REGULATORY STANDARD

S-106 (E)

TECHNICAL AND QUALITY ASSURANCE STANDARDS FOR DOSIMETRY SERVICES IN CANADA

A Joint Federal-Provincial Standard

Published by the
Atomic Energy Control Board
(March 20, 1998)

Atomic Energy Control Board | Commission de contrôle de l'énergie atomique

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NOTICE

On March 20, 1997, Bill C-23, the *Nuclear Safety and Control Act*, received Royal Assent. It is not yet in force. The Atomic Energy Control Board is using Regulatory Standard S-106 now in relation to regulatory activities involving dosimetry services. The technical content of this document is not expected to change when the new act and regulations to be made under it come into effect. However, when they do come into effect, this document will be replaced by a revised version that will fully reflect the new legislation. The existing *Atomic Energy Control Act* and its regulations will remain in force until further notice.

Technical and Quality Assurance Standards for Dosimetry Services in Canada

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1 INTRODUCTION

Licensees of the Atomic Energy Control Board (AECB) and owners of x-ray equipment under provincial jurisdiction are required to establish programs to determine or estimate the radiation doses or exposures received by workers exposed to ionizing radiation as a result of the activities of the licensee or owner. As indicated in the *Atomic Energy Control Regulations*, AECB licensees are required to provide necessary devices for detecting and measuring radiation. Since compliance with the regulatory dose or exposure limits is demonstrated by means of measurements, the methods used to produce dosimetry results must be acceptable to the regulatory authority, *i.e.*, the AECB or the provincial government agencies. This document was prepared in order to provide applicants, licensees and owners of x-ray equipment with guidance on dose and exposure measurement methods that would be acceptable to the regulatory agency. Other methods may also be acceptable, but these would have to be assessed by the regulatory authority to determine if they are equivalent to the methods described in this document. In order to help ensure the integrity of the dose and exposure data, users of dosimetry services must also meet certain quality assurance specifications. Although this document is aimed explicitly at dosimetry services, both commercial and in-house, the quality assurance specifications for both dosimetry services and users are included in this document for completeness. The user specifications will also be outlined in a subsequent document and will be enforced through other regulatory instruments, *e.g*., licence conditions.

The means by which regulatory authorities expect that dose and exposure measurements would be performed are described in the following paragraphs.

Radiation dose from external (*i.e.*, outside the body) sources is usually measured with a personal dosimeter. For internal sources (*i.e.*, radioactive substances taken into the body), some form of bioassay or *in vivo* monitoring is the usual method used to estimate dose. In some cases, particularly for radon progeny and long-lived radioactive dust, an estimate of intake is made by means of air monitoring techniques, and the dose or exposure is derived from the intake.

The determination of radiation dose is a two-part process. First, a measurement is made, using, for instance, a dosimeter, a urine specimen or an air sample. Second, this measurement is used in a "dosimetric model" to calculate, or estimate, the dose. The dosimetric model used depends on the type of dosimetry which is to be performed. For example, in the case of external gamma exposure, a dosimeter reading is converted to dose by means of a conversion factor. For bioassay, the conversion of a biological sample measurement to a dose requires knowledge of many factors such as the metabolism of the radionuclide and the time and route of intake. To estimate a person's exposure to radon progeny and radioactive dusts from air monitoring measurements requires assumptions about such factors as breathing rate and variations with time and place of contaminant concentrations in air.

This document is concerned with the first step of the dose or exposure determination process and addresses measures associated with assuring accurate dose or exposure measurement and assignment. Consequently, this document specifies the technical standards for dosimetry services and the quality assurance program which, when implemented, will provide confidence that these standards are achieved and maintained. The second step, that is, the use of models to obtain a dose from a dosimetric measurement, is not covered in this

document. However, in order to ensure that all the information that can realistically be collected is available for dose determination, this document includes specifications for the documenting and reporting of monitoring data. These specifications are given in Appendix D which is entitled Specifications for Dose Records.

It must be noted that the AECB and the provinces of Canada require that dose and exposure records be deposited with the National Dose Registry (NDR) of Health Canada by the dosimetry service or by the AECB licensee if the latter operates the dosimetry service. Since the records deposited with the NDR will be routinely inspected by AECB and Provincial staff for regulatory purposes, they must be deposited without undue delay.

Some dosimetry services are operated by AECB licensees to provide dosimetry for their own employees. Some dosimetry services are operated commercially for any users (*i.e.*, customers) who wish to subscribe to them. The AECB will assess a dosimetry service against the standards in this document in determining whether use of the service by AECB licensees can be approved. A new service, which is in the process of being established with the intention of providing dosimetry to AECB licensees, should contact the AECB at an early stage to discuss the standards. The dosimetry results from a service that has obtained AECB approval will be accepted for compliance purposes for AECB licensees. Organizations wishing to know which dosimetry services have received AECB approval may contact the AECB. Users of dosimetry services will also be assessed according to the criteria listed in Appendix G.

In the case of x-ray dosimetry services, the provincial regulatory authority will assess a dosimetry service against the standards in this document in determining whether use of the service by x-ray users can be approved. The dosimetry results from new or existing dosimetry services that have obtained approval from the Provincial Radiation Dosimetry Review Committee (PRDRC) will be accepted for compliance with provincial regulations.

In 1982, the AECB set up working groups of experts in various aspects of radiation dosimetry to recommend appropriate reference standards. The recommendations of the three working groups — on external dosimetry, internal dosimetry and the exposure to radon progeny — are contained in the AECB publication *Practical Reference Radiation Standards in Canada* (AECB 1983). The recommendations were that standards for external dosimetry should be referenced to the national primary radiation measurement standard maintained by the Institute for National Measurement Standards (INMS) of the National Research Council of Canada (NRC), for internal dosimetry by the Radiation Protection Bureau of Health Canada, and for radon progeny by CANMET of Natural Resources Canada. However, in 1996, the CANMET laboratory, which was designated by the working group, ceased to operate. The AECB has, since then, selected Bowser Morner of Dayton, Ohio, as its replacement. For services which Bowser Morner cannot provide, the Environmental Measurements Laboratory (EML) of the U.S. Department of Energy may be used. For the purposes of this document, these organizations are known as Reference Calibration Centres. Primary standards for x-ray dosimetry are also developed and maintained by the INMS, and any secondary standards used by an external agency laboratory acting as a Reference Calibration Centre for x radiation measurements should be directly traceable to the primary standards of the NRC. One of the specifications in this document is the participation of all dosimetry services in routine independent tests carried out by their appropriate Reference Calibration

Centre. The procedures to be followed by dosimetry services when taking part in these tests are contained in Appendices A, B, C and H of this document.

Applications for AECB approval and for joint AECB-PRDRC approval must be sent to the following address:

Director
Radiation and Environmental Protection Division
Atomic Energy Control Board
P.O. Box 1046, Station B
Ottawa, Ontario K1P 5S9
CANADA

Applications for PRDRC approval only must be sent to the following address:

Chair — Provincial Radiation Dosimetry Review Committee
Ontario Ministry of Labour
Radiation Protection Service
81 Resources Road
Weston, Ontario M9P 3T1
CANADA

For further information on the approval process, AECB personnel may be contacted at (613) 995-1732. Information on matters pertaining to the PRDRC may be obtained by phoning (416) 235-5922.

2 DEFINITIONS

Coefficient of Variation

This is a measure of reproducibility of the measurements. It is defined, for the purposes of this document, as:

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

where s = standard deviation of the set of measurements
m = mean of the set of measurements

Dosimetry Service This is an organization or part of an organization in charge of estimating either radiological doses or exposures to monitored workers, or parameters related to such doses or exposures. There are two categories of dosimetry service and three types. These are described as follows:

Categories of Dosimetry Service

There are basically two ways by which a licensee can perform dosimetry for workers: the use of an in-house dosimetry service or the use of an outside dosimetry service. In some cases, a licensee may use both approaches (*e.g.*, an outside service for external beta and gamma exposures, and their own laboratory for urinalysis). It should be noted that the licensed dosimetry service is responsible for ensuring that work performed on its behalf, under contract, by an outside organization is in accordance with the specifications contained in this document. For the purposes of this document, two categories of dosimetry services are defined as follows:

Category I — An outside or commercial service or laboratory which carries out dosimetry measurements for one or more AECB licensees or x-ray facilities.

Category II — Either (a) an in-house service operated by a licensee that carries out dosimetry measurements for workers and for visitors to the licensed premises, or (b) an in-house x-ray dosimetry service such as may be operated by a hospital or corporation for x radiation workers at facilities under provincial jurisdiction.

Types of Dosimetry Service

Dosimetry services may furnish one or more of three basic types of dosimetry:

(a) external dosimetry: this is usually for x and gamma (*i.e.*, photon) radiation, but may also be for beta and neutron radiation. This document addresses only doses from external sources due to photon and beta radiation, in fields which are assumed to be relatively uniform. Criteria for neutron dosimetry, as

well as dosimetry for special situations (*e.g.*, exposure of the extremities, eyes, etc.) will be dealt with in separate documents.

(b) internal dosimetry: this involves bioassay in the form of either *in vitro* monitoring, that is, the analysis of urine, faecal, breath or other samples of biological material, or *in vivo* monitoring, that is, the direct measurement by external detectors of body or organ burdens of radioactivity, or a combination of the two.

(c) the measurement of radioactive atmospheres: this is usually accomplished by means of air monitoring techniques. Typical measurements are for radon progeny and radioactive dusts in uranium mines.

Independent Testing

For the purposes of this document, this term means participating in tests conducted by the appropriate Reference Calibration Centre.

Influence Quantity

This is a quantity which may have an effect on the accuracy or uncertainty of a measurement. Lists of influence quantities, for the purposes of this document, are provided in sections 3.1.3 i) and 3.3.3.3.

Mean Relative Bias

This indicates the accuracy of a set of measurements, *i.e.*, how closely the measurements correspond to the actual radionuclide concentration or activity in analyzed samples. It is defined as:

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

where B = mean relative bias of a set of measurements
n = number of measurements in the set

B_i = relative bias of a single measurement = $\frac{A_i - A}{A}$
A_i = value of a single measurement
A = conventionally true value

Minimum Detectable Activity (MDA)

The smallest amount (activity or mass) of an analyte in a sample that can be detected. It is implied that there is a *probability b* of not detecting a quantity of analyte that is present (Type II error) and a *probability a* of erroneously deciding that a positive (non-zero) quantity of analyte is present when it is not (Type I error).

Minimum Testing Level (MTL)

The amount of radioactive material that the dosimetry service should be able to measure for participation in the independent testing program.

Relative Precision

Relative precision, S_B, is a measure of the reproducibility of an analysis, and is given by:

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

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

Response

The response of a dosimeter, R, is defined as the result of a measurement under defined conditions divided by the conventionally true dose that would be received under those conditions. See equation (1) in section 3.1.2.

