

**ESTABLISHING PERFORMANCE, QUALITY ASSURANCE
& LISTING CRITERIA FOR HOME RADON ALARMS
- A C-NRPP INITIATIVE**

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Abstract

Early in 2015, the Canadian Association of Radon Scientists & Technologists (CARST) technical committee developed a performance specification for Home Radon Alarms. These electronic, radon monitoring devices are designed and intended for homeowners to use much like the radon equivalent of a smoke detector. An alarm condition indicates elevated radon concentrations in indoor air (prompting a C-NRPP certified professional radon test). Said devices are not intended to be used for commercial purposes, nor professional radon concentration measurements, nor to make radon mitigation decisions.

This paper summarizes the Home Radon Alarm performance and “Type Test” requirements developed by CARST; and details major sections of C-NRPP’s “Home Radon Alarm Listing Implementation & Review Manual.” An overview of the C-NRPP listing process will be presented, as will requirements for the manufacturer’s QA manual, and a discussion of documents each radon device manufacturer has to submit to C-NRPP for review and approval.

Introduction

In the fall of 2015, the Canadian – National Radon Proficiency Program (C-NRPP), identified the need for a domestic, i.e., Canadian, radon monitoring and measuring device listing program. At that time it was decided that a C-NRPP device listing would entail more than just the successful radon performance testing in a reference radon calibration chamber; C-NRPP device listing would mean qualification of the device design and approval of the manufacturer’s design and documentation control processes, and QA manual.

The first C-NRPP document in support of the aforementioned program, was C-NRPP’s “Home Radon Alarm Listing Implementation & Review Manual,” completed in spring 2016.

Terms & Definitions

C-NRPP (Canadian – National Radon Proficiency Program) is an independent certification and accreditation program designed to establish guidelines for radon professionals and measurement device manufacturers serving the Canadian marketplace.

DSC (Document Status Chart) – The manufacturer’s primary Design Control Document. The DSC lists all documents (schematics, drawings, procedures, reports, manuals) associated with the product, as well as revision numbers, approvals, and dates of approvals.

MDL (Master Document List) – Equivalent to the DSC.

Parts List - A comprehensive list of all parts/components/materials required to build an electronic circuit or associated assembly.

QA (Quality Assurance) - A program which has been established to monitor and evaluate activities, including the establishment and adherence to type testing procedures, use of proper documentation, and implementation of a quality improvement program, as required to ensure high standards of quality have been met.

QC (Quality Control) – An ongoing system of measurements conducted to ensure a testing device meets pre-established performance standards; these measurements include background radiation and response to known radon concentrations.

Quality Improvement - A dynamic process practiced by the quality department within an organization to ensure its quality control procedures comply with the evolving requirements of normative standards and industry guidelines.

Radon Performance Test – An independent test performed in a Reference Radon Calibration Chamber to validate a radon monitor’s radon measurement accuracy.

Reference Radon Calibration Chamber - A radon test facility (often called a “radon chamber”) which provides a standard test atmosphere for radon concentration measurement and has been accepted by the listing agency. The chamber provides sufficient size, configuration, radon concentration range, and radon concentration controls that testing may be conducted in a radon-in-air atmosphere that is stable or can vary under controls (increasing or decreasing) with precision that exceeds the precision of the device being tested.

SARA (Submit for Agency Review & Approval) – Those Manufacturer’s documents which have to be submitted to C-NRPP for listing compliance review and approval.

TTU (Type Test Unit) - A device provided by the manufacturer for type testing. The TTU is manufactured at the same facility, using the same personnel, procedures, equipment, and components/materials as the commercial units provided for homeowners at large.

Type Testing - A series of tests performed to qualify the design and performance of the device

addressed by this protocol. Type Tests are performed on a single unit provided by the manufacturer for this purpose as a representative of the technology.

C-NRPP Specifications for Home Radon Alarms

The design specifications as per CARST Performance Specification “The Home Radon Alarm Device Listing Requirements Document,” Revision No. 6.24.6, 2015, are summarized as shown in Figure (1).

