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Guide for estimating uncertainties in dosimetry for radiation processing

Guide pour l'estimation des incertitudes en dosimétrie pour le traitement par irradiation

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75% of the member bodies casting a vote.

ASTM International is one of the world's largest voluntary standards development organizations with global participation from affected stakeholders. ASTM technical committees follow rigorous due process balloting procedures.

A project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this project, ASTM Subcommittee E10.01, Dosimetry for Radiation Processing, is responsible for the development and maintenance of these dosimetry standards with unrestricted participation and input from appropriate ISO member bodies.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. Neither ISO nor ASTM International shall be held responsible for identifying any or all such patent rights.

International Standard ISO/ASTM 51707 was developed by ASTM Committee E10, Nuclear Technology and Applications, through Subcommittee E10.01, and by Technical Committee ISO/TC 85, Nuclear energy.

This second edition cancels and replaces the first edition (ISO/ASTM 51707:2002), which has been technically revised.

Standard Guide for Estimating Uncertainties in Dosimetry for Radiation Processing[1]

This standard is issued under the fixed designation ISO/ASTM 51707; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision.

1. Scope

1.1 This guide defines possible sources of uncertainty in dosimetry performed in gamma, X-ray (bremsstrahlung), and electron irradiation facilities and offers procedures for estimating the resulting magnitude of the uncertainties in the measurement of absorbed dose using a dosimetry system. Basic concepts of measurement, estimate of the measured value of a quantity, "true value", error, and uncertainty are defined and discussed. Components of uncertainty are discussed and methods are given for evaluating and estimating their values. How these contribute to the standard uncertainty in the reported values of absorbed dose are considered and methods are given for calculating the combined standard uncertainty and an estimate of expanded (overall) uncertainty. The methodology for evaluating components of uncertainty follows ISO procedures (see 2.3). The traditional concepts of precision and bias are not used in this document. Examples are given in five annexes.

1.2 This guide assumes a working knowledge of statistics. Several statistical texts are included in the references **(1-4)**.[2]

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced documents

2.1 *ASTM Standards:* [3]

E 170 Terminology Relating to Radiation Measurements and Dosimetry

E 177 Practice for Use of the Terms Precision and Accuracy as Applied to Measurement of a Property of a Material

E 178 Practice for Dealing With Outlying Observations

E 456 Terminology Relating to Quality and Statistics

E 876 Practice for Use of Statistics In the Evaluation of Spectrometric Data

E 1249 Practice for Minimizing Dosimetry Errors in Radiation Hardness Testing of Silicon Electronic Devices Using Co-60 Sources

2.2 *ISO/ASTM Standards:*[3]

51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing

51205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System

51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing

51275 Practice for Use of a Radiochromic Film Dosimetry System

51400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory

51431 Practice for Dosimetry in Electron Beam and X-ray (Bremsstrahlung) Irradiation Facilities for Food Processing

2.3 *ISO Documents:*

ISO, 1995, ISBN 92-67-10188-9 Guide to the Expression of Uncertainty in Measurement[4]

ISO 11137 Sterilization of Health Care Products-Requirements for Validation and Routine Control-Radiation Sterilization[5]

2.4 *ICRU Reports:*[6]

ICRU Report 14 Radiation Dosimetry: X Rays and Gamma Rays with Maximum Photon Energies Between 0.6 and 50 MeV

ICRU Report 17 Radiation Dosimetry: X Rays Generated at Potentials of 5 to 150 kV

ICRU Report 34 The Dosimetry of Pulsed Radiation

ICRU Report 35 Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV

[1] This guide is under the jurisdiction of ASTM Committee E10 on Nuclear Technology and Applications and is the direct responsibility of Subcommittee E10.01 on Dosimetry for Radiation Processing, and is also under the jurisdiction of ISO/TC 85/WG 3.

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[2] The boldface numbers in parentheses refer to the bibliography at the end of this guide.

[3] For referenced ASTM and ISO/ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[4] Available from ISO Central Secretariat, Postal 56, 1211 Geneva 20 Switzerland.

[5] Available from Association for the Advancement of Medical Instrumentation, 1110 North Glebe Road, Suite 220, Arlington, VA 22201-4795, U..S.A.

[6] Available from International Commission on Radiation Units and Measurements, 7910 Woodmont Ave., Suite 800 Bethesda, MD 20814, U.S.A.

ICRU Report 37 Stopping Powers for Electrons and Positrons

ICRU Report 60 Fundamental Quantities and Units for Ionizing Radiation

3. Terminology

3.1 *Definitions:*

3.1.1 *absorbed dose, D*—quantity of ionizing radiation energy imparted per unit mass of a specified material. The SI unit of absorbed dose is the gray (Gy) where 1 gray is equivalent to the absorption of 1 joule per kilogram of the specified material (1 Gy = 1 J/kg). The mathematical relationship is the quotient of $d\bar{\epsilon}$ by dm, where $d\bar{\epsilon}$ is the mean energy imparted by ionizing radiation to matter of mass dm (see ICRU 60).

$$D = d\bar{\epsilon}/dm \quad (1)$$

3.1.2 *accuracy of measurement*—closeness of the agreement between the result of a measurement and the true value of the measurand.

3.1.3 *calibration curve*—graphical representation of the dosimetry system's response function.

3.1.4 *coefficient of variation*—sample standard deviation expressed as a percentage of sample mean value (see 3.1.38 and 3.1.39).

$$CV = S_{n-1}/\bar{x} \times 100\ \% \quad (2)$$

3.1.5 *combined standard uncertainty*—standard uncertainty of the result of a measurement when that result is obtained from the values of a number of other quantities, equal to the positive square root of a sum of terms, the terms being the variances or covariances of these other quantities weighted according to how the measurement result varies with changes in these quantities.

3.1.6 *confidence interval*—interval estimate that contains the mean value of a parameter with a given probability.

3.1.7 *confidence level*—probability that a confidence interval estimate contains the value of a parameter.

3.1.8 *corrected result*—result of a measurement after correction for systematic error.

3.1.9 *correction*—value that, added algebraically to the uncorrected result of a measurement, compensates for systematic error.

3.1.9.1 *Discussion*—The correction is equal to the negative of the systematic error. Some systematic errors may be estimated and compensated for by applying appropriate corrections. However, since the systematic error cannot be known perfectly, the compensation cannot be complete.

3.1.10 *correction factor*—numerical factor by which the uncorrected result of a measurement is multiplied to compensate for a systematic error.

3.1.10.1 *Discussion*—Since the systematic error cannot be known perfectly, the compensation cannot be complete.

3.1.11 *coverage factor*—numerical factor used as a multiplier of the combined standard uncertainty in order to obtain an expanded uncertainty.

3.1.11.1 *Discussion*—A coverage factor, k, is typically in the range of 2 to 3 (see 8.3).

3.1.12 *dosimeter batch*—quantity of dosimeters made from a specific mass of material with uniform composition, fabricated in a single production run under controlled, consistent conditions and having a unique identification code.

3.1.13 *dosimetry system*—system used for determining absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use.

3.1.14 *error (of measurement)*—result of a measurement minus a true value of the measurand.

3.1.14.1 *Discussion*—The quantity is sometimes called "absolute error of measurement" when it is necessary to distinguish it from relative error. If the result of a measurement depends on the values of quantities other than the measurand, the errors of the measured values of these quantities contribute to the error of the result of the measurement.

3.1.15 *expanded uncertainty*—quantity defining the interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand.

3.1.15.1 *Discussion*—Expanded uncertainty is also referred to as "overall uncertainty" (see 2.3, Guide to the Expression of Uncertainty in Measurement). To associate a specific level of confidence with the interval defined by the expanded uncertainty requires explicit or implicit assumptions regarding the probability distribution characterized by the measurement result and its combined standard uncertainty. The level of confidence that may be attributed to this interval can be known only to the extent to which such assumptions may be justified.

3.1.16 *expected value*—sum of possible values of a variable weighted by the probability of the value occurring. For a discrete random variable it is found from the expression:

$$E = \Sigma_i P_i V_i \quad (3)$$

where:

V_i = i^{th} value of discrete random variable, and

P_i = probability of i^{th} value.

For a continuous random variable x it is found from the expression:

$$E = \int x f(x) dx \quad (4)$$

where:

$f(x)$ = probability density function and the integral is extended over the intervals of variation of x.

3.1.17 *influence quantity*—quantity that is not included in the specification of the measurand but that nonetheless affects the result of the measurement.

3.1.17.1 *Discussion*—This quantity is understood to include values associated with reference materials, and reference data upon which the result of the measurement may depend, as well as phenomena such as short-term instrument fluctuations and parameters such as temperature, time, and humidity.

3.1.18 *measurand*—specific quantity subject to measurement.

3.1.18.1 *Discussion*—A specification of a measurand may include statements about other quantities such as time, humidity, or temperature. For example, equilibrium absorbed dose in water at 25°C.

3.1.19 *measurement*—set of operations having the object of determining a value of a quantity.

3.1.20 *measurement procedure*—set of operations, in specific terms, used in the performance of particular measurements according to a given method.

3.1.21 *measurement system*—system used for evaluating the measurand.

3.1.22 *measurement traceability*—ability to demonstrate by means of an unbroken chain of comparisons that a measurement is in agreement within acceptable limits of uncertainty with comparable nationally or internationally recognized standards.

3.1.23 *method of measurement*—logical sequence of operations used in the performance of measurements according to a given principle.

3.1.23.1 *Discussion*—Methods of measurement may be qualified in various ways such as: substitution method, differential method, and null method.

3.1.24 *outlier*—measurement result that deviates markedly from others within a set of measurement results.

3.1.25 *primary standard dosimeter*—dosimeter of the highest metrological quality, established and maintained as an absorbed dose standard by a national or international standards organization.

3.1.26 *principle of measurement*—scientific basis of a method of measurement.

3.1.27 *quadrature*—method of estimating combined uncertainty from independent sources by taking the square root of the sum of the squares of individual components of uncertainty (for example, coefficient of variation).

3.1.28 *random error*—result of a measurement minus the mean result of a large number of measurements of the same measurand that are made under conditions of repeatability (see 3.1.32).

3.1.28.1 *Discussion*—In this definition (and that for systematic error), the term mean result of a large number of measurements of the same measurand is understood as the expected value or mean of all possible measured values of the measurand obtained under conditions of repeatability. The definition of random error cannot be misinterpreted to imply that for a series of observations, the random error of an individual observation is known and can be eliminated by applying a correction.

3.1.29 *reference standard dosimeter*—dosimeter of high metrological quality, used as a standard to provide measurements traceable to measurements made using primary standard dosimeters.

3.1.30 *reference value (of a quantity)*—value attributed to a specific quantity and accepted, sometimes by convention, as having an uncertainty appropriate for a given purpose; for example, the value assigned to the quantity realized by a reference standard.

3.1.30.1 *Discussion*—This is sometimes called "assigned value," or "assigned reference value."

3.1.31 *relative error (of measurement)*—error of measurement divided by a true value of the measurand.

3.1.31.1 *Discussion*—Since a true value cannot be determined, in practice a reference value is used.

3.1.32 *repeatability (of results of measurements)*—closeness of the agreement between the results of successive measurements of the same measurand carried out subject to all of the following conditions: the same measurement procedure, the same observer, the same measuring instrument, used under the same conditions, the same location, and repetition over a short period of time.

3.1.32.1 *Discussion*—These conditions are called "repeatability conditions." Repeatability may be expressed quantitatively in terms of the dispersion characteristics of the results.

3.1.33 *reproducibility (of results of measurements)*—closeness of agreement between the results of measurements of the same measurand, where the measurements are carried out under changed conditions such as differing: principle or method of measurement, observer, measuring instrument, location, conditions of use, and time.

3.1.33.1 *Discussion*—A valid statement of reproducibility requires specification of the conditions that were changed for the measurements. Reproducibility may be expressed quantitatively in terms of the dispersion characteristics of the results. In this context, results of measurement are understood to be corrected results.

3.1.34 *response function*—mathematical representation of the relationship between dosimeter response and absorbed dose for a given dosimetry system.

3.1.35 *result of a measurement*—value attributed to a measurand, obtained by measurement.

3.1.35.1 *Discussion*—When the term "result of a measurement" is used, it should be made clear whether it refers to: the indication, the uncorrected result, the corrected result, and whether several values are averaged. A complete statement of the result of the measurement includes information about the uncertainty of the measurement.

