Standard Practice for Calibration of Routine Dosimetry Systems for Radiation Processing[1]

This standard is issued under the fixed designation ISO/ASTM 51261; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision.

1. Scope

1.1 This practice specifies the requirements for calibrating routine dosimetry systems for use in radiation processing, including establishing measurement traceability and estimating uncertainty in the measured dose using the calibrated dosimetry system.

NOTE 1—Regulations or other directives exist in many countries that govern certain radiation processing applications such as sterilization of healthcare products and radiation processing of food requiring that absorbed-dose measurements be traceable to national or international standards (ISO 11137-1, Refs (**1-3**)[2]).

1.2 The absorbed-dose range covered is up to 1 MGy.

1.3 The radiation types covered are photons and electrons with energies from 80 keV to 25 MeV.

1.4 This document is one of a set of standards that provides recommendations for properly implementing dosimetry in radiation processing, and describes a means of achieving compliance with the requirements of ASTM E2628 "Practice for Dosimetry in Radiation Processing" for the calibration of routine dosimetry systems. It is intended to be read in conjunction with ASTM E2628 and the relevant ASTM or ISO/ASTM standard practice for the dosimetry system being calibrated referenced in Section 2.

1.5 *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.*

1.6 *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:*[3]

E170 Terminology Relating to Radiation Measurements and Dosimetry
E178 Practice for Dealing With Outlying Observations
E2628 Practice for Dosimetry in Radiation Processing
E2701 Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing

2.2 *ISO/ASTM Standards:*[3]

51607 Practice for Use of an Alanine-EPR Dosimetry System
51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

2.3 *International Commission on Radiation Units and Measurements Reports:*[4]

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

2.4 *ISO Standards:*[5]

ISO 11137-1 Sterilization of health care products—Radiation—Requirements for the development, validation and routine control of a sterilization process for medical devices

2.5 *ISO/IEC Standards:*[5]

17025 General Requirements for the Competence of Testing and Calibration Laboratories

2.6 *Joint Committee for Guides in Metrology (JCGM) Reports:*[6]

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

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[1] This practice is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.01 on Dosimetry, and is also under the jurisdiction of ISO/TC 85/WG 3.

Current edition approved Oct. 1, 2020. Published November 2020. Originally published as ASTM E 1261 – 88. Last previous ASTM edition E 1261 – 00. ASTM E 1261 – 94$^{\varepsilon 1}$ was adopted by ISO in 1998 with the intermediate designation ISO 15556:1998(E). The present International Standard ISO/ASTM 51261:2013(20)(E) replaces and is a reapproval of the last previous edition ISO/ASTM 51261:2013(E).

[2] The boldface numbers given in parentheses refer to the bibliography at the end of this guide.

[3] For referenced ASTM and ISO/ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[4] Available from International Commission on Radiation Units and Measurements, 7910 Woodmont Avenue, Suite 800, Bethesda, MD 20814, USA.

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

[6] 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).

3. Terminology

3.1 *Definitions:*

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

3.1.1.1 *Discussion*—A recognized national metrology institute or other calibration laboratory accredited to ISO/IEC 17025 should be used 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.

3.1.2 *calibration*—set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

3.1.3 *calibration curve*—expression of the relation between indication and the corresponding measured quantity value.

3.1.4 *charged-particle equilibrium* (referred to as *electron equilibrium* in the case of electrons set in motion by photon beam irradiation of a material*)*—condition in which the kinetic energy of charged particles (or electrons), excluding rest mass, entering an infinitesimal volume of the irradiated material equals the kinetic energy of charged particles (or electrons) emerging from it.

3.1.5 *dosimeter batch*—quantity of dosimeters made from a specific mass of material with uniform composition, fabricated in a single production run under controlled, consistent conditions, and having a unique identification code.

3.1.6 *dosimeter stock*—part of a dosimeter batch held by the user.

3.1.7 *dosimetry system*—system used for measuring absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use.

3.1.8 *electron equilibrium*—charged particle equilibrium for electrons. (See *charged-particle equilibrium*.)

3.1.9 *influence quantity*—quantity that is not the measurand but that affects the result of the measurement.

