Designation: 51707 – 22

Standard Guide for Estimation of Measurement Uncertainty in Dosimetry for Radiation Processing[1]

This standard is issued under the fixed designation 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 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 (Practice for 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

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

E456 Terminology Relating to Quality and Statistics

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

E3083 Terminology Relating to 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 at energies between 50 keV and 7.5 MeV

51649 Practice for Dosimetry in an Electron Beam Facility

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

Current edition approved Dec. 1, 2022. Published May 2024. Originally approved in 1995. Last previous edition approved in 2015 as ISO/ASTM 51707:2015(E). DOI: 10.1520/51707-22.

[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.

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

2.3 *ISO Documents:*

ISO 11137-1 Sterilization of Health Care Products — 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:*

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 by ISO/IEC 17025.

3.2.1.1 *Discussion*—A recognized national metrology institute or other calibration laboratory accredited 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.

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

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

where:

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

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

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

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

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

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

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

3.2.5.1 *Discussion*—

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

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

3.2.7 *expanded uncertainty* [GUM, 2.3.5]—quantity defining the interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand.

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

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

3.2.8.1 *Discussion*—In radiation processing dosimetry, this

[3] Available from Association for the Advancement of Medical Instrumentation (AAMI), 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633, http://www.aami.org.

[4] Available from International Organization for Standardization (ISO), 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 (ICRU), 7910 Woodmont Ave., Suite 400, Bethesda, MD 20841-3095, http://www.icru.org.

term includes temperature, relative humidity, time intervals, light, radiation energy, absorbed dose rate, and other factors that might affect dosimeter response, as well as quantities associated with the measurement instrument.

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

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

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

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

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

3.2.12.1 *Discussion*—

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

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

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

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

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

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

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

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

3.2.17.1 *Discussion*—

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

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

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

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

3.2.18.1 *Discussion*—

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

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

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

3.2.19 *sample standard deviation (S)*—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 $(n - 1)$, 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 of measurement' or 'standard uncertainty.'

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

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

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

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

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

3.2.25.1 *Discussion*—An uncertainty budget should include the measurement method, estimates, and measurement uncertainties associated with the quantities in the measurement 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 radiation measurement and dosimetry may be found in ISO/ASTM Practice 52628. Other terms that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E3083 and ISO Terminology ISO 12749-4. Where appropriate, definitions used in these standards 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 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 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 Although this guide provides a framework for assessing uncertainty, it cannot substitute for critical thinking, intellectual honesty, and experience. The evaluation of uncertainty depends on detailed knowledge of the nature of the measurand and of the measurement method and procedure used. The 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 (GUM 3.4.8 JCGM 100:2008).

5. Determination of the uncertainty budget

5.1 *Measurement:*

5.1.1 The objective of a measurement is to determine the value of the measurand, that is, the value of the specific quantity to be measured (absorbed 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 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.

5.2 *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

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 %	

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 uncertainty associated with a measurement can arise from several different components. In the assessment of measurement uncertainty, it is necessary to consider all steps associated with making a measurement and assign to each step an uncertainty value, in the form of a standard deviation or standard uncertainty. These individual components can be collected to produce a combined uncertainty for the measurement, generally by summing in 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 4. Components of uncertainty are generally classified as Type A or Type 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.

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 The Type B component of uncertainty is evaluated by using all relevant information on the possible variability of the input quantities X_i. For the input value X_i that has not been obtained from repeated measurements, the estimated variance, $u_B{}^2$, or standard uncertainty, u_B, is evaluated by judgment using all relevant information on the possible variability of X_i. This pool of information may include previous measurement data or documented performance characteristics of the dosimetry system.

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 The combined standard uncertainty, denoted by u_c, of the 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.

5.4 *Uncertainty Components Related to Specific Methods of Dosimetry System Calibration:*

5.4.1 For the "in-situ" calibration method (and the in-situ verification process for a calibration-laboratory calibration), it is important for the user to consider potentially significant sources of uncertainty such as:

5.4.1.1 The effect irradiation temperature on the reference dose measurement; and

5.4.1.2 The potential variation in dose within the phantom containing the reference and routine dosimeters and might contain a temperature indicator.

5.4.2 These sources of uncertainty are often treated as Type B estimates (i.e. prior knowledge of the temperature variation in the irradiator can be estimated).