3.1.36 *routine dosimeter*—dosimeter calibrated against a primary-, reference-, or transfer-standard dosimeter and used for routine absorbed-dose measurement.

3.1.37 *sample mean*—measure of the average value of a data set which is representative of the mean of the population. It is determined by summing all the values in the data set and dividing by the number of items *(n)* in the data set. It is found from the expression:

$$\bar{x} = \frac{1}{n}\sum_i x_i,\ i = 1, 2, 3 \ldots n \tag{5}$$

where:

x_i = individual values of parameters with $i = 1, 2, 3 \ldots n$.

3.1.38 *sample standard deviation, S_{n-1}*—measure of dispersion of values expressed as the positive square root of the sample variance.

3.1.39 *sample variance*—sum of the squared deviations of individual values from the sample mean divided by (n–1), given by the expression:

$$S_{n-1}^2 = \frac{\Sigma (x_i - \bar{x})^2}{(n-1)} \quad (6)$$

where:

x_i = individual value of parameter with $i = 1, 2 \ldots n$, and
$\bar{x}$ = mean of n values of parameter (see 3.1.37).

3.1.40 *standard uncertainty*—uncertainty of the result of a measurement expressed as a standard deviation.

3.1.41 *systematic error*—mean result of a large number of repeated measurements of the same measurand minus a true value of the measurand.

3.1.41.1 *Discussion*—The repeated measurements are carried out under conditions of "repeatability." Like true value, systematic error and its causes cannot be completely known. The error of the result of a measurement may often be considered as arising from a number of random and systematic effects that contribute individual components of error to the error of the result (see ASTM Terminologies E 170 and E 456, and Practice E 177).

3.1.42 *traceability*—see *measurement traceability*.

3.1.43 *transfer standard dosimeter*—dosimeter, often a reference standard dosimeter, suitable for transport between different locations, used to compare absorbed-dose measurements.

3.1.44 *true value*—value of measurand that would be obtained by a perfect measurement.

3.1.44.1 *Discussion*—True value is by its nature indeterminate and only an idealized concept. In this guide the terms "true value of a measurand" and " value of a measurand" are viewed as equivalent (see 5.1.1).

3.1.45 *Type A evaluation (of standard uncertainty)*—method of evaluation of a standard uncertainty by the statistical analysis of a series of observations.

3.1.46 *Type B evaluation (of standard uncertainty)*—method of evaluation of a standard uncertainty by means other than the statistical analysis of a series of observations.

3.1.47 *uncertainty (of measurement)*—parameter, associated with a measurand or derived quantity, that characterizes the distribution of the values that could reasonably be attributed to the measurand or derived quantity.

3.1.47.1 *Discussion*—For example, uncertainty may be a standard deviation (or a given multiple of it), or the width of a confidence interval. Uncertainty of measurement comprises, in general, many components. Some of these components may be evaluated from the statistical distribution of the results of series of measurements and can be characterized by experimental standard deviations. The other components, which can also be characterized by standard deviations, are evaluated from assumed probability distributions based on experience or other information. It is understood that all components of uncertainty contribute to the distribution.

3.1.48 *uncorrected result*—result of a measurement before correction for the assumed systematic error.

3.1.49 *value (of a quantity)*—magnitude of a specific quantity generally expressed as a unit of measurement multiplied by a number, for example, 25 kGy.

4. Significance and use

4.1 Gamma, electron, and X-ray (bremsstrahlung) facilities routinely irradiate a variety of products such as food, medical devices, aseptic packaging and commodities (see ISO/ASTM Practices 51204 and 51431). Process parameters must be carefully controlled to ensure that these products are processed within specifications (see ISO 11137, Section 2.3). Accurate dosimetry is essential in process control (see ISO/ASTM Guide 51261). For absorbed dose measurements to be meaningful, the combined uncertainty associated with these measurements must be estimated and its magnitude quantified.

NOTE 1—For a comprehensive discussion of various dosimetry methods applicable to the radiation types and energies discussed in this guide, see ICRU Reports 14, 17, 34, 35 and Refs **(5, 6)**.

4.2 This guide uses the methodology adopted by the International Organization for Standardization for estimating uncertainties in dosimetry for radiation processing (see 2.3). ASTM traditionally uses the terms of precision and bias where precision is a measure of the extent to which replicate measurements made under specified conditions are in agreement and bias is a systematic error (see ASTM Terminologies E 170 and E 456, and Practice E 177). As seen from this standard, components of uncertainty are evaluated as either Type A or Type B rather than in terms of precision and bias. Error is different from Type A and Type B components of uncertainty.

4.3 Although this guide provides a framework for assessing uncertainty, it cannot substitute for critical thinking, intellectual honesty, and professional skill. The evaluation of uncertainty is neither a routine task nor a purely mathematical one; it depends on detailed knowledge of the nature of the measurand and of the measurement method and procedure used. The quality and utility of the uncertainty quoted for the result of a measurement therefore ultimately depends on the understanding, critical analysis, and integrity of those who contribute to the assignment of its value.

4.4 Process requirements may necessitate establishment of a target uncertainty, which provides a point of reference for evaluating whether the calculated value of uncertainty is acceptable for the process under consideration.

4.5 Results of an uncertainty assessment may be used to aid in the evaluation of the statistical control in the given application. Controllable components of uncertainty may be ranked by comparison to total uncertainty. This ranking may be used to identify areas for corrective action to reduce the total uncertainty.

5. Basic concepts—components of uncertainty

5.1 *Measurement*:

5.1.1 The objective of a measurement is to determine the value of the measurand, that is, the value of the specific quantity to be measured. A measurement therefore begins with

an appropriate specification of the measurand, the method of measurement, and the measurement procedure.

5.1.2 In general, the result of a measurement is only an approximation or estimate of the value of the measurand and thus is complete only when accompanied by a statement of the uncertainty of that estimate.

5.1.3 In practice, the specification or definition of the measurand depends on the required accuracy of the measurement. The measurand should be defined with sufficient completeness relative to the required accuracy so that for all practical purposes the measurand value is unique.

5.1.3.1 Although a measurand should be defined in sufficient detail that any uncertainty arising from its incomplete definition is negligible in comparison with the required accuracy of the measurement, it must be recognized that this may not always be practicable. The definition may, for example, be incomplete because it does not specify parameters that may have been assumed, unjustifiably, to have negligible effect; or it may imply conditions that can never fully be met and whose imperfect realization is difficult to take into account.

5.1.4 In many cases, the result of a measurement is determined on the basis of repeated observations. Variations in repeated observations are assumed to arise from not being able to hold completely constant each influence quantity that can affect the measurement result.

5.1.5 The mathematical model of the measurement procedure that transforms the set of repeated observations into the measurement result is of critical importance since, in addition to the observations, it generally includes various influence quantities that are inexactly known. This lack of knowledge contributes to the uncertainty of the measurement result along with the variations of the repeated observations and any uncertainty associated with the mathematical model itself.

5.2 *Errors, Effects, and Corrections*:

5.2.1 In general, a measurement procedure has imperfections that give rise to an error in the measurement result. Traditionally, an error is viewed as having two components, namely, a random component and a systematic component.

5.2.2 Random error presumably arises from unpredictable or stochastic temporal and spatial variations of influence quantities. The effects of such variations, hereafter referred to as random effects, give rise to variations in repeated observations of the measurand. The random error of a measurement result cannot be compensated by correction but it can usually be reduced by increasing the number of observations; its expectation or expected value is zero.

NOTE 2—The experimental standard deviation of the arithmetic mean or average of a series of observations is not the random error of the mean, although it is so referred to in some publications on uncertainty. It is instead a measure of the uncertainty of the mean due to random effects. The exact value of the error in the mean arising from these effects cannot be known. In this guide great care is taken to distinguish between the terms "error" and "uncertainty;" they are not synonyms but represent completely different concepts; they should not be confused with one another or misused.

5.2.3 Systematic error, like random error, cannot be eliminated but it too can often be reduced. If a systematic error arises from a recognized effect of an influence quantity on a measurement result, hereafter referred to as a systematic effect, the effect can be quantified and, if significant in size relative to the required accuracy of the measurement, an estimated correction or correction factor can be applied. It is assumed that after correction, the expectation or expected value of the error arising from a systematic effect is zero.

NOTE 3—The uncertainty of an estimated correction applied to a measurement result to compensate for a systematic effect is not the systematic error. It is instead a measure of the uncertainty of the result due to incomplete knowledge of the value of the correction. In general, the error arising from imperfect compensation of a systematic effect cannot be exactly known.

5.2.4 It is assumed that the result of a measurement has been corrected for all recognized significant systematic effects.

NOTE 4—Often, measuring instruments and systems are adjusted or calibrated using measurement reference standards to eliminate systematic effects; however, the uncertainties associated with these standards must still be taken into account.

5.3 *Uncertainty*:

5.3.1 The uncertainty of the result of a measurement reflects the lack of exact knowledge of the value of the measurand. The result of a measurement after correction for recognized systematic effects is still only an estimate of the value of the measurand because of the uncertainty arising from random effects and from imperfect correction of the result for systematic effects.

NOTE 5—The result of a measurement (after correction) can unknowingly be very close to the value of the measurand (and hence have a negligible error) even though it may have a large uncertainty. Thus the uncertainty of the result of a measurement should not be interpreted as representing the remaining unknown error.

5.3.2 In practice there are many possible sources of uncertainty in a measurement, including:

5.3.2.1 incomplete definition of the measurand;

5.3.2.2 imperfect realization of the definition of the measurand;

5.3.2.3 sampling—the sample measured may not represent the defined measurand;

5.3.2.4 inadequate knowledge of the effects of environmental conditions on the measurement procedure or imperfect measurement of environmental conditions;

5.3.2.5 personal bias in reading analog instruments;

5.3.2.6 instrument resolution or discrimination threshold;

5.3.2.7 values assigned to measurement standards;

5.3.2.8 values of constants and other parameters obtained from external sources and used in the data reduction algorithm;

5.3.2.9 approximations and assumptions incorporated in the measurement method and procedure; and

5.3.2.10 lack of identical conditions in repeated observations of the measurand.

NOTE 6—These sources are not necessarily independent and some may contribute to 5.3.2.10. Of course, an unrecognized systematic effect cannot be taken into account in the evaluation of the uncertainty of the result of a measurement but contributes to its error.

5.3.3 Uncertainty components are classified into two categories based on their method of evaluation, "Type A" and "Type B." These categories are not substitutes for the words

"random" and "systematic." The uncertainty of a correction for a known systematic effect may be obtained by either a Type A or Type B evaluation, as may be the uncertainty characterizing a random effect.

5.3.4 The purpose of the Type A and Type B classification is to indicate the two different ways of evaluating uncertainty components. Both types of evaluation are based on probability distributions and the uncertainty components resulting from each type are quantified by a standard deviation or a variance.

5.3.5 The population variance u^2 characterizing an uncertainty component obtained from a Type A evaluation is estimated from a series of repeated observations. The best estimate of u^2 is the sample variance s^2. The population standard deviation u, the positive square root of u^2, is thus estimated by s and for convenience is sometimes referred to as a Type A standard uncertainty. For an uncertainty component obtained from a Type B evaluation, the population variance u^2 is evaluated using available knowledge and the estimated standard deviation u is sometimes referred to as a Type B standard uncertainty.

5.3.5.1 Thus a Type A standard uncertainty is obtained from a probability density function derived from an observed frequency distribution, while a Type B standard uncertainty is obtained from an assumed probability density function based on the degree of belief that an event will occur. The two approaches are both valid interpretations of probability.

NOTE 7—A Type B evaluation of an uncertainty component is often based on a pool of comparatively reliable information.

5.3.6 The total uncertainty of the result of a measurement, termed combined standard uncertainty and denoted by u_c, is an estimated standard deviation equal to the positive square root of the total variance obtained by summing all variance and covariance components, however evaluated, using the law of propagation of uncertainty (see Annex A3).

5.3.7 To meet the needs of some industrial and commercial applications, as well as requirements in the areas of health and safety, an expanded uncertainty U is calculated. The purpose of the expanded uncertainty is to provide an interval about the result of a measurement within which the values that could reasonably be attributed to the measurand may be expected to lie with a high level of confidence. The value of U is obtained by multiplying the combined standard uncertainty u_c by a coverage factor k (see 8.3).

