Quality Assurance Plan for Conducting Radon Measurements

MDH Standard QA Plan V3.2

Date of original QA Plan
10/31/2019

Date of Last Revision
03/31/2022

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Updated 02/15/2022
To obtain this information in a different format, call: 651-201-4601.

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Introduction

Policy and Commitment

In order to protect health and financial interests of building owners and occupants, it is the policy of our organization to provide accurate, reproducible, and valid measurements of indoor radon concentrations. Each measurement employee is individually and collectively committed to the highest quality work in accordance with this plan.

Quality Assurance Plan Purpose

The purpose of this Quality Assurance (QA) Plan is to: set policies, performance goals, and objectives; identify responsibilities; establish procedures for assessing performance relative to quality; and to define corrective actions when needed.

It is important to recognize that usually quality assurance practices result not in the identification of out-of-control processes, but in the continued documentation of stable, within limits operations. Only with such documentation can the validity of measurement results be defended.

This QA plan will be revised with any adjustments involving changes of personnel and measurement devices as well as regulatory requirements or professional association recommendations. If there are no revisions triggering changes, this plan will be reviewed a minimum of annually.

Quality Assurance Goal and Objectives

Our staff are committed to providing customers with accurate, valid, reproducible, and defensible radon measurements which may be used to make critical decisions about radiation-related environmental health.

The objectives of the QA plan are to maintain a quality measurement program and to document relative quality. In addition, a QA program adds greatly to an operators understanding of the methods they use and provides early detection of problems so that they can be rectified quickly and completely.

We collect evidence of the relative quality of our performance and evaluate that evidence through Quality Control (Section 6), take Corrective Action as needed (Section 7), and conduct Quality Assurance Audits (Section 9). A record of this evidence and resulting actions are maintained with this QA Plan.

Organization

Licensed radon professionals are responsible for our organization's field radon measurements. The owner/president is responsible for all aspects of operations. The Quality Assurance Officer is responsible to the President for all QA as related to field operations and for field measurements and data analysis.

This QA Plan was reviewed by all personnel involved with radon work and will continue to be made available for future reference.

Description of Operations

Duties of the Quality Assurance Officer

The Quality Assurance Officer's responsibilities are to:

- ensure proper storage of radon measurement devices;

- design and present training to new employees and, on an annual basis, to all employees;
- oversee measurement device use including placement and retrieval;
- create and maintain QA records;
- prepare or oversee client test reports and to specify how they are distributed to clients;
- manage and oversee quality control (QC) measures;
- initiate QA audits;
- make recommendations on corrective action and to insure corrective action is carried out;
- initiate QA audit reporting to management; and
- participate in all meetings regarding staffing, training, equipment, record keeping, and changes in practices and procedures.

Personnel and Subcontractor Qualifications

Staff members and/or contractors conducting radon measurement services are individually licensed as radon measurement professionals by Minnesota Department of Health (MDH). This includes anyone placing and/or retrieving testing devices.

Documents and Records

All records and documents are maintained so they are legible, retrievable, and protected from fire, water, theft, and deterioration for a minimum period of 3 years. Computer software and records for our radon measurements are routinely backed up to the cloud or a remote server.

Measurement Procedures

We perform radon measurements in accordance with Minnesota state statutes, rules, adopted measurement standards of practice, and the instructions of the measurement device manufacture(s).

Measurement Devices

The measurement devices used shall be listed for meeting the requirements of Minnesota state statutes and rules and be approved for use by the state and NRPP.

Until use, radon measurement devices shall be stored in dry, low radon environments, and per manufacturer instructions.

Safety

The licensed radon professional shall not enter any area or perform any test that would damage property or risk the professional's own or another's safety. If it is known that closed-house conditions are detrimental to the health of the occupants, then the radon survey using a short-term test shall not be done.