5.4.3 Dosimeter phantoms should be designed to minimize the dose variation within the dosimeter volume. However, in practice, differences will exist and can be estimated or calculated using mathematical methods.

5.4.4 The effective standard deviation for a rectangular distribution is $a/\sqrt{3}$.

5.4.5 If the calculated differences are within predefined limits, a component of uncertainty should be included. This component is estimated using $a/\sqrt{3}$ and carried forward as a Type B uncertainty.

5.4.5.1 If the calculated differences are outside predefined limits but have a consistent bias over the full range, a correction factor can be applied to the calibration curve.

5.4.5.2 The component of uncertainty associated with the correction factor is carried forward as a Type B uncertainty.

5.4.6 For the "calibration laboratory" calibration method, it is important for the user to consider potentially significant sources of uncertainty:

5.4.6.1 The approximate correction for the effects seen in the calibration verification and can be estimated from the difference between the measurements of the reference dosimeters and from the calibration dosimeters.

5.4.6.2 Corrections for differences between the laboratory's reference-standard dosimeter and the routine dosimeter within the dosimeter stand.

5.4.6.3 The effect irradiation temperature on the reference dose measurement.

5.4.6.4 The dosimeter measurements are those obtained when replicates have been averaged and correction made for potential systematic offsets.

5.4.6.5 There are two approaches for estimating the value for this standard uncertainty:

5.4.6.6 Calculate the root-mean-square value of the individual differences observed between the two types of dosimeter; or

5.4.6.7 Use the formula $a/\sqrt{3}$ where "a" is the maximum calculated difference between the reference dosimeters and the calibration dosimeters.

5.4.6.8 If the calculated differences are within predefined limits, a component of uncertainty should be included. This component is estimated using $a/\sqrt{3}$ and carried forward as a Type B uncertainty.

5.4.6.9 If the calculated differences are outside predefined limits but have a consistent bias over the full range, a correction factor can be applied to the calibration curve.

5.4.6.10 The component of uncertainty associated with the correction factor is performed according to 5.4.6.6 or 5.4.6.7 and carried forward as a Type B uncertainty.

5.5 *Uncertainty Due to the Fit of Calibration Function:*

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

5.5.1.1 Variation in response of dosimeters; and

5.5.1.2 Analytical function used in fit.

5.5.2 The absorbed dose is the independent variable (X), and the dosimeter response (Y) is the dependent variable which is expressed as Y=f(X).

5.5.3 The calibration function has an associated uncertainty since the mathematical form does not truly represent the data set; in addition, the function has been derived from a finite number of data points. Accurate determination of the uncertainty due to curve fitting may be complex, but commercial software packages and approved calibration laboratories are available to assist with the evaluation.

5.5.3.1 The calibration curve can be broken into separate dose ranges; each range will have a different uncertainty assessment.

5.5.3.2 One example of the calculation of the curve fit uncertainty is provided in Annex A1. In general terms, the statistics of the fitting process mean the fractional uncertainty will be smallest near the centre of the calibration curve dose range and increase towards the extremes.

5.5.3.3 Depending on the characteristics of the dosimetry system, the uncertainty might increase at the lower extreme of the curve, where the "signal-to-noise" ratio deteriorates (i.e. the signal becomes markedly smaller), and at high doses when the calibration function begins to saturate (i.e. the dosimeter response per unit dose becomes increasingly smaller). In addition, within a dataset, there is more information near the middle portion of the curve than near the dose extremes. This is especially true in an unweighted linear least-squares regression fit where all data points are equally treated.

5.5.3.4 For a given mathematical function, the use of the curve fit uncertainty near the centre of the calibrated range is a common approach. For some applications, it may be necessary to use a separate curve fit uncertainty in the low dose part of the curve. In many applications, a single value for the curve fit percentage uncertainty is carried forward in the uncertainty budget.

5.6 *Uncertainty Due to Influence Quantities:*

5.6.1 Contributions to the combined uncertainty in measured dose from influence quantities which are different during routine use and calibration may include the following:

5.6.1.1 The temperature and humidity at which unirradiated and post-irradiated dosimeters are stored will usually be defined as a range by the dosimeter manufacturer, the user's procedures, and published data.

(1) Dispersion of dosimeter response values caused by variation in temperature and humidity before irradiation may give rise to uncertainty of the dosimeter's unirradiated signal. This component of uncertainty may be evaluated as Type B uncertainty.