Type Testing

Type testing of a dosimetry system is an extensive testing exercise which is performed to identify all potential sources of error and uncertainty in the dose measurement and to quantify those errors and uncertainties that may contribute significantly to the overall error or combined standard uncertainty. See section 3.1.3 for more information.

Statistical terms which are used in this document but which are not included above and are not explained in the text are as defined by the American National Standards Institute (ANSI 1996).

3 TECHNICAL SPECIFICATIONS

The technical specifications given in this section are specific to the type of service (*i.e.*, external dosimetry, internal dosimetry or the measurement of exposures to radioactive atmospheres). Both categories of service (see section 2, above) should meet the same technical specifications for the type of service they supply.

3.1 Dosimetry Services for External Radiation

The types of radiation and the respective energy ranges to which the dosimeters will be exposed during use must be identified and clearly stated in the application for approval.

3.1.1 Quantity to be Measured

In principle, the objective of personal dosimetry is to measure the quantity "personal dose equivalent", $H_p(d)$, as defined by the International Commission on Radiation Units and Measurements (ICRU 1992). 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 cannot be determined (ISO 1995a). Instead, the result of a measurement is compared 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 not a suitable quantity to use for specification of the performance and properties of a dosimeter. It is replaced for this purpose by a conventionally true value of $H_p(d)$, which 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. The conversion coefficient is calculated using a computer model 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 an uncertainty that is negligible compared with the uncertainty in routine dose measurements, and it is therefore used as the reference value for estimating errors in the latter measurements. In the following sections, the conventionally true value of the quantity $H_p(d)$ will be designated by $H_p'(d)$.

3.1.2 Accuracy Specifications and Uncertainty Limits in Dose Measurement

A person or organization who is applying for approval of a dosimetry service must demonstrate that the proposed system can measure $H_p'(d)$ within the accuracy specifications and uncertainty limits contained in this document. The specifications are based on the recommendations of the International Commission on Radiological Protection (ICRP 1982, 1991), and on the AECB and

provincial requirement that external dosimetry services achieve levels of performance consistent with the use of up-to-date equipment and operating methods.

The response of a dosimeter, R, is defined as the result of a measurement under defined conditions, $H_m(d)$, divided by the conventionally true dose that would be received under those conditions:

$$R = \frac{H_m(d)}{H_p(d)}. \qquad (1)$$

The mean response, $\bar{R}$, of a dosimeter under the intended conditions of use may be written as the following product:

$$\bar{R} = R_0 \bar{r}_1 \bar{r}_2 \ldots \bar{r}_i \ldots \bar{r}_n \qquad (2)$$

where R_0 = the response under reference conditions (normally those conditions under which the dosimeter is calibrated),

$\bar{r}_i$ = the mean response relative to R_0 due to variations in the i^{th} influence qantity, and

n = the number of independent 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.)

If the effect of changes in an influence quantity on the dosimeter response is known, and the probability distribution of that influence quantity can be measured or estimated, then the mean relative response due to that influence quantity can be calculated using the usual statistical techniques. If the only information available is the maximum and minimum relative response that may result from varying an influence quantity, then the probability of the relative response taking on a given value may be assumed to be symmetrically distributed about the midpoint of the range, and the mean relative response is

$$\bar{r}_i = \frac{r_i^{\max} + r_i^{\min}}{2}. \qquad (3)$$

The standard uncertainty of measured responses about the mean response can also be calculated with the usual statistical techniques if the detailed probability distributions can be determined or estimated for each of the contributing influence quantities. If this information is not known, the uncertainty in the relative response of each influence quantity can be estimated from the approximate or assumed probability distribution of the relative response. For example, if the

relative response is assumed to be equally likely to take on any value within the range (r_i^{min}, r_i^{max}), corresponding to a rectangular probability distribution, then the standard uncertainty is given by:

$$u_i = \frac{r_i^{max} - r_i^{min}}{\sqrt{12}}. \quad (4)$$

Examples of other distributions that might be assumed are the Gaussian and triangular distributions. Further guidance on estimating standard uncertainties from distributions of input quantities (a Type B evaluation of uncertainty) may be found in the ISO *Guide to the Expression of Uncertainty in Measurement* (ISO 1995a). If u_{Ro} is the uncertainty in R_0, then the standard uncertainty of the measured responses about the mean response is given by combining the component uncertainties in quadrature:

$$u = \bar{R}\sqrt{\left(\frac{u_{R_0}}{R_o}\right)^2 + \sum_{i=1}^{n}\left(\frac{u_i}{\bar{r}_i}\right)^2}. \quad (5)$$

In addition to the uncertainty in the response, there will be an uncertainty, u_s, due to random errors in the measurement process. The size of this uncertainty is determined using a type A evaluation (ISO 1995a). The combined relative uncertainty in a single dose measurement is then:

$$u_c = \sqrt{\left(\frac{u}{\bar{R}}\right)^2 + u_s^2}. \quad (6)$$

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

$$\frac{1}{f} \le \bar{R} \pm 2u_c\bar{R} \le f \quad (7)$$

where f = 1.5 for d = 10 mm and 4 mSv ≤ $H_p'(10)$ ≤ 10 Sv;
= 2 for d = 10 mm and $H_p'(d)$ = 0.4 mSv;
= 1.5 for d = 0.07 mm and 100 mSv ≤ $H_p'(0.07)$ ≤ 10 Sv;
= 2 for d = 0.07 mm and $H_p'(d)$ = 10 mSv.

The combined standard uncertainty $u_c\bar{R}$ 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%. The ability of a dosimetry system to satisfy the overall specification is demonstrated through type testing, described in section 3.1.3. An example of the calculations described above is given in section 3.1.4.

In addition to demonstrating conformance with the overall specification, the applicant must include in the application for approval the lowest values of $H_p'(d)$ that the dosimetry system is capable of measuring at the 95% confidence level. The determination of these values should be done under good laboratory conditions, using the usual calibration radiation at normal incidence to the dosimeter.

The overall specifications for accuracy and precision are summarized in Table 1.

TABLE 1
Specifications for Accuracy and Precision

Quantity	Dose (mSv)	Specifications (95% confidence)
$H_p'(10)$	4 to 10 000	+50% / -33%
	0.4	+100% / -50%
$H_p'(0.07)$	100 to 10 000	+50% / -33%
	10	+100% / -50%

3.1.3 Type Testing

Type testing of a dosimetry system is performed to identify all potential sources of error and uncertainty in the dose measurement, and to quantify those errors and uncertainties that may contribute significantly to the overall error or combined standard uncertainty. This will show whether or not the system can be used to measure doses within the desired accuracy, sensitivity and reliability. Wherever possible, an error introduced by an influence quantity should be corrected by applying a correction factor to the calculation of $H_m(d)$, with the objective of making the mean relative response for that influence quantity close to unity. There may be circumstances, however, where 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.

Type testing need be done only once for a given dosimetry system. However, if changes are made that may affect the result of a dose measurement, *e.g.*, dosimeter design, badge case filters, dose algorithm and temperature cycles (for thermoluminescent dosimetry [TLD]), type tests must be repeated to the extent necessary to demonstrate that the specifications of section 3.1.2 continue to be met. The results of these tests must be submitted to the appropriate regulatory authority as soon as they are available.

In the application for approval, the type test results must be presented in a format that clearly show all the influence quantities and system characteristics that were considered, and their range of possible values. Sample calculations must also be included to show how the mean response and the combined standard uncertainty were calculated. Any assumptions made and techniques used by a dosimetry service must be fully justified in the application for approval.

The remainder of this section provides guidance on performing type tests. If dosimeters in routine use may be exposed to conditions that are not mentioned here, but that may influence the result of a dose measurement, such conditions must be identified and included in the type tests.

i) Influence Quantities and System Characteristics to be Considered

The following influence quantities should be considered, and those that are likely to have a significant effect on accuracy or uncertainty should be evaluated. In deciding on the potential significance of the influence quantities, both the design of the dosimetry system and the intended conditions of use must be taken into account.

< angle of incidence of radiation
< distance of dosimeter from phantom
< dose (*i.e.*, linearity of dose response)
< dose rate, including in pulsed radiation fields
< electrical and magnetic fields, both static and alternating
< energy of photons and beta rays
< humidity and splashing
< ionizing radiations other than those intended to be measured
< mechanical shock, both dropping and vibration
< mixed radiation fields
< temperature variations, both gradual and abrupt
< time between zeroing and irradiation, and between irradiation and reading
< visible and ultraviolet light flux (effect on both dosimeter and reader)
< voltage supply to reader, both voltage spikes and gradual variations

In addition, the effects of the following system characteristics should be estimated, as appropriate:

< batch homogeneity
< calibration uncertainty
< repeatability (a measure of the stability of response of both the dosimeter and the reader)
< residual signal
< self irradiation
< zero-dose variations

Where an influence quantity or system characteristic is determined to cause a large and sudden change in the measured dose, but with a low probability, it is not appropriate to include that

change as a component of the combined standard uncertainty. Instead, steps should 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 then to estimate the reduced probability of occurrence.

ii) Phantoms

During irradiation, dosimeters must 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 other tests 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.

The phantom to be used for photon irradiations is a parallelepiped ("slab"), constructed of polymethylmethacrylate (PMMA) walls and filled with water (ISO 1995b). The external dimensions are 30 cm × 30 cm × 15 cm, and the wall thicknesses are 2.5 mm for the front wall (one of the 30 cm × 30 cm faces) and 10 mm for the other 5 walls. The phantom should be constructed in a way that ensures that the front face remains flat when the phantom is filled with water.

The phantom to be used for beta irradiations may be the same water-filled slab phantom as described above. If desired, however, 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 be used.

iii) Angle of Incidence of Radiation

The test radiations should be incident on the front face of the dosimeter at angles of 0^o, $\pm 20^o$, $\pm 40^o$ and $\pm 60^o$, 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.*, 4 measurements will be required). If cylindrical symmetry does not apply, then the measurements may need to be made in both directions in two perpendicular planes (*i.e.*, up to 13 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 reported as the response for that angle.

iv) Photon Energies

The photon energies used for the test irradiations should conform to the ISO International Standard 4037-1 (ISO 1996a). Coefficients to convert from exposure or air kerma to $H_p'(d)$ have been calculated and published for these energy spectra (see, *e.g.*, ISO 1995b). The calculations are based on a slab phantom made from the International Commission on Radiation Units and

Measurements (ICRU) standard tissue, 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. Since angle of incidence and photon energy are influence quantities whose effect on response is strongly correlated, their combined effect is considered as follows: At each energy for which the response is to be determined, the average response for the four angles specified in the preceding paragraph is calculated. (This is a simple arithmetic average of the four values, as in Christensen 1994.) The angle-averaged energy response is then used to calculate the mean relative response and standard uncertainty.

v) Beta Energies

The following standard beta sources should be used for type testing of dosimeters intended to measure $H_p(0.07)$:

Isotope	Maximum Beta Energy (keV)
$^{90}Sr/^{90}Y$	2 274
^{204}Tl	763
^{147}Pm	225

Further information about these sources is provided in ISO International Standard 6980 (ISO 1996b). They are commercially available with traceable calibrations for irradiation at normal incidence. The conversion coefficients normalized to 0^o for $H_p'(0.07)$ at other angles of incidence have been published (see, *e.g.*, Christensen 1994).

