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An American National Standard

Standard Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing[1]

This standard is issued under the fixed designation E 2701; 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 guide provides guidance on determining the performance characteristics of dosimeters and dosimetry systems used in radiation processing.

1.2 This guide describes the influence quantities that might affect the performance of dosimeters and dosimetry systems and that should be considered during dosimeter/dosimetry system characterization.

1.3 Users of this guide are directed to existing standards and literature for procedures to determine the effects from individual influence quantities and from combinations of more than one influence quantity.

1.4 Guidance is provided regarding the roles of the manufacturers, suppliers, and users in the characterization of dosimeters and dosimetry systems.

1.5 This guide does not address how the dosimeter/dosimetry system characterization information is to be used in radiation processing applications or in the calibration of dosimetry systems.

NOTE 1—For guidance on the use of dosimeter/dosimetry system characterization information for the selection and use of a dosimetry system, the user is directed to Practice E 2628.

NOTE 2—For guidance on the use of dosimeter/dosimetry system characterization information for dosimetry system calibration, the user is directed to ISO/ASTM Guide 51261.

1.6 *This guide does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E 170 Terminology Relating to Radiation Measurements and Dosimetry

E 456 Terminology Relating to Quality and Statistics

E 1026 Practice for Using the Fricke Reference-Standard Dosimetry System

E 1325 Terminology Relating to Design of Experiments

E 2628 Practice for Dosimetry in Radiation Processing

2.2 *ISO/ASTM Standards:*[2]

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

51261 Guide for the Selection and Calibration of Dosimetry Systems for Radiation Processing

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

2.3 *ISO Reports:*[3]

GUM Guide to the Expression of Uncertainty in Measurements, 1995.

VIM International Vocabulary of Basic and General Terms in Metrology

2.4 *International Commission on Radiation Units and Measurements (ICRU) Reports*[4]

Report 60 Fundamental Quantities and Units for Ionizing Radiation

Report 80 Dosimetry Systems for Use in Radiation Processing

3. Terminology

3.1 *Definitions:*

3.1.1 *calibration curve*—expression of the relation between indication and corresponding measured quantity value. **VIM:2008**

3.1.2 *dosimeter*—device that, when irradiated, exhibits a quantifiable change that can be related to absorbed dose in a given material using appropriate measurement instruments and procedures.

3.1.3 *dosimter 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.

3.1.4 *dosimter/dosimetry system characteristization*—determination of performance characteristics, such as useful

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

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

[4] Available from the International Organization for Standardization, 1 rue de Varembe, Case Postale 56, CH-1211, Geneva 20, Switzerland..

dose range, reproducibilty and the effects of influence quantities, for a dosimeter/dosimetry system under defined test conditions.

3.1.5 *dosimeter response*—reproducible, quantifiable effect produced in the dosimeter by ionizing radiation.

3.1.5.1 *Discussion*—The dosimeter response value, obtained from one or more measurements, is used in the estimation of the derived absorbed dose. The response value may be obtained from such measurements as optical absorbance, thickness, mass, peak-to-peak distance in EPR spectra, or electropotential between solutions.

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

3.1.7 *influence quantity*—quantity that is not the measurand but that affects the result of the measurement. **VIM:1993**

3.1.7.1 *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.

3.1.8 *qualtiy system*—documented organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

3.2 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in Terminology E 170. Definitions in E 170 are compatible with ICRU Report 60; this document, therefore, may be used as an alternative reference. Definitions of other terms used in this standard that pertain to statistics and design of experiments may be found in Terminologies E 456 and E 1325, respectively.

4. Significance and Use

4.1 Ionizing radiation produces physical or chemical changes in many materials that can be measured and related to absorbed dose. Materials with radiation-induced changes that have been thoroughly studied can be used as dosimeters in radiation processing.

NOTE 3—The scientific basis for commonly used dosimetry systems and detailed descriptions of the radiation-induced interactions are given in ICRU Report 80.

4.2 Before a material can be considered for use as a dosimeter, certain characteristics related to manufacture and measurement of its response to ionizing radiation need to be considered, including:

4.2.1 the ability to manufacture batches of the material with evidence demonstrating a reproducible radiation-induced change,

4.2.2 the availability of instrumentation for measuring this change, and

4.2.3 the ability to take into account effects of influence quantities on the dosimeter response and on the measured absorbed-dose values.

