State of Illinois
Illinois Emergency Management Agency

Radon Quality Assurance Program Guidance

IEMA

Radon Quality Assurance Program Guidance

Quality Assurance a program for the systematic monitoring and evaluation of the various aspects of a project, service or facility to ensure that standards of quality are being met.

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CONTENTS

GENERAL INFORMATION ABOUT RADON QUALITY ASSURANCE

Contents……3
Introduction……4
Purpose of this Guidance……4
Purpose of Appendices……4
Quality Related Definitions……..5
Pitfalls in Applicant Quality Assurance Program (QAP) Submittals……6

ELEMENTS OF QUALITY ASSURANCE PROGRAMS

Policy Statement……8
Management and Organization……8
Personnel Qualifications……8
Procurement of Items and Services……..8
Control of Documents and Records……8
Calibration……..8
Computer Hardware and Software……..9
Planning……..9
Suggestions and Complaints……10
Corrective Actions……..10
Standard Operating Procedures……10
Appendices to QAP Descriptions……10

APPENDICES AND REFERENCES

Appendix A……11
Appendix B……11
Appendix C……..12
Appendix D……18
Reference Documents……23

General Information About Radon Quality Assurance

INTRODUCTION

The Illinois Emergency Management Agency (IEMA) – Division of Nuclear Safety regulates the detection of radon or radon progeny in dwellings and the reduction of radon or radon progeny in the indoor atmosphere through licensing requirements. Licenses are issued in accordance with the Radon Industry Licensing Act (RILA) and 32 Illinois Administrative Code 422. Professional licensees are required to submit Quality Assurance Program (QAP) descriptions for IEMA-Division of Nuclear Safety approval in their license application package.

PURPOSE OF THIS GUIDANCE

The instructions in this guidance document describe the areas and information needed by the Agency's Radon Program staff to evaluate an applicant's QAP for a Measurement or Mitigation Professional License. Individuals with a technician license work under their professionals QAP.

Prior to submitting an application for a Measurement or Mitigation Professional License, the applicant should carefully study these instructions and the requirements in the RILA and 32 Ill. Adm. Code 422 and submit all applicable information and documentation required. The Radon Program staff will request additional information when necessary to ensure that the applicant has established an adequate QAP. Requests for additional information will delay final action regarding the application and may be avoided by a thorough study of the regulations and these instructions prior to filing the application.

These instructions are intended only for general guidance in the preparation of the QAP description. While this booklet may be used as your initial planning tool in the publication of your QAP, these instructions describe the elements that a QAP should encompass, but not how a specific organization implements these elements. The applicant must assure that his/her QAP correctly and adequately implements the particular objectives, products, processes and specific work practices of their organization.

PURPOSE OF APPENDICES TO THESE INSTRUCTIONS

The regulations require licensees to develop and implement written policies and procedures, which ensure compliance with the RILA and 32 Ill. Adm. Code 422. The Appendices provide guidance on establishing and writing procedures, which the applicant may choose to use in their program.

DEFINITIONS

Audit means an independent review to determine whether quality assurance activities and related results comply with planned objectives.

Document means any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

General Supervision means the overseeing of or participation in the work of each licensed technician by a licensed professional where all of the following conditions are met:

1. Each technician performing radon measurements or mitigations shall be under the professional's overall direction and control, but the professional's presence at the work site is not required during the performance of the measurement or mitigation;
2. The continuous availability of direct communication in person or by radio, telephone, or telecommunications between the technicians and the professional;
3. Professionals must ensure that each technician complies with the Radon Industry Licensing Act, 32 Ill. Adm. Code 422 and their Quality Assurance Program. Professional licensees are responsible for all the required actions of technicians working in accordance with their Quality Assurance Program; and
4. The availability of the licensed professional on a regularly scheduled basis to complete all the following actions:
    a. Review and audit the practices of each technician;
    b. Provide consultation to each technician;
    c. Review required records, documentation and quality controls; and
    d. Educate the technician in the performance of the technicians Quality Assurance Program functions.

IEMA or Agency means the Illinois Emergency Management Agency

Independent review means a review performed by individuals who are not directly responsible for the work performed.

Management means those individuals directly responsible and accountable for planning, implementing, and assessing work.

Measurement means any radon or radon progeny tests, laboratory analysis, or exposure in a known radon or radon progeny environment, as in a radon chamber**.**

Mitigation means *the act of repairing or altering a building or building design for the purpose in whole or in part of reducing the concentration of radon in the indoor atmosphere* [420ILCS 44/15]

Non-conformance means apparent nonfulfillment of, or a question of interference with the fulfillment of, specified requirements in the RILA or 32 Ill. Adm. Code 422.

Quality assurance means a program for the systematic monitoring and evaluation of the various aspects of a project, service or facility to ensure that standards of quality are being met.

RILA means the Radon Industry Licensing Act [420 ILCS 44]

Shall means when the element is required and deviation from the specification will constitute non-conformance with the regulation.

Should means when the element is recommended.

Standard operating procedure (SOP) means a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

PITFALLS IN APPLICANT QUALITY ASSURANCE PROGRAM (QAP) SUBMITTALS

The Agency has noted shortcomings in many of the Radon Quality Assurance Programs it has reviewed. The following list is general guidance that should help licensees shorten the review time needed to supplement incomplete QAP submittals and help to minimize the amount of additional information requested by the Agency.

1) Applicant submittals are not consistent with the 32 Ill. Adm. Code 422. As an example, applicants routinely state that a Non-Interference Agreement will be signed in all real estate transactions. This would imply that Non-Interference Agreements are not required for Home Environment measurements. The regulation requires Non-Interference Agreements for all measurements. Applicants need to thoroughly read the RILA and 32 Ill. Adm. Code 422 to ensure their QAP is consistent with all the requirements.

2) Definitions are not included when terms not previously defined by the RILA and/or 32 Ill. Adm. Code 422 are used. As an example, applicants use the term "technician" without clearly defining the limitations, qualifications and responsibilities of this position title.

3) Diagrams are required in both the measurement protocol and mitigation standard. Yet applicants often overlook including requirements for the performance of diagrams in their SOP's. Diagrams should:
    a) Be drawn to scale and specify the diagram scale.
    b) Identify areas of interest within each room, such as detector placement, primary and secondary.
    c) Indicate the direction of north
    d) Specify the address
    e) Specify the principal use of each room
    f) Clearly identify each foundation type
    g) Indicate all doors and windows
    h) Include a key or legend

4) Technicians don't have the radon professional sign their application acknowledging the technician will be working under the professionals general supervision and in accordance with the professionals QAP.

5) Applicants do not submit changes to the Agency as a request for an amendment to their license.

6) Applicants do not submit SOP's for all measurements to be performed. As an example, measurement professionals state they perform measurements of commercial buildings and schools without submitting SOP's for their performance.

7) Applicants state the use of more than one testing device and only include the primary device's calibration and quality acceptance criteria.

8) Boiler Plate Quality Assurance Programs-Applicants should be familiar with all the stipulations and commitments they have included in their QAP's. Boiler plate QAP's may include commitments the applicant is unaware of, but for which the applicant will be responsible for compliance and implementation.

