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REGULATORY
STANDARD

Technical and Quality Assurance Requirements for Dosimetry Services

S-106 REVISION 1

May 2006

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REGULATORY STANDARD

S-106 revision 1

TECHNICAL AND QUALITY ASSURANCE REQUIREMENTS FOR DOSIMETRY SERVICES

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Technical and Quality Assurance Requirements for Dosimetry Services
Regulatory Standard S-106 revision 1

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TECHNICAL AND QUALITY ASSURANCE REQUIREMENTS FOR DOSIMETRY SERVICES

1.0 PURPOSE

The purpose of this regulatory standard, when incorporated in a dosimetry service licence or other legally enforceable instrument, is to assure that licensed dosimetry services meet certain technical requirements and implement certain quality assurance measures, in accordance with the purpose of the *Nuclear Safety and Control Act* (NSCA).

2.0 SCOPE

This regulatory standard sets out the technical and quality assurance requirements that a licensed dosimetry service shall meet, when a condition of the applicable licence so requires.

3.0 RELEVANT LEGISLATION

The relevant provisions of the NSCA and the regulations made under the act to this standard are as follows:

1. Subsection 24(4) of the NSCA provides that “no licence may be issued, renewed, amended or replaced unless, in the opinion of the Commission, the applicant (a) is qualified to carry on the activity that the licence will authorize the licensee to carry on; and (b) will, in carrying on that activity, make adequate provision for the protection of the environment, the health and safety of persons and the maintenance of national security and measures required to implement international obligations to which Canada has agreed;”
2. Subsection 24(5) of the NSCA provides that a licence issued by the Canadian Nuclear Safety Commission (CNSC) may contain any term or condition that the Commission considers necessary for the purposes of the Act;
3. Section 18 of the *Radiation Protection Regulations* provides that an application for a licence to operate a dosimetry service shall contain, in addition to other information, the following:
 - a) “a description of the proposed operation of the dosimetry service;
 - b) the proposed quality assurance program;
 - c) the types of dosimetry services proposed to be provided, including the types of radiation that will be monitored and their respective energy ranges;
 - d) the precision, accuracy and reliability of the dosimetry services to be provided; and
 - e) the proposed qualification requirements and training program for workers.”

4. Section 19 of the *Radiation Protection Regulations* states “Every licensee who operates a dosimetry service shall file with the National Dose Registry of the Department of Health, at a frequency specified in the licence and in a form compatible with the Registry, the following information with respect to each nuclear energy worker for whom it has measured and monitored a dose of radiation:
 - a) The worker’s given names, surname and any previous surname;
 - b) The worker’s Social Insurance Number;
 - c) The worker’s sex;
 - d) The worker’s job category;
 - e) The date, province, and country of birth of the worker;
 - f) The amount of exposure of the worker to radon progeny; and
 - g) The effective dose and equivalent dose received by and committed to the worker.”
5. Subsection 28(1) of the *General Nuclear Safety and Control Regulations* provides that “Every person who is required to keep a record by the Act, the regulations made under the Act or a licence shall retain the record for the period specified in the applicable regulations made under the Act or, if no period is specified in the regulations, for the period ending one year after the expiry of the licence that authorizes the activity in respect of which the records are kept.”
6. Subsection 28(2) of the *General Nuclear Safety and Control Regulations* states “No person shall dispose of a record referred to in the Act, the regulations made under the Act or a licence unless the person
 - a) is no longer required to keep the record by the Act, the regulations made under the Act or the licence; and
 - b) has notified the Commission of the date of disposal and of the nature of the record at least 90 days before the date of disposal.”

4.0 TECHNICAL REQUIREMENTS

This section provides technical requirements that are specific to external dosimetry, internal dosimetry and the measurement of exposures to radon progeny, radon gas and airborne radioactive material. The requirements apply to outside (commercial) dosimetry services and in-house dosimetry services.

4.1 Dosimetry Services for External Radiation

An external dosimetry service shall comply with the following requirements:

1. Identify, at the licensing stage, the types of radiation and the expected respective energy ranges to which the dosimeters will be exposed during use;
2. Measure the quantity of interest within the accuracy specifications and uncertainty limits that apply to that quantity, as described in subsection 4.1.3, “Accuracy Specifications and Uncertainty Limits”;
3. Demonstrate its ability to satisfy overall specifications through type testing at the licensing stage and when changes are made, as described in subsection 4.1.4, “Type Testing”;
4. Demonstrate that it operates in a predictable and consistent way through routine and special performance testing, as described in subsection 4.1.5, “Performance Testing”;
5. Have its performance and the calibration of its system verified through independent testing, as described in subsection 4.1.6, “Independent Testing”;
6. Notify the CNSC immediately, in writing (electronic format acceptable), when it fails one of its periodic tests (i.e., performance or independent test);
7. Submit to the CNSC within 30 days a detailed written report outlining the cause and consequence of any periodic test failure and a description of corrective action taken; and
8. Repeat the failed test as soon as practicable in consultation with the CNSC and submit the results to the CNSC.

If repetition of the test results in a second consecutive failure, the CNSC may take further licensing action.

Note: Neutron dosimetry services are exempt from the requirements of this section and subsections 4.1.3, 4.1.4, 4.1.5 and 4.1.6. Requirements that apply to neutron dosimetry services are described in subsection 4.1.7, “Requirements for Routine Neutron Dosimetry Services.”

4.1.1 Measurement Quantities

4.1.1.1 Torso

The quantity to be measured is the “personal dose equivalent,” $H_p(d)$, as defined by the International Commission on Radiation Units and Measurements (ICRU) in Report 47.^[1] The values of “d” differ depending on tissue depth, as follows:

1. For a shallow (or skin) dose, the value is 0.07 mm; and
2. For a deep (or whole-body) dose, the value is 10 mm.

The conventionally true value of “d” serves as the reference value for estimating errors in measurements. In the following sections, $H_{p,c}(d)$ designates the conventionally true value of the quantity $H_p(d)$. For more information on conventionally true values, see Section A.2 of Appendix A, “Accuracy and Uncertainty in External Dose Measurement.”

4.1.1.2 Extremities

The quantity to be measured for a specific extremity is the dose equivalent at a depth of 0.07 mm. The International Commission on Radiological Protection (ICRP) recommends the depth of 0.07 mm, which is designated as H_e for the purpose of this document, in its Publication 60.^[2] In the following subsections, $H_{e,c}$ designates the conventionally true value of the quantity H_e . For more information on conventionally true values, see Section A.2 of Appendix A, “Accuracy and Uncertainty in External Dose Measurement.”

4.1.2 Minimum Measurable Dose Equivalent

The dosimetry service shall determine the lowest values of $H_{p,c}(d)$ and $H_{e,c}$ it can measure at the 95% confidence level. These values shall be determined under good laboratory conditions, using the usual calibration radiation at normal incidence to the dosimeter.

The method used to determine these quantities is left to the discretion of the dosimetry service. However, the reference used shall be indicated in the licence application.

4.1.3 Accuracy Specifications and Uncertainty Limits

Neutron dosimetry services are exempt from the accuracy specifications and uncertainty limit requirements described in this subsection.

Table 1 lists the overall specifications for accuracy and precision. Type testing, which is described in subsection 4.1.4, “Type Testing,” and Appendix B, “Type Testing Specifications for External Dosimetry,” determines a dosimetry system’s ability to meet these specifications. Section A.3 of Appendix A, “Accuracy and Uncertainty in External Dose Measurement,” describes the calculation methods for analyzing type test results. Section A.4 of Appendix A provides example calculations.

Table 1: Accuracy and Precision Specifications

Quantity	Dose (mSv)	Specifications
$H_{p,c}(10)$	4 to 10 000	-33% / +50%
	0.4	-50% / +100%
$H_{p,c}(0.07)$	100 to 10 000	-33% / +50%
	10	-50% / +100%
$H_{e,c}$	100 to 10 000	-67% / +200%
	10	-67% / +200%

4.1.4 Type Testing

Neutron dosimetry services are exempt from the requirements for type testing and documenting type test results described in this subsection.

The dosimetry service shall comply with the following requirements:

1. Demonstrate the ability of its dosimetry system to satisfy overall specification requirements through type testing at the licence application stage;
2. Repeat the type tests when the dosimetry service makes changes¹ that may affect the result of a dose measurement to the extent necessary to demonstrate that the specifications of Table 1 subsection 4.1.3, “Accuracy Specifications and Uncertainty Limits,” continue to be met;
3. Report the results of these type tests which have been repeated following changes made to the system, to the CNSC, along with the records described in subsection 4.1.4.1, “Documentation,” and obtain CNSC approval prior to the implementation of these changes; and
4. Comply with the specifications described in Appendix B, “Type Test Specifications for External Dosimetry.”

¹ Examples of such changes are dosimeter design, badge case filters, dose algorithm and temperature cycles (for thermoluminescent dosimetry (TLD)).

4.1.4.1 Documentation

The dosimetry service shall maintain:

1. Type test results in a format that clearly shows all the influence quantities and system characteristics that were considered and their range of possible values, as expected by the dosimetry service, based on the intended use of that particular dosimetry system;
2. Sample calculations that show how the mean response and the combined standard uncertainty were calculated; and
3. The justification for any assumptions made and techniques used.

4.1.5 Performance Testing

Neutron dosimetry services are exempt from the requirements of routine and special performance tests described in this subsection. Information on the requirements for neutron dosimetry services is provided in subsection 4.1.7, “Requirements for Routine Neutron Dosimetry Services.”

4.1.5.1 Routine Performance Tests

The dosimetry service shall conduct routine performance tests.

The dosimetry service shall include provisions for routine performance tests during every routine dosimeter issue period. For commercial dosimetry services, a monthly performance test is acceptable. For extremity dosimetry, performance tests shall be performed at least once every three months. The frequency and nature of special performance tests shall be specified in the licence application.

For routine performance tests, the dosimetry service shall comply with the following requirements:

1. Irradiate test dosimeters to known doses, usually under standard exposure conditions (e.g., at normal incidence with the calibration radiation);
2. Treat test dosimeters in the same way as routine dosimeters; if processing is required, provide test dosimeters without identifying them to the processing laboratory;
3. In test irradiations, include doses comparable to or less than the smaller values in Table 1 subsection 4.1.3; “Accuracy Specifications and Uncertainty Limits,” and
4. Establish, in consultation with the CNSC, control limits on the test results.

The dosimetry service may maintain constant irradiation conditions and doses over time to permit more valid trend analysis.

4.1.5.2 Special Performance Tests

In addition to the routine performance tests, the dosimetry service shall conduct special performance tests on occasion to confirm that the performance of the dosimetry system remains consistent with the results of the type tests.

For special performance tests, the dosimetry service shall subject the dosimeters to a subset of those influence quantities that the type tests showed to be significant and to which the response of the dosimetry system may have changed as a result of aging or replacement of components.

4.1.5.3 Documentation

The dosimetry service shall keep a record of the following information:

1. Routine performance test procedures; and
2. Routine and special performance test results.

The dosimetry service shall submit the routine performance test procedures to the CNSC for approval at the licensing application stage.

4.1.6 Independent Testing

Neutron dosimetry services are exempt from the requirements for independent testing described in this subsection.

The requirements for independent testing include the following:

1. External dosimetry services shall undergo and pass independent testing of each of its dosimeter designs prior to licensing;
2. Upon receipt of a licence, the dosimetry service shall undergo independent testing at regular intervals with a frequency of at least once every 12 months;
3. The dosimetry service shall have the independent tests performed by the relevant reference calibration centre for external dosimetry in Canada (see Appendix J);
4. The dosimetry service shall comply with the specifications described in Appendix C, "Independent Test Specifications for External Photon Dosimetry," and Appendix D, "Independent Test Specifications for Extremity Dosimetry," as applicable; and
5. If the dosimeters used by the dosimetry service require processing (e.g., TLDs), and more than one processing unit (e.g., TLD reader) is used, each processing unit shall be tested annually by using each unit to process at least one set of test dosimeters irradiated by the reference calibration centre.

Note: If the dosimetry service has documented evidence that shows that all of its processing units respond in a consistent manner, only one unit shall be tested annually through the reference calibration centre. However, the dosimetry service shall establish response consistency of the processing units by showing that the mean response (i.e., the mean calculated dose) of a set of dosimeters processed by any given unit is within $\pm 5\%$ (at the 95% confidence level) of the average of the mean responses obtained from all of the processing units. In the case of whole-body dosimeters, the coefficient of variation of dosimeters processed by each unit shall not be greater than 0.075 and 0.2 in the case of extremity dosimeters.

4.1.6.1 Accuracy Specifications

The accuracy specifications that a dosimetry service shall maintain in each of the independent tests for photon and beta radiation are represented in Table 2 by the mean response, \bar{R} , and the coefficient of variation of the responses for the complete set of measurements. For dosimeters worn on the torso, the mean response corresponds with the complete set of measurements of the collision air kermas (or exposures) delivered. For dosimeters worn on the extremities, the mean response corresponds with the complete set of measurements of tissue doses delivered.

Table 2: Accuracy Specifications for Dosimeters

Dosimeter	Mean Response \bar{R}	Coefficient of Variation
Worn on the torso	$0.9 \leq \bar{R} \leq 1.1$	≤ 0.075
Worn on the extremities	$0.80 \leq \bar{R} \leq 1.25$	≤ 0.2

Note: For these tests, Table 2 defines the response relative to the conventionally true value of the appropriate quantity.

4.1.7 Requirements for Routine Neutron Dosimetry Services

A neutron dosimetry service shall comply with the following requirements:

1. Ensure compatibility between the dosimetry service's neutron dosimeters and the neutron fields in which they are to be used, and where possible, include a description of the neutron sources and the expected neutron spectra to which workers will be exposed;
2. Document detailed technical descriptions of the dosimeters and associated equipment;

3. Record data and prepare reports with quantitative information on the performance of the dosimeters and the service (type testing is not required, except to show that the response is appropriate to the neutron energy spectra to which workers may be exposed); and
4. Have the calibration of its system directly traceable to the reference calibration centre (see Appendix J) or another recognized national or international laboratory, in consultation with the CNSC.

If neutron survey meters are used instead of personal neutron dosimeters, the dosimetry service shall meet the requirements listed above regarding such instruments. It shall also establish a routine calibration program with the relevant reference calibration centre (see Appendix J) or another recognized national or international laboratory in consultation with the CNSC.

4.1.7.1 Data and Reports

Further to item 3 in section 4.1.7, the following information shall be recorded as data and provided in reports:

1. A description of the calibration source, the calibration field and a reference to the calibration protocol;
2. The dose equivalent energy response of the dosimeters;
3. A statement on the limitations of the dosimetry system and a qualitative estimate of its accuracy and precision in measuring $H_{p,c}(10)$, under the conditions that the dosimeters are intended to be used, including the variability among the processing components;
4. An estimate of the lowest value of $H_{p,c}(10)$ that the dosimetry system is capable of measuring at the 95% confidence level; and
5. The minimum reportable dose.

