An American National Standard

Standard Guide for Estimation of Measurement Uncertainty 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 standard provides guidance on the use of concepts described in the JCGM Evaluation of Measurement Data – Guide to the Expression of Uncertainty in Measurement (GUM) to estimate the uncertainties in the measurement of absorbed dose in radiation processing.

1.2 Methods are given for identifying, evaluating and estimating the components of measurement uncertainty associated with the use of dosimetry systems and for calculating combined standard measurement uncertainty and expanded (overall) uncertainty of dose measurements based on the GUM methodology.

1.3 Examples are given on how to develop a measurement uncertainty budget and a statement of uncertainty.

1.4 This document is one of a set of standards that provides recommendations for properly implementing dosimetry in radiation processing, and provides guidance for achieving compliance with the requirements of ISO/ASTM 52628 related to the evaluation and documentation of the uncertainties associated with measurements made with a dosimetry system. It is intended to be read in conjunction with ISO/ASTM 52628, ISO/ASTM 51261 and ISO/ASTM 52701.

1.5 This guide does not address the establishment of process specifications or conformity assessment.

1.6 *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:*[2]

E170 Terminology Relating to Radiation Measurements and Dosimetry

E456 Terminology Relating to Quality and Statistics

2.2 *ISO/ASTM Standards:*[2]

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51608 Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing

51649 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV

51702 Practice for Dosimetry in a Gamma Facility for Radiation Processing

52628 Practice for Dosimetry in Radiation Processing

52701 Guide for Performance Characterization of Dosimeters and Dosimetry systems for Use in Radiation Processing

2.3 *ISO Documents:*

ISO 11137-1 Sterilization of Health Care Products – Radiation – Requirements for Development, Validation and Routine Control of a Sterilization Process[3]

ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories[4]

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[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] 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.

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

[4] Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland, http://www.iso.org.

2.4 *Joint Committee for Guides in Metrology (JCGM) Reports:*

JCGM 100:2008, GUM 1995, with minor corrections, Evaluation of measurement data – Guide to the Expression of Uncertainty in Measurement[5]

JCGM 200:2008, VIM, International vocabulary of metrology – Basis and general concepts and associated terms[6]

2.5 *ICRU Reports:*[7]

ICRU Report 80 Dosimetry Systems for Use in Radiation Processing

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

3. Terminology

3.1 *Definitions:*

NOTE 1—For definitions quoted here from VIM, only the text of the definition is kept here. Any NOTES or EXAMPLES are not included. They can be reviewed by referring to VIM (JCGM 200:2008).

3.2 *Definitions:*

3.2.1 *approved laboratory*—laboratory that is a recognized national metrology institute; or has been formally accredited to ISO/IEC 17025; or has a quality system consistent with the requirements of ISO/IEC 17025.

3.2.1.1 *Discussion*—A recognized national metrology institute or other calibration laboratory accredited to ISO/IEC 17025 should be used for irradiation of dosimeters or dose measurements for calibration in order to ensure traceability to a national or international standard. A calibration certificate provided by a laboratory not having formal recognition or accreditation will not necessarily be proof of traceability to a national or international standard.

3.2.2 *arithmetic mean, average* [GUM, C.2.19]—sum of values divided by the number of values:

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

where:

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

3.2.2.1 *Discussion*—The term 'mean' is used generally when referring to a population parameter and the term 'average' when referring to the result of a calculation on the data obtained in a sample.

3.2.3 *calibration curve* [VIM, 4.31]—expression of the relation between indication and corresponding measured quantity value.

3.2.3.1 *Discussion*—In radiation processing standards, the term "dosimeter response" is generally used for "indication".

3.2.4 *coefficient of variation (CV)*—sample standard deviation expressed as a percentage of sample average value (see 3.2.2 and 3.2.19):

$$CV = \frac{S}{\bar{x}} \times 100\ \% \tag{2}$$

3.2.5 *combined standard measurement uncertainty* [VIM, 2.31]—standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model.

3.2.5.1 *Discussion*—

(1) It is also referred to as 'combined standard uncertainty'.

(2) In case of correlations of input quantities in a measurement model, covariances must also be taken into account when calculating the combined standard measurement uncertainty.

3.2.6 *coverage factor (k)* [VIM, 2.38]—number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty.

3.2.6.1 *Discussion*—A coverage factor, *k*, is typically in the range of 2 to 3 (see 5.2.4).

3.2.7 *expanded uncertainty* [GUM, 2.3.5]—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.

3.2.7.1 *Discussion*—Expanded uncertainty is obtained by multiplying the combined standard uncertainty by a coverage factor, the value of which determines the magnitude of the 'fraction'. Expanded uncertainty is also referred to as 'overall uncertainty'.

3.2.8 *influence quantity* [VIM, 2.52]—quantity that, in a direct measurement, does not affect the quantity that is actually measured, but affects the relation between the indication and the measurement result.