9) Applicants do not provide proof of successful completion of 1) the USEPA Radon Measurement or Mitigation Course, or an equivalent indoor radon and radon progeny measurement course approved by the Agency, and 2) USEPA Radon Measurement or Mitigation Examination, or an equivalent examination approved by the Agency in accordance with 32 Ill. Adm. Code 422.

WHY HAVE A QAP?

Individuals or organizations applying to IEMA to become licensed radon or radon progeny measurement or mitigation service providers must develop and implement a quality assurance program. The requirements are outlined in the RILA and 32 Ill. Adm. Code 422.

The primary concern of any individual or company measuring or mitigating radon or radon progeny must be the quality of the results of those programs. The management of an organization is influenced by the objectives of the organization, by its services and by the practices and policies specific to that organization. Therefore, quality assurance programs vary from one organization to another. A major goal of quality management is to improve the processes so that continued improvement of quality can be achieved. Planning a good quality assurance program, when properly designed and diligently followed, ensures that you will be able to produce the type and quality of measurement and mitigation results you need and expect.

If, after reading this document, the RILA and 32 Ill. Adm. Code 422, you still have questions about setting up a QAP, or how you should meet the licensing requirements, contact the IEMA Radon Program at (800-325-1245). Some private consultants can also assist you.

A QAP has two components. The first component is its written structure, the quality assurance plan, which establishes all the goals and general procedures of the program. The second component is the documentation, which establishes that all the steps of the quality assurance plan have been followed and the goals of the program have been reached. Together, these components provide the structure by which you undertake your licensed activities. This gives you a documented record of your work, which will validate your performance and help protect you and your customers.

ELEMENTS OF A QUALITY ASSURANCE PROGRAM:

This section describes the contents of each of the following QAP elements:

- a policy statement committing to provide quality work;
- a description of management and structure of the organization;
- a listing of personnel, their qualifications and training;
- procedures for procurement of equipment and services;
- procedures for maintaining documents and records;
- a description of relevant computer hardware and software;
- a planning process for radon and radon progeny services;
- procedures for calibration and testing of instruments;
- a procedure for responding to complaints;
- a corrective action program; and
- standard operating procedures.

POLICY STATEMENT

A policy statement briefly explains, in the most general terms, what you are doing and why. This should include a commitment to providing quality services to your clients, and working in accordance with the requirements of the RILA and 32 Ill. Adm. Code 422.

MANAGEMENT AND ORGANIZATION

All individuals who have responsibilities in providing radon services must be identified. In a subsection about applicability, this should include the individuals' job titles, job descriptions, responsibilities, and reporting structure. This should also include a statement of who holds ultimate responsibility for work, who carries out work, and who has the authority to stop unsafe or inadequate work.

Another section should be concerned with review of the program. Periodically (at least once a year), the QAP should be reviewed, revised or upgraded, and approved for use.

A third section should discuss provisions for periodic audits of the program. Audits are formal, structured and comprehensive reviews. An audit can be conducted by the licensee, an employee, or an outside auditor. An audit should include a written report of findings, a written assessment of whether or not the QAP is achieving its goals, and suggestions for improving the program due to changes in technology, quality concepts, regulations or environmental conditions.

PERSONNEL QUALIFICATIONS AND TRAINING

Your radon staff needs to be qualified. Part of the QAP is to establish what training and qualification requirements you have for your radon staff. This includes identifying the training requirements for both licensed and unlicensed workers. For each worker, you are required to keep and maintain evidence of all training for the duration of employment, and for five years past the end of employment.

PROCUREMENT OF ITEMS AND SERVICES

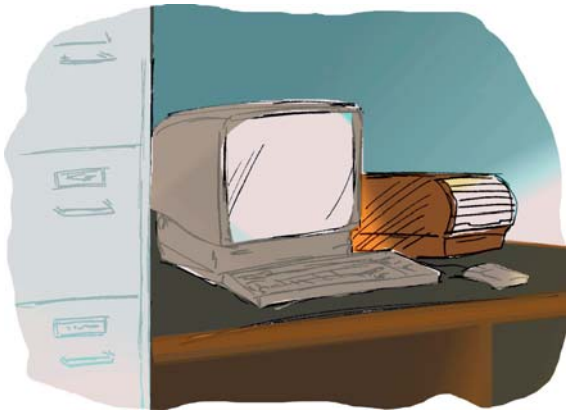
To ensure that your radon services are reliable, you need to plan and control your purchase of equipment and services from suppliers. When you order equipment, you should be sure to clearly describe the item or service being purchased and the associated technical and quality specifications of the purchase.

CONTROL OF DOCUMENTS AND RECORDS

All documents and records relating to your radon work must be carefully controlled. In the QAP, you need to spell out which documents you are going to use, how you are going to use them, how you will replace outdated documents, and how you are going to store your documents and records to ensure their future protection and availability. Records of radon measurements, mitigations, QAP, calibration measurements, equipment repairs and worker protections plans shall be retained by the licensee for at least 5 years or the length of time of any warranty or guarantees, whichever is longer.

CALIBRATION

Use of instruments and testing equipment used in your radon program needs to be controlled, and the devices need to be calibrated at specified intervals so that their accuracy is kept within regulatory limits. In the QAP, you need to lay out your program for ensuring that each of your instruments will be calibrated.