The accurate measurement of $H_p'(0.07)$ for beta radiation becomes increasingly difficult as the beta energy decreases and the angle of incidence increases. The overall specification in section 3.1.2 will therefore be applied as follows:

For $^{90}Sr/^{90}Y$ beta radiation: the specification must be met at all angles of incidence specified in paragraph iii), above.

For ^{204}Tl beta radiation: the specification must be met only at 0^o, and the response measured at the other angles specified in paragraph iii), above.

For ^{147}Pm beta radiation: the response must be measured at the angles specified in paragraph iii), above.

The mean relative responses and standard uncertainties for photons and betas are determined separately for comparison with the specifications defined by eqn. (7).

3.1.4 Example Calculations

This section contains some simplified calculations to illustrate the process described in section 3.1.2. The dosimeter is assumed to be calibrated so that its response under reference conditions (^{137}Cs gamma irradiation at normal incidence and 20°C) is unity, *i.e.*, $R_0 = 1$.

(a) Energy and Angular Response

If the angle-averaged relative response of a dosimeter over the range of photon energies for which it will be used is measured and found to range from 0.90 to 1.30, then, according to eqn (3), the mean relative response is taken to be

$$\overline{r_E} = \frac{1.30 + 0.90}{2} = 1.10. \tag{8}$$

If the photon energies to which the dosimeter will be exposed could result in any value of the response with equal probability *(i.e.*, there is no additional information available and a rectangular distribution is assumed), then, from eqn (4), the standard uncertainty is

$$u_E = \frac{1.30 - 0.90}{\sqrt{12}} = 0.115. \tag{9}$$

(b) Temperature Response

The relative response of the dosimeter over the range of temperatures to which it might be exposed is measured and found to range from 0.95 to 1.00, relative to the response at the reference temperature (20°C). The mean relative response [from eqn (3)] is then

$$\overline{r_T} = \frac{1.00 + 0.95}{2} = 0.975. \tag{10}$$

If the temperatures to which the dosimeter is most likely to be exposed will result in a response that is near the middle of the range, then it may be appropriate to assume a Gaussian distribution for the temperature response. If the range is taken to correspond to 95% of the Gaussian distribution, then the standard uncertainty is

$$u_T = \frac{1.00 - 0.95}{2 \times 1.96} = 0.013. \tag{11}$$

(c) Repeatability

A series of readings of dosimeters treated in the same way (*i.e.*, with all known influence quantities and operating conditions held constant) results in a distribution of measured doses with a relative standard deviation of 0.100. This component of uncertainty is due to random errors, and the standard uncertainty attributable to this characteristic of the dosimetry system is:

$$u_s = 0.100. \tag{12}$$

(d) Combined Response and Standard Uncertainty

If the energy and temperature are the only two influence quantities known to be significant, then, inserting the results from eqns (8) and (10) into eqn (2), the mean response is

$$\overline{R} = 1.00 \times 1.10 \times 0.975 = 1.073. \tag{13}$$

Assuming the uncertainty in the response under reference conditions, *i.e.*, u_{Ro}, to be negligible, the uncertainty in the response from eqn (5) is:

$$u = 1.073 \times \sqrt{\left(\frac{0.115}{1.100}\right)^2 + \left(\frac{0.013}{0.975}\right)^2} = 0.113. \tag{14}$$

The combined relative uncertainty, from eqn (6) is:

$$u_c = \sqrt{\left(\frac{0.113}{1.073}\right)^2 + 0.100^2} = 0.145. \tag{15}$$

In this example, the overall specification for 4 mSv $\leq H_p'(10) \leq$ 10 Sv is, from eqn (7),

$0.67 < (1.073 \pm 2) \times 0.145 \times 1.073 < 1.5$

and the inequalities are satisfied.

More examples of the selection and uses of distributions may be found in ISO 1995a.

3.1.5 Performance Testing

Routine performance tests are done to verify that a dosimetry system is operating in a predictable and consistent way. Test dosimeters are irradiated to known doses, usually under standard exposure conditions (*e.g.*, at normal incidence with the calibration radiation). They are

treated by the dosimetry service in the same way as routine dosimeters; if processing is required, test dosimeters should not be identified to the processing laboratory. The irradiation conditions and doses may be maintained constant over time to permit more valid trend analysis. The tests should include irradiations to a dose close to the minimum dose reported by the dosimetry service. Reasonable control limits must be set on the test results in consultation with AECB or Provincial Radiation Dosimetry Review Committee (PRDRC) staff.

The quality assurance program of a dosimetry service must include provisions for routine performance tests during every dosimeter issue period. In addition, the test procedure must be included with the application for approval of the dosimetry service. Performance test results do not need to be submitted to the AECB or the PRDRC as they are obtained. However, they must be retained by the dosimetry service for inspection during audits by the regulatory authorities. Performance tests in which the control limits have been exceeded must be reported to the appropriate regulatory authority, along with a description of the corrective action taken. In addition to the above control limits, a dosimetry service may wish to set more stringent in-house control limits, on the same test results. In such cases, the dosimetry service's performance with respect to the more stringent in-house limits will not be subject to official review by the regulatory authorities.

In addition to the routine performance tests, occasional special performance tests are to be conducted to confirm that the performance of the dosimetry system is consistent with the results of the type tests. In these tests, dosimeters are subjected 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. The test results should show no significant deterioration in performance, when compared with those obtained in the course of the type testing. The application for approval must specify the frequency and the nature of these special performance tests. Results of these tests will be treated in the same manner as those of the routine performance tests.

3.1.6 Independent Testing in External Dosimetry

Prior to being granted AECB or PRDRC approval and at regular intervals with a frequency of at least annually, a dosimetry service must participate in the independent testing of each of its dosimeter designs. For gamma dosimetry, these tests are to be performed by the National Research Council of Canada (NRC) which has been designated by the AECB as the Reference Calibration Centre for external gamma dosimetry in Canada. For x-ray dosimetry, these tests are to be performed either by the NRC itself or some other reference calibration centre for x-ray dosimetry in Canada whose radiation measurement standards are traceable to the primary standards maintained by the NRC (see section 4.3.10); however, such an alternate reference calibration centre must demonstrate that the uncertainty in calibration is sufficiently low, *e.g.*, 5%. These tests are essentially a verification of a dosimetry service's performance under simplified, well defined and controlled irradiation conditions. They also serve as an independent

test of the calibration of a dosimetry system. Appendices A and H contain the appropriate protocols to be followed by dosimetry services.

The accuracy which a dosimetry service must attain in each of these tests is as follows:

i) the mean response for the complete set of measurements of the air kermas (or exposures) delivered by the NRC (or other reference calibration centre) must not be less than 0.9 and not larger than 1.1;

ii) the coefficient of variation of the responses for the complete set of measurements must not be greater than 0.075.

Note that, for this test, the response is defined relative to the conventionally true value of the air kerma.

Ideally, if a dosimetry service's dosimeters are of a type that require processing, *e.g.*, TLDs, and if more than one processing unit, *e.g.*, TLD reader, is used by that service, then each such unit should be tested on an annual basis by using it to process at least one set of test dosimeters irradiated by the NRC. However, if the dosimetry service has documented evidence that shows that all of its processing units respond in a consistent manner, then only one of them must be tested through the NRC on an annual basis. In the latter case, in order to establish response consistency of the processing units, it must be shown 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 addition, the coefficient of variation of dosimeters processed by each unit must not be greater than 0.075. The dosimetry service's quality assurance program must ensure that the above accuracy specifications are maintained for each of the processing units which are used by the service.

A dosimetry service seeking approval must pass this test prior to being approved. If a dosimetry service fails one of these periodic tests, then the reason for the failure must be immediately investigated by that service, corrective action must be taken and a brief summary report must be submitted to the AECB or the PRDRC; the test must then be repeated and passed. If repetition of the test results in a second consecutive failure, the service's approval may be withdrawn. A dosimetry service whose approval has been withdrawn may have it re-instated once it has demonstrated that it can meet the specifications in this document.

3.1.7 Intercomparisons

In addition to requiring that dosimetry services undergo independent testing, the AECB and the PRDRC encourage all approved services to participate voluntarily in national and international intercomparisons and to submit the results to the AECB or the PRDRC.

3.1.8 Handling of Dosimeters

In a routine dosimetry service operation, a significant source of uncertainty is attributable to the distribution and handling of the dosimeters. Wrong assignment of identity, improper storage of control dosimeters and improper usage by the personnel being monitored are just a few examples. Users of a category I external dosimetry service are therefore responsible for ensuring that correct records are kept of the allocation of dosimeters, that control dosimeters are stored and handled as instructed by the operator of the dosimetry service, and that procedures for lost, damaged, or improperly exposed dosimeters are followed. These specifications are subject to the quality assurance considerations given in section 4.3.6.

3.2 Dosimetry Services for Internal Radiation

3.2.1 Scope

The AECB accepts that, because of the many uncertainties involved, the overall uncertainty in estimates of committed doses may reach or exceed a factor of 3. However, the uncertainties in the actual measurements on which the dose estimates are based shall be much less. The operator of a dosimetry service must be able to demonstrate that the service can measure the presence of radionuclides within certain ranges of activity and with acceptable accuracy and precision. This document does not address, however, the procedures for faecal, alpha and total beta analyses, any of which can be an important basis for dose calculations in some instances. In these cases, the AECB should be contacted for more information.

3.2.2 Values to be Measured

Table 2 shows Minimum Detectable Amounts (MDAs) based on the recommendations of the International Commission on Radiological Protection (ICRP 1988) and the American National Standards Institute (ANSI 1996) for selected radionuclides. The dosimetry service's MDAs may be greater than the values in Table 2 by a factor of 2 or more if the dosimetry service can demonstrate that the dose implication is minimal, *i.e.*, the effective dose resulting from a sample measurement at the licensee's MDA is 10 µSv or less. The minimum testing level (MTL) is defined in section 2 of this document. It is assumed that the samples are free of interference from other radionuclides unless specifically addressed. The MTLs should not be construed as being the appropriate minimum detectable amount (MDA) required for a specific internal dosimetry program, but rather an acceptable minimum testing level for radiobioassay service laboratories based on good measurement practice. The MTL will be 5 times or more the MDA.