SPECIFICATION SUMMARY CHART

Power Input: Voltage Frequency	115 VAC ± 15VAC 60 Hz ± 3Hz
Ambient Temperature Range	10 – 30°C (21°C typical) 50 – 86°F (70°F typical)
Relative Humidity	Up to 75% (non-condensing)
Pressure	101.325 kPa 1 atm or about 30” Hg
Audible Alarm	≥ 80dB (mutable up to 5 days)
Electro-magnetic Interference - Electrostatic discharge (CEI IEC 61000-4-2), operator/user interference, 8kV contact - Cell phone interference, 5 call initiations at 60 second intervals 100 mm (about 4”) from face of TTU, and repeated at a distance of 100 mm from the top horizontal surface of the TTU	≤ 20% error ≤ 20% error
Radon Measurement Accuracy	± 20% error

Note: TTU = "Type Test Unit"

Figure (1): Specification Summary

The Listing Process

The Listing Process is presented graphically in Figures (2) and (3) which follow. Please check <http://c-nrpp.ca> for updated Listing Application Fees and Requirements. **Note:** *Manufacturer documentation submitted to C-NRPP in support of a Home Radon Alarm device listing application shall be maintained in Confidence by C-NRPP as Proprietary Information specific to the providing manufacturer ONLY. C-NRPP will execute a non-disclosure agreement with the manufacturer prior to the submission of any manufacturer documents to C-NRPP.*