3.1.10 *in-situ/in-plant calibration*—calibration where the dosimeter irradiation is performed in the place of use of the routine dosimeters.

3.1.10.1 *Discussion*—In-situ/in-plant calibration of dosimetry systems refers to irradiation of dosimeters along with reference or transfer standard dosimeters, under operating conditions that are representative of the routine processing environment, for the purpose of developing a calibration curve for the routine dosimetry systems.

3.1.11 *measurand*—specific quantity subject to measurement.

3.1.12 *measurement management system*—set of interrelated or interacting elements necessary to achieve metrological confirmation and continual control of measurement processes.

3.1.13 *primary standard dosimetry system*—dosimetry system that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity.

3.1.14 *reference standard dosimetry system*—dosimetry system, generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived.

3.1.15 *routine dosimetry system*—dosimetry system calibrated against a reference standard dosimetry system and used for routine absorbed dose measurements, including dose mapping and process monitoring.

3.1.16 *traceability*—property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

3.1.16.1 *Discussion*—Measurement traceability is a requirement of any measurement management system (see Annex A4).

3.1.17 *transfer standard dosimetry system*—dosimetry system used as an intermediary to calibrate other dosimetry systems.

3.1.18 *type I dosimeter*—dosimeter of high metrological quality, the response of which is affected by individual influence quantities in a well-defined way that can be expressed in terms of independent correction factors.

3.1.19 *type II dosimeter*—dosimeter, the response of which is affected by influence quantities in a complex way that cannot practically be expressed in terms of independent correction factors.

3.1.20 *uncertainty (of measurement)*—parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand or derived quantity.

3.1.21 *uncertainty budget*—quantitative analysis of the component terms contributing to the uncertainty of a measurement, including their statistical distribution, mathematical manipulation and summation.

3.2 *validation (of a process)*—establishment of documented evidence, which provides a high degree of assurance that a specified process will consistently produce a product meeting its predetermined specifications and quality attributes.

3.3 *verification*—confirmation by examination of objective evidence that specified requirements have been met.

3.3.1 *Discussion*—In the case of measuring equipment, the result of verification leads to a decision either to restore to service or to perform adjustments, repair, downgrade, or declare obsolete. In all cases it is required that a written trace of the verification performed be kept on the instrument's individual record.

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

4. Significance and use

4.1 Ionizing radiation is used to produce various desired effects in products. Examples of applications include the sterilization of medical products, microbial reduction, modification of polymers and electronic devices, and curing of inks, coatings, and adhesives (**4**).

4.2 Absorbed-dose measurements, with statistical controls and documentation, are necessary to ensure that products receive the desired absorbed dose. These controls include a program that addresses requirements for calibration of routine dosimetry system.

4.3 A routine dosimetry system calibration procedure as described in this document provides the user with a dosimetry system whose dose measurements are traceable to national or international standards for the conditions of use (see Annex A4). The dosimetry system calibration is part of the user's measurement management system.

5. Dosimeter system calibration overview

5.1 Calibration of a routine dosimetry system consists of the following:

5.1.1 Selection of the calibration dosimeters from the user stock (see Section 8).

5.1.2 Irradiation of the calibration dosimeters (see 9.1 and 9.2).

5.1.3 Calibration and/or performance verification of measurement instruments (see Section 7).

5.1.4 Measurement of the calibration dosimeters response (see 9.1.6 and 9.2.5.1).

5.1.5 Analysis of the calibration dosimeter response data (see 9.1.7 and 9.2.6).

5.1.6 Verification of the calibration curve for conditions of use, if appropriate (see 9.1.8 and Note 2).

5.1.7 Estimation of the combined uncertainty for the conditions of use (see 9.1.10 and 9.2.7).

5.1.8 Verification of the calibration curve at a time other than calibration for assessment of continuing validity of the calibration curve (see 9.1.11, 9.2.9, and Note 2).

NOTE 2—Calibration verification is conducted as part of the calibration when the calibration irradiation conditions are different from the conditions of use (5.1.6). Calibration verification is also conducted between calibrations to ensure continued suitability of the calibration curve for the conditions of use (5.1.8).

