures, forms, documentation, and the responsibilities of each person is needed to ensure both the technical validity and the legal defensibility of data obtained from all measurements. For field operations, this would include examples of labels, custody seals, and field tracking forms, the documentation of procedures for transporting detectors from the field to the laboratory, including identification of the individuals or organizations responsible for transport. For laboratory operations, this would include a description of how the detectors are handled by each laboratory facility when they are received after exposure, including copies of forms and references to procedures for the disbursement and transfer of detectors within the laboratory and between the laboratory and service organization.

Calibration Procedures and Frequency (For Analysis Laboratories) (element 8)

This section of the QAP would describe the calibration procedures, and frequency of calibration, for each analytical system, instrument, device, and any components (e.g., scales, flowmeter) used to obtain measurement results. A summary table can be useful to present information such as references to standard methods; definition of specific acceptance criteria for all calibration measurements; and specific procedures for calibration.

Analytical procedures (For Analysis Laboratories; element 9)

The procedures by which the detectors will be analyzed would appear in this section. The laboratory SOPs can be referenced and attached.

Data Reduction, Validation, and Reporting (element 10)

This section of the QAP describes how the organization plans to maintain good data quality throughout data reduction (i.e., calculation of results), transfer, storage, retrieval, and reporting. Topics that may be appropriate include the names of individuals responsible, a summary of data reduction procedures, examples of data sheets, a description of how results from field and laboratory blanks will be used in the calculations, the presentation of all calculations (equations) and significant underlying assumptions, the means by which the data will be checked for errors, the procedures for determining outliers and flagging data, and a flowchart of the data handling process, covering all data collection, transfer, storage, recovery, and processing steps, and including QC data for both field and laboratory operations.

This section may also describe the procedures for analyzing detectors or measurement results that do not conform to the SOPs, such as when detectors are returned opened, late, or when some other deviation from the planned circumstances has occurred.

Internal Quality Control Checks (element 11)

Internal QC measurements should be conducted by both laboratory and service organizations. This section would describe:

- Routine instrument performance checks, their frequency, treatment of results, (e.g., use of means control charts) and plans for corrective action if results fall outside pre-determined criteria;
- Duplicate measurements made to assess precision, their frequency, the criteria by which locations for duplicate measurements will be chosen, the procedures for deploying and documenting duplicates, and the procedures for assessing the need for corrective action;
- Known exposure (spiked) measurements made to assess relative bias, the calibration facility where spikes are exposed, their frequency, the range of concentrations to which they will be exposed, the procedures for documenting their results, and the procedures for assessing the need for corrective action (e.g., analysis of results and comparison with predetermined limits); and
- Proficiency testing of operations.

In addition, this section may describe the QA checks on *incoming* detectors, equipment, and supplies, for both new shipments of detectors and for detectors mailed back after deployment.

Quality Assurance Audits (element 12)

This section of the QAP would describe the plans for audits, including who will conduct them, when they will be conducted, and the focus of the audits.

Preventive Maintenance (element 13)

Descriptions of the types of preventive maintenance needed for adhering to schedules and for achieving good quality data would appear in this section. The descriptions may include a schedule of important preventive maintenance tasks for measurement systems; a list of critical spare parts; and references to current maintenance contracts and standard maintenance procedures for measurement systems.

This information may not be relevant for a service organization, or may apply only to computer or other non-analysis equipment.

Procedures to Assess Data Precision, Relative Bias, and Lower Limit of Detection (element 14)

This part of the QAP would include the processes (including equations and descriptions of calculations, statistical tests, control charts, etc.) by which the duplicate measurement results will be analyzed to estimate precision, and the limits of acceptability for precision; the known exposure (spiked) measurement results will be used to assess relative bias, and the limits for acceptable levels of relative bias; and the field and laboratory background measurement results used to assess the background level and lower limit of detection.

Corrective Action (element 15)

A corrective action plan is a contingency plan spelled out in IF...THEN... statements ("IF this happens, THEN we will do the following"). For each critical measurement, the topics that would be presented (in table form, if adequate) include trigger points, such as pre-specified conditions that automatically require corrective action; personnel, including who initiates, approves, implements, evaluates, and reports corrective action; and response, including specific procedures to be used if the corrective action is needed.