3.2.8.1 *Discussion*—In radiation processing dosimetry, this term includes temperature, relative humidity, time intervals, light, radiation energy, absorbed dose rate, and other factors that might affect dosimeter response, as well as quantities associated with the measurement instrument.

3.2.9 *level of confidence*—probability that the value of a parameter will fall within the given range.

3.2.10 *measurand* [VIM, 2.3]—quantity intended to be measured.

3.2.10.1 *Discussion*—In radiation processing dosimetry, the measurand is the absorbed dose (Gy) or simply 'dose'.

3.2.11 *measurement* [VIM, 2.1]—process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity.

3.2.12 *measurement uncertainty* [VIM, 2.26]—non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

3.2.12.1 *Discussion*—

(1) Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement

[5] Document produced by Working Group 1 of the Joint Committee for Guides in Metrology (JCGM/WG 1). Available free of charge at the BIPM website (http://www.bipm.org).

[6] Document produced by Working Group 2 of the Joint Committee for Guides in Metrology (JCGM/WG 2). Available free of charge at the BIPM website (http://www.bipm.org).

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

standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.

(2) The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

(3) Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which may be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.

(4) In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

3.2.13 *metrological traceability* [VIM, 2.41]—property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

3.2.13.1 *Discussion—*

(1) The unbroken chain of calibrations is referred to as "traceability chain".

(2) Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.

(3) The abbreviated term "traceability" is sometimes used to mean 'metrological traceability' as well as other concepts, such as 'sample traceability', 'document traceability', 'instrument traceability' or 'material traceability', where the history ("trace") of an item is meant. Therefore, the full term of "metrological traceability" is preferred if there is any risk of confusion.

3.2.14 *quadrature*—method used in estimating combined standard uncertainty from independent sources by taking the positive square root of the sum of the squares of individual components of uncertainty, for example, coefficient of variation.

3.2.15 *quantity* [VIM, 1.1]—property of a phenomenon, body, or substance, where the property has a magnitude that can be expressed as a number and a reference.

3.2.16 *quantity value* [VIM, 1.19]—number and reference together expressing magnitude of a quantity.

3.2.16.1 *Discussion*—For example, absorbed dose of 25 kGy.

3.2.17 *repeatability (of results of measurements)* [GUM, B.2.15]—closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement.

3.2.17.1 *Discussion—*

(1) These conditions are called 'repeatability conditions'.

(2) Repeatability conditions include: the same measurement procedure, the same observer, the same measuring instrument used under the same conditions, the same location, repetition over a short period of time.

(3) Repeatability may be expressed quantitatively in terms of the dispersion characteristics of the results.

3.2.18 *reproducibility (of results of measurements)* [GUM, B.2.16]—closeness of the agreement between the results of measurements of the same measurand carried out under changed conditions of measurement.

3.2.18.1 *Discussion—*

(1) A valid statement of reproducibility requires specification of the conditions changed.

(2) The changed conditions may include: principle of measurements, method of measurement, observer, measuring instrument, reference standard, location, conditions of use and time.

(3) Reproducibility may be expressed quantitatively in terms of the dispersion characteristics of the results.

3.2.19 *sample standard deviation (S)* [adapted from GUM, C.2.21]—measure of dispersion of values of the same measurand expressed as the positive square root of the sample variance.

3.2.20 *sample variance* [GUM, C.2.20]—measure of dispersion, which is the sum of the squared deviations of observations from their average divided by (n –1), given by the expression:

$$S^2 = \frac{\sum (x_i - \bar{x})^2}{(n - 1)} \quad (3)$$

where:

x_i = individual value of parameter with $i = 1, 2 \ldots n$, and
$\bar{x}$ = mean of n values of parameter (see 3.2.2).

3.2.21 *standard measurement uncertainty* [VIM, 2.30]—measurement uncertainty expressed as a standard deviation.

3.2.21.1 *Discussion*—Also referred to as 'standard uncertainty of measurement' or 'standard uncertainty'.

3.2.22 *true value* [VIM, 2.11]—quantity value consistent with the definition of a quantity.

3.2.22.1 *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).

3.2.23 *Type A evaluation of measurement uncertainty* [VIM, 2.28]—evaluation of a component of measurement uncertainty by a statistical analysis of measured quantity values obtained under defined measurement conditions.

3.2.24 *Type B evaluation of measurement uncertainty* [VIM, 2.29]—evaluation of a component of measurement uncertainty determined by means other than a Type A evaluation of measurement uncertainty.

3.2.25 *uncertainty budget* [VIM, 2.33]—statement of a measurement uncertainty, of the components of that measurement uncertainty, and of their calculation and combination.

3.2.25.1 *Discussion*—An uncertainty budget should include the measurement model, estimates, and measurement uncertainties associated with the quantities in the measurement model, covariances, type of applied probability density functions, degrees of freedom, type of evaluation of measurement uncertainty, and any coverage factor.

