United States
Environmental Protection
Agency

National Air and Radiation
Environmental Laboratory
540 South Morris Avenue
Montgomery, AL 36115-2601

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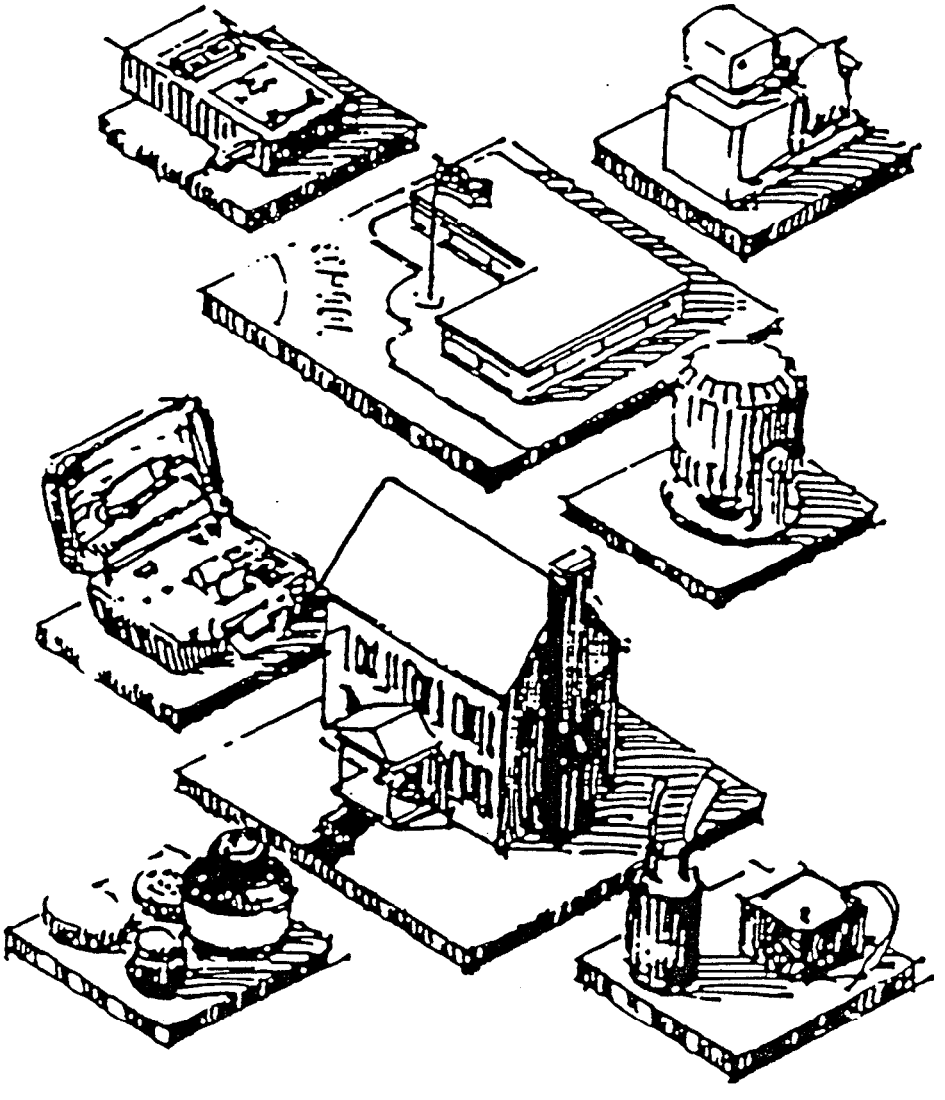
National Radon Proficiency Program

Guidance on Quality Assurance



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NATIONAL RADON PROFICIENCY PROGRAM
GUIDANCE ON QUALITY ASSURANCE
EPA 402-R-95-012

U.S. Environmental Protection Agency
Office of Radiation and Indoor Air
National Air and Radiation Environmental Laboratory (NAREL)
540 South Morris Avenue
Montgomery, AL 36115-2601

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NATIONAL RADON HEALTH ADVISORY

(September 1988)

Indoor radon gas is a national health problem. Radon causes thousands of deaths each year. Millions of homes have elevated radon levels. Most homes should be tested for radon. When elevated levels are confirmed, the problem should be corrected.

U.S. Public Health Service

U.S. Environmental Protection Agency

DISCLAIMER

This *Guidance on Quality Assurance* was prepared by the U.S. Environmental Protection Agency (EPA). The purpose of this document is to provide applicants to and participants in the Radon Proficiency Program (RPP) with the necessary information about the Program's policies, requirements, and procedures regarding quality assurance. The mention of laboratories, companies, individuals, trade names, or commercial products herein should not be interpreted as an endorsement or recommendation.

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A listing in the RPP does not confer Federal certification, licensing, or accreditation, and participants should **not** represent themselves as having such credentials.

The EPA reserves the right to release all information submitted by participants in the RPP or generated as a result of participation. This includes information and numerical performance data created as a result of the device performance tests conducted at EPA laboratories, an individual's measurement or mitigation exam results, and information relevant to a participant's history with the Program.

PREFACE

This *Guidance* is intended for use by participants in and applicants to the U.S. Environmental Protection Agency's (EPA) Radon Proficiency Program (RPP). The document provides guidance in the areas of quality assurance (QA) and quality control (QC) for applicants to and participants in the RPP.

To obtain an *Application* or other information about the Program, contact:

Radon Proficiency Program Information Service (RIS) at TEL: (800) 962-4684 or (334) 272-2797, FAX: (334) 260-9051, or e-mail: *mail10554@pop.net*

or write: RPP Quality Assurance Coordinator (RQAC)
c/o Sanford Cohen & Associates, Inc. (SC&A)
1000 Monticello Court
Montgomery, AL 36117

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The Privacy Act dictates: 1) the types of information the Federal government can collect from individuals, 2) how this information may be used, and 3) to whom this information may be disclosed. The Act also requires that individuals subject to information requests be informed of the following:

The information is being collected under the authority of Section 305 of Title III (Indoor Radon Abatement) of the Toxic Substance Control Act, 15 U.S.C. 2665. Collecting social security numbers, which are used solely for identification purposes, is also authorized by Executive Order 9397. The Indoor Radon Abatement provision of Title III directs the Environmental Protection Agency (EPA or Agency) to develop a program to evaluate the proficiency of radon mitigation and measurement service providers and provide information to the public on proficient service providers. Information obtained through the application form, testing, training, and other aspects of this Program will be used in the development and operation of this Program.

State and local governments are permitted access to an EPA on-line Proficiency Listing containing the names of individuals and organizations who have met the requirements of the Program, their addresses, and telephone numbers. This listing will be made available to the public upon request. EPA contractors and subcontractors who are engaged to assist the Agency in the performance of activities under this Program will maintain all information collected under this Program. Contractors and subcontractors will be required to maintain such information in confidence. All or part of the information collected under this Program may be disclosed to: 1) a member of Congress at their request, 2) appropriate law enforcement authorities if the information indicates a violation of law -- in connection with litigation involving the government in which the information is relevant, and 3) the appropriate Federal agency in connection with records management inspections.

Participation in this Program and furnishing requested information is voluntary, but failure to provide the information may preclude your participation in the Program and the listing of your name in the Proficiency Listing.

ACKNOWLEDGEMENT

This document was prepared for the U.S. Environmental Protection Agency's *National Radon Proficiency Program Manager*, by Melinda Ronca-Battista of Sanford Cohen & Associates, under Contract 68D20185. Many persons provided useful suggestions and generously provided thorough reviews and comments. In particular, the members of the American Association of Radon Scientists and Technologists Technical Committee provided extensive comments in their effort to ensure that this document provides clear, practical, and state-of-the-art guidance on quality assurance in radon measurements.

1. Introduction

This document provides guidance in the areas of quality assurance (QA) and quality control (QC) for participants in the U.S. Environmental Protection Agency's (EPA) National Radon Proficiency Program (RPP) (U.S. EPA 1995a). The QA practices described in this report are necessary and expected components of high quality radon and radon decay product measurements. The specific QC measurements, recordkeeping, and analysis methods outlined here are consistent with routine procedures for radiation measurements and standard practices by Federal laboratories and contractors.

This report contains recommendations for a variety of organizations involved in the radon measurement industry, including organizations who do not analyze detectors, but who deploy devices and provide clients with measurement results (see Section 4.2). The report is designed to provide a framework of QA practices that can be modified, and added to, according to the specific needs of the measurement program.

This document first presents a general introduction to quality terminology, including quality management and quality systems, and introduces current national and international guidance on these topics. Section 2 reviews the definitions of QA and QC specifically as they relate to radon measurements, and presents some important considerations regarding quality management. Basic elements of a quality assurance program are reviewed in Section 3. Section 4 defines the QA responsibilities of analytical and residential service organizations. Quality management, including the responsibilities of management regarding quality, the role of a quality assurance officer, and training are discussed in Section 5. Section 6 describes quality assurance documentation, reporting, and chain-of-custody, including standard operating procedures and audits. Section 7 provides guidance for performing calibrations. Guidelines and terminology for specific quality-control measurements are described in Section 8. The concluding chapter (Section 9) describes recommended components of a quality assurance plan (QAP). Appendix A provides methods for analyzing QC measurements, including preparation of control charts and assessing lower limits of detection. Appendix B reviews information recommended by EPA for inclusion in a measurement report, and Appendix C provides a list of acronyms. Finally, a Glossary with an index defines terms used in this report.

These guidelines are recommendations for the radon measurement industry as a whole. They are specifically intended to guide RPP participants in meeting their QAP requirements. EPA recognizes that this guidance will therefore serve as de facto required practices for anyone operating a radon measurement business in the U.S. Because of this, and because these guidelines are meant to serve the public and the measurement industry, EPA is interested in receiving constructive comments about this guidance. If you have comments, please address them to:

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2. Quality Assurance: Definitions and Philosophy

The International Organization for Standardization (ISO) defines a **quality system** as the organized structure, responsibilities, procedures, processes, and resources needed for implementing **quality management** (ANSI/ASQC 1994). Quality management includes defining roles and responsibilities, planning the level of quality provided to the customer, clearly defining objectives for quality, and defining accountability and reporting. It is implemented at the management level, and focuses not only on systems, policies, criteria, documentation, and procedures, but also on program structure, which includes the delegation of authority and responsibility needed to ensure adequate quality of the product.

Quality Assurance (QA) is defined by the American Society of Testing and Materials (ASTM) as all activities required to provide the evidence needed to establish confidence that data provided are of the required precision and accuracy. The U.S. EPA (U.S. EPA 1995b) similarly defines QA as "an integrated system or program of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality."

ASTM defines **Quality Control** as the process through which an organization measures its performance, compares its performance with standards, and acts on any differences (ASTM 1988). In other words, the intent of QA/QC is to maintain a good quality-measurement program and to ascertain and document the quality. Quality control consists of measurements and associated activities needed to control and assess measurement-program quality, as measured by estimated precision, relative bias, the lower limit of detection (as well as other factors, such as the rates of data entry errors) on an ongoing basis and to revise procedures to improve quality if necessary.

QA/QC must be an integral part of any measurement program. The results of measurements that are not associated with a program to ensure and document their reliability are useless, because the validity of each measurement rests upon the QA program. 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 and not know it. In either case, the lack of adequate documentation makes it impossible for their measurement results to be as incontrovertible as they need to be.

There are benefits of conducting a QA program other than substantiating the adequacy of each measurement result. First, making some of the types of measurements that are described in this document will add greatly to an operator's understanding of the methods employed. This will enable organizations to improve their techniques, or to justify results that they would not otherwise understand. 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 includes procedures for monitoring the performance of 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 event of a legal dispute.

A credible measurement program cannot exist without QA activities. Measurement companies are providing results to clients that may become critical to the sale of property. If the measurement result is questioned, the tester may be liable 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 substantiated validity of the result is only possible in a program that implements appropriate QA practices.

3. Elements of a Quality Assurance Program for Radon and Decay-Product Measurements

This section briefly describes elements of a program for planning, measuring, and ensuring the quality of radon and/or decay-product measurements. Each of these elements is discussed in great detail elsewhere; this section introduces the activities that should be included in a quality assurance program and that comprise the quality system. The necessary components of a Quality Assurance Plan are described in Section 9 and are more specific than the five broad categories of activities described in this section.

3.1 QUALITY MANAGEMENT: COMMITMENT, QUALITY ASSURANCE PLANNING, AND QUALITY OBJECTIVES

No endeavor will be completely successful without the interest, involvement, and commitment of management. The role and responsibilities of management regarding QA, including QA planning and methods of reporting and oversight, should be documented. Small organizations with limited personnel and resources may have an advantage regarding QA management, because one person may be responsible for all company policies. In this case, the commitment of management ensures the commitment of the organization. Quality-assurance management is discussed in Section 5.

3.2 QUALITY ASSURANCE DOCUMENTATION

There are many forms of documentation that are important in planning and implementing quality-control procedures. Most of these can be referenced in the QA Plan (QAP), which is a document that includes specifics on those procedures (chain-of-custody, quality control measurements, etc.) that are used to ensure that the planned quality is achieved. General QA documentation is discussed in Section 6, and QA Plans are discussed in Section 9.

3.3 MEASUREMENT SYSTEM CALIBRATION

Measurement equipment requires initial and periodic calibrations. General guidelines for calibrations are described in Section 7.

3.4 INTERNAL QUALITY CONTROL AND ASSESSMENT

There are many quality-control measurements that are performed to assess the quality of procured material and equipment, the continued performance of instruments and procedures, estimated errors of imprecision and bias, and contributions of field and laboratory background. Internal quality-control measurements are described in Section 8. Appendix A discusses the analysis of quality-control measurements.

3.5 CORRECTIVE ACTION

Corrective action may be necessary as a result of unsatisfactory quality control results, client dissatisfaction, audit reports, or for other reasons. The responsibility for taking action and for verifying that the action was successful in correcting the problem should be documented for various personnel and categories of activities. Corrective action for specific occurrences (e.g., quality control results outside of specified numeric bounds, more than a specified rate of data input errors, etc.) should also be documented, along with the timeframe for action and the person responsible. Corrective action procedures are under the oversight of the QA Officer. Control charts for quality control are described in Appendix A.

3.6 TRAINING

Training is an important quality issue. The responsibilities, goals, and schedules for training, both on general procedures and on specific quality-assurance activities, should be clear and documented. Training issues are generally addressed in Section 5.3.

4. Responsibilities of RPP Participants

As defined in the EPA Radon Proficiency Program Handbook (U.S. EPA 1995a), an **analytical** radon measurement service provider performs the analysis or reading of the radon measurement devices. A **residential** service provider is an individual who offers radon measurement services, but relies on an analytical organization for analysis or reading of the measurement device. Services provided by a residential service provider may include consulting with the homeowner or realtor, packaging, placing and retrieving measurement devices, and preparing and issuing measurement reports (using the values provided by the analytical organization). Over-the-counter retailers of measurement devices are not considered analytical or residential service providers, because they merely make the devices available and provide no services to the consumer.

It is possible for an organization to function as an analytical organization and employ individuals listed in the RPP to provide residential measurement services. The roles and responsibilities of analytical and residential service providers in terms of quality assurance are described in this section and outlined in Exhibit 4-1. The requirements in terms of developing and implementing a QA Plan are described in Section 9.

4.1 ANALYTICAL SERVICE PROVIDERS

4.1.1 Roles

Analytical service providers analyze the detectors or read the monitors and produce the final result that is reported to clients. Any organization or individual that obtains the final results from continuous radon (CR) or working level monitors (CW), performs grab measurements made with the pump-collapsible bag (GB) method, the grab activated charcoal (GC) method, the scintillation cell (GS) method, or the grab working level (GW) method is classified as an analytical service provider. An organization or individual that uses an electret reader to obtain results from electret ion chambers (EL or ES) is an analytical service provider. Similarly, the analysis of detectors such as alpha track detectors (AT), activated charcoal adsorbers (AC), charcoal liquid scintillation devices (LS), pump-collapsible bag devices (PB), radon progeny integrated sampling units (RP),

Exhibit 4-1
Responsibilities of Analytical and Residential Service Providers

Responsibility	Analytical Service Provider	Residential Service Provider
Preparing, updating, and implementing a QA Plan (see Section 9).	**X**	**X**
Obtaining copies of the analytical organization's QA Plan, including schedules of calibration, and ensuring their adequacy (see Sections 7 and 9).		**X**
Calibrating analysis equipment as recommended by the manufacturer or at least once every 12 months, as described in EPA's *Indoor Radon and Radon Decay Product Measurement Device Protocols* (U.S. EPA 1992a).	**X**	
Conducting laboratory/field background measurements at a rate in accordance with the recommendations in Section 8.2; recording the results in control charts and other documentation; and using the results to calculate (for analytical service providers) or check against (for residential service providers) the lower limit of detection.	**X**	**X** (Laboratory background measurements and calculation of LLD are not expected)
Employing a QA Officer who is responsible for conducting audits, monitoring QC data, the oversight and accountability for corrective action, and reporting to management (see Section 5.2).	**X**	**X**
Conducting known exposure or cross check measurements at a rate in accordance with the recommendations in Section 8.3.	**X**	**X**
Conducting side-by-side duplicate or comparison measurements at a rate in accordance with the recommendations in Section 8.1.	**X**	**X**
Making available the results of laboratory background measurements, the lower limit of detection, and estimates of precision (see Appendix A) to those service organizations using the analytical service provider.	**X**	
Conducting routine instrument performance checks, including battery, electronics, pump flow rates, and the stability of the system using a check source or cell, as the instrument configuration allows (See Section 8.4).	**X**	**X** (for residential service providers using active instruments, as specified by the manufacturer and analytical organization)
Maintaining a documented system to track measurement devices (chain-of-custody), locations, dates, clients, methods/laboratories, and results (see Section 6).	**X**	**X**
Conforming to EPA guidelines for conducting measurements, reporting measurement results, and providing information to clients (Appendix B).	**X**	**X**

and unfiltered track detectors (UT) classify an organization or individual as an analytical service provider. The RPP listings are device-specific (U.S. EPA 1995a).