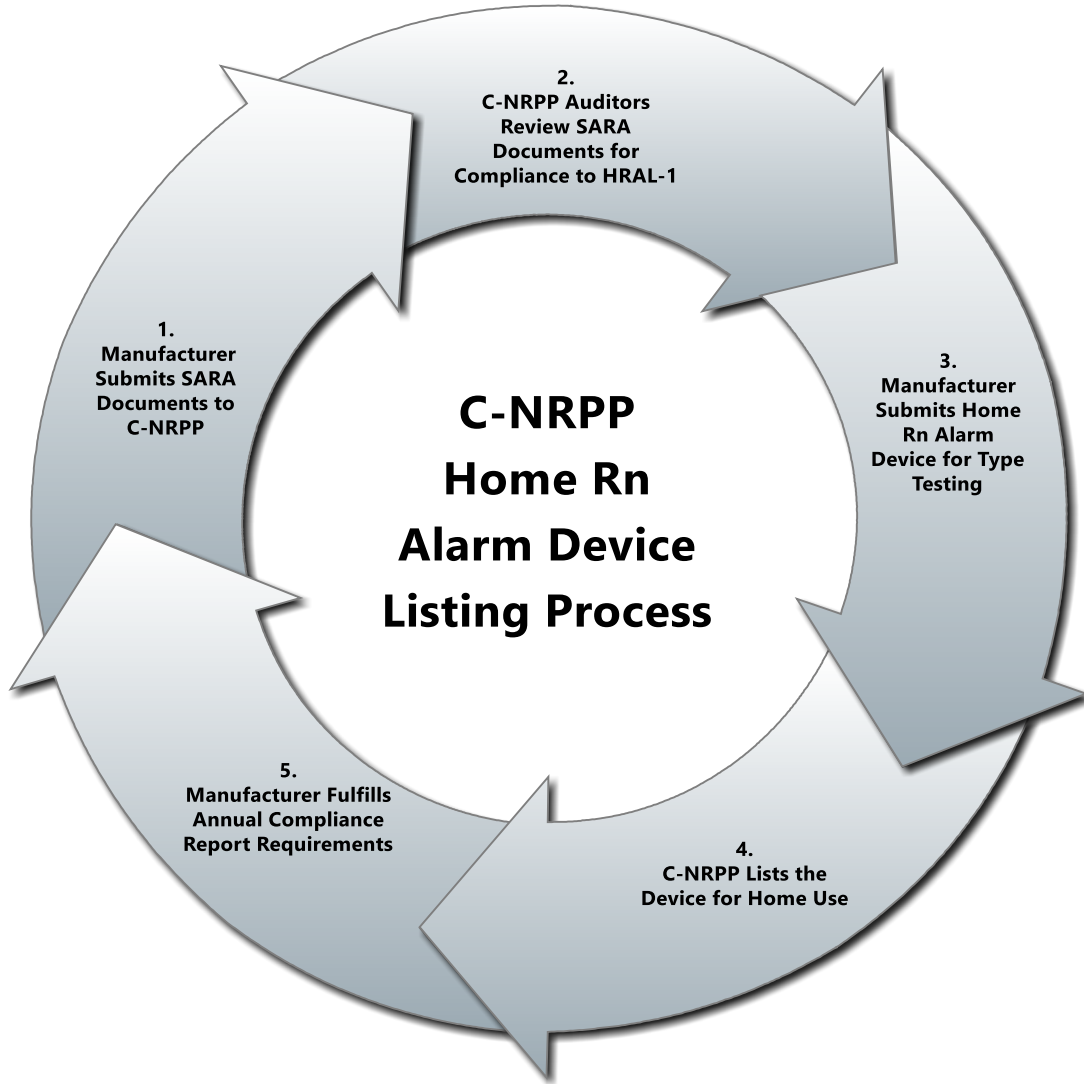


Figure (2): The Device Listing Cycle

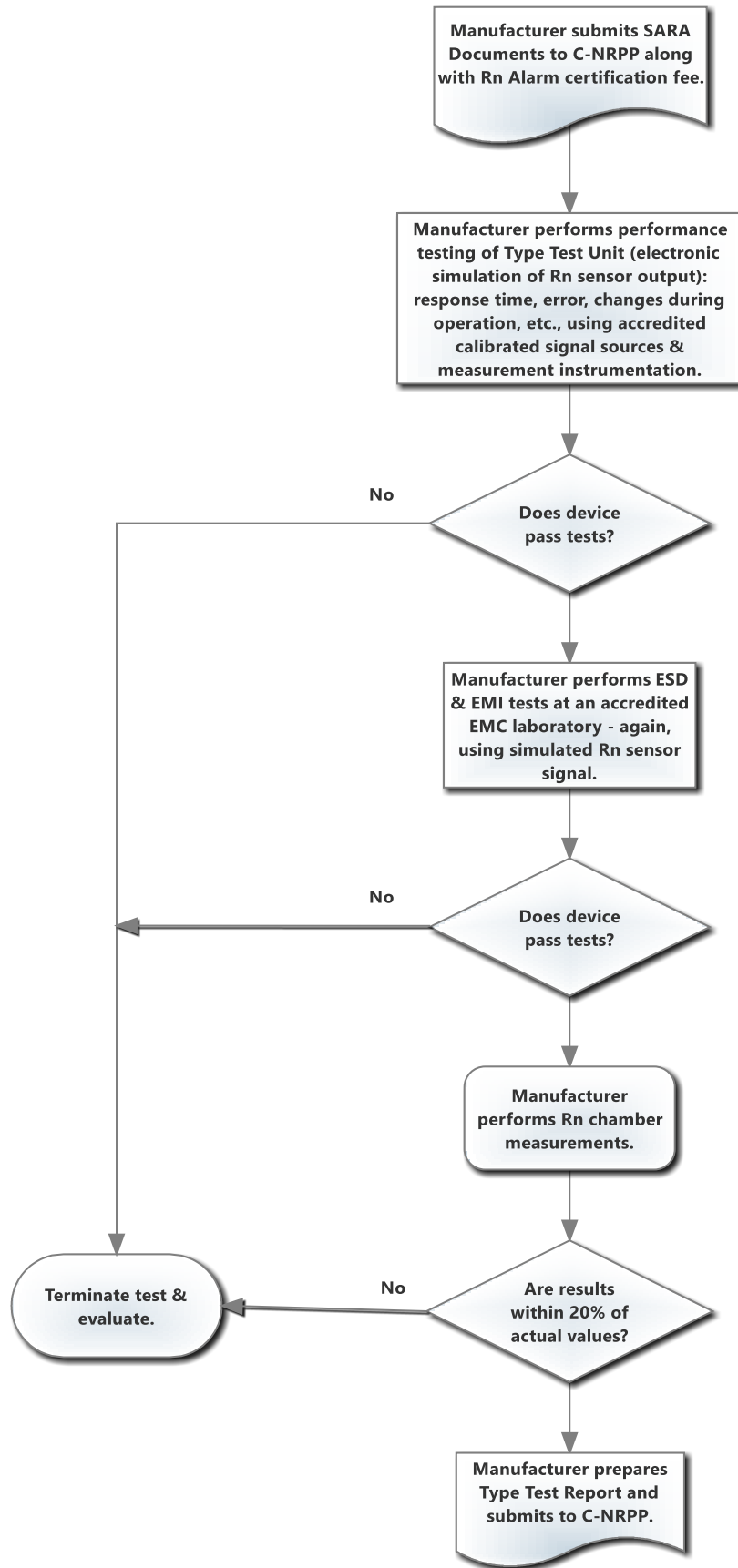


Figure (3): The Device Listing Sequence

The Manufacturer's QA Manual

The Home Radon Alarm manufacturer must submit a current copy of their QA manual along with their listing application, application fee, and other required SARA documents.

The QA manual shall include:

- a statement of management's Quality Policy and Commitment to the quality assurance program as described therein,
- clearly defined areas of authority and responsibility pertaining to review and approval regarding Document and Design Control,
- a list of the Quality Objectives,
- specifics regarding Document and Design Control
 - document and part numbering scheme,
 - document generation and revision process,
 - document review and approval responsibilities,
 - preparation and control of the Master Document List or Document Status Chart,
 - responsibilities for document control,
 - document storage and security,