Measurement Procedures

Our company will follow the Minnesota Radon Licensing Act and rules and standards listed below:

- ANSI/AARST Protocol for Conducting Measurements of Radon and Radon Decay Products in Homes (ANSI/AARST MAH-2019) or successor ANSI/AARST standards, and test each unique foundation type;
- ANSI/AARST Standard: Protocol for Conducting Radon and Radon Decay Product Measurements in Multifamily Buildings (ANSI/AARST MAMF-2017) or successor ANSI/AARST standards;
- ANSI/AARST Protocol for Conducting Measurements of Radon and Radon Decay Products in Schools and Large Buildings (ANSI/AARST MALB-2014) or successor ANSI/AARST standards.

Data Validation

Valid data is produced when a measurement system, including storage, field deployment, transport, analysis, and reporting are operating "in control" and within QC limits and when in-control QC checks have been made both before and after a set of validated data. It is the responsibility of the qualified measurement professional to conduct, record, and make available the results of QC checks relevant to each reported result.

The Quality Assurance Officer will review radon reports to ensure the QA Plan is being followed. Validation factors include proofreading files to see that information entered into the computer from the test placement/retrieval checklist is correct. Any errors found during validation checks are documented including who made the errors, the dates of the errors, and how these errors were resolved.

Internal Quality Control

Quality control refers to the technical activities that measure the attributes and performance of a process, item, or service against defined standards in order to verify that they meet established specifications, including documentation.

Commitment to Quality and Objective

Our staff is committed to providing customers with accurate, valid, reproducible, and defensible radon measurements which may be used to make critical decisions about radiation-related environmental health. The due diligence of each employee and contractor involved with radon measurement is critical for achieving this goal.

A critical step to insure radon measurements meet nationally accepted quality standards is to conduct quality control (QC) measurements at prescribed rates and systematically over time. QC measurements shall be recorded electronically or in a logbook as soon as practicable, and shall be maintained for a minimum of three years. Failed QC measurements should be repeated prior to investigation and corrective action.

A measurement system must operate in such a way as to produce repeatable and stable quality control results. This is accomplished by performing calibration (with background checks) and duplicates for CRMs, and duplicates, spikes, and blanks for passive methods, as well as other method-specific checks.

Continuous Radon Monitors

Calibration

Calibration refers to the process of determining the response of a measurement device to a series of known radon concentrations and making necessary adjustments to the device. Calibration is made every 12 months or after repair for each CRM by either, the monitor manufacturer or a national radon proficiency program approved calibration laboratory approved by the device manufacturer.

Any monitor that does not have a calibration certification, dated within 12 months, must be removed from service.

In addition to calibration, an annual **background check** is performed by purging with clean aged air or nitrogen. The manufacturer or calibration laboratory completes this process at the time of calibration.

Routine Instrument Checks

Instrument checks involve using the manufacturer's instructions for checking for proper working condition including checking battery voltage levels, cleaning screen inlet ports, and verifying that calibration is up-to-date. Performance checks will be made before every measurement.

Duplicates

Radon measurements, like all measurements, usually do not produce exactly the same results, even for simultaneous, co-located measurements. Duplicate are two side-by-side measurement devices placed 4 to 8 inches apart, or as specified by the manufacturer, that simultaneously measure radon.

The objective of duplicate tests is to verify and document that there have been no increases in the measurement system imprecision since the last passing QC check or calibration. Passing duplicate tests before and after a set of measurements gives assurances that the device was functioning properly during all tests between those two QC measurements. Duplicates shall be made at a rate of every 10^{th} measurement per device (10%). Tests should be randomly distributed and deployed in the normal course of business across a variety of projects, operators, and environments.

Certain events may occur that create the need to do a duplicate test to ensure the device is functioning accurately before the device is placed into service again. When a CRM is received, either new or from recalibration, when a device has been mishandled or dropped, or when exposed to harsh environments. This practice can identify inaccurate recalibrations, malfunctions, or damage during shipping, handling, or misuse.