4.3 Dosimeter/dosimetry system characterization is conducted to determine the performance characteristics for a dosimeter/dosimetry system related to its capability for measuring absorbed dose. The information obtained from dosimeter/dosimetry system characterization includes the reproducibility of the measured absorbed-dose value, the useful absorbed-dose range, effects of influence quantities, and the conditions under which the dosimeters can be calibrated and used effectively.

NOTE 4—When dosimetry systems are calibrated under the conditions of use, effects of influence quantities may be minimized or eliminated, because the effects can be accounted for or incorporated into the calibration method (see ISO/ASTM Guide 51261).

4.4 The influence quantities of importance might differ for different radiation processing applications and facilities. For references to standards describing different applications and facilities, see Practice E 2628.

4.5 Classification of a dosimeter as a type I dosimeter or a type II dosimeter (see Practice E 2628) is based on performance characteristics related to the effects of influence quantities obtained from dosimeter/dosimetry system characterization.

4.6 The dosimeter manufacturer or supplier is responsible for providing a product that meets the performance characteristics defined in product specifications, certificates of conformance, or similar types of documents. Dosimeter specifications should be developed based on dosimeter/dosimetry system characterization.

4.7 The user has the responsibility for ensuring that the dosimetry requirements for the specific applications are met and that dosimeter/dosimetry system characterization information has been considered in:

4.7.1 determining the suitability of the dosimeter or dosimetry system for the specific application (see Practice E 2628),

4.7.2 selecting the calibration method (see ISO/ASTM Guide 51261),

4.7.3 establishing dosimetry system operational procedures (see respective dosimetry system practice listed in Practice E 2628), and

4.7.4 estimating the uncertainty components in the measured dose values (see ISO/ASTM Guide 51707).

4.8 Dosimeter/dosimetry system characterization information provided by manufacturers or suppliers, or available in the literature, should be reviewed by the user to determine the tests that should be performed prior to the use of the dosimeter or dosimetry system. Information on performance characteristics should be verified before using.

5. Dosimeter/Dosimetry System Characterization

5.1 *Performance Characteristics*:

5.1.1 Some examples of performance characteristics of dosimeters/dosimetry systems that may affect the measurement of absorbed dose are given in Table 1.

5.2 *Measurement Instruments*:

5.2.1 Prior to conducting performance characterization of the dosimeters, it is necessary to establish procedures for the operation of the measurement instruments.

5.2.2 Operating procedures should be developed to control and optimize the performance of all measurement instruments and auxiliary systems, including those used for measuring mass or thickness or used for a post irradiation heat treatment.

TABLE 1 Examples of Performance Characteristics of Dosimeters/Dosimetry Systems

Performance Characteristic	Description
Absorbed-dose range	Range over which the dosimetry system can be used within a maximum specified uncertainty
Applicable radiation type and energy	X-radiation, gamma radiation, and electron beam
Effect of influence quantities	Effects from individual influence quantities (see Table 2) and from combinations of more than one influence quantity (see 6.6)
Uncertainty	Achievable maximum level of uncertainty
Spatial resolution	Spatial resolution may be limited by dosimeter size, volume or area over which measurement is taken

5.2.3 The instruments used in a given dosimetry system with specific dosimeters should be calibrated with evidence of traceability and be tested to provide evidence of their suitability for use with the dosimeters. This should include a determination of repeatability and reproducibility for the specific measurement methods to be used.

5.2.4 The influence on measurement values attributable to rounding error, short term instrument drift, etc. over the expected range of use should be determined.

5.2.5 The performance of accessories such as dosimeter holders or dosimeter positioning apparatus within the measurement instrument should be determined.

5.2.6 The supplier of the performance characterization information should provide information on all instrumentation used in the characterization, including relevant performance specifications for the measurement instruments and characterization results.

NOTE 5—Characterization results are specific to the measurement instruments and measurement parameters used for the tests. Results cannot be used with other measurement instruments without adequate data to support equivalency.