MDAs depend upon the selected technique. The known performance of Canadian laboratories has been taken into consideration in setting the MDA specifications given in this section.

3.2.3 *In Vitro* Accuracy Specifications

Analytical performance is tested at levels of activity encountered in routine personnel monitoring as well as at expected levels following accidental exposures. For the independent tests described in section 3.2.5, test samples will be spiked with a known quantity of a traceable activity greater than or equal to the MTL and measurement reproducibility will be tested by providing several identical samples (*e.g.*, five aliquots) of each level of activity. To assess compliance with accuracy specifications, bias and precision must be considered separately. The mean relative bias, B as defined in section 2., must 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 will be tested at several concentrations no less than the MTL. For acceptability, B must be between -0.25 and +0.50, while the absolute value of the relative precision S_B, as defined in section 2., must be less than or equal to 0.4. The same relative bias and precision should be used for radionuclides not listed in Table 2. Corrective action must be taken when values do not satisfy these criteria. Such factors as chemical recovery, quenching, concentration range, sample preparation methods, etc. must be taken into account where applicable. If bioassay is required for any radionuclides not listed in Table 2, then the AECB should be contacted to determine independent test specifications.

Certain significant sources of uncertainty in a routine dosimetry operation impact on the quality of service but are beyond the control of the service laboratory. These include sample contamination during collection, leakage of samples and the adsorption of sample material, *i.e.*, activity, on container walls. Therefore, users of internal dosimetry services are responsible for the collection of properly labelled and preserved samples, free of extraneous contamination, and their shipment to the operator in appropriate containers. These specifications are subject to quality assurance considerations as given in section 4.3.6. For independent testing of *in vitro* measurements refer to section 4.3.10(b) and Appendix B.

3.2.4 *In Vivo* Accuracy Specifications

In vivo counters are calibrated by means of a phantom containing a source or sources traceable to the Radiation Protection Bureau (RPB) of Health Canada. For accurate calibration at gamma energies below 100 keV, the phantom must be constructed of tissue-equivalent material and must be anthropomorphic. For gamma energies above 100 keV, acceptable phantoms can be made from other materials. For operators of dosimetry services wishing to perform *in vivo* measurements it will be sufficient to participate in an independent test as discussed in section 3.2.5, below. Then, provided that the measurement system or method remains the same as at the time of the independent test, a daily check with a long-lived check source will serve to confirm the stability of the measurement system. This check source must be of energy similar to that of the radionuclide to be measured and its activity must be determined at the time of the independent test. If the response of the system to the check source changes, or alterations which may affect the calibration are made to the detectors, counting geometry, or the electronics of the

measurement system, then a further independent test is necessary. Even if such changes are not made, independent tests must be carried out on an annual basis so that continuing competence can be demonstrated. Such factors as variation of source distribution within the phantom, variations in ambient background and positioning error shall be taken into account where applicable.

For acceptability, the mean relative bias determined through independent testing, as defined in section 2, must be between -0.25 and +0.50. The same relative bias and precision should be used for radionuclides not in Table 2. Also, for practical reasons there are no criteria given in Table 2 for the relative precision.

TABLE 2
Minimum Detectable Amounts for Selected Radionuclides

Radionuclide	***In Vitro*** **(Bq/L)**	***In Vivo*** **(Bq)**
Hydrogen-3 (HTO)	400	N/A
Technetium-99m	N/A	5×10^4
Iodine-125	4	100
Iodine-131	4	100
Carbon-14	70	1.5×10^7 (lung)
Cesium-137	4	400
Americium-241	0.01	20 (lung)
Iron-59	N/A	500
Cobalt-60	5	500
Strontium-90	0.4	N/A
Zirconium/ Niobium-95	N/A	400
Cerium-144	100	1×10^4
Natural uranium	5 µg/L	4 mg (lung)

3.2.5 Independent Testing in Internal Dosimetry

Prior to being granted AECB approval and at a frequency of at least annually, an internal dosimetry service must undergo independent testing [see section 4.3.10(b)]. These tests are normally to be performed through the National Calibration Reference Centre for Bioassay and *In Vivo* Monitoring of RPB, which is recognized by the AECB as the Reference Calibration Centre for *in vitro* (bioassay) and *in vivo* monitoring in Canada. If the required intercomparison program is not offered by the National Calibration Reference Centre and prior authorization is granted by the AECB, an applicant may fulfil its independent testing specification through a different organization. Independent tests are discussed in Appendix B. A dosimetry service seeking AECB approval must pass the independent tests prior to being approved. If any of the performance specifications are not met in a given test, that test constitutes a failure. If a dosimetry service which has already been approved by the AECB fails one of these tests, the reason for the failure must be immediately investigated and corrective action taken. If repetition of the test results in a second consecutive failure, the AECB may withdraw the service's approval. A dosimetry service whose approval has been withdrawn may have it re-instated once it has demonstrated that it can meet the specifications in this document.

It should be noted that independent test results for a dosimetry service are treated as confidential and will be reported only to the dosimetry service by RPB. The dosimetry service will be requested to report the results of the independent testing to the AECB. The dosimetry service is, of course, free to publicize its own results if it wishes. If a request for release of these results is made under the *Access to Information Act*, the disclosure of the information will be subject to the applicable process for the protection of personal or confidential information.

3.3 Dosimetry Services for Radon Progeny and Long-Lived Radioactive Dust

The objective of monitoring for radon progeny and long-lived radioactive dust is to estimate individual exposures to radon progeny and intakes of long-lived radioactive dust (LLRD) for the workers in uranium processing facilities. This has been done either by grab sampling measurements combined with occupancy time records, or by personal monitoring. In AECB-licensed uranium processing facilities, the monitoring for radon progeny and LLRD must be done using personal monitors unless it can be demonstrated that exposures can be determined, with the necessary level of accuracy, by other means proposed by the licensee.

3.3.1 Units of Measurement

The quantities of interest in this section of this document are:

i) the concentration in air of radon potential alpha energy from short-lived radon progeny;

ii) the exposure to airborne short-lived radon progeny, and

iii) the concentration in air of long-lived radioactive dust.

There are historical and SI (Système international d'unités), 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 brackets.

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}):

1 WL = 20.8 μJ m^{-3}
1 μJ m^{-3} = 4.8 × 10^{-2} 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}):

1 WLM = 3.54 mJ h m^{-3}
1 mJ h m^{-3} = 0.283 WLM

The concentration of LLRD in air is measured in activity per unit volume of that atmosphere, *i.e.*, Bq m^{-3}.

3.3.2 Minimum Measurable Exposure

A dosimetry service must determine the lowest concentration or exposure which it can measure at the 95% confidence level. This information must be included in the application for approval for each type of air contaminant. The minimum measurable exposure shall be expressed in the same units as the measured quantity.

3.3.3 Radon Progeny Measurements

In Tables 3 and 4, below, the column title "Overall Accuracy (95% Confidence)" means that under the expected conditions of use, the monitoring systems used to evaluate concentrations of, or exposures to radon progeny must be able to produce values within the indicated limits from the true values 95% of the time. In other words, 95% of the values obtained in a series of measurements taken in an environment with stable and fixed concentration should fall within the confidence interval limits. This accuracy must take into account all uncertainties under all the anticipated environmental conditions of use (*e.g.*, ambient temperature, dust levels, vibration, impact, etc.) which may have a bearing on the accuracy of measurement. All the properties of the personal monitoring system which have a bearing on accuracy must all be taken into account

when determining the overall accuracy. This accuracy must be met over the entire range of concentrations of radon progeny indicated in Tables 3 and 4. In addition, the lower and upper limits of the range of exposure that a specific piece of equipment can cover must be indicated by the dosimetry service.

The performance of personal monitors with respect to measurement accuracy must be demonstrated through a type testing exercise (see section 2, above). In addition to establishing a personal monitor's overall accuracy, type testing also establishes the limitations of the device, such as conditions which 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, etc.

3.3.3.1 Accuracy Specifications and Uncertainty Limits in the Measurement of Exposure to Radon Progeny

Personal monitors provide a direct measurement of exposure to radon progeny over a determined period of time. Therefore the accuracy specification concerns the exposure value given from the reading of the personal monitor. Table 3 gives the accuracy specifications for a one-month dosimetry period. When a different dosimetry period is used, the ranges of measurement must be pro-rated accordingly.

TABLE 3
Performance Specifications for Measurement of Exposure to Radon Progeny for a One-Month Period

Range of Measurement	Overall Accuracy (95% Confidence)
< 0.03 WLM (106 µJ h m^{-3})	No accuracy specifications
0.05 WLM (177 µJ h m^{-3})	+100% / -50%
≥ 0.10 WLM (354 µJ h m^{-3})	+50% / -33%

3.3.3.2 Accuracy Specifications and Uncertainty Limits in the Measurement of the Concentration in Air of the Potential Alpha Energy of Short-Lived Radon Progeny

Grab sampling measurements are used to estimate individual exposures when a licensee can demonstrate that personal samplers are not practical and that the necessary level of accuracy can be achieved without personal monitors. In this case,

accuracy specifications are set for the concentration in the air of potential alpha energy contained in radon progeny. These specifications are given in Table 4.

TABLE 4
Performance Specifications for Measurement of Concentration of Potential Alpha Energy in Air

Range of Measurement	Overall Accuracy (95% Confidence)
< 0.03 WL (0.62 µJ m^{-3})	No accuracy specifications
0.05 WL (1.04 µJ m^{-3})	+100% / -50%
≥ 0.10 WL (2.08 µJ m^{-3})	+50% / -33%

3.3.3.3 Type Testing for Radon Progeny Measuring Instruments

Two categories of instruments are used to monitor individual exposures to radon progeny: personal monitors, which give a direct estimation of individual exposures, and 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.

Type testing for instruments used to determine exposures to radon progeny (personal monitors) will identify all possible sources of error and will quantify their contribution to the overall error and uncertainty in individual exposures.

Type testing for grab sampling radon instruments will only identify and quantify all possible sources that contribute to the overall error and uncertainty in measured instantaneous radon progeny concentrations. Errors and uncertainties in actual personal exposures which are derived from grab sampling measurements are excluded.