NOTE 8—The coverage factor k is always to be stated so that the standard uncertainty of the measured quantity can be recovered.

5.4 *Practical Considerations*:

5.4.1 By varying all parameters on which the result of a measurement depends, its uncertainty could be evaluated by statistical means. However, because this is rarely possible in practice due to limited time and resources, the uncertainty is usually evaluated using a mathematical model of the measurement procedure and the law of propagation of uncertainty. Thus implicit in this guide is the assumption that a measurement procedure can be modeled mathematically to the degree imposed by the required accuracy of the measurement.

5.4.2 Because the mathematical model may be incomplete, all parameters should be varied to the fullest practicable extent so that the evaluation of uncertainty is based as much as possible on observed data. Whenever feasible, the use of empirical models of the measurement procedure founded on long-term quantitative data, and the use of performance tests and control charts that can indicate if a measurement procedure is under statistical control, should be part of the effort to obtain reliable evaluations of uncertainty. A well-designed experiment can greatly facilitate such efforts and is an important part of the art of measurement.

5.4.3 In order to decide if a measurement system is functioning properly, the experimentally observed variability of its output values is often compared with the variability predicted by combining the appropriate uncertainty components that characterize its constituent parts. When calculating the predicted standard deviation of the distribution of experimentally observed output values, only those components (whether obtained from Type A or Type B evaluations) that could contribute to the observed variability of these values should be considered.

NOTE 9—Such an analysis may be facilitated by gathering those components that contribute to the variability and those that do not into two separate and appropriately labeled groups. The evaluation of overall uncertainty must take both groups into consideration.

5.4.4 An apparent outlier in a set of measurement results may be merely an extreme manifestation of the random variability inherent in the data. If this is true, then the value should be retained and processed in the same manner as the other measurements in the set. On the other hand, the outlying measurement may be the result of gross deviation from prescribed experimental procedure or an error in calculating or recording the numerical value. In subsequent data analysis the outlier will be recognized as unlikely to be from the same population as that of the others in the measurement set. An investigation shall be undertaken to determine the reason for the aberrant value and whether it should be rejected (see ASTM Practice E 178 for methods of testing for outliers).

5.5 *Graphical Representation of Concepts*:

5.5.1 Fig. 1 depicts some of the ideas discussed in this Section. It illustrates why the focus of this guide is uncertainty and not error. The exact error of a result of a measurement is, in general, unknown and unknowable. It is only possible to estimate the values of input quantities, including corrections for recognized systematic effects, together with their standard uncertainties (estimated standard deviations), either from unknown probability distributions that are sampled by means of repeated observations, or from subjective or a priori distributions based on the pool of available information; and then calculate the measurement result from the estimated values of the input quantities and the combined standard uncertainty of that result from the standard uncertainties of those estimated values. Two a priori distributions are shown in Fig. 2.[7]

[7] Figs. 1 and 2 have been reproduced with the permission of the International Organization for Standardization (ISO). The complete guide can be obtained from any ISO member or from the ISO Central Secretariat, Postal 56, 1211 Geneva 20 Switzerland. Copyright remains with ISO.

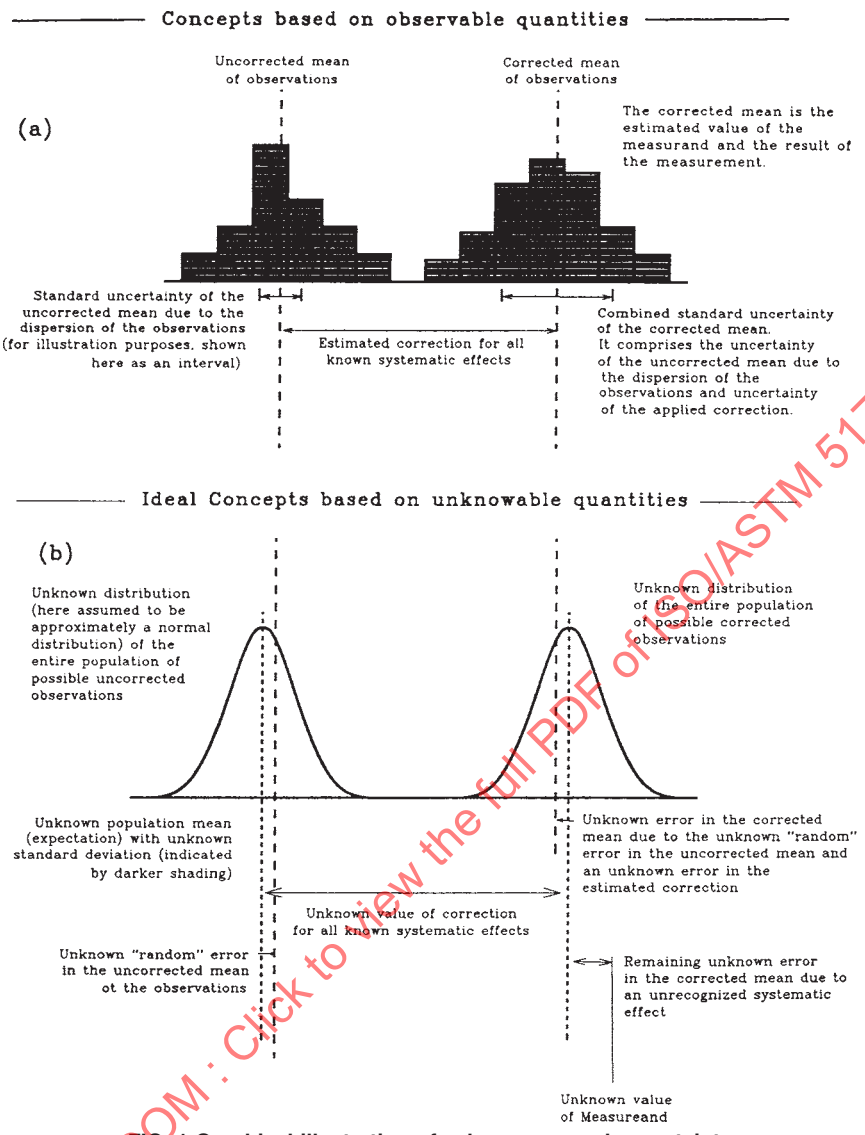

FIG. 1 Graphical illustration of value, error, and uncertainty

6. Evaluation of standard uncertainty

6.1 *Measurement Procedure*:

6.1.1 The measurand Y (absorbed dose) is generally not measurable directly, but depends on N other measurable quantities X_1, X_2, ..., X_N through a functional relationship f:

$$Y = f(X_1, X_2, ..., X_N) \quad (7)$$

6.1.1.1 The input quantities X_1, X_2, ... X_N and their associated uncertainties may be determined directly in the current measurement process by means of repeated observations and may include effects of influence quantities such as temperature or humidity. They may also involve uncertainties that arise from activities such as calibration of routine dosimetry systems under conditions that differ from actual irradiator facility conditions (different dose rates, temperature cycle, etc.). Other quantities that may be involved are those due to use of reference or transfer standard dosimeters and their associated uncertainties.

6.1.1.2 The input quantities X_1, X_2, X_3... X_N and associated uncertainties are grouped either individually, for example, X_1 or X_2 or as aggregates, for example, (X_3... X_p) where $p < N$.

6.1.1.3 Grouping of input quantities is determined by the characteristics of the selected dosimeter, method of calibration, measurement application environment, and the ability within these sets of conditions to generate experimental measurements either for individual or aggregate input quantities.

6.1.1.4 Both individual and aggregate input quantities and associated estimates of uncertainty may be used to compare estimates of uncertainty. A comparison increases the confidence that major components of uncertainty have not been omitted nor have some sources been included more than once.

6.2 *Type A Evaluation of Standard Uncertainty*:

6.2.1 The best estimate of the expected value of a quantity is obtained by n independent measurements made under conditions of repeatability and is given by the arithmetic mean,

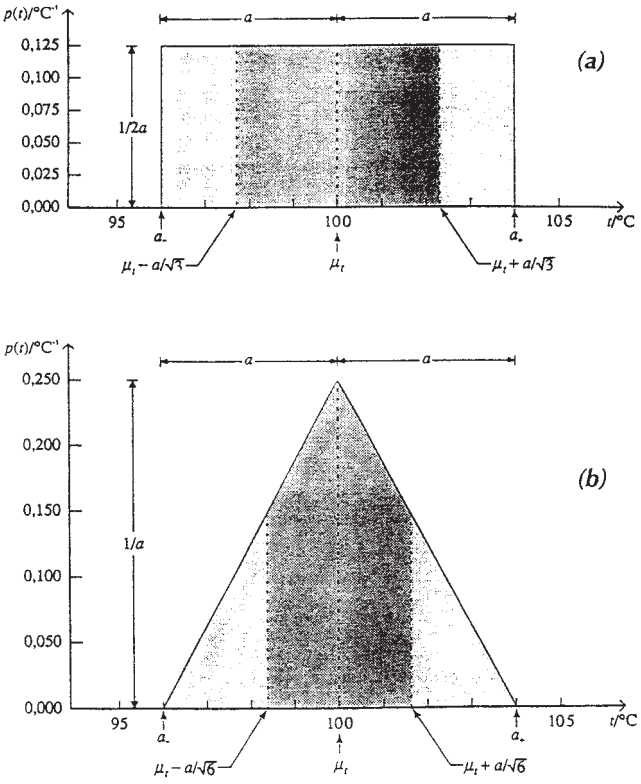

FIG. 2 Graphical illustration of evaluating type B standard uncertainty

$\bar{x}$, or average of those measurements. The sample standard deviation, s_{n-1}, of these observations characterizes the variability of the observed values or their dispersion about their mean. For example, at a production irradiator facility, repeated measurements of dose at the same location within product of the same density, radiation absorption properties, and geometry, for the same processing and environmental conditions would provide an estimate of the sample standard deviation in the dosimetry system. Possible changes in dose due to variations in processing conditions should be taken into account in the estimate of sample standard deviation. The sample standard deviation, s_{n-1}, can be referred to as a Type A standard uncertainty, u_A.

6.2.1.1 The types of uncertainty represented by a Type A estimate are determined by the experimental design that is used to collect the observations for the uncertainty estimate. If the Type A uncertainty so estimated is unacceptably large, the components of uncertainty may be estimated by a more refined experimental design. Knowledge of the components of variability may allow identification of components that can be controlled so as to reduce variability. For example, if absorbance of a film dosimeter is measured during calibration without controlling film thickness, relative humidity, or temperature, the uncertainty of dose estimates from this calibration may be unacceptably large. An experimental design that controls these factors may indicate the film thickness and relative humidity have significant effects on measured absorbance. Controlling these effects during calibration and routine dosimetry will reduce the uncertainty in dose estimates.

6.2.2 For well-characterized measurement procedures under a state of statistical control, a combined or pooled variance s_P^2 or pooled sample standard deviation s_P may be available (see ASTM Practice E 876). In such cases the variance of the mean of n independent repeated measurements is s_P^2/n and the Type A standard uncertainty is $u_A = s_P/\sqrt{n}$.

6.2.3 For Type A components of uncertainty, increasing the degrees of freedom will reduce the uncertainty in the estimate of the standard deviation and improve the quality of the estimate of uncertainty.

6.2.4 The magnitude of Type A components of uncertainty that are due to lack of repeatable conditions during calibration and during measurements at the production irradiator facility can be estimated by repeating replicate measurements.

6.3 *Type B Evaluation of Standard Uncertainty*:

6.3.1 The Type B component of uncertainty can be evaluated by using all relevant information on the possible variability of the input quantities X_i. For the input value X_i that has not been obtained from repeated measurements, the estimated variance, u_B^2 or standard uncertainty, u_B, is evaluated by judgment using all relevant information on the possible variability of X_i. This pool of information may include previous measurement data, documented performance characteristics of the dosimetry system, and uncertainties assigned to reference or transfer standard dosimeters. The uncertainty u_B estimated in this way is referred to as a Type B standard uncertainty. Sources of these Type B standard uncertainty components are discussed in Section 7.

6.3.2 Several methods may be used to develop estimates of the magnitude of Type B uncertainty components. One method is to estimate reasonable maximum magnitudes of each component based on the known operating conditions of the calibration and production irradiator facilities and the documented uncertainty characteristics of the dosimetry system. Another method estimates the magnitude of each component as a function of these facilities' operations.