4.1.7.2 Independent Testing

The dosimetry service shall undergo independent testing with the relevant reference calibration centre (see Appendix J) prior to licensing and, upon receipt of a licence, at regular intervals with a frequency of at least once every 12 months.

This is a consistency test that enables dosimetry services to demonstrate consistency of performance on a periodic basis. The conditions upon which the consistency will be judged are established at the time of licensing. Table 3 shows the pass criteria for the complete set of measurements.

Table 3: Accuracy Specifications for Neutron Dosimeters

Dosimeter	Mean Response \bar{R}	Coefficient of Variation of the Responses
All types	$0.7 \leq \bar{R} \leq 1.5$	≤ 0.25

When neutron survey meters are used for dosimetry, the requirement for an annual independent test may be combined with the requirement described in subsection 4.1.7, “Requirements for Routine Neutron Dosimetry Services,” for routine calibration. It is sufficient to send one neutron survey meter for such a test, providing that any additional neutron survey meters used by the dosimetry service are calibrated against the one sent to the reference calibration centre.

The dosimetry service shall comply with the specifications described in Appendix E, “Independent Test Specifications for Neutron Dosimetry.”

4.1.7.3 Performance Testing

The dosimetry service shall comply with the following requirements:

1. Establish a program for routine performance tests on the dosimetry systems;
2. Conduct performance tests on a regular basis, as determined in consultation with the CNSC; and
3. Submit relevant documentation, including the frequency of the testing, to the CNSC at the licence application stage.

4.1.7.4 Documentation

The neutron doses shall be recorded and reported separately from other types of doses.

4.2 Dosimetry Services for Internal Radiation

An internal dosimetry service shall comply with the following requirements:

1. Measure the activities and activity concentrations for selected radionuclides, as described in subsection 4.2.1, “Measurement Quantities”;
2. Measure the quantity of interest within the accuracy and precision specifications, as described in subsection 4.2.2, “In Vitro Accuracy and Precision Specifications,” and subsection 4.2.5, “In Vivo Accuracy and Precision Specifications”;
3. Demonstrate that the internal dosimetry service operates in a predictable and consistent way through performance testing, as described in subsection 4.2.3, “Performance Testing for In Vitro Measurements”;

4. Demonstrate that it operates in a reliable way by participating in independent testing, as described in subsection 4.2.4, “Independent Testing for In Vitro Measurements,” and subsection 4.2.6, “Independent Testing for In Vivo Measurements”;
5. Ascertain doses as described in subsection 4.2.7, “Interpretation of Bioassay Data”;
6. Notify the CNSC immediately, in writing (electronic format acceptable), when it fails one of its periodic tests (i.e., performance or independent test);
7. Submit to the CNSC within 30 days a detailed written report outlining the cause and consequence of the failure of any periodic test and a description of corrective action taken; and
8. Repeat any failed test as soon as practicable in consultation with the CNSC and submit the results to the CNSC.

If a repetition of the test results in a second consecutive failure, the CNSC may take further licensing action.

4.2.1 Measurement Quantities

The internal dosimetry service shall be capable of measuring the activities and activity concentrations² equal to the minimum testing levels (MTLs) shown in Table 4³ for the radionuclides for which they are licensed. Values greater than those in Table 4 may be used as MTLs if the internal dosimetry service can demonstrate that the dose consequence is not significant (e.g., less than 1 millisievert (mSv) per year). This does not preclude the dosimetry service from carrying out its performance tests at levels below the MTLs.

To simulate working conditions, radionuclides other than those listed in Table 4 may be introduced during the required independent testing described in subsection 4.2.4, “Independent Testing for In Vitro Measurements,” and subsection 4.2.6, “Independent Testing for In Vivo Measurements.” These radionuclides are considered separate from the test but are added as interferences to challenge the service’s analytical system. Consequently, the dosimetry service may pass the test without identifying or measuring them. However, failure to correct for such interferences would jeopardize performance of the test and may result in a failed test.

² Radionuclide activities and activity concentrations are measured in becquerels (Bq) and becquerels per litre (Bq/L).

³ The list of radionuclides in Table 4 is not comprehensive for fission and activation products, but is representative for demonstrating competence in measurement techniques.

Table 4: Minimum Testing Levels

Radionuclide	In Vitro – Urine Bioassay (Bq/L)	In Vivo Bioassay (Bq)
Hydrogen-3 (HTO)	2000	Test not available
Carbon-14	2000	3 x 10 ⁵ (lung)
Iron-59	Test not available	2500
Cobalt-57 ^a	25	2500
Cobalt-60	25	2500
Strontium-90	2	Test not available
Zirconium-95 + Niobium-95	Test not available	2000
Antimony-124	Test not available	2000
Iodine-125 ^b	20	1000
Iodine-131 ^c	20	1000
Cesium-137	20	2000
Cerium-144	250	25000
Radium-226	0.05	5000
Thorium-230	0.02	Test not available
Natural thorium ^d	0.02	150 (lung)
Natural uranium ^e	25 µg/L	20 mg (lung)
Uranium-235	0.02	30 (lung)
Plutonium-238/239/240	0.01	9000 (lung)
Americium-241	0.05	100 (lung)
Notes:		
a) Cobalt (Co)-57 is used as a surrogate for Cerium (Ce)-144.		
b) If Iodine (I)-129 is used as a surrogate for I-125, the same MTL values apply as for I-125.		
c) If Barium (Ba)-133 is used as a surrogate for I-131, the same MTL values apply as for I-131.		
d) One gram of natural thorium contains equal quantities, 4.06E+03 Bq, of Thorium (Th)-232 and Th-228. The mass percentages are 99.9999%, 1.3E-08% for Th-232 and Th-228 respectively while the specific activity is 8.12E+03 Bq/gram(g).		
e) One gram of natural uranium contains equal quantities, 1.26E+04 Bq, of Uranium (U)-234 and U-238, and 569 Bq of U-235. The mass percentages are 99.2837%, 0.7110% and 0.0053% for U-238, U-235 and U-234 respectively; and the specific activity is 2.52E+04 Bq/g.		

4.2.2 In Vitro Accuracy and Precision Specifications

Table 5 lists the *in vitro* accuracy and precision specifications for independent and performance tests. To assess compliance with accuracy specifications, bias and precision shall be considered separately. The mean relative bias, B, shall be calculated from replicate measurements, A_i , of each concentration or level of activity, A. Since bias is often greater at lower concentrations near the limits of detection than at higher concentrations, dosimetry service laboratories shall be tested at several concentrations no lower than the MTL.

Table 5: Accuracy and Precision Specifications

Mean Relative Bias (B)	Relative Precision (S_B) (Absolute Value)
$-0.25 \leq B \leq 0.50$	≤ 0.40

4.2.3 Performance Testing for In Vitro Measurements

The dosimetry service shall conduct routine performance tests. It shall include provisions for routine performance tests for *in vitro* bioassay, which are to be performed at least once every three months, or, for infrequently used *in vitro* measurements, at a frequency determined in consultation with the CNSC.

For routine performance tests, the dosimetry service shall comply with the following requirements:

1. Prepare the test samples to concentrations of analyte not known to the person analyzing the test samples;
2. Determine the concentration of analyte in the test samples;
3. Treat the test samples in the same way as, so that they are indistinguishable from, routine *in vitro* bioassay samples; and
4. Include the same categories of radionuclides in the performance tests that are included in the independent tests in which the dosimetry service participates.

4.2.3.1 Documentation

The dosimetry service shall keep the following records:

1. Performance test procedures; and
2. Performance test results.

The dosimetry service shall submit the performance test procedures to the CNSC for approval at the licence application stage.

4.2.4 Independent Testing for In Vitro Measurements

Internal dosimetry services shall undergo and pass independent testing prior to licensing. Upon receipt of a licence, the dosimetry service shall undergo independent testing at regular intervals at least every 12 months, or at other intervals determined in consultation with the CNSC.

If a dosimetry service uses more than one measurement instrument (e.g., several liquid scintillation counters for tritium analysis), the instruments that were not used for the independent test shall be verified at regular intervals at least every 12 months against the measurement instrument that was used for the test. The laboratory shall show that all other measurement instruments also meet the accuracy and precision requirements. It shall take factors, such as chemical recovery, quenching, concentration range, sample preparation methods, and so on, into account where applicable.

The dosimetry service shall have the independent tests performed by the relevant reference calibration centre (see Appendix J) unless otherwise stated in the dosimetry service licence. If the relevant reference calibration centre does not offer the test, the dosimetry service shall seek CNSC approval to use a different organization to perform the independent tests.

Dosimetry services shall also have their analytical performance tested at levels of activity encountered in routine personnel monitoring as well as at expected levels following accidental exposures. Test samples will be spiked with a known quantity of a traceable activity greater than or equal to the MTL. Measurement reproducibility will be tested by providing several identical samples of each level of activity.

The dosimetry service shall comply with the specifications described in Appendix F, "Independent Test Specifications for Internal Dosimetry."

4.2.5 In Vivo Accuracy and Precision Specifications

Table 6 lists the *in vivo* accuracy and precision specifications for independent tests. To assess compliance with accuracy specifications, bias and precision shall be considered separately. The mean relative bias, B , shall be calculated from measurements, A_i , of each level of activity, A , included in the test. Since bias is often greater at lower levels of activity near the limits of detection than at higher levels of activity, dosimetry service laboratories shall be tested at several levels of activity no lower than the MTL.

Table 6: Accuracy and Precision Specifications

Mean Relative Bias (B)	Precision of the Bias (P_B) (Absolute Value)
$-0.25 \leq B \leq 0.50$	≤ 0.40

4.2.6 Independent Testing for In Vivo Measurements

Internal dosimetry services shall undergo and pass independent testing prior to licensing. Upon receipt of a licence, the dosimetry service shall undergo independent testing at regular intervals at least every 12 months, or at other intervals determined in consultation with the CNSC.

Independent tests shall be carried out at least once every 12 months so that continuing competence can be demonstrated even if no changes are made to the measurement system. Such factors as variation of source distribution within the phantom, variations in ambient background, and positioning error shall be taken into account where applicable.

The dosimetry service shall have the independent tests performed by the relevant reference calibration centre (see Appendix J) unless otherwise stated in the dosimetry service licence. If the relevant reference calibration centre does not offer the test, the dosimetry service shall seek CNSC approval to use a different organization to perform the independent tests.

If the dosimetry service makes alterations to the detectors, counting geometry, or the electronics of the measurement system that may affect the calibration, a further independent test is required. Phantoms used for calibration at photon energies below 100 kiloelectron volts (keV) shall be constructed of tissue-equivalent material and shall be anthropomorphic. For photon energies above 100 keV, acceptable phantoms can be made from other materials.

The dosimetry service shall comply with the specifications described in Appendix F, "Independent Test Specifications for Internal Dosimetry."

4.2.7 Interpretation of Bioassay Data

4.2.7.1 Ascertaining the Committed Effective Dose

Internal dosimetry services shall ascertain and record the committed effective dose to workers from the types of measurements referred to in the licence, taking into consideration appropriate human physiological parameters and other relevant information on the conditions of exposure. The method used to ascertain the dose shall be submitted to the CNSC for approval.

When ascertaining the committed effective dose to workers, dosimetry services shall consider site-specific parameters, unless other values (e.g., default values) have been previously approved by the CNSC. All key parameters shall be documented.

4.2.7.2 Independent Tests

The requirements of independent testing for the interpretation of bioassay data include the following:

1. Internal dosimetry services shall undergo independent testing for the interpretation of bioassay data at a frequency determined by the CNSC;
2. Independent tests shall be carried out so that continuing competence can be demonstrated even if no changes are made to the procedures, and shall include ascertaining the committed effective doses from hypothetical exposure scenarios that are relevant to the activities carried on by CNSC licensees that use the dosimetry service; and
3. The internal dosimetry service shall have the independent test administered by the relevant reference calibration centre (see Appendix J) unless otherwise stated in the dosimetry service licence.

4.2.7.3 Documentation

The internal dosimetry service shall submit the procedures for ascertaining the committed effective dose to workers to the CNSC for approval at the licence application stage.

4.3 Dosimetry Services for Radon Progeny and Radon Gas

Exposures to radon progeny and radon gas are estimated from grab-sampling measurements combined with occupancy time records or from personal monitoring.

A dosimetry service for radon progeny and radon gas shall comply with the following requirements:

1. Determine the lowest exposure or concentration in air that the dosimetry service can measure at the 95% confidence level with the overall accuracies specified, as described in subsection 4.3.2, "Minimum Measurable Exposure or Concentration;"
2. Measure the quantity of interest within the accuracy specifications and uncertainty limits that apply to that quantity, as described in subsection 4.3.3, "Accuracy Specifications for Radon Progeny Measurements," and subsection 4.3.6, "Accuracy Specifications for Radon Gas Measurements;"
3. Demonstrate its ability to satisfy overall specifications through type testing, as described in subsection 4.3.4, "Type Testing for Radon Progeny Measuring Instruments," and subsection 4.3.7, "Type Testing for Radon Gas Monitoring;" and
4. Demonstrate that it operates in a reliable way through independent testing, as described in subsection 4.3.5, "Independent Testing for the Monitoring of Radon Progeny," and subsection 4.3.8, "Independent Testing for Radon Gas Measurements."

4.3.1 Measurement Quantities

The quantities to be measured include the following characteristics:

1. The concentration in air of potential alpha energy from short-lived radon progeny;
2. The exposure to airborne short-lived radon progeny; and
3. The concentration in air of radon gas.

There are historical and International System of Units (SI), or SI-compatible units of measurement for the concentration of short-lived radon progeny in air and exposure to radon progeny. In this section, historical units are given first, followed by SI or SI-compatible units in parentheses.

The Working Level (WL) is the historical unit for the measurement of radon progeny concentration in air. The corresponding SI unit is the joule per cubic metre (J m^{-3}), where

$$1 \text{ WL} = 20.8 \mu\text{J m}^{-3} \quad \text{and} \quad 1 \mu\text{J m}^{-3} = 4.8 \times 10^{-2} \text{ WL}$$

The Working Level Month (WLM) is the historical unit used to express exposures to radon progeny. The SI-compatible unit is the joule-hour per cubic metre (J h m^{-3}) where

$$1 \text{ WLM} = 3.54 \text{ mJ h m}^{-3} \quad \text{and} \quad 1 \text{ mJ h m}^{-3} = 0.283 \text{ WLM}$$

The concentration of radon gas in air is measured in activity per unit volume of that atmosphere (i.e., Bq m^{-3}). The intake (Bq) from this concentration is calculated by multiplying the concentration by a defined breathing rate (i.e., $1.2 \text{ m}^3 \text{ h}^{-1}$) and the occupancy time (h). Alternatively, exposure can be determined in Bq h m^{-3} and the intake would be this value multiplied by the breathing rate.