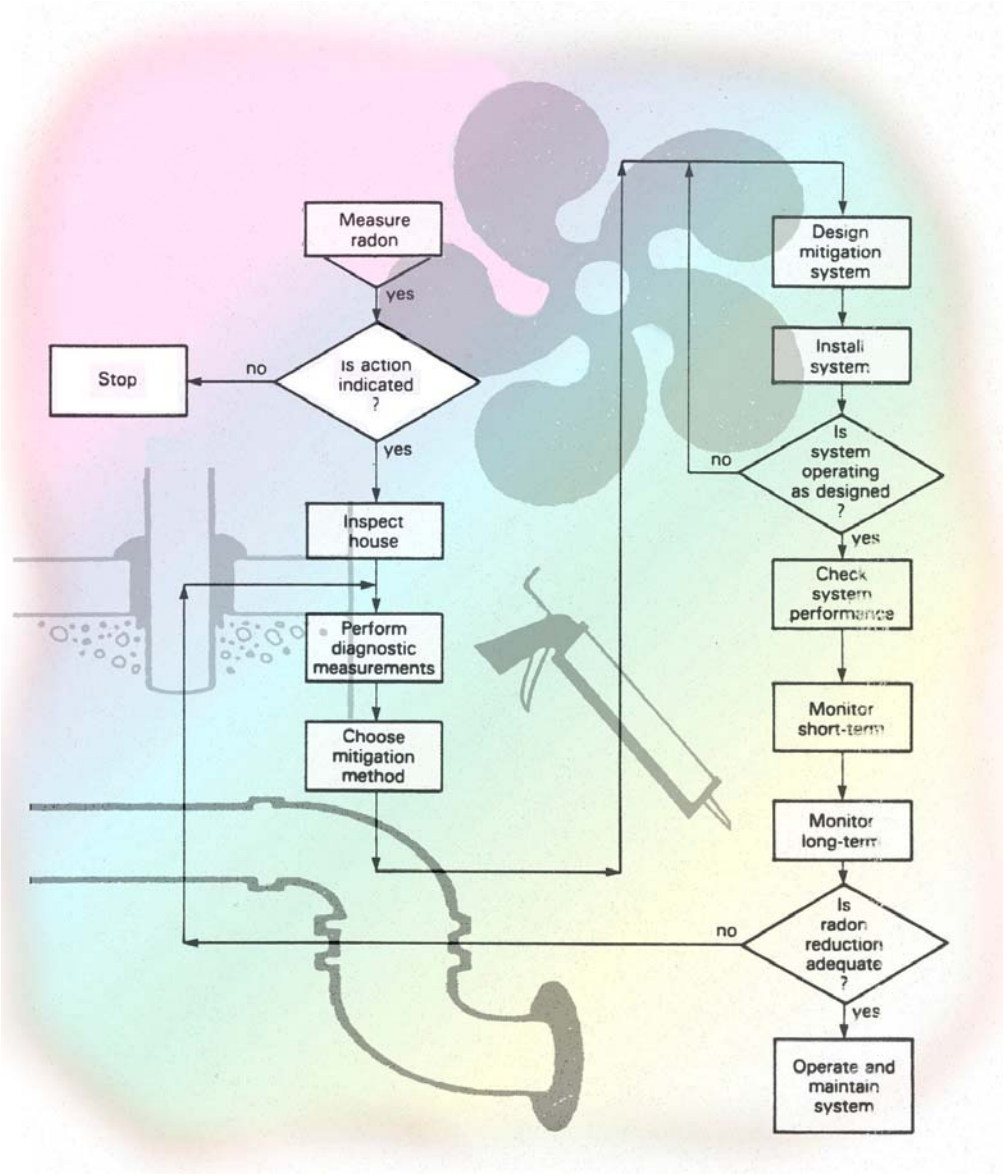


COMPUTER HARDWARE AND SOFTWARE

Any computer hardware and software developed specifically for use in your radon business must be documented, including where they were acquired and how they are installed, tested, used, maintained, modified and controlled. Any changes to hardware or software must be tested and documented.

PLANNING

For a radon measurement or mitigation organization, there is a business need to attain and maintain a desired, or required, level of quality of services. The consistent fulfillment of this need is related to the planned and efficient use of technology, personnel, and materials. Planning provides applicants for a Radon Professional License an opportunity to ensure that functions are consistent with and fulfill specified requirements in the RILA, 32 Ill. Adm. Code 422 and the applicant's quality goals and procedures. The elements of QAP's presented in this booklet may serve as the basic structure of your published quality commitments. However, the applicant must decide the means and methods by which the organization implements these elements.

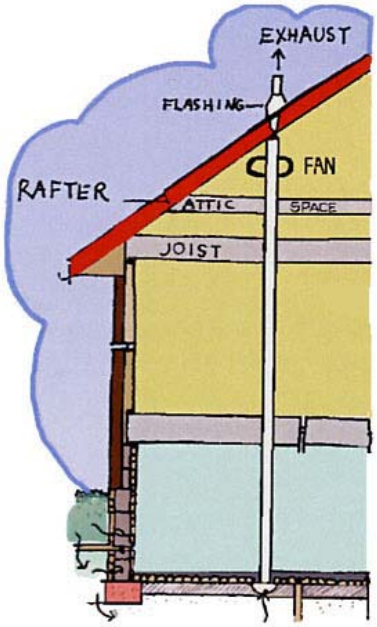


SUGGESTIONS AND COMPLAINTS

Your QAP should include a procedure for accepting, assessing and responding to suggestions and complaints from customers, regulatory agencies, and others. This procedure should include documenting the suggestion or complaint, assessing it, determining how you will consider alternative resolutions for the problem and carrying out a response.

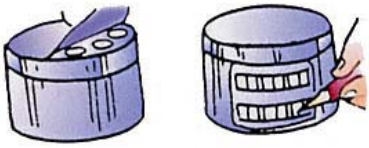
CORRECTIVE ACTIONS

You need to describe how corrective actions-whether they originate in a periodic review, an annual program audit, or from suggestions or complaints-will be determined and implemented. This includes detailing how the proposed remedy will be implemented and how you will verify its effectiveness once implemented. This should also include assessing any impact the corrective action will have on other aspects of your program. Important considerations regarding corrective actions are outlined in Appendix A.



STANDARD OPERATING PROCEDURES

All relevant aspects of your radon activities should have written standardized procedures. In your QAP, you need to establish which standard procedures are necessary, who will develop and use them, and how staff will be trained in their use. Appendix B includes an outline of the information typically included in SOPs.



APPENDICES TO QUALITY ASSURANCE PROGRAM DESCRIPTIONS

In your QAP descriptions include pertinent information such as definitions, acronyms, illustrations, standard forms, tables, charts, etc.

APPENDICES AND REFERENCES

Appendix A

Corrective Action. The corrective action program should assure the prompt incorporation of the proposed remedy and the verification of its effectiveness.

a) The responsibility and authority for instituting corrective action shall be defined. The coordination, recording, and monitoring of corrective action related to all quality related aspects of the organization should be assigned.

b) The significance of a problem affecting quality should be evaluated in terms of its potential impact on such aspects as testing and customer satisfaction.

c) The relationship of cause and effect should be determined, with all potential causes considered. Important variables affecting the capability of the process to meet required standards should be identified.

d) In the analysis of a quality related problem, the root cause should be determined before the preventive measures are planned. Often the root cause is not obvious, thus requiring careful analysis of all related processes, methods, quality records, staff, and work force input, and technical complaints.

e) In order to prevent recurrence of a quality related problems, preventive action should be initiated to a degree appropriate to the magnitude of the potential problems.

f) Sufficient control of methods and procedures shall be implemented to prevent recurrence of quality related problems. When the preventive measures are implemented, their effect should be monitored in order to ensure that desired goals are met.

g) Permanent changes resulting from corrective or preventive action shall be recorded in the QAP description. It may also be necessary to revise the procedures used to detect and eliminate potential problems. When QAPs are amended, the changes must be submitted to IEMA for review and approval..

Appendix B

Standard Operating Procedures (SOP). Radon or radon progeny measurements shall be performed in accordance with written standard operating procedures for each measurement system in use. The standard operating procedures shall be approved by the applicant / licensee responsible for radon or radon progeny measurement services.

a) All standard operating procedures shall be consistent with applicable sections of the 32 Ill. Adm. Code 422.

b) The sections in each procedure are indicated below and are underlined. All sections are included even if there is no information given, in which case the word “None or “Not Applicable” is placed directly under the section title.