4.1.2 Responsibilities

Analytical service providers are responsible for the following activities:

- Preparing, updating, and implementing a QA Plan that adheres to the guidelines described in Section 9 of this report.
- Ensuring that all equipment is calibrated and re-calibrated according to the schedules described for that method in this report, by the manufacturer, or in EPA's *Indoor Radon and Radon Decay Product Measurement Device Protocols* (U.S. EPA 1992a); see Section 7.
- Conducting background measurements (laboratory and field, as appropriate; see Section 8.2), recording the results in control charts and other relevant documentation, and using the results to calculate the lower limit of detection.
- Employing a QA Officer who is organizationally independent of the analysis and distribution processes. The responsibilities of a QA Officer are described in Section 5.2.
- Conducting routine and on-going measurements to assess bias according to the EPA recommendations (see Section 8.3), and recording and analyzing the results (see Appendix A).
- Conducting routine and on-going measurements to track precision error (see Section 8.1), recording the results in control charts and other documentation (see Appendix A), and using the results to estimate precision.
- Making available the results of background measurements, the lower limit of detection, and estimates of precision error (see Appendix A) to residential service providers using the analytical organization regularly.
- Conducting routine instrument performance checks (see Section 8.4).
- Maintaining a documented system to track measurement devices (chain-of-custody), locations, dates, clients, methods/laboratories, and results, as described in Section 6.

- Conforming to EPA guidelines for conducting measurements, reporting measurement results, and providing information to clients (see Appendix B and U.S. EPA 1993).

4.2 RESIDENTIAL SERVICE PROVIDERS

4.2.1 Roles

Residential service providers distribute measurement devices to clients and report results, but do not analyze the detectors or generate the result that is reported to the client. These individuals may, however, have considerable impact on the measurement process and result. Residential service providers must exercise skill and judgement in assessing measurement conditions, deploying and retrieving devices, and communicating with clients.

4.2.2 Responsibilities

The QA-related responsibilities of residential service providers are to ensure that their activities do not contribute to any degradation of the measurement quality (such as by excessive storage time or storage in unsuitable environments, improper placement, errors in reporting or recordkeeping, or other factors), and to understand and monitor the performance of their measurement system, which includes their operation as well as the operation of the analysis laboratory that they are using. There should be clear and open communication between residential service providers and the analysis laboratory they use. Specific requirements of residential service providers include:

- Preparing, updating, and implementing a QA Plan according to the guidelines described in Section 9 of this report.

- Reviewing the analytical organization's QA Plan.

- Conducting field background measurements (as appropriate; see Section 8.2) and recording the results in control charts and other relevant documentation.

- Employing a QA Officer (see Section 5.2).

- Conducting routine and on-going measurements to assess bias according to the EPA recommendations (see Section 8.3), and recording and analyzing the results (see Appendix A).

- Conducting routine and on-going measurements to estimate precision error, as feasible, (see Section 8.1) and recording the results in control charts and other documentation (see Appendix A).

- Conducting routine instrument performance checks according to directions from the analytical service provider (see Section 8.4).

- Maintaining a documented system to track measurement devices (chain-of-custody), locations, dates, clients, methods/laboratories, and results, as described in Section 5.

- Conforming to EPA guidelines for conducting measurements, reporting measurement results, and providing information to clients (see Appendix B and U.S. EPA 1993).

5. Quality Management

5.1 MANAGEMENT COMMITMENT AND RESPONSIBILITY

A primary concern of any organization must be the quality of its products and services. In order to meet its objectives, the organization should function so that the technical, administrative, and operational factors affecting the quality of its products and services is known and is under control. An effective quality-management system should be designed to satisfy customer needs and expectations, while serving to protect the organization's interests (ANSI/ASQC 1994a). Quality management is just as important in small organizations as in large ones. Small organizations may, however, find that communicating and implementing changes in policy-related procedures to be simpler than in large organizations because fewer people are involved. In addition, small organizations are often comprised of highly motivated people who are committed to the success of the company. Since small organizations generally consist of people with multiple responsibilities, they are likely designate their single technical expert as the QA Officer. In these cases, it may be helpful to obtain the services of an outside expert to serve as an auditor for several hours each quarter, in order to ensure an outside review of procedures.

The responsibility for and commitment to quality in delivered services belongs to the highest level of management. If the organization's management does not provide an environment which supports a QA program and in which concerns and suggestions for improving quality can be raised, the quality of the measurements will suffer. Management should foster a "no-fault" attitude to encourage the identification of quality issues and problems (U.S. DOE 1991). The terms continuous improvement and quality improvement refer to a structure and environment in which improvement is considered part of the daily work and resources are provided for eliminating problems at their source (NIST 1995). The quality policy of the organization should be a statement that is realistic, implemented, and documented in the QA Plan or other written materials.

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. The term "management

by fact" refers to the use of quality control data, market data, and other information and their analysis as input to the organization's assessment and improvement.

Accountability is an important part of QA management. Each person in the organization needs to understand the organizational framework in order to understand, and be accountable for, his/her own QA responsibilities.

The term "quality system" refers to the organization's structure and function relating to managing, overseeing, and improving quality. The system includes documentation (quality assurance plans, procedures, logs and accountability for their maintenance and review) and procedures for audits and reviews for quality assurance and quality control. The national standard for quality systems (ANSI/ASQC 1994a) describes elements of quality management. These include:

- Management and organization.
- Quality system and description.
- Personnel qualification(s) and training.
- Procurement of items and services.
- Documents and records.
- Computer hardware and software.
- Planning.
- Implementation of work processes.
- Assessment and response.
- Quality improvement.

These elements are essentially equivalent to the requirements found in other standards, including the ISO 9000 series (ANSI/ASQC 1994a) and ASME NQA-1 (ASME 1989). These elements of quality management may be described in the QA Plan or in a separate quality-management plan.

5.2 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 high quality data. This person may have these duties as a sole responsibility or, in smaller organizations, may have other responsibilities. The QA Officer should be assimilated into the organization, reporting to the lowest level at which he/she can be effective

and be unbiased in objectively serving the needs of the organization. Even organizations consisting of one or two people need to designate the responsibilities of a QA Officer to someone involved in the day-to-day operations. In addition, however, an outside expert can be used to review statistical methods, procedures, training, or other QA issues.

The QA Officer assists management in interpreting and developing the QA policy for the organization. The QA Officer also provides technical support and review, and approves QA products for the top manager. The QA Officer should, at a minimum, be responsible for:

- Developing and ensuring the implementation of a QA program, including procedures for chain-of-custody, statistical analyses, and data verification, among others, which will help the organization to meet the authorized standards of quality at minimum cost.
- Advising and assisting management in the installation, staffing, and supervision of a QA program.
- Monitoring QA/QC activities of the laboratory to determine conformance with authorized policies and procedures and with recognized industry practices.
- Making appropriate recommendations for correction and improvement of QA/QC activities, as necessary.
- Assisting in the development of specifications and acceptance criteria for purchased items and materials.
- Seeking out and evaluating new ideas and current developments in the field of QA, and recommending means for their application wherever advisable.
- Advising management in reviewing technology, methods, and equipment with respect to quality aspects.

In addition, the organization's QA Officer needs to have sufficient authority and responsibility to exercise whatever oversight is necessary to assure that:

- All data-collection activities are covered by appropriate QA planning documentation (such as in the QA Plan, as discussed in Section 9).

- All routinely used procedures that impact data quality are documented in standard operating procedures (SOPs) that are complete and have been reviewed and approved by both management and the staff responsible for implementing those procedures (see Section 6.1.1).

- Audits/reviews are done to assure adherence to approved QAPs and to identify deficiencies in QA/QC systems.

- Adequate follow-through actions are implemented in response to audit/review findings.

- All laboratory, field, or office personnel involved in data collection have access to any training or QA information needed to be knowledgeable in QA requirements, protocols, and technology.

In implementing these oversight 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.

5.3 QUALITY ASSURANCE TRAINING

All personnel involved in any function affecting data quality (detector custody, sample analysis, data reduction, and QA) should receive training in their appointed jobs to contribute to the reporting of complete and high quality data. The expectations and qualifications for each position should be documented (e.g., as in a job description). The QA Officer is responsible for periodic reviews of the requirements for training.

6. Quality Assurance Documentation and Reporting

6.1 DOCUMENTATION

6.1.1 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 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. A schedule and responsibility for reviewing and updating SOPs should be documented as one of the QA Officer's responsibilities.

Anyone performing radon measurements should have a written, device-specific SOP in place for each radon measurement system used. An SOP must include specific information describing how to operate and/or analyze a particular measurement device. Organizations that analyze devices should develop their own SOP or adapt manufacturer-developed SOPs for their devices. Organizations that receive results from a laboratory should have a device-specific SOP for each brand/model/type of device that they use. In addition, both analytical and residential service providers need to document their procedures for validating data (including client information) and preparing reports.

6.1.2 Record keeping and Chain-of-Custody

There are sources of error other than errors inherent in the measurement process. Inadequate recordkeeping can lead to errors such as transposing results from different locations, or misplacing results or detectors. There are computer spreadsheets and other programs available that can be adapted for many uses and large quantities of data. 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. A very useful tool in large operations is the bar-code system.

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 immediately following exposure, a daily check that all detectors received have been shipped/analyzed may be appropriate.

Logbooks are 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 entered in pen. Every entry should include the name of the person making the entry and the date. Any relevant printouts or plots should be photocopied and pasted into the logbook. Such a log can serve as an invaluable record, with all relevant information in one place.

The following items should be included in a separate QA logbook for each active instrument or passive method:

- Equipment calibration records (for analytical service providers), including:
  - The date of the calibration and the date the calibration expires, as appropriate.
  - The facility where the calibration was performed.
  - The procedures used (an SOP or calibration report can be referenced).
  - Results.
  - Changes in calibration factors implemented.

- Laboratory background measurements (for analytical service providers), including:
  - The date of the background measurement.
  - The location and type of measurement (e.g., aged air or nitrogen).
  - The procedures used (an SOP can be referenced).
  - Results.
  - Changes in LLD or background values.

- Field background measurements (for both analytical and residential service providers), including:
  - The date and location of the field background measurement.
  - The procedures used (appropriate documentation can be referenced).
  - Results.
  - Changes implemented because of the results.

- Results of all QC measurements (for both analytical and residential service providers), including:
  - Results of comparison measurements (for users of active instruments).
  - Results of duplicate measurements.
  - Results of spiked measurements.

- Routine instrument performance checks (for analytical and some residential service providers using active devices), including the dates and results of
  - Battery checks/replacement.
  - Check source/cell measurements.
  - Pump flow-rate measurements.
  - Self-diagnostic checks.

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

Each organization should derive its own system for tracking measurements. Residential service providers may use a logbook or a system of duplicate copies of data sheets to record the information gathered and generated for each measurement. Information stored for each measurement should include:

- A copy of the final report, including the measurement results, and the statement (or reference to the statement in the SOP) outlining any recommendations concerning retesting or mitigation provided to the client.

- The address of the building and room numbers to identify the location of the measurement. It may be useful to diagram the test area, noting the exact location of the detector.

- Exact start and stop dates and times of the measurement duration.

- A description of the device used, including its manufacturer, model or type, and identification (serial) number.

- A description of the condition of any permanent vents, such as crawl-space vents or combustion-air supply to combustive appliances.

- The name and RPP identification number (U.S. EPA 1995a) of the providers used to analyze devices.

- The name and RPP identification number (or State license number) of the individual who conducted the test.

- A description of any variations from, or uncertainties about, standard measurement procedures, closed-building conditions, or other factors that may affect the measurement result.

- A description of any non-interference controls used and copies of signed non-interference agreements.

- A record of any QC measures associated with the test, such as results of simultaneous measurements.

Regardless of the system used, SOPs for tracking the detectors (part of detector custody) should be written, adhered to, and revised as appropriate. All personnel should be trained and should understand the importance of maintaining proper correlation of information with the detector and measurement result.

Computer files should be copied regularly onto backup disks to ensure against data loss. Retention time and location for different types of records should be specified in an SOP.

6.2 DATA VALIDATION

Each step in the process between obtaining the original counts, tracks, or voltage losses and the final results reported to clients should receive some data validation. In general, at least several percent of each phase of the data should be checked. Handchecking is sufficient if it is done conscientiously (e.g., calculations are performed again on a hand-calculator, information is compared field by field, and these procedures are documented). There must be a record of which files 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.

6.3 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. These audits may be formally specified in a contract, or consist of less formal on-site visits or written requests for QC data and procedures. In any case, all logbooks and QA records should be easily available when not actually in use in the field. Both residential and analytical service providers should maintain records appropriate for their activities in the event of an audit or a request for information.

The focus of QA audits should be on the following topics:

- The existence and adequacy of a written and signed QA Plan (see Section 9) for all measurement methods and operations.
- The performance of measurements to assess precision, their results, and how frequently they are performed.
- The performance of measurements to assess bias, their results, and how frequently they are performed.
- The performance of background measurements, their results, and how frequently they are performed.

- The proper recording and analysis of QC measurements, including the use of control charts.
- The operating conditions of all equipment.
- The existence of SOPs (see Section 6.1.1) for each measurement method and operation.
- The records and the person responsible for preventive maintenance on all equipment.
- The existence of a detector tracking (custody) procedure.
- The existence of adequate records for tracking measurement location, condition, operator, etc.
- An adequate system for data validation, including records, procedures, and corrective action in the case of discovery of errors.
- The conditions under which detectors and equipment are stored (e.g., low humidity, radon concentration).
- Documentation of the specific serial numbers of the equipment or counters used in each analysis.
- The backups of all computer files.
- Corrective action procedures and how they are implemented.
- The complete records of any changes in materials or technicians.

For analytical organizations, audits should be conducted on the topics described above, as well as on:

- Appropriate client reporting, including use of the LLD as calculated from laboratory background measurements (which may change over time), appropriate use of significant figures, and furnishing clients with relevant information about what their measurement results mean (see recommended information in Appendix B).

- The calibration of the equipment and whether it is done in conformance with the QA Plan.

- The records and results from performance evaluations (Federal, State or industry).

Internal audits may be conducted by the QA Officer or his/her designee. Audits should be performed by someone not having direct authority or responsibilities in the areas being audited (U.S. NRC 1991). Checklists prepared by the QA Officer may be helpful during the audit.

6.4 QUALITY ASSURANCE REPORTING

There should be periodic reports to management on the results of QC measurements, reviewing any problems that were encountered and their solutions, or proposed solutions. These reports should be included in the QA logbooks and be available during audits. At a minimum, there should be one report after every six months of operation.

7. Calibration

The term **calibration** refers to the process of determining the response of an instrument (or measurement system) to a series of known values over the range of the instrument (or measurement system). This process results in conversion factors relating instrument or system response (in counts, voltage loss, or track density per unit of time) to radon or decay product concentrations. Before utilizing any given calibration facility, RPP participants and others should consider the facility's capability to provide the calibration services being sought. The following provides guidance for designing a calibration program and selecting a facility.

Calibration, as referred to in this report, 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 (Ra-226) standard. NIST produces Standard Reference Material (SRM) Ra-226 solutions that may be used to produce working laboratory standards for radon-222. There is no SRM for radon. General procedures for producing these working standards are described by the NCRP (NCRP 1988), EPA, and NIST (NIST 1990). These working standards of radon are usually constructed by bubbling nitrogen or another 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 and measurements, 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.

The U.S. Department of Energy Environmental Measurements Laboratory conducts an international laboratory intercomparison program (U.S. DOE 1985; U.S. DOE 1994). In this intercomparison program, radon concentrations are measured in a controlled environment (radon calibration chamber) using equipment that has been calibrated by exposure to concentrations produced from a NIST Ra-226 standard using a quantitative gas-transfer system. Several commercial calibration facilities in the U.S. participate in this program, and with careful recordkeeping have established traceability to this international de facto standard.

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 (see Section 8.3).

