C-NRPP Quality Assurance Guidance for Radon Test Devices

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1. Purpose

The purpose of a Quality Assurance/Quality Control (QA/QC) program is to ensure proper processes are followed by all individuals responsible for radon measurements so that if errors do arise they will be recognized early on. The source of the error should be identified, and adjustments shall be made to correct issues to ensure that high quality results are obtained.

This document will detail information for quality assurance of C-NRPP approved radon measurement devices. Professionals should understanding proper test placement and device protocols. However, if the C-NRPP certified professional is performing according to standards but the devices are not, the end result is inaccurate and unreliable test results, therefore the bulk of this manual will cover how to ensure the devices are performing properly.

2. Definitions

Accuracy - refers to the closeness of a measured value to a standard or known value.

Calibration - correcting a measuring instrument by measuring values whose true values are known **Change Control** – measures that need to be taken after an error is discovered

Lowest Level of Detection (LLD) LLD is based on the detector and analysis system's background and can restrict the ability of some measurement systems to measure low concentrations.

Organization's Radon QA/QC Coordinator: one individual in an organization who is responsible for ensuring C-NRPP Quality Assurance measures are followed by all radon professionals in the organization and for all the devices used in an organization

Measured Value (MV) – level given by a measurement device

Precision – refers to the closeness of two or more measurement results to each other.

Quality Assurance Plan – the planned and systematic activities implemented in a quality system to ensure that quality requirements are met.

Quality Control – the process of measuring the ongoing performance of its devices to ensure continued conformance to established performance standards;

Relative percent differences (RPD) – comparison of two measured values

Relative Percentage Error (RPE) – a measurement of inaccuracy

Reference value (RV) – the fixed or known amount of either the exposed radon level or voltage on an electret

Uncertainty - is the total error generated by precision and accuracy errors.

3. Quality Assurance Plan

A proper Quality Assurance Plan should be in place when a company begins offering radon measurement services. It will take into account all employees who will be interacting with the measurement process. It should be a process that is appropriate for the number of employees in the organization and should be familiar to all employees. At least one individual in the organization should be responsible to ensure the Quality Assurance Plan is accurate to current practices within the organization, ensure that the protocols are known by all individuals in the organization and is informed

of any errors and ensures any corrective action is taken. This individual should be identified in the Quality Assurance Plan as the Organization's *Radon QA/QC Coordinator*.

A Quality Assurance Plan must include the following elements:

- I. Background information on the organization
- II. Name of Organization's Radon QA/QC Coordinator
- III. Organization's Radon Services Offered
- IV. Identify Radon Devices Used
- V. Identify Employees Using Radon Measurement Devices and Personnel Qualifications
- VI. Work Flow Control and Radon Test Procedures (measurement Protocols)
- VII. Documentation and Record Control
- VIII. Change Control
- IX. Calibration and Maintenance Plans
- X. Procedures for Non-Conformances and Corrective Action
- 4. Calibration

Measurement device calibration is to be conducted in accordance with the manufacturer's recommended calibration schedule. The calibration is to be conducted by the manufacturer or an authorized representative of the manufacturer. Calibration ensures that the machine is operating properly and measuring accurately. Typically a measurement device or associated equipment will require calibration once a year, but the manufacturer's recommendations should be verified and followed.

Calibration records for all devices should be maintained and labels provided on calibrated devices to identify upcoming calibration dates.

Devices requiring Calibration: Electret Ion Chamber Voltage Readers and CRMs

5. Spikes/Performance Tests

Spike/Performance tests or inter-comparisons (blind proficiency test) are to be conducted according to the C-NRPP recommended schedule. Blind performance testing or inter-comparisons involve sending the radon devices to the organizer of the inter-comparison, where the radon devices will be placed in an accredited radon chamber and exposed to a known radon concentration. Upon receipt of the exposed devices, the measurement lab or Electret Ion Chamber user will determine the radon concentration and report the radon level (kBq/m³*h or Bq/m³) to the organization conducting the inter-comparison. Spikes/Performance tests are designed to measure the accuracy of the radon measurement device.

To calculate the acceptance range you need to use the calculation to determine the Relative Percentage Error (RPE).