4.3.2 Minimum Measurable Exposure or Concentration

The dosimetry service shall perform the following tasks:

1. Determine and record the lowest exposure or concentration in air that it can measure at the 95% confidence level with the overall accuracies of +50% / -33%; and
2. Express the minimum measurable exposure in the same units as the measured quantity.

Section H.1 of Appendix H, "Example Calculations for Minimum Measurable Concentration and Counting Certainty," provides examples of the statistical method used to determine the minimum measurable activity concentration.

4.3.3 Accuracy Specifications for Radon Progeny Measurements

Two categories of instruments monitor individual exposures to radon progeny:

1. Personal monitors, which give a direct estimation of individual exposures; and
2. Grab-sampling instruments, which provide a measure of radon progeny concentration at a given place and time, and whose readings are used in combination with occupancy time records to calculate individual exposures.

Both categories of instruments shall meet the corresponding requirements of this section.

4.3.3.1 Personal Monitors

The test for personal monitors shall be conducted in an environment with stable and fixed concentration. The 95% confidence limit calculated from the test results shall fall within the confidence interval limits indicated in Table 7.

Table 7: Accuracy Specifications for Measurement of Exposure to Radon Progeny for One Dosimetry Period

Range of Measurement	Overall Accuracy (95% Confidence)
≥ 0.05 WLM ($177 \mu\text{J h m}^{-3}$) to < 0.10 WLM ($354 \mu\text{J h m}^{-3}$)	+100% / -50%
≥ 0.10 WLM ($354 \mu\text{J h m}^{-3}$)	+50% / -33%

4.3.3.2 Grab Sampling

The 95% confidence limit calculated from the test results shall fall within the confidence interval limits indicated in Table 8.

Table 8: Accuracy Specifications for Measurement of Concentration of Potential Alpha Energy in Air

Range of Measurement	Overall Accuracy (95% Confidence)
≥ 0.05 WL ($1.03 \mu\text{J m}^{-3}$) to < 0.10 WL ($2.08 \mu\text{J m}^{-3}$)	+100% / -50%
≥ 0.10 WL ($2.08 \mu\text{J m}^{-3}$)	+50% / -33%

For grab sampling, the testing program highlighted in Section G.3 of Appendix G, “Independent Test Specifications for Radon Progeny and Radon Gas,” may be used to assess compliance with the accuracy requirements of Table 8.

4.3.4 Type Testing for Radon Progeny Measuring Instruments

The dosimetry service shall demonstrate its ability to satisfy overall specification requirements through type testing at the licence application stage. The type testing requirements for radon progeny measuring instruments are as follows:

1. Type testing for personal monitors shall identify all possible sources of error and quantify their contribution to the overall error and uncertainty in individual exposures;
2. In addition to establishing a personal monitor’s overall accuracy, the type testing shall indicate the limitations of the device, such as conditions that may result in the onset of filter saturation problems, the time during which the device can be reliably used without the need to recharge the battery and so on;

3. Type testing for grab-sampling instruments shall identify and quantify all possible sources that contribute to the overall error and uncertainty in measured instantaneous radon progeny concentrations, except for errors and uncertainties in actual personal exposures derived from grab-sampling measurements, which are excluded;
4. When the dosimetry service makes changes (e.g., to the instrumentation or methods used) that may affect the performance of personal monitors and grab-sampling instruments, the dosimetry service shall repeat the type tests for measurement accuracy and precision to the extent necessary to demonstrate that the specifications of Tables 7 and 8 continue to be met; and
5. The dosimetry service shall report the results of these type tests, which have been repeated following changes made to the system, to the CNSC along with the records described in subsection 4.3.4.2, "Documentation," and shall obtain CNSC approval prior to the implementation of these changes.

4.3.4.1 Influence Quantities That May Affect Accuracy or Uncertainty

The dosimetry service shall consider the following influence quantities and evaluate those that are likely to significantly affect accuracy or uncertainty. Other influence quantities that may contribute to overall uncertainty shall also be considered (i.e., all influence quantities contributing to the uncertainty of the measurement shall be taken into account.)

For sampling parameters of personal monitors, the following quantities shall be taken into account:

1. Duration of operation at design performance at full charge of the battery;
2. Sampling flow rate;
3. Flow rate variability; and
4. Influence of particle size distribution, particularly unattached fraction of radon progeny on sampling efficiency.

For detection and counting parameters of personal monitors, the following quantities shall be taken into account:

1. Filter-detector geometry;
2. Energy-dependent detection efficiency;
3. Sensitivity to radiation emitted from sources other than radon progeny;
4. Sensitivity to deviations from detector processing specifications; and
5. Sensitivity to time variability of radon progeny concentrations.

For grab-sampling instruments, the following quantities shall be taken into account:

1. Sampling flow rate;
2. Flow rate variability;
3. Sensitivity to particle size distribution, particularly unattached fraction of radon progeny in the test atmosphere;
4. Calibration and stability of field alpha counters; and
5. The method used to calculate radon progeny concentrations.

4.3.4.2 Documentation

The dosimetry service shall maintain:

1. Type test results in a format that clearly shows all the influence quantities and system characteristics that were considered, and the range of possible values expected of them by the dosimetry service, based on the intended use of that particular dosimetry system;
2. Sample calculations that show how the mean response and the combined standard uncertainty were calculated; and
3. The justification for any assumptions made and techniques used.

4.3.5 Independent Testing for the Monitoring of Radon Progeny

The dosimetry service shall comply with the following requirements:

1. Undergo independent testing to demonstrate that it meets the accuracy specifications, as described in subsection 4.3.3, “Accuracy Specifications for Radon Progeny Measurements;”
2. Perform the independent tests through the relevant reference calibration centre for the monitoring of radon progeny in Canada (see Appendix J);
3. Send a representative sample of its personal monitors to the reference calibration centre at regular intervals at least every 12 months, or at other intervals determined in consultation with the CNSC, and also following any changes in design that could affect the performance of monitors;
4. Comply with the specifications for grab sampling described in Appendix G, “Independent Test Specifications for Radon Progeny and Radon Gas”;
5. Notify the CNSC immediately, in writing (electronic format acceptable), when it fails an independent test;
6. Submit to the CNSC within 30 days a detailed written report outlining the cause and consequence of failure and a description of corrective action taken; and
7. Immediately repeat the failed test and submit the results to the CNSC.

If a repetition of the test results in a second consecutive failure, the CNSC may take further licensing action.

4.3.6 Accuracy Specifications for Radon Gas Measurements

4.3.6.1 Personal Monitors

The test for personal monitors shall be conducted in an environment with stable and fixed concentration. The 95% confidence limit calculated from the test results shall fall within the confidence interval limits indicated in Table 9.

Table 9: Accuracy Specifications for Measurement of Personal Radon Gas Exposure for a Dosimetry Period

Range of Measurement	Overall Accuracy (95% Confidence)
$\geq 2.0 \text{ MBq h m}^{-3}$ to $< 4.0 \text{ MBq h m}^{-3}$	+100% / -50%
$\geq 4.0 \text{ MBq h m}^{-3}$	+50% / -33%

4.3.6.2 Grab Sampling

Table 10 shows the specifications with which monitoring systems shall comply under expected conditions of use.

Table 10: Accuracy Specifications for Measurement of Concentration of Radon Gas in Air

Range of Measurement	Overall Accuracy (95% Confidence)
$\geq 10 \text{ kBq m}^{-3}$ to $< 20 \text{ kBq m}^{-3}$	+100% / -50%
$\geq 20 \text{ kBq m}^{-3}$	+50% / -33%

4.3.7 Type Testing for Radon Gas Monitoring

The dosimetry service shall demonstrate, through type testing at the licence application stage, its ability to satisfy the following overall specification requirements:

1. Type testing for instruments used to determine exposures to radon gas shall identify all possible sources of error and shall quantify their contribution to the overall error and uncertainty in individual exposures; and
2. If the dosimetry service changes the monitor design or the measurement method (i.e., different detector or filters, different casing, different sampling

protocol, etc.), it shall repeat the type tests to the extent necessary to demonstrate the influence on overall accuracy and uncertainty.

4.3.7.1 Influence Quantities That May Affect Accuracy or Uncertainty

The dosimetry service shall consider the following influence quantities and evaluate those that are likely to significantly affect accuracy or uncertainty. Other influence quantities that may contribute to the overall uncertainty, in addition to those listed here, shall also be considered;

For personal radon gas monitors, the following quantities shall be taken into account:

1. Detector efficiency;
2. Sensitivity to radiation emitted from sources other than radon progeny;
3. Sensitivity to deviations from detector processing specifications; and
4. Durability for the work environment.

For grab-sampling instruments, the following quantities shall be taken into account:

1. Sampling flow rate;
2. Flow rate variability;
3. Detector efficiency;
4. Sensitivity to radiation other than from radon;
5. Sensitivity to other physical and chemical agents in the environment;
6. Saturation; and
7. Durability for the work environment.

4.3.7.2 Documentation

The dosimetry service shall maintain:

1. Type test results in a format that clearly shows all the influence quantities and system characteristics that were considered, and the range of possible values expected of them by the dosimetry service, based on the intended use of that particular dosimetry system;
2. Sample calculations that show how the mean response and the combined standard uncertainty were calculated; and
3. The justification for any assumptions made and techniques used.

4.3.8 Independent Testing for Radon Gas Measurements

The dosimetry service shall comply with the following requirements:

1. Undergo independent testing to demonstrate that it meets the accuracy specifications described in subsection 4.3.6, “Accuracy Specifications for Radon Gas Measurements”;
2. Perform the independent tests through the relevant reference calibration centre for the monitoring of radon gas in Canada (see Appendix J);
3. Send a representative sample of its personal monitors to the reference calibration centre at regular intervals at least every 12 months, or at other intervals determined in consultation with the CNSC, and also following any changes in design that could affect the performance of monitors;
4. Comply with the specifications for grab sampling described in Appendix G, “Independent Test Specifications for Radon Progeny and Radon Gas”;
5. Notify the CNSC immediately, in writing (electronic format acceptable), when it fails an independent test;
6. Submit to the CNSC within 30 days a detailed written report outlining the cause and consequence of failure and a description of corrective action taken; and
7. Immediately repeat the failed test and submit the results to the CNSC.

If a repetition of the test results in a second consecutive failure, the CNSC may take further licensing action.

4.4 Dosimetry Services for Intakes from Airborne Radioactive Material

Airborne radioactive material refers to any suspension in air of radioactive material whose characteristics or concentrations are such that there is no practical means to determine dose through bioassay. Such materials may include, but are not limited to, U-238 and its decay products (other than radon and radon progeny), Th-232, and some plutonium isotopes. Airborne radioactive materials exist in various physical and chemical forms including dust, gas, fumes, or vapours. This section applies to measurements of radioactive material in air that are used for dosimetry purposes.

Monitoring for airborne radioactive material helps to estimate individual doses or exposures to those radiological risks for workers in uranium processing facilities, research facilities, and at other facilities where radioactive-material-laden atmospheres are found. Estimates are made from personal monitoring or from grab-sampling measurements combined with occupancy time records.

4.4.1 Measurement Quantities

The concentrations of airborne radioactive material in air are measured in activity or mass per unit volume of that atmosphere (e.g., Bq m⁻³). The intake (e.g., Bq) from this concentration is calculated by multiplying the concentration by a defined breathing rate (e.g., 1.2 m³ h⁻¹) and the occupancy time (h). Alternatively, exposure can be determined in Bq h m⁻³ and the intake would be this value multiplied by the breathing rate.

The concentration of airborne radioactive material may also be expressed in units of derived air concentration (DAC). The DAC is the concentration of radioactive material in air breathed by a worker for 2000 hours that results in a committed effective dose of 20 mSv. The worker is assumed to breathe the air at a rate of 1.2 m³ h⁻¹. Similarly, exposure may be expressed in terms of DAC-hours.

4.4.2 Minimum Measurable Exposure or Concentration

Standardized type testing methods, criteria, and facilities, as well as independent testing facilities are currently unavailable for airborne radioactive material measurements. Therefore, this standard does not specify requirements for type testing and independent testing for airborne radioactive material measurements. However, a dosimetry service for airborne radioactive material measurements shall perform the following tasks:

1. Measure the quantity of interest within the accuracy specifications that apply to that quantity, as described in subsection 4.4.3, “Accuracy for Airborne Radioactive Material Measurements”; and
2. Determine and record the lowest exposure or concentration in air that it can measure at the 95% confidence level with the overall accuracies of +50% / -33%.

Section H.1 of Appendix H, “Example Calculations for Minimum Measurable Concentration and Counting Uncertainty,” provides examples of the statistical method used to determine the minimum measurable activity concentration. The minimum measurable exposure shall be expressed in the same units as the measured quantity.

4.4.3 Accuracy for Airborne Radioactive Material Measurements

The CNSC will assess the accuracy of airborne radioactive material measurements from the quality and reliability of the sampling and counting systems used. Sampling procedures that are consistent with industrial hygiene standards⁴ will also be considered to be adequate for sampling airborne radioactive material.

The dosimetry service shall demonstrate that it follows standard good practices expected in routine industrial hygiene monitoring in the measurement of airborne radioactive material concentration in air. In particular, the flow rate of sampling pumps, where used, shall not deviate by more than five percent from the value used to calculate concentration.

Since all inhaled radionuclides, whatever the size of the carrier particle, ultimately contribute to the committed dose, air sampler particle collection efficiency shall be insensitive to size, to the greatest extent possible. This excludes the use of cyclones to collect and measure airborne radioactive material.

The dosimetry service shall determine the overall uncertainty in airborne radioactive material measurements from the combination of all the uncertainties in all the parameters used to derive the airborne radioactive material concentration from the activity measured on the monitor's filter.

Section H.2 of Appendix H, "Example Calculations for Minimum Measurable Concentration and Counting Uncertainty," provides examples of the statistical method used to estimate uncertainties in counting.

4.4.4 Documentation

The dosimetry service shall maintain

1. test results in a format that clearly displays all the sample calculations of the influence quantities, showing how the mean response and the combined standard uncertainty were calculated; and
2. the justification for any assumptions made and techniques used.

⁴ Includes but is not limited to the following documents: Section II: Chapter 1, "Personal Sampling for Air Contaminants," *U.S. Department of Labor Occupational Safety & Health Administration (OSHA) Technical Manual*; *National Institute for Occupational Safety and Health (NIOSH) Manual of Analytical Methods*, 4th ed., Publication 94-113; International Organization for Standardization (ISO) 2889:1975, *General Principles for Sampling Airborne Radioactive Materials*, or more recent versions of these documents.

5.0 QUALITY ASSURANCE REQUIREMENTS

5.1 General

Quality in a dosimetry service is defined by accuracy and repeatability of dose measurements. The objective of a quality assurance program in a dosimetry service is to implement a management system that ensures dosimetry results are accurate, repeatable, verifiable, and properly recorded. The following requirements represent a minimum basis for licensees developing an effective quality assurance program in a dosimetry service.