The term **measurement-assurance program** refers to activities designed to relate a measurement to national standards, and to establish the uncertainty of values reported by the measurement. Useful information for establishing or evaluating a measurement assurance program can be found elsewhere (NBS 1985, NCRP 1985, ANSI/ASQC 1994a, ANSI 1994b). Definitions and nomenclature can be found in American National Standards Institute (ANSI) documents (ANSI 1978, ANSI/ASQC 1987, ANSI 1994b, ASTM 1988, ISO 1990).

Annual calibrations are required of RPP participants (U.S. EPA 1992a), but the measurement methods and the magnitude and type of the measurement program, as well as whether equipment or procedures have changed since the last calibration govern how detailed the calibration needs to be. For example, a radical change in instrument configuration may necessitate calibrating to at least three concentrations. If equipment and procedures remain unchanged since the previous calibration, however, and the instrument's response is well-established, a single-point calibration plus background measurements may be sufficient.

The range of environmental conditions (temperature, humidity, changing concentrations and conditions, air flow) under which measurements are routinely or expected to be performed should be considered when forming a plan for calibration. Environmental conditions that may effect the measurement result should be measured, and be maintained as stable as possible during the calibration. The QA Officer and anyone else familiar with the limitations or peculiarities of the measurement system should provide input to how the calibrations are to be performed.

7.1 THE CALIBRATION FACILITY

The EPA strongly recommends that RPP participants obtain calibration services from facilities that have successfully participated in recent laboratory intercomparison exercises such as those hosted by the U.S. DOE EML (U.S. DOE 1994) at their laboratory in New York. The results are published with coded participant identifications; the calibration facility should provide clients with

a copy of the EML report identifying their facility's code and any supplementary information regarding their most recent intercomparisons.

Commercial calibration facilities vary in their design, radon source, and ability to generate and control radon and decay-product concentrations and other environmental parameters. Calibrations should be performed at concentrations that are high enough to provide sufficient signal, but low enough to ensure that concentrations routinely measured (e.g., less than 10 pCi/L or about 400 Bq/m^3) can be considered to be within the range of linearity of the calibration. The QA Officer should review the capabilities of the facility to ensure that it can meet the objectives for the calibration.

7.2 DEVELOPMENT OF A CALIBRATION PLAN

The agreement about how the calibration is to be performed should be as specific as possible, so that all the needed information is obtained during the same operation. The calibration facility may have established procedures; the QA Officer should carefully review these procedures prior to initiating the contract.

A calibration plan developed for each calibration should specify:

- The number/types/serial or i.d. numbers of the equipment to be calibrated.
- The radon concentrations or range of radon concentrations, and the number of devices to be exposed at each concentration.
- Durations of exposure.
- Other factors that affect results, including equilibrium ratios, temperature, humidity, and storage conditions or durations.
- Specific protocols for handling/opening/operating the devices, including unexposed chamber and trip blanks, as appropriate.

This plan should be reviewed and agreed to by the calibration facility prior to initiating the measurements.

The QA Officer should be prepared to analyze, report to management, and use the information obtained during the calibration. The calibration operation should provide useful information regarding the systematic error (bias) of the measurements of various concentrations under various conditions. If multiple simultaneous measurements are made, information about the random component of error (precision error) will also be obtained. The QA Officer is responsible for ensuring that this information is used appropriately, including changing calibration factors if warranted. The calibration plan should ensure that sufficient measurements are made to warrant changing calibration factors if necessary based on the single operation, or have contingency plans for repeat measurements at the same facility if there is a need to resolve an uncertainty.

The QA Officer is responsible for ensuring that the calibration results are completely documented, including the conditions, concentrations, unusual occurrences, and results.

7.3 CALIBRATION RECORDS

Calibration records should be maintained by the QA Officer, and be available for inspection by management, potential clients, and auditors. Labels should be affixed to active instruments listing the calibration facility, the calibration date, initials of the measurement organization's QA Officer (or person designated by the QA Officer), and the projected date for the next calibration.

8. Quality Control

QA is an umbrella term that includes many activities designed to ensure the validity of measurements and measure their quality. The measurements that are made for the purpose of assessing and monitoring data quality are called QC measurements. The QC measurements described here are those that are recommended specifically by EPA and others for radon measurements. Guidance for QA in radon or related measurements can also be found in documents written by the American National Standards Institute (ANSI 1989), the National Council on Radiation Protection and Measurements (NCRP 1988) and the American Association of Radon Scientists and Technologists (AARST 1994). Guidance for accreditation of laboratories used by the American Association for Laboratory Accreditation (ISO 1990) is available, and the recommendations in this section are consistent with that guidance.

8.1 MEASUREMENTS TO MONITOR PRECISION ERRORS

Duplicates are defined as co-located measurements, in which side-by-side detectors measure over the same time interval. Replicate measurements, consisting of more than two simultaneous side-by-side measurements, can be used to estimate the precision error of the system and are especially useful initially and whenever the measurement system is altered. The purpose of making duplicate measurements is to track over time the variation(s) that are observed between two identical measurements of the same concentration. A program of performing duplicate or replicate measurements allows the organization to monitor the component of measurement error caused by random differences in devices and/or the measurement process. Some precision error is unavoidable, and may be due to the detector manufacture or configuration, inconsistent 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.

The ideal estimate of precision is that which is inherent in the entire measurement system. This includes random component(s) of error introduced during shipping, distribution, storage, placement, and report generation. Different organizations may be involved in only a portion of this measurement system; for example, some analytical service providers may sell or lease detectors to residential service providers and never or rarely perform actual field measurements.

Each measurement organization (e.g. even if they are a residential service provider or an analytical organization that does not perform field measurements) should perform some measurements to estimate precision error. In addition, clear and frequent communication between analytical and residential service providers will help track the quality of the measurements and quickly identify any changes.

Specific recommendations for different types of organizations are described in the following sections.

8.1.1 Duplicate Measurements for Analytical Service Providers Distributing Passive Detectors Directly to Homeowners

Analysis laboratories that sell detectors directly to homeowners can estimate and track the precision inherent in their entire measurement system, including distribution. Duplicate measurements for passive detectors should be side-by-side measurements made in at least 10 percent of the total number of measurement locations, or 50 pairs each month, whichever is smaller. The locations selected for duplication should be distributed systematically throughout the entire population of samples. Groups selling measurements directly to homeowners can do this by providing two measurements, instead of one, to a random selection of purchasers, with instructions for the measurements to be made side-by-side.

The measurement locations selected to receive duplicate detectors should be distributed among all measurement locations. In other words, it is not adequate to place all duplicate devices in one 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, traveling 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 inherent in all the measurements. One way to implement this program is to target every tenth detector or client number to receive a duplicate.

An exception to this rule is when all the systematically selected locations that receive duplicates have radon concentrations less than 4 pCi/L (about 150 Bq/m^3). In this case, a portion of the duplicates should be placed in environments with higher concentrations. This can be accomplished by periodically placing side-by-side devices in an environment with radon concentrations known to be elevated.

8.1.2 Duplicate Measurements for Analytical Organizations Selling Passive Detectors to Residential Service Providers

An analysis laboratory must estimate the precision error inherent in its portion of the measurement operation by analyzing devices that have been exposed to the same radon environment. The QA Officer should manage a program to regularly place at least two detectors side-by-side in the same radon environment. The QA Officer should determine the frequency of duplicate measurements, but they should be systematically distributed (e.g., every twentieth analysis should be a duplicate) so that the entire range of handling, technicians, background, and other laboratory conditions impact the duplicate analyses just as those conditions impact the normal analyses of detectors. A range of radon concentrations, spanning the concentrations usually encountered in the field, should be used. In addition, the QA Officer is responsible for making these results available to the residential service providers that use the analysis services, and for obtaining the results of duplicates arranged by the residential service provider.

The organization performing analyses should measure duplicate (or replicate) devices at a frequency designed to ensure that a reliable estimate of laboratory analysis precision error is obtained. A rate of at least 25 pairs per month or five percent of the total number of devices analyzed (whichever is smaller) may be sufficient; this rate is for the analysis portion of the measurement system only, and assumes that additional duplicate devices as exposed by the residential service organizations will also be processed by the same analysis laboratory.

8.1.3 Duplicate Measurements for Residential Service Providers Using a Passive Detector System

Residential service providers perform activities that may impact the precision of the measurement. These include handling, storage, shipping, deployment and data transcription. In fact, it is the residential service provider that bears the responsibility of the critical portion of the measurement—exposure—and often the ultimate reporting of the result to the client. Because of this, it is important that residential service providers expose and arrange the analysis of duplicate detectors and track their results. The residential service provider's QA Officer should manage a program ensuring that the following guidelines for duplicate devices are met.

Duplicate measurements for passive detectors exposed by residential service providers should be side-by-side measurements made in at least five percent of the total number of measurement locations, or 25 pairs each month, whichever is smaller. The locations selected for duplication should be distributed systematically throughout the entire population of measurements. The residential service provider can provide two measurements, instead of one, to a random selection of purchasers, with the measurements made side-by-side. Special instructions and detector packaging may be necessary to ensure that the detectors are not separated during exposure.

The measurement locations selected to receive duplicate detectors should be distributed among all measurement locations. In other words, it is not adequate to place all duplicate devices in one basement. Some duplicate measurements must be made in locations that require all the different handling modes that are routine in the operation, such as mailing to various locations, traveling by car, handling by different technicians, and recording by different office personnel. This is the only way to estimate and monitor the average precision error inherent in the measurements. One way to implement this program is to target every twentieth detector or customer number to receive a duplicate.

An exception to this rule is when all the systematically selected locations that receive duplicates have radon concentrations less than 4 pCi/L (about 150 Bq/m^3). In this case, a portion of the duplicates should be placed in environments with higher concentrations.

8.1.4 Duplicate and Comparison Measurements for Analytical Service Providers Using an Active System

Precision error cannot be easily estimated for users of active systems. The ideal estimate of the actual precision error inherent in a field measurement would be made by making simultaneous, side-by-side measurements with two identical units having identical calibration schedules, procedures and history. Manufacturers can perform such measurements most frequently with new instruments. Analytical service providers should perform side-by-side measurements in approximately 10 percent of the total number of measurements, or 50 side-by-side measurements each month (whichever is smaller), when such monitors are available at the same location.

The precision error caused by the uncertain nature of radioactive decay (counting statistics error) is only one component of precision, and is usually a deceptively small estimate of the overall precision error caused by electronic noise, variability in background, and other factors that are caused by differences between instruments and over time in the same instrument.

8.1.5 Duplicate Measurements for Residential Service Providers Using an Active System

Residential service providers using an active monitor cannot read the results from the instrument. These organizations must rely completely on the analytical service provider for the estimation of precision, and should ensure that the analytical service provider is following the procedures recommended in Section 8.1.4. The residential service organization should request a copy of the analytical organization's QA Plan as well as the results of duplicate and/or comparison measurements performed by the analytical service provider. The residential service organization’s QA Officer is responsible for regularly performing some comparison measurements (as described in Section 8.4.3) to ensure that transport of the monitor or transmission of data from the monitor to the analytical service provider does not contribute to any degradation of quality. These comparison measurements cannot be used to assess precision error, however.

8.1.6 The Analysis of Duplicate or Comparison Measurements

The analysis of data from duplicates (identical passive or active devices deployed with identical start and stop times) should follow the methodology described in Section A.4 of Appendix A of this document. Analytical and residential service providers should regularly communicate and exchange data on duplicate results; close collaboration may result in streamlined practices for duplicate placement and analysis.

8.2 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 (background radiation). All radon or decay product measurement methods require some type of background measurements.

There are two categories of background measurements: laboratory background measurements made to assess the background signal of the instrumentation used to analyze the detectors and any signal generated by the material of the detector itself, and field blanks, made to assess the background that accumulates or to identify any degradation of measurement quality caused during shipping and handling in the field (trip blanks).

8.2.1 Laboratory Background Measurements for Analytical Service Providers of Passive Devices

Laboratory background measurements are used by analytical service providers to assess the counts or signal that result from instrument “noise” and the signal generated from the detector material itself, in the case of alpha-track detectors and charcoal-adsorbing devices. In general, this signal is subtracted from the results of field (the environment being measured) detector analyses. In the case of electret ion chamber devices, the background of the electret reader is that signal produced when a metallic but uncharged material replaces the electret in the reader, and this signal is measured, recorded, and checked for stability and magnitude as per instructions from the manufacturer.

Laboratory background measurements are generally 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 the environment being measured. This may be done for specific time periods (e.g. daily or weekly) or for batches of material and then re-evaluated. The analytical service provider that processes the detectors assesses laboratory background. Residential service providers should request copies of and understand their analytical laboratory's procedures for assessing laboratory background, so that there is no misunderstanding regarding background, and to ensure that a background value is not subtracted twice.

The second use of laboratory background measurements is to calculate the lower limit of detection, or LLD. The method and derivation of the LLD are described in Section A.5 of Appendix A. Note that this derivation assumes a Poisson distribution of counts, and this is not a valid assumption for the background distribution of signal from electret ion chamber readers. The manufacturer of electret ion chambers has derived a minimum detectable activity based upon a series of assumptions and calculations, and this value quoted by the manufacturer should be referenced in the QA Plan of the analytical service provider analyzing the electrets.

8.2.2 Instrument Background Measurements for Analytical Service Providers Using Active Instruments

Analytical service providers using active instruments assess the background of their instruments using aged air or nitrogen in a glove box or by direct flow into the detector. Manufacturers provide specific information on recommended techniques for assessing instrument background; the radon concentration in outdoor air is too variable and high to use successfully for repeatable background measurements. Background measurements should be made as one of the first steps of a calibration and, where feasible, crosscheck.

8.2.2.1 Instrument Background Measurements for Analytical Service Providers Using Continuous Radon Monitors

The EPA Device Protocols (U.S. EPA 1992a) recommend that users of scintillation-cell type continuous monitors perform instrument background measurements after at least every 1,000 hours of operation (about every twentieth 48-hour measurement). Background checks this often may not be necessary for a system that is not used in extremely high radon concentrations and that exhibits small or stable background count rates. However, a reduced schedule for assessing background should be supported by data indicating the relative stability of the background count rate in various environments. If a residential service provider is using the monitor, the analytical organization needs to document its system for ensuring that the monitor is returned to them for background measurements according to a schedule that follows the QA Officer's recommendations. In addition, the analytical organization should make available to the residential organization their written procedures for measuring background and the results of the background measurements made during periodic calibrations..

8.2.2.2 Instrument Background Measurements for Analytical Service Providers Using Continuous WL Monitors

The EPA Device Protocols (U.S. EPA 1992a) recommend that users of continuous working level monitors conduct instrument background measurements after at least every 168 hours (after every fourth 48-hour measurement). Background checks this often may not be necessary for a system that is not used in extremely high decay-product concentrations and that exhibits small or stable background count rates. However, a reduced schedule for performing background checks should be supported by data indicating the stability of the background count rate in various environments. If a residential service provider is using the monitor, the analysis organization needs to document its system for ensuring that the monitor is returned to them for background measurements according to a schedule that follows the QA Officer's recommendations. In addition, the analytical organization should make available to the residential organization their written procedures for measuring background and the results of the background measurement made during periodic calibrations.

8.2.3 Instrument Background Measurements for Residential Service Providers Using Active Instruments

Residential service providers using active instruments should verify that their analytical organization performs background measurements according to the minimum schedule described in Section 8.2.2.1 (for CR users) or Section 8.2.2.2 (for CW users). Residential service providers should request copies of background reports with the calibration reports.

8.2.4 Field Blanks for Users of Passive Devices

The purpose of field background measurements, or field blanks, is to identify effects due to exposure other than in the environment being measured, and to identify any unexpected device response other than due to exposure (e.g., handling causing leakage, effects of high or low humidities or temperatures, effects due to high background radiation). 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 transported with other detectors, and this is often critical in cases where detectors to be calibrated are brought to a calibration facility. If there is any effect due to background exposure of the detectors used to calculate the calibration factor, it is important that it be accounted for before calibration factors are calculated.

8.2.4.1 Field Blanks for Analytical Service Providers of Passive Devices

Many analytical organizations sell detectors two ways: in bulk to residential service providers and individually to homeowners or other end users. Analytical organizations should develop a system for shipping some field blanks with the bulk detectors to measure any effect due to shipping or handling. Field blanks (unopened detectors) should be sent with bulk shipment of detectors at a rate sufficient to measure and track changes in field background.

The rate of field blanks should be determined by the QA Officer. Some types of devices may exhibit significant and varying background (e.g., alpha track detectors) and therefore require a thorough program of monitoring background. Other types of devices (e.g., charcoal adsorbing

devices) may require only occasional field blanks to monitor the measurement-system background.

The analytical organization should provide instructions to the residential service provider for handling the blanks. These instructions should specify that the blanks not be deployed, but remain with the bulk of the detectors to assess background due to shipping, storage, and handling.

The analysis laboratory should monitor the results of the field blanks and compare the results with the value of LLD calculated using the laboratory blanks. If the field blank results are consistently different than the LLD, then an investigation into the cause of the difference should be conducted. If appropriate, and after the investigation, the average result of the field blanks can be used to adjust the results of the other detectors in that exposure group.