RPE = [(MV-RV)/RV]*100% *where:* RPE = relative percentage error; MV = measured value of spiked measurement; and RV = reference value.

Tests are acceptable if they are within +/-25% at radon levels of 150 Bq/m³ or greater.

Accuracy should be focusing levels radon levels near the action level therefore, chamber levels should be between 150 and 600 Bq/m³ equivalent for the average test duration length.

Spikes are also a method of determining the lowest and highest level of detection of a device. This should be determined by a manufacturer, however a device user who is using more than 1000 tests per year, may want to discuss with the chamber about having spikes exposed to a variety of levels on each batch of spikes that are sent out, for example the first spike should be within a level of guideline, a subsequent spike could be high and the following could be low.

6. Field Duplicates

Field duplicate tests (or Duplicates) are quality control measurements designed to assess the precision of radon measurement devices. Duplicate tests are required for every 10% of tests deployed by an organization. The first detector deployed by the measurement provider should be a duplicate and every 10th test after that should also be a duplicate test.

Duplicate tests should be conducted by placing two radon devices side-by-side, 10 cm (4") apart. The test duration for the two devices must be the identical, meaning that the start and stop must be the same. Duplicates provide assurance to an organization that the tests are providing acceptable precision. Duplicate measurements should be compared by calculating their relative percent difference (RPD)

Calculating Relative percent differences:

<u>|Test 1 – Test 2|</u> ((Test 1 + Test 2)/2) X 100

The following chart provides guidance on allowable variances in RPD for duplicate tests.

Average Test	Acceptable RPD	Warning Level
Measurement		
<75 Bq/m ³	No limits	No limits
75 – 149 Bq/m ³	Less than +/- 25%	+/- 25 to 50%
Over 150 Bq/m ³	Less than +/- 14%	+/- 14 to 28%

Duplicate measurements should be recorded and tracked on a spreadsheet by the organization and analyzed for changes or trends via control charts.

If Duplicate measurements fall outside the Acceptable RPD than action should be taken to determine why the error occurred and how many past tests may have been affected. The C-NRPP certified professional should document the investigation and record why the error occurred and how many past tests were reported incorrectly and what corrective action was followed as a result.

7. Blanks

Blank tests are designed to measure the limit of detection of the radon measurement device by assessing any background exposure which may increase the lowest limit of detection from the manufacturers stated levels. The detection limit is defined to be the lowest concentration of radon that can be measured with a certain confidence. The detection limit is calculated by the manufacturer of measurement devices but then it could be elevated by background exposure which interferes with the actual radon test. Blank tests are required for every 5% of tests deployed by an organization. The second test deployed by the organization should be a blank and every 20th test after that should also be a blank test.

The lowest level of detection must be supplied to the measurement provider by the lab as this is a value calculated on each batch.

There a multiple types of blank tests depending on the device type.

Lab Blanks – these are blanks that are sent away by the lab after manufacturing to assess any background exposure that a device has while waiting to be deployed by a measurement professional. A lab must retain 5 % of its devices to expose at least one device each time a batch is sent to a purchaser.

Transit Blanks – these are blanks that are sent back to the lab by the measurement professional to ensure that there was no contamination to the shipment of radon tests during transit from the lab to the measurement professional.

Field Blanks – these are blanks that are sent to the lab as blind tests to verify that the devices are not being exposed to background exposure which would interfere with regular radon tests. Field Blanks should be conducted by following the same procedure as used for duplicates – however the blank detector or device will not be opened or activated until the end of the test, where it would be opened and sent to the lab to be treated the same as one of the exposed devices when analyzed by the lab.

A Field Blank measurement should be conducted by placing a device in the same location 10 cm (4") apart from an activated device. The activated device is opened while the Field Blank remains closed or not activated. Both tests are then analyzed at the same time as if they were both active tests. It is important that the Field Blank follow the same path and be stored together with those devices that will be activated.

Transit Blanks and Field Blanks should be recorded and tracked on a spreadsheet by the organization and analyzed for changes or trends.

Blank tests are acceptable if they are within +/-10 % the devices lowest level of detection as determined by the manufacturer.