5.2 Quality Assurance Program Requirements

5.2.1 Management Policy

1. Senior management shall document its quality policy. The quality policy shall be appropriate for a dosimetry service (see subsection 5.1) and shall include a commitment to operate according to its quality assurance program, to regularly review its adequacy, and to continually improve.
2. The quality policy and objectives shall be communicated to staff.

5.2.2 Quality Assurance Program Description

The description of the quality assurance program shall consist of interrelated documents that collectively provide clear, comprehensive and accurate descriptions of the following information:

1. Statements of quality policy and quality objectives;
2. Documented processes, procedures and instructions;
3. Documents needed by the dosimetry service to ensure effective planning, operation and control of its processes; and
4. Records required to demonstrate compliance with the quality assurance program.

Note: The documentation can be in any form or medium.

5.2.3 Review by Management

1. Managers shall perform self-assessments of their areas of responsibility on an ongoing basis. These self-assessments shall determine whether the dosimetry service meets standards and objectives, and the effectiveness of processes and procedures. Performance metrics shall be developed and used in self-assessments.

2. At least annually, senior management shall conduct a formal review to ensure that processes are optimized, under control, and producing accurate results that conform to specifications. The review shall include assessing opportunities for improvement and the need for changes to policies, processes, and requirements in the quality assurance program, including the quality policy and objectives. The annual review shall encompass at a minimum the following sources of information:
 - a) Comparisons of quality objectives and standards against actual achievements;
 - b) Analyses of inspection and test results;
 - c) Analyses of non-conformances (e.g., frequency, significance, consequence, cause and accountability), of corresponding corrective and preventive measures, and of deficiency trends;
 - d) Analyses of results from internal audits;
 - e) Complaints and implementation problems or errors;
 - f) Results of management self-assessments; and
 - g) Analysis of the effectiveness of corrective actions.
3. Records of the reviews shall also be maintained.

5.2.4 Organization and Authority

1. Management shall define the responsibilities and authorities of managers and staff. The lines of internal and external communications shall be defined.
2. Management shall appoint an individual who will be responsible for independently assessing the effectiveness of the quality assurance program, and who reports to a level of management such that sufficient freedom from the pressures of cost and schedule considerations is preserved.

5.2.5 Personnel Qualifications

1. All personnel performing dosimetry service activities, including the tasks described in subsection 5.2, "Quality Assurance Program Requirements," shall have the training, qualifications and competence necessary to perform their assigned tasks effectively.
2. Standards of training, qualification and competence shall be set by the dosimetry service.

5.2.6 Procurement

1. The purchase of equipment and material needed for accurate dose or exposure measurement shall be controlled by procedures established by the dosimetry service.
2. Purchasing procedures shall ensure that purchased materials conform to specified purchase requirements. Specified purchase requirements shall include a clear description of the item on a requirement or technical data sheet that includes measuring accuracy and repeatability, traceability of calibration to national standards, inspection and testing specifications, acceptance criteria, the quality assurance program specifications that the supplier shall meet, and recording specifications.
3. Suppliers shall be evaluated and selected based on their ability to meet specifications.
4. Purchased materials and equipment shall be verified as having met the specified purchase requirements.

5.2.7 Work Control

1. All work or activities that can influence the assignment of the correct dose to the right individual and the maintenance of an effective dose record system shall be controlled by established procedures that provide details of the following items:
 - a) work methods and sequence,
 - b) equipment to be used and special working environments,
 - c) acceptance criteria,
 - d) inspection points, and
 - e) logging specifications.
2. Work control procedures shall control the preservation of identification through marking and number control of dosimeters, samples, standards, measurements, dose records and other data on which dose is based, and maintain their traceability to the individuals concerned.
3. Work control procedures shall prescribe specifications and special precautions to control the handling, storage and shipping of dosimeters and samples to protect against loss of sensitivity, loss of information, loss of accuracy, and against damage to, or complete loss of the dosimeters or samples. Distribution, use and handling of control dosimeters and handling of samples shall also be described.
4. Conclusions regarding assigned dose shall be adequately documented to enable traceability to the input data (e.g., identification information, measurements and models used) and to show conformance to standards.

5. The method of transferring dose data meet the specifications described in Appendix I, "Specifications for Dose Records".

5.2.8 Change Control

1. Changes to dosimetry processes and dose records shall be controlled by the dosimetry service.
2. Change control shall provide equivalent reviews and approvals to those applied to the original dosimetry processes, dose records, or both.
3. Proposed changes shall be reviewed and approved by qualified persons before implementation.
4. Records of proposed and implemented changes shall be kept.
5. Procedures shall prescribe standards to ensure that changes to dose records are properly documented.
6. Where changes involve a revision to approved procedures and instructions, the specifications of subsection 5.2.9, "Document Control," shall be met.

Note: To request the CNSC to change dose records, users of dosimetry services follow the requirements of CNSC regulatory standard S-260.^[3]

5.2.9 Document Control

1. Procedures shall be established for the preparation, review, approval, issue, distribution, and revision of documents and procedures. This includes those documents and procedures that contain technical specifications or prescribe activities for the achievement and verification of technical specifications. Examples are technical standards, dosimetry manuals, specifications and procedures for dose records, operating procedures, software programs, calibration techniques and analytical methods. It also includes the quality assurance program procedures.
2. Documents shall be legible, available and readily identifiable.
3. Documents shall be removed from use when obsolete or be clearly identified as obsolete if retained for other uses.

5.2.10 Calibration and Maintenance

1. Recording, measuring, testing, analyzing or counting devices, instruments or standards whose performance is critical to accurate dose measurements shall be identified, controlled and maintained.
2. Such devices, instruments, and standards shall be of a type, sensitivity and accuracy that meet the appropriate minimum specifications set out in Section 4.0, "Technical Requirements."

3. Periodic calibration and maintenance requirements shall be determined based on the necessary accuracy, purpose, degree of usage, stability characteristics and other factors affecting measurement control.
4. Maintenance and calibration procedures shall be documented.
5. Calibration status shall be recorded and maintained, and calibrated equipment shall be clearly and indelibly identified (e.g., through the use of labels). When calibration is performed before use or with a high frequency (e.g., daily), logging of calibrations may be sufficient.
6. Inaccurate, uncalibrated or malfunctioning equipment shall be removed from use.
7. Measurement equipment that has been repaired or modified shall be calibrated and have its performance checked before being placed in use.
8. Calibrations shall be traceable to national reference standards⁵. Equipment used as calibration transfer standards shall have calibration traceable to national standards. Where calibrated reference standards are used as transfer standards to set the reference level by which data is directly measured, methods shall be established to preserve the integrity of the process and the results.
9. When equipment is found to be inaccurate (see subsection 5.2.12 “Non-conformance”), reviews shall be conducted to determine the validity of data or results and corrective action is to be taken (see subsection 5.2.13 “Corrective Action”).

5.2.11 Verification

1. Verifications of the intermediate and final stages of work shall be identified, planned, resourced, controlled, documented and conducted in accordance with defined acceptance and performance criteria.
2. Verification shall be carried out by qualified persons other than those who have participated in the work being verified.
3. The method, timing and results of the verifications shall be recorded, and the person performing the verification shall be identified in the record.
4. Inspections, checks and reviews shall be identified and planned to verify that work is performed (see subsection 5.2.7, items 1 to 4) in an acceptable manner.
5. The dosimetry service operator shall participate in independent tests as described in Section 4.0, “Technical Requirements,” and discrepancies shall be processed according to the specifications provided in subsection 5.2.12, “Non-conformance,” and subsection 5.2.13, “Corrective Action.”

⁵ National reference standards are traceable to any Canadian or international government standard setting authority (National Research Council of Canada (NRCC), National Institute of Standards and Technology (NIST), etc.).

5.2.12 Non-conformance

1. Non-conforming items, services and activities shall be identified, reported and documented.
2. Non-conformances shall be reviewed and remedial actions identified, executed, verified and recorded, and the impact of the non-conformance on previous work shall be assessed for potential effects on dose assignments.
3. Non-conforming items or services shall be controlled to prevent unauthorized use.
4. Backup arrangements in case of equipment or other failure or error shall be described.

Note: Non-conformances may occur as a result of, for example, inadequate procedures, equipment failure, equipment inaccuracy, calculation error, wrong identification, wrong input data, the use of inappropriate dosimeter or sample, or improper handling or processing of information.

5.2.13 Corrective Action

1. Significant or recurring non-conformances shall be analyzed to determine their cause, and corrective action taken to prevent repetition.
2. The cause and the subsequent corrective action shall be reported to the appropriate level of management, and follow-up reviews conducted to verify the effectiveness of the corrective action.

Note: Significant non-conformances are those that lead to, or could lead to, an undetected overexposure, an incorrect dose being assigned to an individual, or a dose being assigned to the wrong person.

5.2.14 Records

1. The dosimetry service shall control the identification, storage, protection, retrieval, and disposition of records, in a format that will be defined by the licensee.
2. Records shall be prepared and retained as evidence of the satisfactory accomplishment of specified activities and the acceptability of results.
3. Sufficient records shall be retained to support final conclusions and to show traceability.
4. Sufficient records and documentation shall be prepared during the work process to enable reasonable recreation and checking of results from the referenced input data.
5. A list of records that relate to the licensed operation shall be maintained. Retention and disposal of records shall be in accordance with section 28 of the *General Nuclear Safety and Control Regulations*.

6. Records shall remain legible, readily identifiable and retrievable as and when needed.
7. Records shall be maintained in a secure manner to protect against the release of personal information, in accordance with relevant applicable legislation.

5.2.15 Independent Audits

1. Management shall have an internal audit program. The internal audit shall determine whether procedures and processes are being effectively implemented and are resulting in the satisfactory performance of the dosimetry service.
2. The entire quality program shall be audited on an annual basis.
3. Internal audits shall be planned and performed by appropriately trained personnel. Auditors shall not have direct responsibility for the activity being assessed.
4. Audit results shall be documented. These results shall be reviewed by the manager responsible for the activity that has been assessed. This person shall take action to correct any deficiencies and their causes. Follow-up actions shall include verification of actions taken (see subsection 5.2.13 “Corrective Action”).

Note: See the Canadian Standards Association publication CAN/CSA-ISO 19011:03^[4] for guidance.

GLOSSARY

For the purpose of this Regulatory Standard, the following terms and definitions apply. Statistical terms used in this document not included in the list below are defined in the Health Physics Society Standard N13.30, *Performance Criteria for Radio Bioassay*.^[5]

Air Kerma

The quotient of dE_{tr} by dm , where dE_{tr} is the sum of the initial kinetic energies of all the charged particles, e.g., electrons, liberated by uncharged particles, e.g., photons, in a mass dm of air. Unit: $J\ kg^{-1}$ also called gray (Gy).

Bioassay

A measurement of the amount or concentration of radioactive material in the body, or in biological material excreted from the body and analyzed for purposes of estimating the quantity of radioactive material in the body. The term bioassay includes both *in vitro* and *in vivo* measurements.

BOMAB

Bottle manakin absorption calibration phantoms

CNSC

Canadian Nuclear Safety Commission

Coefficient of Variation, C

A measure of the reproducibility of the measurements, as expressed in the following equation:

$$C = \frac{s}{m}$$

where

s = standard deviation of the set of measurements; and

m = mean of the set of measurements.

Conventionally True Value

The value attributed to a particular quantity and accepted, sometimes by convention, as having an uncertainty appropriate for a given purpose. It is sometimes called “best estimate”, “conventional value” and “reference value”. For example, the conventionally true value of $H_p(d)$ is established by measuring the free-in-air air kerma (or exposure) in a well-defined field with a calibrated instrument and then applying a conversion coefficient to the result.

Derived Air Concentration (DAC)

The concentration of radioactive material in the air that a worker has breathed for 2000 hours and that results in a committed effective dose of 20 mSv.

Dosimetry Service

A prescribed facility for the measurement and monitoring of doses of radiation.

Dosimetry Types

External dosimetry: Usually employed for photon (i.e., X and gamma) radiation, but may also be used for beta and neutron radiation sources outside of the body.

Internal dosimetry: Involves bioassay in the form of either *in vitro* monitoring (i.e., the analysis of urine, fecal, breath or other samples of biological material) or *in vivo* monitoring (i.e., the direct measurement by external detectors of body or organ burdens of radioactivity), or a combination of the two.

The measurement of radioactive atmospheres: Usually accomplished by means of air monitoring techniques. Typical measurements are for radon progeny and radioactive dusts in uranium mines.

Extremities

Parts of the human body that are furthest from the head and torso, and that share similar sensitivities to ionizing radiation. The extremities are defined as those parts of the anatomy from and including the elbows to the tips of the fingers (i.e., upper extremities) and from and including the knees to the tips of the toes (i.e., lower extremities).

ICRP

International Commission on Radiological Protection

ICRU

International Commission on Radiation Units and Measurements

Independent Testing

Tests conducted by the applicable reference calibration centre to verify licensed dosimetry services. Independent testing helps the dosimetry service demonstrate that its results are reliable and meet CNSC regulatory requirements, including the requirements of this standard.

Influence Quantity

A quantity that may affect the accuracy or uncertainty of a measurement.

In Vitro Measurement

A measurement to determine the presence of, or to estimate the amount of, radioactive material in excreta or in other biological materials removed from the body. The term *in vitro* measurement is synonymous with indirect bioassay.

In Vivo Measurement

A measurement of radioactive material in the human body using instrumentation that detects radiation emitted from radioactive material in the body. The term *in vivo* measurement is synonymous with direct bioassay.

LLRD

Long-lived radioactive dust

Mean Relative Bias, B

The relative accuracy of a set of measurements (i.e., how closely the measurements correspond to the actual radionuclide concentration or activity in analyzed samples), as expressed in the following equation:

$$B = \frac{1}{n} \sum_{i=1}^n B_i$$

where

n = number of measurements in the set;

B_i = relative bias of a single measurement = $\frac{A_i - A}{A}$; and

where

A_i = value of a single measurement; and

A = conventionally true value.

Minimum Measurable Concentration (MMC)

The smallest amount (activity or mass) of an analyte in a sample that can be detected. Implicit in this definition is the probability, “b”, of failing to detect a quantity of analyte that is present (Type II error) and the probability, “a”, of erroneously deciding that a positive (non-zero) quantity of analyte is present (Type I error).

Minimum Testing Level (MTL)

The smallest amount of radioactive material that the dosimetry service shall be able to measure as part of the independent testing program. Samples or phantoms provided to dosimetry service applicants or licensees for independent tests shall contain at least the MTL in order to be considered part of the tests required in this regulatory standard.

NDR

National Dose Registry

Performance Testing

A testing exercise performed to verify that a dosimetry system is operating in a predictable and consistent way.