- procedures addressing Non-Conformance and Corrective Action,
- description of the process for Internal Audits.

The QA manual shall also specify the requirements for:

- Manufacturing Procedures,
- Quality Control Procedures (including Function Test Procedures, Type Test Procedures, Sampling Plans, and Receiving Inspections, e.g., visual, dimensional, measurement of critical parameters and comparison to technical specifications such as capacitance & tolerance for capacitors),
- Commercial Dedication Plan - a method for validating the use of commercial off-the-shelf components for use in a monitoring device,
- Disposition of Rejects,
- Design Specifications,
- Assembly Drawings & Schematics,
- Operation Manuals,
- Test Reports and other documents pertaining to the Home Radon Alarm.

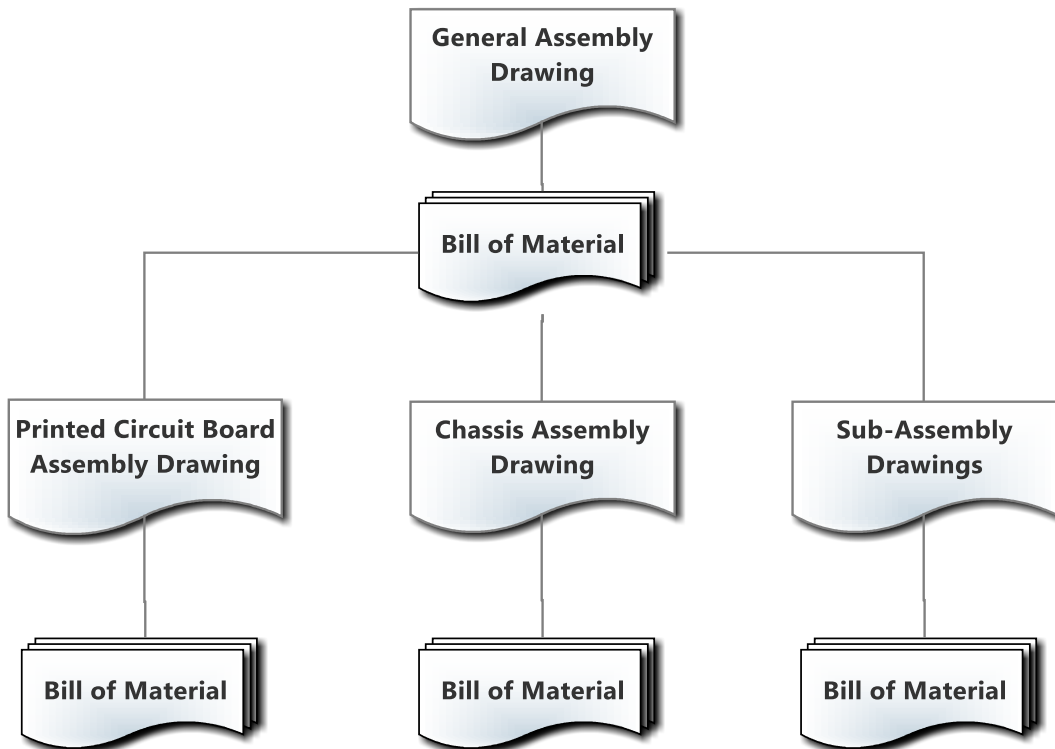
SARA Documents

In addition to the QA manual, the Home Radon Alarm manufacture has to provide C-NRPP with the following SARA documents at time of listing application:

