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An American National Standard

Standard Guide for ~~Estimating Uncertainties~~ 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 ~~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~~ Methods are given for identifying, 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~~the components of measurement uncertainty associated with the use ~~2.3). The traditional concepts of precision and bias are not used in this document. Examples are given in five annexes.~~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 ~~assumes a working knowledge of statistics. Several statistical texts are included in the references~~does not address the establishment ~~(of1-4).~~ 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

~~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]~~

[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.~~

[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.

E1249 Practice for Minimizing Dosimetry Errors in Radiation Hardness Testing of Silicon Electronic Devices Using Co-60 Sources

2.2 *ISO/ASTM Standards:*[2]

51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing

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

51261 GuidePractice for Selection and Calibration of Routine Dosimetry Systems for Radiation Processing

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

5127551649 Practice for Use of a Radiochromic Film Dosimetry SystemDosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV

5140051702 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration LaboratoryDosimetry in a Gamma Facility for Radiation Processing

5143152628 Practice for Dosimetry in Electron Beam and X-ray (Bremsstrahlung) Irradiation Facilities for Food 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]

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

ISO, 1995, ISBN 92-67-10188-9JCGM 100:2008, GUM 1995, with minor corrections, Evaluation of measurement data – Guide to the Expression of Uncertainty in Measurement[5]

ISO 11137JCGM 200:2008, VIM, Sterilization of Health Care Products-Requirements for Validation and Routine Control-Radiation SterilizationInternational vocabulary of metrology – Basis and general concepts and associated terms[6]

2.5 *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 3480 The Dosimetry of Pulsed RadiationDosimetry Systems for Use in Radiation Processing

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 6085a 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] The last approved version of this historical standard is referenced on www.astm.org.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 ISO Central Secretariat, Postal 56, 1211 Geneva 20 Switzerland. International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland, http://www.iso.org.

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

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 *absorbed dose, D—arithmetic mean, average* [GUM, C.2.19]—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 dsum of values divided $\bar{\varepsilon}$by dm, where $d\bar{\varepsilon}$ is the mean energy imparted by ionizing radiation to matter of mass dthe number of values:m (see ICRU 60).

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

$$\bar{x} = \frac{1}{n}\sum_{i} x_i, i = 1, 2, 3 \ldots n \quad (1)$$

where:

x_i = individual values of parameters with i = 1, 2, 3 ... 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.

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

3.2.3 *calibration ~~curve~~—curve* [VIM, 4.31]—~~graphical representation of the dosimetry system's response function.~~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~~—variation (CV)*—sample standard deviation expressed as a percentage of sample ~~mean~~average value (see ~~3.1.38~~3.2.2 and 3.2.19~~3.1.39).~~):

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

$$CV = \frac{S}{\bar{x}} \times 100\ \% \quad (2)$$

3.2.5 *combined standard ~~uncertainty~~—measurement uncertainty* [VIM, 2.31]—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.~~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.

~~3.1.6 *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.~~

3.2.6 *coverage ~~factor~~—factor (k)* [VIM, 2.38]—~~numerical factor used as a multiplier of the combined standard uncertainty in order~~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 ~~8.3~~5.2.4).

~~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.~~

3.2.7 *expanded ~~uncertainty~~—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 ~~also referred to as "overall uncertainty" (see~~ obtained ~~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.~~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'.

~~3.1.16 *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:~~

$$E = \sum_i P_i V_i \tag{3}$$

~~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:~~

$$E = \int x\, f(x)\, dx \tag{4}$$

~~where:~~

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

3.2.8 *influence ~~quantity~~—quantity* [VIM, 2.52]—quantity ~~that is not included in the specification of the measurand but that nonetheless affects the result of the measurement.~~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*—

~~This quantity is understood to include values associated with reference materials, and reference data upon which the result of the measurement may depend,~~ 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 ~~phenomena such as short-term instrument fluctuations and parameters such as temperature, time, and humidity.~~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*—~~*measurand* [VIM, 2.3]—~~specific~~ quantity ~~subject~~intended to ~~measurement.~~be measured.

