

Establishing Performance, Quality Assurance & Listing Criteria for Home Radon Alarms - A C-NRPP Initiative

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Abstract

- Early 2015, the Canadian Association of Radon Scientists & Technologists (CARST) technical committee developed a performance specification for Home Radon Alarms.
- This paper:
 - summarizes Home Rn Alarm performance and “Type Test” requirements developed by CARST,
 - details major sections of C-NRPP’s “Home Rn Alarm Listing Implementation & Review Manual,”

Abstract (continued)

- This paper also:
 - presents an overview of the C-NRPP listing process,
 - provides requirements for the Manufacturer's QA Manual,
 - discusses the documents each manufacturer has to submit to C-NRPP for review and approval.

What is a Radon Home Alarm?

- electronic, radon monitoring device,
- intended for homeowners to use,
- radon equivalent of a smoke detector,
- alarm condition indicates elevated radon in indoor air concentrations,
- **NOT intended for:** commercial use, professional Rn measurements, Rn mitigation decisions.

Contents of the Implementation Manual

- Introduction
- Scope
- Definitions
- References
- Specifications
- The Listing Process
- The Manufacturer's QA Manual
- SARA Documents
- The C-NRPP Audit

Select Listing Process Definitions

- BOM – An acronym for Bill of Material.
- DSC (Document Status Chart) – The Manufacturer's primary Design Control Document. The DSC lists all documents associated with the product, as well as revision no., approvals, and dates of approvals.
- SARA (Submit for Agency Review & Approval) – Those Manufacturer's documents which have to be submitted to C-NRPP for listing compliance review and approval.

Select Listing Process Definitions

- 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 Tests - 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 being representative of the design and technology.

Listing Process References

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

Performance Requirements

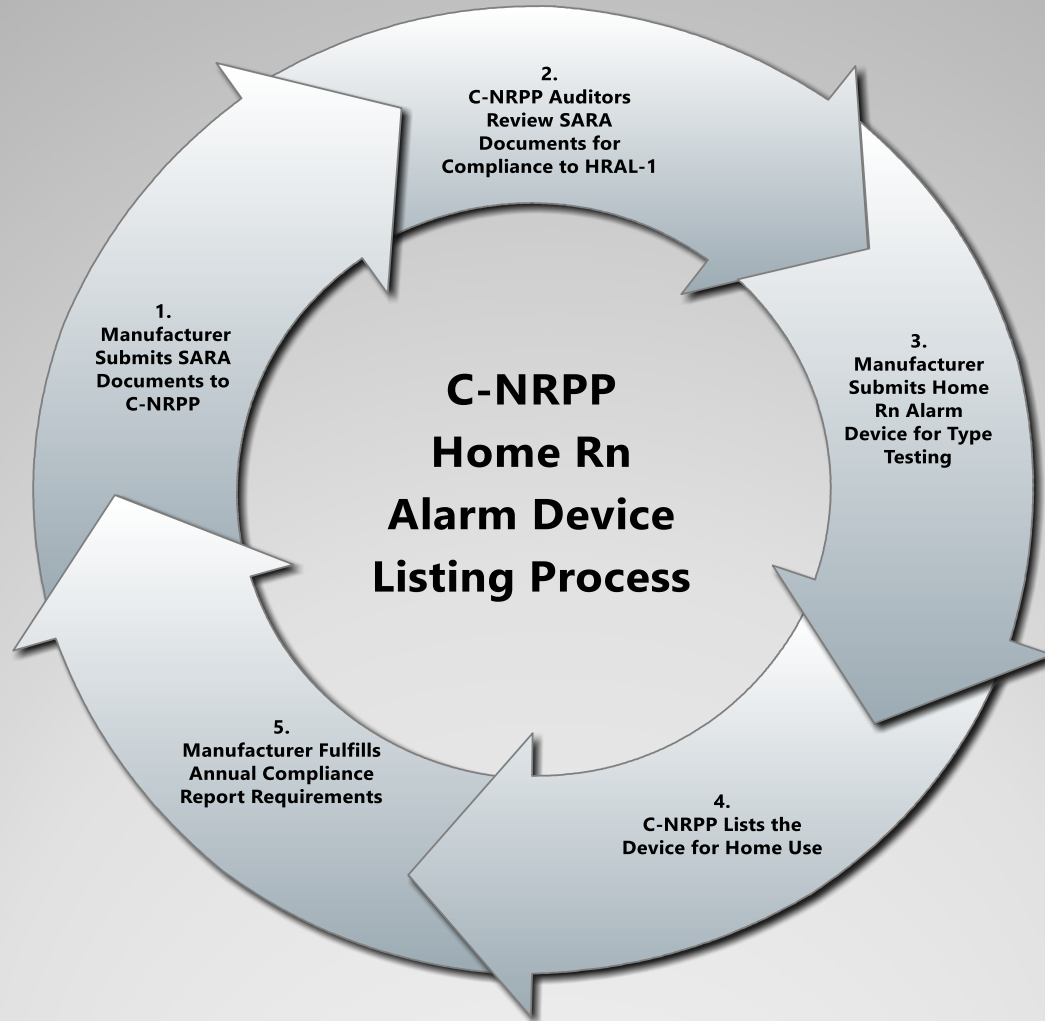
Voltage Frequency	115 VAC \pm 15VAC 60 Hz \pm 3Hz
Ambient Temperature Range	10 – 30°C (21°C typ.) 50 – 86°F (70°F typ.)
Relative Humidity	Up to 75% (non-condensing)
Pressure	101.325 kPa 1 atm or about 30" Hg
Audible Alarm	\geq 80dB (mutable up to 5 days)
Visible Alarm	Must activate when Rn conc. exceeds 200 Bq/m ³ (5.4 pCi/L) for 30 days.