- General Assembly Drawing – see Figure (4)
 - usually presented as an “exploded view” or isometric view drawing which depicts the relationship of all component parts and sub-assemblies within the device, to one another
 - components and sub-assemblies usually numbered from left to right and from top to bottom using a numeric or alpha-numeric format
 - numbers used are cross-referenced to an associated parts list (either appearing on the same sheet as the General Assembly or on a separate sheet of a multi-sheet drawing,
 - shall bear the signatures and date signed of the preparer (the manufacturer’s design authority), the draftsman, the technical check (independent cognizant design authority), quality assurance review and approval designate, and engineering or management approval designate,
 - shall also bear a title, document and revision number which must match the information appearing on the Document Status Chart (not submitted to C-NRPP).

Figure (4): General Assembly Drawing & Bills of Material Relationship

GENERAL ASSEMBLY & BILL OF MATERIAL CHART



- Bills of Material (General Assembly, Printed Circuit Board(s), Sub-Assembly)

- a comprehensive list of all parts/components/materials required to build an associated assembly. A bill of material for a complete product or device usually lists sub-assemblies as component parts of the main assembly or complete product.
- shall bear the signatures and date signed of the preparer (the manufacturer's design authority), quality assurance review and approval designate, and engineering or management approval designate,
- shall bear a title, document and revision number, and list the assembly number it is associated with.
- Schematic(s)
 - a graphical representation of the electronic circuit associated with a specific printed circuit assembly,
 - components are represented by graphic symbols consistent with IEC 60617 - Graphical Symbols for Diagrams and/or IEEE STD 315- Graphic Symbols for Electrical and Electronics Diagrams,
 - shall have an associated parts list (either appearing on the same sheet as the schematic or on a separate sheet of a large multi-sheet schematic),
 - shall bear the signatures and date signed of the preparer (the manufacturer's design authority), the draftsman, the technical check (independent cognizant electronic design authority), quality assurance review and approval designate, and engineering or management approval designate,
 - shall also bear a title, and document and revision number.
- Inspection and Test Plan
 - a report-style document which typically contains: sections outlining document purpose, scope, references, integrated manufacturing & quality plan, sub-contracted services, characteristics to be inspected, test equipment identification & calibration records, jurisdiction and customer hold/witness points (if applicable), sampling plan, quality level, and workmanship standards.
- IMQP Chart
 - a pictorial presentation of all manufacturing and QC steps involved (in sequence) from receiving inspection of components through to final QC function test of the TTU. As shown in Figure (5), references to "(QC Procedures)" are usually a list from QC-1 to QC-X (*where X is the last procedure*). A related chart cross-references the QC numbers to the manufacturer's Quality Control procedures, e.g., QC-1 = Visual Inspection, QC Proc. No. XXX Rev. XX.
- Type Test Procedure
 - applies to tests specific to the Type Test Unit only,
 - shall be prepared for: Electrostatic Discharge Immunity Test, Electromagnetic Immunity Test, and Radon Measurement Accuracy Performance Test.