3.3 Definitions of other terms used in this standard that pertain to quality and statistics may be found in ASTM Terminology E456. Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E170. Definitions in ASTM Terminology E170 are compatible with ICRU 85a; that document, therefore, may be used as an alternative reference.

4. Significance and use

4.1 All measurements, including dose measurements, have an associated uncertainty. The magnitude of the measurement uncertainty is important for assessing the quality of the results of the measurement system.

4.2 Information on the range of achievable uncertainty values for specific dosimetry systems is given in the ISO/ASTM standards for the specific dosimetry systems. While the uncertainty values given in specific dosimetry standards are achievable, it should be noted that both smaller and larger uncertainty values might be obtained depending on measurement conditions and instrumentation. For more information see also ISO/ASTM 52628.

4.3 This guide uses the methodology adopted by the GUM for estimating uncertainties in measurements (see 2.4). Therefore, components of uncertainty are evaluated as either Type A uncertainty or Type B uncertainty.

4.4 Quantifying individual components of uncertainty may assist the user in identifying actions to reduce the measurement uncertainty.

4.5 Periodically, the uncertainty should be reassessed to confirm the existing estimate. Should changes occur that could influence the existing component estimates or result in the addition of new components of uncertainty, a new estimate of uncertainty should be established.

4.6 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 (JCGM 100:2008).

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 (for example, dose), that is, the value of the specific quantity to be measured (dose). A measurement therefore begins with an appropriate specification of the measurand, the method of measurement, the measurement system and the measurement procedure.

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

5.2 *Uncertainty:*

5.2.1 The uncertainty of the measurement result reflects the inability to know the true value of the measurand. A lower value of overall uncertainty reflects a higher degree of confidence in the estimate of the value of the measurand.

NOTE 2—The result of any individual measurement can unknowingly be very close to the value of the measurand even though it may have a large uncertainty. Thus the uncertainty of a measurement result should not be confused as the unknown error.

5.2.2 The uncertainty associated with a measurement can arise from a number of different components, examples of some of which are listed in Section 7. In assessing measurement uncertainty, it is necessary to consider all steps associated with making a measurement and assign to each step a value for the uncertainty introduced. These individual components can then be collected together to produce a combined uncertainty for the measurement. The results of this type of analysis are often presented in the form of a table, referred to as an uncertainty budget (see Annex A2). Components of uncertainty are generally classified as Type A or Type B, depending on the method used to evaluate them.

5.2.2.1 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.

5.2.2.2 Thus, a Type A standard uncertainty is obtained from a probability density function derived from a series of repeated observations (see 8.1), 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 (see 8.2). Both approaches are valid interpretations of probability.

5.2.3 The combined standard uncertainty, denoted by u_c, of the result of a measurement is obtained by combining all the components of uncertainty of both categories (see 9.1.1).

5.2.4 Typically, an expanded uncertainty U is calculated to provide an interval about the result of a measurement within which the true value is expected to lie. The value of U is obtained by multiplying the combined standard uncertainty u_c by a coverage factor k (see 9.2).

NOTE 3—The coverage factor k is always to be stated when reporting expanded uncertainty, so that the combined standard uncertainty of the measured quantity can be recovered.

6. Evaluation of Type A and Type B standard uncertainty

6.1 *Measurement Procedure:*

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

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 (such as Type A); these input quantities may include influence quantities such as temperature or humidity. They may also involve input quantities related to activities such as calibration of routine dosimetry systems under conditions that differ from those during use (different dose rates, temperature cycle, etc.). Other quantities that may be involved are those due to use of reference or transfer standard dosimeters.

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

6.1.1.3 Grouping of input quantities is determined by the characteristics of the selected dosimetry system, 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 may be used to estimate the combined standard uncertainty.

6.2 *Type A Evaluation of Standard Uncertainty:*

6.2.1 Type A evaluations of uncertainty are made by statistical analysis of a series of measurement results of a quantity value.

6.2.2 In most cases, the best estimate of the expected value of a quantity is obtained by n independent measurements made under repeatability conditions and is given by the arithmetic mean, $\bar{x}$, or average of those measurement results. The sample standard deviation, s, of these observations characterizes the variability of the observed values or their dispersion about their mean. The standard uncertainty of the mean value is given by $s/\sqrt{n}$. Therefore, for Type A components of uncertainty, increasing the number of measurements will reduce the standard uncertainty of the mean.

6.2.3 In cases where only a single, or very few, measurements are made, the estimate of the sample standard deviation has to be taken from prior measurements made using the same dosimetry system. The sample standard deviation could be determined from a single set of prior measurements, or derived as a pooled standard deviation from several sets of prior measurements.

NOTE 4—See GUM H.3.6 for further information on pooled variance and pooled standard deviation.

NOTE 5—Repeatability of dosimeter response is an example of a Type A component of uncertainty that is usually determined from a set, or sets, of prior measurements.