There may be different types of corrective action that will be required as a result of QC measurement results. This section of the QAP should describe the corrective action to be taken based on the results of the control charts; the corrective action taken to correct problems found during audits; and the corrective action to be taken when there are deviations from the usual or proper procedure (for example, detectors not returned within 10 days of exposure, or incoming unused detectors with high backgrounds).

Quality Assurance Reports to Management (element 16)

The purpose of this section of the QAP is to: (1) identify the individuals responsible for reporting; (2) describe the form and content of anticipated reports; and (3) plan the presentation of QA/QC data so that management can monitor data quality effectively.

THE ANALYSIS AND INTERPRETATION OF QUALITY CONTROL MEASUREMENTS

This section reviews methods of calculating and monitoring the various sources of error that can be expected with your operating system. The total error is comprised of both random and systematic errors. For the purposes of this discussion, the following terms are defined:

Error: The difference between the measurement result and the true value (or best estimate) of the quantity being measured.

Systematic errors: Those errors that occur consistently (errors caused during calibration that impact all subsequent measurements is a typical example) and cause a consistently high or low *bias* in the result (note that there may be multiple systematic errors in a measurement system).

Random errors: Those errors that give rise to a range of results distributed around an average value (a distribution); random errors cause *imprecision*.

Precision: The closeness of agreement between measurement results obtained under prescribed like conditions (e.g., replicate measurements in the same environment).

Accuracy: The closeness of agreement between a measurement result (or the average of more than one result) and an accepted reference value. There are two schools of thought on defining the accuracy of a measuring process (Mandel 1984, Murphy 1961). One school argues that accuracy should connote the agreement between the *long-run average* of the measurement results and the reference value, in which case accuracy represents bias or systematic error. In this case, errors of precision are reduced because of the use of a large number of measurements. This definition has been in wide use among experimenters.

The other school of thought defines accuracy as the agreement between an *individual* measurement result and the reference value. In this case, the errors of precision are not reduced, and the total error depends on both precision (random errors) and bias (systematic errors). Because of these different usages, the American Society of Testing and Materials (ASTM) *Standard Practice for Use of the Terms Precision and Bias in ASTM Test Methods* (ASTM 1990b) states: "In order to avoid confusion resulting from use of the word accuracy, only the terms precision and bias should be used as descriptors of ASTM test methods."

This paper maintains consistency with ASTM nomenclature, and use the terms precision and bias to describe the components of error.

The combination of both systematic errors and random errors form the total error. The *estimate* of overall uncertainty associated with a measurement result should be comprised of upper bounds of estimates of bias and precision errors.

Means Control Chart for Repeated Measurements of Background and Routine Instrument Performance Checks

Control charts are basic tools for evaluating internal QC data (Goldin 1984, U.S. EPA 1984, ANSI Z1.1, Z1.2, Z1.3, ASTM 1992). Taylor (Taylor 1987) provides an excellent discussion of a variety of control charts, including those described here. See Taylor's "property" or "x-chart" for the means chart described in this section. A control chart can be used to evaluate the variation of replicate measurements either about a mean value to assess instrument stability (means chart) or among themselves to assess precision (range chart). A means control chart consists of measurement results plotted on the y-axis and their dates plotted sequentially with time on the x-axis. Limits (± three-sigma from the mean) are plotted as horizontal lines, and data falling within these limits indicate that the system is "in control" and operating as it was when the limits were established based on previous data. A control chart may be used for a limited period, such as a month or two months, and then replaced by a new chart.

A standard Shewhart (Shewhart 1931, Duncan 1965) means control chart may be used for making day-to-day checks on whether any repetitive measurement (such as of background or a check source) is "in control." The control chart shows the mean of the measurements, the *warning levels* that are two standard deviations above and below the mean, and the *control limits* that are three standard deviations above and below the mean.

After data from check sources or background have been gathered for several weeks or months, and well over 20 measurements have been made and plotted, the data can be analyzed in terms of the standard deviation. Lines denoting the mean ± one-, two-, and three-sigma can be plotted. If the system produces results that are consistent, ± one-sigma should contain two-thirds (2/3) of the points, ± two-sigma should contain 19/20 of the points, and ± three-sigma should contain nearly all of the points. The probability of obtaining a value outside the control limits is very low (less than one percent). If a value is obtained that is outside the control limits, then measurements should be stopped and the situation evaluated and corrected. If results are outside the warning levels (± two-sigma), measurements can continue while the QA Officer checks the chart, as follows.