6.3.3 The first method estimates the maximum magnitude likely to be observed for each component. For example, if the response of the dosimetry system is known to vary with temperature, then the uncertainty for the maximum operational temperature range is used for this component of uncertainty. If there is no specific knowledge about the possible values of X_i within its estimated bounds of a_- to a_+, it is assumed that it is equally probable for X_i to take on any value within those bounds (that is a rectangular distribution, see Fig. 2(*a*)). As shown in Fig. 2(*a*) the sample standard deviation is $a/\sqrt{3}$. In some cases it is more realistic to expect that values near the bounds are less likely than those near the midpoint. It is then reasonable to replace the rectangular distribution with a symmetric triangular distribution with a base width of $a_- - a_+ = 2a$, see Fig. 2(*b*). Assuming such a triangular distribution for X_i, the expectation value of X_i is $(a_- + a_+)/2$ and its variance is $u_B^2 = a^2/6$. Thus, the Type B standard uncertainty is $u_B = a/\sqrt{6}$.

6.3.4 A second method of evaluating Type B uncertainties defines the component as a function of the operating characteristics of the irradiation facility. The mathematical relationship may not be known.

6.3.4.1 For example, when the response of the dosimetry system to a given dose varies with the temperature in a known relationship, the uncertainty may be estimated as a function of the temperature at which each fraction of dose was received. The uncertainty can be determined from the relationship between response and temperature that also requires detailed knowledge of the temperature regimen during irradiation.

6.3.4.2 When the relationship between the dose rates and temperature profile is not known an assumed distribution function may be used to describe that relationship and the procedure discussed in 6.3.4.1 can be used to estimate uncertainty.

6.3.5 For the case where a reference or transfer standard dosimeter is employed, and the uncertainty quoted by the supplier is given as a multiple of a standard deviation, the Type B standard uncertainty, u_B, may be taken as equal to the quoted value divided by the multiplier. If the uncertainty is given at a confidence level, such as 95 % or 99 %, then it may be assumed that the multipliers are approximately 2 and 3, respectively (see 8.3.1). The value for u_B is obtained by dividing the estimate of uncertainty at the given confidence interval by the appropriate multiplier.

7. Sources of uncertainty

7.1 Contributions to the combined uncertainty in the measured values of absorbed dose include the following:

7.1.1 Uncertainty in the absorbed dose received by the dosimeters during system calibration,

7.1.2 Uncertainty in analysis of dosimeter response,

7.1.3 Uncertainty in fit of dosimetry data to a calibration curve, and

7.1.4 Uncertainty in routine use of dosimeters in a production irradiation facility.

7.2 Each source of uncertainty usually consists of several components of both Type A and Type B. Components of uncertainty from each source are combined first by type, that is, the Type A components together and Type B components together. Then the Type A contributions are combined with the Type B contributions to give a combined standard uncertainty, u_c. Methods for combining uncertainties are discussed in Section 8 and Annex A3.

7.3 Calibration irradiation of routine dosimeters shall be performed at *(a)* a national or accredited calibration laboratory using criteria specified in ISO/ASTM Practice 51400, *(b)* an in-house calibration facility that provides an absorbed dose (or absorbed dose rate) having measurement traceability to nationally or internationally recognized standards. or *(c)* a production irradiatior under actual production irradiation conditions together with reference- or transfer-standard dosimeters that have measurement traceability to nationally or internationally recognized standards (see ISO/ASTM 51261). In case of option *(a)* or *(b)*, the resulting calibration curve shall be verified for the actual conditions of use. Annex A4 and Annex A5 give examples of estimates of total uncertainty for different methods of calibration. Values for estimates of uncertainty in measured dose referred to in these annexes are only representative of components of uncertainty that typically are associated with the measurement system and must not be construed to favor a particular method of calibration or dosimetry system.

7.4 Each method of calibration has its own potential advantages depending on the type of routine dosimeter selected and its application. It is the responsibility of the user of the dosimetry system to justify the method of calibration.

7.4.1 Calibration irradiation of routine dosimeters at a high-dose calibration laboratory using criteria specified in ISO/ASTM 51400 has the advantage that the dosimeters are irradiated to accurately known absorbed doses under well-controlled and documented conditions. For these reasons, the uncertainty in the absorbed dose received by the dosimeters is relatively small. In-plant verification is required for this method of calibration (see ISO/ASTM 51261).

7.4.2 Calibration irradiation of routine dosimeters at an in-house calibration facility has the advantage that the pre- and post-irradiation conditions of the dosimeters can be adjusted and controlled so they are similar to those encountered during routine production. In-plant verification is required for this method of calibration (see ISO/ASTM 51261).

7.4.3 The calibration irradiation of routine dosimeters by irradiating the dosimeters together with reference- or transfer-standard dosimeters in the production irradiator has the advantage that the influence quantities during irradiation are similar to those encountered during routine production. This method of calibration reduces the requirements to make corrections for influence quantities.

7.5 Components of uncertainty that are associated with system calibration depend on the method of calibration.

7.5.1 Calibration irradiation of routine dosimeters at a high-dose calibration laboratory.

7.5.1.1 Some components of uncertainty that are associated with the calibration of routine dosimeters at a high-dose calibration laboratory are listed in Table 1. Dependent on the method of analysis some components are only evaluated as Type B while others may be Type A or Type B.

NOTE 10—For each of the quantities in Tables 1- 4, the first subscript denotes the source of uncertainty, for example, c = calibration and the second subscript denotes the component of uncertainty, for example, d = decay. An NA means there is no assignable component and a prime signifies the component is estimated by Type B evaluation.

NOTE 11—Uncertainty that affects all dosimeters in a batch (for example, seasonal effects) should be reported separately. This uncertainty is combined linearly with other components to obtain the total uncertainty.

TABLE 1 Examples of uncertainty in absorbed dose administered by a gamma ray calibration facility

Component of Uncertainty	Type A	Type B
Response of primary or reference standard	u_{cs}	u'_{cs}
Irradiation time	u_{ct}	u'_{ct}
Decay corrections[A]	u_{cd}	u'_{cd}
Non-uniformities in standard radiation field	u_{cf}	u'_{cf}
Corrections for attenuation and geometry	NA	u'_{ca}
Conversion of absorbed dose to reference material	NA	u'_{cc}

[A] Only applicable to a gamma calibration laboratory.

7.5.1.2 For irradiation at a high-dose calibration laboratory, the calibration laboratory is responsible for estimating the components of uncertainty that are listed in Table 1. The calibration laboratory normally presents the user with a single number for combined uncertainty that is given at a 95 % or 99 % confidence level. The standard uncertainty is obtained by dividing this number by the appropriate coverage factor, for example, 2 for an approximate 95 % confidence level and 3 for an approximate 99 % confidence level (see 6.3.5 and 8.3). The standard uncertainty resulting from the calibration irradiation is typically combined in quadrature with other components of uncertainty to obtain an estimate of combined uncertainty in absorbed dose.

7.5.2 Calibration of routine dosimeters that uses an in-house calibration facility.

7.5.2.1 In-house calibration facilities maintain traceability by demonstrating the dose rate is traceable to appropriate national (or international) standards. This requires the in-house calibration facility to irradiate reference or transfer standard dosimeters. As a result, an additional component of uncertainty (beyond those specified in Table 1) must be included based on the standards laboratory's estimate of the uncertainty associated with the absorbed dose measurements using the reference or transfer standard dosimeters. This additional component of uncertainty value is then incorporated into the in-house calibration facility's statement of calibration uncertainty.

7.5.3 Calibration of routine dosimeters in a production irradiator that uses reference or transfer standard dosimeters.

7.5.3.1 With this method of calibration not all of the components of uncertainty in Table 1 apply since the calibration occurs in the production irradiator rather than at a calibration laboratory. However, uncertainty in the response of the reference or transfer standard dosimeters still need to be taken into account as well as uncertainties related to co-location of reference standard dosimeters with the routine dosimeters so both receive the same dose. All of these components of uncertainty must be addressed by the user and combined to give a single number for uncertainty.

7.6 Components of uncertainty that are due to dosimeter response are common to the three methods of calibration. Some components of uncertainty that are due to analysis of dosimeter response are given in Table 2. These components apply equally to calibration at gamma, electron beam, and X-ray/bremsstrahlung irradiators.

TABLE 2 Examples of uncertainty in dosimeter readings

Component of Uncertainty	Type A	Type B
Intrinsic variation in dosimeter response	u_{si}	NA
Variation in thickness of an individual dosimeter	u_{st}	u'_{st}
Measurement of thickness of individual dosimeters	u_{sx}	u'_{sx}
Variations in readout equipment	NA	u'_{sq}

7.6.1 Variation in the absorbance of several dosimeters that are irradiated under the same conditions can be used to estimate the Type A components of uncertainty in Table 2. Sets of dosimeters used in calibration of a batch of dosimeters or irradiated under the same conditions at an irradiator can be used for this purpose.

7.6.2 The measurement equipment may introduce Type B components of uncertainty in the determination of dosimeter response. For example, some types of dosimetry systems require knowledge of dosimeter thickness in the calculation of absorbed dose. Possible uncertainties associated with the thickness gage may need to be taken into account. If thickness of individual dosimeters is not measured, that is, an average thickness for the lot or manufacturer's specification is used, uncertainty associated with variations in thickness of individual dosimeters may need to be taken into account. In those cases where a spectrophotometer serves as the readout equipment, a source of uncertainty could be introduced if the wavelength setting differs from the reference value.

7.7 Components of uncertainty that are traceable to fit of dosimetry data to a calibration curve are common to the three methods of calibration. Dosimetry calibration data must be fitted to an analytical form, for example, linear, exponential, power, or polynomial that provides a good fit to the measurement data. The uncertainty in absorbed dose associated with the fit of the calibration curve depends on the data used in the fit and the type of analytical function. These components of uncertainty that apply equally to calibration at gamma, electron beam, and X-ray/bremsstrahlung irradiators are given in Table 3.

TABLE 3 Examples of uncertainty in calibration curve

Component of Uncertainty	Type A	Type B
Variation in response of dosimeters	u_{fm}	u'_{fm}
Analytical function used in fit	u_{fa}	u'_{fa}

NOTE 12—The component of uncertainty due to variability in response of dosimeters is taken into account when replicate measurements are used to fit the calibration data rather than average values. In this case, the component of uncertainty in Table 2 that is due to variability in dosimeter response should not be included in the estimate of combined uncertainty.

NOTE 13—The calibration curve will generally cause the uncertainty in dose to differ from the uncertainty in response due to the non-linearity of the calibration curve. The uncertainty may not be constant along the calibration curve but may vary depending on the distribution of data fitted and on the analytical function.

7.7.1 Different analytical forms may be selected to fit the data. The analytical form is characterized by parameters that are estimated by fitting the analytical form to the calibration data. Dose should be the independent (x-axis) variable and the instrument response the dependent (y-axis) variable when least squares regression or maximum likelihood methods are used to find the best-fit parameter estimates. Dose and dose uncertainty are estimated by inverting the fitted equation either analytically or numerically. The appropriate analytical form and applicable dose range depends on the dosimetry system. The following elements should guide the selection of the analytical form used:

7.7.1.1 If the response of the dosimeter obeys a known physical relationship, for example, logarithmic, that function should be used.

7.7.1.2 Otherwise, the data should be plotted and inspected to ascertain if a particular relationship provides a good fit to the data. This exercise also can reveal the presence of possible outliers (**3**).

7.7.1.3 If the response of the dosimeters is best fitted using a polynomial, the degree of the polynomial selected should be the lowest order that gives a good fit to the data set. Selection of higher orders can introduce oscillatory behavior in the curve that may not accurately relate to the physical response of the dosimetry system.

7.7.1.4 The fit should not be used to predict values of absorbed dose that are outside the range of calibration.

7.7.1.5 Care should be taken in selecting and fitting the mathematical function so that no singularities occur or the algorithm used to fit the function avoids singularities close to the range of use.

NOTE 14—At present, most software requires a manual change of equation location to avoid the instabilities associated with nearby singularities during parameter fitting. Some packages such as SIGMA-FIT, provide an option to do this automatically.

