Designation: ~~ISO/ASTM 51707 – 2015(E)~~ 51707 – 22

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. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This standard provides guidance on the use of concepts described in the JCGM (*Joint Committee for Guides in Metrology*) 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.

1.3.1 Key components of uncertainty are derived as part of the derivation of the uncertainty budget. This standard identifies which components of uncertainty are carried forward as part of other analyses (e.g., assessment of process capability and process targets, and process variability), and which components from other standards are brought forward into this standard (e.g., precision of the dose measurement, calibration curve fit, and indirect measurement of dose).

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 11137-1 (radiation sterilization of health care products), ISO 14470 (treatment of food), and 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~~,~~ (Standard Practice for Dosimetry in Radiation Processing), and ISO/ASTM 51261 ~~and ISO/ASTM~~(Practice for ~~52701~~.Calibration of Routine Dosimetry Systems for Radiation Processing).

1.5 To achieve compliance with the requirements of ISO 11137-1 (radiation sterilization of health care products), ISO 14470 (treatment of food), and other applications, a measurement is accompanied by a statement of the uncertainty.

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

1.7 *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~~safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

[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~~ . Originally developed as a joint ASTM/ISO standard in conjunction with ISO/TC 85/WG 3.

Current edition approved Dec. 1, 2022~~Sept. 8, 2014.~~ . Published May 2024~~February 2015. Originally published as ASTM E 1707–95. Last previous ASTM edition E 1707–95~~. Originally approved in 1995. Last previous edition approved~~ε1~~. ~~ASTM E 1707–95~~ ~~ε1~~ ~~was adopted by ISO in 1998 with the intermediate designation ISO 15572:1998(E). The present International Standard ISO/ASTM 51707:2015(E) is a major revision of the last previous edition ISO/ASTM 51707:2005(E), which replaced ISO/ASTM 51707:2002(E).~~in 2015 as ISO/ASTM 51707:2015(E). DOI: 10.1520/51707-22.

1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced documents

2.1 *ASTM Standards:*[2]

E178 Practice for Dealing With Outlying Observations

~~E170~~E456 Terminology Relating to ~~Radiation Measurements and Dosimetry~~Quality and Statistics

E2232 Guide for Selection and Use of Mathematical Methods for Calculating Absorbed Dose in Radiation Processing Applications

~~E456~~E3083 Terminology Relating to ~~Quality and Statistics~~Radiation Processing: Dosimetry and Applications

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~~dosimetry in an X-ray (bremsstrahlung) facility for radiation processing at energies between 50 keV and 7.5 MeV

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~~— Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices[3]

ISO 11137-3 Sterilization of Health Care Products — Radiation — Part 3: Guidance on Dosimetric Aspects of Development, Validation and Routine Control[3]

ISO 11137-4 Sterilization of health care products — Radiation — Part 4: Guidance on process control. General information[3]

ISO 12749-4 Nuclear energy, nuclear technologies, and radiological protection — Vocabulary — Part 4: Dosimetry for radiation processing

ISO 14470 Food irradiation — Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food[4]

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

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 *VIM 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).~~

---

[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.~~Instrumentation (AAMI), 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633, http://www.aami.org.

[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.~~ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, https://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] 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,~~ Measurements (ICRU), 7910 Woodmont Ave., Suite ~~800~~400, Bethesda, MD ~~20814, U.S.A.~~20841-3095, http://www.icru.org.

3.1.1 For definitions quoted here from the VIM, only selected NOTES and EXAMPLES are included in 3.2. See VIM for further information.

3.2 *Definitions:*

3.2.1 *approved calibration laboratory*—calibration 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~~ by ISO/IEC 17025.

3.2.1.1 *Discussion*—

A recognized national metrology institute or other calibration laboratory accredited ~~to~~by 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 ... 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”.~~“indication.”

3.2.4 *coefficient of variation (CV)*—sample standard deviation expressed as a percentage of sample average ~~value (see~~ value:~~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’.~~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. A description of covariances may be found in the GUM reference, Annex C.