8.2.4.2 Field Blanks for Residential Service Providers Using Passive Devices

Residential service providers using passive devices are responsible for monitoring the background of their operations by deploying and tracking the reported results of field blanks. These blanks are additional detectors purchased for use as blanks, and should not be deployed, but should remain with the bulk of the detectors to assess background due to storage and handling. Residential service organizations should consult with the analysis laboratory regarding the rate of blanks that should be sent for analysis.

8.2.5 The Analysis of Background Measurements

Residential as well as analytical service providers must record and analyze the results of the background measurements that they conduct. The organization's QA Officer is responsible for recording and monitoring the results of background measurements, for reporting the results to management, for corrective action when needed, and for verifying changes in measurement results. Means control charts can be used for monitoring both laboratory and field background; this is discussed in Section A.3.1 of Appendix A of this report.

8.3 MEASUREMENTS MADE TO ASSESS BIAS

The type of QC measurements that are made to determine the relative bias inherent in the measurements are termed known exposure measurements, or spikes. Analytical and residential service providers should include known exposure or spiked measurements in their measurement program and monitor the results. Known exposure measurements are an ongoing and continuous way to monitor the differences between measurement results and the "correct" value. They are extremely useful and necessary for ensuring that results are consistently unbiased.

8.3.1 Measurements Made to Assess the Bias of Passive Detectors

Spiked measurements consist of detectors that have been exposed to known concentrations in a radon calibration chamber. All organizations should arrange for the exposure of devices in a radon calibration chamber on a regular basis (e.g. monthly, quarterly, biannually). If the organization uses detectors of different types, at least three per 100 of each type should be spiked. For those organizations processing few detectors, a minimum of three per year is recommended. Organizations processing many detectors may be able to obtain useful information with a maximum number of six spikes per month, although the QA Officer may deem more to be appropriate.

The EPA recommends that all organizations using passive devices expose, record and interpret the results of three spikes per 100 measurements (as averaged over the anticipated number of measurements during a several month period), with a minimum of three per year and a maximum (although more may be conducted) of six per month.

The QA Officer is responsible for ensuring that the detectors to be spiked include a representative sample of detectors so that the results will reflect the error inherent in the detectors being processed for clients. If possible, some of these detectors should be labeled and submitted to the laboratory in the same manner as ordinary measurements to preclude special processing, and thereby serving as an internal check on the measurement system. If appropriate, chamber blanks and trip blanks should be sent with the detectors to be spiked to assess any background signal due to shipping, handling, gamma exposure in the chamber, or other factors.

8.3.1.1 The Analysis of Measurements to Assess the Bias of Passive Devices

The QA Officer is responsible for recording and monitoring the results of spiked measurements, for reporting the results to management, for corrective action when needed, and for verifying changes in measured results in response to changes in procedures. The results of spikes may be analyzed following the guidance in Appendix A.

8.3.2 Measurements Made to Assess Bias for Analytical and Residential Service Providers Using Active Instruments

All active instruments used regularly should be checked for bias on a regular basis. Ideally, such measurements are made in a radon calibration chamber (see Section 7) in a known radon environment. Exposure in a calibration chamber is required during calibration of the devices, and it can be difficult to expose active instruments in a recognized calibration chamber more often than once every 12 months. It is important, however, to perform some measurements to assess instrument response more frequently. The EPA recommends that users of active instruments perform crosschecks with a recently calibrated active instrument during the 12-month interval between calibrations, and approximately six months after calibration, so that no more than about six months elapses between either a calibration or a crosscheck.

Crosschecks should be performed according to the following recommendations and any device-specific directions from the manufacturer. Where feasible, a crosscheck should begin with an instrument background measurement (see Section 8.2.2) using aged air or nitrogen, and instrument performance checks. The crosscheck measurement should be made in an environment that has been chosen for its stability and radon concentration that is well above the lower limit of detection for both devices (preferably greater than 4 pCi/L or 150 Bq/m^3).

A second active instrument that produces results in the same units (i.e., both in pCi/L [Bq/m^3] or both in WL [J/m^3]) and that has been calibrated within the last 3 months should be placed with its air intake adjacent to the instrument to be cross checked. A measurement of at least 48 hours duration should be conducted, with the first four hours of data not used in the calculation (or as recommended by the manufacturer).

Analytical service providers that furnish active devices to residential service organizations and who analyze the signal from those devices need to provide written instructions and training to the residential service providers regarding checks of instrument function. Analytical service providers need to ensure that field checks are being performed.

8.3.2.1 The Analysis of Measurements to Assess the Bias of Active Devices

The comparison of two results from devices that are different (e.g., your organization's device next to a comparison measurement made with different equipment) should follow procedures developed specifically for your system by your QA Officer. The QA Officer may designate values of relative percentage difference (see Glossary) between the active result and the secondary result as triggers for corrective action. For example, a relative percentage difference of ten percent between the active and the comparison measurement may signal the QA Officer to investigate by performing two similar measurements.

A relative percentage difference of twenty percent may indicate a potential problem and the QA Officer needs to stop further measurements until either the problem is identified and corrected or it is determined that there is no problem with the active monitor. (These values of ten and twenty percent are given here only as examples and specific values for each system should be determined, evaluated, and modified as necessary by your organization's QA Officer.) The QA Officer is responsible for recording and monitoring the results of measurements made to estimate precision, for reporting the results to management, for corrective action when needed, and for verifying improvement.

8.4 ROUTINE INSTRUMENT PERFORMANCE CHECKS

This category of 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. Regular monitoring of equipment and operators is vital to ensure consistently unbiased results.

Check sources for alpha counters include thorium or americium sources that are used to test the counting system and ensure that the electronics are stable and operating the same way they were the day before. Analytical service providers find such routine checks extremely useful for

detecting instrument drift or other problems that are minor if corrected quickly. Specific guidance for such operations is beyond the scope of this document; all organizations should develop methods for regularly (daily, prior to beginning a measurement) monitoring their system, and for recording and reviewing results.

8.4.1 Routine Instrument Performance Checks for Analytical Service Providers of Passive Devices

Analytical service providers of charcoal or alpha track devices use routine instrument performance checks of their equipment to verify the analysis equipment's continued stable operation. These may consist of standard detector material with known track densities (for alpha track detector equipment) or charcoal detectors impregnated with radioactive material.

Analytical service providers analyzing electrets should use a reference electret to check the response of the reader prior to beginning the analysis of a set of electrets.

The QA Officer is responsible for documenting the procedures for routine instrument performance checks and for setting criteria for action based upon the results of such checks. Such criteria could involve the use of means control charts, so that limits are based on the probability of obtaining certain results. Such schemes are most appropriate for routine instrument performance checks involving radioactive check sources. Alternatively, criteria can be based upon upper (and lower) limits, or changes in response of a certain magnitude; this may be most appropriate for reference electrets.

8.4.2 Routine Instrument Performance Checks for Analytical Service Providers Operating Active Monitors

Users of active monitors must take special care to ensure that the frequent handling of their equipment does not impact response. Some types of continuous monitors are designed to allow the user to perform checks of the instrument's response; this can allow frequent documentation of stable response. The most useful checks are those that test the majority of the measurement system (e.g., a sealed Ra-226 cell for scintillation-cell monitors); other checks of a portion of the

system are also useful (e.g., a check of the electronics). These routine checks should be made 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.

The QA Officer is responsible for documenting the procedures for routine instrument performance checks and for setting criteria for action based upon the results of such checks. Such criteria could involve the use of means control charts, so that limits are based on the probability of obtaining certain results. Such schemes are most appropriate for routine instrument performance checks involving radioactive check sources (e.g., sealed cells). Alternatively, criteria can be based upon upper and lower limits; this may be most appropriate for pump flow rate or other non-Poisson processes.

8.4.3 Routine Instrument Performance Checks for Residential Service Providers Operating Active Monitors

Residential service providers using active monitors provided by an analytical organization should have some means to assess the continued satisfactory operation of the active monitor they are using. The analytical service organization should provide written instructions and training for performing tests of the equipment and set up a system for obtaining and analyzing results from the residential service provider. Particularly important are pump flow-rate checks prior to and after each continuous WL measurement. Also useful are built-in self-diagnostic tests of the detector and electronics. Routine instrument performance checks can be monitored using means control charts (see Section A.3.1 of Appendix A).

If a check source is unavailable or incompatible with the type of active monitor being used, and a system and detector diagnostic check is impossible, the organization should perform a comparison measurement with approximately ten percent of the measurements. This comparison measurement will serve as a check of the continued satisfactory operation of the instrument. Because the two results were not obtained with identical equipment, however, a statistical analysis for the purpose of assessing precision would not be appropriate.

The comparison of the two results from devices that are different (e.g., your organization's device next to a comparison measurement made with different equipment) should follow your procedures developed specifically for your system by your QA Officer. The QA Officer may designate values of relative percent difference (see Glossary) between two results triggers for corrective action. For example, a relative percentage difference of ten percent between the measurements may signal to the QA Officer to investigate by performing two similar measurements.

A relative percentage difference of twenty percent may indicate a potential problem and the QA Officer may need to stop further measurements until the problem is identified and corrected or it is determined that there is no problem with the measurement. (These values of ten and twenty percent are given here only as examples; specific values for each system should be determined, evaluated, and modified as necessary by each organization's QA Officer.)

9. 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, U.S. EPA 1992b).

The QAP serves three main purposes. First, and most important, it is the culmination of the discussion and planning that went into designing the operation to produce results that are of the quality needed. Second, it is a historical record that documents the operation in terms of measurement methods used, calibration standards and frequencies planned, auditing planned, etc. Lastly, a QAP 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, precision error, and other indicators of quality.

The Agency's draft interim final requirements for Quality Assurance Project Plans for Environmental Data Operations (EPA QA/R-5, U.S. EPA 1992a) provides guidance regarding components of a QA Plan. This and other EPA QA guidance is being written using ANSI/ASQC guidance (ANSI/ASQC 1994a) as a framework. When EPA QA/R-5 becomes final, it will supersede previous Agency guidance (QAMS-005/80; U.S. EPA 1980). This guidance is intended for organizations that gather data on behalf of EPA through contracts, financial assistance agreements, and interagency agreements. Although most radon measurement organizations do not fall into this category, this section provides information regarding format and terminology from both the Agency's 1980 guidance and the draft interim final guidance.

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). These elements are described here along with terminology used by other organizations. These elements should be present in a QAP, and presentation in the order described in this section will facilitate review by EPA and others (for example, by residential service providers). Exhibit 9-1 describes which elements are necessary for the QAPs of analytical and residential service providers.

Exhibit 9-1
Required Elements of a Quality Assurance Plan for
Analytical and Residential Service Providers

Element	Analytical	Residential
1. Signature page	Required	Required
2. Table of contents, with revision numbers and dates	Required	Required
3. Description of operations	Required	Required
4. Organization and responsibilities	Required	Required
5. QA objectives for measurement data in terms of precision error and relative bias	Required	Required—obtain this information from the analytical organization
6. Measurement procedures (brief discussion of measurement method, procedures for selecting measurement location, and procedures for Record keeping and shipping)	Required	Required
7. Detector custody for field and laboratory operations	Required	Required—describing sample custody for the residential organization's operations only
8. Calibration procedures and frequency	Required	Not required
9. Analytical procedures	Required	Not required
10. Data reduction, validation, and reporting	Required	Required—omitting the data reduction conducted by the analytical organization's operations
11. Internal QC checks	Required	Required
12. QA audits	Required	Required—only pertaining to activities relevant to the residential organization's responsibilities
13. Preventive maintenance	Required	Required—only pertaining to equipment used by the residential organization
14. Procedures used to assess precision, relative bias, and lower limit of detection (LLD)	Required	Required—except for the assessment of LLD
15. Corrective action	Required	Required—only pertaining to the residential organization's operations
16. QA reports to management	Required	Required

There is considerable information available on preparing quality assurance plans and quality management plans (U.S. DOE 1991, NIST 1995, Taylor 1987). A QAP that is written in addition to a separate quality management plan and extensively referenced SOPs may be fairly lean. A QAP that serves as the sole quality document and contains the procedures for many quality control procedures may be lengthy and detailed.

The responsibility for reviewing and updating the QAP lies with the QA Officer. As this may require periodic expenditures of time, this task must be supported by management.

9.1 SIGNATURE PAGE

The title page of the QAP must include the signatures of the organization's QA Officer (see Section 5.2) and his/her supervisor. Other individuals who are also responsible for the quality of measurements should sign and date the completed QAP, indicating that they have reviewed and approved of the plan and consider the plan final.

This corresponds with EPA QA/R-5 Element A1: Title and Approval Sheet (U.S. EPA 1992b).

9.2 TABLE OF CONTENTS

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

This material corresponds with EPA QA/R-5 Element A2: Table of Contents.

9.3 DESCRIPTION OF OPERATIONS

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 sufficiently comprehensive for someone unfamiliar with the operations to understand the numbers and types of measurements made by the

organization. Although SOPs may be referenced, the QAP should included a brief description of operations.

The corresponding elements in EPA QA/R-5 are A5: Problem Definition and A6: Project/Task Description.

9.4 ORGANIZATION AND RESPONSIBILITIES

This part of the QAP usually includes a detailed organization 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 be listed.

The information presented in this Section corresponds to EPA QA/R-5's Element A4: Project Task Organization.

An important person to identify is the QA Officer (see Section 5.2), and the line of authority for his/her activities. This section should include a description of the regular methods of communication regarding quality assurance issues. Unless a separate Quality Manual or Quality Management Plan is written, this section should include a statement of commitment to quality (quality policy) by the organization's management.

Work performed by parties outside the organization should be identified, with a description of management and technical responsibilities for this work.

9.5 QUALITY ASSURANCE OBJECTIVES

The quantitative QA objectives should be discussed and presented in this section. In general, objectives for relative bias and precision error should be listed, and other objectives may be listed as well. These may include, for example, numeric objectives relevant to marketing (e.g., measures of customer satisfaction, referrals) or employee performance (e.g., data entry errors). Analytical service organizations may need to set objectives for the parameters necessary for the calculation

of final concentrations (for example, flow rates or weight gains). The objectives for intermediate parameters may be, for example, that flow rate will remain between values x and y; corrective action will be taken and the QA Officer notified if values deviate beyond these boundaries.

The corresponding element in EPA QA/R-5 is A7: Quality Objectives and Criteria for Measurement Data.

9.5.1 Precision Error

Precision is defined as the measure of the variability of a process used to make repeated measurements under carefully controlled (identical) conditions. Duplicate measurements provide a check on the quality of the measurement result, and allow the user to monitor precision error. Large precision errors may be caused by inconsistencies in detector manufacture, or inconsistent data transcription or handling by suppliers, laboratories, or technicians performing placements. Precision error can be an important component of the overall error, so it is important that all users monitor precision error.

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 should be specified.

The estimate of precision error may be specified in terms of a) relative percentage difference, defined as the absolute value of the difference between two measurements divided by their average, b) by coefficient of variation, defined as the sample standard deviation of two or more measurements divided by their average, c) by the range, defined as the difference between the two measurements, or d) by some other parameter. The quantitative goals for precision could be specified, for example, as an average relative percentage difference of less than 25 percent for duplicates where at least one result is less than 4 pCi/L (150 Bq/m^3), and an average relative percentage difference of less than 14 percent for duplicates where both results are greater than 4 pCi/L (150 Bq/m^3). Technical guidance for calculating and assessing precision error is found in Section A.4 of Appendix A.

9.5.2 Relative Bias

Relative bias is defined as the degree of agreement of a measurement result with an accepted reference or true value. In the case of passive detectors, the reference value is the concentration in the radon calibration facility where the spiked measurements are performed. In the case of active instruments for which bias was assessed with a cross check, the reference value is that given by the recently calibrated instrument. Bias may be expressed in terms of relative percent error, or as

$$RPE = [(MV-RV)/RV]*100\%$$

where: RPE = relative percentage error;
MV = measured value of spiked measurement; and
RV = reference value.

Note that the definition of relative percentage error is similar to the definition of Individual Relative Error (IRE), as defined in the Radon Proficiency Program (RPP) Handbook (U.S. EPA 1995a), except that the numerator of the IRE is the absolute value of the difference while RPE 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 RPE of ±15 percent or less at radon concentrations greater than 4 pCi/L (150 Bq/m^3).

Another expression of bias is performance ratio, which can be defined as the measured value divided by the reference value. Note that the difference between percentage bias and performance ratio is 1.0, so that, for example, if percentage difference is 0.25, the performance ratio will be 1.25.

More information on the monitoring of relative bias can be found in Appendix A; a discussion of equipment calibration is given in Section 7.

9.6 MEASUREMENT PROCEDURES

This part of the QAP should describe the following:

- The method by which the radon or radon-decay product concentrations are to be measured. A technical person unfamiliar with the method must be able to understand the descriptions of the method used. The RPP Handbook (U.S. EPA 1995a) contains a brief description of each of the measurement methods currently described by EPA's *Indoor Radon and Radon Decay Product Measurement Device Protocols* (U.S. EPA 1992a).

- The guidelines used to select the locations for detector deployment, including the procedures for choosing the exact sampling locations.

- Measurement conditions, as described in *Protocols for Radon and Radon Decay Product Measurements in Homes* (U.S. EPA 1993).