7.8 Components of uncertainty that are traceable to routine use of dosimeters in a production irradiation facility depend on the method of calibration.

7.8.1 For calibrations that are performed at a calibration laboratory or in-house calibration facility the use of dosimeters during routine production introduces uncertainty due to the differences in environmental conditions found at the production facility and those at the high dose calibration laboratory or in-house calibration facility. Some components that may contribute to these sources of uncertainty are given in Table 4.

TABLE 4 Examples of uncertainty due to routine use

Component of Uncertainty	Type A	Type B
Deviations in environment from calibration conditions	u_{re}	u'_{re}
Influence of adjacent product on dosimeter	u_{rp}	u'_{rp}
Reproducibility in placement of dosimeter within product unit	u_{rr}	u'_{rr}
Orientation of dosimeters to source of radiation	u_{ro}	u'_{ro}

NOTE 15—Calculations based on dosimetry measurements may contribute additional uncertainty. For example, a dosimeter used in routine production may be placed in a position within or on product that is not a maximum or minimum absorbed-dose position (that is, a reference position). An additional source of uncertainty is introduced when converting the dose measurement at the reference position to a maximum or minimum absorbed dose. This source of uncertainty is not due to the absorbed-dose measurement; rather, it is a source of uncertainty in the calculation of maximum or minimum absorbed dose based on the reference dose measurement.

7.8.1.1 By proper packaging, dosimeters can be protected from variations in some influence quantities, for example, light, atmosphere, humidity; however, the effects of other influence quantities, for example, temperature, energy spectrum, dose rate and dosimeter orientation need to be taken into account. Calibration at temperatures and dose rates similar to production conditions will reduce the effect of differences in these influence quantities on dosimeter response.

7.8.1.2 Each aspect of the production irradiation environment may introduce another element of uncertainty into the estimation of the absorbed dose. The resulting uncertainty should be estimated by considering the sensitivity of the dosimetry system to production conditions. The effect of environment should be verified by irradiating reference standard dosimeters with the routine dosimeters in the production irradiator. The uncertainty associated with the difference between the calibration environment and production environment may be estimated from results of the verification tests (see ISO/ASTM 51261).

7.8.2 Calibration of routine dosimeters by co-location with reference or transfer standard dosimeters and irradiation in the production irradiator take into account effects of environment on response of the routine dosimeters. However, remaining components of uncertainty that are listed in Table 4 need to be taken into account.

8. Combining uncertainties—statement of uncertainty

8.1 For sources of uncertainty that are independent (not correlated), the combined uncertainty is obtained by combining all Type A standard uncertainties and all Type B standard uncertainties in quadrature. If absolute values are used for the standard deviations, the components of uncertainty must be weighted by appropriate sensitivity coefficients. If a functional relationship between variables is known to exist, use the procedures of Annex A3 to determine the combined standard uncertainty. This combined standard uncertainty is designated as u_c (**7**).

8.2 For sources of uncertainty that are related, the effects of those correlations must be taken into account in determining the combined standard uncertainty. Full treatment of correlation effects is beyond the scope of this guide; however, in the special case where all estimates of input quantities are perfectly correlated, the combined standard uncertainty is the linear sum of the Type A and Type B standard uncertainties (**8**). This has the effect of giving a maximum limit to the estimate of the combined uncertainty.

8.3 Although u_c can be used as the final expression of uncertainty of a measurement result, it is often necessary to give the uncertainty in terms of an interval about the measurement result within which the values that could reasonably be attributed to the measurand may be expected to lie with a high level of confidence. This additional measure of uncertainty that provides such a confidence interval is termed expanded uncertainty and denoted as U. The expanded uncertainty U is obtained by multiplying the combined standard uncertainty u_c by a coverage factor k:

$$U = ku_c \tag{8}$$

8.3.1 The choice of a coverage factor that corresponds to an exact confidence level is difficult to achieve in practice. This is true because it requires the full knowledge of the probability distribution of the measurand. However, for a large number of measurements and a probability distribution that is approximately normal, coverage factors of 2 and 3 correspond approximately to confidence levels of 95 % and 99 %, respectively.

8.3.1.1 To obtain a better approximation of the coverage factor than that assumed above, it is necessary to determine the factor by means of the Student's *t* distribution. When the number of observations is limited (small number of degrees of freedom), it may be necessary to calculate the effective degrees of freedom by use of the Welch-Satterwaite formula (see Ref **4** and section 2.3, ISO Guide to the Expression of Uncertainty in Measurement)).

9. Information provided by uncertainty

9.1 The value of the expanded uncertainty in the measurement of absorbed dose should provide the level of confidence appropriate to the specific application.

9.2 Knowledge of the expanded uncertainty in the measurement process has several purposes.

9.2.1 The value of expanded uncertainty serves as a guide for determining if the measurement system is under control and proper procedures for use of the dosimetry system are being followed.

9.2.2 Results of the estimate of expanded uncertainty can be used to evaluate the suitability of the method of calibration and type of routine dosimeter that is being used to make the measurements. Depending on these results it may be necessary to change the method of calibration, change the instrumentation that is used for analysis or select a different dosimetry system that is more appropriate for the environment of use.

9.2.3 The results of the estimate of expanded uncertainty can be used as a guide for setting process parameters, for example, cycle time, to account for statistical variability in the measurement of absorbed dose. A quantitative version of this technique, which is referred to as the target dose concept, is sometimes proposed as a method for reducing the probability of not meeting the prescribed dosing specification. The application of this quantitative approach and the effect on processing specifications is outside the scope of this guide.

9.3 Performance of the detailed analysis of the components contributing to the expanded uncertainty has the following purposes.

9.3.1 Identification of possible sources of uncertainty and assessment of the effects of these sources of uncertainty on measurement of dose lessen the chance that the measurand will be influenced in an unknown way by a component of uncertainty that could significantly affect the accuracy of the reported value.

9.3.2 Variability in measured dose values may be traceable to uncertainty in the dosimetry system or due to changes in the process. Without knowledge of the uncertainty in the measurement system it is not possible to differentiate between these two potential sources of variability in the measurements of absorbed dose. Knowledge of the sources of variability in measurements of absorbed dose has practical value when investigating root causes for apparent deviations in dose.

9.3.3 Components of uncertainty that may be unacceptably large can be identified, which may require improvements in the measurement techniques.

10. Keywords

10.1 absorbed dose; accuracy; bias; dosimeter; dosimetry; electron beams; error; gamma radiation; ICS 17.240; radiation processing; Type A evaluation; Type B evaluation; uncertainty; X-ray

ANNEXES

(informative)

A1. UNCERTAINTY ASSOCIATED WITH FIT OF CALIBRATION DATA

A1.1 *Overview*:

A1.1.1 Dosimetry calibration data must be fitted to an analytical form, for example, linear, exponential, power, or polynomial that provides a good fit to the measurement data. Methods for fitting the calibration data to an analytical form are discussed in this annex. Dependent on the method of calibration, several components of uncertainty in measurement of absorbed dose may be captured in fit of the calibration data.

A1.1.2 A calibration model is a mathematical expression developed to describe the relationship between the absorbed dose and the dosimeter response at any point within the calibration range with an accompanying estimate of the uncertainty. The inverse of the response function derived from the calibration model is used to estimate absorbed dose from response during use of the dosimetry system.

NOTE A1.1—The dosimeter response is the value determined from the readout of the measurement instrument or the value derived from measurement data, for example, specific absorbance obtained by dividing the measured absorbance by the measured or mean thickness of the dosimeter, used for estimation of absorbed dose.

A1.1.3 The generic calibration model is written mathematically as: $R = f(p, D) + e\ (0, \sigma^2)$ where R is the dosimeter response, f, is the response function with the set of parameters p and the absorbed dose D, and e is the residual variability, normally distributed with mean 0 and variance σ^2. During calibration, the parameters p and variance σ^2 are estimated from calibration data.

A1.1.4 Calibration data are collected following ISO/ASTM 51261 and the specific practice for the dosimetry system in use. Dosimeters are irradiated under controlled conditions at several absorbed doses that cover the calibration range. At each absorbed-dose point, several dosimeters are irradiated simultaneously. The calibration procedure results in a data set consisting of several absorbed-dose points each associated with multiple dosimeter response values. These data allow the

residual variance σ^2 to be partitioned into lack of fit and intrinsic variability of dosimeter response components.

A1.2 *Response Function Estimation*:

A1.2.1 The response function, $f(p, D)$, in the calibration model $R = f(p, D) + e(0, \sigma^2)$ is a mathematical function that relates absorbed dose to the dosimeter response. If a theoretical form exists for this function then this form should be used and the parameters p and σ^2 estimated.

A1.2.1.1 For some routine dosimetry systems, the measured radiation-induced chemical or physical change is directly related to the absorbed dose and the response function is linear. For other systems, the rate of chemical or physical change begins as an increasing function, follows a linear response over a portion of the absorbed-dose range and then decreases or saturates at higher absorbed-dose values. For this form of reaction, the S-shaped curve can be approximated by a sigmoidal or logistic function.

A1.2.1.2 Commonly, the functional form must be selected prior to estimating the parameters. Some software packages will choose the most suitable functional form based on predefined statistical considerations, but careful consideration should be given to the selection of an appropriate functional form.

A1.2.2 The parameters of linear functions may be estimated by direct algebraic operations. Parameters of non-linear functions are estimated iteratively. Standard deviations for the fitted parameters should be reported.

A1.2.3 Least squares regression is used to estimate the parameters of the response function. The least squares algorithm minimizes the sum of squared differences between the measured response and the response estimated by the function $f(p, D)$. The minimal sum of squared differences is used to estimate the variance parameter σ^2 and the total uncertainty of the fit of the response is proportional to the square root of σ^2.

A1.2.3.1 The sum of squared differences between the measured response of individual dosimeters and the estimated response at a dose is used to estimate dosimeter variance. This requires the use of individual dosimeter responses in the regression calculation (also see A1.3.2).

NOTE A1.2—Mean values of the dosimeter responses and their associated variance "σ^2" may provide useful data on the reproducibility of the dosimeter response, but should not be used as the estimate of "σ^2" in A1.1.3 and A1.1.4.

A1.2.3.2 Dosimeters often have variability that depends in part on the magnitude of the absorbed dose. For such dosimeters, the ordinary least squares regression may over-estimate the dosimeter variability over the lower parts of the absorbed-dose range.

A1.2.4 Sometimes, when it is difficult to obtain a suitable fit over the entire range, two calibration equations should be developed; one for the lower (or higher) absorbed-dose range and one for the entire range. The equation for the limited absorbed-dose range may provide a better estimate of the response in the specified range. When two equations are developed, procedures may specify when each equation is to be used.

A1.2.5 It is sometimes possible to transform a non-linear form into a linear form by use of an appropriate transformation function. This is not recommended as the transformation not only changes the response function, $f(p, D)$ but also the residual variability $e(0, \sigma^2)$. Computer programs are readily available for estimating the parameters of a non-linear function without the need for a linearizing transformation.

A1.2.6 A polynomial is often used for the response function. The parameters of a polynomial can be estimated using ordinary least squares, that is, multivariate linear regression. A polynomial function can theoretically be used to approximate any other functional form. The lowest order of polynomial that provides an acceptable fit should be used to avoid oscillation of the calculated response values between the calibration points.

A1.3 *Diagnostics*:

A1.3.1 The response function used for a calibration model should be carefully examined for appropriateness and consistency. The residual values (the differences between the actual dosimeter response and the response estimated from the response function) are extremely useful diagnostics.

A1.3.1.1 The residual values for all data points should be examined to confirm that they are normally distributed with mean 0 and variance σ^2. A normal probability plot of the residuals should be linear. It is sufficient that the variation be approximately normally distributed.

A1.3.1.2 The plot of residual values versus absorbed dose should show values that scatter randomly about zero. Outlier values may indicate defective dosimeters or deviations from protocol that warrant investigation. Periodic patterns may indicate an inappropriate selection of the response function. Sequential variation of the residuals (residual values alternately positive and negative) may indicate dosimeter handling or processing effects warranting investigation.

A1.3.2 The data structure of dosimeter calibration with multiple dosimeters used at each dose point allows the lack of fit of a response function to be directly estimated. Lack of fit is the difference between the variability of the dosimeters about the mean response at each absorbed-dose point (intrinsic variability) and the variability of the dosimeters about the calculated response at each absorbed-dose point (residual variability). This difference is compared to the variability of the dosimeters about the mean response at each absorbed-dose point (intrinsic variability) by use of an F test. The model should be reviewed if the lack of fit F test is significant.