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’.~~‘fraction.’ Expanded uncertainty is also referred to as ‘overall ~~uncertainty’.~~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’.~~‘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 ~~standards, as well as the definitional uncertainty.~~ standards. 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,~~is comprised of many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from a 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.

(5) In radiation processing applications, the quantity of interest is usually absorbed dose to water. The uncertainty estimate therefore should also pertain to absorbed dose to water. Any differences between absorbed dose to water and absorbed dose to product are outside the scope of this guide.

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”.~~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’,~~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.~~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'.~~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:~~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) (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.

3.2.19.1 *Discussion*—

This definition has been adapted from GUM.

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),~~ – 1), given by the expression:

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

where:

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

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

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' ~~uncertainty'.~~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,~~method, estimates, and measurement uncertainties associated with the quantities in the measurement ~~model,~~method, 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~~radiation measurement and dosimetry may be found in ~~ASTM Terminology~~ISO/ASTM Practice ~~E456~~52628. ~~Definitions of other terms used in this standard~~ Other terms that pertain to radiation measurement and dosimetry may be found in ASTM Terminology ~~E170~~E3083. ~~Definitions in ASTM Terminology~~ and ISO Terminology ISO 12749-4. Where appropriate, definitions used in these standards ~~E170 are compatible with ICRU 85a; that document, therefore, may be used as an alternative reference.~~have been derived from and are consistent with definitions in ICRU Report 85a, and general metrological definitions given in the VIM.

4. Significance and use

4.1 ~~All measurements, including dose measurements, have an associated~~ Standards such as ISO 11137-1 (radiation sterilization of health care products) and ISO 14470 (irradiation of food) contain requirements that dosimetry used in the development, validation, and routine control of the process shall have measurement traceability to national or international standards and shall have a known level of uncertainty. The magnitude of the measurement uncertainty is important for assessing the ~~quality of the~~ results of the measurement system.

4.1.1 This guide provides information on how to meet the fundamental requirement to determine a known level of uncertainty associated with a dose measurement, how to calculate the overall uncertainty, and how the uncertainty may differ depending on the application (e.g., OQ and PQ dose measurements, routine dose measurement, determination of minimum absorbed dose (D_{min}) or maximum absorbed dose (D_{max}) from the monitoring location dose (D_{mon})). Information is provided on how to identify and calculate different components of uncertainty used to establish an uncertainty budget.

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.

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

4.4 Although this guide provides a framework for assessing uncertainty, it cannot substitute for critical thinking, intellectual honesty, and ~~professional skill.~~ experience. 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).~~ (GUM 3.4.8 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.

5. Evaluation of Type A and Type B standard uncertainty Determination of the uncertainty budget

5.1 *Measurement Procedure: Measurement:*

5.1.1 The measurandobjective Yof (absorbed dose) is generally not measurable directly, but depends ona measurement is to determine the value of the measurand, Nthat other quantitiesis, the Xvalue$_T$, Xof$_2$, ..., the Xspecific$_N$ through a functional relationship:quantity to be measured $Y = f(X_1, X_2, \ldots, X_N)$. (absorbed dose). A measurement therefore begins with an appropriate specification of the measurand, the method of measurement, the measurement system, and the measurement procedure.

6.1.1.1 The input quantities $X_1, X_2, \ldots X_N$ 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 $X_1, X_2, X_3 \ldots X_N$ and associated uncertainties may be treated either individually, for example, X_1 or X_2 or as aggregates, for example, $(X_1 \ldots X_p)$ 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.

5.1.2 With the completion of the dosimetry system's calibration and establishment of metrological traceability, the result of each dose measurement represents the best estimate of dose. The associated uncertainty should always be included when reporting a dose measurement, but the reported measurement result should not be corrected for the 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.

5.2 *Type B Evaluation of Standard Uncertainty:*

5.2.1 A measurement is always accompanied by a statement of the uncertainty. 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.

5.2.2 This guide will allow the user to evaluate known and potentially significant components of uncertainty that should be included in the uncertainty estimate, including those arising from calibration, dosimeter response, instrument stability, and the effect of influence quantities.