6.2.4 The Type A standard uncertainties are determined by the experimental design that is used to collect the observations for the uncertainty estimate. If the estimated Type A uncertainty is unacceptably large, the individual components of uncertainty may be estimated by a more refined experimental design. Knowledge of the components contributing to the estimated uncertainty might allow identification of components that can be controlled so as to reduce uncertainty.

NOTE 6—For example, if optical 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 influence quantities during calibration and routine dosimetry will reduce the uncertainty in dose estimates.

6.3 *Type B Evaluation of Standard Uncertainty:*

6.3.1 The Type B component of uncertainty is 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 or documented performance characteristics of the dosimetry system. The uncertainty estimated in this way is referred to as a Type B standard uncertainty, u_B.

6.3.2 Several methods may be used to develop estimates of the magnitude of Type B standard uncertainty. One method estimates the maximum magnitude likely to be observed for each input quantity. For example, if the dosimeter response is known to vary with irradiation temperature, then the temperature range routinely seen in operation should be used to estimate 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). As stated in JCGM 100:2008 (GUM), the sample standard deviation is $a/\sqrt{3}$ for such a distribution. In some cases it is more realistic to expect that values near the bounds are less likely than those near the midpoint. It may then be reasonable to replace the rectangular distribution with a symmetric triangular distribution with a base width of $a_+ - a_- = 2a$, see Fig. 2. Assuming such a triangular distribution for X_i, the expectation value of X_i is $(a_- + a_+)/2$ and its variance is $a^2/6$. Thus, the Type B standard uncertainty, $u_B = a/\sqrt{6}$ (see JCGM 100:2008 (GUM)).

6.3.3 It is important not to "double-count" uncertainty components. For example, if a component of uncertainty arising from a particular effect is obtained from a Type B evaluation, it should be included as an independent component of uncertainty in the calculation of the combined standard uncertainty of the measurement result only to the extent that the effect does not contribute to the observed variability of the observations. This is because the uncertainty due to that portion of the effect that contributes to the observed variability is already included in the component of uncertainty obtained from the statistical analysis of the observations (GUM 4.3.10).

7. Examples of uncertainty budget components associated with absorbed dose measurements

NOTE 7— See also ISO/ASTM 51261 and ISO/ASTM 52701 for additional details.

7.1 Components of the combined uncertainty in the measured values of absorbed dose which are identified and characterized during the dosimetry system calibration include the following:

7.1.1 Uncertainty in the absorbed dose reported by the approved laboratory. During calibration irradiations, the dose to dosimeters that was delivered or measured by an approved laboratory is subject to uncertainty. The uncertainty of this dose value is obtained from the certificate from the approved laboratory. This component of uncertainty estimate may include:

7.1.1.1 Response of primary or reference standard,

7.1.1.2 Irradiation time of the calibration dosimeters,

7.1.1.3 Gamma source decay corrections,

7.1.1.4 Non-uniformities in the reference standard irradiation field,

7.1.1.5 Corrections for attenuation and irradiation geometry.

7.1.2 Uncertainty in dosimeter response measurements. The uncertainty of the response of the dosimeters is obtained from the measurement of dosimeters irradiated during calibration to the same doses. This component of uncertainty is evaluated as a Type A uncertainty from the statistical analysis of repeated dosimeter response measurements. This component of uncertainty estimate may include:

7.1.2.1 Intrinsic variation in dosimeter response,

7.1.2.2 Variation in thickness/mass of individual dosimeters,

7.1.2.3 Measurement of thickness/mass of individual dosimeters,

7.1.2.4 Variations in performance of measurement equipment (including dosimeter positioning).

7.1.3 Uncertainty in fitting a calibration curve. The uncertainty arising from fitting the measurement results to a calibration curve can be obtained from the residuals, i.e. the difference between doses calculated using the calibration curve and doses actually applied during calibration. This component of uncertainty may be evaluated as a Type A uncertainty. This component of uncertainty estimate may include:

7.1.3.1 Variation in response of dosimeters,

7.1.3.2 Analytical function used in fit.

7.2 Contributions to the combined uncertainty in the measured values of absorbed dose that arise from influence quantities relevant during routine use of dosimeters that are different from the calibration conditions may include the following:

7.2.1 *Dosimeter Storage Conditions (temperature and humidity)*—The temperature and humidity at which dosimeters are stored will usually be defined as a range. Dispersion of dosimeter response values caused by variation in temperature and humidity within this range may give rise to uncertainty of dosimeter response. This component of uncertainty may be evaluated as Type B uncertainty.

7.2.2 *Dosimeter Temperature and Humidity during Irradiation*—The temperature and humidity at which dosimeters are irradiated will usually be known within a given range. Uncertainties in response caused by variation in temperature and humidity within this range may give rise to uncertainty of dosimeter response. This component of uncertainty may be evaluated as Type B uncertainty.