This paper presents one strategy for assessing instrument performance and background based on control charts. It involves simple "rule-of-thumb" concepts and is taken from Taylor (Taylor 1985, Taylor 1987). Other more sophisticated criteria for evaluating whether a measurement system is "out-of-control" is found in the reference by Goldin (Goldin 1984) and is also presented by EPA (U.S. EPA 1993; U.S. EPA 1982a; U.S. EPA 1982b).

As the data are plotted, indicators that the measurement system may be "out-of-control" include:

- Two successive points outside the two-sigma limits;
- Four successive points outside the one-sigma limits; and
- Any systematic trends high or low.

A systematic trend includes a series of points in the same direction or successive points all on the same side of the mean, even if all are within the control limits. If the data exhibit any of these indicators, the measurement system should be checked.

Means Control Chart to Evaluate Relative Bias From the Results of Spikes

The results of spiked, or known exposure measurements, can also be plotted on a means control chart. In this application, the percent difference (%D), or Individual Relative Error (defined as the difference between the measured and the chamber values divided by the chamber value) can be plotted. The mean line should be set at zero, and the two-sigma and three-sigma limits can be set using 1) the standard deviation among the %D values from at least 20 spikes, or 2) the average coefficient of variation as determined via duplicate measurements at close to these concentrations. This application makes use of the mathematical identity between the coefficient of variation of duplicate measurements and the standard deviation shown by the %D of spiked measurements, when the spike (target) value is the same as the average value of the duplicates (U.S. NRC 1986). Because of this, it may be appropriate to construct separate control charts for different ranges of radon concentrations; for example, greater than 150 Bq m^{-3}, and other ranges, as determined by the variability of the %D of the spiked measurements.

An example of data from known exposure measurements to be plotted on a means control chart is shown in Table 1. Two types of continuous radon monitors (CRMs) were placed side-by-side and exposed to the same radon concentrations. The "known" concentrations were determined by the recently calibrated CRM A. A means control chart can be constructed from the data from CRM B, by plotting %D versus run number. The mean line is a horizontal line set at zero, and the %D values fall in a distribution around that line. Previous data were used to set the two-sigma limit for CRM A at ± 16% and the three-sigma limit at ± .21. (The previous data were from duplicate CRM type A measurements at these radon concentrations which had an average coefficient of variation [COV, defined as the standard deviation divided by the mean] of around 8%. Alternatively, data from previous spikes can be used to calculate the standard deviation of the %D values, and that can be used to obtain the two and three-sigma limits.) The %D values for CRM A can be plotted on this control chart as results are obtained. The "rule-of-thumb" techniques described in the previous section can be used to evaluate the results as they are produced.

Assessing Precision Using Control Charts

For radiation measurements, counting statistics are sometimes given as the measure of the variability or repeatability of the measurements, often because of the ease of calculations. Counting error (i.e., using the square root of the total number of counts as the one-sigma error) is a valid description of the variability of a measurement only when the other sources of variability such as that due to procedures and background are negligibly small in comparison to counting error. Williams (Williams et al. 1981) describe the difficulties that arise when only counting statistics are considered.

There is a variety of ways to quantitatively assess the precision error based on duplicate measurements. It is first necessary to understand that precision is characterized by a *distribution*; that is, side-by-side measurements will exhibit a range of differences. There is some chance that any level of disagreement will be encountered, due merely to the statistical fluctuations of counting radioactive decays. The probability of encountering a very large difference between duplicates is smaller than the chance of observing a small difference similar to those that are routinely observed. It is important to recognize that a few duplicate results with high precision errors do not necessarily mean that the measurement system is flawed.

Ideally, the results of duplicates should be assessed in a way that allows for the determination of *what level of chance* is associated with a particular difference between duplicates. This will allow for the pre-determination of limits for the allowable differences between duplicates before an investigation into the cause of the large differences is made. For example, the *warning level*, or the level of discrepancy between duplicates which triggers an investigation, may be set at a five percent probability (or some other level, as desired). This level is a difference between duplicates that is so large that, when compared with previous precision errors, should only be observed five percent of the time. A *control limit*, where further measurements should cease until the problem is corrected, may be set at one percent probability or less.

A control chart for duplicates is not as simple as a control chart used to monitor instrument performance, as for a check source. This is because the instrument's response to a check source should be fairly constant with time. Duplicates are performed at various radon concentrations, however, and the differences between two measurements are expected to increase as radon levels increase.