1.0 INTRODUCTION: - A concise statement of the procedure intent.

2.0 SUMMARY: - Summarizes the extent of the procedure or areas to which the procedure applies.

3.0 DEFINITIONS: - Contains definitions of unique terms / words used in the procedure.

4.0 STANDARDS: - Identifies reference materials / standards to be used with field equipment as listed in Section 7.0.

5.0 CALIBRATION REQUIREMENTS: - Identifies calibration requirements and operability checks for equipment required as listed in Section 7.0.

6.0 QC REQUIREMENTS: - Identifies any QC requirements to be satisfied to ensure compliance with the procedure, or to ensure the quality of required equipment, standards or the installation process.

7.0 EQUIPMENT REQUIRED: - Identifies any standard or unique equipment needed to satisfy the procedure process.

8.0 PROCEDURE: - Describes the performers, actions and controls to be followed to implement the intended, controlled process.

9.0 RECORDS: - Identifies the quality assurance records to be created and retained which demonstrate compliance with, and completion of, the controlled process.

REFERENCES: - Lists the documents used to prepare the procedure or to be used to implement the procedure.

ATTACHMENTS: - This section identifies included information or sample forms needed to implement the procedure.

NOTE: The top of each procedure page shall contain a procedure number, revision number and effective date. When changes are made, the dates must be revised and a copy of the revisions submitted to the Agency for review and approval.

Appendix C

Interpretation Of The Results Of Side-By-Side Measurements

Section C.1 Assessment Of Precision

Radon and working level measurements, like all measurements, usually do not produce exactly the same results, even for co-located measurements. It is therefore critical to understand, document, and monitor the variability, or precision, of the measurements. This knowledge and proper documentation will allow you to characterize precision error to clients. Furthermore, the continual monitoring of precision provides a check on every aspect of the measurement system.

The objective of performing simultaneous or duplicate measurements is to assess the precision error of the measurement method, or how well two side-by-side measurements agree. This precision error is the "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 accuracy of the weighing process, and variations of analysis among detectors).

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, your 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 similar to those that are routinely observed. It is important to recognize that a few 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 before an investigation into the cause of the large differences is made. For example, the **warning level**, or the level of discrepancy between duplicates which triggers an investigation, may be set at a five percent probability. This level is a difference between duplicates that is so large that, when compared with previous precision errors, should only be observed five percent of the time. A **control limit**, where further measurements should cease until the problem is corrected, may be set at one percent probability.

A control chart for duplicates is not as simple as a control chart used to monitor instrument performance, with a check source. This is because the instrument's response to a check source should be fairly constant with time. Duplicates are performed at various radon concentrations, however, and the total difference between two measurements is expected to increase as radon levels increase.

Use of 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 a control chart 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 0.02 WL. At lower concentrations, for example, between 2 pCi/L (or 0.01 WL) and 4 pCi/L (or 0.02 WL), 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 that proportion at levels above 4 pCi/L or 0.02 WL At concentrations less than about 2 pCi/L, or 0.01 WL, the lower limit of detection may be approached, and the precision error may be so large as to render a control chart not useful.

Example control charts, using three different **statistics**, are described in the following sections.

Section C.2 Example Control Charts For Precision

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 duplicate pairs of measurements at each range of radon concentrations for which a control chart is to be prepared. For example, if you will only assess precision at concentrations greater than 4 pCi/L or 0.02 WL, you will need at least 20 pairs of measurements at concentrations greater than 4 pCi/L or 0.02 WL, to assess the "in control" level. The average precision error (RPD or COV) should be 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, USEPA and IEMA as a goal for precision, for example, a 10 percent COV (corresponding to a 14 percent RPD). 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 the correct probability limits for your system.

Sequential Control Chart Based on Coefficient of Variation

It can be shown (Iglewicz and Myers 1970, EPA 600/9-76-005; 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 variance or the square of 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 (x^2) test:

$$\chi^2_{n-1} \approx B[(n-1)COV_n^2/(n+(n-1)COV_n^2)] \qquad \text{(Equation 1)}$$

where $B = n[1 + (1/COV^2)]$;

COV_n = the observed COV of the nth pair (the pair that is to be evaluated); and

COV = the "in control" COV (e.g., 10 percent at levels greater than 4.0 pCi/L).

For duplicates, where n=2, Equation 1 becomes

$$\chi^2 = [2 + (2/COV^2)][COV_n^2/(2 + COV_n^2)] \qquad \text{(Equation 2)}$$

For a value of 0.10 for COV, it further reduces to

$$\chi^2 = 202[COV_n^2/(2 + COV_n^2)] \qquad \text{(Equation 3)}$$

Referring to a x^2 chart, you learn that the probability of exceeding a x^2 of 3.84 is only five percent. Inserting this value of 3.84 for x^2 and solving for COV_n produces a COV_n of 0.20. This level of probability forms the **warning level** shown in Exhibit C-1. The **control limit** corresponds to a x^2 of 6.63 and a COV_n of 0.26, where the probability of exceeding those values is only 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.

Sequential Control Chart Based on Relative Percent Difference

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

$$RPD = [100|x_1 - x_2|]/[(x_1 + x_2)/2] \qquad \text{(Equation 4)}$$

For n=2,

$$RPD = COV\sqrt{2} \qquad \text{(Equation 5)}$$

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 shown in Exhibit C-2. 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 is shown in Exhibit C-3. 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 4.0 pCi/L.

Exhibit C-1 CONTROL CHART* FOR COEFFICIENT OF VARIATION (COV) BASED ON AN "IN CONTROL" LEVEL OF 10%
(For duplicates where average ≥4.0 pCi/L or 0.02 WL)