7.2.3 *Dosimeter Thickness or Mass*—The thickness or mass of dosimeters might be determined by measurement, in which case this component of uncertainty is evaluated as a Type A uncertainty. Dosimeter thickness or mass might also be considered to be within a range, in which case this component of uncertainty may be evaluated as Type B uncertainty.

7.2.4 *Time of Response Measurement after Irradiation*—The response of some dosimeters might not be stable with time after irradiation. The time of measurement is usually specified to be within a given range. Variation in time within this range may give rise to uncertainty of dosimeter response. This component of uncertainty may be evaluated as Type B uncertainty.

7.2.5 *Instrument Stability*—Information about stability of measurement instruments can be obtained from characterization measurement using standard reference materials, such as optical filters in case of spectrophotometers. This component of uncertainty may be evaluated as either a Type A or Type B uncertainty.

7.3 Each example of uncertainty may consist of several components of both Type A and Type B. The Type A contributions are combined with the Type B contributions to give a combined standard uncertainty.

8. Characterization of uncertainty components based on probability distributions

8.1 *Normal Distribution:*

8.1.1 The normal (or Gaussian) distribution, shown in Fig. 1, is a continuous probability distribution that has a bell-shaped probability density function, known as the Gaussian function or informally as the bell curve:

$$f(x\;;\;\mu\;,\;\sigma^2) = \frac{1}{\sigma\sqrt{2\pi}}e^{-\frac{1}{2}\left(\frac{x-\mu}{\sigma}\right)^2} \tag{4}$$

The parameter μ is the mean or expected value; a value within the range with the highest likelihood or frequency of observation (location of the peak) and σ^2 represents the expected variation about the mean value. σ is known as the standard deviation. The standard deviation in the normal distribution characterizes a range of values about the mean that represents approximately 68 % of the population values. The distribution with μ=0 and σ^2=1 is called the standard normal distribution or the unit normal distribution. A normal distribution is often used as a first approximation to describe real-valued random variables that cluster around a single mean value (JCGM 100:2008).

8.1.2 Examples of individual components of uncertainty arising from assumed normal distributions are:

8.1.2.1 *Uncertainty of Dosimeter Response Values*—Dose measurement uncertainty from variation of the dosimeter response for repeated measurements at given dose level results in a corresponding uncertainty in calculated dose (see A1.1). Dosimeters irradiated to the same dose will exhibit intrinsic variability in their response that can be characterized and statistically analyzed, and therefore this component of uncertainty may be evaluated as a Type A uncertainty based on a normal distribution.

8.1.2.2 *Uncertainty Arising from Instrument Instability*—Variation of repeated measurements of the same dosimeter for the same instrument results in a corresponding uncertainty in calculated dose. The ability of measurement equipment to deliver repeated values can be characterized and statistically

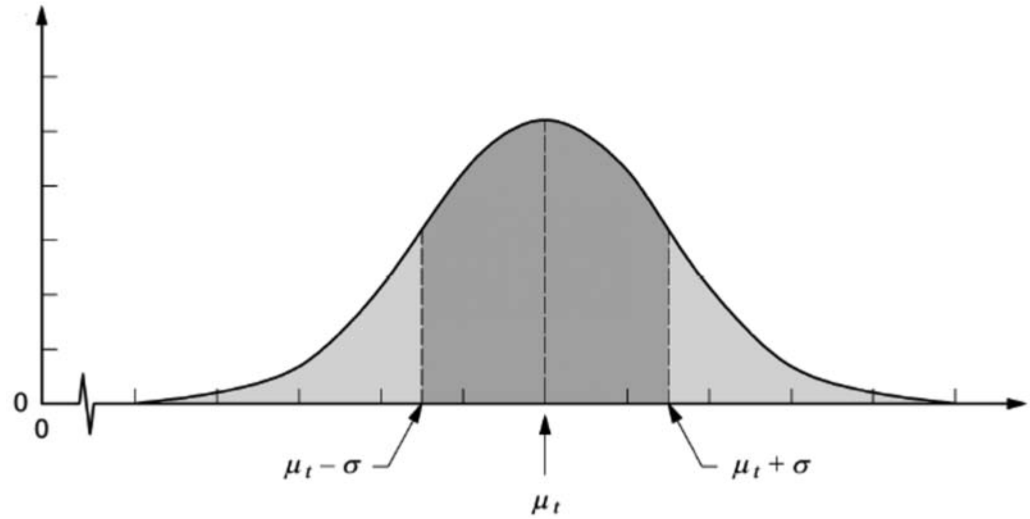

FIG. 1 Normal distribution, also called Gaussian or "bell curve", the most important continuous random distribution (JCGM 100:2008)

analyzed, and therefore this component of uncertainty may be evaluated as a Type A uncertainty based on a normal distribution.