5.2.3 A quantitative analysis of components of uncertainty is referred to as an *uncertainty budget* and is often presented in the form of a table (see Table 1 and Annex A1). Typically, the *uncertainty budget* will identify all significant components of uncertainty together with their methods of estimation, statistical distributions (for example, rectangular, triangular, Gaussian), magnitudes, and methods of combination. The Gaussian and rectangular probability distributions are discussed in more detail in Annex A2. Step-by-step guidance is in the GUM (JCGM 100:2008, GUM 1995, Section 4.3).

5.2.4 The Type B component of uncertainty is evaluated by using all relevant information on the possible variability of the input quantitiesuncertainty associated with a measurement can arise from several different components. In the assessment of measurement uncertainty, it Xis_i. For the input valuenecessary to consider all X$steps_i$ that has not been obtained from repeated measurements, the estimated variance,associated with making a measurement and assign to each step an u$uncertainty_B^2$, or standard uncertainty, value, in the form of a standard deviation or standard uncertainty. u$These_B$, is evaluated by judgment using all relevant information on the possible variability ofindividual components can be collected to produce a combined uncertainty for the measurement, generally by X$summing_i$. This pool of information may include previous measurement data or documented performance characteristics of the dosimetry system. The uncertaintyin quadrature the individual component standard uncertainties (i.e. calculating the square root of the sum of the squares of the individual components). Refer to Eq 4estimated in this way is referred to as a Type B standard uncertainty,. Components of uncertainty are generally classified as Type A or Type uB_B, depending on their evaluation method.

5.2.4.1 The purpose of the Type A and Type B classification is to indicate 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.

~~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 %~~	

TABLE 1 Example of an uncertainty budget (dosimetry system calibration)

Component of Uncertainty	Reference	Probability Distribution	Relative Standard Deviation (k=1)	
			Type A	Type B
Approved calibration laboratory Certified Dose (u_{lab})	Sections 5.3, 5.4 Annex A1	Gaussian		1.30 %
Calibration Curve Fit (u_{fit})	Section 5.5 Annex A1.5	Gaussian	0.95 %	
Environmental Effects (Irradiation Temperature, Dose Rate, Energy Spectrum) ($u_{environment}$)	Section 5.6 Annex A1.6	Rectangular		0.70 %
Dosimeter Thickness Uncertainty (or mass) ($u_{thickness}$)	Section 5.6 Annex A1.7	Gaussian		1.35 %
Uncertainty in Dosimeter Response (Precision of the measurement) ($u_{precision}$)	Section 5.7 Eq A1.1, Annex A1.4	Gaussian	1.55 %	
Combined Uncertainty (k=1)	Eq 4			2.7 %
Combined Expanded Uncertainty (k=2)	Eq 5		5.4 %	

5.2.4.2 A Type A standard uncertainty is obtained from a probability density function (PDF) inferred from a series of repeated observations, 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. Both approaches are considered statistical methods and are valid interpretations of probability. For example, the random scatter between replicate dosimeters is a Type A component of uncertainty, whereas estimations of the effect of irradiation temperature are generally evaluated as Type B components, based on the known ranges of temperature during the irradiation.

NOTE 1—In specific cases, either a Type A or a Type B route may be used in the assessment of the component of uncertainty, for example uncertainty due to dosimeter placement might be estimated using a rectangular distribution or a mathematical model.

5.2.4.3 In many cases, an estimate of the expected value of a quantity is obtained by multiple independent measurements made under conditions of repeatability 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 the 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.

5.2.4.4 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.

5.2.4.5 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 to reduce uncertainty.

NOTE 2—For example, if optical absorbance of a film dosimeter is measured during calibration without controlling film thickness, relative humidity, or temperature, the dose uncertainty 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.

5.2.5 ~~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~~ The Type B component of uncertainty is evaluated by using all relevant information on the possible variability of the input quantities X_i. ~~within its estimated bounds of~~ For ~~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~~ the input ~~$a/\sqrt{3}$ 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 (that has a_- + not a been $_+$)/2 and its variance is~~ obtained from repeated measurements, ~~a~~the ~~$^2/6$. Thus, the~~ estimated variance, ~~*Type* u_B^2 B,~~ or standard uncertainty, u_B, ~~=~~ is evaluated by judgment using all relevant information on the possible variability of ~~a~~X_i. ~~$/\sqrt{6}$ (see JCGM 100:2008 (GUM)).~~ This pool of information may include previous measurement data or documented performance characteristics of the dosimetry system.