PMMA

Polymethylmethacrylate

Precision of the Bias, P_B

A measure of the reproducibility of the results in a series of *in vivo* measurements made on all phantoms, as expressed in the following equation:

$$P_B = \sqrt{\frac{\sum_{i=1}^n (B_i - B)^2}{n-1}}$$

where

B_i = relative bias of a single measurement;

B = mean relative bias; and

n = number of measurements made on all phantoms.

Radon Progeny

Short-lived radon progeny include Polonium (Po)-218, Lead (Pb)-214, Bismuth (Bi)-214, and Po-214 radioisotopes.

Relative Precision, S_B

A measure of the reproducibility of an analysis, as expressed in the following equation:

$$S_B = \frac{s}{A}$$

where

s = standard deviation of a series of measurements of a variable with a known, true value A .

Response, R

The result of a dose measurement under defined conditions divided by the conventionally true dose that would be received under those conditions.

SI

International System of Units (Système international d'unités)

TLD

Thermoluminescence dosimeter

Type Testing

An extensive testing exercise that is performed to identify all potential sources of error and uncertainty in the measurement, and to quantify those errors and uncertainties that may contribute significantly to the overall error or combined standard uncertainty.

WL

Working Level

WLM

Working Level Month

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APPENDIX A

ACCURACY AND UNCERTAINTY IN EXTERNAL DOSE MEASUREMENT

A.1 Introduction

This appendix provides information and instructions on how to demonstrate that the accuracy and precision requirements of this regulatory standard can be met. The sample calculations in Section A.4, “Example Calculations,” illustrate how various quantities are evaluated.

A.2 Conventionally True Value

In principle, the objective of personal dosimetry is to measure the “personal dose equivalent,” $H_p(d)$, as defined by International Commission on Radiation Units and Measurements (ICRU) Report 47.^[1] The values of “d” are 0.07 mm for shallow (or skin) dose and 10 mm for deep (or whole-body) dose. In practice, the “true” value of a quantity is impossible to determine, as explained in the International Organization for Standardization (ISO) *Guide to the Expression of Uncertainty in Measurement*.^[6] Instead, compare the result of a measurement with the “conventionally true value” of that quantity to assess errors in the measured results.

Even if a perfect measurement of $H_p(d)$ were possible, its definition would lead to different, expected true values for persons of different sizes and shapes who are exposed to the same photon radiation field. It is, therefore, an unsuitable quantity to use for specification of the performance and properties of a dosimeter. A conventionally true value of $H_p(d)$ replaces the true measurement. In the case of photon radiation, for example, the conventionally true value is established by measuring the free-in-air collision air kerma (or exposure) in a well-defined field with a calibrated instrument and by applying a conversion coefficient to the result. A computer model calculates the conversion coefficient to simulate irradiation of a standard phantom, which approximates the torso of a human body. The conventionally true value obtained in this way is assumed to have a negligible uncertainty compared with the uncertainty in routine dose measurements. It therefore serves as the reference value for estimating errors in the latter measurements.

A.3 Accuracy and Precision

The information contained in this section follows the method developed by C. R. Hirning and P. S. Yuen.^[7] The specifications at the end of this section are based on the recommendations of the International Commission on Radiological Protection (ICRP) Publication 60^[2] and Publication 75,^[8] and on the CNSC requirement that external dosimetry services achieve levels of performance consistent with the use of up-to-date equipment and operating methods.

In analyzing dosimeter response uncertainty, one should first decide on the number, N , of influence quantities to be considered that would affect the dosimeter response significantly, such as energy, angle of incidence, temperature, humidity and so on. Each influence quantity should be treated as a statistical variable, as denoted by the following symbol:

$$x_i$$

where

$$i = 1, 2, \dots, N$$

For example, x_2 denotes all the values that influence quantity number 2 can take on between a lower and an upper limit.

After deciding on the number of influence quantities to consider, one should group the N influence quantities into single, first-type composite, second-type composite, or third-type composite independent influence quantities. This will enable the dosimeter response to become a separable function of these independent influence quantities and to be expressed as a product of relative responses. The conditions for separability are satisfied if, for each grouped independent influence quantity, the fractional change in the overall relative response at conditions other than the reference conditions arising from a change in the grouped influence quantity is independent of other grouped influence quantities.^[7]

A.3.1 Types of Influence Quantities

A single independent influence quantity, x_q , consists of only one influence quantity such that the above condition of overall relative-response separability is satisfied. The dose linearity of a thermoluminescence dosimeter (TLD) is an example of a single independent influence quantity, in which the response of the TLD tends to increase as the absorbed dose in the dosimeter increases to a high value in the order of grays. The increase in the dosimeter response does not depend on the type of photon source (photon energy) that has delivered the absorbed dose or any other influence quantities.

A composite influence quantity consists of a subset of the N influence quantities being considered. Similar to a single independent influence quantity, the fractional change in the overall relative response depends only on this independent composite influence quantity alone.

A first-type composite influence quantity consists of influence quantities x_i and x_j and can be extended to more than two. The relative response as a function of x_i and x_j is not separable and therefore, in discrete form, consists of a matrix whose elements are linearly independent of one another. The occurrence probability, p_{ij} , however, can be separable into independent probability functions p_i and p_j . An example of a first-type composite influence quantity is given by the combination of photon energy and angle of incidence (i.e., energy-angle or $E-\theta$). Energy-angle is a first-type composite influence quantity because the dosimeter relative response depends on both the energy and angle and is not

separable. Therefore, the relative response, in discrete form, must be expressed as a two-dimensional matrix, $r_{E\theta}$, whose elements are linearly independent of one another. The occurrence probability function, however, is separable into two independent probability functions, p_E and p_θ , as energy and angle are not correlated.

A second-type composite influence quantity consists of influence quantities x_k and x_l . The dosimeter relative response function is separable and therefore, in discrete form, consists of two independent vectors (as opposed to a matrix), each of which is dependent on only one influence quantity, x_k or x_l . The occurrence probability function, p_{kl} , however, cannot be separated. An example of a second-type composite influence quantity is humidity-temperature (or $H-T$). The dosimeter relative response is separable into two independent relative response functions, r_H and r_T , because the fractional change of the relative response due to the change in either influence quantity is independent of each other. The occurrence probability function, however, is not separable because relative humidity depends on temperature and, in discrete form, is denoted by a matrix p_{HT} .

A third-type composite influence quantity consists of influence quantities x_u and x_v , in which neither the relative response, r_{uv} , nor the occurrence probability function, p_{uv} , is separable. Thus, in discrete form, each of r_{uv} and p_{uv} consists of a two-dimensional matrix whose elements are linearly independent of one another. No example is provided because it is rare to encounter such a composite influence quantity in external dosimetry.

A.3.2 Dosimeter Response

The response of a dosimeter, R , is defined as the result of a measurement under defined conditions, H_m , divided by the conventionally true dose that would be received under those conditions, H_c , as shown in the following equation:

$$R = \frac{H_m}{H_c} \tag{1}$$

The mean response, \bar{R} , of a dosimeter under the intended conditions of use may be expressed as a separable function and written as the following product:^[7]

$$\bar{R} = R_0 \overline{r_1} \overline{r_2} \dots \overline{r_q} \dots \overline{r_{ij}} \dots \overline{r_k} \overline{r_l} \dots \overline{r_{uv}} \dots \overline{r_N} \tag{2}$$

where

- R_0 = the reference response of a dosimeter; that is, the response when all influence quantities are held at reference conditions (normally those conditions under which the dosimeter is calibrated). The overall relative response of the dosimeter, r , is defined as the ratio R/R_0 , and a relative response, r_q , applicable to an independent influence quantity, q , is defined as the overall relative response of the dosimeter when all influence quantities except q are held at the reference conditions;
- N = the number of influence quantities that may affect the response (when two or more influence quantities are not independent, they may be combined into a composite influence quantity, which is independent of other influence quantities);
- \overline{r}_q = the mean relative response arising from variations in the values x_q attainable by the q^{th} single independent influence quantity;
- \overline{r}_{ij} = mean relative response arising from variations in the values x_i and x_j attainable by the i^{th} and j^{th} influence quantities that form a composite independent influence quantity of the first type introduced when the relative response for this composite independent influence quantity, r_{ij} , cannot be separated into independent relative responses r_i and r_j , while the occurrence probability function p_{ij} is separable and expressed as the product of individual probability functions p_i and p_j , which are independent of each other;
- $\overline{r}_k r_l$ = mean relative response arising from variations in the values x_k and x_l attainable by the k^{th} and l^{th} influence quantities that form a composite independent influence quantity of the second type introduced when the relative response for this composite independent influence quantity, r_{kl} , can be separated into independent relative responses r_k and r_l , while the occurrence probability function p_{ij} is not separable into independent probability functions p_i and p_j ; and
- \overline{r}_{uv} = mean relative response arising from variations in values x_u and x_v attainable by the u^{th} and v^{th} influence quantities that form a composite independent influence quantity of the third type introduced when neither the relative response r_{uv} nor occurrence probability p_{uv} for this composite independent influence quantity can be separated into individual relative responses r_u and r_v , or independent occurrence probabilities p_u and p_v .

If the effect of a change in an influence quantity on the relative response is known and the probability distribution of that influence quantity can be measured or estimated, the mean relative response due to that influence quantity can be calculated using the usual statistical techniques, as follows.

For an independent influence quantity, q , the mean relative response in Equation 2 is expressed as shown in the following equation:

$$\bar{r}_q = \sum_{s=1}^{M_q} r_{q,s} P_{q,s} \quad (3)$$

where

- M_q = the number of measured relative responses for the q^{th} influence quantity;
- $r_{q,s}$ = the s^{th} of M_q measured relative responses for the corresponding s^{th} interval in x_q ; and
- $p_{q,s}$ = the probability that x_q will take on a value in the s^{th} interval.

For a composite influence quantity of the first type, the mean relative response is expressed as shown in the following equation:

$$\bar{r}_{ij} = \sum_{s=1}^{M_i} \sum_{t=1}^{M_j} r_{ij,s,t} P_{i,s} P_{j,t} \quad (4)$$

where

- $r_{ij,s,t}$ = a response matrix that is dependent on both the i^{th} and j^{th} influence quantities and $p_{i,s}$ and $p_{j,t}$ are occurrence probability vectors that are independent of each other.

For a composite influence quantity of the second type, the mean relative response is expressed as shown in the following equation:

$$\bar{r}_k r_l = \sum_{s=1}^{M_k} \sum_{t=1}^{M_l} r_{k,s} r_{l,t} P_{kl,s,t} \quad (5)$$

where

- $p_{kl,s,t}$ = an occurrence probability matrix that is dependent on the k^{th} and l^{th} influence quantities, and $r_{k,s}$ and $r_{l,t}$ are relative response vectors that are independent of each other.

For a composite influence quantity of the third type, the mean relative response is expressed as shown in the following equation:

$$r_{uv} = \sum_{s=1}^{M_u} \sum_{t=1}^{M_v} r_{uv,s,t} p_{uv,s,t} \quad (6)$$

where

$r_{uv,s,t}$ and $p_{uv,s,t}$ = relative response and occurrence probability matrices respectively, which are both dependent on influence quantities u and v .

The probabilities are normalized so that

$$\sum_{s=1}^{M_i} p_{i,s} = 1 \quad \text{and} \quad \sum_{t=1}^{M_j} p_{j,t} = 1$$

and

$$\sum_{s=1}^{M_k} \sum_{t=1}^{M_l} p_{kl,s,t} = 1 \quad \text{and} \quad \sum_{s=1}^{M_u} \sum_{t=1}^{M_v} p_{uv,s,t} = 1$$

In the special case where all values of x_i within the range of possible values $[x_i^{\min}, x_i^{\max}]$ are equally likely, the probability is just equal to the width of the interval, $\Delta x_{i,s}$, divided by width of the range:

$$p_{i,s} = \frac{\Delta x_{i,s}}{x_i^{\max} - x_i^{\min}} \quad (7)$$

Probabilities may also be estimated in this way when information on the actual probabilities is unavailable.

The variance, u^2 , of measured responses about the mean response can also be calculated with the usual statistical techniques, and its positive square-root yields the standard uncertainty in the dosimeter response, u . The general expression for the variance in the response is as follows:

$$u^2 = R_0^2 \overline{r_1^2} \overline{r_2^2} \dots \overline{r_q^2} \dots \overline{r_{ij}^2} \dots \overline{r_k^2} \overline{r_l^2} \dots \overline{r_{uv}^2} \dots \overline{r_N^2} - (\overline{R})^2 \quad (8)$$

In this equation, the factors related to relative responses that depend on single influence quantities are given by the following equation:

$$\overline{r_q^2} = \sum_{s=1}^{M_q} r_{q,s}^2 P_{q,s} \quad (9)$$

The terms in Equation 8 involving composite influence quantities of the first type become expressed as shown in the following equation:

$$\overline{r_{ij}^2} = \sum_{s=1}^{M_i} \sum_{t=1}^{M_j} r_{ij,s,t}^2 P_{i,s} P_{j,t} \quad (10)$$

Similarly, the second type of composite term in Equation 8 is expressed as shown in the following equation:

$$\overline{r_k^2 r_l^2} = \sum_{s=1}^{M_k} \sum_{t=1}^{M_l} r_{k,s}^2 r_{l,t}^2 P_{kl,s,t} \quad (11)$$

while the third type of composite term in Equation 8 is expressed as shown in the following equation:

$$\overline{r_{uv}^2} = \sum_{s=1}^{M_u} \sum_{t=1}^{M_v} r_{uv,s,t}^2 P_{uv,s,t} \quad (12)$$

In addition to the standard uncertainty in the response, there will be a statistical relative uncertainty, u_s , arising from random errors in the measurement process. The size of this uncertainty is determined using a Type A evaluation.^[6] The combined standard uncertainty in a single dose measurement is expressed as shown in the following equation:

$$u_c = \overline{R} \sqrt{\left(\frac{u}{R}\right)^2 + u_s^2} \quad (13)$$

Using these definitions, the overall specification for accuracy and precision is given by the following expression:

$$\frac{I}{\rho} \leq \bar{R} \pm 2u_c \leq \rho \quad (14)$$

where

$$\begin{aligned} \rho &= 1.5 \text{ for } d = 10 \text{ mm and } 4 \text{ mSv} < H_{p,c}(10) < 10 \text{ Sv}; \\ &= 2 \text{ for } d = 10 \text{ mm and } H_{p,c}(10) = 0.4 \text{ mSv}; \\ &= 1.5 \text{ for } d = 0.07 \text{ mm and } 100 \text{ mSv} < H_{p,c}(0.07) < 10 \text{ Sv}; \\ &= 2 \text{ for } d = 0.07 \text{ mm and } H_{p,c}(0.07) = 10 \text{ mSv}; \\ &= 3 \text{ for } 100 \text{ mSv} < H_{e,c} < 10 \text{ Sv}; \text{ and} \\ &= 3 \text{ for } H_{e,c} = 10 \text{ mSv} \end{aligned}$$

The combined standard uncertainty u_c is multiplied by a coverage factor of 2 to give an uncertainty interval for individual measurements of R corresponding to a level of confidence of approximately 95%. Section A.4, “Example Calculations,” provides a practical example of the calculation described above.