NOTE A1.3—Implicit in this analysis is the fundamental assumption that the dosimeter response is well behaved between calibration points. The F test does not specifically assess variability in areas between the calibration absorbed-dose points.

A1.4 *Absorbed-Dose Estimation*:

A1.4.1 Estimating the absorbed dose corresponding to a dosimeter response is performed by inverting the response function. The original response function is $R = f(p, D)$ and the inverted response function is $D = f^{1}(p, R)$. An algebraic inversion is used if possible, otherwise the inversion is done numerically. Commercial software packages such as Excel have numeric inversion functions built-in.

NOTE A1.4—Where available, confidence limits for the mean or individual values should be included.

A1.4.2 The uncertainty of the absorbed-dose estimate can be estimated by dividing the uncertainty of the measured dosimeter response by the slope of the response function at the point of estimation. The slope may be calculated algebraically as the first derivative of the response function. Alternately, the absorbed-dose uncertainties may be calculated numerically similarly to the absorbed-dose estimate.

NOTE A1.5—Examination of the residuals between the absorbed doses calculated from the response function and the calibration absorbed doses may also provide information for assessing the uncertainty of the absorbed-dose estimates.

A1.4.2.1 The uncertainty bounds in the absorbed-dose estimate are calculated as prediction limits. These limits are intended to bound some percentage, for example, 95 %, of all future absorbed doses where the dosimeter response is the value R.

A1.5 *Computer Software*:

A1.5.1 The complexity of the calculations required for fitting a calibration model and estimating absorbed dose invariably result in the use of computer software to perform the calculations. Many commercial packages are available that can perform some or all of the desired calculations.

A1.5.2 Examples of software packages include general statistics packages such as SAS, Statistica, Statlab, Stata, Sigma Stat, or Minitab; specialized packages/languages such as MathCad, Splus, or GraphPad; or the routines built into spreadsheets such as Excel.

NOTE A1.6—All trademarks are property of their respective owners.

A1.5.3 Many statistics packages assume that data are collected in independent (X,Y) pairs. For these statistics packages, the data structure of dosimeter calibration where one X value is used for multiple Y values is unusual. Because of this, the appropriate goodness of fit tests are not available as an option but rather must be constructed from the appropriate elements of standard printouts. Detailed understanding of both the calculations performed by the statistics package and the desired calculations is required to perform this construction.

A1.5.4 Most statistics packages do not have numerical inversion routines for estimating absorbed dose and absorbed-dose uncertainties. This capability is regarded as a mathematical function and is therefore found in the more mathematically oriented packages such as MathCad or MatLab, or in the mathematical spreadsheet functions.

A1.5.5 Performing dosimeter calibration and dose estimation using general-purpose statistical packages and/or spreadsheets may require combining several outputs to obtain the desired calculations.

A2. UNCERTAINTY ASSOCIATED WITH ROUTINE USE

A2.1 Dependent on the source of radiation, type of irradiator, and products being processed, some components in Table 4 (see 7.6) could significantly contribute to the total uncertainty in reported values of absorbed dose or alternately could be ignored. For example, variability in orientation of dosimeters to an electron beam could significantly contribute to the estimate of uncertainty in absorbed dose. Whereas, orientation of dosimeters may have little effect in the value of absorbed dose in large panoramic gamma irradiators **(9)**. Rather than cite examples for all of the components of uncertainty in Table 4, only those components that may significantly contribute to total uncertainty regardless of the source of radiation, type of irradiator or product are considered here. The user of this guide, however, is alerted to the importance of the remaining components of uncertainty in Table 4 and possible need to take them into account.

A2.2 Change in the environment during routine use from calibration conditions represents a potentially significant source of uncertainty in measurements of absorbed dose at the irradiator facility. This component of uncertainty usually appears as a systematic error in the measurement. By proper packaging, dosimeters can be isolated from certain environments, for example, ultraviolet radiation and humidity; however, the effect on response of other environmental factors such as temperature, dose rate, and energy spectrum must be taken into account (see ASTM Practice E 1249 and Refs **10-13**). For this reason, calibration conditions should approximate those for routine use when possible. In addition, selection of a dosimetry system that is insensitive to variation in environment will reduce systematic errors in the measurements. Irradiation of this type of dosimeter with the routine system offers one method of correcting for systematic errors. Unfortunately, the ideal dosimeter does not exist and corrections for environmental factors with estimates of systematic error may be required.

A2.2.1 Information on the temperature dependence of dosimetry systems is usually available from the manufacturer and published literature **(10-12)**. Fig. A2.1 provides an example of

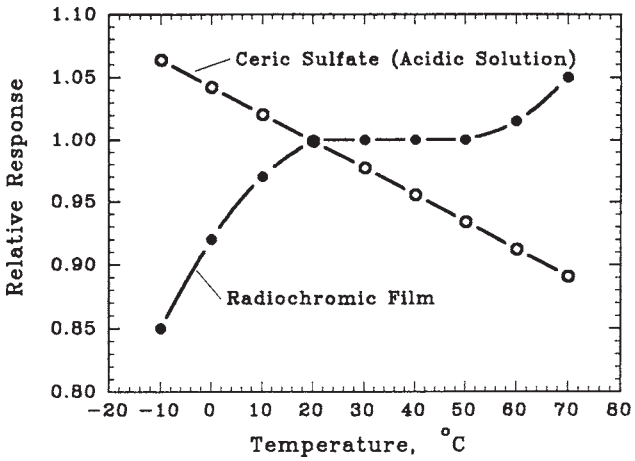

FIG. A2.1 Irradiation temperature dependence

the temperature response for two types of dosimetry systems (see ISO/ASTM Practices 51205 and 51275 and Refs **10, 12**). Both curves, which are normalized to a response of one at 20°C, were generated at given dose levels and dose rates. As seen from this figure, a correction of several percent in dosimeter response would be required if the temperature of irradiation deviates significantly from 20°C.

A2.2.2 Dose rates during irradiation of product may differ significantly from the calibration conditions. Even at a single irradiator facility, dose rate may vary by a factor of ten or more during the irradiation cycle. Fortunately, dosimeters routinely used to monitor dose at irradiators are relatively insensitive to dose rate effects. Even so, corrections in response of several percent may be necessary. Calibration of dosimeters at the dose rate extremes of the irradiator can be used to bracket the effect of dose rate on response. Co-location of dose rate independent dosimeters with the routine dosimeters also can be used to estimate the systematic error in the response of the routine system.

A2.2.3 For X-ray and gamma sources, correction for the spectral dependence of dosimeters can be assessed through the use of cavity theory **(14)**. At the extremes of "thin" and "thick" dosimeter, the correction factor that relates absorbed dose in dosimeter to the medium of interest is given by the ratio of mass collision stopping powers and mass energy absorption coefficients respectively (see ISO/ASTM Guide 51261). This approach has been used to estimate the correction factor that should be applied to various types of dosimeters when they are exposed to different photon spectra **(13)**. Knowledge of the response functions of the dosimeter and photon spectrum at the irradiator are required for calculation of the correction factor (see ASTM Practice E 1249). If the response is not corrected for energy dependence, a systematic error of several percent is possible.

A2.2.4 For electron beam irradiators, the variation of mass collision stopping powers over dosimeter thickness may in practice introduce uncertainties depending on the beam energy, scatter conditions, and the depth of measurement (see ICRU Reports 35 and 37). For these reasons, dosimeters must be thin and the ratio of mass collision stopping powers (material/dosimeter) must be essentially constant over the range of secondary electron energies.

A3. LAW OF PROPAGATION OF UNCERTAINTY (15)

A3.1 In many cases a measurand Y is not measured directly, but is determined from N other quantities $X_1, X_2, \ldots X_N$ through a functional relation f:

$$Y = f(X_1, X_2, \ldots X_N) \tag{A3.1}$$

Included among the quantities X_i are corrections (or correction factors) as described in Section 6, as well as quantities that take into account other sources of variability, such as different observers, instruments, samples, laboratories, and times at which observations are made (for example, different days). Thus the function f of Eq A3.1 should express not simply a physical law but a measurement process, and in particular, it should contain all quantities that can contribute significant uncertainty to the measurement result.

A3.2 An estimate of the measurand or output quantity Y, denoted by y, is obtained from Eq. A3.1 using input estimates $x_1, x_2, \ldots x_N$ for the values of the N input quantities $X_1, X_2, \ldots X_N$. Thus the output estimate y, which is the result of the measurement, is given by:

$$y = f(x_1, x_2, \ldots x_N) \tag{A3.2}$$

A3.3 The combined standard uncertainty of the measurement result y, designated by $u_c(y)$ and taken to represent the estimated standard deviation of the result, is the positive square root of the estimated variance $u_c^2(y)$ obtained from:

$$u_c^2(y) = \sum_{i=1}^{N} \left(\frac{\partial f}{\partial x_i}\right)^2 u^2(x_i) + 2 \sum_{i=1}^{N-1} \sum_{j=i+1}^{N} \frac{\partial f}{\partial x_i} \frac{\partial f}{\partial x_j} u(x_i, x_j) \tag{A3.3}$$

Eq A3.3 is based on a first-order Taylor series approximation of $Y = f(X_1, X_2, \ldots, X_N)$ and is conveniently referred to as the law of propagation of uncertainty. The partial derivatives of $\partial f/\partial x_i$ (often referred to as sensitivity coefficients) are equal to $\partial f/\partial X_i$ evaluated at $X_i = x_i$; $u(x_i)$ is the standard uncertainty associated with the input estimate x_i; and $u(x_i, x_j)$ is the estimated covariance associated with x_i and x_j.

A3.3.1 For sources of uncertainty that are independent (not correlated), the combined uncertainty is obtained by combining all standard uncertainties in quadrature.

A3.4 As an example of a Type A evaluation, consider an input quantity X_i whose value is estimated from n independent observations $X_{i,k}$ of X_i obtained under the same conditions of measurement. In this case the input estimate x_i is usually the sample mean:

$$x_i = \bar{X}_I = 1/n \sum_{k=1}^{n} \bar{X}_{I,k} \tag{A3.4}$$

and the standard uncertainty $u(x_i)$ to be associated with x_i is the estimated standard deviation of the mean

$$u(x_i) = s(\bar{x}_i) = \left\{ \frac{1}{n(n-1)} \sum_{k=1}^{n} (X_{i,k} - \bar{X}_i)^2 \right\}^{1/2} \tag{A3.5}$$

NOTE A3.1—Eq A3.5 provides an unbiased estimate of the standard deviation.

A3.5 As an example of a Type B evaluation, consider an input quantity X_i whose value is estimated from an assumed rectangular probability distribution of lower limit a_- and upper limit a_+. In this case the input estimate is usually the expectation of the distribution.

$$x_i = (a_+ + a_-)/2 \tag{A3.6}$$

and the standard uncertainty $u(x_i)$ to be associated with x_i is the positive square root of the variance of the distribution:

$$u(x_i) = \frac{a}{\sqrt{3}} \tag{A3.7}$$

where:
$a = (a_+ - a_-)/2$ (see Section 6).

NOTE A3.2—When x_i is obtained from an assumed distribution, the associated variance is appropriately written as $u^2(X_i)$, but for simplicity, $u^2(x_i)$ and $u(x_i)$ are used. Similar considerations apply to the symbols $u_c{}^2(y)$ and $u_c(y)$.

A4. EXAMPLE OF DOSIMETRIC UNCERTAINTY FOR ROUTINE USE OF RED 4034 PERSPEX BASED ON IN-HOUSE CALIBRATION

A4.1 *Methodologies for Estimating Individual Components of Uncertainty*:

A4.1.1 The following sections address the methods for estimating the Type A and Type B components of uncertainties based on an in-house calibration procedure.

NOTE A4.1—Uncertainties estimated by the in-house facility calibrating the dosimeters are reported as a single value (Type A and Type B combined) and uncertainty reported by the calibration service, for example, NIST or NPL as Type B.