- The logbooks or recordkeeping procedures, with a list of the information routinely gathered with each measurement.

- Relevant information about shipping detectors to the laboratory, including the schedule for shipping detectors.

The corresponding elements in EPA QA/R-5 are B1: Sampling Process Design and B2: Sampling Method Requirements.

9.7 DETECTOR CUSTODY

A complete description of all 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.

The information presented in this part of a QA Plan corresponds to EPA QA/R-5's Element B3: Sample Handling and Custody Requirements.

9.7.1 Field Operations

The information that is relevant under this part is a description of:

- Names of field operators/technicians.
- How, by whom, and where the records of measurement data, including location, time, and other pertinent parameters are kept.
- Examples of labels, custody seals, and field tracking forms.
- Office documentation of procedures for transporting detectors from the field to the laboratory, including identification of the individuals or organizations responsible for transport.

9.7.2 Laboratory Operations

This part of the QAP describes how the detectors are handled by each laboratory facility when they are received after exposure. The following information should be included:

- Names of laboratory detector custodians responsible for logging in devices or data.
- Forms for laboratory detector tracking.
- Records of laboratory chain-of-custody.
- Specification of procedures for detector handling, storage, and final disposition.
- Documentation of procedures for disbursement and transfer of detectors within the laboratory and between the analytical and residential service provider.

A residential service provider's QAP must include the identification of the person responsible for the detectors, and a description of the laboratory-detector handling procedures.

9.8 CALIBRATION PROCEDURES AND FREQUENCY (For Analytical Service Providers Only)

This section of the QAP should include descriptions of 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 should be used, whenever possible, to present the following information:

- References to EPA-recognized, or other standard, methods.
- Complete description of non-standard or modified methods.
- Appended instrument-specific calibration SOPs, as needed to support SOPs that do not include detailed calibration procedures.
- Definition of specific acceptance criteria for all calibration measurements.

The information that needs to be included in this part of the QAP or the appendix of SOPs should be specific, for example: shipment of 20 detectors every six months to the calibration facility (provide the name and address); exposure to humidities and radon levels (specify ranges of values) at the calibration facility; adjustment of calibration curves accordingly; and other information as described in Section 7.

Calibration information corresponds to EPA QA/R-5's Element B7: Instrument Calibration and Frequency.

9.9 ANALYTICAL PROCEDURES (For Analytical Service Providers Only)

This part of the QAP should describe the procedures for analyzing the detectors. The laboratory SOPs should be reproduced and appended to the QAP, or referenced and kept available.

Element B4: Analytical Methods Requirements is the corresponding section in EPA QA/R-5.

9.10 DATA REDUCTION, VALIDATION, AND REPORTING

This section of the QAP describes how the organization maintains good data quality throughout data reduction (i.e., calculation of results), transfer, storage, retrieval, and reporting. The following topics are recommended for discussion.

- For data reduction:
  - Names of individuals responsible.
  - Summary of data reduction procedures.
  - Examples of data sheets.
  - Description of how results from field and laboratory blanks are used in the calculations.
  - Presentation of all calculations (equations) and significant underlying assumptions.

- For data validation:
  - Means by which the data are checked for errors.
  - Names of individuals responsible.
  - Procedures for determining outliers and flagging data for review by the QA Officer or others.

- For data reporting:
  - Names of individuals responsible.
  - 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 must also describe the procedures and persons responsible for non-routine occurrences, such as when detectors are returned opened, late, or when some other deviation from the planned circumstances has occurred. Finally, this section of the QAP should describe the procedures for rechecking results that indicate exposures to radon concentrations greater than a specified limit (e.g., 100 pCi/L or about 4,000 Bq/m^3) or the limit above which all measurements are recalculated before being reported as final.

The information in this section corresponds to EPA QA/R-5's Elements D1: Data Review, Validation, and Verification Requirements, and D2: Validation and Verification Methods.

9.11 INTERNAL QUALITY CONTROL CHECKS

Internal QC measurements must be conducted by both analytical and residential service providers. The following QC activities should be described:

- Use of internal laboratory standards (check sources, canisters, etc.), self-diagnostic tests, and other routine instrument performance checks, their frequency, treatment of results, (e.g., use of means control charts [see Appendix A]) and plans for corrective action if results fall outside predetermined criteria.

- Duplicate or replicate measurements made to estimate 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 (see Appendix A for control charts for precision).

- Comparison measurements, in which different types of devices are placed side-by-side and results compared.

- 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).

- Proficiency testing of analysts and operators.

In addition, this part should describe the QA checks on incoming detectors, equipment, and supplies, for <u>both</u> new shipments of detectors and for detectors mailed back after deployment. For example, some fraction of incoming charcoal canisters should be checked for high background rates and package integrity; detectors mailed in after deployment should be checked to ensure that they were sealed properly and that the paperwork was completed correctly. The corrective action to be taken if the results of either of these types of internal QA checks indicate unusual results should be discussed here and referenced in the “Corrective Action” chapter of the QAP, as described in Section 9.15.

9.12 QUALITY ASSURANCE AUDITS

After the procedures for field and laboratory operations have been developed, an audit must be conducted to ensure that all the procedures work as planned. QA audits are based on the QAP. Therefore, the QAP should be sufficiently detailed to form the basis of a meaningful audit. QA audits can be conducted by the QA Officer, or an outside expert, who reviews the written procedures for completeness. All QA audits should be documented in a written report that specifies the nature and findings of the audit. Additional audits are conducted periodically during the operations to check on the accuracy of the reported results.

This section of the QAP should describe the plans for these audits, including who will conduct them, when they will be conducted, and the focus of the audits. The QA Officer should conduct an audit after any change in method or procedure, and conduct additional audits at least once every six months.

The corresponding element in EPA QA/R-5 is C1: Assessments and Response Actions.

9.13 PREVENTIVE MAINTENANCE

This section should include descriptions of the types of preventive maintenance (for example, mechanical maintenance of laboratory equipment) needed for adhering to schedules and for achieving good quality data. The descriptions may include:

- A schedule of important preventive maintenance tasks for measurement systems and the responsible person for their implementation.
- A list of critical spare parts.
- Reference to current maintenance contracts and standard maintenance procedures for measurement systems.

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

This information corresponds to EPA QA/R-5's Element B6: Instrument/Equipment Testing, Inspection, and Maintenance Requirements.

9.14 PROCEDURES TO ESTIMATE DATA PRECISION, RELATIVE BIAS, AND LOWER LIMIT OF DETECTION

This part of the QAP should describe the processes (including equations and descriptions of calculations, statistical tests, control charts, etc.) by which the

- Duplicate or replicate measurement results will be analyzed to estimate precision, and the limits of acceptability for precision error.
- Known exposure (spikes or crosschecks) measurement results will be used to assess and monitor relative bias, and the limits for acceptable levels of relative bias.
- Field and laboratory background-measurement results will be used to assess and track the background level and lower limit of detection, as appropriate for that method.

The corresponding section in EPA QA/R-5 is Element D3: Reconciliation with User Requirements of EPA QA/R-5.

9.15 CORRECTIVE ACTION

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 following topics should be presented (in table form, if adequate):

- Trigger points: What pre-specified conditions will automatically require corrective action?
- Personnel: Who initiates, approves, implements, evaluates, and reports corrective action?
- Response: What specific procedures will be followed if the corrective action is needed?

There may be different types of corrective actions that will be required as a result of QC measurement results. This section of the QAP should describe at least three types:

- The corrective action to be taken if results are outside the action limits when plotted on the control charts.
- The corrective action taken to correct problems found during audits.
- The corrective action to be taken when there are deviations from the routine circumstances (for example, detectors not returned within 10 days of exposure, or incoming unused detectors with high backgrounds).

It may be appropriate to describe most types of corrective action in various sections described previously (e.g., corrective action due to an occurrence related to preventive maintenance may be discussed in that section); the section on corrective action should mention that other corrective action procedures are described in other portions of the QAP.

Correction action information corresponds with EPA QA/R-5's Element C1: Assessments and Response Actions.

9.16 QUALITY ASSURANCE REPORTS TO MANAGEMENT

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

- The names and titles of the people who prepare and receive the reports.
- The type of report (written or oral) and their frequency.

- The contents of the various reports, such as
  - Changes in the QAP.
  - A summary of the current QA/QC programs, training, and accomplishments.
  - Results of QA audits.
  - Significant QA/QC problems, recommended solutions, and results of corrective actions.
  - Data quality assessment in terms of precision, relative bias, field and laboratory background, and lower limit of detection.
  - Limitations on the use of the measurement data.

This information corresponds to EPA QA/R-5's Element C2: Reports to Management.

Appendix A

The Analysis and Interpretation of Quality Control Measurements

The Analysis and Interpretation of Quality Control Measurements

This Appendix contains a review of the methods of calculating and monitoring the various sources of error that can be expected with a radon or radon-decay product measurement 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. (See Trueness in the Glossary). In this case, errors of precision are reduced because of the use of a large number of measurements. This definition is 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 1990) 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 report will maintain consistency with ASTM nomenclature, and use the terms precision error and bias (or relative bias) to describe the components of error.

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

This Appendix will also discuss the calculation of the lower limit of detection (LLD) and related concepts. The LLD is important to understand, report properly, and place in context of your measurement program.

A.1 ROUTINE INSTRUMENT PERFORMANCE CHECKS

Proper operation of analytical instruments requires that their response to a given radon or decay-product concentration be as consistent as possible from one measurement to the next. This consistency can be checked using a reference source, counting background, and verifying that the results fall within predetermined limits. In addition, proper operation of an energy-sensitive instrument requires that its energy response be constant. Instrument quality control (QC) therefore requires regular measurements of the following responses.

Instrument check sources are used for monitoring the constancy of response of an instrument. The response characteristics of instrument reference sources should be as similar as possible to those of real measurements, and the response caused in the instrument should be stable (or predictable) over time.

Energy alignment sources (Coats and Goldin 1966) are used to check the overall gain and linearity of spectrometers. The sources should emit radiation of two energies at least, and preferably of a number of energies covering the range for which the spectrometer is set. In some cases, the same source can be used both for instrument checks and energy alignment. Gamma alignment sources can be made by the laboratory. They are also available as Standard Reference Materials from the National Institute of Standards and Technology.

Internal diagnostics can be performed evaluating specific components of measurement systems, including voltages, pump flow rates, and other parameters. Some instruments provide pre-programmed self-diagnostic procedures.

Routine instrument performance checks should be conducted following manufacturer instructions, whenever the equipment has been significantly handled, whenever the operator requires assurance that the equipment is providing a stable response, and according to a regular schedule (e.g., daily, weekly, prior to sets of measurements or each measurement). The results of the routine instrument performance checks need to be recorded in a log, with the date, time, and initials of the person who performed the check. If the check yields numeric results, it should be plotted on a means control chart, as described in Section A.3.1. The QA Officer is responsible for setting up the control chart with limits and guidelines for corrective action, for monitoring the results, and is accountable for oversight of the investigation and corrective action when needed.

A.2 BACKGROUND MEASUREMENTS

A.2.1 Laboratory Background Measurements for Analytical Service Providers

Laboratory background measurements should be as similar as possible to actual measurements, but without the influence of radon or decay products. Various types of background measurements may be needed, including those for incoming materials, equipment, and unexposed devices. Background measurements for continuous monitors should be made in a glove box or with direct flow into the detector of aged air or nitrogen. Background measurements are a component of the calibration process.

A.2.2 Field Background Measurements for Analytical and Residential Service Providers

The results of field background measurements performed by analytical or residential service providers should be compared with the reported LLD (see Section A.5.1). If the results of the field blanks are consistently (e.g., more than several blank results in a row) significantly greater than the LLD, the analytical organization should be consulted and the potential for extraneous background be investigated. The analytical organization should be responsible for changing background labels or adjusting results due to changed background.

The results of field background measurements may also be plotted on a means control chart in the manner described in Section A.3.1 to ensure that a change in background levels can be quickly identified.

A.3 EVALUATION OF QUALITY CONTROL DATA

A.3.1 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 1985, 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 error (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" (see later in this Section). 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. An example means control chart is shown in Exhibit A-1; example background control chart data are plotted in Exhibit A-1a.

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). Note that these limits are two-tailed limits (values near both limits or tails are of interest), as opposed to the limits for duplicates, which are one-tailed (see Section A.4.1.4). If a value is obtained that is outside the three-sigma control limits, then the count should be repeated. If the repeat value is still outside the three-sigma limit, 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 evaluates the situation.

As the data are plotted, "rule-of-thumb" indicators (Taylor 1985) that the measurement system may be "out-of-control" include:

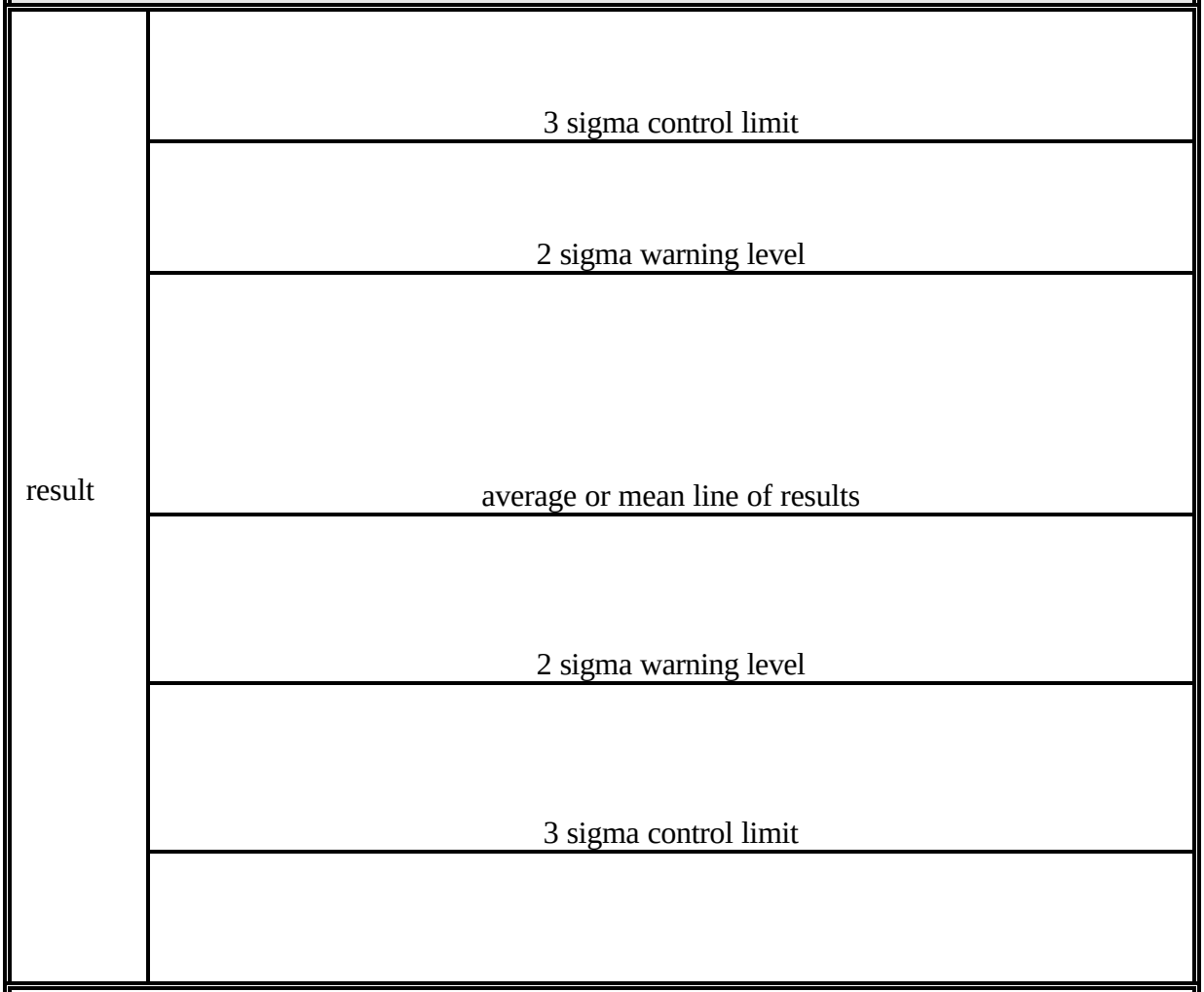
- Two successive points outside the two-sigma limits.
- Four successive points outside the one-sigma limits.
- Any systematic trends high or low.

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. Note that one does expect to see measurements outside the warning limits, and this does not necessarily mean that the process is out of control (ANSI/ASQC 1987). Repeated data falling outside the limits are evidence of loss of control, and requires an investigation. If no cause of increased variability or shift can be found, then the control limits should be broadened and a sufficient number of data points should be gathered so that the QA Officer is confident that the new limits are appropriate.

Note that the count rate of radioactive check sources changes with time. If the user is not aware of the pattern of change, it may appear that the instrument is drifting when, in fact, it is not. Instead of plotting total counts in a given period of time, it may be appropriate to plot another parameter, such as counts per disintegration.