Use of statistics such as the *relative percent difference* (RPD; difference divided by the mean) or the *coefficient of variation* (COV; standard deviation divided by the mean) can be used in a control chart for duplicate measurements at radon concentrations where the expected precision error is fairly constant in proportion to the mean, e.g., at levels greater than around 150 Bq m^{-3}. At lower concentrations, e.g., less than 150 Bq m^{-3}, a control chart may be developed by plotting these same statistics; however, the proportion of the precision error to the mean will be greater than the proportion at levels above 150 Bq m^{-3}. In either case, the assumption that the precision error is a constant fraction of the mean is a simplification and represents a conservative and convenient way to monitor precision. At concentrations less than about 70 Bq m^{-3} the LLD may be approached, and the precision error may be so large as to render a control chart not useful.

If the data from a particular group of measurements are to be used for a study, and it is desired to attach confidence limits for the precision errors to results, the *pooled standard deviation* can be calculated for ranges of different radon concentrations. A method of pooling results of duplicate detectors is outlined by the NCRP (NCRP 1985).

Control charts using a variety of statistics are described by the EPA (U.S. EPA 1993); a precision control chart using coefficient of variation and relative percent difference for concentrations greater than 150 Bq m^{-3} are described in this paper.

Before a control chart can be developed, it is necessary to know, from a history of making good quality measurements with the exact measurement system (detectors, analysis equipment, and procedures), the level of precision that is routinely encountered when the system is operating well or "in control." It is that "in control" precision error that forms the basis of the control chart, and upon which all the subsequent duplicate measurements will be judged. There are two ways of *initially* determining this "in control" level. The first, and preferable, way is to perform at least 20 duplicate pairs of measurements at each range of radon concentrations for which a control chart is to be prepared. For example, if you will only assess precision at concentrations greater than 150 Bq m^{-3}, you will need at least 20 pairs of measurements at concentrations greater than 150 Bq m^{-3}, to assess the "in control" level. The average precision error (RPD) should be the "in control" level, and measurements that were suspect should not be included.

The second way to initially set the "in control" precision error level is to use a level that has been used by others, and that is recognized by industry as a goal for precision, for example, a 10 percent COV (corresponding to a 14 percent RPD). After at least 20 pairs of measurements are plotted, it will become apparent whether the 10 percent COV (or 14 percent RPD) is appropriate for your system. If it is not, a new control chart should be prepared so that the warning and control limits are set at appropriate probability limits.

Sequential Control Chart Based on Coefficient of Variation

It can be shown (U.S. EPA 1984) that when the expected precision is a constant function of the mean, control limits can be expressed in terms of the COV (COV=S/Xm where S is the variance or the square of the standard deviation, and Xm is the mean or average of the two measurements). One method for obtaining percentiles for the distribution of the COV is to apply a chi-squared ($\chi 2$) test, where $\chi 2$ can be approximated as follows (Iglewicz and Myers 1970, McKay 1932):

$$\chi^2_{n-1} \approx B[(n-1)COV_n^2/(n+(n-1)COV_n^2)] \qquad \text{(Equation 1)}$$

where $B = n[1 + (1/COV^2)]$;

COV_n = the observed COV of the n^{th} pair (the pair that is to be evaluated); and

COV = the "in control" COV (e.g., 10 percent at levels greater than 150 Bq m^{-3}).

For duplicates, where n=2, Equation 1 becomes

$$\chi^2 \approx [2 + (2/COV^2)][COV_n^2/(2 + COV_n^2)] \qquad \text{(Equation 2)}$$

For a value of 0.10 for COV, it further reduces to

$$\chi^2 \approx 202[COV_n^2/(2 + COV_n^2)] \qquad \text{(Equation 3)}$$

Referring to a χ^2 chart, one learns that the probability of exceeding a χ^2 of 3.84 is only five percent. Inserting this value of 3.84 for χ^2 and solving for COV_n, produces a COV_n of 0.20. This level of probability forms the *warning*

level. The *control limit* corresponds to a χ^2 of 6.63 and a COV_n of 0.26, where the probability of exceeding those values is only one percent.

This sequential control chart should be used by plotting results from each pair on the y-axis, and noting the date and measurement numbers on the x-axis.