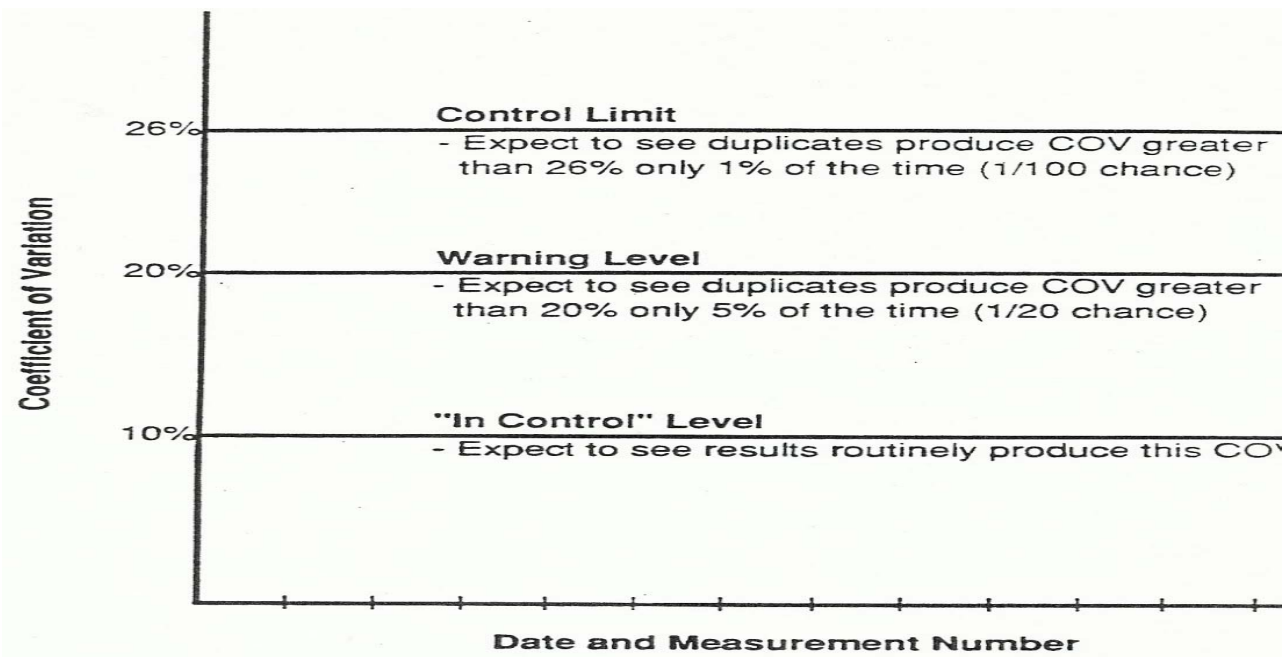
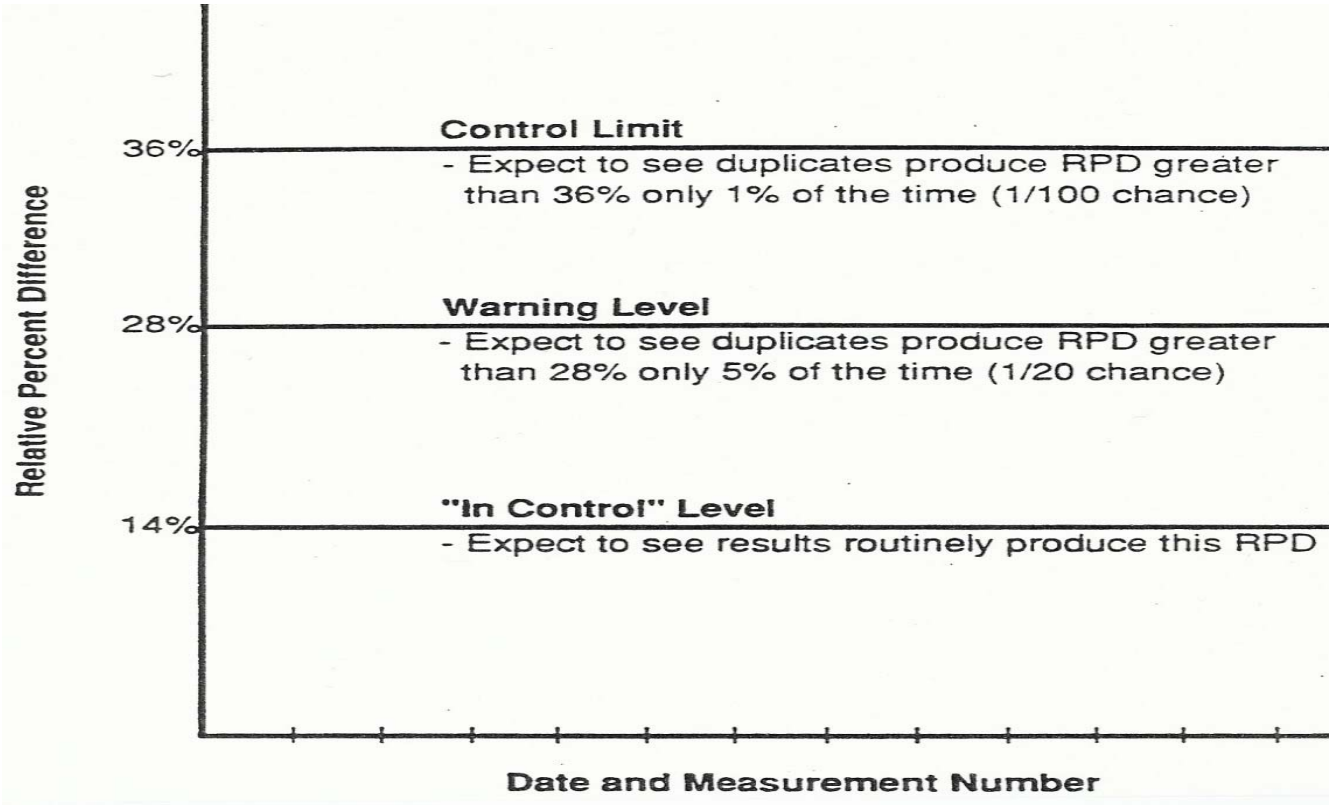


Exhibit C-2 Control Chart* for Relative Percent Difference (RPD)
Based on an "In Control" Level of 14% (=COV of 10%)
(For duplicates where average ≥4.0 pCi/L or 0.02 WL)



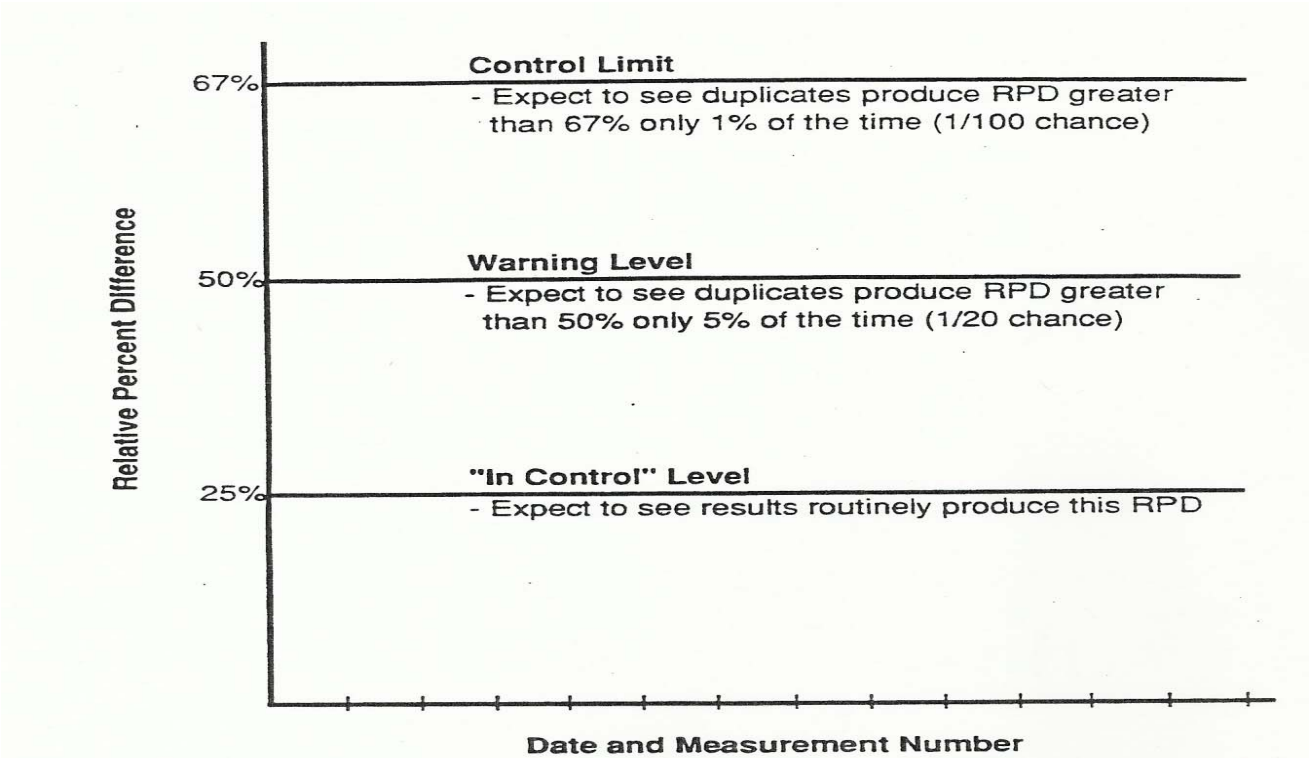
RPD = difference between two measurements divided by the average
Example: Detector A=5.0 pCi/L, B=6.0 pCi/L, RPD=18%