Exhibit A-1

Means Control Chart for Background or Check Source Results

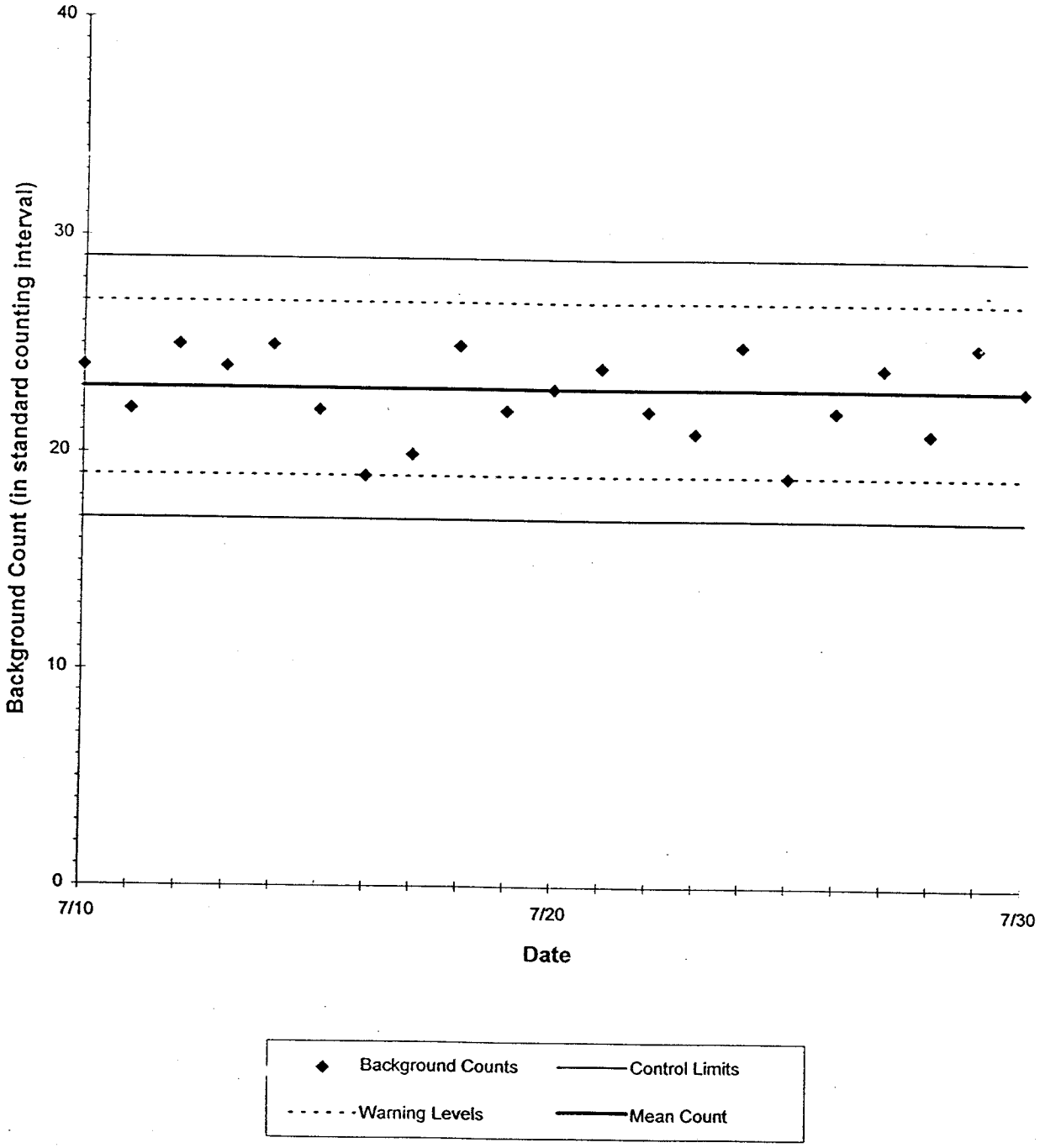


date . . . . . .

The results plotted on these charts should be in sequential order by date. At least about 20 "in-control" measurements should be made before calculating the sample standard deviation of the results (see the Glossary for the equation for sample standard deviation). "In-control" means that the operator has confidence that the instruments are operating properly and there is no evidence to suspect that there is anything faulty about the result. The QA Officer is responsible for periodically assessing the spread of values on the charts, recalculating the sample standard deviation based on new results and determining whether the limits on the charts should be revised.

Exhibit A-1a

Example Means Control Chart for Background



Example Means Control Chart for Background

Date	Background Count (in standard counting interval)
7/10/95	24
7/11/95	22
7/12/95	25
7/13/95	24
7/14/95	25
7/15/95	22
7/16/95	19
7/17/95	20
7/18/95	25
7/19/95	22
7/20/95	23
7/21/95	24
7/22/95	22
7/23/95	21
7/24/95	25
7/25/95	19
7/26/95	22
7/27/95	24
7/28/95	21
7/29/95	25
7/30/95	23

Plotted Results	
Mean (average) =	23 counts
Sample Standard Deviation =	1.95 counts
Upper Warning Level =	27 counts
Lower Warning Level =	19 counts
Upper Control Limit =	29 counts
Lower Control Limit =	17 counts

This report 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" can also be used (Goldin 1984).

A.3.2 Means Control Chart to Evaluate Relative Bias From the Results of Known Exposure Measurements

The results of known exposure measurements (spikes for passive methods and crosschecks for active methods) can also be plotted on a means control chart. Bias may be expressed in terms of relative percent error, or as

$$RPE = [(MV-RV)/RV]*100\%$$

where: RPE = relative percent error;
MV = measured value of the spiked measurement or the instrument being evaluated; and
RV = reference value (chamber or recently-calibrated instrument).

Note that the definition of relative percent error is similar to the definition of Individual Relative Error (IRE), as defined in the RPP Handbook (U.S. EPA 1995a), except that the numerator of the IRE is the absolute value of the difference while RPE can have positive or negative values.

The mean line should be set at zero, and the two-sigma and three-sigma limits can be set using

1) the coefficient of variation among the RPE values from at least 20 spikes or crosschecks,

or, and *only until the results of 20 spikes or crosschecks are available,*

2) the average standard deviation as determined via duplicate measurements (see Section A.4.1). Note that this option is a temporary measure that should be used only at the inception of an operation, until the RPE values from valid spikes or crosschecks are available.

It may be appropriate to construct separate control charts for different ranges of radon concentrations; for example, less than and greater than 4 pCi/L (150 Bq/m^3) or 10 pCi/L (370 Bq/m^3), for example, if the bias changes nonlinearly with concentration.
An example means control chart for using data from spikes from a passive system is shown in Exhibit A-2, and a means control chart for plotting the results of crosschecks using an active system is shown in Exhibit A-3. Data from example spiked measurements are plotted on a means control chart in Exhibit A-2a.

A.4 ESTIMATING PRECISION

The precision of a measurement expresses the degree of reproducibility (repeatability) of that measurement. Precision can be expressed in terms of the standard deviation*, s, or equivalently, by the variance, s^2. The variance of a measured quantity x, denoted by $s^2(x)$, is the combination of two contributing variances, $s_n^2(x)$ and $s_p^2(x)$:

$$s^2(x) = s_n^2(x) + s_p^2(x)$$

$s_n^2(x)$ is the component of the variance associated with signal-to-noise problems and is closely related to the variability of the noise level; $s_p^2(x)$ is the component of the variance associated with procedures and with measurements not affected by noise variability, such as weighing and handling (U.S. EPA 1982a). At low concentrations, s_n^2 becomes the major part of the total variance. This assumption is extremely important because it allows the treatment of the counts measured at low concentrations as exhibiting a Poisson distribution. The value for sigma may be different at different radon levels, so assess RPE values at different radon concentrations. If appropriate, keep different control charts for different ranges of radon levels.

The objective of performing more than one measurement is to assess the precision error of the measurement method, or how well side-by-side measurements agree. This precision error is the

* The standard deviation and the variance are parameters of the population of replicate measurements. As such, the standard deviation is commonly designated by the Greek letter sigma (σ) and the variance by σ^2. Since the population parameters are unknown, empirical estimates designated by s and s^2 are used.

Exhibit A-2
Means Control Chart for Spiked Results of Passive Methods
(Chart Used to Assess Bias)

RPE = [(MV-RV)/RV] * 100

MV = measured spiked result
RV = reference or chamber value

	30%	3 sigma control limit
	20%	2 sigma warning level
RPE 0		
	-20%	2 sigma warning level
	-30%	3 sigma control level

Run number or date . . . . . .

The value of sample standard deviation (sigma) of the RPE values should be calculated from the results of at least about 20 spiked results (within the same range of radon concentrations). If this number of spikes has not yet been conducted, the sigma may temporarily be assumed to be 10%, and then revised after calculating the sample standard deviation from the actual RPE values of the spiked results. The control limits on the chart should be drawn at 0 +- 3 * sigma, and the warning levels at 0 +- 2 * sigma.

The value for sigma may be different at different radon levels, so assess RPE values at different radon concentrations. If appropriate, keep control charts for ranges of radon levels (e.g., 4 - 20 pCi/L or about 150 - 750 Bq/m^3).

Example Means Control Chart for Relative Bias Based Upon Results of Spikes

Date	Spike Number	Reference (chamber) Value	Measured Value (pCi/L)	Relative Percent Error (RPE)
7/14/95	1	25.1	23.5	-6.4
7/14/95	2	25.1	22.9	-8.8
7/14/95	3	25.1	28.0	11.6
7/14/95	4	25.1	26.1	3.9
7/14/95	5	25.1	25.0	-0.4
7/30/95	6	21.6	19.4	-10.2
7/30/95	7	21.6	22.0	1.9
7/30/95	8	21.6	23.1	6.9
7/30/95	9	21.6	21.5	0.5
7/30/95	10	21.6	21.6	0.0
8/13/95	11	32.5	33.1	1.8
8/13/95	12	32.5	34.0	4.6
8/13/95	13	32.5	33.0	1.5
8/13/95	14	32.5	32.9	1.2
8/13/95	15	32.5	31.6	-2.7
8/29/95	16	45.8	46.5	1.5
8/29/95	17	45.8	44.2	-3.5
8/29/95	18	45.8	48.9	6.8
8/29/95	19	45.8	41.8	-8.7
8/29/95	20	45.8	45.0	1.7

Plotted Results	
Mean (center) Line =	0
Coefficient of Variation of the 20 RPE Values =	5.60%
Warning Limits =	+ 11.2%
Control Levels =	+ 16.8%

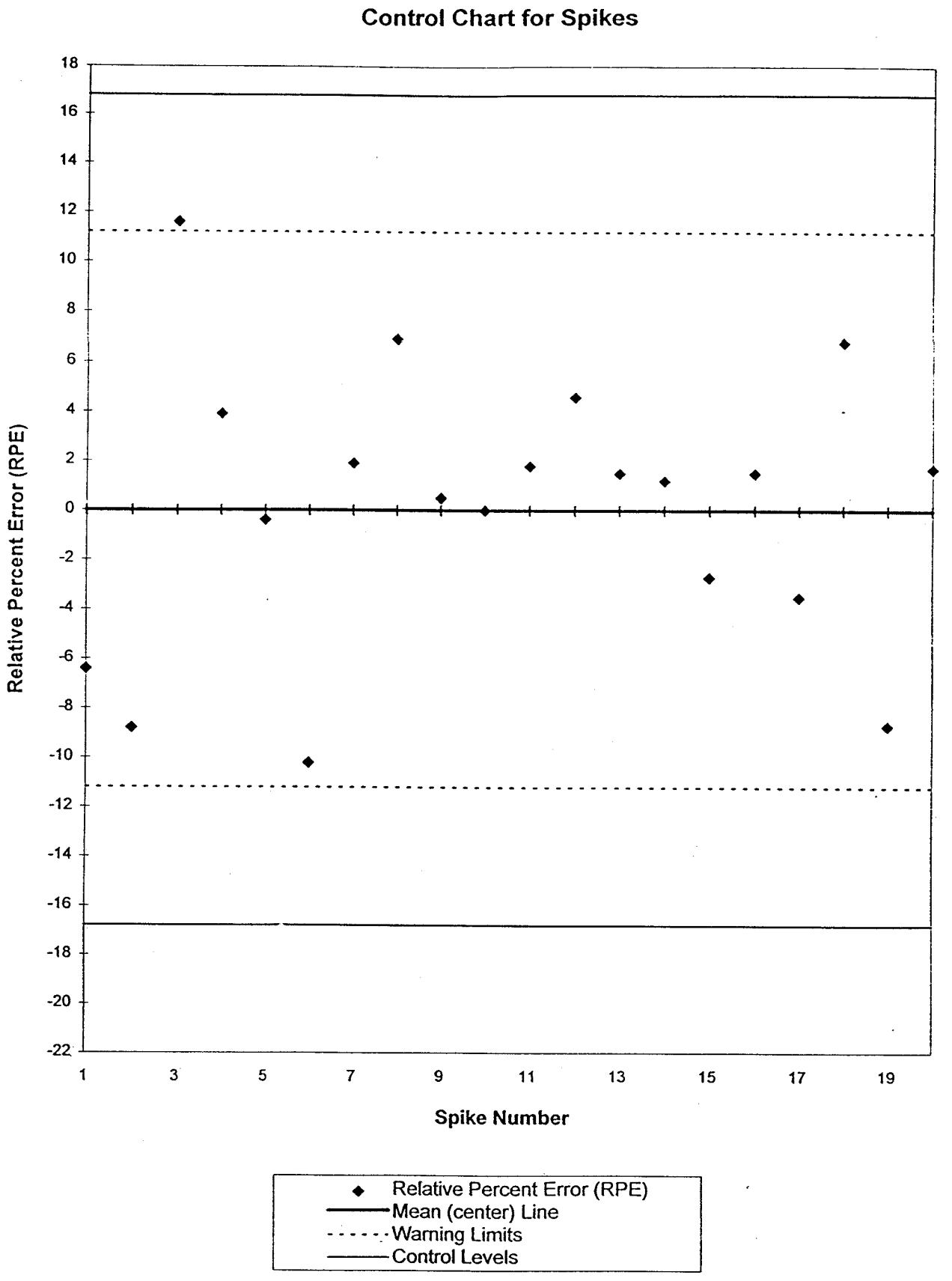

Control Chart for Spikes
Relative Percent Error (RPE)
18
16
14
12
10
8
6
4
2
0
-2
-4
-6
-8
-10
-12
-14
-16
-18
-20
-22
1
3
5
7
9
11
13
15
17
19
Spike Number
Relative Percent Error (RPE)
Mean (center) Line
Warning Limits
Control Levels

Exhibit A-3
Means Control Chart for Crosschecks Using Active Methods
(Chart Used to Assess Bias)

RPE = [(MV-RV)/RV] * 100

MV = measured result from instrument to be checked
RV = reference value from recently calibrated instrument

	30%	3 sigma control limit
	20%	2 sigma warning level
RPE 0		
	-20%	2 sigma warning level
	-30%	3 sigma control limit

Run number or date . . . . . .

The value of sample standard deviation (sigma) of the RPE values should be calculated from the results of at least about 20 crosschecks (within the same range of radon concentrations). The sample standard deviation of the RPE values is used. If this number of crosschecks has not yet been conducted, the sigma may temporarily be assumed to be 10%, and then revised after calculating the sample standard deviation from the actual RPE values of the crosscheck results. The control limits on the chart should be drawn at 0 +- 3 * sigma, and the warning levels at 0 +- 2 * sigma.

"random" component of error (as opposed to the calibration error, which is systematic). The precision error, or the degree of disagreement between duplicates, can be composed of many factors. These include the error caused by the random nature of counting radioactive decay, slight differences between detector construction (for example, small differences in the amount of carbon in activated carbon detectors), and differences in handling of detectors (for example, differences in the errors of the weighing process, and variations of analysis among detectors).

It is critical to understand, document, and monitor precision error. This continual monitoring and documentation provides a check on every aspect of the measurement system.
For radiation measurements, counting statistics are often given as the measure of the variability or repeatability of the measurements, primarily because of the ease of calculations. Counting statistics 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 quantity of nuclide present is so small that the procedure-calibration variability is negligible in contrast with the background variability (U.S. EPA 1982b); and
- All other sources of variability in the background are negligibly small in comparison to counting error (a very rare occurrence).

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. 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 as triggers for an investigation into the cause of the large differences. 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 (for example) five percent of the time. A **control limit**, where further measurements should cease until the problem is corrected, may be set at a one percent probability or less. The normal practice is to set control limits corresponding to a three-sigma level, which means that a difference this large would only occur by chance about one-tenth of one percent of the time.

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).

The range ratio is defined as the difference between two measurements divided by the expected difference at that concentration (see the following section). Use of this statistic is recommended because it is normalized to the expected precision at that concentration, and therefore the same limits can be used for all concentrations. Other 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 control charts 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 4 pCi/L or 150 Bq/m^3, and with some upper bound, as determined by duplicate measurements at various concentrations. At lower concentrations, e.g., between 2 pCi/L (or 80 Bq/m^3) and 4 pCi/L (or 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 higher concentrations. 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 (see Section A.4.2). At concentrations less than about 2 pCi/L, or 80 Bq/m^3, the LLD may be approached, and the precision error may be so large as to render a control chart not useful.