5.2.5.1 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. A2.2). 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. A2.2. 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)).

5.2.5.2 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).

NOTE 3—An example is time-dependent (or seasonal) drift in dosimeter response. This drift would not be seen in a Type A experiment, but could be captured as a Type B component.

5.2.6 ~~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~~ The combined standard uncertainty, denoted by u_c, 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).~~ result of a measurement is obtained by combining the components of uncertainty of both types. This is done by taking the square root of the sum of the squares of each component of uncertainty.

5.2.7 The coverage factor k is generally taken as k=2, approximating equivalent a 95 % level of confidence for a two-sided Gaussian distribution, or a 97.5 % level of confidence for a one-sided Gaussian distribution. Two-sided distributions are used for calculating combined standard measurement uncertainty and expanded uncertainty of dose measurements based on the GUM methodology. Therefore, a dose measurement established with k=2 means that there is 5 % chance (risk) that the dose might lie outside the defined confidence interval. Different values of k are applicable based on the risk assessment for the product and process assumed by the user and customer. See Annex A1 for a description of the normal distribution.

NOTE 4—The coverage factor *k* is always stated when reporting expanded uncertainty in order that the combined standard uncertainty of the measured quantity can be recovered.

5.2.8 An understanding of the individual uncertainty components is essential when assessing the significance of routine measurements. For example, in relative dose mapping the only significant component of uncertainty may be dosimeter reproducibility, whereas it will be necessary to consider all components of uncertainty for traceable dose measurements.

5.2.9 The uncertainty budget should be periodically re-assessed by the user to confirm the estimate is still valid.

5.2.9.1 There should be a documented rationale for the time interval between re-assessments that should include, for example, the potential effects on the dosimetry system calibration of seasonal changes in temperature and humidity and changes in dose rate.

5.2.10 The user should define limits for acceptable changes of the uncertainty budget, and the user should perform assessment of effects of changes.

5.2.11 As per ISO/ASTM 51261, the calibration of a routine dosimetry system consists of:

5.2.11.1 The selection of the calibration dosimeters;

5.2.11.2 The determination of the target dose levels and the irradiation of the calibration dosimeters;

5.2.11.3 The calibration and performance verification of measurement instrumentation;

5.2.11.4 The measurement of the calibration dosimeter response;

5.2.11.5 The analysis of the calibration dosimeter response data;

5.2.11.6 The calibration curve determination;

5.2.11.7 The verification of the calibration curve for actual conditions of use, if required; and

5.2.11.8 The determination of the uncertainty budget.

Note that 5.2.11.1, 5.2.11.2, and 5.2.11.3 do not have an associated component of uncertainty, but they will have an impact on the components of uncertainty associated with the calibration curve and dosimeter response data.

5.3 *Uncertainties in Calibration Doses from the Approved Calibration Laboratory:*

5.3.1 The approved calibration laboratory's certificate contains the uncertainty of the absorbed-dose value (i.e. calibration irradiations performed by the approved calibration laboratory), or the absorbed-dose measurement (i.e. reference dosimeter), typically at 95 % confidence level, but the value of the uncertainty and its confidence level should be stated.

5.3.2 The component of uncertainty in the dose reported by the approved calibration laboratory may include:

5.3.2.1 Response of the reference dosimeters;

5.3.2.2 Irradiation time of the calibration dosimeters;

5.3.2.3 Gamma source decay corrections;

5.3.2.4 Non-uniformities in the irradiation field; and

5.3.2.5 Corrections for attenuation and irradiation geometry (between the reference dosimeter and the calibration dosimeter).

5.3.3 The approved calibration laboratory may provide the details of their uncertainty budget, or simply provide a single value for the combined overall uncertainty. In either case, the combined uncertainty reported by the approved lab is, by convention, carried forward by the user as a Type B component of uncertainty.