In type testing, the following influence quantities should be considered, and those that are likely to have a significant effect on accuracy or uncertainty should be evaluated. This list is not exhaustive. Other influence quantities that may contribute to the overall uncertainty must also be considered, *i.e.*, only influence quantities contributing to the uncertainty of the measurement must be taken into account.

i) Personal Monitors

For personal monitors, the following quantities should be taken into account.

a) Sampling Parameters

- < duration of operation at design performance at full charge of the battery
- < sampling flow rate
- < flow rate variability
- < influence of particle size distribution, and particularly unattached fraction of radon progeny on sampling efficiency

b) Detection and Counting Parameters

- < filter-detector geometry
- < energy-dependent detection efficiency
- < sensitivity to radiation emitted from sources other than radon progeny
- < sensitivity to deviations from detector processing specifications
- < sensitivity to time variability of radon progeny concentrations

ii) Grab Sampling Instruments

- < sampling flow rate
- < flow rate variability
- < sensitivity to particle size distribution, and particularly unattached fraction of radon progeny in the test atmosphere
- < calibration and stability of field alpha counters
- < the method used to calculate radon progeny concentrations

3.3.3.4 Independent Testing for the Monitoring of Radon Progeny

Prior to being granted AECB approval, a dosimetry service must successfully undergo independent testing [see section 4.3.10(b)]. These tests are normally to be performed through the Bowser Morner laboratory which is recognized by the AECB as the Reference Calibration Centre for the monitoring of radon progeny in Canada. Alternatively, if prior authorization is granted by the AECB, an applicant may fulfil its independent testing specification through a different organization. The independent testing specifications applying to dosimetry services which determine radon progeny exposures are discussed in Appendix C.

3.3.4 LLRD Measurements

Estimates of intakes of LLRD are derived from concentration measurements, the duration of exposure, and an assumed volume of air breathed by the worker during the monitoring period. It is assumed that there is no uncertainty in the duration of the monitoring or sampling period nor in the volume of air breathed by the worker. With personal monitors, the average concentration of LLRD in air is calculated from the total long-lived alpha activity measured on the monitor's filter and the volume of air sampled over the monitoring period.

Since there exists no standard nor reference facility for dust measurement, radioactive or not, there is no specification for independent testing. However, the accuracy of LLRD measurements can be assessed from the quality and reliability of the sampling and counting systems used. Sampling procedures considered to be reliable by industrial hygienists would also be considered to be adequate for sampling airborne LLRD, provided their reliability is supported by appropriate references. The overall uncertainty in LLRD measurements will be determined from the combination of all the uncertainties in all the parameters used to derive the LLRD concentration from the alpha activity measured on the monitor's filter. The dosimetry services shall demonstrate that standard good practices expected in routine industrial hygiene monitoring are followed in the measurement of LLRD concentration in air. In particular, the flow rate of sampling pumps must not deviate by more than 5% from the value used to calculate concentration.

Since all inhaled radionuclides, whatever the size of the carrier particle, contribute ultimately to the committed dose, samples used to collect dust must be, to the greatest extent possible, size-insensitive. This excludes the use of cyclones to collect and measure airborne radioactive dust.

3.3.4.1 Minimum Measurement Level

The Annual Limit of Intake (ALI), and consequently the Derived Air Concentration (DAC), for LLRD depend on the physical and chemical characteristics of the radioactive material being extracted or handled. Therefore, ALI and DAC values will be either a conservative default value or site-specific. In uranium mines and mills, the lowest ALI values will be for uranium ore, as opposed to those for uranium concentrate and tailings, because all the radionuclides of the uranium decay series are present in the ore dust and will contribute to the committed dose.

The concentration of LLRD in mine atmospheres is generally low, of the order of at most tens of mBq/m^3, and currently available sampling techniques draw air volumes of the order of less than 1 m^3 per sample. Therefore, the activity measured on a sample filter will generally be of the same order as the background count rate of alpha counters. Furthermore, for lack of standards and reference facilities, it is not possible to determine, unambiguously, the collection efficiency of sampling trains

under actual workplace conditions. These considerations place constraints and limitations on the setting of minimum measurement levels for radioactive dust in general, and for uranium ore dust in particular.

Due to the small activity emitted by a sample filter, statistical uncertainties in counting will be the main source of error, notwithstanding the unknown errors in sampling efficiency. Taking these practical limitations into consideration, the minimum LLRD concentration that a dosimetry service will need to measure is 10% of a default DAC value for uranium ore dust, that is 1.167 Bq m^{-3}; site-specific DACs are greater than this default value. The statistical method used to estimate uncertainties in counting, and an example of the determination of the minimum measurable LLRD concentration are given below.

3.3.4.2 Example Calculations

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% of the time (Ballot 1982).

$$Lower\ limit = (N_2 - N_1) - 1.96\sqrt{N_2 + N_1} + 1$$

$$Upper\ limit = (N_2 - N_1) + 1.96\sqrt{N_2 + N_1} + 1$$

where N_1 = background count, for the sample counting time
N_2 = total count
N = $N_2 - N_1$ = net count

with a default ALI for uranium ore dust of 2 800 Bq;
a default DAC of 1.167 Bq m^{-3};
a sampling rate of 2.5 L min^{-1} (2.5×10^{-3} m^3 min^{-1});
a duration of sampling of 6 hours;
a counting efficiency of 0.4;
a background count rate of 1 cpm;

and when the LLRD concentration is 1/10 of the default DAC (*i.e.*, 0.1167 Bq m^{-3}),

the activity collected on the filter is

$$0.1167\ Bq\ m^{-3} \times 2.5 \times 10^{-3}\ m^3\ min^{-1} \times 60\ min\ h^{-1} \times 6\ h = 0.105\ Bq$$

and the total count rate (sample plus background) is

$$1 \text{ cpm} + (60 \text{ s min}^{-1} \times 0.105 \text{ Bq} \times 0.4) = 3.52 \text{ cpm.}$$

If both the background and the sample are counted for 20 minutes, then the background count is 20, and the sample count (total count) is $20 \times 3.52 =$ 70 (rounded to the nearest integer)

Solving the above equations with the above values, *i.e.*, with $N_1 = 20$ and $N_2 = 70$, one obtains:

lower limit of the 95% confidence interval: 30;

upper limit of the 95% confidence interval: 70.

Therefore, there is a 95% probability that the true count is larger than 30, and smaller than 70.

Since 50 is the best estimate of the true count, there is a 95% probability that the uncertainty in the LLRD concentration measurement lies within - (50 - 30)/50 and + (70 - 50)/50, that is within ± 40%.

3.3.4.3 Type Testing for LLRD Measurements

Type testing methods, criteria and facilities are not currently available for LLRD measurements. Sampling procedures considered to be reliable by industrial hygienists would be considered to be adequate for sampling airborne LLRD, provided their reliability is supported by appropriate references.

3.3.4.4 Independent Testing for LLRD Measurements

Testing facilities are not currently available for LLRD measurements, and therefore no independent testing specifications are specified. However, the LLRD measurement procedures will be reviewed, at least annually, by AECB inspectors.

4 QUALITY ASSURANCE SPECIFICATIONS

4.1 General

Quality assurance programs addressing the elements listed in Appendix G are necessary for operators and users of dosimetry services.

Quality in a dosimetry service relates to the accuracy with which measurements of effective dose to monitored individuals and the recorded results conform to technical standards. The objective of a program to assure quality is to implement a systematic process which will engender confidence that the results are accurate, conform to specifications and retrievable,and can be verified.

The basic specifications of a quality assurance program involve identifying what has to be done, planning how to do it, doing what has been planned, and being able to demonstrate that it has been done correctly with satisfactory results. This requires:

(a) strategic activities by management (*i.e.*, the establishment and identification of management policies and specifications), and the communication of these to the line organization, and

(b) tactical activities by staff (*i.e.*, implementing the means to ensure compliance with management policies and standards), to achieve quality.

Management's method of communication is the quality assurance program manual; the means of ensuring compliance with management policies and standards is the quality assurance programmatic procedure. The achievement of quality follows from performing the work in accordance with appropriate work procedures and instructions. The first step to assuring quality, therefore, involves preparing and documenting the quality assurance program; appendix E shows the most frequently used approach. Then the controls needed must be implemented and their effectiveness monitored. This document adapts accepted quality assurance principles specifically to dosimetry.

4.2 Establishing the Quality Assurance Program

The first step towards establishing the quality assurance program is to review the work and work processes which have to be performed and to identify those aspects of the work which bear most importantly on the desired and required results. A specific quality assurance program can only be defined in terms of the control specifications which are to be applied to the work which has to be done. This of course means that the scope of work to be performed by individual organizational elements should be fully identified, before each can determine its contribution to the quality assurance program. Appendix F illustrates a suggested process for users to follow to establish a dosimetry quality assurance program.

In general, therefore, the less important, the less complicated, the less extensive the work, the less comprehensive the corresponding quality assurance program. However, users and operators of a dosimetry service must demonstrate that the specifications of Appendix G are being met.

4.3 Quality Assurance Program Specifications

In the following sections, the symbol [u] in front of a specification indicates that the specification applies to users as well as to dosimetry service operators. This is summarized in Appendix G.

4.3.1 Management Policy

[u] (1) Operator and user management shall document its policy regarding quality and the roles and responsibilities of the organization within the dosimetry program.

(2) A policy statement shall be issued by the senior management representative of the operator's organization committing the organization to operate according to the specifications contained in the quality assurance program, and to regularly review its adequacy and continuing suitability. Any planned departure from the prescribed standards must be approved by management.

4.3.2 Review by Management

(1) Management shall perform self-assessments, on an on-going basis, to determine the status and the adequacy of the quality assurance program and to ensure its continuing suitability and effectiveness in meeting standards and objectives.

(2) In addition, senior management shall conduct an annual review to determine that processes are optimized, under control, and produce accurate results which conform to specifications. Sources of information for the annual review shall include, for example:

(a) analyses of inspection and test results;
(b) analyses of non-conformances (frequency, significance, consequence, cause, accountability) of corresponding preventive measures, and of deficiency trends;
(c) analyses of results from independent assessments;
(d) effectiveness of preventive measures, and
(e) complaints and implementation problems or errors.

4.3.3 Organization and Authority

A plan detailing the organizational structure, the functional responsibilities, the levels of authority and the lines of internal and external communications is required, showing that:

(a) those responsible for achieving quality are those who have been assigned responsibility for performing the work;

(b) persons verifying that quality specifications are met are not those directly responsible for performing the work. Sufficient authority is assigned to them to enable them to ensure that specifications are satisfied. Supervisors may carry out verification activities provided they have not taken part in or contributed to the performance of the work, and

[u] (c) management has appointed an individual who is 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.

4.3.4 Personnel Qualifications

[u] (a) All personnel performing dosimetry service activities, including those described in section 4.3, shall have the training, qualifications and competence necessary to perform their assigned tasks effectively. Standards of training, qualification and competence shall be set by the dosimetry service and the user and are subject to AECB or Provincial Radiation Dosimetry Review Committee (PRDRC) review on request.

(b) The individual with responsibility for the dosimetry service shall be named and a resume of qualifications, training and experience shall be maintained.