When duplicate measurements are made, the results are reported as such to the customer who receives the test. The individual results and the average of the two will be reported. In addition, results of duplicates are recorded on Duplicate Control Charts.

Precision involving duplicates is calculated by using Relative Percent Difference (RPD). RPD is equal to the difference between the higher test result minus the lower test result divided by the average of the two duplicate test results, which is then multiplied by 100. The RPD result is then compared to warning levels and control limits. The Warning Level is set at the deviation from ideal performance that would be expected to occur by chance only 5% of the time, and Control Limits are set at that deviation from ideal performance that would be expected to occur by chance only 1% of the time. The Warning Level indicates a potential problem, which should be investigated. The Control Level indicates that the measurement system should be subject to corrective action and probable recalibration.

The control and warning limits for duplicates are:

- at concentrations averaging less than 2 pCi/L, the warning limit is 1 pCi/L,
- between 2 and 3.9 pCi/L,
  - the warning level is 50% RPD;
  - the control limit is 67% RPD;
- 4 or more pCi/L,
  - the warning level is 28% RPD;
  - the control limit is 36% RPD.

If within any 30-day period, precision errors are found that exceed control limits or if any two exceed warning levels within a month, an investigation will be launched, if applicable, in consultation with the analytical laboratory and state authorities.

Passive Devices

Routine Instrument Checks

Checks include examining packaging upon both receipt and disbursement of the devices.

Duplicates

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The objective of duplicate tests is to assess the precision error of the measurement method or, in other words, how well two side-by-side measurements agree or disagree.

Duplicates shall be made at a rate of 10% of all measurement locations. Tests should be randomly distributed and deployed in the normal course of business across a variety of projects, operators, and environments.

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  - the warning level is 28% RPD;
  - the control limit is 36% RPD.

If within any 30-day period, precision errors are found that exceed control limits or if any two exceed warning levels within a month, an investigation will be launched, if applicable, in consultation with the analytical laboratory and state authorities.

Blanks

Blanks are measurements performed to determine if the measurement device may have unintended exposure (background) during storage, handling and shipping. A blank is an unexposed measurement device that is opened, immediately closed and sealed, and, like an exposed measurement device, labelled with plausible start and stop dates and times, and then returned to the analytical laboratory. Blanks must be the same type, configuration, and from the same analytical laboratory as the other devices used by the provider. To facilitate problem investigations, it is important to track the environments that the measurement devices are stored, transported, and used.

Blanks are made at a rate of 5% of measurements or 25 per month, whichever is less. The results of blank measurements are recorded on a Blank Control Chart.

Blank test results should be less than the minimum detectable concentration of the passive measurement device. If background is detected with any blank, investigation shall be made into the cause which could include contacting the analytical laboratory. Corrective action shall be made as necessary to remedy any discovered issues.

Spikes

Spikes are also called known exposure measurements and are made to determine accuracy at a rate of 3 per 100 measurements per device type, minimum of 3 per year, and a maximum of 6/month. Spike measurements are obtained from a spiking chamber that is certified by NRPP or NRSB. The process involves: 1) sending an unused passive measurement device(s) to the approved chamber; and 2) then, after it is returned, sending the device to the device's analytical laboratory.

Spiked devices must be the same type and configuration as those used by the measurement provider. In the event of an order of more than 50 passive measurement devices, at least one spiked measurement should be made before using the remaining devices as well as periodically over the course of the year.

The results of spiked measurements are recorded on a Spike Control Log and Chart. Relative Percent Error (RPE) is calculated by subtracting the spiking chamber's value from the value obtained from the analytical laboratory, and that difference is divided by the spiking chamber's value. The expectation is that the values of RPE fall between +10% and -10%, but the entire range of +20% to -20% is considered "in control." Outside of +/- 20% but inside of +/- 30% is the warning level and outside of +/- 30% is the control limit. Any RPE outside of 20% will be investigated and documented.