5.2 *Calibration Irradiation Methods*—There are two methods for irradiating dosimeters for calibration:

5.2.1 Calibration irradiations performed at an approved laboratory followed by a calibration verification exercise.

5.2.2 In-situ/in-plant calibration irradiations of routine dosimeters along with transfer standard dosimeters issued and analyzed by an approved laboratory.

NOTE 3—Valid in-situ/in-plant calibration irradiations result in a calibration curve generated under conditions that are representative of the routine processing environment. An in-situ/in-plant calibration may not be valid or may require calibration verification if the calibration conditions can not be maintained during routine use. For example, the calibration irradiations are carried out as a single exposure, but the dosimeter is used for dose measurement of fractionated irradiations.

5.3 *Uncertainties:*

5.3.1 All measurements of absorbed dose need to be accompanied by an estimate of uncertainty (see ISO/ASTM 51707, Refs (**5**,**6**) and GUM).

5.3.2 All components of uncertainty should be included in the estimate, including those arising from calibration, dosimeter reproducibility, instrument stability and the effect of influence quantities. A full quantitative analysis of components of uncertainty is referred to as an *uncertainty budget* and is often presented in the form of a table. Typically, the *uncertainty budget* will identify all significant components of uncertainty together with their methods of estimation, statistical distributions and magnitudes.

5.3.3 Examples of components of uncertainty in the dosimetry system calibration include inherent variation in dosimeter response, uncertainty in the calibration irradiation dose, uncertainty in the calibration curve fit and uncertainty in dosimeter response correction parameters such as dosimeter thickness, dosimeter mass, unirradiated response and irradiation temperature.

5.3.4 Additional components of uncertainty might be present when the conditions of use are different than the conditions of calibration. In these instances, a calibration verification is conducted to quantify a component of uncertainty to account for these differences (see 9.1.8 and 9.2.9).

6. Requirements for a routine dosimetry system calibration

6.1 Dosimetry system calibration shall be conducted for each new dosimeter batch.

NOTE 4—The response of different dosimeter stocks purchased at different times from a given dosimeter batch should be verified to ensure equivalent response. A statistical test should be used to determine if there is any significant difference between the stocks. This should be repeated at several doses over the calibration dose range.

6.2 Routine dosimetry systems shall be calibrated using one of the methods described in 9.1 and 9.2.

6.3 The rationale for selecting a method for calibration shall be documented (see 9.1.4 and 9.2.3).

6.4 Recalibration of an existing batch or stock shall be conducted at a frequency specified by the user based on the known characteristics of the dosimetry system.

6.4.1 Additional calibration or calibration verification may be required to determine if changes have occurred that affect the calibration. Examples are changes in the values of influence quantities, such as temperature or humidity, changes in the use of the dosimetry system and change in response due to dosimeter aging. Changes in influence quantities can result from seasonal changes in ambient conditions or changes in source activity or distribution.

6.5 Calibration curves are specific to the measurement instrument used to generate them. They shall not be used with other instruments unless it has been demonstrated that the dose measurements agree within user defined limits.

6.6 All software associated with dosimetry system and calibration data analysis shall be validated for its intended use.

7. Requirements for measurement instruments calibration and performance verification

7.1 All measurement instrumentation associated with the dosimetry system shall either be calibrated, or have its performance verified, before use. Performance checks and/or recalibration shall be carried out at user-specified intervals, based on the known characteristics of the instrument.

7.1.1 Where recognized standards exist, the calibration of the instrument shall be traceable to national or international standards.

7.1.2 Where recognized standards do not exist, the performance of the instrument shall be verified in accordance with industry or manufacturer recommended practices and procedures.

NOTE 5—For example, the Alanine-EPR dosimetry system employs electron paramagnetic resonance (EPR) spectroscopy for analysis. The proper operation of the EPR spectrometer is verified with appropriate EPR spin reference such as irradiated alanine dosimeters, pitch sample, or Mn(II) in CaO (see ISO/ASTM Practice 51607).

7.1.3 When maintenance or modification of the measurement instrumentation has occurred that may affect its performance, instrument performance shall be verified and, if necessary, the instrument shall be re-calibrated.