Sequential Control Chart Based on Relative Percent Difference

The RPD (or percent difference) is another expression of precision error, and is given by

$$RPD = [100|x_1-x_2|]/[(x_1+x_2)/2] \qquad \text{(Equation 4)}$$

For n=2,

$$RPD = COV\sqrt{2} \qquad \text{(Equation 5)}$$

The control limits for RPD can be obtained simply by multiplying the control limits for COV by the square root of two, or 1.41. This sequential control chart for RPD should be used in the same way as the control chart for COV, that is, with the vertical scale in units of RPD and the horizontal scale in units of date and measurement numbers.

Table 2 provides data from duplicate charcoal canisters (CCs) and electret ion chambers (EICs) that can be plotted on sequential control charts for relative percent difference. Assuming that an "in control" level for relative percent difference as shown by the average of previous duplicate results is a 14% RPD (corresponding to a 10% COV) at these concentrations, then the warning level would be set as a horizontal line at 28% and the control limit set at 36%. Table 2 shows that all duplicate CC results fall below the warning level, but one EIC result is greater than the warning level and one is greater than the control limit. In this case, the single duplicate result outside the warning level served as a signal to verify that all the EICs were being used strictly according to procedures (e.g., blowing off dust, ensuring temperature stabilization, etc.) but the result outside the control limit caused those two EICs to be taken out of operation, put into a low radon environment, and their voltage drops checked over several months for stability.

Interpretation of Precision Control Charts

The control chart should be examined carefully every time a new duplicate result is plotted. If a duplicate result falls outside the control limit, repeat the analyses if possible. If the repeated analyses also fall outside the control limit, stop making measurements and identify and correct the problem. If any measurements fall outside the *warning level*, use the "rule-of-thumb" guidance described previously in the section on Means Control Charts.

Note that the example control charts shown here are simplifications of actual conditions, because they are premised on the assumption that the precision error is a *constant* fraction of the mean concentration. In fact, the total precision error may best be represented by a different function of the mean concentration, for example, the square root of the concentration. The most accurate control chart can be rendered by a range control chart using the measurement uncertainty expressed as the standard deviation, s(x), expected *at the concentrations* where measurements are made. If the precision error is not a constant fraction of the mean, the control limits will not appear as straight lines, but may exhibit changing slope. However, methods discussed here present a conservative way to monitor, record, and evaluate precision error and are useful for comparing observed precision errors with an industry standard.

Minimum Detectable Levels

There is a variety of terms used to express the smallest amount of radioactivity that can be reliably measured. Each term has a specific meaning and is calculated differently. This section reviews some of these terms, and the purposes for which they can be used.

These limits are based on *counting statistics alone* and *do not include* other errors of precision including errors caused during manufacture, handling, and analysis. Because of this, the reporting of limits of detection using the following methods must be tempered with the user's knowledge of his/her system and its capabilities. It is instructional, however, to calculate the lowest detection limit *possible* based solely on counting statistics, and to

know that a practical detection limit lies somewhere close to or greater than that level. In addition, it is also useful to review the various terms and their definitions to allow meaningful comparisons among results reported by different programs.

Lower Limit of Detection (LLD): The lower limit of detection (LLD) is defined as "the smallest amount of sample activity that will yield a net count sufficiently large as to imply its presence" (Pasternack and Harley 1971, U.S. AEC 1972). It is based on work by Altshuler and Pasternack (Altshuler and Pasternack 1963), and Currie (Currie 1968). Altshuler and Pasternack termed this quantity "minimum detectable true activity" and Currie termed L_D, the *"a priori* detection limit." The LLD concept involves balancing the risk of "detecting" activity that is not actually there (Type I error) against the risk of missing activity which is actually present (Type II error). Values a and b represent the probabilities of these errors, respectively.

The derivation of the LLD can be described in the following way. (This discussion is patterned after Harley and colleagues [U.S. AEC 1972].) A series of measurements of background made at different times will produce different results. These results will be distributed as a Gaussian frequency distribution, with a spread indicative of the variability of the background. Some laboratories base their LLD only on this frequency distribution; for example, by using two times the standard deviation of the background, and estimating a 95 percent confidence limit from this value. This method does not take into account the fact that the measurements of true activity (with background subtracted) will also show a frequency distribution. In cases where the radon concentration measured is low, the two distributions will overlap.