Corrective Action

This section specifies procedures and corrective action taken when: problems have been revealed by QC measures or internal QA audits; deviations from routine circumstances are found; and complaints or suggestions are received from customers or licensed radon professionals.

The QA Officer is responsible for assessing the potential impact or effects of problems on radon testing and initiating corrective action. To avoid problem recurrence, corrective action includes initiation of preventive actions. Documentation of your investigation and corrective action is an essential part of the QA plan. Having an unusual QC measurement is possibly acceptable, however, not investigating the issue defeats the whole purpose of the doing the test.

If there is a pattern of quality control measurements that is not within the expected range of results, then the system may be out of control and all results are questionable. When a QC measurement is in the warning level, there may be a potential problem and investigation is required. When a QC measurement is outside the control limit, the measurement system shall be subject to corrective action and possibly recalibration.

Investigation includes communicating with MDH, instrument providers, the analysis laboratory and shippers (as relevant) to find and fix the cause of poor measurement performance, as well as thorough documentation of the problem, the solution and preventive action. Failed QC checks may indicate a problem with already-completed measurements, and corrective action in that case may include retesting environments where previous measurements are not defensible. Investigation records document how the results of QC checks were used to validate or invalidate measurements already conducted with that measurement system.

It is important to note that some failed QC results, especially those near the limits, may occur solely by chance and not be due to a correctible problem. This can be the case if the QC check is repeated and is within limits. In such cases, no corrective action is needed, but it shall be documented.

Important Duplicate Requirement: If one measurement is equal to or greater than 4 pCi/L and the other below, the higher result may not be twice or more than the other. Such measurements **MUST** be repeated. Examples are 2.0 and 4.1 or 1.9 and 4.0.

If blanks exceed the lower limit of detection, investigation will be performed to identify the cause of the problem. The remainder of the test kits will not be used until the problem is identified to determine if all of the kits have been contaminated. Necessary corrective actions will be taken as advised by the analysis laboratory and MDH.

If problems are found during internal audits or inspections, the QA Plan will be reviewed and staff will be trained on proper procedures. Potential problems with proper procedures could include detectors not returned within the time limit, closed house conditions not being maintained, improperly returned devices, device tampering, etc.

Quality Assurance Training

The Quality Assurance (QA) Officer is responsible for reviewing and developing the training plans for all staff and the plans for retraining when procedures change. New staff shall receive QA training prior to conducting radon measurements. Adequate training is given high priority, since the implementation of this QA plan is dependent upon the staff's understanding of its requirements. The training includes an emphasis on each employee's ethical and legal responsibilities for reliable and valid measurement test results as well as reporting of those results.

Personnel are responsible for knowing everything in this QA Plan, which falls within their particular area of responsibility. This QA Plan is the principle source document for the QA procedures and protocols, which must be known and practiced by responsible company personnel.

The QA Officer provides each employee with a copy of this QA Plan in which the specific QA activities and responsibilities for that particular employee are clearly marked and indexed.

Prior to conducting radon measurements and at least annually thereafter, the QA Officer checks each involved employee's knowledge and understanding of their QA duties and responsibilities as defined in this Plan. If, in the judgment of the QA Officer, an employee does not adequately understand his/her responsibilities, follow-up instructions and checks are carried out until acceptable understanding is demonstrated. The QA Officer notifies the employee's supervisor of each check result and these results are given consideration in compensation and job advancement reviews.

Quality Assurance Audits and Reports

QA Audits are formal, structured comprehensive and independent reviews to determine whether quality activities comply with planned arrangements and are suitable to achieve objectives.

The QA Officer conducts QA Audits periodically and reports audit results in writing to the Owner or Manager. QA Audit Reports contain the following information about measurement data quality: record keeping; results of duplicates, blank and spike test results; calibration completions; routine instrument checks; source check results; results of any additional audit steps; revisions of the QA Plan; and corrective action needed and enacted.