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

3.2.11 ~~*measurement*—~~*measurement* [VIM, 2.1]~~—set of operations having the object of determining a value of a~~ process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity.

3.2.12 *measurement* ~~*procedure*—~~*uncertainty* [VIM, 2.26]~~—set of operations, in specific terms, used in the performance of particular measurements according to a given method.~~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 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.

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

3.2.13 ~~*measurement traceability*—~~*metrological traceability* [VIM, 2.41]~~—ability to demonstrate by means of an~~property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of ~~comparisons that a measurement is in agreement within acceptable limits of uncertainty with comparable nationally or internationally recognized standards.~~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.

~~3.1.23 *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.~~

3.2.14 *quadrature*—method ~~of~~ 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~~uncertainty, for example, coefficient of ~~variation).~~variation.

3.2.15 ~~*random*~~*quantity* ~~error—~~[VIM, 1.1]~~—result~~property 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~~phenomenon, body, or substance, where the property has a magnitude that can be expressed as a number and ~~3.1.32~~).a reference.

~~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."

3.2.16 *relative errorquantity value* (of measurement)—[VIM, 1.19]—error of measurement divided by a true value of the measurand.number and reference together expressing magnitude of a quantity.

3.1.31.1 *Discussion*—

Since a true value cannot be determined, in practice a reference value is used.

3.2.16.1 *Discussion*—

For example, absorbed dose of 25 kGy.

3.2.17 *repeatability (of results of measurements)—measurements)* [GUM, B.2.15]—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.conditions of measurement.

3.2.17.1 *Discussion*—

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

(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)—measurements)* [GUM, B.2.16]—closeness of the agreement between the results of measurements of the same measurand, where the measurements are measurand carried out under changed conditions such as differing: principle or method of measurement, observer, measuring instrument, location, conditions of use, and time.of measurement.

3.2.18.1 *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.

(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.

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

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

3.1.35.1 *Discussion*—

When the term "result of a measurement" is used, it should be made clear whether it refers to: the indication, the uncorrected result,

~~the corrected result, and whether several values are averaged. A complete statement of the result of the measurement includes information about the uncertainty of the measurement.~~

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

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

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

~~where:~~

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

3.2.19 *sample standard ~~deviation, S~~deviation* $(S)_{n-1}$ [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—~~variance* [GUM, C.2.20]—measure of dispersion, which is the sum of the squared deviations of ~~individual values from the sample mean~~ observations from their average divided by (n_-1), given by the expression:

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

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

where:

x_i = individual value of parameter with $i = 1, 2 \ldots n$, and

~~$\bar{x}$ = mean of n values of parameter (see 3.1.37).~~

$\bar{x}$ = mean of n values of parameter (see 3.2.2).

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

3.2.21.1 *Discussion—*

Also referred to as 'standard uncertainty of measurement' or 'standard uncertainty'.

~~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.~~

3.2.22 *true ~~value~~—value* [VIM, 2.11]—~~value of measurand that would be obtained by a perfect measurement.~~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 "~~"value of a measurand" are viewed as equivalent (see 5.1.1).

3.2.23 *Type A evaluation ~~(of standard uncertainty)—~~of measurement uncertainty* [VIM, 2.28]—~~method of~~ evaluation of a ~~standard~~ component of measurement uncertainty by ~~the~~a statistical analysis of ~~a series of observations.~~measured quantity values obtained under defined measurement conditions.

3.2.24 *Type B evaluation ~~(of standard uncertainty)—~~of measurement uncertainty* [VIM, 2.29]~~—method of~~ evaluation of a ~~standard uncertainty~~ component of measurement uncertainty determined by means other than ~~the statistical analysis of a series of observations.~~a Type A evaluation of measurement uncertainty.

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

3.2.25.1 *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.~~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.