4.3.5 Procurement

The purchasing of equipment and material necessary for accurate dose or exposure measurement shall be controlled by procedures established by the operator. Such procedures must include:

(a) preparation of a clear description of the item via a requirement or technical data sheet that includes, *e.g.*, measuring accuracy and repeatability, inspection and testing specifications, acceptance criteria, and recording specifications;

(b) a method of determining the quality assurance program specifications that the supplier must meet to satisfy the specifications in (a), above;

(c) evaluation and selection of suppliers based on their ability to meet specifications; and

(d) verification that the specifications in (a), above, have been met.

4.3.6 Work Control

Reliable means of measuring, counting, analyzing and calculating, and maintaining traceability of data to the individual shall be implemented.

[u] (1) All work or activities which 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 which provide details of, for example:

(a) work methods and sequence;
(b) equipment to be used and special working environments;
(c) acceptance criteria;
(d) inspection points, and
(e) logging specifications.

[u] (2) Such procedures shall control the preservation of identification through marking and number control of dosimeters, samples, measurements, dose records, and other data on which dose is based, and maintaining their traceability to the individuals concerned.

[u] (3) Such 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 prescribed.

(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.

[u] (5) The method of transferring dose data to dose records to meet the specifications of Appendix D and communicating with the National Dose Registry (NDR) of the Radiation Protection Bureau, shall be prescribed.

4.3.7 Change Control

(1) Procedures shall be implemented to ensure that proposed changes to techniques and methods of measuring and counting, including models, and in interpreting the results are reviewed and approved, prior to their implementation, by the individuals or organizational group who reviewed and approved the originals.

[u] (2) Procedures shall prescribe standards to ensure that changes to dose records are properly documented. If a user, or operator, wishes to alter a dose record, that user or operator must first seek the approval of AECB or PRDRC staff. Once the regulatory authority has granted the approval the individual must be informed of the correction, and the reason for it, by the initiator of the change request. The changes, if approved by the regulatory authority, will then be communicated to the NDR by AECB or PRDRC staff.

[u] (3) Where changes involve a revision to approved procedures and instructions, the specifications of section 4.3.8 shall be met.

4.3.8 Document Control

[u] Procedures shall be established for the preparation, review, approval, issue, distribution, and revision of documents and procedures. This includes particularly those documents and procedures which contain technical specifications or prescribe activities for the achievement and verification of technical specifications. Examples are technical standards, dosimetry manual, specifications and procedures for dose records, operating procedures, software programs, calibration techniques, and analytical methods (refer to Appendix E). It also includes the quality assurance program procedures. Provisions shall be made to remove obsolete documents from use and to have current documents available at the locations where the activities which they cover are to be performed.

4.3.9 Calibration

When the validity of dose data is dependent on the accuracy of recording, measuring, testing, analyzing or counting devices, instruments or standards, all such equipment shall be controlled and maintained, and shall be of a type, sensitivity and accuracy to meet the appropriate minimum specifications set out in section 3.

The quality assurance program procedures shall require:

(a) the implementation of instructions describing the calibration methods and acceptance criteria;

(b) periodic calibration based on the necessary accuracy, purpose, degree of usage, stability characteristics, and other factors affecting measurement control;

(c) that all measuring and counting equipment be identified and that calibrations be traceable to approved reference standards;

(d) that the calibration status be recorded and maintained (*e.g.*, by tags, labels and cards). When calibration is performed before use or with a high frequency (*e.g.*, daily), logging of calibrations may be sufficient;

(e) that inaccurate or uncalibrated equipment be removed from use and that reviews be conducted to determine the validity of data or results when the equipment used is found to be inaccurate, and

(f) that equipment requiring consistency checks prior to use be identified.

4.3.10 Verification

Appropriate inspections, checks and reviews shall be performed to verify that work is performed [see sections 4.3.6(1) to (4)] in an acceptable manner. Such verification shall be accomplished in accordance with prescribed standards and, at a minimum, consist of the following:

[u] (a) inspecting dosimeters/plaques and samples before shipment and upon receipt to ensure that they have been correctly identified and protected and are in satisfactory condition;

(b) performing prescribed tests during the measuring process, to ensure that reading and counting equipment are functioning satisfactorily, that all devices (*e.g.*, dosimeters, air sampling pumps), are in good working order and that procedures have been followed in order to give confidence in the reliability of the dose data. Such testing may involve comparisons with pre-established norms of equipment performance and previously reported data. In addition, the operator must participate in independent tests as described in section 3. Discrepancies shall be processed according to the specifications given in 4.3.11 and 4.3.12. The AECB or the PRDRC may also require performance monitoring to be carried out.

(c) Reviewing and checking data, calculations and the logging of entries to ensure that doses are correct and are attributed to the right individuals.

[u] (d) Appraising dose data to determine whether they are reasonable estimates for the individual considering the nature, location and duration of the work performed and are consistent with the doses estimated before the work was performed. If

discrepancies are identified by this appraisal, then an investigation shall be conducted by a specialist in radiation protection. This may involve the individual himself and his supervisor; comparisons may be made with the exposures, uptakes or dose received in previous periods when similar work was done or with that received by other workers doing similar jobs, and, in the case of external dosimetry services, further comparisons may be possible if a separate dosimetry system is used for dose control purposes (*e.g.*, direct-reading dosimeters worn in conjunction with a thermoluminescence dosimetry badge). It is appropriate also to verify that comparisons have been made to determine whether accumulated doses exceed regulatory limits or administrative control levels.

[u] (e) Checking final dose records to ensure that they are accurate and acceptable.

4.3.11 Non-Conformance

[u] 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. Procedures shall be implemented for reporting and remedying all non-conformances and correcting their causes. Backup arrangements in case of equipment (or other) failure or error shall be described.

4.3.12 Corrective Action

[u] Procedures shall be implemented to ensure that the cause of significant non-conformances is determined and corrective action taken to prevent repetition. Significant non-conformances are those which lead to, or could lead to, an undetected overexposure, a wrong dose being assigned to an individual, or a dose being assigned to the wrong person. The cause and the subsequent corrective action shall be reported to the appropriate level of management, and follow-up reviews conducted to verify proper implementation of the corrective action.

4.3.13 Records

[u] (1) Records shall be prepared and retained as evidence of the satisfactory accomplishment of specified activities and the acceptability of results. Sufficient records shall be retained to support final conclusions and to show traceability.

[u] (2) Records include, for example, dosimeter, sample and personnel data and identification; evidence of the accomplishment of verifications confirming the

acceptability of results and data accuracy; personnel qualifications; non-conformance and corrective action reports.

(3) Also included are, for example, instrument performance data; calibration certificates; calculations and calculation checks; assessment reports.

(4) Sufficient records and documentation shall be prepared during the work process to enable reasonable re-creation and checking of results from the referenced input data. They shall be readily identifiable, retrievable, and stored in such a manner as to permit suitable protection from deterioration and damage.

[u] (5) Records shall be retained by the licensee which meet one or more of the following objectives:

(a) to furnish objective evidence of satisfactory operation;
(b) to permit verification of the technical evaluation of dose data, and
(c) to demonstrate compliance with regulatory dose limits.

[u] (6) A list of records that relate to the certified operation shall be given.

[u] (7) Dose records are dealt with in Appendix D.

4.3.14 Independent Assessments

Planned and periodic independent assessments shall be carried out for management to determine that management procedures are being implemented and result in satisfactory performance of the Dosimetry Service. Such assessments shall be planned and performed by appropriately trained personnel not having direct responsibility for the activity being assessed.

Results shall be documented, and reviewed by the person responsible for the activity which has been assessed. This person shall take action to correct any deficiencies found. Follow-up action including reassessment shall be taken where appropriate.

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APPENDIX A
Independent Test Specifications for Dosimetry Services: External Gamma Radiation

A1 Introduction

In addition to the in-house quality assurance program described in section 4, there is a specification for independent testing which is described in section 3.1.6 and also referred to in section 4.3.10. Independent testing of a service's dosimeters helps the dosimetry service operator to demonstrate to the appropriate clientele (*e.g.*, employees, customers) and the AECB that the service's results are reliable.

The National Research Council of Canada (NRC) is recognized by the AECB as the Reference Calibration Centre for the dosimetry of external radiation in Canada. Dosimetry services which are ready to undergo independent testing must make arrangements directly with NRC staff. Dosimetry services using dosimeters which require processing, *e.g.*, TLDs, must follow the protocol outlined in section A2, below. Dosimetry services using dosimeters which do not require processing, *e.g.*, electronic dosimeters, must follow the protocol outlined in section A3, below. Although air kerma units are used below, corresponding exposure units may also be used, if preferred by the dosimetry service, in consultation with NRC staff.

A2 Protocol for Dosimeters Which Require Processing

(a) At regular intervals and at a frequency of at least annually, or otherwise in consultation with the AECB, each dosimetry service shall send to the Ionizing Radiation Standards Section of the Institute for National Measurement Standards, NRC (see address below) at least 50 identified dosimeters per processing unit being tested plus sufficient control dosimeters to satisfy the readout process. For each unit being tested, NRC staff will then 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 ^{60}Co photon beam to a different but known air kerma between 1.0 mGy and 50 mGy. The air kerma delivered to the dosimeters will not be revealed at this time to the dosimetry service.

(b) 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 air kerma units will then reported to NRC by the dosimetry service.

(c) NRC will compare the reported results with the NRC values of air kerma. The results (giving both the service's and NRC's values) will be reported to the AECB (see address below) by the NRC, with a copy to the dosimetry service. In order to pass this test, the reported results must lie within the criteria described in section 3.1.6.

A3 Protocol for Dosimeters Which Do Not Require Processing

(a) Where necessary, a dosimetry service using dosimeters which do not need processing must determine a factor to convert from $H_p(10)$, as measured by the dosimeters on a phantom, to air kerma free-in-air (or exposure free-in-air) due to ^{60}Co gamma radiation. This is necessary since the irradiations done at NRC are free-in-air.

(b) At regular intervals and at a frequency of at least annually, or otherwise in consultation with the AECB, each dosimetry service shall send at least 10 identified dosimeters to the Ionizing Radiation Standards Section of the Institute for National Measurement Standards, NRC (see address below). NRC staff will then irradiate at least 10 groups of at least five dosimeters each, free in air, in a ^{60}Co photon beam to different but known air kermas of between 1.0 mGy and 50 mGy. The dosimeters in each group of five will either be exposed to the same air kerma or to different air kermas but within a similar range. This will result in a total of at least 50 readings that will be recorded by NRC staff. In view of the number of dosimeters involved in this case, this means that any given dosimeter may be irradiated several times.

(c) NRC staff will correct the dosimeter readings using the conversion factors determined in (a), above and compare the results with the NRC values of air kerma. The results (giving both the participant's and NRC's values) will be reported to the AECB (see address below) by the NRC, with a copy to the dosimetry service. The dosimeters will be returned to the dosimetry service when all irradiations are completed. In order to pass this test, reported results must lie within the criteria described in section 3.1.6.