If a Blank test measured above the acceptable range, and there is no evidence of tampering then a retest should be recommended, a second blank test should be deployed in the same manner as the previous Blank Test. In the case of Electret Ion Chambers, prior to conducting a retest, the gamma level

should be verified. If the second test is above the acceptable level then corrective action should be taken in order to determine the root cause of the failure

8. Cross-Checks (for CRMs only)

Cross-checks are similar to duplicate tests however the device used needs to be a C-NRPP approved device. In a situation where a professional is using a continuous radon monitor a cross check should be done every six months to identify any anomalies with the testing equipment in between calibrations. If a standard check source is available for the device, it can be used for the cross–check purpose. i.e (such as an in-built one)

A cross-check should be conducted for at least a 48 h period and can be conducted using a second device setup up side by side (within 10 cm or 20 cm apart). The devices should be with in allowable limits as specified in the Section 6. Duplicates.

9. Electret Ion Chamber Reader Electret Reference Checks

Electret Ion Chamber Electret Voltage Reader must be monitored on a regular basis in order to ensure accurate reading response; manufacturer's recommended frequency for monitoring should be followed. Using Reference Electrets, provided by the manufacturer, the response of the Electret Ion Chamber Electret Voltage Reader can be verified and monitored.

Included with the Reference Electrets is a blank or "Zero" electret. The response from the "Zero" electret should be within the acceptance criteria determined by the manufacturer.

If the voltage meter is reading the electrets more than 3-volts from their nominal values, the manufacturer should be contacted for corrective actions.

10. C-NRPP Requirements

10.1 Placement Protocols

All measurement professionals should be familiar with and using proper placement procedures for placing radon measurement devices when using a measurement to base a recommendation of mitigation. Placement must be based on Health Canada's *Guide for Radon Measurements in Residential Dwellings (Homes)* and Health Canada's *Guide for Radon Measurements in Public Buildings (Schools, Hospitals, Care Facilities, Detention Centres)*

10.2 Continuous Radon Monitors

Manufacturers of these devices typically require or recommend calibration of the device once a year. CRM users must verify the recommended calibration frequency by checking the user's manual or contact the manufacturer to ensure manufacturer's recommendations on calibration are being followed. C-NRPP requires that these devices be calibrated annually at minimum, however if the manufacture recommends more frequent calibration these shall be followed.

In addition to annual calibration on equipment, a cross-check should also be performed semi-annually by all CRM users.

Professionals who are C-NRPP listed Continuous Radon Monitors (CRM) but are not an Analytical Laboratory for other devices are required to submit annual calibration certificates to C-NRPP offices with their certification renewal, every two years. *Performance test and submission of a full Quality Assurance Plan to C-NRPP is not required.*

Professionals using a CRM who are also an Analytical Laboratory for other devices (such as Alpha Track or Electret Ion Chamber) are required to develop and submit a full Quality Assurance plan and include annual calibration and cross-checks of all CRMs in the Quality Assurance plan. Annual calibration certificates should be submitted with the regular submission of quality control documents.

10.3 Laboratories using Passive Devices

When a laboratory manufactures a batch of devices, 3% if the devices must be sent to a chamber for inter-comparison/performance tests and 5% of the devices must be set aside as blanks to be analyzed until all devices have been received back for analysis. With each order of 20 tests or more ordered by a customer, a blank must be analyzed.

If a laboratory sells devices to homeowner's then they also issue a duplicate detector in 10% of the tests and have a blank analyzed every 5% of the tests.

10.4 Electret Ion Chamber Users

10.4.1 Draft a Quality Assurance Plan: Electret Ion Chamber Users will need to draft a Quality Assurance plan to detail their handling of the devices to ensure that all professional in the organization follow proper placement and quality assurance protocols and any errors are noticed and corrected.