A4.2 *Uncertainty in Absorbed Dose Due to Calibration*—An example of the derivation of the uncertainty associated with a dosimetry system calibrated using an accredited in-house gamma facility is described in the following sections. In this example, the equipment includes a Gammacell 220 (GC 220) self-contained dry storage gamma irradiator (manufactured by MDS Nordion) and a 10-position temperature-controlled dosimeter holder. The holder is cylindrical with all 10 positions equally spaced.

A4.2.1 Sources of uncertainty that contribute to the overall measurement uncertainty using the GC 220 and 10-position holder assembly include those listed in Table A4.1. All uncertainties are reported as relative standard uncertainty values (coverage factor, $k = 1$, approximately 68 % confidence level).

A4.2.2 *Response of Reference or Transfer Standard*:

A4.2.2.1 To establish traceability of the absorbed dose rate of the GC220 to national standards, reference or transfer standard dosimeters are supplied by a recognized standards organization/laboratory for irradiation in the GC220. Certification of calibration includes the laboratory's estimate of the overall uncertainty associated with the absorbed dose evaluation, which is reported here as a Type B uncertainty.

TABLE A4.1 Components of uncertainty ($k = 1$) for dose delivered to dosimeters

Component	Uncertainty at 1 Standard Deviation (%)	
	Type A	Type B
Response of reference or transfer standard	N/A	1.1
Irradiation time	N/A	0.1
Decay corrections		0.03
Non-uniformities in the radiation field	0.11	
Attenuation and geometry due to holder	N/A	0.5
Conversion of absorbed dose to reference material	N/A	N/A
Type A and Type B combined separately in quadrature	0.01	1.22
Type A and Type B combined in quadrature (1σ)	1.22	

A4.2.2.2 For dosimeters supplied by laboratories such as NIST or NPL, overall uncertainty is approximately ±1.1 % (or less) at the 68 % confidence level.

A4.2.3 *Irradiation Time*:

A4.2.3.1 Based on variation in movement of the sample chamber, uncertainty in irradiation time is estimated to be 0.1 % at the 68 % confidence level. Transit absorbed dose (see ISO/ASTM 51261) is included during the establishment of irradiation time.

A4.2.4 *Radioisotope Decay Corrections*:

A4.2.4.1 *Type B Uncertainty*—Decay corrections are performed each day irradiations are performed. The maximum uncertainty due to the decay correction between any two days is 0.01 % at the 68 % confidence level (0.04 %/3), which was not taken into account in the estimate of combined uncertainty because of its small magnitude.

A4.2.4.2 *Type B Uncertainty*—The half-life of Cobalt-60 is 1925.5 ± 0.5 days **(16)**. The uncertainty in the half-life value is 0.03 % (0.5/1925.5 × 100 %) at the 68 % confidence level.

A4.2.5 *Non-uniformities in Standard Radiation Field*:

A4.2.5.1 Dosimeters are irradiated in the 10-position aluminum holder. The effect of variation in absorbed dose received by individual dosimeters due to positioning within the holder is estimated to be 0.25 % at 68 % confidence level. For sets of 5 dosimeters used for calibration, divide by the square root of the number of samples 0.25 %/$\sqrt{5}$ to obtain the Type A estimate of 0.11 %.

A4.2.6 *Correction for Attenuation and Geometry*:

A4.2.6.1 Irradiation of dosimeters is performed based on the 10-position holder/ampoule geometry.

A4.2.6.2 The absorbed doses for all dosimeters irradiated are based upon the absorbed dose (rate) for this geometry. An estimate of uncertainty (Type B) of 0.5 % at the 68 % confidence level is assigned for differences in attenuation characteristics between the ampoule-type and perspex-type materials.

A4.2.7 *Conversion of Absorbed Dose to Reference Material*:

A4.2.7.1 All absorbed dose results are reported as absorbed dose in water. Reporting absorbed dose values in other materials (for example, PMMA, silicon, and graphite) require an additional component of uncertainty due to the ratio of the mass energy absorption coefficients.

A4.2.7.2 For a photon spectrum having significant scatter component down to approximately 100 keV, the uncertainty is approximately ±0.3 % at 68 % confidence level **(17)**. If this component of uncertainty is taken into account, an additional Type B component of uncertainty of 0.3 % at 68 % confidence level should be added.

A4.2.8 Combining the Type A and Type B components in quadrature, the overall uncertainty for irradiation of dosimeters in the Gammacell 220 is estimated to be ±1.22 % at the 68 % confidence level.

A4.3 *Analysis of Dosimeters* :

A4.3.1 *Intrinsic Variation in Dosimeter Response*:

A4.3.1.1 *Type A*—Under conditions of repeatability, a pooled estimate of specific absorbance values from calibration samples (reference data in Table A4.2) was taken. Five (5) samples were each irradiated to eleven absorbed dose points. Relevant information collected or calculated include the following:

(1) Number of measurements of each dose (n_i)

(2) Specific absorbance (k cm^{-1})

(3) Mean value of absorbed dose ($\bar{d}_i$)

(4) Sample standard deviation (SD_i)

(5) Coefficient of variation ($\%CV = \{ [\Sigma(n_i-1)(SD^2_i/\bar{d}^2_i)]^{1/2}/[\Sigma(n_i-1)]\} \times 100\ \%$)

TABLE A4.2 Example of intrinsic variation in dosimeter response

Calibration Lab Certified Absorbed Dose (kGy, water)	Dosimeter ID	Absorbance Reading	Thickness Reading (cm)	Specific Absorbance, k (cm^{-1})	Mean Calculated Dose, $\bar{d}_i$(kGy)	Sample Standard Deviation, SD_i(kGy)	$SD_i^2/\bar{d}^2_i$
3.5	1	0.152	0.279	0.545	3.36	0.09	7.732E-04
3.5	2	0.157	0.294	0.534			
3.5	3	0.163	0.312	0.522			
3.5	4	0.158	0.296	0.534			
3.5	5	0.163	0.311	0.524			
5.0	1	0.207	0.297	0.697	5.09	0.06	1.298E-04
5.0	2	0.218	0.310	0.703			
5.0	3	0.229	0.322	0.711			
5.0	4	0.218	0.312	0.699			
5.0	5	0.220	0.315	0.698			
10.0	1	0.379	0.312	1.215	10.22	0.04	1.180E-05
10.0	2	0.403	0.331	1.218			
10.0	3	0.371	0.306	1.212			
10.0	4	0.377	0.312	1.208			
10.0	5	0.346	0.285	1.214			
15.0	1	0.501	0.308	1.627	14.94	0.14	8.724-05
15.0	2	0.458	0.277	1.653			
15.0	3	0.511	0.312	1.638			
15.0	4	0.447	0.275	1.625			
15.0	5	0.467	0.286	1.633			
20.0	1	0.570	0.284	2.007	19.98	0.24	1.397E-04
20.0	2	0.573	0.288	1.990			
20.0	3	0.623	0.307	2.029			
20.0	4	0.625	0.313	1.997			
20.0	5	0.679	0.340	1.997			
25.0	1	0.683	0.300	2.277	24.65	0.22	7.767E-05
25.0	2	0.678	0.296	2.291			
25.0	3	0.700	0.304	2.303			
25.0	4	0.741	0.326	2.273			
25.0	5	0.714	0.313	2.281			
30.0	1	0.739	0.288	2.566	29.89	0.30	9.751E-05
30.0	2	0.713	0.280	2.546			
30.0	3	0.732	0.287	2.551			
30.0	4	0.741	0.290	2.555			
30.0	5	0.708	0.280	2.529			
35.0	1	0.882	0.317	2.782	35.20	0.35	9.812E-05
35.0	2	0.768	0.276	2.783			
35.0	3	0.875	0.317	2.760			
35.0	4	0.894	0.323	2.768			
35.0	5	0.822	0.294	2.796			
40.0	1	0.779	0.260	2.996	40.70	0.54	1.753E-04
40.0	2	0.872	0.292	2.986			
40.0	3	0.851	0.285	2.986			
40.0	4	0.840	0.280	3.000			
40.0	5	0.856	0.290	2.952			
45.0	1	0.796	0.254	3.134	44.76	0.48	2.448E-05
45.0	2	0.915	0.295	3.102			
45.0	3	0.945	0.303	3.119			
45.0	4	0.948	0.302	3.139			
45.0	5	0.974	0.313	3.112			
50.0	1	0.996	0.305	3.266	49.70	0.50	2.010E-05
50.0	2	0.905	0.277	3.267			
50.0	3	0.887	0.269	3.297			
50.0	4	0.990	0.302	3.278			
50.0	5	1.076	0.330	3.261			

A4.3.1.2 Using the equation in A4.3.1.1, and substituting the values listed in Table A4.2, which are expressed in terms of uncertainty in dose, the average %CV (pooled estimate), reported as the Type A uncertainty for this data set, was determined to be 1.28 %.

A4.3.2 *Variation in Spectrophotometric Wavelength Setting*:

A4.3.2.1 *Type B*—Three (3) dosimeters with nominal absorbances of 0.3 A, 0.6 A, and 0.9 A were measured on a spectrophotometer (Table A4.3). Absorbances were measured over the range 638.0 to 642.0 nm at 0.1 nm increments.

NOTE A4.2—Instruments were set to the corresponding wavelength and the instrument set to 0.000 A prior to making a measurement.

A4.3.2.2 Assuming a triangular distribution (that is, midpoint wavelength values are more likely than those at the extremes), the average percent difference relative to the reference wavelength of 640.0 nm, 2.1 %, was divided by $\sqrt{6}$ to obtain a Type B uncertainty of 0.86 %. The uncertainty in absorbance was expressed in terms of uncertainty in dose using the relationship between absorbance and dose that is given by the calibration curve. At a dose of 25 kGy the uncertainty in dose due to an uncertainty of 0.86 % in absorbance was 1.10 %.

TABLE A4.3 Example of variation in spectrophotometric readout (Type B)

Wavelength (nm)	ABS (0.3)	ABS (0.6)	ABS (0.9)
638.0	0.382	0.696	0.957
638.1	0.382	0.695	0.957
638.2	0.381	0.695	0.954
638.3	0.381	0.694	0.954
638.4	0.381	0.694	0.954
638.5	0.380	0.693	0.952
638.6	0.379	0.692	0.951
638.7	0.379	0.692	0.950
638.8	0.379	0.692	0.950
638.9	0.379	0.691	0.949
639.0	0.378	0.690	0.947
639.1	0.377	0.689	0.947
639.2	0.377	0.688	0.945
639.3	0.376	0.687	0.944
639.4	0.376	0.687	0.944
639.5	0.376	0.687	0.943
639.6	0.375	0.686	0.942
639.7	0.375	0.685	0.941
639.8	0.374	0.684	0.940
639.9	0.374	0.683	0.939
640.0	0.373	0.682	0.937
640.1	0.373	0.682	0.937
640.2	0.373	0.682	0.937
640.3	0.373	0.681	0.936
640.4	0.371	0.680	0.933
640.5	0.371	0.679	0.933
640.6	0.370	0.678	0.933
640.7	0.370	0.677	0.929
640.8	0.369	0.677	0.929
640.9	0.370	0.677	0.929
641.0	0.369	0.676	0.928
641.1	0.368	0.674	0.925
641.2	0.368	0.674	0.925
641.3	0.368	0.674	0.925
641.4	0.367	0.672	0.923
641.5	0.366	0.671	0.922
641.6	0.366	0.671	0.921
641.7	0.366	0.670	0.920
641.8	0.365	0.669	0.918
641.9	0.364	0.669	0.918
642.0	0.364	0.668	0.917

A4.3.3 *Post-irradiation Handling—Fade/Development (Type B only)*:

A4.3.3.1 *Type B*—The uncertainty due to dosimeter fade/development characteristics prior to readout is estimated to be 1.0 %.

A4.3.4 *Conversion of Absorbed Dose in Reference Material, Water, to Absorbed Dose in Dosimeter Material, PMMA (Type B only)*:

A4.3.4.1 *Type B*—This is only applicable if the absorbed dose reference material is something other than water. If so, it is estimated to be 0.3 % **(17)**.

A4.4 *Curve Fitting*:

A4.4.1 *Variation in Response of Dosimeters*:

A4.4.1.1 Fig. A4.1 is a plot of the data from Table A4.2—response is the dependent variable and absorbed dose is the independent variable. A polynomial (3rd order) was selected as the analytical function to describe the relationship between these two parameters.