If RPD exceeds the **control limit** – cease measurements until the problem is identified and corrected.

If RPD exceeds the **warning level** - follow guidance in Section C.3 and see Exhibit C-5.

* As calculated from guidance provided in "Quality Assurance Handbook for Air Pollution Measurement Systems: Volume I" (EPA 600/9-76-005; U.S. EPA 1984)

Exhibit C-3 CONTROL CHART* FOR RELATIVE PERCENT DIFFERENCE (RPD) BASED ON AN "IN CONTROL" LEVEL OF 25% (=COV OF 18%)
(For duplicates where average <4.0 pCi/L or 0.02 WL)



RPD = difference between two measurements divided by the average
Example: Detector A=2.0 pCi/L, B=3.0 pCi/L, RPD=40%

If RPD exceeds the **control limit** – cease measurements until the problem is identified and corrected.

If RPD exceeds the **warning level** - follow guidance in Section C.3 and see Exhibit C-5.

* As calculated from guidance provided in "Quality Assurance Handbook for Air Pollution Measurement Systems: Volume I" (EPA 600/9-76-005; U.S. EPA 1984)

Range Control Chart

A range control chart (Goldin 1984) can be constructed to evaluate precision, using the statistics of the range (difference between two measurements) plotted against the average 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.

$R_m = 1.128\ s(x)$ (Equation 6)

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:

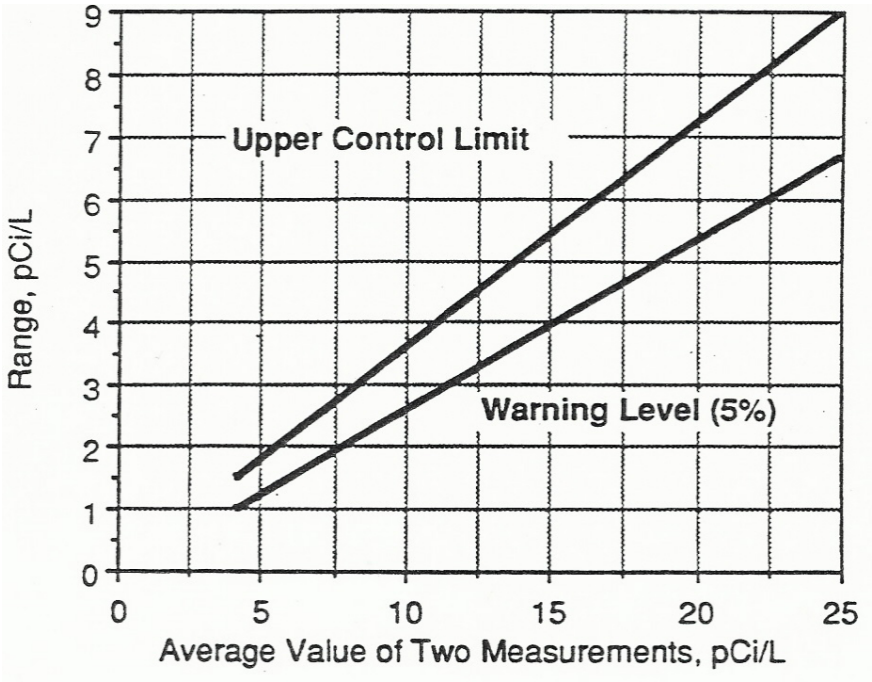
Control limit = 3.69 s(x) (Equation 7)

Warning level = 2.53 s(x) (Equation 8)

An example range control chart, using an assumed s(x) equal to 10 percent of the mean concentration, is shown in Exhibit C-4. The chart is used by plotting the range versus average concentration as duplicate measurements are analyzed.

Exhibit C-4 **RANGE CONTROL CHART TO EVALUATE PRECISION**

(Limits Based on $s(x)=0.1x_m$



If results exceed the **control limit** – cease measurements until the problem is identified and corrected. If results exceed the **warning level** - follow guidance in Section C.3 and see Exhibit C-5.

Section C.3 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**, use the table in Exhibit C-5. Refer to the row showing the number of duplicate results outside the **warning level**. If the total number of duplicate results accumulated in the control chart is contained in column A, investigate the cause of the high level of precision error but continue making measurements. If the total number of duplicate results on the chart is contained in column B, stop making measurements until the cause for the high precision error is found, and it is determined that subsequent measurements will not suffer the same high level of precision error.

Note that the example control charts shown 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. The most accurate control chart can be rendered by a range control chart using the measurement uncertainty expressed as the standard deviation, s(x), expected at the concentrations where measurements are made. If the precision error is not a constant fraction of the mean, the control limits will not appear as straight lines, but may exhibit changing slope. However, methods discussed here present a conservative way to monitor, record, and evaluate precision error and are very useful for comparing observed precision errors with an industry standard.

Exhibit C-5 Criteria for Taking Action for Measurements Outside the Warning Level*

Number of Duplicate Results Outside the Warning Level	Total Number of Duplicates	
	Investigate, But Continue Operations **A**	Stop Operations Until Problem is Corrected **B**
2	8-19	2-7
3	17-34	8-16
4	29-51	17-28
5	41-67	29-40
6	54-84	41-53
7	67-100	54-66

* Modified from Goldin (Goldin 1984) and based upon cumulative probability tables of the binomial distribution.

Appendix D

Sample Quality Management Plan

NOTE TO APPLICANTS

The Illinois Emergency Management Agency (IEMA) Division of Nuclear Safety (DNS) is providing this EXAMPLE Quality Assurance Program (QAP) to assist radon license applicants with completing the required elements of the Professional License application. While this document contains all the required quality commitments, it alone does not fulfill all the quality program requirements for a license. You must still describe your radon business practices and processes in standard operating procedures, to which you are committed in this QAP. Also, you must provide copies of all forms, charts, etc. that are specified in your radon practice procedures. Failure to submit complete procedures pertinent to your license category (i.e., measurement or mitigation) will delay issuance of your license.