A.4 Example Calculations

This section gives an example of the calculation of mean response and combined standard uncertainty, using hypothetical data. For simplicity, only five influence quantities are assumed to significantly affect the response of the dosimeter, and only photon fields will be addressed. The five influence quantities are photon energy, photon angle of incidence, relative humidity, temperature and dose (dose linearity in dosimeter). The five influence quantities are grouped into one single (dose), one first-type composite (energy-angle) and one second-type composite (humidity-temperature) independent grouped influence quantities. It is assumed that the dosimeter will be used in the environment of a nuclear generating station.

A.4.1 Photon Energy and Angle of Incidence

For the first step, measure the relative response for a range of energies and angles that represents those expected to be present in the station, while maintaining all other influence quantities at the reference values. The results form the array r_{ij} or $r_{E\theta}$ are shown in Table A.1.

Table A.1: Hypothetical Measured Relative Response, $r_{E\theta,s,t}$, as a Function of Photon Energy and Angle of Incidence, with Reference to the Cs-137 Gamma Ray Response at 0 Degrees

Energy (E)		Angle (θ)				
		Index, t				
		1	2	3	4	5
		Value (deg)				
Index, s	Value (keV)	0	20	40	60	80
1	33	0.85	0.84	0.82	0.80	0.75
2	48	0.97	0.97	0.96	0.94	0.89
3	65	1.08	1.08	1.07	1.05	1.00
4	83	1.16	1.16	1.15	1.13	1.09
5	100	1.14	1.14	1.13	1.12	1.08
6	118	1.10	1.10	1.10	1.09	1.05
7	164	1.08	1.08	1.08	1.07	1.03
8	208	1.05	1.05	1.05	1.04	1.00
9	250	1.02	1.02	1.02	1.01	0.98
10	662	1.00	1.00	1.00	0.99	0.96
11	1250	0.95	0.95	0.95	0.94	0.92

Next, for each measurement point, define intervals of energy and angle, and estimate the probability of exposure in each interval. Tables A.2 and A.3 show the results. Although it is possible that the energy and angle of incidence will be correlated for a particular location and orientation, the averaging effect of moving about in the field will greatly reduce any correlation, and the two influence quantities can be treated as uncorrelated.

Table A.2: Energy Intervals and Estimated Probability, $p_{E,s}$, of Receiving Dose in Each

Index, s	E (keV)	Interval (keV)	Probability $p_{E,s}$
1	33	0–40	0.01
2	48	41–55	0.01
3	65	56–74	0.03
4	83	75–91	0.05
5	100	92–109	0.05
6	118	110–141	0.05
7	164	142–186	0.05
8	208	187–229	0.05
9	250	230–450	0.25
10	662	451–950	0.30
11	1250	951–1500	0.15
Sum			1.00

Table A.3: Angle of Incidence Intervals and Estimated Probability, $p_{\theta,t}$, of Receiving Dose in Each

Index, t	θ(deg)	Interval (deg)	Probability $p_{\theta,t}$
1	0	0–10	0.20
2	20	11–30	0.30
3	40	31–50	0.30
4	60	51–70	0.10
5	80	71–90	0.10
Sum			1.00

The mean relative response for photon energy-angle is given by Equation 4,¹ and may be calculated from the relative responses in Table A.1 and the probability distributions in tables A.2 and A.3 using matrix multiplication. By substituting E for i , θ for j , 11 for M_i , and 5 for M_j , Equation 4 becomes expressed as shown in the following equation:

$$\overline{r_{E\theta}} = \sum_{s=1}^{11} \sum_{t=1}^5 r_{E\theta,s,t} p_{E,s} p_{\theta,t} \quad (4A)$$

¹ The equations referred to in this section are found in Section A.3 of this appendix.

yielding the following

$$\overline{r_{E\theta}} = 1.018$$

Similarly, after squaring the elements of the response matrix, Equation 10 becomes expressed as shown in the following equation:

$$\overline{r_{E\theta}^2} = \sum_{s=1}^{s=11} \sum_{t=1}^{t=5} r_{E\theta,s,t}^2 P_{E,s} P_{\theta,t} \quad (10A)$$

resulting in the following

$$\overline{r_{E\theta}^2} = 1.041$$

A.4.2 Relative Humidity and Temperature

Since these two influence quantities are assumed to affect the dosimeter response independently, the relative responses can be measured for a series of values for each quantity while maintaining the other at its reference value. Again, intervals are defined about each of the measured values, so that the full range of interest is covered. Tables A.4 and A.5 give the measurement points, the corresponding intervals and the relative responses.

Table A.4: Measured Relative Response, $r_{H,s}$, as a Function of Relative Humidity, H, with Reference Value of 50 Percent

Index, s	H (%)	Interval (%)	Relative Response $r_{H,s}$
1	40	0–50	1.00
2	60	51–70	0.99
3	80	71–90	0.98
4	95	91–100	0.95

Table A.5: Measured Relative Response $r_{T,t}$ as a Function of Temperature T, with Reference Value of 20°C

Index, t	T (°C)	Interval (°C)	Relative Response $r_{T,t}$
1	-10	(-15)–(-5)	1.05
2	0	(-6)–(-5)	1.03
3	10	6–15	1.01
4	20	16–25	1.00
5	30	26–35	0.99
6	40	36–45	0.95
7	50	46–55	0.90

Since temperature and relative humidity are correlated in the workplace environment, a probability matrix, p_{HT} , is estimated as shown in Table A.6.

Table A.6: Estimated Relative Probability of Occurrence, $p_{HT,s,t}$ in the Workplace of Each Combination of Temperature and Relative Humidity Interval

		Temperature							Sum
		Index, t							
		1	2	3	4	5	6	7	
Humidity		Interval (°C)							Sum
Index s	Interval (%)	(-15)–(-5)	(-6)–(-5)	6–15	16–25	26–35	36–45	46–55	
1	0–50	0.01	0.01	0.02	0.00	0.00	0.00	0.00	0.04
2	51–70	0.00	0.00	0.11	0.30	0.05	0.00	0.00	0.46
3	71–90	0.00	0.00	0.00	0.25	0.15	0.03	0.00	0.43
4	91–100	0.00	0.00	0.00	0.00	0.05	0.01	0.01	0.07
									1.00

Substituting H for k , T for l , 4 for M_k , and 7 for M_l Equation 5 becomes expressed as shown in the following equation:

$$\overline{r_H r_T} = \sum_{s=1}^{s=4} \sum_{t=1}^{t=7} r_{H,s} r_{T,t} p_{HT,s,t} \quad (5A)$$

yielding the following

$$\overline{r_H r_T} = 0.980$$

Similarly, Equation 11 becomes expressed as shown in the following equation:

$$\overline{r_H^2 r_T^2} = \sum_{s=1}^{s=4} \sum_{t=1}^{t=7} r_{H,s}^2 r_{T,t}^2 p_{HT,s,t} \quad (11A)$$

resulting in the following

$$\overline{r_H^2 r_T^2} = 0.961$$

A.4.3 Dose Linearity

In this simpler case of a single independent influence quantity, the relative responses, r_q , and corresponding probabilities of occurrence, p_q , can be represented in the form of the independent vectors shown in Table A.7.

Table A.7: Measured Relative Response, $r_{D,s}$, to Increasing Dose (Linearity) and the Estimated Probability $p_{D,s}$, of Receiving Dose in Each Interval

Index, s	Dose, D (mSv)	Range, q (mSv)	Relative Response $r_{D,s}$	Probability $p_{D,s}$
1	0.1	0–0.2	1.05	0.900
2	0.5	0.2–0.7	1.02	0.050
3	1.0	0.7–2.0	1.00	0.030
4	5.0	2.0–7.0	1.00	0.010
5	10	7–20	1.00	0.009
6	50	20–70	1.00	0.001
7	100	70–200	1.00	0.000
8	500	200–700	1.00	0.000
9	1000	700–1500	1.02	0.000
10	2000	1500–3000	1.05	0.000
11	4000	3000–5000	1.08	0.000
12	6000	5000–7000	1.11	0.000
13	8000	7000–9000	1.15	0.000
14	10000	9000–11000	1.20	0.000
Sum				1.000
Note: The reference value is 10 mSv.				

In this case, by substituting D for q and 14 for M_q , Equation 3 becomes expressed as shown in the following equation:

$$\bar{r}_D = \sum_{s=1}^{s=14} r_{D,s} p_{D,s} \quad (3A)$$

yielding the following

$$\bar{r}_D = 1.046$$

Similarly, Equation 9 becomes expressed as shown in the following equation:

$$\overline{r_D^2} = \sum_{s=1}^{s=14} r_{D,s}^2 p_{D,s} \quad (9A)$$

resulting in the following:

$$\overline{r_D^2} = 1.094$$

A.4.4 Mean Response and Combined Uncertainty

If the dosimeter has been calibrated to give the conventionally true value of the dose at the reference conditions, then $R_0 = 1$. Equation 2 can now be expressed as shown in the following equation:

$$\overline{R} = I * \overline{r_D} * \overline{r_{E\theta}} * \overline{r_H} * \overline{r_T} \quad (2A)$$

Using this value and the results of preceding sections in Equation 2A gives a mean response of the following:

$$\overline{R} = 1.044$$

The variance in the response is given by Equation 8 which can be rewritten as shown in the following equation:

$$u^2 = I^2 * \overline{r_D^2} * \overline{r_{E\theta}^2} * \overline{r_H^2} * \overline{r_T^2} - (\overline{R})^2 \quad (8A)$$

resulting in the following

$$u^2 = 0.0045$$

A series of replicated measurements at doses greater than 4 millisieverts (mSv), with all of the five influence quantities held constant at the reference conditions, shows a statistical relative uncertainty, u_s , of 10 percent. This can be taken as the Type A assessment of uncertainty due to random errors.

Combining the standard uncertainty in the response with the statistical relative uncertainty according to Equation 13 leads to the combined standard uncertainty in a single measurement:

$$u_c = 1.044 \sqrt{\frac{0.0045}{(1.044)^2} + (0.1)^2}$$

$$u_c = 0.1240$$

The upper and lower limits defined by Equation 14 are 0.80 and 1.29, which lie well within the required limits of 0.67 and 1.5, corresponding to $\rho = 1.5$.

At 0.4 mSv, where the requirement is given by $\rho = 2$, the mean relative response and the uncertainty in the response are likely to be the same as at higher doses. The uncertainty arising from random errors is the component of the overall uncertainty that is likely to increase and must be separately determined at this lower dose.

APPENDIX B

TYPE TEST SPECIFICATIONS FOR EXTERNAL DOSIMETRY

B.1 Introduction

In addition to the in-house quality assurance program described in Section 5.0, “Quality Assurance Requirements,” subsection 4.1.4, “Type Testing,” describes a requirement for type testing. Dosimeters in routine use may be exposed to conditions other than those mentioned here, which may influence the result of a dose measurement. Such conditions shall be identified and included in the type tests, in addition to those listed below.

Wherever possible, an error introduced by an influence quantity should be corrected by applying a correction factor to the calculation of H_m (the result of a measurement under defined conditions) with the objective of making the mean relative response for that influence quantity close to unity. Circumstances may exist, however, in which it is impractical or undesirable to apply a correction for a particular influence quantity. In such cases, the error introduced by the influence quantity will be included in the determination of the mean response.

B.2 Influence Quantities and System Characteristics

The dosimetry service shall consider the following influence quantities and evaluate those that are likely to significantly affect accuracy or uncertainty. In deciding on the potential significance of the influence quantities, both the design of the dosimetry system and the intended conditions of use shall be taken into account.

Influence quantities include the following:

1. Angle of incidence of radiation;
2. Distance of dosimeter from phantom;
3. Dose (i.e., linearity of dose response);
4. Dose rate, including in pulsed radiation fields;
5. Electrical and magnetic fields, both static and alternating;
6. Energy of photons and beta rays;
7. Humidity and splashing;
8. Ionizing radiations other than those intended to be measured;
9. Mechanical shock, both dropping and vibration of the dosimeter;
10. Mixed radiation fields;
11. Temperature variations, both gradual and abrupt;
12. Time between zeroing and irradiation, and between irradiation and reading;
13. Visible and ultraviolet light flux (effect on both dosimeter and reader); and

14. Voltage supply to reader, both voltage spikes and gradual variations.

In addition, the dosimetry service shall estimate the effects of the following system characteristics, as applicable:

1. Batch homogeneity;
2. Calibration uncertainty;
3. Repeatability (a measure of the stability of response of both the dosimeter and the reader);
4. Residual signal;
5. Self-irradiation; and
6. Zero-dose variations.

Where an influence quantity or system characteristic causes a large and sudden change in the measured dose, but has a low probability of occurring, it is inappropriate to include that change as a component of the combined standard uncertainty. Instead, steps shall be taken to minimize the probability that the influence quantity will cause the effect, either by changing the dosimeter design or by instituting procedural controls, and estimating the reduced probability of occurrence.

B.3 Phantoms

During irradiation, dosimeters shall be mounted on an appropriate phantom for type tests of the following influence quantities: angle of incidence of radiation, distance of dosimeter from phantom, and energy of photons and beta rays. For tests of other influence quantities requiring irradiation, any convenient irradiation geometry may be used, provided that the relative doses delivered to the dosimeters are known to the degree of accuracy appropriate to the test. The signal produced by the dosimeters in these tests can be related to the corresponding conventionally true dose using the results of the on-phantom irradiations.

For dosimeters to be worn during torso (whole-body) irradiations, the phantom to be used for photon irradiations is a parallelepiped (“slab”), constructed of polymethylmethacrylate (PMMA) walls and filled with water.^[9] The external dimensions are 30 cm x 30 cm x 15 cm, and the wall thicknesses are 2.5 mm for the front wall (one of the 30 cm x 30 cm faces) and 10 mm for the other five walls. The phantom shall be constructed in a way that ensures that the front face remains flat when the phantom is filled with water. For beta irradiations, the phantom to be used may be the same water-filled slab phantom as described above. A solid PMMA slab phantom of the same face dimensions and a thickness greater than one half of the range of the most energetic beta particles may also be used.

For extremity dosimeters, the phantoms to be used shall be radiologically suitable representations of the appropriate parts of the extremities where the dosimeters will be worn. These will usually be the fingers, wrists and ankles. The phantoms to be used shall be appropriate to both the dosimeter design and the radiological environment in which they will be used. Two possible phantoms for use are indicated below. Only the one that is most representative of the limb on which the dosimeter would be most frequently placed, shall be used in the type testing. The dosimetry service shall consult the CNSC prior to using other phantoms.

