ISO/ASTM51707:2005(E)

An American National Standard

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]

E170 Terminology Relating to Radiation Measurements and Dosimetry

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E178 Practice for Dealing With Outlying Observations

E456 Terminology Relating to Quality and Statistics

E876 Practice for Use of Statistics in the Evaluation of Spectrometric Data (Withdrawn 2003)[4]

E1249 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[5]

ISO 11137 Sterilization of Health Care Products-Requirements for Validation and Routine Control-Radiation Sterilization[6]

2.4 *ICRU Reports:*[7]

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

[1] This guide is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.01 on Dosimetry, 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] The last approved version of this historical standard is referenced on www.astm.org.

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

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

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

ICRU Report 35 Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV
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 $d\bar{\varepsilon}$ by d*m*, where $d\bar{\varepsilon}$ is the mean energy imparted by ionizing radiation to matter of mass d*m* (see ICRU 60).

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

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:

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

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:

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

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:

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

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 E170 and E456, and Practice E177).

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 E170 and E456, and Practice E177). 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 E178 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.[8]

6. Evaluation of standard uncertainty

6.1 *Measurement Procedure:*

[8] 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.

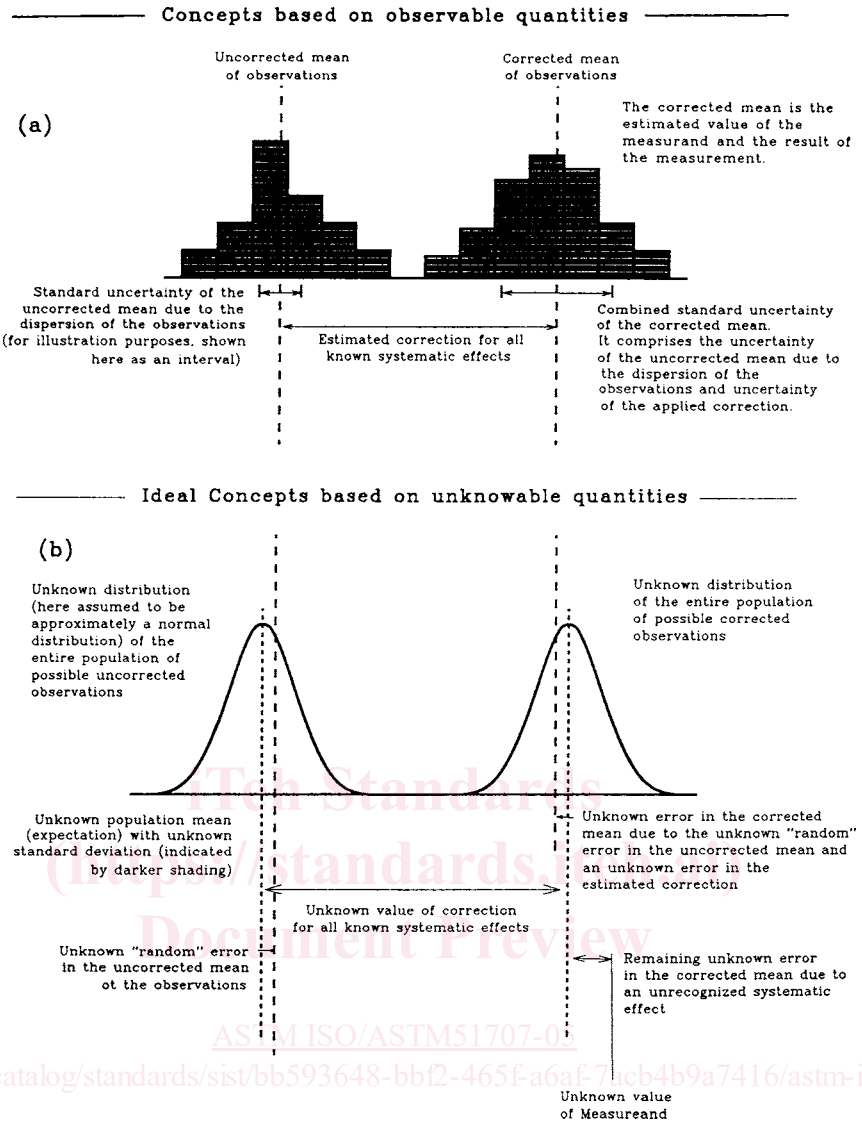

FIG. 1 Graphical illustration of value, error, and uncertainty

6.1.1 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:

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

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, $\bar{x}$, 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

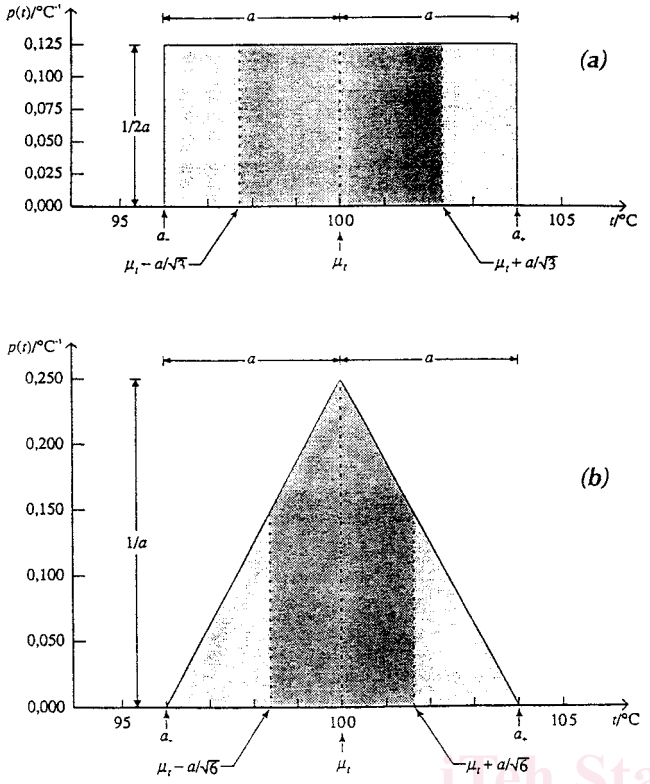

FIG. 2 Graphical illustration of evaluating type B standard uncertainty

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 E876). 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.

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

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.

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

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}

apply equally to calibration at gamma, electron beam, and X-ray/bremsstrahlung irradiators.

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.