BE AWARE, that upon issuance of your license, the Radon Program will hold you accountable for fulfilling all the commitments made in your QAP.

IEMA SAMPLE OF A

Quality Assurance Program

ORGANIZATION NAME

POLICY STATEMENT

ORGANIZATION NAME commits to providing quality radon related services to our clients, and to working in accordance with the requirements of the Radon Industry Licensing Act, 32 Illinois Administrative Code 422, Licensing of Radon Measurement and Mitigation Services, and this Quality Assurance Program (QAP). Compliance with this policy is mandatory for all **ORGANIZATION NAME** employees involved in radon-related services or practices.

I. MANAGEMENT AND ORGANIZATION

Management and Organizational information is presented in three sections:

- Position Descriptions and Reporting Structure
- Periodic Review of the Quality Program
- Annual Audits

Position Descriptions and Reporting Structure

VERSION ONE:

ORGANIZATION NAME is a sole proprietorship with no employees. **APPLICANT NAME** has ultimate responsibility for radon related work and will ensure only safe and adequate work is performed.

VERSION TWO:

This section identifies all **ORGANIZATION NAME** individuals responsible for providing radon services. Individual's listed below carry out radon related activities. Below each individual's name is a description of the individual's position/ job title, position description, position responsibilities, and reporting structure. This information is represented graphically in the attached Organization Chart.

The individual with ultimate responsibility for radon related work is **APPLICANT NAME**.

The individual(s) who has/have authority to stop unsafe or inadequate work is/are listed below:

1)
2)
3)

Periodic Review of the Quality Assurance Program (QAP)

At least annually, but as often as needed, the QAP and its Standard Operating Procedures are reviewed and may be revised in order to document improved practice. All substantive changes are mailed to **IEMA** at least 30 days prior to the effective date of the revision. Substantive changes must be approved by IEMA prior to implementation.

Annual Audits

At least annually, a formal, structured, and comprehensive audit of the QAP is performed. ORGANIZATION NAME Radon Professional Licensee, employee(s), or a qualified outside auditor may conduct audits.

Audit findings are described in a written Audit Report, along with a written assessment of whether or not the QAP is achieving its goals and including suggestions for improvement due to changes in technology, quality concepts, regulations, laws, or environmental conditions.

The Audit Report is reviewed by **INDIVIDUAL NAME**, **TITLE**, a senior manager with authority over all radon related work and authority to see that audit findings are corrected, corrections are verified, and verification is documented.

* NOTE TO APPLICANTS: Qualified means knowledgeable of the RILA and 32 Ill. Adm. Code 422 requirements or an experienced quality assurance professional auditor.

II. PERSONNEL QUALIFICATIONS AND TRAINING

Qualified radon staff is important. **ORGANIZATION NAME** employees who perform radon **LICENSE CATEGORY** are licensed by the Illinois Emergency Management Agency, Division of Nuclear Safety. Training on safety and operational policies and proper use of equipment is provided to all employees, licensed or unlicensed, in accordance with 32 Illinois Administrative Code 422.70 (e).

For each individual, **ORGANIZATION NAME** maintains evidence of all training for the duration of employment, and for five years past the end of employment.

III. PROCUREMENT OF ITEMS AND SERVICES

To ensure that **ORGANIZATION NAME** radon services are reliable, purchases of equipment and services from suppliers is planned and controlled. When equipment is ordered, a written description of the item or services being purchased is included along with the associated technical and quality specifications of the purchase. A list of approved equipment or services is provided with this QAP description.

IV. CONTROL OF DOCUMENTS AND RECORDS

All documents and records related to **ORGANIZATION NAME** radon activities are carefully controlled. A list of quality procedures is provided with this QAP. Procedures, programs, forms, and other documents related to radon activities are uniquely identified by document title, revision number, and revision date. Revisions are reviewed and approved in accordance with **PROCEDURE NAME AND NUMBER** and undergo the same approval process as new documents. Outdated documents are replaced and withdrawn from service. Documents are stored to ensure availability and are protected from fire, vermin, water, soiling, and deterioration. All documents required by 32 Ill. Adm. Code 422 in accordance with Section 422.70 (L) are maintained at **INSERT ADDRESS**.

> Note to applicants: Include complete copies of pertinent standard operating procedures (SOP's) with your QAP submittals. Ensure that all forms, graphs, and other example documents are included in these procedures. See the commitment element X. STANDARD OPERATING PROCEDURES. **Also be aware that to provide measurement or mitigation for School and Commercial Measurements you must outline these services with standard operating procedures.**
>
> Also, your Worker Protection Program must be either: (1) a procedure for protecting worker health and safety, OR (2) a separate document with worker protection procedures. Whichever option you choose, the worker protection documents are also controlled in accordance to your commitments in this section.
>
> With either option, be sure that your worker protection activities comply with the requirements in the 32 Ill. Adm. Code 422 and those descriptions of your worker protection activities are included in your license application package. Failure to provide a complete application package will delay review of your license application.

V. COMPUTER HARDWARE AND SOFTWARE

Any computer hardware or software developed specifically for use in the **ORGANIZATION NAME** radon program is documented, including where it is acquired and how it is installed, tested, used, maintained, modified and controlled. Changes to hardware and software are tested and documented.

Spreadsheets used for radon calculations such as worker exposure to radon, are tested quarterly, at least, to ensure that the equations are not corrupted.

VI. PROGRAMING

ORGANIZATION NAME recognizes that a business needs to attain and maintain a desired, or required, level of quality of services. Consistent fulfillment of this need is related to the programmed and efficient use of technology, personnel, and materials. Programming provides an opportunity for **ORGANIZATION NAME** to ensure that functions are consistent with and fulfill specified requirements of the RILA, 32 Ill. Adm. Code 422, and this QAP and its Standard Operating Procedures. Elements of the QAP presented here serve as the basic structure for **ORGANIZATION NAME** published quality commitments. **ORGANIZATION NAME** implements the elements of this QAP in accordance with its Standard Operating Procedures for each element and other key activities.

VII. CALIBRATION

ORGANIZATION NAME controls the use of instruments and testing equipment. Devices are calibrated at least every 12 months so that their accuracy is maintained within required limits. **ORGANIZATION NAME** ensures that its instruments are calibrated prior to their first use after purchase. Further, **ORGANIZATION NAME** ensures that each instrument is calibrated prior to its first use after it has been repaired. Documentation of calibration is maintained as a quality record.

NOTE TO APPLICANTS**:** Calibration of instruments and equipment applies to both measurement and mitigation licenses. Specific guidance for individual radon measurement devices is outlined in 32 Ill. Adm. Code 422.140.

VIII. SUGGESTIONS AND COMPLAINTS

ORGANIZATION NAME accepts, assesses, and responds to suggestions and complaints from customers, regulatory agencies, and others in accordance with **PROCEDURE NAME AND NUMBER.** This procedure includes documenting the suggestion or complaint, assessing it, determining how alternative resolutions may be applied and carrying out a response.