A4.4.1.2 Fig. A4.2 is a plot of the residuals. Taken collectively, the relatively small residuals, the randomness of the residuals (equally distributed), and the high R^2 value, are indicative of the goodness of fit.

A4.4.1.3 Computer software that offers solutions to nonlinear regression typically includes features for establishing prediction limits. Once the prediction limits to the response curve (Fig. A4.1) are added, an estimate of the uncertainty in absorbed dose can be determined using iterative techniques to solve for absorbed dose based upon a known response. Through inversion of axes, the lower and upper prediction limits of response become the upper and lower prediction limits of absorbed dose. In the solution to this example, the uncertainty in the 95 % prediction limits for absorbed dose ranged from approximately 5.4 % (for absorbed doses below 5 kGy) to approximately 2 to 3 % for absorbed doses above 5 kGy. The average value of 2.7 % (1.35 % at one standard deviation) is reported as a Type A uncertainty.

A4.4.1.4 *Type B*—Insignificant.

A4.4.2 *Analytical Function Used in Fit (Type B only)*:

A4.4.2.1 *Type B*—Insignificant.

A4.5 *Routine Use*:

A4.5.1 Differences in the calibration and routine processing environments, primarily due to the combined effects of irradiation temperature, variation in absorbed dose rate, and post-irradiation storage, require adjustment of the calibration relationship of the routine dosimeters.

A4.5.1.1 Routine and transfer standard dosimeters are irradiated together under routine process conditions, and the measured absorbed dose value of the routine dosimeter is adjusted, as needed using an appropriate mathematical relationship, to match the measured absorbed dose value of the transfer standard dosimeter.

A4.5.1.2 The "residual" differences between the adjusted routine dosimeter absorbed dose response and the transfer

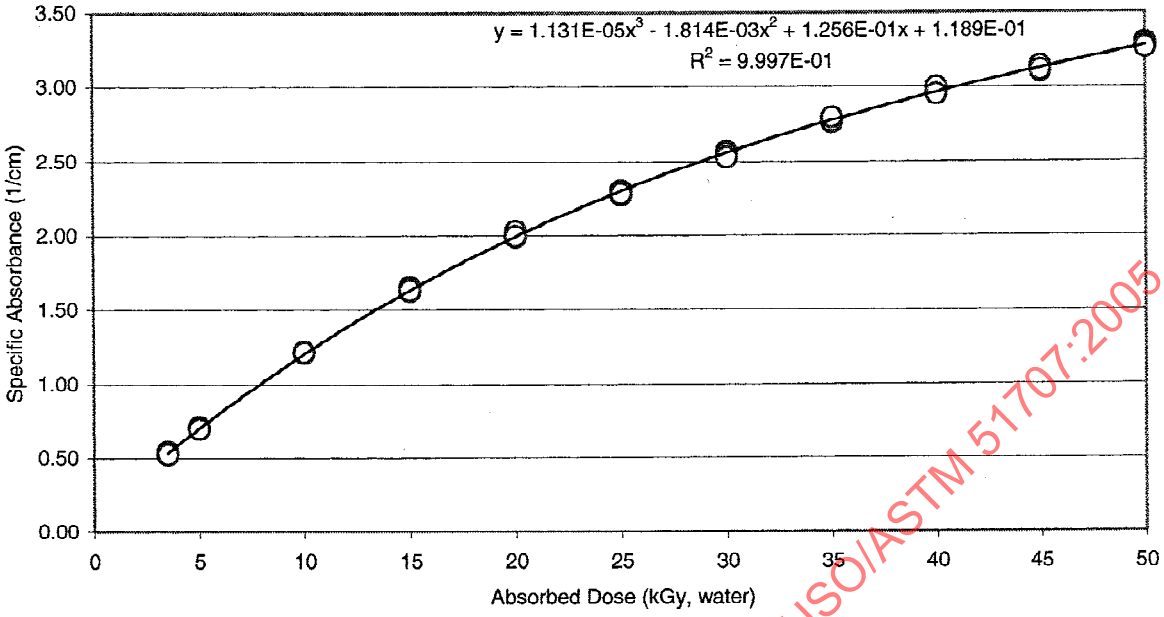

FIG. A4.1 Response curve (3rd order polynomial) for Red 4034 dosimetry data in Table A4.2

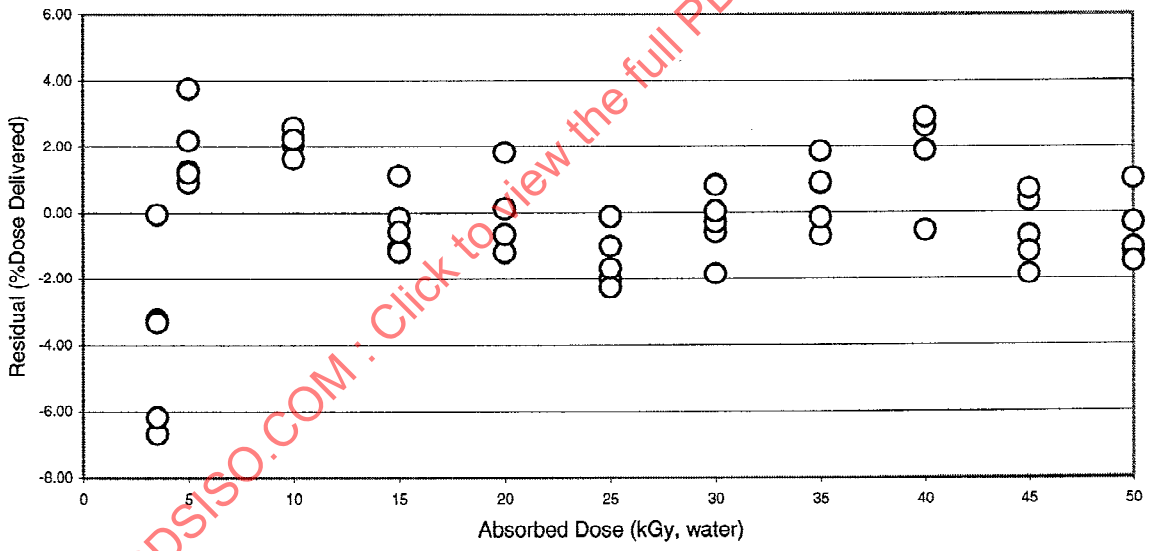

FIG. A4.2 Calculated dose residuals for Red 4034 perspex dosimetry

dosimeter provide an estimate of the Type B uncertainty. Based upon long-term inter-comparison studies using transfer standard dosimeters and Red 4034 dosimeters, the Type B uncertainty is estimated to be approximately 1.5 %.

A4.5.2 *Orientation of Dosimeters to Radiation Source (Type B only)*:

A4.5.2.1 *Type B*—Estimated to be no greater than 1 % **(9)**.

A4.5.3 *Variation in Dosimeter Response Over Time (Type A only: Insignificant)*:

A4.5.3.1 Assessment of the change in response over time was performed by repeating the calibration of a given dosimeter batch used at a facility. Recalibrations of an existing batch were performed for 3 batches and 5 facilities; the first and second calibrations separated by anywhere from 6 to 13 months.

A4.5.3.2 A two-factor analysis of variance was performed on each set of data. This model assumes dosing is the same at each absorbed dose point in time and the only "error" is strictly due to random variation.

A4.5.3.3 Statistical analysis of the ratio of k-values at each absorbed dose point for the repeat calibrations of these 3 batches (first calibration/second calibration) indicates an average ratio for all batches (57 ratios) of 0.999. This indicates dosing consistency and further supports the insignificance of

TABLE A4.4 Estimate of uncertainty based on sample data

	Type A (%)	Type B (%)
Calibration Lab (A4.2)		1.22
Type A and B combined in quadrature	1.22	
Dosimeter Readout (A4.3)		
Intrinsic variation in calculated dose(kGy)	1.28	
Variation in spectrophotometer ABS		1.10
Fade/development		1.00
Absorbed dose reference conversion		0.30
Type A and B combined in quadrature	1.98	
Calibration & Curve Fitting (A4.4)	1.35	
Type A and B combined in quadrature	1.35	
Routine Use (A4.5)		
Environmental Effects		1.50
Orientation to source		1.00
Type A and B combined in quadrature	1.80	
Variations in Product and Placement (A4.5.4)		
Adjacent product		1.00
Reproducibility in placement		1.00
Type A and B combined in quadrature	1.41	
Overall (1 standard deviation; coverage $k = 1$)	3.53	
Overall (2 standard deviations; coverage $k = 2$)	7.06	

any change in dosimeter response over the time which dosimeter batches are routinely used.

A4.5.4 Additional uncertainties arise which are product-dependent and not dosimeter-dependent. The impact of adjacent product and reproducibility in placement of dosimeters—which are due to variations in the product itself—also contribute to the variability in dosing. These sources of uncertainty are each estimated to be 1 % (Type B only).

A4.6 *Overall Statement of Uncertainty*:

A4.6.1 The expanded (overall) uncertainty in measuring absorbed dose using the Red 4034 dosimetry system is estimated to be ±7.06 % at the 95 % confidence level.

A4.6.2 Table A4.4 summarizes the uncertainty analysis.

A5. EXAMPLE OF THE UNCERTAINTY IN THE CALIBRATION AND USE OF ROUTINE DOSIMETERS IN PRODUCTION IRRADIATORS USING CERIC-CEROUS TRANSFER-STANDARD DOSIMETERS

A5.1 *General*:

A5.1.1 This is an example of an estimate of expanded (overall) uncertainty in the calibration of Red Perspex routine dosimetry systems in production irradiators using Ceric-Cerous transfer standard dosimeters. This method takes combined environmental factors into account to the extent that the reference or transfer dosimeter response can be corrected for differences in environmental factors between the calibration facility and production irradiator. Refer to ISO/ASTM 51261 for a detailed description of this calibration methodology. Although this example is specific to Red Perspex and Ceric-Cerous dosimeters, the in situ calibration methodology may be applied to other routine dosimetry systems. In addition to ceric-cerous dosimeters, other types of transfer-standard dosimeters may be used.

A5.2 *Calibration Irradiations*:

A5.2.1 Nine packages of dosimeters, each consisting of two Ceric-Cerous dosimeters, four Red Perspex dosimeters, and one Thermolabel, were irradiated to different dose levels in a ^{60}Co production irradiator. Refer to ISO/ASTM 51261 for typical dosimeter package geometries. Each dosimeter package was placed on simulated product where the absorbed-dose variation over the area containing the dosimeters was within ±2 %. For each dose point, four replicate measurements of absorbance and dosimeter thickness were made. The routine dosimeters were analyzed on site and the transfer-standard dosimeters were returned to an accredited dosimetry laboratory for analysis. Measured data are found in Table A5.1.

NOTE A5.1—A possible source of uncertainty in this technique is the lack of electron equilibrium during irradiation. When thick and thin dosimeters are irradiated together, surround the thin dosimeters by sufficient build up material to ensure that the attenuation characteristics are similar, and to ensure that the dosimeters receive the same dose. For a ^{60}Co radiation source, 3 to 5 mm of polystyrene (or equivalent polymeric material) should surround the dosimeter in all directions. Refer to ISO/ASTM 51261 for more details on the calibration method and dosimeter package geometry.

A5.3 *Uncertainty in Absorbed Dose Measured by Transfer-standard Dosimeters*:

A5.3.1 This method takes the combined effect of environmental factors into account to the extent that the reference or

TABLE A5.1 Comparison of dosimetry systems

No.	Ceric-Cerous Vial # 1 (kGy)	Ceric-Cerous Vial # 2 (kGy)	Average Ceric-Cerous Dose (kGy)	Measured Specific Absorbance Red Perspex Dosimeters (1/cm)			
				#A	#B	#C	#D
1	5.16	5.08	5.12	0.698	0.706	0.712	0.696
2	7.44	7.91	7.68	0.947	0.957	0.977	0.944
3	9.84	9.74	9.79	1.178	1.192	1.182	1.163
4	12.26	12.34	12.30	1.414	1.387	1.396	1.397
5	15.47	15.74	15.61	1.671	1.68	1.664	1.67
6	19.08	19.41	19.25	1.922	1.934	1.916	1.961
7	20.10	20.50	20.30	2.013	2.003	2.031	1.993
8	22.80	23.64	23.22	2.268	2.252	2.284	2.231
9	26.22	26.08	26.15	2.456	2.419	2.403	2.412