(2) Dispersion of dosimeter response values caused by variation in storage temperature and humidity after irradiation may give rise to uncertainty of dosimeter response. This component of uncertainty may be evaluated as Type B uncertainty.

5.6.1.2 The temperature and humidity at which dosimeters are irradiated should be known within a given range. Uncertainties in response caused by variation in temperature and humidity within this range may give rise to uncertainty of dosimeter response. This component of uncertainty may be evaluated as Type B uncertainty.

5.6.1.3 The thickness or mass component of uncertainty can be determined by measurement and carried forward as a Type A uncertainty. Dosimeter thickness or mass might also be within a range, in which case this component of uncertainty may be evaluated as Type B uncertainty. One method for determining this component of uncertainty is given in Annex A1.

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

5.6.1.5 *Instrument Stability*—Variations in the instrument performance may have a direct effect on dosimetry uncertainty. Information about stability of measurement instruments can be obtained from characterization measurement using standard reference materials, such as optical filters in case of spectrophotometers. This component of uncertainty may be evaluated as either a Type A or Type B uncertainty. Periodic instrument recalibration in combination with regular instrument performance checks enable the instrument stability to be determined, and its effect on dose measurements expressed.

5.6.2 Changes in the environmental conditions in the plant relative to calibration or verification conditions (e.g., temperature, dose rate, or humidity) can influence the routine dosimeter's response. This additional uncertainty should be understood and quantified based on published data and information from the dosimeter manufacturer. It is the user's responsibility to ensure this information is correctly applied.

5.6.2.1 One method to quantify this component of uncertainty is to determine the maximum effect of such changes on the routine dosimeter response and calculate an effective standard uncertainty using $a/\sqrt{3}$ where "a" is the maximum calculated difference between the transfer-standard dosimeters and the calibration dosimeters. An example is found in Annex A1.

5.6.2.2 If seasonal variations in temperature and humidity lead to significant effects, recalibration or a redetermination of the uncertainty may be necessary. For example, calibration verification exercises conducted during extremes of seasonal variation, or immediately following a source reload in a gamma facility, can be used to detect these effects.

5.7 *Uncertainty in Dosimeter Response (Precision of the dose measurement):*

5.7.1 The uncertainty of the response of the dosimeters is obtained from the measurement of dosimeters irradiated during calibration to the same doses. This component of uncertainty is evaluated as a Type A uncertainty from the statistical analysis of repeated dosimeter response measurements. The uncertainty in dosimeter response determined during calibration is the first estimate; the uncertainty during routine measurements is expected to increase relative to the first estimate but has to be quantified by the user. This component of uncertainty estimate associated with dosimeter response may include:

5.7.1.1 Intrinsic variation in the dosimeter response;

5.7.1.2 Intrinsic variations in the dosimeter thickness/mass;

5.7.1.3 Measurement of thickness/mass of individual dosimeters; and

5.7.1.4 Intrinsic variation in the measurement equipment performance (which may include variation in dosimeter positioning within the instrument).

5.7.2 A well-controlled radiation process requires an accurate estimate of the repeatability of the routine dose measurement. Repeatability of the dose measurement is estimated using the inverse of the fit regression curve (X=f(Y)) and the calibration dosimeter's measured response.

5.7.3 An estimate of measurement repeatability may be calculated as a pooled relative variance given by Eq A1.1. Refer to Annex A1 for an example. The dosimeter's response is used to calculate the dose for each calibration sample replicate.

6. Examples of uncertainty budget components

6.1 An example of an uncertainty budget listing some of the components of uncertainty is given in Table 1. It is based on a calibration carried out by the in-situ calibration method and should be taken only as guide.

6.1.1 As per JCGM 100:2008, GUM 1995, each component of uncertainty in Table 1 includes the type of applied probability density functions (PDF). Knowledge of the type of PDF and the *k* value help to ensure the correct divisor is applied in the determination of the relative standard deviation (RSD). Refer to Table 1.

6.2 Additional components of uncertainty associated with the use of the dosimetry system are discussed in 6.3.

NOTE 5—The combined uncertainty can be determined for any value of *k*. Table 1 uses a divisor of 2 when the initial value is displayed at *k*=2. A divisor of $\sqrt{3}$ is used when the effective standard deviation for a rectangular distribution is $a/\sqrt{3}$.