8.1.2.3 *Uncertainty of Dosimeter Thickness or Mass Values*—Measurement uncertainty arising from the variation of an assumed value of dosimeter thickness or mass that results in a corresponding uncertainty in calculated dose. Dosimeter batches are usually comprised of a range of thicknesses or masses and are identified by the average for that range. The variability within the range can be characterized and statistically analyzed, and therefore this component of uncertainty may be evaluated as a Type A uncertainty based on a normal distribution.

8.2 *Rectangular Distribution:*

8.2.1 The continuous uniform distribution or rectangular distribution is a probability distribution where all values are equally probable within specified limits; a_- and a_+, which are its minimum and maximum values (JCGM 100:2008).

8.2.2 *Examples of approaches to evaluating the contribution of an individual component of uncertainty using assumed rectangular probability distributions:*

8.2.2.1 *Temperature (storage or irradiation)*—Temperature at which dosimeters are stored or the temperature at which dosimeters are irradiated is usually defined as a range. Each value in the range is assumed to have the same probability of occurrence and thus, this component of uncertainty is evaluated as a Type B uncertainty based on a rectangular distribution.

8.2.2.2 *Humidity (storage or irradiation)*—Humidity at which dosimeters are stored or the humidity at which dosimeters are irradiated is usually defined as a range. Each humidity level in the range is assumed to have the same probability of occurring and thus, this component of uncertainty is evaluated at a Type B uncertainty based on a rectangular distribution.

8.2.2.3 *Dosimeter Thickness or Mass*—Unless the batch of dosimeters is assessed with a sampling of the thickness or mass

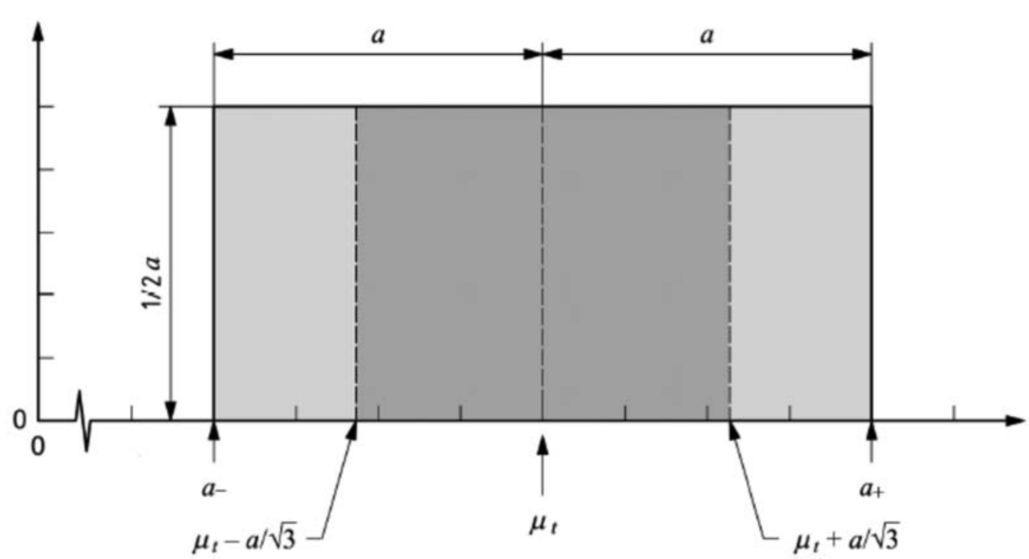

FIG. 2 Rectangular distribution, also called continuous uniform distribution (JCGM 100:2008)

distribution, each value of thickness or mass within the batch range should be assumed to have the same probability of occurrence and therefore the component of uncertainty is evaluated as a Type B uncertainty based on a rectangular distribution.

NOTE 8—These are two of many different types of probability distributions that can be used. The choice of distribution is dependent on the ability to quantify the influence quantity.

8.3 In order to combine different uncertainty components, all components should be in the same form, for example, relative standard uncertainty.

8.4 Examples of uncertainty calculations can be found in Annex A1.

9. Statement of uncertainty

9.1 *Combined Standard Uncertainty:*

9.1.1 For sources of uncertainty that are independent (not correlated), the combined standard uncertainty is obtained by combining all components (Type A and Type B) of standard uncertainties in quadrature $\left(u_c = \sqrt{(u_1^2 + u_2^2 + u_3^2 + ...)}\right)$. If absolute values are used for the standard uncertainties, the components of uncertainty must be weighted by appropriate sensitivity coefficients. This combined standard uncertainty is designated as u_c.

9.1.2 For sources of uncertainty that are correlated, 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. Guidance is given in GUM.

NOTE 9—In the special case where input quantities are perfectly correlated, the combined standard uncertainty is the linear sum of all the standard uncertainty components (**1**).[8] This has the effect of giving a maximum limit to the estimate of the combined standard uncertainty.