The LLD can be approximated by:

$$LLD = (K_a + K_b)\,(s_o^2 + s_b^2)^{1/2}$$

where K_a = the value for the upper percentile of the standardized normal variate corresponding to the preselected risk for concluding falsely that activity is present (e.g., a value of 1.96 for an upper-tail risk of a = 0.025);

K_b = the corresponding value for the predetermined degree of confidence for detecting the presence of activity (1 - b); and

s_o and s_b = the standard deviation for the observed (true activity plus background) and background activity, respectively.

If the values of a and b are set at the same level (i.e., if one is willing to take the same risk for concluding falsely that activity is present as for missing the presence of activity), then $K_a = K_b$. The formula then reduces to:

$$LLD = 2K_a\,(s_o^2 + s_b^2)^{1/2}$$

If $s_o = s_b$ (i.e., the variability of the observed activity is the same as the variability of the background), then

$$LLD = 2^{3/2}\,K_a\,s_b$$

Assuming that the background follows a Poisson distribution, s_b is equivalent to the counting rate (r_b) divided by time (t_b). Thus,

$$LLD = 2^{3/2}\,K_a\,(r_b/t_b)^2.$$

The values of K are given as tables of the normal distribution in statistical texts: for a=0.05 and b=0.95, K=1.645, and $2^{3/2}K=4.65$.

Therefore, for a 95 percent confidence level, the LLD is set equal to 4.65 times the standard deviation of the background counts. This means that with this LLD, one accepts the chance of detecting activity when it is present 95 percent of the time but missing it five percent of the time. The value of K for a 50 percent chance shows that the LLD is zero if one is willing to accept a 50 percent chance of detecting activity when it is present.

The nature of the LLD should be kept in mind. It is an *a priori* estimate of the quantity of activity that will be detected with a given confidence.

The limitations of the LLD should also be considered. Foremost among these are the assumptions that $s_o = s_b$ and that the variability in the background is entirely Poisson. For example, with a background count rate of 1 cpm and a 50-minute counting time, the LLD is 4.65 $(.02)^{1/2}$, or 0.66 cpm. The counting rate for sample-plus-background is 1.66 cpm, so that its Poisson variance is 1.66/50, or 0.033. Approximating this by the variance of the background counting rate, 0.02, introduces an underestimate of 15 percent in the LLD. This underestimate is larger for a small number of background counts (low background counting rate combined with short counting times) and smaller for a larger number of background counts.

An alternate and more statistically sophisticated formula accounts for the case when repeated measurements of the blank yield significant variation (U.S. NRC 1986). This formula adds a term (Currie 1968):

$$LLD = 2.71 + 4.65s_b$$

In the case of stable blank measurements, however, the LLD can be calculated:

$$LLD = 4.65s_b$$

Note that both formulas apply only for equal blank and sample counting times. For unequal counting times (Strom and Stansbury 1992):

$$LLD = [3 + 3.29 (R_b t_g [1+t_g/t_b])^{1/2}]/t_g$$

where R_b = background count rate;

t_b = background count time; and

t_g = gross count time.

Note that the electret ion chamber manufacturer does not calculate the LLD using these formulas, which were developed for radiation counting. Users of electret systems should consult the manufacturer for details of the LLD approximations specific to electret ion chamber systems.

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Table 1. Data from known exposure measurements of continuous radon monitor for control chart analysis

"Known" Concentration, Bq m^{-3}	CRM A, Bq m^{-3}	RPD[a]
988	977	0.01
422	451	-0.07
1750	1846	-0.05
1184	1055	0.11
751	770	-0.02
455	496	-0.09
1617	1676	-0.04
1321	1370	-0.04
570	522	0.08
1506	1288	0.14
1569	1410	0.10

[a] RPD=the difference between the result of CRM A and the "known" concentration, divided by the "known" concentration.

Table 2. Data from charcoal canister (CC) and electret ion chamber (EIC) duplicate measurements

CC Results			EIC Results		
CC A	CC B	RPD[a]	EIC A	EIC B	RPD[a]
818	847	-0.04	1469	1040	0.34
333	355	-0.06	507	485	0.04
1743	1894	0.08	1987	1865	0.06
1291	1273	0.01	1402	951	0.38
703	736	0.05	803	770	0.04
477	500	0.05	518	477	0.08
1743	1339	0.03	1624	1684	-0.04
892	1025	-0.14	1384	1436	-0.04
585	585	0.00	862	844	0.02
1695	1491	0.13	574	559	0.03
1709	1413	0.19	1432	1476	-0.03

[a] RPD= the difference between duplicate results A and B, divided by their mean.