1. *Finger*: solid PMMA cylinder with a 19 mm diameter and a length of 300 mm.^{[10], [11], [12], [13], [14]} and
2. *Wrist/ankle*: water-filled PMMA cylinder with an outer diameter of 73 mm, a wall thickness of 2.5 mm and a length of 300 mm.^[14]

The references include the associated air-kerma-to-dose conversion coefficients. More recent references containing more up-to-date information may also be used as they become available. However, the dosimetry service shall consult the CNSC prior to using other references.

B.4 Angle of Incidence of Radiation

For dosimeters that are irradiated on the slab phantom described above, the test radiations shall be incident on the front face of the dosimeter at angles of 0°, 20°, 40° and 60°, relative to normal incidence. If the design of the dosimeter results in an angular response that is cylindrically symmetric about the axis perpendicular to its front face, it will be sufficient to make the measurements along only one direction in one plane (i.e., four measurements will be required). If cylindrical symmetry does not apply, the measurements may be required in both directions in two perpendicular planes (i.e., up to thirteen measurements may be required) to adequately characterize the angular response of the dosimeter. In the latter case, the average response for each angle is calculated and indicated as the response for that angle.

For extremity dosimeters, the test radiations shall be incident on the front face of the dosimeter at angles of 0°, 30° and 60° relative to normal incidence in two perpendicular planes (i.e., a minimum of five measurements will be required). If the dosimeter is not cylindrically symmetrical, nine measurements may be required. The average response for each angle is calculated and indicated as the response for that angle.

B.5 Photon Energies

For all types of dosimeters, the photon energies used for the test irradiations shall conform to ISO 4037-1.^[15] Coefficients to convert from exposure or collision air kerma to $H_{p,c}(d)$ have been calculated and published for these energy spectra (see ISO 4037-3^[9]). The calculations are based on a slab phantom made from the ICRU standard tissue that is of the same dimensions as the water-filled phantom described above. The difference in backscatter between the ICRU tissue phantom and the water-filled phantom is small enough that it can be neglected. Coefficients to convert from collision air kerma to $H_{e,c}$ on cylindrical phantoms have been calculated and published.^[14] A need may exist to add build-up material in front of the dosimeter for higher photon energies for $H_{p,c}(0.07)$ and $H_{e,c}$ to ensure charged particle equilibrium.

B.6 Beta Energies

The standard beta sources listed in Table B.1 shall be used for type testing dosimeters intended to measure $H_p(0.07)$ and H_e .

Table B.1: Standard Beta Sources

Isotope	Maximum Beta Energy (keV)
Sr-90/Y-90	2274
Kr-85 or Tl-204	763 or 687
Pm-147	225

Note that for intermediate beta energies, either Krypton (Kr)-85 or Thallium (Tl)-204 shall be used. ISO 6980^[16] (or more recent revisions of this reference) provides further information about these sources, except for Kr-85. The source manufacturer will provide information for Kr-85. These sources are commercially available with traceable calibrations for irradiation at normal incidence. For extremity dosimeters irradiated at off-normal angles of incidence, the angular dependence factors for a tissue equivalent slab phantom may be used. The conversion coefficients normalized to 0° for $H_p(0.07)$ at other angles of incidence have been published (see the European Commission report, *Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation*^[17]).

The accurate measurement of $H_p(0.07)$ and H_e for beta radiation becomes increasingly difficult as the beta energy decreases and the angle of incidence increases. The overall specification in subsection 4.1.2, “Minimum Measurable Dose Equivalent,” and Table 1, subsection 4.1.3, “Accuracy Specifications and Uncertainty Limits,” will, therefore, be applied as follows:

For Strontium (Sr)-90/Yttrium (Y)-90 beta radiation:

The responses at all angles of incidence specified in Section B.4, “Angle of Incidence of Radiation,” shall be used in the calculation of the mean response.

For Kr-85 or Tl-204 beta radiation:

The response at 0°, shall be used in the calculation of the mean response. However, the response shall be measured at the other angles specified in Section B.4, “Angle of Incidence of Radiation.”

For Promethium (Pm)-147 beta radiation:

The response shall be measured at the angles specified in Section B.4, “Angle of Incidence of Radiation.” However, the data need not be used in the calculation of the mean response.

The mean relative responses and standard uncertainties for photons and betas are determined separately for comparison with the specifications defined by Equation 14 in Section A.3, “Accuracy and Precision,” of Appendix A, “Accuracy and Uncertainty in External Dose Measurement.”

APPENDIX C

INDEPENDENT TEST SPECIFICATIONS FOR EXTERNAL PHOTON DOSIMETRY

C.1 Introduction

In addition to the in-house quality assurance program described in Section 5.0, “Quality Assurance Requirements,” subsection 4.1.6, “Independent Testing,” describes a requirement for independent testing.

Dosimetry services that are ready to undergo independent testing shall make arrangements directly with the relevant reference calibration centre (see Appendix J). Dosimetry services using dosimeters that require processing (e.g., TLDs) shall follow the protocol outlined in Section C.2, “Protocol for Dosimeters That Require Processing.” Dosimetry services using dosimeters that do not require processing (e.g., electronic dosimeters) shall follow the protocol outlined in Section C.3, “Protocol for Dosimeters That Do Not Require Processing.” Although Section C.3 describes the use of air kerma units specifically, corresponding exposure units may also be used, if preferred by the dosimetry service, in consultation with the reference calibration centre.

C.2 Protocol for Dosimeters That Require Processing

1. Where necessary, a dosimetry service shall determine a factor to convert from $H_p(10)$, as measured by the dosimeters on a phantom, to collision air kerma free-in-air (or exposure free-in-air) due to Cobalt (Co)-60 gamma radiation. This is necessary since the irradiations performed at the reference calibration centre are free-in-air.
2. Prior to licensing and subsequently at regular intervals with a frequency of at least once every 12 months, each dosimetry service shall send to the relevant calibration centre at least 50 identified dosimeters per processing unit being tested plus sufficient control dosimeters to satisfy the readout process. For each unit being tested, the calibration centre will divide the submitted dosimeters into at least 10 groups of at least five dosimeters per group and irradiate each group of dosimeters, free-in-air, in a Co-60 photon beam to a different but known collision air kerma between 1.0 milligray (mGy) and 50 mGy. The collision air kerma delivered to the dosimeters will not be revealed at this time to the dosimetry service.
3. The irradiated dosimeters and controls will be returned to the dosimetry service for processing by the established routine procedures of the service. The results in collision air kerma units, adjusted as necessary using the factor determined in the first protocol above, will be reported to the reference calibration centre by the dosimetry service.

4. The reference calibration centre will compare the reported results with its values of collision air kerma and report the results, including the values of both the service and the centre, to the CNSC, with a copy sent to the dosimetry service. In order to pass this test, the reported results shall lie within the criteria described in subsection 4.1.6, "Independent Testing."

C.3 Protocol for Dosimeters That Do Not Require Processing

1. Where necessary, a dosimetry service using dosimeters that do not require processing shall determine a factor to convert from $H_p(10)$, as measured by the dosimeters on a phantom, to collision air kerma free-in-air (or exposure free-in-air) due to Co-60 gamma radiation. This is necessary since the irradiations performed at the reference calibration centre are free-in-air.
2. Prior to licensing and subsequently at regular intervals with a frequency of at least once every 12 months, each dosimetry service shall send at least 10 identified dosimeters to the reference calibration centre. The reference calibration centre will irradiate at least 10 groups of at least five dosimeters each, free-in-air, in a Co-60 photon beam to different but known collision air kermas of between 1.0 mGy and 50 mGy. The dosimeters in each group of five will either be exposed to the same collision air kerma or to different collision air kermas but within a similar range. This will result in a total of at least 50 readings that will be recorded by the reference calibration centre. In view of the number of dosimeters involved in this case, any given dosimeter may be irradiated several times.
3. The reference calibration centre will correct the dosimeter readings using the conversion factors determined in the first protocol above and compare the results with the reference calibration centre values of collision air kerma. The reference calibration centre will report the results, including the values of both the participant and the reference calibration centre, to the CNSC at the address below, and send a copy to the dosimetry service. The dosimeters will be returned to the dosimetry service upon completion of all irradiations. In order to pass this test, reported results shall lie within the criteria described in subsection 4.1.6, "Independent Testing."

C.4 Reporting

The reference calibration centre reports the results to the CNSC at the following address:

Dosimetry Services Licensing Specialist
Canadian Nuclear Safety Commission
P.O. Box 1046, Station B
Ottawa, ON K1P 5S9
Canada

Further details on these tests may be obtained from the reference calibration centre.

APPENDIX D

INDEPENDENT TEST SPECIFICATIONS FOR EXTREMITY DOSIMETRY

D.1 Introduction

In addition to the in-house quality assurance program described in Section 5.0, “Quality Assurance Requirements,” subsection 4.1.6, “Independent Testing,” describes a requirement for independent testing.

Dosimetry services that are ready to undergo independent testing shall make arrangements directly with the relevant reference calibration centre (see Appendix J). Dosimetry services using dosimeters that require processing (e.g., TLDs) shall follow the protocol outlined in Section D.2, “Protocol for Dosimeters That Require Processing.” Dosimetry services using dosimeters that do not require processing (e.g., electronic dosimeters) shall follow the protocol outlined in Section D.3, “Protocol for Dosimeters That Do Not Require Processing.”

D.2 Protocol for Dosimeters That Require Processing

1. Prior to licensing and subsequently at regular intervals with a frequency of at least once every 12 months, each dosimetry service shall send to the reference calibration centre at least 25 identified extremity dosimeters per processing unit being tested plus sufficient control dosimeters to satisfy the readout process. For each unit being tested, the reference calibration centre will divide the submitted dosimeters into at least five groups of at least five dosimeters per group and irradiate each group of dosimeters to a known absorbed dose to soft tissue of between 10 mGy and 90 mGy at a depth of 7 mg/cm² using its Sr-90/Y-90 source. The doses delivered to the dosimeters will not be revealed at this time to the dosimetry service.
2. The irradiated dosimeters and controls are returned to the dosimetry service for processing by the established routine procedures of the service. The dosimetry service reports the results in absorbed dose units to the reference calibration centre.
3. The reference calibration centre will compare the reported doses with those that were given to the dosimeters and report the results, including the values of both the service and the centre, to the CNSC (see the address in Section D.4, “Reporting,” below), with a copy sent to the dosimetry service. In order to pass this test, the reported results shall lie within the criteria described in subsection 4.1.6, “Independent Testing.”

D.3 Protocol for Dosimeters That Do Not Require Processing

1. Prior to licensing and subsequently at regular intervals with a frequency of at least once every 12 months, each dosimetry service shall send at least 10 identified dosimeters to the reference calibration centre. The reference calibration centre will irradiate them to different but known absorbed doses to soft tissue of between 10 mGy and 90.0 mGy at a depth of 7 mg/cm² using its Sr-90/Y-90 source.
2. The reference calibration centre will compare the results with the doses to which the dosimeters were irradiated and report the results, including the values of both the participant and the centre, to the CNSC at the address below, with a copy sent to the dosimetry service. The dosimeters will be returned to the dosimetry service upon completion of all irradiations. In order to pass this test, reported results within the accuracy described in subsection 4.1.6, "Independent Testing," are required.

D.4 Reporting

The reference calibration centre reports the test results to the CNSC at the following address:

Dosimetry Services Licensing Specialist
Canadian Nuclear Safety Commission
P.O. Box 1046, Station B
Ottawa, ON K1P 5S9
Canada

Further details on these tests may be obtained from the reference calibration centre.

APPENDIX E

INDEPENDENT TEST SPECIFICATIONS FOR NEUTRON DOSIMETRY

E.1 Introduction

In addition to the in-house quality assurance program described in Section 5.0, “Quality Assurance Requirements,” subsection 4.1.7.2, “Independent Testing,” describes a requirement for independent testing.

Dosimetry services that are ready to undergo independent testing shall make arrangements directly with the reference calibration centre. Dosimetry services using dosimeters that require processing (e.g., solid-state nuclear track detectors) shall follow the protocol outlined in Section E.2, “Protocol for Personal Dosimeters That Require Processing.” Dosimetry services using dosimeters that do not require processing (e.g., electronic dosimeters) shall follow the protocol outlined in Section E.3, “Protocol for Personal Dosimeters That Do Not Require Processing.”

E.2 Protocol for Personal Dosimeters That Require Processing

1. Prior to licensing and subsequently at regular intervals with a frequency of at least once every 12 months, each dosimetry service shall send to the reference calibration centre at least 10 identified dosimeters plus sufficient control dosimeters to satisfy the readout process. The reference calibration centre will divide the submitted dosimeters into two groups of at least five dosimeters per group and irradiate each group of dosimeters in an Americium (Am)-241-Beryllium (Be) neutron field to a different but known value of $H_p(10)$ due to neutrons of between 1 mSv and 10 mSv. The delivered values will not be revealed at this time to the dosimetry service.
2. The irradiated dosimeters and controls will be returned to the dosimetry service for processing by the established routine procedures of the service. The dosimetry service reports the results to the reference calibration centre.
3. The reference calibration centre will compare the reported results with its values and report the results, including the values of both the service and the centre, to the CNSC at the address below, with a copy sent to the dosimetry service. In order to pass this test, the reported results shall lie within the criteria described in subsection 4.1.7, “Requirements for Routine Neutron Dosimetry Services.”

E.3 Protocol for Personal Dosimeters That Do Not Require Processing

1. Prior to licensing and subsequently at regular intervals with a frequency of at least once every 12 months, each dosimetry service shall send a representative sample of identified dosimeters to the reference calibration centre. The reference calibration centre will irradiate them in an Am-241-Be neutron field to two different but known values of $H_p(10)$ due to neutrons of between 1 mSv and 10 mSv.
2. The reference calibration centre will compare the readings with its values and report the results, including the values of both the participant and the centre, to the CNSC at the address below, with a copy sent to the dosimetry service. The dosimeters will be returned to the dosimetry service upon completion of all irradiations. In order to pass this test, reported results shall lie within the criteria described in subsection 4.1.7, "Requirements for Routine Neutron Dosimetry Services."

E.4 Reporting

The reference calibration centre reports the test results to the CNSC at the following address:

Dosimetry Services Licensing Specialist
Canadian Nuclear Safety Commission
P.O. Box 1046, Station B
Ottawa, ON K1P 5S9
Canada

Further details on these tests may be obtained from the reference calibration centre.

APPENDIX F INDEPENDENT TEST SPECIFICATIONS FOR INTERNAL DOSIMETRY

F.1 Introduction

In addition to the in-house quality assurance program described in Section 5.0, “Quality Assurance Requirements,” subsection 4.2.4, “Independent Testing for In Vivo Measurements,” and subsection 4.2.6, “Independent Testing for In Vitro Measurements,” describe requirements for independent testing.

Dosimetry services shall make arrangements for participating in these independent tests directly with the relevant reference calibration centre.