8. Requirements for the sampling of calibration dosimeters

8.1 Dosimeters selected for the calibration shall constitute a representative sample of the dosimeter stock held by the user to be used in routine processing. These dosimeters are referred to as 'calibration dosimeters'.

8.2 Calibration dosimeters shall be labelled to ensure segregation and identification throughout the calibration exercise.

8.3 The number of dose levels required for developing the calibration curve depends on the range of utilization. At least five dose levels shall be used for each factor of ten span of absorbed dose (for example, choose five dose levels for a 5 to 50 kGy range).

8.3.1 The minimum number of dose levels to be used in the calibration can be determined as follows: divide the maximum dose (D_{max}) of the dose range by the minimum dose (D_{min}) of the dose range; calculate log (base 10) of this ratio: $Q = \log(D_{max}/D_{min})$. If Q is equal to or greater than 1, calculate 5 × Q, and round this up to the nearest integer value. This value represents the minimum number of dose levels to be used. If Q is less than 1 use five dose levels.

8.4 A minimum of four dosimeters for each dose level shall be used. However, using a larger number of dosimeters per dose level may reduce the uncertainty associated with the calibration.

9. Calibration of dosimetry systems

9.1 *Calibration of Dosimetry Systems using irradiations at an approved laboratory:*

9.1.1 *Overview*—The routine dosimeter may be a Type I or Type II dosimeter. The calibration irradiation at an approved laboratory has the advantage that the dosimeters are irradiated to known doses under well-controlled and documented conditions. However, when conditions of use (in-situ/in-plant) differ from calibration conditions, significant uncertainties may be introduced in the combined uncertainty of the routine absorbed dose measurement. Transport of the dosimeters to and from the approved laboratory may also introduce uncertainties from pre- and post-irradiation influence quantities that are difficult to characterize.

9.1.2 *Post Irradiation Response*—Post-irradiation response characteristics of the routine dosimeter shall be determined prior to calibration irradiation and incorporated into the calibration procedure.

9.1.3 *Transport of Calibration Samples*—The effect of intended transportation on dosimeter response shall be evaluated to establish criteria for acceptable packaging and transportation of calibration dosimeters. The evaluation should be based on characterization data of the routine dosimetry system (see ASTM E2701).

9.1.4 *Irradiation Conditions*—A rationale shall be prepared for the calibration target dose levels, their spacing and irradiation conditions, for example, dose rate and irradiation temperature specified to the approved laboratory. Document the allowable variation from these conditions.

9.1.4.1 For example, for dose ranges of less than one decade (factor of ten), dose levels should be distributed arithmetically uniformly (for example, 10, 20, 30, 40, 50 kGy). For dose ranges of more than one decade, dose levels should be distributed geometrically uniformly (for example, 1.0, 1.5, 2.3, 3.4, 5.1, 7.6, 11.4, 17.1, 25.6, 38.4, 57.7, 86.5 kGy).

9.1.5 *Dosimeter Irradiation*—The dosimeters shall be irradiated at an approved laboratory to the specified absorbed doses. The absorbed dose is usually specified in terms of absorbed dose to water.

9.1.5.1 The approved laboratory shall report deviations from the conditions specified by the user (see 9.1.4).

9.1.6 *Dosimeter Response Measurement*—The performance of measurement instrumentation shall be verified (see 7.1).

9.1.6.1 Measure the calibration dosimeter response upon return from the approved laboratory in accordance with the users calibration and measurement procedures.

9.1.7 *Analysis of Dosimetry Data:*

9.1.7.1 If required, each dosimeter response shall be adjusted for dosimeter parameters such as dosimeter thickness, mass or unirradiated dosimeter response following established measurement practice.

9.1.7.2 The individual dosimeter response, the sample standard deviation and the coefficient of variation of the replicate measurements at each dose level shall be determined and documented.

NOTE 6—In general, if the coefficient of variation at any dose level is greater than a user-defined limit, a re-determination of the data should be considered (for example, perform a visual inspection to identify potential dosimeter damage, repeat the calibration irradiation at the dose level or perform an outlier test).