6.3 *Components of Uncertainty Associated with OQ/PQ Dose Mapping and Routine Use of the Dosimetry System:*

6.3.1 An example of an uncertainty budget established for the dosimetry system calibration is shown in Table 1. There will be separate uncertainty budgets for dose mapping and

routine dose monitoring since their components of uncertainty are not derived in the dosimetry system calibration. Components of uncertainty associated with radiation processing will manifest themselves in routine processing (e.g., dosimeter placement error, variation in irradiation container positioning, variation in product mass, weight, and dimensions).

6.3.2 *Uncertainty Associated with Dosimeter Placement:*

6.3.2.1 Dosimeter placement error during routine monitoring will lead to a component of uncertainty associated with routine use. This component can be estimated based on the expected dose gradients in the vicinity of the known dosimeter location.

6.3.2.2 Mathematical methods and dosimeter strips can assist with the understanding of dose gradients in the direct vicinity of the routine dosimeter.

(1) If the uncertainty associated with dosimeter placement exceeds a user-defined expectation value (e.g., 2 %), an alternative monitoring location should be considered.

6.3.2.3 This component of uncertainty can be added in quadrature with the overall uncertainty to better estimate the uncertainty associated with routine use.

6.3.3 *Uncertainty Associated with Indirect Dose Measurement:*

6.3.3.1 The routine monitoring location(s) may be at the locations of maximum and minimum dose or at a separate monitoring location. Potential additional component of uncertainty is associated with the calculation of D_{max} or D_{min} based on the use of adjustment factors ($R_{min/mon} = D_{min} / D_{mon}$ or $R_{max/mon} = D_{max} / D_{mon}$).

6.3.3.2 The routine monitoring location(s) can be at the locations of maximum and minimum dose, or at a monitoring location. For processes with routine dose measured at a separate monitoring location, the range of target monitoring doses can be calculated by taking into account uncertainty.

$$D_{target}{}^{upper} = D_{max}{}^{limit} / R_{max/mon}$$

$$D_{target}{}^{lower} = D_{min}{}^{limit} / R_{min/mon}$$

6.3.3.3 This approach requires the calculation of UF_{lower} and UF_{upper} which depends on a specified level of confidence that D_{ster} is met or exceeded, or $D_{max,acc}$ is not exceeded during routine processing.

6.3.3.4 UF_{lower} and UF_{upper} are process factors used to calculate $D_{target}{}^{lower}$ and $D_{target}{}^{upper}$, respectively. (See ISO 11137-4.)

6.3.4 *Uncertainty Associated with Different Post-Irradiation Readout Times:*

6.3.4.1 The signal from many routine dosimeters is not stable and changes with time after irradiation. The magnitude of such instability needs to be determined and limits estimated for the maximum effect that variability in time of measurement will have on the dose measurement.

6.3.4.2 This source of uncertainty is often treated as a Type B estimate (i.e. prior knowledge of the variation in dosimeter response as a function of post-irradiation time).

6.3.4.3 If the calculated differences are within predefined limits, a component of uncertainty should be included. This component is estimated using $a/\sqrt{3}$ and carried forward as a Type B uncertainty. If the calculated differences are outside predefined limits, the allowed post-irradiation reading time may have to be further restricted. The component of uncertainty associated with the correction factor is carried forward as a Type B uncertainty.

6.3.5 *Uncertainty Associated with Processing Conditions That Differ from Dosimetry System Calibration Conditions:*

6.3.5.1 This component of uncertainty has been established as part of the in-situ environmental check, or as part of the seasonal variation check. Changes in the environmental conditions in the plant from the calibration conditions (e.g., temperature, dose rate, or humidity) can influence the response of routine dosimeters and lead to additional uncertainties. It is necessary to estimate the maximum effect of such changes on the routine dosimeters and then calculate an effective standard uncertainty using the formula $a/\sqrt{3}$. If seasonal variations in temperature and humidity lead to significant effects, it may be necessary to recalibrate dosimeters at intervals during the year. Calibration verification exercises conducted, for example, during summer and winter, or immediately following a source reload in a gamma plant, can be used to detect effects resulting from changes in plant environment.

6.3.6 *Uncertainty Associated with Applying One Calibration Curve to the Entire Dosimeter Batch:*

6.3.6.1 Facilities will often have a dosimeter inventory large enough to last twelve months, the typical batch calibration period. Differences in dosimeter response are expected for a given dosimeter batch which can be due to slight variations in the dosimeter manufacturing and dosimeter radiation-sensitive materials through the entire batch.