~~3.1.48 *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.~~

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 ~~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~~Information on the range of achievable uncertainty values for specific dosimetry systems is given in the ISO/ASTM standards ~~51204~~ and for the ~~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~~ 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 ~~51261~~52628~~). 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).~~

4.3 This guide uses the methodology adopted by the ~~International Organization for Standardization for~~ GUM for estimating uncertainties in ~~dosimetry for radiation processing~~ measurements (see ~~2.3~~2.4). ~~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~~ Therefore, ~~E170~~ and ~~E456~~, and Practice ~~E177~~). ~~As seen from this standard,~~ components of uncertainty are evaluated as either Type A uncertainty or Type B ~~rather than in terms of precision and bias. Error is different from Type A and Type B components of~~ 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.~~value (JCGM 100:2008).

~~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,~~ measurand (for example, dose), that is, the value of the specific quantity to be ~~measured.~~ 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 ~~only an~~ 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.

~~5.1.3 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.~~

5.2 *Uncertainty:*

5.2.1 The uncertainty of the ~~result of a measurement reflects the lack of exact knowledge of the~~ measurement result reflects the inability to know the true value of the measurand. ~~The result of a measurement after correction for recognized systematic effects is still only an~~ A lower value of overall uncertainty reflects a higher degree of confidence in the 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.~~ measurand.

~~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.~~

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.

~~5.3.3 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.~~

5.2.2 The ~~purpose of the Type A and Type B classification~~ uncertainty associated with a measurement can arise from a number of different components, examples of some of which are listed in Section 7~~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~~. 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~~or a variance.~~). 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.

~~5.3.5 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.~~

5.2.3 The ~~total uncertainty of the result of a measurement, termed combined standard uncertainty and~~ combined standard uncertainty, 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~~ of the result of a measurement is obtained by combining all the components of uncertainty of both categories (see ~~Annex A3~~9.1.1).

5.2.4 ~~To meet the needs of some industrial and commercial applications, as well as requirements in the areas of health and safety,~~ Typically, an expanded uncertainty U is ~~calculated. The purpose of the expanded uncertainty is~~ calculated 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.~~ 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 ~~8.3~~9.2).

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

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.

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

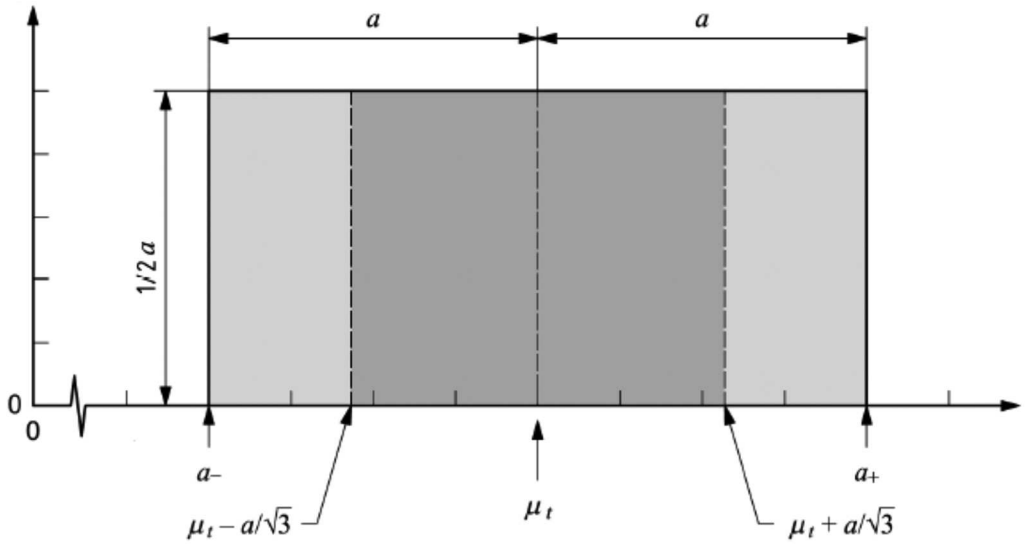

FIG. 12 ~~Graphical illustration of value, error, and uncertainty~~Rectangular distribution, also called continuous uniform distribution (JCGM 100:2008)

~~FIG. 2 Graphical illustration of evaluating type B standard uncertainty~~