9.1.7.3 Derive the calibration curve in mathematical form, $y = f(x)$, where dosimeter response is the dependent variable (y)

and absorbed dose is the independent variable (x). Choose an analytical form (for example, linear, polynomial, or exponential) that provides an appropriate fit to the measured data. The ease of deriving dose from measured dosimeter response (the mathematical inverse of the analytical form) may also be a consideration in selecting the analytical form (see Annex A2 and Annex A3).

(1) The resulting calibration curve shall be evaluated for goodness of fit within user defined limits.

9.1.8 *Calibration Verification* (as part of calibration)—Prior to implementation of a calibration curve, a calibration verification shall be performed to assess the suitability of the calibration curve for the conditions of use. This is usually achieved by in-situ/in-plant irradiation of transfer standard dosimeters supplied by an approved laboratory alongside representative samples from the routine dosimeter stock under the conditions of use. The dosimetry system being calibrated and the transfer standard dosimetry system used for calibration verification should, if possible, be based on different types of dosimeters. For example, if the dosimetry system being calibrated is based on alanine dosimeters, and the transfer standard dosimetry system is also based on alanine dosimeters, then the effect of an inappropriate correction for influence quantities, such as temperature, will not be apparent as both systems will respond in the same way.

9.1.8.1 The calibration verification shall be conducted at a minimum of three dose levels targeted near the extremes and near the center of the calibration dose range.

9.1.8.2 The routine dosimeters for the calibration verification shall be selected from the same dosimeter stock as the calibration dosimeters.

9.1.8.3 The irradiation of the routine dosimeters and transfer standard dosimeters shall consist of complete pathways through the irradiator.

9.1.8.4 The routine and transfer dosimeters shall be irradiated so that it is ensured that they receive the same dose within predetermined limits (see Annex A1).

NOTE 7—The temperatures associated with the calibration verification irradiations should be similar to those expected to be encountered during routine use of the dosimetry system.

9.1.8.5 In a few instances it may be impossible to conduct the calibration verification as described. In these instances, the user shall develop a verification method and rationale that is capable of demonstrating that the calibration curve of the routine dosimetry system is suitable for the conditions of use. The rationale for the need to use this alternative method shall be documented.

9.1.8.6 The calibration verification results shall be evaluated to identify difference between the measured dose values of the routine and transfer standard dosimetry systems and to provide an estimate of one of the components of calibration uncertainty (see Annex A3).

9.1.9 *Corrective Action*—If the calibration verification result exceeds a user defined acceptable limit, corrective action in accordance with the measurement management system shall be implemented.

9.1.9.1 Corrective action may include: repeating the calibration using more appropriate influence quantity conditions during calibration irradiation, reducing the dose range of the calibration curve, developing calibration curves for specific irradiator pathways, applying a correction factor to the routine dosimeter response in cases where a single factor is applicable over the entire calibration curve, or calibrating using an in-situ/in-plant calibration method (see 9.2).

9.1.10 *Dosimetry System Measurement Uncertainty*—Prepare an estimate of the combined uncertainty in the measured dose using the calibrated dosimetry system for the conditions of use (see Annex A3 and ISO/ASTM 51707).

9.1.11 *Stability Verification*—The suitability of the calibration curve shall be verified over its period of use in accordance with the requirements of 6.4.1.

9.2 *In-situ/In-plant Calibration of Routine Dosimetry Systems in a Production Irradiator Using Transfer Standard Dosimetry System:*

9.2.1 *Overview*—The routine dosimeter may be a Type I or Type II dosimeter. The calibration irradiation of the routine dosimeters together with the transfer standard dosimeters in the production irradiator has the advantage that the influence quantity value ranges will be very similar in routine application and calibration, provided the calibration irradiation conditions are chosen appropriately. This method takes into account the effect of the influence quantities of the conditions of use to the extent that the transfer standard dosimeter response can be corrected for the difference between the fixed influence quantity values of its calibration and the production irradiation influence quantities profile by the approved laboratory issuing and analyzing the transfer standard dosimeters. Care must be taken to ensure that the routine dosimeters and transfer standard dosimeters irradiated together receive the same absorbed dose.

9.2.2 *Post-Irradiation Response*—Post-irradiation response characteristics of the dosimeter shall be determined prior to calibration irradiation and incorporated into the calibration procedure.