6.3.6.2 The approximate correction for this effect can be estimated from the difference between the measurements of the reference dosimeters and from the routine dosimeters at different periods following the initial calibration (i.e. calibration verification exercise).

6.3.6.3 Two possible approaches for estimating the value for this standard uncertainty are given:

(1) Calculate the root-mean-square value of the individual differences observed between the reference dosimeters and from the routine dosimeters; or

(2) Use the formula $a/\sqrt{3}$ where "a" is the maximum calculated difference between the reference dosimeters and from the routine dosimeters.

6.3.6.4 If the calculated differences are within predefined limits, a component of uncertainty should be included. This component is estimated using $a/\sqrt{3}$ and carried forward as a Type B uncertainty. If the calculated differences are outside predefined limits but have a consistent bias over the full range, a correction factor can be applied to the calibration curve. The component of uncertainty associated with the correction factor is performed according to 6.3.6.3*(1)* or 6.3.6.3*(2)* and carried forward as a Type B uncertainty.

6.3.7 Uncertainty components due to transitioning between different product densities or due to process interruptions should be determined, although they are not expected to significantly affect the overall uncertainty.

6.4 *Components of Uncertainty Associated with Processing Conditions:*

6.4.1 The understanding of key components of uncertainty derived within these standards can be carried forward to other standards.

7. The statement of uncertainty

7.1 *Combined Standard Uncertainty:*

7.1.1 For sources of uncertainty that are independent (not correlated), the combined standard uncertainty is obtained by combining 'n' components (Type A and Type B) of standard uncertainties in quadrature:

$$u_c = \sqrt{(u_1^2 + u_2^2 + u_3^2 + \quad + \ldots \quad u_n^2)} \tag{4}$$

7.1.1.1 If absolute values are used for the standard uncertainties, the components of uncertainty are weighted by appropriate sensitivity coefficients. This combined standard uncertainty is designated as u_c.

7.1.1.2 Uncertainty contributions must be in the same units of measurement before they can be combined. Sensitivity coefficients are not needed if the components of uncertainty are quantified in the same units of measurement. Ensure the individual components of uncertainty use the same units before entering the data into the uncertainty budget.

7.1.2 For sources of uncertainty that are correlated, the effects of those correlations must be considered when determining the combined standard uncertainty. Full treatment of correlation effects is beyond the scope of this guide. A description of correlation effects, or covariances, may be found in the GUM reference, Annex C.

7.2 *Expanded Uncertainty:*

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

$$U = k u_c \tag{5}$$

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

NOTE 6—The choice of a coverage factor that corresponds to an exact

TABLE 2 Handoffs of terms to/from other standards

Component ISO 11137 Part 4	Description	Reference
σ_{cal}	component of uncertainty related to the calibration of the dosimetry system including the uncertainty reported by the approved calibration laboratory, uncertainty in the mathematical fit of the calibration function, and uncertainties due to influence quantities, but excluding components due to the reproducibility of the dosimeter measurement (see σ_{rep})	Approved calibration laboratory Certified Dose (u_{lab}) Section 5.3, 5.4, Annex A1 Calibration Curve Fit (u_{fit}) Section 5.5, Annex A1.5 Environmental Effects (Irradiation Temperature, Dose Rate, Energy Spectrum) ($u_{environment}$) Sections 5.4, 5.6, Annex A1.6
$\sigma_{machine}$	component of variability related to the radiation source and convey or system	This source of variability will impact the dose measurement, but not its associated uncertainty. Refer to Section 8.2.3.
σ_{map}	component of variability measured during a dose mapping exercise	This source of variability will impact the dose measurement, but not its associated uncertainty. Refer to Section 8.2.3 and Annex A1.8.
$\sigma_{process}$	standard deviation associated with the irradiation process used for setting process target doses $\sigma_{process}^{max}$ — The standard deviation associated with the process maximum dose $\sigma_{process}^{min}$ — The standard deviation associated with the process minimum dose	Process Uncertainty Sections 1.3, 1.5, 6.3.3, 6.3.7, 8.4, 8.5
σ_{rep}	component of variability associated with the reproducibility of the dosimeter measurement	$u_{precision}$ Sections 5.5, 5.7, Eq A1.1, Annex A1.4