10.4.2 Verify Voltage of Electrets: Verifying voltages of electrets is to alert the user to any erroneous reduction in voltage. Voltage levels should be verified when the electrets are received from the manufacturer and prior to each use. The voltage of each electret should not be decreasing when it is properly capped and stored, and not in use for radon measurements. By reviewing the

voltage upon first usage and by comparing with the voltage report sent by the manufacturer, issues of voltage decrease with the device should be identified. The voltage also needs to be verified upon each prior usage and the starting voltage of each electret should be compared with the ending voltage of its previous use. If the voltage differs from the previous reading by more than 3 volts per month, the electret should be set aside and monitored. If the electret was stored in the chamber between uses, the user should remove it from the chamber and store with in the cap. If the electret continues to lose voltage at a rate greater than 3 volts per month, when not in use for radon measurement, the electret should not be used for radon measurement and can be returned to the manufacturer.

Recommendations of the manufacturer must be followed for procedures to be followed when reading the voltage of the electrets. These procedures include, but are not limited to, ensuring a consistent environment and relative rate of humidity when using the voltage meter and consistent placement of the electret on the voltage meter when readings are made. Please see the manual provided with the devices for detailed instructions on Electret Ion Chamber use procedures.

10.4.3 Verify Reference Electrets: Reference electrets are used to alert the user to any issues with the voltage meter. Reference Electrets are to be verified when the voltage meter is received from the manufacture either upon purchase or return from the manufacture after calibration. They are also to be used weekly on the voltage meter. If the measurement provider is not conducting measurements at a weekly rate, than the reference electrets are to be used prior to use of an electret, to a maximum of one time per week. The reference electret readings should be recorded in a spreadsheet to track the voltage readings. If the reference voltages vary from the stated voltage by +/- 3 volts, the user should contact the manufacture for instruction and the voltage meter may need to be sent for calibration.

10.4.4 Calibrate the Voltage Meter: When the voltage meter is received from the manufacture it should come with a certificate confirming that it has been calibrated. Every year after that it should be returned to the manufacturer for an annual calibration and a copy of the certificate should be provided which will be provided to C-NRPP as part of the Quality Control documents and the user must maintain a copy as part of their records.

10.4.5 Quality Control Tests: For professionals using the Electret Ion Chambers they must also include measurements of Quality Control measures as detailed above. When a Measurement Provider receives the devices from the manufacturer a Performance Tests should be completed. The measurements should then include 10% duplicates, 5% blanks and 3% spikes for explanation on each of these see the description in Section 5-7 and Section 8. Data should be tracked on Quality Control charts to identify any errors and for submission for certification renewal.

10.5 Measurement Providers Using Passive Devices – No Analysis

Measurement providers will need to draft a Quality Assurance plan to detail their handling of passive radon devices to ensure that all professional in the organization follow proper placement and quality assurance protocols.

Upon receiving a batch of devices from a manufacturer, a measurement provider should send one Transit Blank back to the laboratory for analysis to ensure no contamination occurred during shipment. A measurement provider will then need to ensure they are including 10% of the measurements with Duplicates and 5% as Field Blanks and following the process as stated above.

11. Reporting Quality Assurance/Quality Control to C-NRPP Office

Each measurement professional is to ensure that they are following the requirements as stated above. One set of Quality Assurance and Quality Control documents can be submitted by organization as per the above stated C-NRPP Requirements according to the devices a certified professional is using.

12. Procedures for Non-Conformances and Corrective Action

Quality control charts are only useful if the errors are recognized and corrective action is taken. Therefore, Quality Control charts should include a feature to alert readers to non-conformance readings and corrective actions should include identifying as much as possible where and when the error occurred so the reason can be determined and modifications can be completed to eliminate further errors and correct any future readings. Some examples of Corrective Actions are included in the chart in Appendix 2, however these are only suggested errors. Please contact the laboratory or device manufacturer to discuss before taking corrective actions.

Appendix 1 – Chart of Requirements

	Alpha Track Lab or other passive devices laboratory	Electret Ion Chamber User	CRM only User	Measurement Provider – No Analysis
Developing a Quality Assurance Plan	Yes	Yes	Yes	Yes
Submit Quality Assurance Plan to C- NRPP	Yes – yearly on anniversary date	Yes – yearly on anniversary date	No	Yes
Calibrating Equipment as required by manufacturer or at least once per 12 months	Yes	On voltage meter	On all CRMs	No
Blanks	Yes – 5% of tests	Yes – 5% of tests	No	Yes – 5 % of tests
Duplicates	Only required if lab is selling to customers in batches of less than 20 10% of devices sold on individual or small batch basis	Yes – 10% of tests	No	Yes – 10% of tests
Cross-Checks	No	No	Yes – every 6 months using a minimum 48 h test	No
Spikes	Yes – 3% of tests	Yes – 3% of tests	No	No
Performance Tests	No	Yes – First 3 tests	No	No
Reference Checks	No	Yes – Once a Week	No	No