Upon completion of the testing and analysis of the results, the reference calibration centre staff submits a report containing the identity of each participating dosimetry service and its corresponding test results to the CNSC. When the reference calibration centre staff becomes aware that a licensed internal dosimetry service has failed an independent test, it informs the CNSC and the dosimetry service. The reference calibration centre also submits to each participating laboratory a report of the test results in which the identities of the laboratories are represented by a code.

F.2 In Vitro Measurement Independent Tests

Prior to licensing and subsequently at regular intervals at least once every 12 months, or at other intervals determined in consultation with the CNSC, the reference calibration centre supplies each participating laboratory with appropriate samples and blanks. (Dosimetry services participate for the applicable radionuclides.) The dosimetry service analyzes the samples according to a schedule supplied by the reference calibration centre. Results are entered on a standard reporting form and returned to the reference calibration centre. When all laboratories have responded, the reference calibration centre analyzes the results and issues a report, with each laboratory identified only by a code. The reference calibration centre informs each laboratory of its own code and informs the CNSC of the codes for all the dosimetry services (licensees and applicants).

Further details of the independent tests and the method of analysis may be obtained from the reference calibration centre. Dosimetry services shall participate in these independent tests and obtain passing results prior to being granted a dosimetry service licence by the CNSC, and at least once per year thereafter, or at intervals determined in consultation with the CNSC, to demonstrate continuing capability. The procedure shall be repeated if the measurement method or equipment undergo any significant changes that may have an adverse impact on the precision, accuracy, and reliability of the measurements.

The independent tests for *in vitro* bioassay will be designed so that the following precautions can or will occur:

1. Each laboratory is provided with up to five aliquots of each spiked sample as well as a urine blank from which the spiked samples were prepared;
2. Colour quenching may be increased for some samples;
3. The *in vitro* independent test for Fission/Activation Products may include up to three radionuclides, which may be varied from one year to another;
4. For a given test, all participating laboratories are sent aliquots of the same samples; and
5. Instructions for sample analysis and the date of spiking are enclosed with the samples.

F.3 In Vivo Measurement Independent Tests

The reference calibration centre has tissue equivalent phantoms available for a variety of radionuclides in the lung, I-125 and I-131 thyroid neck phantoms and water-filled bottle manikin absorption (BOMAB) calibration phantoms of varying size for higher photon energies.

Prior to licensing and subsequently at regular intervals at least once every 12 months, or at other intervals determined in consultation with the CNSC, the dosimetry service shall undergo independent testing to demonstrate continuing capability. If the measurement method or equipment undergo any significant changes that may have an adverse impact on the precision, accuracy and reliability of the measurements after a dosimetry service licence has been granted and prior to implementing the new measurement method or putting the equipment back into service, the affected bioassay method and equipment shall pass an independent test.

The independent tests for *in vivo* bioassay will be designed so that the following precautions can or will occur:

1. The radionuclide mixtures for measurement in phantoms are limited to three radionuclides chosen from Table 4 in subsection 4.2, "Dosimetry Services for Internal Radiation," not including Potassium (K)-40;
2. The location of the activity in the phantoms is realistic (e.g., in the lungs or gastrointestinal region);
3. The radionuclides used in *in vivo* testing may vary from one test to another;
4. The water-filled BOMAB phantoms that are used for *in vivo* testing all contain K-40 and include
 - a) reference female,
 - b) 5th percentile male,

- c) reference male, and
- d) 95th percentile male.

Also, in order to be representative of the chest wall thickness of individuals in the workplace, overlay plates may be used in *in vivo* tests.

F.4 Independent Test for Ascertaining the Committed Effective Dose

The reference calibration centre supplies each participating laboratory with relevant exposure scenarios at a frequency set by the CNSC. The dosimetry service assesses the committed effective dose from the exposure scenarios that are relevant to the activities carried on by CNSC licensees that use the dosimetry service. When all laboratories have responded, the reference calibration centre analyzes the results and issues a report, with each laboratory identified only by a code. The reference calibration centre informs each laboratory of its own code and informs the CNSC of the code for all of the dosimetry services (licensees and applicants).

Specifications of the independent tests may be obtained from the reference calibration centre. Dosimetry services shall participate in these independent tests to demonstrate continuing capability.

F.5 Reporting

The reference calibration centre reports the tests results to the CNSC at the following address:

Dosimetry Services Licensing Specialist
Canadian Nuclear Safety Commission
P.O. Box 1046, Station B
Ottawa, ON K1P 5S9
Canada

Further details on these tests may be obtained from the reference calibration centre.

APPENDIX G

INDEPENDENT TEST SPECIFICATIONS FOR RADON PROGENY AND RADON GAS

G.1 Introduction

In addition to the in-house quality assurance program described in Section 5.0, “Quality Assurance Requirements,” subsection 4.3.5, “Independent Testing for the Monitoring of Radon Progeny,” and subsection 4.3.8, “Independent Testing for Radon Gas Measurements,” describe requirements for independent testing.

Dosimetry services for radon and radon progeny that are ready to undergo independent testing shall make arrangements for participating in these tests directly with the relevant reference calibration centre (see Appendix J).

G.2 Protocol for Personal Monitors

The instruments sent shall be clean and uncontaminated, and in working order. The overall performance of a given system shall meet the accuracy specifications for measuring exposure to radon progeny and radon gas described in Table 7, subsection 4.3.3, “Accuracy Specifications for Radon Progeny Measurements,” and in Table 9, subsection 4.3.6, “Accuracy Specifications for Radon Gas Measurements.” The dosimetry service shall contact the reference calibration centre to arrange suitable scheduling before instruments are sent.

G.3 Grab Sampling

Independent testing is also required for dosimetry services that use grab sampling to determine exposure of workers to radon progeny and radon gas. Grab sampling for radon gas may be used in situations where there are high concentrations of radon gas in the air but without the simultaneous presence of the corresponding levels of radon progeny (i.e., where the gas does not have time to decay significantly). In situations where there is time for the radon gas to decay, it is assumed that the air will be sampled for progeny.

The use of grab sampling for the determination of radon progeny exposures is a staged process that requires the collection of aerosols on a filter over a short time period, the measurement of the radioactivity of the aerosols and a calculation of the potential alpha radiation (working levels (WL), or $\mu\text{J}/\text{m}^3$) due to the short-lived radon progeny. Calibration procedures are also required for the air-sampling train and for the counting system. The determination is complex and sources of error include instrumental sources and variances in the implementation of the collection procedure by the technicians conducting the determination.

A conventional independent testing program to validate the performance of the measurements may be impractical since it would require all measurement systems and the techniques of individual technicians to be verified at the CNSC reference calibration facility on a routine basis. As an alternative, a designated CNSC inspector's qualifications in measuring radon progeny and radon gas will be verified by the reference calibration centre on an annual basis. Dosimetry services may have the performance of their technicians verified on an annual basis by one of the following two methods:

1. The designated CNSC inspector individually validates all technicians at each dosimetry service; or
2. The CNSC validates a designated technician representing the dosimetry service in the above-described method, and that technician in turn validates all other technicians on site who conduct radon progeny and radon gas grab sampling for dosimetry purposes. The results of the validations shall be recorded and retained by the dosimetry service.

The validations described above require a minimum of 10 samples. The differences in the results of the overall performance of the instruments and sampling technicians shall enable the dosimetry service to meet the accuracy specifications in Table 8, subsection 4.3.3, "Accuracy Specifications for Radon Progeny Measurements," and in Table 10, subsection 4.3.6, "Accuracy Specifications for Radon Gas Measurements."

Questions with respect to direct validation of technicians at the reference calibration centre should be directed to the reference calibration centre.

G.4 Reporting

For personal monitors, the reference calibration centre reports the test results to the CNSC at the following address:

Dosimetry Services Licensing Specialist
Canadian Nuclear Safety Commission
P.O. Box 1046, Station B
Ottawa, ON K1P 5S9
Canada

If the second method is used for grab sampling, the licensee's designated technician reports the test results to the CNSC at the address indicated above.

APPENDIX H

EXAMPLE CALCULATIONS FOR MINIMUM MEASURABLE CONCENTRATION AND COUNTING UNCERTAINTY

H.1 Example Calculation for the Determination of the Minimum Measurable Concentration

The minimum measurable activity concentration (MMC) in air varies with the parameters of the counting system and the volume of the sample. The following equation, derived from Strom and Stansbury,^[18] is such that the probability of failing to detect the activity concentration is not greater than five percent. Other equations may be acceptable depending upon the situation.

$$MMC = \frac{2.71 + 4.65\sqrt{C_b}}{T_c} * \frac{1}{E * V}$$

where

C_b = the background count of the detector;

T_c = the count time in seconds;

E = the efficiency of the detector in counts per second per Bq; and

V = the volume of the sample in m³.

An MMC of 0.05 Bq/m³ can be achieved by varying the parameters in the equation. For example, if a background count of 250 is used with a total count time of 3600 seconds, a counter efficiency of 0.35, and a volume of 1.2 m³, the MMC would be:

$$MMC = \frac{2.71 + 4.65\sqrt{250}}{3600} * \frac{1}{0.35 * 1.2}$$

$$MMC = 0.05 \text{ Bq/m}^3$$

which is acceptable.

Note: The volume of the sample is dependent upon both the flow rate of the air-sampling pump and the duration of the sample collecting period.

H.2 Example Calculation for Uncertainty

When the difference in count rate, expressed in counts per minute (cpm), is 2 or more, and the total number of counts (sample plus background) is more than 40, the following equations can be used to calculate the limits within which the true (unknown) count lies, 95 percent of the time.^{[19], [20]}

$$\text{Lower limit} = (C_t - C_b) - 1.96\sqrt{C_t + C_b}$$

$$\text{Upper limit} = (C_t - C_b) + 1.96\sqrt{C_t + C_b}$$

where

C_b = background count for the sample counting time;

C_t = total count; and

$C_t - C_b$ = net count.

For example, with

1. a default ALI for uranium ore dust of 3190 Bq and consequently a DAC of 1.33 Bq m⁻³;
2. 2000 hr of work/year and a breathing rate of 1.2 m³/hr;
3. A sampling rate of 2.5 L min⁻¹ (2.5 x 10⁻³ m³ min⁻¹);
4. Duration of sampling of 6 hours;
5. Counting efficiency of 0.4;
6. Background count rate of 1 cpm; and
7. The airborne radioactive material concentration is 1/10 of the DAC (i.e., 0.133 Bq m⁻³)

the activity collected on the filter is

$$0.133 \text{ Bq m}^{-3} \times 2.5 \times 10^{-3} \text{ m}^3 \text{ min}^{-1} \times 60 \text{ min h}^{-1} \times 6 \text{ h} = 0.120 \text{ Bq}$$

and the total count rate (sample plus background) is

$$1 \text{ cpm} + (60 \text{ s min}^{-1} \times 0.120 \text{ Bq} \times 0.4) = 3.87 \text{ cpm}$$

If both the background and the sample are counted for 20 minutes, the background count is 20 and the sample count (total count) is expressed in the following equation:

$$20 \times 3.87 = 77 \text{ (rounded to the nearest integer)}$$

Solving the above equations with the above values (i.e., with $C_b = 20$ and $C_t = 77$), one obtains the following:

Lower limit of the 95% confidence interval is 38; and

Upper limit of the 95% confidence interval is 76

Therefore, there is a 95 percent probability that the true count is larger than 38, and smaller than 76.

Since 57 is the best estimate of the true count, there is a 95 percent probability that the airborne radioactive material concentration measurement lies within $-(57-38)/57$ and $+(76-57)/57$, that is within $\pm 33\%$.

APPENDIX I

SPECIFICATIONS FOR DOSE RECORDS

I.1 Introduction

All dosimetry services shall submit dose data on a regular basis to the National Dose Registry (NDR) at the frequency specified in their licence. Operators of such services shall ensure that the data to be transmitted to the NDR is in a form compatible with the NDR.

I.2 Individual Identification

Unambiguous individual identification is required; therefore, some redundancy is necessary. The following minimum information is required:

1. Social Insurance Number (SIN);
2. Surname/previous surnames;
3. First given name (formal form, not nickname);
4. Second given name (formal form, not nickname);
5. Sex;
6. Date of birth (year/month/day);
7. Place of birth (province, if born in Canada, or country, if born outside Canada); and
8. Individual occupational codes or classifications.

I.3 Dose Data

I.3.1 Dose from External Sources

Measurements of $H_p(10)$ shall be reported as effective dose. Measurements of $H_p(0.07)$ shall be reported as equivalent dose to the skin. Measurements of doses to the extremities or the lens of the eye shall be reported as equivalent doses to those tissues.

I.3.2 Dose from Internal Sources

Dose estimates from internal sources other than those given in subsection 4.2, "Dosimetry Services for Internal Radiation," are to be reported to the NDR by indicating the radionuclide that was taken in and the associated committed effective dose.

I.3.3 Exposures to Radon, Radon Progeny, and Intakes of Airborne Radioactive Material

Exposures to radon progeny shall be recorded in working level months (WLM). Doses from intakes of radon and airborne radioactive material shall be recorded in millisieverts (mSv).

I.4 Supporting Information

In addition to the dose data, the dosimetry services shall retain all pertinent data used to generate the dose, exposure, or concentration totals, where applicable, such as the following:

1. Readings of personal dosimeters and other data used for measuring external radiation;
2. Measurements of organ burdens;
3. Estimates of intakes of prescribed substances;
4. Method of measurement of concentrations in bioassay samples;
5. Chemical forms;
6. Dosimetry models used;
7. Measurements of radon gas and radon progeny exposures;
8. Measurements of radon gas and radon progeny concentrations in air; and
9. Time spent by individuals in specific locations of a mine.

Any reports made as a result of the investigation of overexposures or other unusual doses shall also be kept.

APPENDIX J REFERENCE CALIBRATION CENTRES⁷

This section lists the reference calibration centers, and the corresponding dosimetry type for which each is responsible, that the CNSC recognizes.

J.1 Independent Testing for External Photon Dosimetry, Extremity Dosimetry, and Neutron Dosimetry

National Research Council of Canada

Contact information:

Head, Ionizing Radiation Standards Section
Institute for National Measurement Standards
National Research Council of Canada
Ottawa, ON K1A 0R6
Canada
Telephone: (613) 993-2715

J.2 Independent Testing for In Vitro Measurements, In Vivo Measurements, and Interpretation of Bioassay Data

National Calibration Reference Centre for Bioassay and In Vivo Monitoring, Health Canada

Contact information:

Chief, Environmental Radiation Hazards Division
Health Canada
775 Brookfield Road
Ottawa, ON K1A 1C1
Canada
Telephone: (613) 954-6672

⁷ Last updated on June 25, 2004.

J.3 Independent Test Specifications for Radon Gas and Radon Progeny

Bowser Morner

Contact information:

Director, Radiological Services Division
Bowser Morner
4518 Taylorsville Road
P.O. Box 51
Dayton, OH 45401-0051
U.S.A.
Telephone: (937) 236-8805