9.2 *Expanded Uncertainty:*

9.2.1 Although u_c can be used as the 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 dose values that could reasonably be attributed to the measurand (dose estimate) are expected to lie with a high level of confidence. This additional measure of uncertainty 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:

$$U = ku_c \quad (5)$$

9.2.2 Dose measurement uncertainty is commonly expressed for a coverage factor k=2 (two standard deviations) providing about 95 % level of confidence.

NOTE 10—The choice of a coverage factor that corresponds to an exact level of confidence is difficult to make in practice. This is true because it requires the full knowledge of the probability distribution of the estimate of the measurements. In practice, coverage factors of 2 and 3 approximate a 95 % and 99 % level of confidence, respectively.

[8] The boldface numbers in parentheses refer to the corresponding reference in the bibliogrpahy at the end of this guide.

9.2.2.1 The level of confidence is an estimate of the probability that the true value will fall within the given range of the expanded uncertainty about the measured value.

9.3 *Statement of Uncertainty for the Measurement Result:*

9.3.1 It is typical to form a statement of uncertainty based on the expanded uncertainty estimate for k=2. This statement is to be used in conjunction with all measurements associated with the validated measurement system, including well characterized test methods.

EXAMPLE: An example of a statement of uncertainty for measurements using a PMMA dosimetry system is as follows: "The reported doses are based on measurements using a calibrated dosimetry system operated in compliance with ISO/ASTM 52628, ISO/ASTM 52701, ISO/ASTM 51261 and ISO/ASTM 51276. The expanded uncertainty associated with these measurements is *X.Y* % at a level of confidence approximately 95 %."

9.3.2 The summary statement should be supported by an uncertainty assessment practice or document containing comprehensive uncertainty assessment detail. The JCGM 100 (GUM) recommends the documentation should include the following information:

(a) Describe clearly the methods used to derive the measurement result and its uncertainty from the experimental observations and input data;

(b) List all uncertainty components and document fully how they were evaluated (that is, uncertainty budget);

(c) Present the data analysis in such a way that each of its important steps can be readily followed and the calculation of the reported result can be independently repeated, if necessary;

(d) Give all corrections and constants used in the analysis and their sources.

10. Uses of measurement uncertainty estimates

10.1 The estimated value of expanded uncertainty serves as a guide for determining if the measurement system is appropriate for the intended use.

NOTE 11—Adherence to industry standards, such as ISO/ASTM 52628, ISO/ASTM 52701, ISO/ASTM 51261 and applicable dosimetry system practices, will help ensure the dosimetry system measurements are of good metrological quality.

10.2 Performance of the detailed analysis of the components contributing to the expanded uncertainty through the development of an uncertainty budget has the following benefits.

10.2.1 Identification of possible sources of uncertainty and assessment of the effects of these lessen the chance that the measurement will be influenced in an unknown way.

10.2.2 Components of uncertainty that may be unacceptably large can be identified, which may help identify improvements in the measurement techniques.

10.2.3 Variability in measured dose values may be caused by uncertainty related to the dosimetry system and by variability in the irradiation process. Without knowledge of the components of uncertainty related to the measurement system it is not possible to differentiate between the two potential sources of variability. Knowledge of the components of uncertainty in measurements of absorbed dose has practical value when investigating root causes for apparent deviations in measured value of dose.

10.3 Some components of dosimetry measurement uncertainty will contribute to the variability in the measured dose results during an irradiation process.

10.4 For routine controlled processing of product, the expanded uncertainty of the dose measurements is taken into account during the specification of process parameters.

11. Keywords

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

ANNEXES

Informative

A1. EXAMPLES OF ESTIMATING UNCERTAINTY COMPONENTS

A1.1 Uncertainty in measured dose values – dosimeter response – normal probability distribution

A1.1.1 This is an example of a Type A estimate of uncertainty. Additional examples are shown in ISO/ASTM 51261.

A1.1.2 This example below shows individual response measurements of four dosimeters irradiated to a single dose level as part of a dosimetry system calibration exercise. Upon completion of the response measurement of all dosimeters from all dose levels, a calibration curve is generated across the dose range evaluated. The uncertainty associated with the dosimeter response measurement results should be evaluated in terms of dose.

Dosimeter response of calibration dosimeters			
0.525	0.528	0.524	0.529

A1.1.3 Therefore each response measurement should be converted to dose by using the generated calibration curve or look up table. The average (see 3.2.2), sample standard deviation (see 3.2.19) and coefficient of variation (see 3.2.4) for these four dose values can be calculated. The coefficient of variation, referred to as relative standard uncertainty, will approximate the standard uncertainty associated with repeated measurements for the given dose level.

Calibration curve:

$$y = a + b * x \qquad x = \left(\frac{y - a}{b}\right) \tag{A1.1}$$

where:

a = 0.015,
b = 0.02,
y = Dosimeter Response, and
x = dose.