5.2.7 Information obtained during the measurement system development to determine optimum or recommended instruments, including precautions to avoid known sources of error, should be made available to potential users.

5.3 *Characterization*:

5.3.1 All dosimeter samples used in the characterization must be representative of dosimeters supplied by the manufacturer/distributor.

5.3.2 The performance of dosimeter/dosimetry system characterization should be conducted in accordance with an experimental design that can effectively assess both individual and combined effects of the influence quantities being tested.

5.3.3 For performance characterization, dosimeters should be irradiated in facilities that can provide highly reproducible dose rates and well-quantified values of influence quantities.

NOTE 6—When studying the effects of irradiation conditions such as temperature or relative humidity, the conditions experienced by the dosimeters must be known within established limits. Dosimeter temperatures should be monitored. Reliance should not be placed on monitoring the air temperature and assuming that there is temperature equilibrium. Difference between dosimeter temperature and air temperature may be associated with dose and may introduce bias in the characterization results over the dose range. For studies on the effects of changes of relative humidity, the time required for the water and oxygen content of the dosimeters to reach equilibrium should be taken into account. It is necessary to validate controlled irradiation conditions to verify that specified conditions can be achieved.

5.3.4 An initial calibration curve may be obtained by irradiating dosimeters over a range of absorbed doses at defined conditions, for example, specified temperature, relative humidity, and absorbed dose rate, and by measuring dosimeter response under defined measurement conditions. The defined conditions for the irradiation should approximate the expected range of values to be encountered during use of the dosimetry system.

NOTE 7—A calibration curve may be developed using a relationship expressed by response = f (dose).

5.4 *Characterization Informaition*:

5.4.1 Information on dosimeter and dosimetry system characterization carried out by the dosimeter manufacturer or supplier should be documented and made available to potential users.

5.4.2 The user is responsible for the evaluation of the effect of influence quantities or combinations of influence quantities, or both, on the dosimetry system performance over the full range of its intended use.

6. Effect of Influence Quantities

6.1 *Influence Quantities to be Considered*:

6.1.1 All influence quantities that might affect absorbed-dose determination should be considered. These influence quantities include those related to the dosimeter before, during, and after irradiation and those related to the dosimeter response measurements. Table 2 gives examples of some of these influence quantities.

6.1.2 The influence quantities shown with an asterisk (*) in Table 2 can be controlled by packaging the dosimeter material under specific conditions of relative humidity in light-tight gas-impermeable pouches. When the packaging is essential for the performance of the dosimeter, the packaging and the dosimeter are sometimes collectively referred to as the dosimeter.

6.1.3 If only one influence quantity is suspected to have an effect on dosimeter performance over the range of dose, the individual effect can be studied by varying its value (see 6.2–6.5).

6.1.4 Due to interactions between influence quantities, combined effects might differ from the summed individual effects. The combined effects of several influence quantities can be explored and estimated efficiently and effectively when the influence quantities are dealt with simultaneously (see 6.6). For example, use of design of experiments provides a systematic approach to experimentation that considers several influence quantities simultaneously (see 6.6.2).

TABLE 2 Examples of Influence Quantities

Category	Section, Influence Quantity	Conditions to be Considered
Pre-irradiation conditions	6.2.1 Dosimeter conditioning and packaging	Conditioning for optimum/stable response
	6.2.2 Time since manufacture	Gradual changes in dosimeter over prolonged time intervals
	6.2.3 Temperature	Long-term & short-term effects at extremes of temperature
	6.2.4 Relative humidity*	Long-term & short-term effects at extremes of humidity
	6.2.5 Exposure to light*	Long-term & short-term effects on dosimeters from light
Condiitons during irradiation	6.3.1 Irradiation temperature	Variation of response with temperature
	6.3.2 Absorbed-dose rate	Variation of response with absorbed-dose rate
	6.3.3 Dose fractionation	Effect on response when irradiation is interrupted
	6.3.4 Relative humidity*	Variation of response with relative humidity
	6.3.5 Exposure to light*	Effect of light on response
	6.3.6 Radiation energy	Variation of response with radiation energy
Post-irradiation conditions	6.4.1 Storage time	Variation of response with time between irradiation & measurement
	6.4.2 Storage temperature	Variation of response with temperature following irradiation
	6.4.3 Conditioning treatment	Deliberate exposure to a conditioning treatment to obtain stable response
	6.4.4 Storage relative humidity*	Variation of response with relative humidity
	6.4.5 Exposure to light*	Effect of light on response
Response measurement conditions	6.5.1 Light	Effect of light during measurement
	6.5.2 Temperature	Effect of temperature during measurement
	6.5.3 Relative humidity	Effect of relative humidity during measurement

* See 6.1.2.