For disputes regarding radon activities, where resolution cannot otherwise be achieved, **ORGANIZATION NAME** refers the complaint and complainant to the Illinois Emergency Management Agency, Division of Nuclear Safety (DNS*)* and abides by the DNS resolution decision.

NOTE TO APPLICANTS**:** This procedure should be included with your QAP submittal.

IX. CORRECTIVE ACTIONS

ORGANIZATION NAME describes in **PROCEDURE NAME AND REVISION NUMBER** how corrective actions – whether they originate in a periodic review, an annual review, or from suggestions or complaints – are determined and implemented. This procedure details how a proposed remedy is implemented and how effectiveness of the remedy is evaluated or verified. Also included in the procedure is our process for assessing the impact that the corrective action has on other aspects of the **ORGANIZATION NAME** program. The **ORGANIZATION NAME** corrective action program assures the prompt incorporation of the proposed remedy and the verification of its effectiveness, including:

a) The responsibility and authority for instituting corrective action is defined. Coordination, recording, and monitoring of corrective action related to all quality related aspects of the organization are assigned.
b) Significance of a problem affecting quality is evaluated in terms of its potential impact on such aspects as testing, and public health and safety.
c) The relationship between cause and effect is determined, with all potential causes considered. Important variables affecting the capability of the process to meet required standards are identified.
d) In the analysis of a quality-related problem, the root cause is determined before the preventive measures are programmed. Often the root cause is not obvious, thus, requiring careful analysis of all related processes, methods, quality records, staff, and work force input, and technical complaints.
e) In order to prevent recurrence of a quality related problem, preventive action is initiated to a degree appropriate to the magnitude of the potential problems.
f) Sufficient control of methods and procedures is implemented to prevent recurrence of quality related problems. When the preventive measures are implemented, their effect is monitored in order to ensure that desired goals are met.
g) Permanent changes resulting from corrective or preventive action is recorded in the QAP or in revised Standard Operating Procedure(s) pertinent to detection and elimination of potential problems.

NOTE TO APPLICANTS**:** This procedure should be included with your QAP submittal.

X. STANDARD OPERATING PROCEDURES

All relevant aspects of the **ORGANIZATION NAME** radon activities are described in written, standardized procedures. Standard Operating Procedures are developed in accordance with **PROCEDURE NAME AND REVISION NUMBER** that stipulates necessary procedures, the development process, procedure format, procedure initiation, and how staff is trained in approved procedure uses. **Also be aware that to provide measurement or mitigation for School and Commercial Measurements, you must outline these services with standard operating procedures.**

APPENDICES

Include pertinent information such as definitions, acronyms, illustrations, standard forms, tables, charts, etc in numbered appendices. Be sure that references to these appendices in the QAP are correct.

Check the glossary of 32 Illinois Administrative Code 422, Licensing of Radon Measurement and Mitigation Services for definitions and acronyms.

Be sure to include separate Standard Operating Procedures (SOP's) as described in the commitment sections above formatted in accordance with Appendix B of the Radon Quality Assurance Program Guidance document.

REFERENCE DOCUMENTS

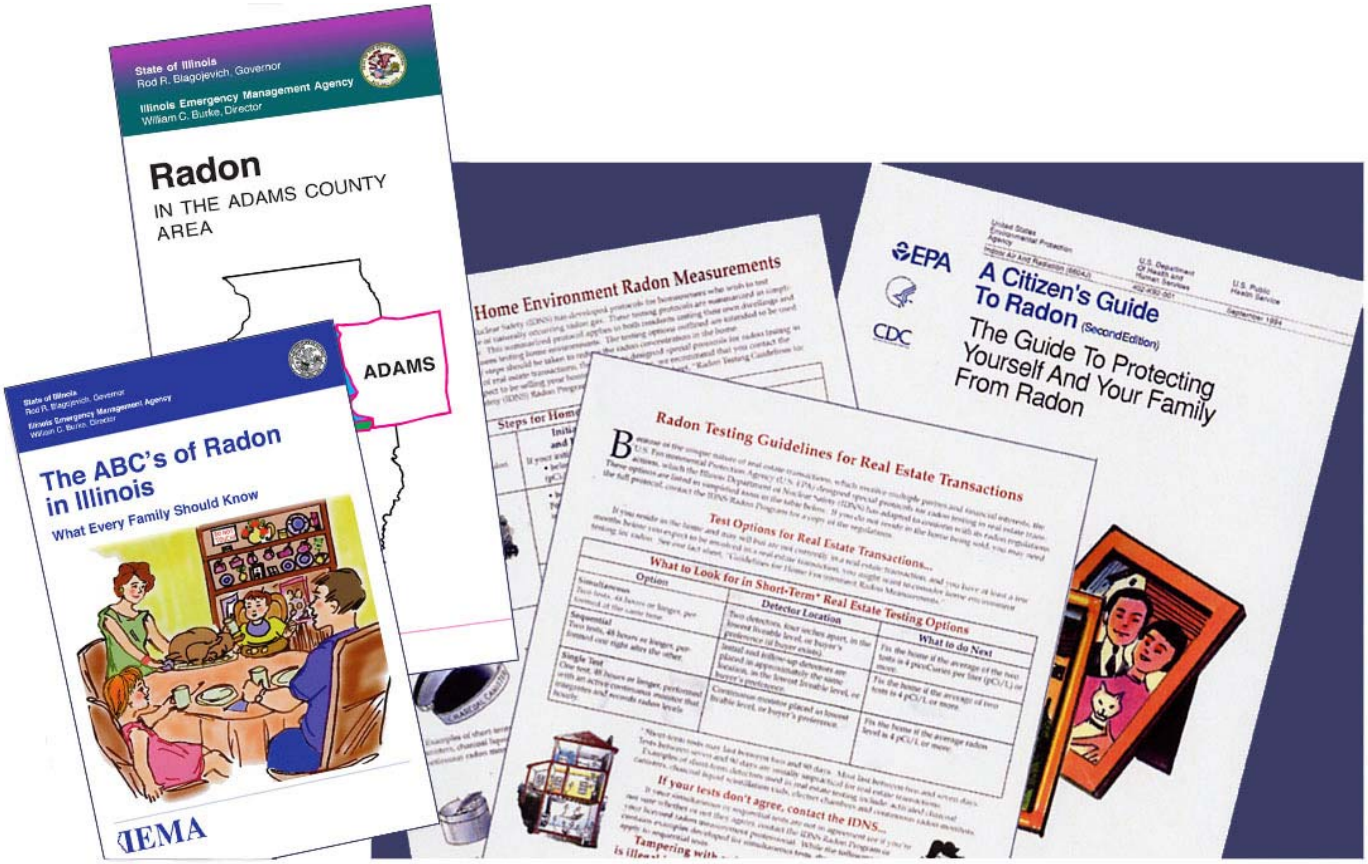
The following documents are sources of additional quality assurance information and are recommended reading for all applicants.

"Radon Industry Licensing Act," Act 420 ILCS 44

32 Illinois Administrative Code 422, "Licensing of Radon Detection and Mitigation Services".

ANSI/ASQC E4-1994, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs."

USEPA, "Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans (QAMS-005/80), December 29, 1980.



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