A.4.1 Control Charts For Monitoring Precision Error

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 simultaneous, side-by-side measurements at each range of radon concentrations for which a control chart is to be prepared. For example, if you will only estimate precision at concentrations greater than 4 pCi/L, or 150 Bq/m^3, you will need at least 20 measurements at concentrations greater than 4 pCi/L, or 150 Bq/m^3, to assess the "in control" level. The average precision error should be the "in control" level, and measurements that were suspect should not be included. If using a range ratio control chart (see below), the average range between duplicates exposed to similar concentrations can be used as the "in control" level.

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 and EPA as a goal for precision, for example, a 10 percent COV (corresponding to a 14 percent RPD; see Exhibit A-4). 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 (using the guidelines below) should be prepared so that the warning and control limits are set at appropriate probability limits for your system.

A.4.1.1 Range Ratio Control Chart

A range ratio control chart (Taylor 1987) is an easily understood type of precision control chart that can be very useful when the variability (precision) cannot be simplified as a constant fraction of the mean (see Section A.4.2). The range ratio chart allows all results (greater than the LLD) to be plotted on the same chart, regardless of concentration. This is a sequential chart, on which duplicate results are plotted as they are analyzed, with the date and/or other identification on the

Exhibit A-4

Range (Difference) Between Two Measurements
With a 14% Relative Percent Difference
(Or a 10% Coefficient of Variation)

where Relative Percent Difference (RPD) = [(A - B) / mean] * 100

and A = the larger result,
B = the smaller result, and
mean = the average of the two results

and where Coefficient of Variation (COV) = s / mean

and s = sample standard deviation (see Glossary)

Note that a 14% RPD corresponds to a 10% COV.

mean	range (difference), based on 14% RPD
4.3 pCi/L	0.6 pCi/L
4.8	0.7
5.5	0.8
6.1	0.9
7.4	1.0
10.8	1.5
16.2	2.3
21.5	3.0
26.9	3.8
32.3	4.5
43.0	6.0
53.8	7.5
80.6	11.3
108.0	15.0
215.0	30.0
323.0	45.0
430.0	60.0

Conversion from the traditional U.S. units is not provided for each value here;
1 pCi/L corresponds to 37 Bq/m^3; see the Glossary for conversions.

x-axis. The value that is plotted is the actual difference between duplicates divided by the expected difference at that concentration.

The range ratio, R, is defined as

$$R = R_o/R_c$$

where: R_o = the observed range between duplicates, and
R_c = the expected range between duplicates at that concentration.

The center line for this chart would be set at one, and the upper control limit set at 3.3 (corresponding to about a one-tenth of one percent probability of seeing a range this large) and warning level of 2.5 (corresponding to about a 2.3 percent probability of seeing a range this large) or a warning level of 2.2 (corresponding to a 5 percent probability) (ASTM 1992, Taylor 1987, Goldin 1984). An example chart with various limits is shown in Exhibit A-5. Exhibit A-5a presents example duplicate data plotted on a range ratio control chart.

The expected value of the range can be taken from a plot of range versus concentration, as determined from previous measurements at or near that concentration. In the absence of a considerable number of previous measurements, a plot of expected range versus concentration developed from a ten percent coefficient of variation can be used (see Exhibit A-4). After about ten "in control" measurements have been made near that concentration, the expected range on the plot can be changed.

The probability limits for the range ratios (one-tenth of one percent probability at 3.3 and five percent at 2.2) can be understood using one-tailed statistics, as follows. The difference between two measurements can be termed the range. A frequency plot of the range on the x-axis versus the number of observed duplicates with that range on the y-axis would show that most duplicates have a value near the mean range, and fewer are out in the tails near zero and the maximum range. The mean range is equal to 1.128 times the standard deviation of a measurement (Rosenstein 1965, ASTM 1992). This can be used to calculate the percentiles for the right-hand tail of the distribution, where large ranges are found. We are not interested in the probabilities in

Exhibit A-5

Control Chart for Duplicates Using the Range Ratio Statistic (To Assess Precision)

where the range ratio, R, is defined as

$R = R_o/R_c$

R_o = the observed range between duplicates, and
R_c = the expected range between duplicates at that concentration.

and the expected range between duplicates is taken from experience with duplicates near that concentration or, if sufficient data are not yet available, using a plot constructed from the data in Exhibit A-4.

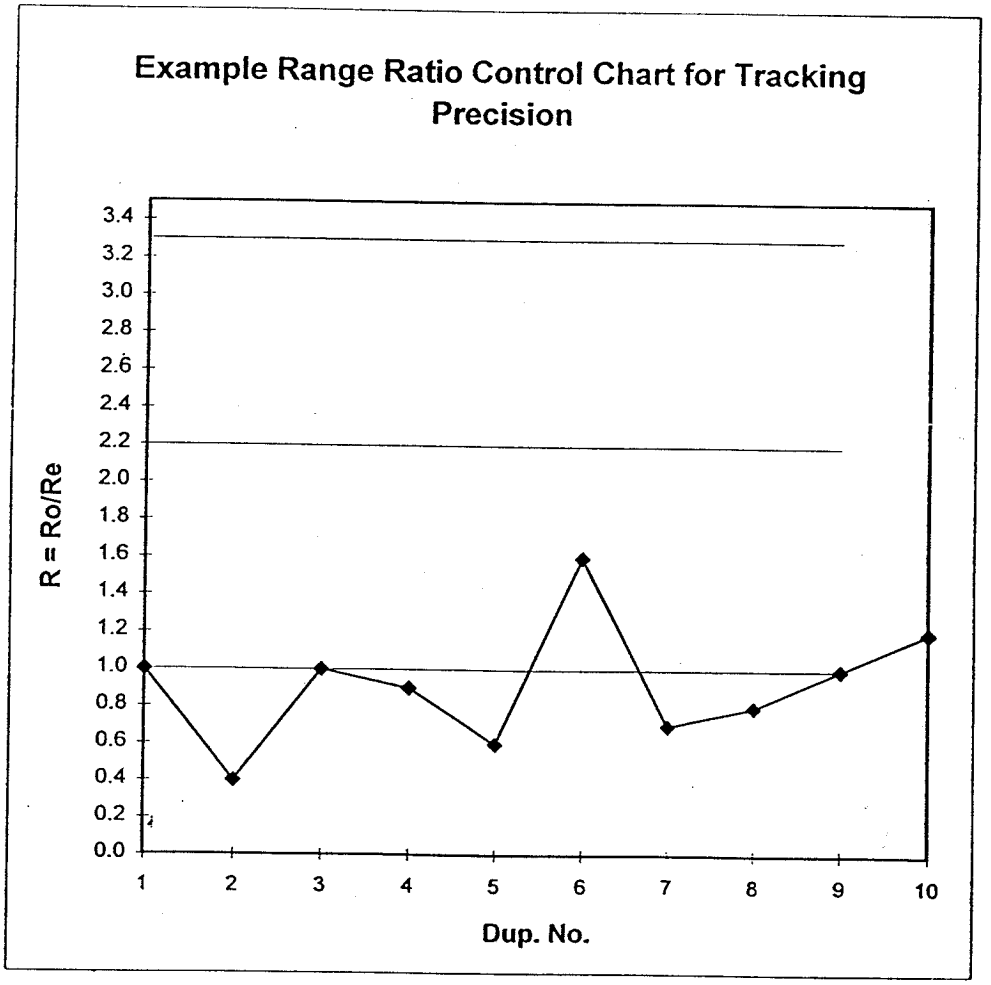
3.3	99.99% control limit; expect to see a range this great
	only about 0.13% of the time if all is operating in control
2.7	99.0% control limit; expect to see a range this great
	only about 1% of the time if all is operating in control
2.2	95% warning level; expect to see a range this great
	only about 5% of the time if all is operating in control
1.0	"in control" level; range ratio results will routinely be
	around this level of precision

date or sequential duplicate i.d. number . . . . . .

Example Range Ratio Control Chart for Tracking Precision

data (only when both results > 4 pCi/L)						
Date	Dup. No.	A (pCi/L)	B (pCi/L)	R_o	R_e	$R = R_o / R_e$
6/19/95	1	5.5	4.8	0.7	0.7	1.0
6/19/95	2	6.1	5.8	0.3	0.8	0.4
6/22/95	3	6.0	5.2	0.8	0.8	1.0
6/23/95	4	10.2	11.5	1.3	1.5	0.9
6/25/95	5	4.9	5.3	0.4	0.7	0.6
6/25/95	6	4.7	5.8	1.1	0.7	1.6
6/30/95	7	8.5	9.4	0.9	1.3	0.7
7/10/95	8	6.3	7.0	0.7	0.9	0.8
7/14/95	9	10.4	9.0	1.4	1.4	1.0
7/14/95	10	9.8	11.6	1.8	1.5	1.2

Ro = range observed (larger minus smaller result)
Re = range expected at this concentration (initially based on a 14% Relative Percent Difference)



the left tail of the distribution, where the ranges are near zero, and will include all those small values in the percentiles. Therefore approximately 50 percent of the ranges will be between zero and the mean range, 34 percent will be between the mean range and the mean range plus sigma, etc. Only about 0.0013 (about one-tenth of one percent) of the ranges should fall outside the mean range plus three sigma (sigma of the range).

Experience with control charts in industry has shown that the exact percentages (such as 0.13%) often do not apply, and these percentiles should not be treated as exact numbers. However, the limits are useful as trigger points and reference values (Parkany 1993).

The probabilistic interpretations of the control chart (e.g., less than one percent of the measurements outside the control limit by chance, and five percent outside the warning limit by chance) will not apply if the expected range is not representative of actual in-control measurements. However, comparing your results with the range given in Exhibit A-4 can serve as a starting point.

A.4.1.2 Sequential Control Chart Based on Coefficient of Variation

An alternate method of plotting the results of duplicates is to use a sequential control chart based on the 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 ($COV=S/X_m$ where S is the standard deviation, and X_m 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 (χ^2) test, where χ^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 4 pCi/L).

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

$$\chi^2 \approx 202[COV_n^2/(2 + COV_n^2)]$$

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 of 0.20. The control limit corresponds to a χ^2 of 6.63 and a COV_n of 0.26, where the probability of exceeding that value is only about 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.

A.4.1.3 Sequential Control Chart Based on Relative Percent Difference

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

$$RPD = [100|x_1-x_2|]/[(x_1+x_2)/2]$$

For n=2,

$$RPD = COV\sqrt{2}$$

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. These limits are 28% and 36%, respectively. 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.

A control chart using the statistic RPD based on an "in control" level of 25 percent RPD can also be constructed. The warning level and control limit are set at 50 percent and 67 percent, respectively. Use of these limits may be appropriate for measured radon concentrations less than 4 pCi/L, or 150 Bq/m^3, as determined by multiple simultaneous measurements at these low concentrations.

A.4.1.4 Range Control Chart

A range control chart (Goldin 1984), also termed a Range Performance Chart (Taylor 1987), can be constructed to evaluate precision, using the statistics of the range (difference between two measurements) plotted against the mean of the two measurements. The control limits are again based on the variability of the measurements, as decided upon from previous results or using an industry standard (e.g., 10 percent).

In this type of control chart, the limits are expressed in terms of the mean range (R_m), where, for n=2,

$$R_m = 1.128\ s(x)$$

where s(x) is the standard deviation of a single measurement, which reflects counting and other precision errors. Goldin shows that the limits can be expressed as follows:

Control limit = 3.69 s(x)
Warning level = 2.53 s(x)

This type of chart is used by plotting the range versus mean concentration as duplicate measurements are analyzed.

A.4.2 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, the QA Officer is responsible for investigating the system and determining if corrective action is appropriate.

Note that with the exception of the range ratio control chart, the charts described 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. However, methods discussed here present a conservative way to monitor and record measurement error and are useful for comparing observed errors with an industry standard.

A.5 MINIMUM DETECTABLE LEVELS

Many terms are now 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.

A.5.1 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, U.S. DOE 1990). It is based on work by Altshuler and Pasternack (Altshuler and Pasternack 1963), and Currie (Currie 1968). It is the quantity that Altshuler and Pasternack called “minimum detectable true activity” and Currie called L_D, the “*a priori* detection limit.” The LLD is based on a balance of the risk of false detection of activity not actually present (Type

I error, or false positive) against the risk of missing activity which is actually present (Type II error, or false negative). Values of 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

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

The values of K are given as tables of the normal distribution in statistical texts; some common values are given below.

a	1-b	K	$2^{3/2}K$
0.01	0.9	2.327	6.59
0.02	0.98	2.054	5.81
0.025	0.975	1.960	5.54
0.05	0.95	1.645	4.65
0.10	0.90	1.282	3.63
0.20	0.80	0.842	2.38
0.50	0.50	0.000	0.00

Therefore, for a 95 percent confidence level for detecting activity when it is present (1-b = 0.95), the LLD is set equal to 4.65 times the standard deviation of the background counts, or

$LLD = 4.65 s_b$, when the:

1) background is relatively stable;
2) measurement and background counting times are equal;
3) the distribution of the background counts follows a Gaussian distribution.

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 U.S. NRC (U.S. NRC 1980) applies the same definition: "the LLD is defined as the smallest concentration of radioactive material sampled that has a 95 percent probability of being detected, with only a five percent probability that a blank sample will yield a response interpreted to mean that radioactive material

is present. In other words, there is only a 5% chance of concluding that activity is present when it is not, and a 95% chance of correctly concluding that activity is present when it actually is."

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. This limitation of the LLD is particularly severe in alpha spectrometry, where the total background count in a peak area may be only one or two, even with counting times of several hundred minutes. For such low total counts, the assumption that the Poisson distribution can be approximated by a normal distribution also breaks down.

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:

$$LLD = 4.65 s_b$$

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.

A.5.2 Minimum Significant Measured Activity (MSMA)

Altshuler and Pasternack defined the minimum significant measured activity (MSMA) as the smallest measurement interpreted to demonstrate the presence of activity in the sample (Altshuler and Pasternack 1963). Currie (Currie 1968) called this quantity, L_C, the critical level. These terms refer to the evaluation of a gross measurement, after it has been made, as being significantly greater than background, or equivalently, a net measurement as being greater than zero. The test for this is the conventional statistical test of a difference as being greater than zero (Student's test).

If expressed in terms of counting rate, the net counting rate, r, is the difference between the gross observed counting rate, r_o, and the background counting rate, r_b. The variance of r is:

$$s^2(r) = s^2(r_o) + s^2(r_b)$$
$$= (r_o/t_o) + (r_b/t_b)$$

when only Poisson variability is included.

If $t_o = t_b = t$ (i.e., the counting times for the sample and background are equal),

$$s^2(r) = (r_o + r_b)/t$$

If $r_o = r_b$, then $s^2(r) = 2\ r_b/t$.

The net measurement has conventionally been considered to be significantly different from zero at the .05 level if $t > 1.96$. Actually, the one-sided test for which $t_{.05} = 1.65$, is probably more appropriate.

The t statistic is defined as:

$$t = (r_o - r_b)/s(r)$$

For t = 1.96, the MSMA is the corresponding difference of counting rates:

$$MSMA = 1.96\ (2r_b/t_b)^{1/2} = 2.77\ (r_b/t_b)^{1/2}$$

A.5.3 Use of LLD and MSMA

Both the LLD and the MSMA are useful, when each is restricted to its proper sphere. LLD is a prediction of measurement capability; MSMA is an evaluation of a completed measurement. The LLD should be used when describing a system's measurement capability (e.g., in proposals).

The LLD has been used improperly to evaluate a completed measurement. When this is done, there is a gray area between the point where the measurement, as evaluated by MSMA, has not been shown to be different from background, 2.77 s_b, and the LLD, 4.65 s_b. LLD cannot address measurements in this range.

The MSMA has been used, also improperly, to estimate minimum detectable activity. The MSMA is equal to an LLD with $k_b = 0$. This corresponds to a probability of 0.5 of detection. The MSMA, when used in this way, corresponds to only a 50 percent chance of detecting activity.

A.5.4 Reporting Low Values

The result obtained in a measurement, which is a sample of the infinite population of possible results, is the best estimate of the mean value of the population. These actual results, whether greater than or less than the LLD, and whether positive, negative, or zero, should be used in averaging. Elimination of results less than the LLD, or of results less than zero, introduces a bias into the overall average value (Wall and Goldin 1966).

Measurement organizations need to maintain records of all results as measured, which will include negative values in some cases. However, reporting results less than the LLD or less than zero to most clients will not serve the clients' or the measurement organizations' interests. When appropriate, results less than the LLD should be reported as "less than the lower limit of detection of ___," including the LLD as recently calculated using results of background measurements.

Appendix B

Information to be Included in a Measurement Report

Information to be Included in a Measurement Report

Measurement Provider Information:

name, address, phone and fax numbers
RPP ID #
any applicable State ID #
Analysis Laboratory RPP ID #, if different
Measurement Operator (or placement technician) RPP ID # (if applicable)
Date of Report:

Client Information:
name, address, phone numbers

Measurement Location:
address, other information (room, floor)

Measurement #:

The device used to measure radon/decay product concentrations was a ....., serial #/detector #.....