9.2.3 *Irradiation Conditions*—A rationale for target dose levels and irradiation conditions for calibration irradiation shall be prepared and documented. The irradiation conditions selected for calibration irradiation should be such that the irradiation conditions are similar to those expected during the intended use of the irradiator, for example, during performance qualification and routine process monitoring.

9.2.3.1 For example, for dose ranges of less than one decade (factor of ten): dose levels should be distributed arithmetically uniformly (for example, 10, 20, 30, 40, 50 kGy). For dose ranges of more than one decade, dose levels should be distributed geometrically uniformly (for example, 1.0, 1.5, 2.3, 3.4, 5.1, 7.6, 11.4, 17.1, 25.6, 38.4, 57.7, 86.5 kGy).

9.2.4 *Dosimeter Irradiation*—The calibration dosimeters shall be irradiated with transfer standard dosimeters issued and analyzed by an approved laboratory. The irradiation phantom used to co-locate the calibration dosimeters and the transfer standard dosimeters shall be characterized to ensure both the calibration dosimeters and the transfer standard dosimeters receive the same absorbed dose (see Annex A1). The absorbed dose is usually specified in terms of absorbed dose to water.

NOTE 8—The temperatures of the routine dosimeters during calibration irradiation should be similar to those expected to be encountered during routine use of the dosimetry system.

9.2.5 *Dosimeter Response Measurement*—Verify the performance of the measurement instrumentation (see 7.1 – 7.1.3).

9.2.5.1 The calibration dosimeter response shall be measured in accordance with the users' calibration and measurement procedures.

9.2.6 *Analysis of Dosimetry Data*—If required, each dosimeter response shall be adjusted for response parameters such as dosimeter thickness, mass or unirradiated dosimeter response following established measurement practice.

9.2.6.1 The individual dosimeter response, the sample standard deviation and the coefficient of variation of the replicate measurements at each dose level shall be determined and documented.

NOTE 9—In general, if any coefficient of variation is greater than a user-defined limit, a re-determination of the data should be considered (for example, perform a visual inspection to identify potential dosimeter damage, repeat the calibration irradiation at the dose level or perform an outlier test).

9.2.6.2 Derive the calibration curve in mathematical form, $y = f(x)$, where dosimeter response is the dependent variable (y) and absorbed dose is the independent variable (x). Choose an analytical form (for example, linear, polynomial, or exponential) that provides an appropriate fit to the measured data. The ease of deriving dose from measured dosimeter response (the mathematical inverse of the analytical form) may also be a consideration in selecting the analytical form (see Annex A2 and Annex A3).

9.2.6.3 The resulting calibration curve shall be evaluated for goodness of fit within user defined limits.

9.2.7 *Dosimetry System Measurement Uncertainty*—Prepare an estimate of the combined uncertainty in the measured dose using the calibrated dosimetry system for the conditions of use (see Annex A3 and ISO/ASTM 51707).

9.2.8 *Corrective Action*—If the combined uncertainty exceeds a user defined acceptable limit, corrective action in accordance with the measurement management system shall be implemented.

9.2.8.1 Corrective action may include: repeating the calibration using more appropriate calibration irradiation conditions, reducing the dose range of the calibration curve, developing calibration curves for specific irradiator pathways.

9.2.9 *Stability Verification*—The suitability of the calibration curve shall be verified over the period of use in accordance with the requirements of 6.4.1.

9.2.9.1 Changes to the intended conditions of use of the routine dosimetry system may render the calibration curve unsuitable. An example of such a change is that of dose fractioning during the intended use when the calibration irradiation consists of a single exposure. In such instances, the effect of the change shall be evaluated.

NOTE 10—Performing a calibration verification is one method of evaluating the effect of changes to the conditions of intended use, reference 9.1.8 and Note 7.

10. Minimum documentation requirements

10.1 Document the dosimetry system being calibrated including the dosimeter manufacturer, type and batch number, and measurement instrumentation.

10.2 Document the rationale for the calibration method.

10.3 Document the dosimetry system calibration data, irradiation parameters, irradiation date, transfer standard dosimeters, and description of the irradiation facility used.