Type Test Requirements

<p>Electro-magnetic Interference</p> <ul style="list-style-type: none">• 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	<p>≤ 20% error</p> <p>≤ 20% error</p>
<p>Radon Measurement Accuracy</p>	<p>± 20% error</p>

The C-NRPP Listing Process

- The Listing Process is presented graphically in the following figure.
- C-NRPP will execute a Non-Disclosure Agreement with the Manufacturer prior to the submission of any Manufacturer documents to C-NRPP.
- 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.



The Manufacturer's QA Manual

- 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,
- Quality Objectives,

The Manufacturer's QA Manual

- 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; and description of the process for Internal Audits.

The Manufacturer's 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), Disposition of Rejects,
 - Commercial Dedication Plan - a method for validating the use of commercial off-the-shelf components for use in a monitoring device,
 - Design Specifications; Assembly Drawings & Schematics; Operation Manuals,
 - Test Reports and other documents pertaining to the Home Radon Alarm.

The Manufacturer's QA Manual

- Shall also shall describe the following re. Document & Design Control :
 - Document & Part numbering scheme,
 - Document generation & revision process,
 - Document Review & Approval process,
 - Preparation & control of the DSC or MDL,
 - Responsibilities for Document Control,
 - Document storage & security.

Example DSC

MASTER DOCUMENT LIST or DOCUMENT STATUS CHART					
Issued By: <i>Product Manager</i>			MDL or DSC No.:		
Date:			Issue No.:		
Product: <i>Radon Home Alarm</i>					
QA Manual			Revision No.:		
SARA Documents					
Title	Doc. No.	Rev.	QA Approval	Eng. Approval	Agency Approval
<u>Drawings</u>					
General Assembly Schematic					
IMQP Chart					
<u>Bills of Material</u>					
General Assembly Printed Circuit Board					
Sub-Assembly					
<u>Procedures</u>					
Type Test Procedure					
<u>Reports</u>					
Type Test Report					
<u>Other Documents</u>					
Owner's Operation Manual (with installation instructions)					
Internal Documents					
Title	Doc. No.	Rev.	QA Approval	Eng. Approval	Agency Approval
<u>Drawings</u>					
<u>Bills of Material</u>					
<u>Process Sheets</u>					
<u>Manufacturing Procedures</u>					
<u>Quality Control Procedures</u>					

SARA Documents

- General Assembly drawing – usually an exploded or isometric view.
- Schematic(s) – graphical presentations of the electronic circuit(s).
- Inspection & Test Plan – a report style document.
- IMQP Chart – a pictorial presentation of all manufacturing and QC steps from RI to final QC function test.

SARA Documents (continued)

- BOMs – comprehensive lists of all parts and components/materials required to build the device (including part specifications).
- Type Test Procedure – specific to TTU. Required for: ESD, EMI, & Rn Measurement Performance Tests.
- Type Test Report – certified results of the Type Tests.
- Owner's Operation Manual – describing location, installation, and operation details.

STATUS

- Listing Implementation & Review Manual has received initial review.
- “Implementation & Application Process for Home Radon Alarm Manufacturers – Auditor’s Guide & Checklist,” is in development.
- On-line template for ‘Annual Home Radon Alarm Manufacturer’s Compliance Report,’ to be developed.
- C-NRPP is presently planning similar work for CRMs.