Appendix 2 – Chart of Suggested Procedures including Quality Control and Non-Conformance and Corrective Action

Detector Type	Tasks	Quality Assurance Required	Possible errors and actions required
Passive Devices			
Manufacturer:			
	Batch is finished manufacturing	3% of devices are sent to an independent certified/ recognized chamber for spiking	-Error in batch; further testing would be required to identify issue
		5% of devices are set aside as blanks; analyzed periodically until all devices have been received back for analysis	
	Devices are sent to customer in a bulk order	One of the blanks is analyzed after each large order sale	-If blank is higher than previous blanks background interference may be present if a blank is elevated; determine issue to assess course of action to correct errors
	Devices are sent direct to homeowner's	Duplicate used in 10% of tests;	-Possible error in transit. Duplicate to determine replication and then determine course of action to correct.
		Blank analyzed every 5% of tests;	
Measurement Professional:			
	Receives tests from manufacturer	Ensure serial numbers accurate and recorded	
		Ensure number of devices ordered are received	
		Send a transit blank back for analysis	- Transit blank higher than Lab Blanks possible contamination in

		transit. Repeat process and discuss
		with manufacturer corrective actions.
Perform test for homeowner	Ensure that test set up follows proper test guidance	
	Note in records serial number that has been released to homeowner, with homeowner's contact info for follow up if device is not deployed	
	Perform duplicate test on first and every 10% of tests	- Error above allowable levels may indicate a contaminated test. Review past quality control measures to ensure it's the first error and determine possible times and locations of errors to determine corrective actions.
Perform test for commercial customer with more than 10 devices	Develop a testing protocol with test locations, durations and number of tests required; include additional 10% of tests for Quality assurance and 5% for blanks	
	Record test serial numbers of devices removed from stock	
	Record serial numbers and locations of devices; including which devices are used as duplicates and blanks	
	Record anomalies in file	
	Establish agreed upon procedures for device return with customer	
	When devices are sent to lab, verify serial numbers consistent with those removed from stock	

When reports are received from lab, record duplicate test results on spreadsheet
Verify that duplicate results are within acceptable limits
Record blank test result in spreadsheet and verify results are within acceptable limits.

Electret Ion Chamber			
Devices			
Manufacturer or Distributor:			
	Batch of Devices sent to customer	Provide report with serial numbers and voltage amounts	
Measurement Professional:			
	Receives electrets from manufacturer	Ensure number of devices ordered are received	
		Ensure serial numbers accurate and recorded; verify voltage amounts are as reported on report sent with electrets.	
		Verify Reference Electrets.	
		Send tests to Chamber to conduct performance test.	- Results outside acceptable levels could be the result of background contamination from transit, error in voltage reader use or error in calculation.
	Perform test for homeowner	Prepare test for placement.	
		Test references weekly. Record data in proper spreadsheet.	- Changing reference values above allowable levels could mean errors in the voltage metre. Contact manufacturer to discuss.
		Verify voltage loss has not been greater than 1 volt per month since previous reading (while electret has not been in use).	Changing values when not in use above allowable levels could mean errors in the voltage metre, improper use of the voltage metre, electrets are not stored in caps properly or background contamination.

Ensure that measurement placement follows proper placement protocols.	Review device manual to ensure following proper procedures used for measurement of devices.
Set up duplicate on first test and every 10% of tests. Record data in proper spreadsheet.	Differences in measured values greater than acceptable levels may mean similar to issues listed above.
5% of tests should be blanks. Record data in proper spreadsheet.	Differences in measured values greater than acceptable levels may mean similar to issues listed above.
3% of tests should be spikes to a minimum of 3 per year or maximum of 6 per month. Record data in proper spreadsheet.	Differences in measured values greater than acceptable levels may mean similar to issues listed above. Plus errors could be a results of background contamination when shipping devices to the chamber. Discuss with chamber contact.