10.4 Document or reference a description of the radiation source(s) used in calibration and processing, including the type, nominal activity or beam parameters, and any available information on the energy spectrum.

10.5 Document irradiation temperatures and, if necessary, the relative humidity.

10.6 Document the combined uncertainty in the measured dose using the calibrated dosimetry system.

10.7 Reference the measurement management system at the radiation facility.

11. Keywords

11.1 absorbed dose; accredited laboratory; dosimeter; dosimetry system calibration; dosimetry system; electron beam; gamma radiation; ionizing radiation; measurement traceability; radiation processing; reference standard dosimetry system; routine dosimeter; transfer standard dosimetry system; Type I dosimeter; Type II dosimeter; X-ray; X-radiation

ANNEXES

(informative)

A1. PHANTOM GEOMETRY

A1.1 A phantom of known homogenous material is used for the irradiation of the dosimeters in order to minimize the difference between the absorbed doses received by the routine and transfer standard dosimeters. The phantom design should hold the two types of dosimeters so that they do not significantly influence each other and provide a geometry that is appropriate for the radiation source employed (see Fig. A1.1 and Fig. A1.2 for examples of such phantoms employed for gamma or X-ray irradiation; see Fig. A1.3 for an example of a phantom suitable for high energy electron-beam irradiation).

A1.2 The use of a phantom can result in different irradiation temperature and temperature profile than the conditions of use of the routine dosimeter without a phantom. The effect of these differences should be evaluated as part of the calibration procedure.

A1.3 When thick and thin dosimeters are irradiated together, the thin dosimeters should be surrounded by sufficient polymeric material to ensure that the attenuation characteristics are similar to the thick dosimeters and that the dosimeters receive the same dose.

A1.4 Dose variation within the phantom can be characterized by irradiating the phantom with the same type of dosimeter in all the dosimeter positions within the calibration irradiation phantom. However, difference in geometry between the routine dosimeters and transfer standard dosimeters must be taken into account.

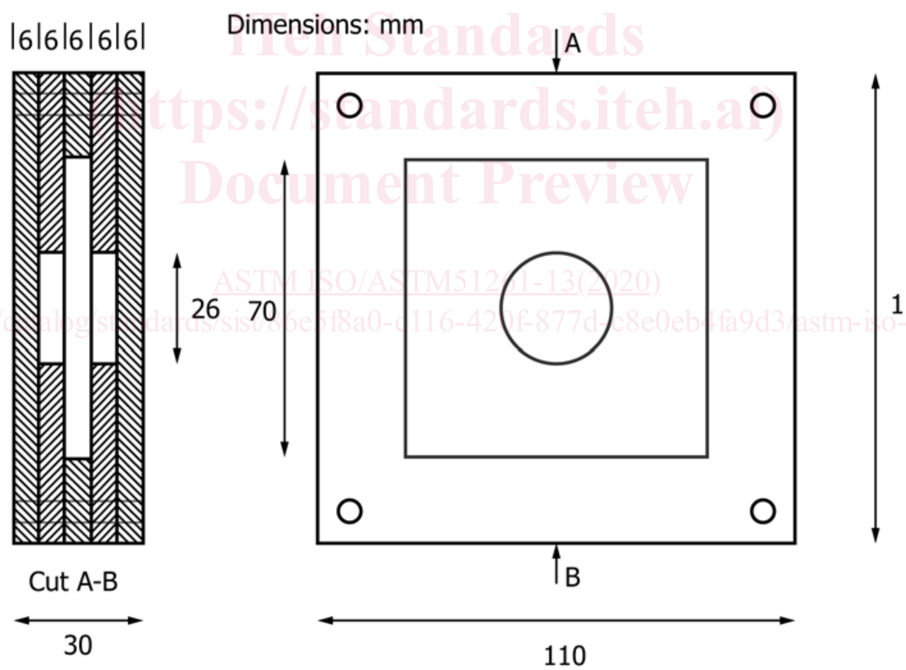

FIG. A1.1 Example of calibration phantom allowing alanine dosimeters to be placed on either side of thin film routine dosimetry system dosimeter