Calculated dose values of calibration dosimeters				M_{AVG}	STDEV	%CV
25.50	25.65	25.45	25.70	25.58	0.12	0.47%[A]

[A] The relative standard uncertainty in the mean value of the measured dose = 0.47 %/$\sqrt{4}$ = 0.23 %.

A1.1.4 This example shows the evaluation for a single dose level from a dosimetry system calibration exercise. This type of analysis must be completed for each dose level in the calibration curve and then evaluated for all dose levels. See ISO/ASTM 51261 for additional information.

A1.2 Uncertainty in measured dose values – irradiation temperature – rectangular probability distribution

A1.2.1 This is an example of a Type B estimate of uncertainty. Additional examples are shown in ISO/ASTM 51261.

A1.2.2 This example shows how to estimate the uncertainty in the measured dose value arising from irradiation temperature with a known or assumed probability distribution. If the dosimeter response is influenced by the irradiation temperature and the effect of temperature is known (i.e. for alanine dosimeters) the associated uncertainty can be estimated. This example shows how to calculate the uncertainty associated with the irradiation temperature, when the temperature during measurement is different than that for calibration of the dosimetry system. A rectangular distribution of irradiation temperature is assumed, where each temperature value in the range has an equal probability of occurring.

Calibration Temperature = 24°C
Minimum Irradiation Temperature = 14°C
Maximum Irradiation Temperature = 34°C
Temperature Coefficient for Dose = 0.14 %/°C
Irradiation Temperature Limits about the Calibration Temperature = ±10°C

A1.2.3 The limits identified are equal to the range of expected temperatures the dosimeters will experience during routine processing and represent the difference from actual irradiation temperature and the temperature utilized during the calibration irradiation.

$$\text{Temperature Uncertainty} = \left(\frac{\mathit{Temperature\ Limits} * \mathit{Coeff}}{\sqrt{3}} \right)$$

$$\text{Temperature Uncertainty} = \left(\frac{10 * 0.14}{1.732} \right) = 0.81\% \qquad (A1.2)$$

A1.2.4 Using the general expression given in GUM (section C.3.2), variance for a rectangular distribution given in Fig. 2 can be calculated as $a^2/3$. Thus, standard deviation or standard uncertainty would be $a/\sqrt{3}$ for inclusion in the uncertainty budget (see 6.3.2). Therefore, the relative standard uncertainty in measured dose due to temperature for this example is 0.81 %.

A2. EXAMPLE OF AN UNCERTAINTY BUDGET

A2.1 An example of an uncertainty budget listing the components of uncertainty is given below, and it should be taken only as a guide to forming an uncertainty budget. This uncertainty budget represents the uncertainty associated with measurements using a calibrated traceable dosimetry system, based on an in-plant calibration. See Table A2.1.

TABLE A2.1

Component of uncertainty	Value	Probability distribution	Relative standard uncertainty	
			Type A	Type B
Calibration doses from laboratory certificate	1.3 %	Normal		1.3 %
Fit of calibration curve	0.8 %	Normal	0.8 %	
Dosimeter response variability due to irradiation temperature	1.0 %	Rectangular		0.6 %
Difference in dose to reference and calibration dosimeters	1.0 %	Rectangular		0.6 %
Dosimeter-to-dosimeter scatter (repeatability)	1.4 %	Normal	1.4 %	
Combined uncertainty			2.2 %	
Expanded uncertainty (*k*=2)			4.4 %	

A2.2 This second example of an uncertainty budget represents the uncertainty associated with calibration and measurement of an alanine / EPR dosimetry system. The calibration was carried out by irradiation at an approved laboratory. See Table A2.2.

TABLE A2.2

Relative uncertainties. Values at 1 s.d. (k = 1) except as noted.				
Measurement instrument: EPR spectrometer EMS-104				
Calibration of alanine pellet dosimeters at gamma facility				
	Probability distribution	Type A		Type B
Doses given during calibration	Normal	1.41		
EPR spectrometer stability	Normal	0.25		
Homogeneity of pellets	Rectangular			0.05
Alanine pellet mass measurement	Normal	0.15		
Response measurement				
reproducibility	Normal	0.25		
angle	Normal	0.10		
height	Normal	0.15		
Irradiation geometry	Rectangular			0.15
Establish calibration function	Normal	0.25		
Combined uncertainty of calibration			1.50	
Measurement with alanine pellet dosimeters at gamma				
	Probability distribution	Type A		Type B
Response measurement	Normal	0.31		
EPR spectrometer stability	Normal	0.25		
Alanine pellet mass measurement	Normal	0.15		
Temperature correction	Rectangular			0.15
Reproducibility of measurement (combined)			0.45	
Combined uncertainty of dose measurement (gamma)			1.57	
Expanded uncertainty at k=2			3.14	

BIBLIOGRAPHY

(1) Hogg, Robert V. and Craig, Allen T., *Introduction to Mathematical Statistics*, Prentice Hall, 1994.