Continuous Radon			
Monitors (CRM)			
Manufacturer:			
	Device sent to customer	Calibration completed with delivery of device	
Measurement Professional:			
	Receives CRM from manufacturer	Verify calibration report received.	
	Perform test for homeowner	Prepare device for placement. Ensure battery has sufficient power for device duration or ensure device is plugged in for duration of test.	
		Ensure that device set up follows proper placement guidance.	
	Semi-Annual Cross- Checks	Perform cross-check on device.	Errors may mean device needs to be re- calibrated. Contact manufacturer.
	Annually	Send device to manufacturer for annual calibration.	

Appendix 3: C-NRPP Reporting Requirements

	New Certification	Annual	Renewal Requirements
	Requirements	requirements	
Passive Device Laboratory	Quality Assurance plan	Submit Quality Control documents: • Duplicates • Spikes • Blanks	Quality Assurance plan - if amended from first submission List of measurement professionals; Annual Calibration certificates Quality Control documents: Duplicates Spikes Blanks
Passive Device	Quality Assurance	No annual	Quality Control documents:
user (no Analysis)	plan	requirements.	DuplicatesBlanks
CRM User only		No annual requirements.	Certificates of annual calibration on CRMs (one for each of the past 2 years)
Electron Ion Chamber user	Quality Assurance Plan	Submit Quality Control documents: • Duplicates • Spikes • Blanks	Quality Assurance plan - if amended from first submission List of measurement professionals; Certificates of annual calibration on Voltage meter (one for each of the past 2 years) Quality Control documents: • Duplicates • Spikes • Blanks • Reference Electrets

Appendix 4 – Quality Control Targets:

Spikes/Performance Tests:

RPE = [(MV-RV)/RV]*100% where: RPE = relative percentage error; MV = measured value of spiked measurement; and RV = reference value.

Tests are acceptable if they are within +/-25% at radon levels of 150 Bq/m³ or greater.

Duplicates/Cross Checks:

Relative percent differences:

<u>|Test 1 – Test 2|</u> ((Test 1 + Test 2)/2) X 100

The following chart provides guidance on allowable variances in RPD for duplicate tests.

Average Test	Acceptable RPD	Warning Level
Measurement		
<75 Bq/m ³	No limits	No limits
75 – 149 Bq/m ³	Less than +/- 25%	+/- 25 to 50%
Over 150 Bq/m ³	Less than +/- 14%	+/- 14 to 28%

Blanks: (Field or transit)

+/- 10 % the device manufacturer's Lowest Limit of Detection

LLD is to be supplied by manufacturer for each batch.

E-Perm Reference:

Less than 3 volts difference.

E-Perm Voltage Slippage Limits:

Less than 3 volts per month.

Appendix 5 – Examples of Templates of Quality Control Charts

<u>C-NRPP Control Charts Templates for E-Perm Devices – Measurement Professionals</u>

<u>C-NRPP Control Charts Templates for Passive Devices – Measurement Professionals</u>

C-NRPP Control Charts Templates for Passive Device Laboratories

<u>C-NRPP Control Charts Templates for CRMs – Measurement Professionals</u>

Appendix 6 - Reference Documents:

Kotrappa, P, 2 June 2008, *Long Term stability of electrets used in electret ion chambers*, Journal of Electorstatics, 66(208) 407-409,

Health Canada, *Guide for Radon Measurements in Public Buildings (Schools, hospitals, Day Care Facilities, Detention Centres),* 2008 <u>http://www.hc-sc.gc.ca/ewh-semt/pubs/radiation/radon_building-edifices/index-eng.php</u>, September 2015

Health Canada, *Guide for Radon Measurements in Residential Dwellings (Homes)*, 2008, <u>http://www.hc-sc.gc.ca/ewh-semt/pubs/radiation/radon_homes-maisons/index-eng.php</u>, September 2015

US Environmental Protection Agency, October 1997, *National Radon Proficiency Program Guidance on Quality Assurance*, EPA 402-R-95-012, National Air and Radiation Environmental Laboratory, Montgomery, AL