Measurement start date/time:
Measurement stop date/time:

Result: Note: The EPA recommends (EPA 1993) that measurement results should be reported in the units that the device measures, and, when using traditional U.S. units, that radon concentrations be reported to no more than one numeral to the right of the decimal (e.g., 4.3 pCi/L) and radon decay-product concentrations be reported in no more than three numerals to the right of the decimal (e.g., 0.033 WL). If the measured decay-product concentration is converted to a radon concentration, and the radon concentration was not actually measured, the report should state that this approximate conversion is based on a typical 50 percent equilibrium ratio, and that this indoor environment may have a different and varying ratio.

If result is greater than or equal to 4 pCi/L (150 Bq m^{-3}) or 0.02 WL ($4x10^{-7}$ Jm^{-3}): This level is greater than the EPA action level. You should consult the EPA recommendations for additional measurements or remedial action. These recommendations are in the enclosed "Citizen's Guide

To Radon" and "Consumer's Guide to Radon Reduction" (and State brochures, if applicable) along with telephone numbers for State officials who can answer your questions.

If the result is less than 4 pCi/L (150 Bq m^{-3}) or 0.02 WL ($4x10^{-7}$ Jm^{-3}): This concentration is less than the EPA action level. However, the EPA recommends retesting sometime in the future, especially if occupancy patterns change.

The Environmental Conditions Agreement (agreement to maintain closed-house conditions) was signed by the client or his/her designee, and the measurement operator found no indications of deviations from these conditions. In addition, no evidence for tampering with the measurement equipment was found. However, this organization is not liable for tampering with the equipment or changes in radon/decay product concentration due to changes in environmental conditions during the measurement.

If evidence of tampering found: The results of this test cannot be delivered because evidence of tampering with the measurement equipment was discovered. This includes: description of evidence. We recommend that another test be conducted.

Disclaimer statement.

Appendix C

Acronyms

Acronyms

AC	Activated charcoal adsorption
AT	Alpha-track detection (ATD)
Bq	Becquerel
CR	Continuous radon monitoring
CW	Continuous working level monitoring
EL	Electret ion chamber—long-term
EML	U.S. Department of Energy Environmental Measurements Laboratory
EPA	U.S. Environmental Protection Agency
ER	Equilibrium ratio
ES	Electret ion chamber—short-term
eV	Electron volt
GB	Grab radon/pump-collapsible bag
GC	Grab radon/activated charcoal
GS	Grab radon/scintillation cell
GW	Grab working level
L	Liter
LLD	Lower limit of detection (see Glossary)
LS	Charcoal liquid scintillation
m^3	Cubic meter
MeV	Mega-electron volt

MV	Measured value
NCRP	National Council on Radiation Protection and Measurements
ORIA	U.S. EPA Office of Radiation and Indoor Air (formerly ORP)
PB	Pump-collapsible bag
pCi/L	Picocuries per liter
QA	Quality assurance (see Glossary)
QAP	Quality assurance plan
QC	Quality control (see Glossary)
RH	Relative humidity
Rn	Radon
RP	Radon progeny integrating sampling unit (also RPISU)
RPD	Relative percent difference (see Glossary)
RPP	Radon Proficiency Program
RV	Reference value, used as the known or "true" value
SC	Evacuated scintillation cell (three-day integrating)
SOP	Standard operating procedure (see Glossary)
T	Temperature
TLD	Thermoluminescent dosimeter
UT	Unfiltered track detection
WL	Working level

GLOSSARY
and
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Accuracy: See Bias and page A-1 of Appendix A.

Analytical service provider: An organization or individual that provides radon measurement services or activities, at a specific business location, that includes the capability to analyze or read the radon measurement device(s) being used. Such an analysis or reading capability may involve a laboratory or portable equipment and operators. This was formerly known as a "primary" in the RMP Program. *(See also Residential service provider, U.S. EPA 1995a.)* 4-1, 4-2

Audit: A planned and documented investigative evaluation of a program to determine the adequacy and effectiveness of as well as compliance with established procedures, QA Plans, and other documentation. 6-5, 9-12

Background field measurement (blanks): Measurements made by analyzing unexposed (closed) detectors that accompanied exposed detectors to the field. The purpose of field background measurements is to assess any change in analysis result caused by exposure other than in the environment to be measured. Results of background field measurements can be subtracted from the actual field measurements before calculating the reported concentration. Background levels may be due to leakage of radon into the detector, detector response to gamma radiation, or other causes. 8-6, 8-9

Background instrument (analysis system, or laboratory) count rate: The nuclear counting rate obtained on a given instrument with a background counting sample. Typical instrument background measurements are: 8-6, A-2

- Unexposed carbon: for activated carbon measurement systems.
- Scintillation vial containing scintillant and sample known to contain no radioactivity: for scintillation counters.
- Background measurements made with continuous radon monitors exposed to radon-free air (aged air or nitrogen).

Background radiation: Radiation arising from radioactive materials, the sun, and parts of the universe, other than that under consideration. Background radiation due to cosmic rays and natural radioactivity is always present; background radiation may also be due to the presence of radioactive substances in building materials. 8-6, 8-9

Becquerel (Bq): A unit of radioactivity representing one disintegration per second. The concentration of radon in air can be expressed in units of Becquerels per cubic meter, or Bq m^{-3}, where 0.027 Bq m^{-3} = 1 pCi/L.

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Bias: The degree of agreement of a measurement (X, or average of a set of measurements that are assumed to be representative of the long-term average) with an accepted reference or true value (T); often expressed as the difference between the two values (X - T), or the difference as a percentage of the reference or true value (100[X - T]/T), and sometimes expressed as a performance ratio (X/T). 8-11, 9-6

Calibrate (calibration): To determine the response or reading of an instrument or measurement system relative to one or more known values over the range of the instrument; results are used to develop correction or calibration factors. 7-1

Chain-of-Custody: An unbroken trail of accountability that ensures the physical security of devices, data, and records. 6-1

Check source: A radioactive source, not necessarily calibrated, which is used to confirm the continuing consistent and satisfactory operation of an instrument. 8-13, 9-11 A-2, A-5

Client: The responsible individual or parties who hire(s) the radon tester. B-1

Coefficient of variation (COV), relative standard deviation (RSD): A measure of precision, calculated as the standard deviation (s or σ) of a set of values divided by the average (X_{avg} or μ), and usually multiplied by 100 to be expressed as a percentage.

$COV = RSD = (s/X_{avg}) \times 100$ for a sample,

or

$COV' = RSD' = (\sigma/\mu) \times 100$ for a population.

See Relative percent difference.

Corrective action: An action taken to rectify conditions adverse to quality and, where necessary, to preclude their reoccurrence. 3-2, 9-11, 9-13

Counting statistics (error): The inherent variability of a radiation measurement due to the random nature of the radioactive disintegration and detection processes. 8-5, A-10 A-15

Curie (Ci): A unit of radioactivity equal to 3.7×10^{10} disintegrations per second. A standard measurement unit for radioactivity, specifically the approximate rate of decay for a gram of radium = 37 billion decays per second.

Data validation: The process of checking measurement information to ensure that it is correctly recorded (transcribed, modemed, faxed, calculated, typed, printed, etc.). Data validation should be conducted on portions of all recorded information. 6-5

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Duplicate measurements: Two measurements made concurrently and in the same location, side-by-side. (Charcoal adsorbing devices should be about 4 in. (10 cm) apart. Other types of devices should be directly adjacent or touching.) The results are used to monitor the precision error of the measurement method.

Energy alignment source: A source containing alpha- or gamma-emitting nuclides covering the range of energies for which a spectrometer is used.

Equilibrium ratio, radon: The equilibrium ratio in traditional U.S. units = [WL(100)]/ (pCi/L). At complete equilibrium (i.e., at an equilibrium ratio of 1.0), 1 WL of radon decay products would be present when the radon concentration is 100 pCi/L. The ratio is never 1.0 in a house. Due to ventilation and plate-out, the radon decay products never reach equilibrium in a residential environment. A commonly assumed equilibrium ratio is 0.5 (i.e., the radon decay products are halfway toward equilibrium), in which case 1 WL would correspond to 200 pCi/L. However, equilibrium ratios vary with time and location, and ratios of 0.3 to 0.7 are commonly observed. Large buildings, including schools, often exhibit equilibrium ratios less than 0.5. B-1

Gamma radiation: Short wavelength electromagnetic radiation of nuclear origin, with a wide range of energies.

Instrument check source: A source used for determining the consistency of response of an instrument. Instrument check sources are counting samples with a predictable count rate, such as a plated uranium oxide or lead-210 planchet, or a tritium scintillant gel. The check source need not be a standard source but counting times should be long enough to give enough counts for good counting statistics.

Lower limit of detection (LLD): The smallest amount of sample activity which will yield a net count for which there is confidence at a predetermined level that activity is present. For a five percent probability of concluding that activity is present when it actually isn't, the LLD may be approximated by a value of 4.65 times the standard deviation of the background counts (assuming large numbers of counts where Gaussian statistics can be used and for equal background and sample counting times [ANSI 1989, Pasternack and Harley 1971, U.S. DOE 1990, U.S. NRC 1986]). 8-7, A-25

Mean: The average. The best estimate of the mean of an entire population, as calculated from k samples (x_1, x_2, ...x_i,...x_k) is given by:

$$m(x) = \sum_{i=1}^{k} x_i/k$$

Normal approximation to the Poisson distribution: A normal distribution is described by two parameters, its mean and standard deviation. If a normal distribution is constructed by assigning the mean value of a Poisson distribution as both the mean and variance, that normal distribution may be used as an approximation to the Poisson distribution. The approximation is better for larger values of the mean value, and is generally considered useable when the mean exceeds about 20 counts (Jarrett 1946).

Picocurie (pCi): One pCi is one trillionth (10^{-12}) of a curie, 0.037 disintegrations per second, or 2.22 disintegrations per minute.

Picocurie per liter (pCi/L): A traditional unit of radioactivity corresponding to an average of one decay every 27 seconds in a volume of one liter, or 0.037 decays per second in a liter of air or water. This unit can be converted to the modern international units of Becquerel per cubic meter; 1 pCi/L = 37 Bq m^{-3}. B-1

Poisson statistics: The number of radioactive disintegrations in a quantity of radioactive material in a given time is described by the Poisson frequency distribution. The number of events recorded by a detector system that counts a constant fraction of the disintegrations is also described by the Poisson frequency distribution. For example, the number of counts obtained by repetitive 10-minute counting of a radium source will cluster about a mean value with a Poisson distribution. The Poisson distribution is described by a single statistic, the mean, which is also equal to the variance. Quantities derived from the number of counts, such as the counting rate, are not necessarily described by Poisson statistics.

Potential alpha energy concentration: The concentration of radon decay products, in air, in terms of the alpha energy that will be released during complete decay of Rn-222 through Po-214.

Precision: A measure of mutual agreement among individual measurements made under similar conditions. Can be expressed in terms of the variance, pooled estimate of variance, range, standard deviation at a particular concentration, relative percent difference, coefficient of variation or other statistic. 8-1, 9-5, 9-13, A-10

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Quality: The total properties or characteristics of a service and product (e.g., measurement results and delivery) that bear on the ability to meet the needs and expectations of the client.	2-1, 3-1
Quality assurance: A system of activities whose purpose is to provide the client with the assurance that the product and/or service meets their needs and expectations in terms of defined standards of quality (precision, bias, and total error over time, for example). Includes management, planning, documentation, and quality control and improvement activities.	2-1, 3-1
Quality Assurance Plan (QAP): A formal technical document containing the detailed procedures for ensuring and documenting quality. The QAP will also contain a description of the management policies, organizational authority, responsibilities, and reporting for ensuring quality services (unless a separate Quality Management Plan is prepared).	9-1
Quality control: The system of activities designed to control the quality of the products, including measurements made to ensure and monitor data quality. Includes calibrations, duplicate, blank, and spiked measurements, routine instrument performance checks, interlaboratory comparisons, audits, and measures of customer satisfaction.	2-1, 8-1
Quality management: That part of the management system that determines and implements quality policies. This may include planning and allocation of resources.	2-1, 3-1 5-1
Quality system: A documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes and products. The QA Plan may serve as the documentation of the quality system.	3-1, 5-2
Radon (Rn): A colorless, odorless, naturally occurring, radioactive, inert, gaseous element formed by radioactive decay of radium (Ra) atoms. The atomic number is 86. Although other isotopes of radon occur in nature, radon in indoor air is primarily Rn-222.	
Radon calibration chamber (calibration facility): An airtight enclosure in which operators can measure and, in some cases, induce and control different environmental parameters and concentrations of radon and decay products. A radon calibration chamber can be used for exposing devices for initial or periodic calibrations, spikes, or evaluating device response to various parameters.	7-1, 7-2 7-3, 8-11

Relative percent difference (RPD): A statistic used to track precision errors, calculated by:

$$RPD = [(|X_1 - X_2|)/X_{avg}] \times 100$$

where: X_1 = concentration observed with the first detector or equipment;
X_2 = concentration observed with the second detector, equipment;
$|X_1 - X_2|$ = absolute value of the difference between X_1 and X_2; and
X_{avg} = average concentration = $((X_1 + X_2)/2)$.

The RPD and coefficient of variation (COV) provide a measure of precision, but they are not equal. Below are example duplicate radon results (in traditional units only for this example) and the corresponding values of RPD and COV:

Rn1 (pCi/L)	Rn2 (pCi/L)	RPD (%)	COV (%)
8	9	12	8
13	15	14	10
17	20	16	11
26	30	14	10
7.5	10	29	20

Note that the $RPD/\sqrt{2} = COV$.

See Coefficient of variation (COV).

Relative standard deviation: See Coefficient of variation.

Residential service provider: An organization that provides consultation (presenting information about radon and its risks, providing advice, making recommendations and referrals), packaging radon measurement devices, and placing or retrieving radon measurement devices in a residential setting. This was formerly known as a "secondary" in the RMP Program (U.S. EPA 1995a). 4-1, 4-2, 4-4

Spiked measurements (spikes), or known exposure measurements: Quality control measurements in which the detector or instrument is exposed to a known concentration in a calibration facility and submitted for analysis. Used to evaluate relative bias. 8-11, 9-6, A-9

Standard deviation (s): A measure of the scatter of several sample values around their average. For a sample, such as several radon measurements

out of the possible population of radon measurements, the sample standard deviation (s) is the positive square root of the sample variance:

$$s = \frac{\sqrt{\sum_{i=1}^{n} (X_i - X_{avg})^2}}{\sqrt{n - 1}}$$

In general, the sample standard deviation should be used.

For a finite population in which all measurements are known, the population standard deviation (σ) is:

$$\sigma = \frac{\sqrt{\sum_{i=1}^{N} (X_i - \mu)^2}}{\sqrt{n}}$$

where μ is the true arithmetic mean of the population and n is the number of values in the population. The property of the standard deviation that makes it most practically meaningful is that it is expressed in the same units as the observed variable X. For example, the upper 99.5 percent probability limit on differences between two values is 2.77 times the sample standard deviation.

Standard operating procedure (SOP): A written document which details an operation, analysis, or action whose mechanisms are prescribed thoroughly and which is officially accepted as the method for performing routine tasks. 6-1

Standard Reference Material (SRM): A term used by the National Institute of Standards and Technology for its calibrated reference materials. 7-1

Statistical control chart (Shewhart control chart): A graphical chart with statistical control limits and plotted values (for some applications in chronological order) of some measured parameter for a series of samples. Use of the charts provides a visual display of the pattern of the data, enabling the early detection of time trends and shifts in level. For maximum usefulness in control, such charts should be plotted in a timely manner (i.e., as soon as the data are available).

Statistical control chart limits: The limits on control charts that have been derived by statistical analysis and are used as criteria for action, or for judging whether a set of data does or does not indicate lack of control. On a means control chart, the warning level (indicating the need for an investigation) may be two sample standard deviations above and below the mean, and the control limit (indicating the need to halt operations until the problem is identified and corrected) may be three sample standard deviations above and below the mean.

Trueness: A term used to describe the difference of the mean of a finite number of measurements from the "true" or assumed value. This term is related to the term bias, which is used to describe the difference between the long-term average difference from the "true" value (Parkany 1993).

Uncertainty: The range of values within which the true value is estimated to lie. It is a best estimate of possible error due to both random errors (imprecision) and systematic errors (that produce bias).

Variance: The best estimate of the variance, from k samples out of the entire population (x_1, x_2,...x_i,...x_k) is given by:

$$s^2 = \frac{\sum_{i=1}^{k} (X_i - X_{avg})^2}{k - 1}$$

Working level (WL): Any combination of short-lived radon decay products in one liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha energy. This number was chosen because it is approximately the alpha energy released from the decay products in equilibrium with 100 pCi of Rn-222. In modern, international units, 1 WL = 2.08×10^{-5} Jm^{-3}. B-1

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