INTEGRATED MANUFACTURING & QUALITY PLAN

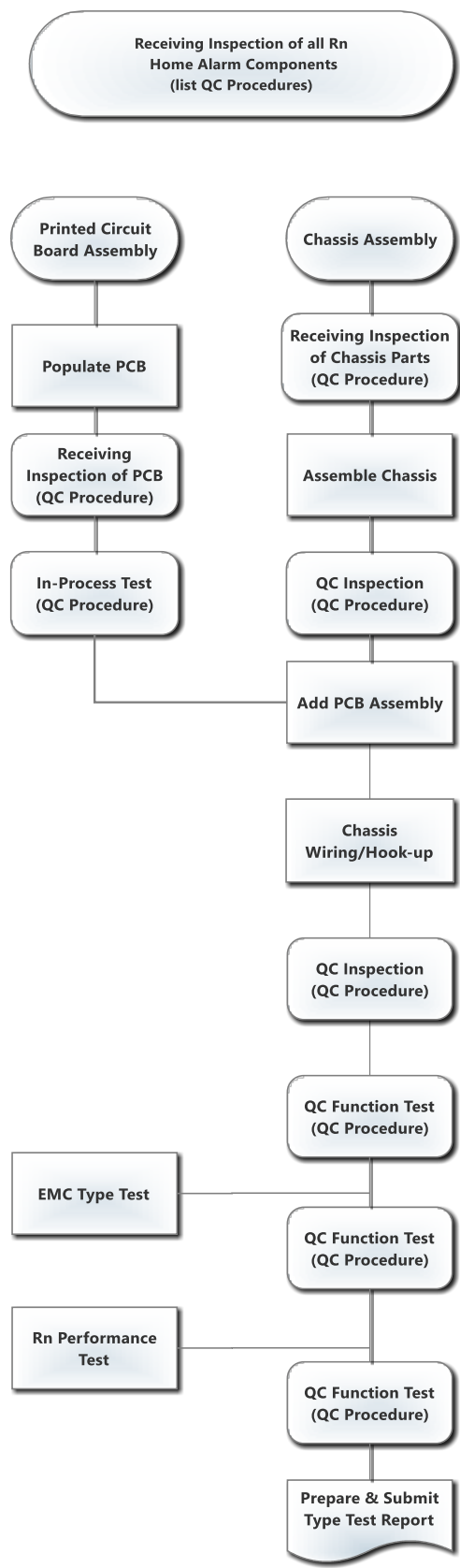


Figure (5): The IMQP Chart

- Owner’s Operation Manual (with installation instructions)
 - should provide the homeowner with all details required for installation and operation of the Home Radon Alarm,
 - should specify location requirements for the device; and provide calibration information specific to the Home Radon Alarm.
- List of typical Health Canada radon reference publications.

C-NRPP Site Audits

C-NRPP audits of the manufacturer (if necessary) shall be conducted in accordance with C-NRPP’s “The Implementation & Application Process for Home Radon Alarm Manufacturers – Auditor’s Guide & Checklist.” Finding types are detailed below.

Major Non-Compliance Finding

Major non-compliance findings are those findings that could likely result in the delivery of a defective or non-compliant Home Radon Alarm to the homeowner. These findings include but are not limited to:

- missing or erroneous Test Records,
- use of unauthorized measurement or test equipment,
- undocumented testing,
- use of un-approved procedures, drawings or other documents,
- use of un-approved components or suppliers,
- missing documentation,
- occurrence of numerous minor non-compliance findings.

Minor Non-Compliance Finding

Minor non-compliance findings are those findings that would have a minimal risk in the delivery of a defective or non-compliant Home Radon Alarm to the homeowner. These findings include but are not limited to:

- use of a single piece of measurement or test equipment beyond its Calibration Due date,
- use of an obsolete drawing or procedure,
- use of an unapproved or partially approved document (drawing, procedure, etc.),
- sub-standard documentation.

Summary

The C-NRPP radon monitoring/measuring device listing program, represents an integrated device design qualification based on performance testing and C-NRPP review and approval of the manufacturer’s QA manual, design and document control policies, and SARA documents.

C-NRPP’s “Home Radon Alarm Listing Implementation & Review Manual,” was designed to serve as both a guide and ready reference for manufacturers of Home Radon Alarm devices wishing to apply for C-NRPP Device Listing. It will become the template for C-NRPP’s “Professional Radon Measuring Device Listing Implementation & Review Manual.”

References

CAN/CSA-ISO 9001 - 2008, Quality Assurance Model for Quality Assurance in Design, Development, Production, Installation and Servicing, 2008.

CARST Performance Specification “The Home Radon Alarm Device Listing Requirements Document,” Revision No. 6.24.6, 2015.

CEI IEC 61000-4-2, Electromagnetic Compatibility - Part 4-2: Testing and Measurement Techniques - Electrostatic Discharge Immunity Test, 2008.

IEC 60617 - Graphical Symbols for Diagrams, 2012.

IEEE STD 315- Graphic Symbols for Electrical and Electronics Diagrams (Including Reference Designation Letters), 1993.