NRC staff will report the test results to the AECB at the following address:

Health Physicist - External Dosimetry
Radiation and Environmental Protection Division
Atomic Energy Control Board
P.O. Box 1046, Station B
Ottawa, Ontario K1P 5S9
CANADA

Further details on this test may be obtained from:

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

APPENDIX B
Independent Test Specifications for Dosimetry Services: Internal Radiation

B1 Introduction

In addition to the in-house quality assurance program described in section 4, there is a specification for independent testing referred to in sections 3.2.5 and 4.3.10. Independent testing enables the dosimetry service operator to demonstrate to the appropriate clientele (*e.g.*, employees, customers) and to the AECB, that the service's results are reliable and meet the specifications of this document. As noted in section 3.2.5, independent testing must be done through the Reference Calibration Centre.

The National Calibration Reference Centre for Bioassay and *In Vivo* Monitoring of the Radiation Protection Bureau (RPB) of Health Canada is recognized by the AECB as the Reference Calibration Centre for *in vitro* (bioassay) and *in vivo* monitoring in Canada. The National Calibration Reference Centre conducts the independent testing through an intercomparison program. Dosimetry services which are ready to undergo independent testing must make arrangements directly with RPB staff.

Once the testing is completed and the results have been analyzed, a report containing the identity of each participating laboratory and its corresponding performance results is submitted annually to the AECB by RPB staff. A report in which the identities of the laboratories are not included but replaced by a code is submitted to each participating laboratory.

B2 *In Vitro* Intercomparison

At a frequency of at least annually, each participating laboratory is supplied by the RPB with appropriate samples and blanks. Dosimetry services participate for each of the applicable radionuclides: H-3, C-14, fission and activation products, uranium. The samples are analyzed by the participating laboratory according to a schedule furnished by the RPB. Results are entered on a standard reporting form and returned to the RPB. When all laboratories have responded, the results are analyzed and a report issued, with each laboratory identified only by a code letter. Each laboratory is informed of its own code letter, and the AECB is informed of all the participating laboratories' code letters.

Further details of the intercomparison and the method of analysis may be obtained from RPB. If the results are within the limits of section 3.2, the quality of the service is satisfactory.

Dosimetry services must participate in these intercomparisons and obtain passing results prior to receiving AECB approval, and at least once per year thereafter in order to demonstrate continuing capability.

B3 *In Vivo* Measurement Intercomparison

The RPB has tissue equivalent phantoms available for a variety of radionuclides in the lung, ^{125}I and ^{131}I thyroid neck phantoms, and water-filled BOMAB (BOttle MAnikin ABsorption) phantoms of varying size for higher gamma energies. Further details may be obtained from RPB.

If the results of the intercomparison are within the limits specified in section 3.2, the quality of the service is satisfactory. A dosimetry service must participate in intercomparisons prior to being granted AECB approval and at least once per year thereafter. The procedure must be repeated if any changes are made to the measurement method or equipment.

RPB staff will report the intercomparison results to the AECB at the following address:

Health Physicist - Internal Dosimetry
Radiation and Environmental Protection Division
Atomic Energy Control Board
P.O. Box 1046, Station B
Ottawa, Ontario K1P 5S9
CANADA

Further details may be obtained from:

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

APPENDIX C
Independent Test Specifications for Dosimetry Services: Radon Progeny

C1 Introduction

In addition to the in-house quality assurance program described in section 4, there is a specification for independent testing referred to in sections 3.3.3.4 and 4.3.10. This may be achieved by means of an intercomparison program, which enables the operator of the service to demonstrate to the appropriate clientele (*e.g.*, employees, customers) and the AECB, that the service's results are reliable.

Bowser Morner and the Environmental Measurements Laboratory (EML) of the U.S. Department of Energy operate calibration services which are recognized by the AECB as Reference Calibration Centres for instruments used by dosimetry services for radon progeny. EML is only to be used for services not provided by Bowser Morner.

C2 Protocol for Personal Monitors

The dosimetry service should send a representative sample of its personal monitors to the Reference Calibration Centre every six months, or at other frequencies approved by the AECB, and also following any changes in design which could affect their performance. The instruments sent must be clean and uncontaminated, and in working order. The overall performance of a given system must be such that the accuracy specifications in Table 3 of section 3.3 are met. The Reference Calibration Centre must be contacted before instruments are sent, to arrange suitable scheduling.

C3 Grab Sampling

Dosimetry services that use grab sampling to determine personal exposures shall send an appropriate number of its sampling teams, with the instruments they use routinely, to participate in scheduled intercomparison and calibration exercises held at EML. The overall performance of the instruments must be such that the accuracy specifications in Table 4 of section 3.3 are met.

A certificate of performance will be issued by the laboratory for instruments which meet the specifications given in section 3.3.

Further details of this service may be obtained from the following, as appropriate:

Director
Radiological Services Division
Bowser Morner
4518 Taylorsville Road
P.O. Box 51
Dayton, OH 45401-0051
U.S.A.

Senior Research Scientist
Environmental Measurements Laboratory
Department of Energy
201 Varick Street
New York, NY 10014-3621
U.S.A.

APPENDIX D
Specifications for Dose Records

D1 Introduction

The principal purpose of submitting dose records to the National Dose Registry (NDR) is to satisfy the regulatory requirements of the AECB. Other uses include Provincial Radiation Dosimetry Review Committee (PRDRC) specifications, use in Workmen's Compensation claims and litigation, and basic data for epidemiological studies. All dosimetry services must submit dose data on a regular basis to the NDR and without undue delay. Operators of such services must ensure that the data to be transmitted to the NDR are in an acceptable format. The specifications that follow are designed to meet minimum AECB and PRDRC regulatory standards only. Additional specifications regarding dose records may be communicated to dosimetry service operators in the future.

D2 Individual Identification

An unambiguous individual identification is required; therefore, some redundancy is necessary. The minimum information required is:

(a) SIN (Social Insurance Number);
(b) Surname/previous surnames;
(c) First given name (formal form, not nickname);
(d) Second given name (formal form, not nickname);
(e) Sex;
(f) Date of birth (Year/Month/Day);
(g) Place of birth (Province, if born in Canada, or country, if born outside Canada);
(h) Individual occupational codes or classifications.

D3 Dose Data

D3.1 Dose from External Sources

This shall be recorded as effective dose, except in specific instances where additional data such as extremity dose is required by conditions in the user's licence.

D3.2 Dose from Internal Sources

Dose estimates from internal sources other than those given in section 3.3 are to be reported to the NDR as committed effective dose and the radioisotope responsible for the the dose must also be reported.

D3.3 Exposures to Radon Progeny and Intakes of Long-Lived Radioactive Dust

Exposures to radon progeny shall be recorded in working level months (WLM). Intakes of long-lived radioactive dust shall be recorded in Bq of alpha activity.

D4 Supporting Information

In addition to the dose data, all pertinent data used to generate the dose, exposure or concentration totals shall be retained where appropriate, such as:

(a) readings of personal dosimeters and other data used for measuring external radiation;
(b) measurements of organ burdens;
(c) estimates of intakes of prescribed substances;
(d) method of measurement of concentrations in bioassay samples;
(e) chemical forms;
(f) dosimetry models used;
(g) measurements of radon progeny product concentrations in air;
(h) time spent by individuals in specific locations of a mine.

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

D5 Changes to Dose Records

If a user wishes to modify a dose record, *i.e.*, a dose magnitude, in the NDR, it shall be done with the approval of AECB or PRDRC staff and with the knowledge of the individual whose dose record is to be changed. The dosimetry service will also be informed of such changes. Refer to section 4.3.7(2) for information regarding changes to dose records requested by the user and also changes initiated by the dosimetry service.

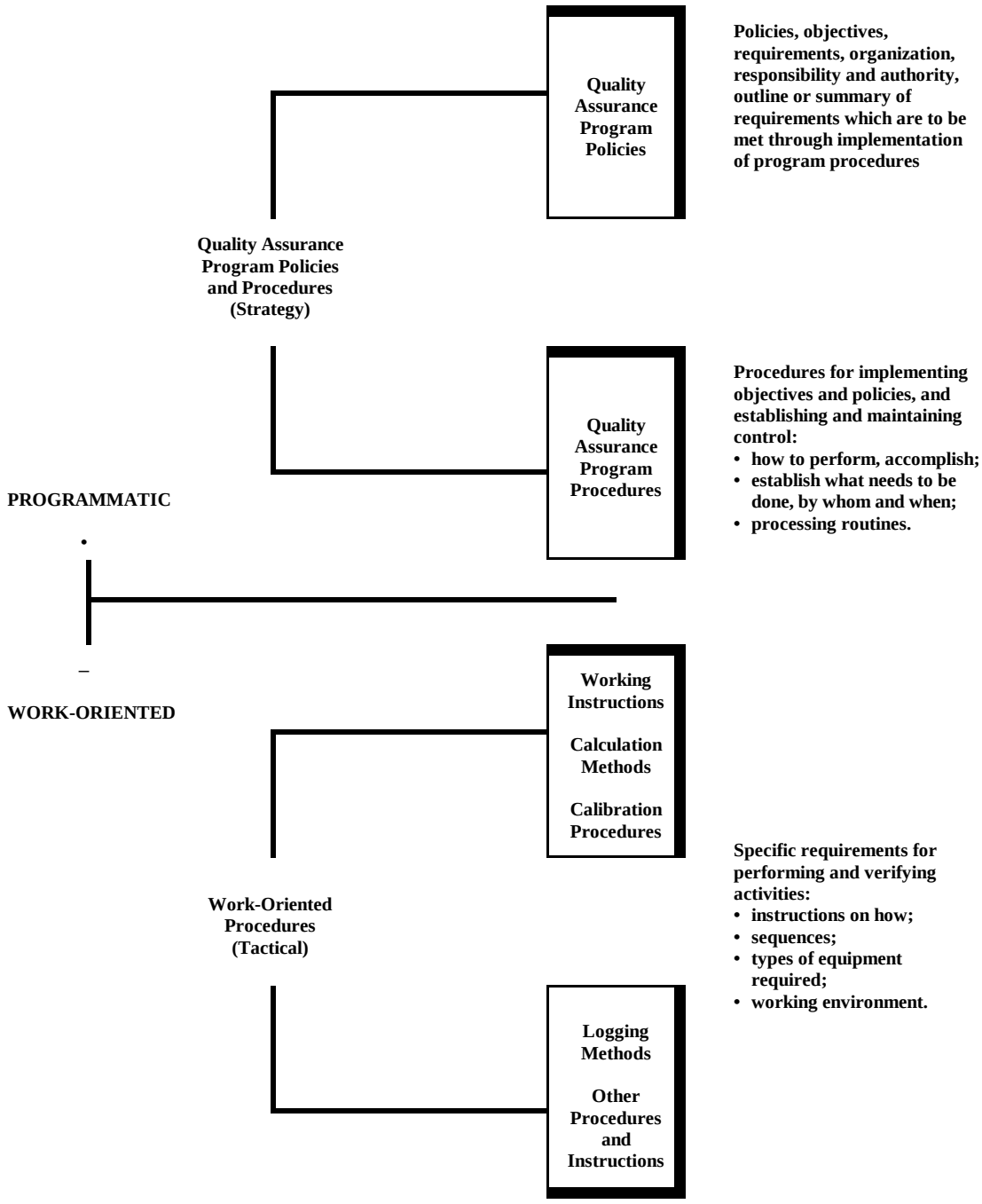
APPENDIX E
Quality Assurance Program Manual and Procedures

The documentation of the quality assurance program is usually structured on two levels; namely strategic and tactical, with the former embodied in Programmatic Policies and Procedures and the latter in Work Planning documents. In broad terms, the strategy is concerned with policy, organization and management, whereas the tactics are concerned with the methods required to implement them. The illustration, below, reflects this concept.

While this illustration represents a logical program structure, other formats may be acceptable provided that the information is arranged in such a fashion that it:

(a) communicates specifications effectively;
(b) demonstrates that all aspects which require control are indeed in control; and
(c) permits regular assessments of program effectiveness by the licensee, the operator and the regulatory body.

For additional information the operator of the dosimetry service and the user may refer to the National Standard of Canada CAN/CSA-Q9000-92 (CSA 1992). Other useful information may be obtained from ISO *Guide 25* (ISO/IEC 1990), provided that it is compatible with the contents of this document. In general, programmatic documentation will be submitted for AECB or Provincial Radiation Dosimetry Review Committee (PRDRC) staff review and approval of the quality assurance program.


Quality Assurance Program Policies
Policies, objectives, requirements, organization, responsibility and authority, outline or summary of requirements which are to be met through implementation of program procedures
Quality Assurance Program Policies and Procedures (Strategy)
Quality Assurance Program Procedures
Procedures for implementing objectives and policies, and establishing and maintaining control:
• how to perform, accomplish;
• establish what needs to be done, by whom and when;
• processing routines.
PROGRAMMATIC
WORK-ORIENTED
Working Instructions
Calculation Methods
Calibration Procedures
Specific requirements for performing and verifying activities:
• instructions on how;
• sequences;
• types of equipment required;
• working environment.
Work-Oriented Procedures (Tactical)
Logging Methods
Other Procedures and Instructions

APPENDIX F
Establishment of a Quality Assurance Program (Ref.: section 4.2)

User of Dosimetry Service

1. Identify full scope of dosimetry program and how it will be subdivided.
2. Identify organizational needs and regulatory requirements.
3. Identify potential commercial operators and the scope of the work.
4. Identify commercial operator's responsibilities and the specifications of his service.
5. Identify *specific* work aspects associated with procuring operator's services and performing in-house work, *e.g.*,
   (a) standards for work to be performed;
   (b) selection of operator of dosimetry service;
   (c) specifications contained in contract;
   (d) receive dosimeters/plaques from operator;
   (e) initiate cross-identification of dosimeters/plaques and samples;
   (f) preparations for dose records system to meet Appendix D specifications;
   (g) control issue, collection of dosimeters/plaques, and taking samples;
   (h) control handling, packaging and shipping of samples and dosimeters/plaques;
   (i) prepare documentation for operator of dosimetry service;
   (j) forward samples and exposed dosimeters/plaques to operator;
   [*Note*: the operator receives the dosimeters/plaques from the user and processes them in accordance with Appendix G and returns the dose data to the user.]
   (k) receive dose data from operator;
   (l) review and appraise dose data;
   (m) review accumulated doses;
   (n) prepare individual dose records according to Appendix D, and
   (o) check final dose records for accuracy and acceptability.

The user's quality assurance program describes specifications associated with performing and verifying the satisfactory accomplishment of *these* activities, and how the user is organized to do so.

Satisfactory performance by the user and good documentation and records are necessary for the operator to meet the specifications contained in Appendix G and for the reliability of the final dose records.

Example: A typical licensee who is the user of a category I service might go through the above process of establishing a quality assurance program. In this case, the user is responsible only for controlling those aspects of his or her own operation which bear on the reliability of the dose data and individual dose records. The consequent quality assurance program will be as above with the corresponding specifications as identified in Appendix G. The program is concerned mainly with the use, identification and handling of dosimeters and the taking of samples, as well as implementing the means of ensuring that the data reported by the dosimetry service is reliable and properly recorded.

APPENDIX G
Quality Assurance Program Specifications for Operators and Users

Elements	Section Reference		Operators	Users
Management Policy	4.3.1	(1)	X	X
		(2)	X	
Review by Management	4.3.2		X	
Organization and Authority	4.3.3	(a)	X	
		(b)	X	
		(c)	X	X
Personnel Qualifications	4.3.4	(a)	X	X
		(b)	X	
Procurement	4.3.5		X	
Work Control	4.3.6	(1)	X	X
		(2)	X	X
		(3)	X	X
		(4)	X	
		(5)	X	X
Change Control	4.3.7	(1)	X	
		(2)	X	X
		(3)	X	X
Document Control	4.3.8		X	X
Calibration	4.3.9		X	**
Verification	4.3.10	(a)	X	X
		(b)	X	
		(c)	X	
		(d)	*	X
		(e)	*	X
Non-Conformance	4.3.11		X	X
Corrective Action	4.3.12		X	X
Records	4.3.13	(1)	X	X
		(2)	X	X
		(3)	X	
		(4)	X	
		(5)	X	X
		(6)	X	X
		(7)	X	X
Independent Assessments	4.3.14		X	

* Category II only.
** Refer to section 3.3.

APPENDIX H

Independent Test Specifications for Dosimetry Services: X Radiation

H1 Introduction

In addition to the in-house quality assurance program described in section 4, there is a specification for independent testing which is described in section 3.1.6 and also referred to in section 4.3.10. This is achieved by means of an independent testing program which enables the dosimetry service operator to demonstrate to the appropriate clientele (*e.g.,* employees, customers) and the Provincial Radiation Dosimetry Review Committee (PRDRC) that the service's results are reliable.

The Institute for National Measurement Standards (INMS) of the National Research Council of Canada (NRC) develops, maintains and disseminates primary standards for the measurement of radiation. The INMS may also act directly as the Reference Calibration Centre for the dosimetry of x radiation. In addition, a laboratory using standards directly traceable to the INMS is recognized by the PRDRC as a reference calibration centre for the dosimetry of x radiation.

Dosimetry services using dosimeters which require processing, *e.g.*, TLDs, must follow the protocol outlined in section H2, below. Dosimetry services using dosimeters which do not require processing, *e.g.*, electronic dosimeters, must follow the protocol outlined in section H3, below.

H2 Protocol for Dosimeters Which Require Processing

(a) At regular intervals and at a frequency of at least annually, or otherwise in consultation with the PRDRC, each dosimetry service shall send, to a reference 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 reference calibration centre conducting the intercomparison will divide the submitted dosimeters into at least 10 groups of at least 5 dosimeters per group. Each group of dosimeters shall be irradiated free-in-air, in an x-ray beam. The x-ray beams used to irradiate the various groups of dosimeters shall be chosen:

(i) with different but known exposure (air kerma) between 3×10^{-5} C/kg (1 mGy to air) and 1.5×10^{-3} C/kg (50 mGy to air); and

(ii) with different but known reference x radiation at 80, 100, 150 and 250 kVcp as defined in the International Standard ISO 4037 Table 2, Narrow Spectrum;

(iii) with known reference x radiation at 30 kVcp and with filtration as defined by the INMS of 1 mm Be and 0.26 mm Al and with a first half value layer of 0.31 mm Al.

The delivered exposures (air kerma) for the irradiated dosimeters will not be revealed at this time to the participants but the kVcp used will be indicated.

(b) The irradiated dosimeters and controls will be returned to the dosimetry service for processing by the established procedures of the service. The results in exposure (air kerma) units are then reported to the Reference Calibration Centre.

(c) The Reference Calibration Centre will compare the reported results with the Reference Calibration Centre values of exposure (air kerma). The results of the independent test (giving both the participant's and the Reference Calibration Centre values) will be reported to the PRDRC (see address below) by the Reference Calibration Centre, with a copy to the participant. In order to pass this test, reported results must lie within the criteria described in section 3.1.6.

H3 Protocol for Dosimeters Which Do Not Require Processing

(a) Where necessary, a dosimetry service using dosimeters which do not need processing must determine a factor to convert from $H_p(10)$, as measured by the dosimeters on a phantom, to exposure free-in-air (or air kerma free-in-air) due to the appropriate x radiation which may be used in this test and which are identified below. This is necessary since the irradiations done at Reference Calibration Centre are free-in-air.

(b) At regular intervals and at a frequency of at least annually, or otherwise in consultation with the PRDRC, each dosimetry service shall send at least 10 identified dosimeters to a reference calibration centre. The Reference Calibration Centre conducting the intercomparison will irradiate at least 10 groups of at least 5 dosimeters per group. Each group of dosimeters shall be irradiated free-in-air in an x-ray beam. The x-ray beams used to irradiate the various groups of dosimeters shall be chosen:

(i) with different but known exposure (air kerma) between 3×10^{-5} C/kg (1 mGy to air) and 1.5×10^{-3} C/kg (50 mGy to air); and

(ii) with different but known reference x radiation at 80, 100, 150 and 250 kVcp as defined in the International Standard ISO 4037 Table 2, Narrow Spectrum;

(iii) with known reference x radiation at 30 kVcp and with filtration as defined by the INMS of 1 mm Be and 0.26 mm Al and with a first half value layer of 0.31 mm Al.

The dosimeters in each group of five will either be exposed to the same exposure (air kerma) or to different exposures (air kermas) but within a similar range. This will result in a total of at least 50 readings. In view of the number of dosimeters involved in this case, this means that any given dosimeter may be irradiated several times.

(c) The Reference Calibration Centre will correct the dosimeter readings using the conversion factors determined in (a), above and compare the results with the Reference Calibration Centre values of exposure (air kerma). The results of this independent test (giving both the participant’s and the Reference Calibration Centre’s values) will be reported to the PRDRC (see address below) by the Reference Calibration Centre, with a copy to the participant. The dosimeters will be returned to the

dosimetry service when all irradiations are completed. In order to pass this test, reported results must lie within the criteria described in section 3.1.6.

INMS staff will report the test results to the PRDRC at the following address:

Chair - Provincial Radiation Dosimetry Review Committee
Ontario Ministry of Labour
Radiation Protection Service
81 Resources Road
Weston, Ontario M9P 3T1
CANADA

Further details on this test may be obtained from:

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