6.2 *Influence Quantities Related to Pre-Irradiation Conditions*:

6.2.1 *Dosimeter Conditioning and Packaging*:

6.2.1.1 Response characteristics of some dosimeters can be optimized or stabilized by conditioning them prior to irradiation. Such conditioning involves storage under controlled conditions of temperature and humidity for specific periods of time. If conditioning is performed to achieve desired level of oxygen content or water content, the dosimeters should be packaged and sealed in gas-impermeable pouches to maintain those conditions. The packaging materials should be specified and the package evaluated for integrity.

6.2.2 *Time since Manufacture*:

6.2.2.1 To determine potential changes in the response for both unirradiated and irradiated dosimeters over the life of a dosimeter batch, dosimeter response testing should be conducted periodically, using dosimeters stored under expected extremes of storage conditions, to determine the extent of this effect.

6.2.3 *Temperature*:

6.2.3.1 The temperature experienced by dosimeters during pre-irradiation storage could affect their response following irradiation; therefore, the effect of long term storage at different temperatures should be determined.

6.2.3.2 The effect on the response of dosimeters exposed for short periods of time to potential extremes of temperatures should also be determined. Shipment during summer and winter represent opposing termperature extremes.

6.2.4 *Relative Humidity*:

6.2.4.1 Changes in relative humidity during storage or shipment of unirradiated non-packaged dosimeters might result in changes in oxygen or water content in the dosimeters that may affect dosimeter response. The response of dosimeters stored or shipped under extremes of relative humidity should be determined and this effect quantified. Packaging dosimeters in gas-impermeable pouches may be used to control and minimize the influence of relative humidity changes on dosimeter response. If pouches are used, the packaging materials should be specified and the packaging effectiveness verified.

6.2.5 *Exposure to Light*:

6.2.5.1 Exposure to light, especially the ultraviolet components from fluorescent lights or sunlight, might affect the dosimeter response. Dosimeters should be exposed to expected light conditions to determine the potential effect. If an effect is found, the dosimeters should be stored, handled, and measured under controlled conditions or supplied and stored in light-protected pouches to prevent such an effect.

6.3 *Influence Quantities Related to Irradiation*—For all the testing described in this section, the response of the irradiated dosimeters should be measured under the same measurement conditions as used for the initial calibration curve. The effect of the influence quantity should be determined for both the dosimeter response and the derived absorbed dose calculated using the initial calibration curve.

6.3.1 *Irradiation Temperature*:

6.3.1.1 The effect of irradiation temperature may be determined by irradiating sets of dosimeters at different temperatures. The testing should address the full intended dose range and anticipated temperature range for the dosimeter material and include more than the minimum and maximum temperatures at which the dosimeters might be used.

NOTE 8—Testing over a temperature-time profile, rather than at a fixed temperature, may provide information more appropriate for some radiation processing applications. For example, with electron beams, the temperature rise is near adiabatic with dose. If fixed temperatures are not used during the testing, it should be clearly stated whether the test temperatures are peak temperatures, mean temperatures, or effective temperatures based on the temperature-time profile.

6.3.2 *Absorbed-Dose Rate*:

6.3.2.1 The effect of absorbed-dose rate on the dosimeter response should be determined by irradiating sets of dosimeters at different absorbed-dose rates. The selected absorbed-dose rate range will depend on the intended type of facility and application.

NOTE 9—The dosimeter temperature may also change as the absorbed-dose rate is varied making it difficult to separate the contribution from the absorbed-dose rate and from the temperature. Measures taken to control or monitor the dosimeter temperature should be documented.

6.3.2.2 If the dosimeter is intended for use with photons and electrons, irradiation response testing of the dosimeter should be performed and evaluated using both photons and electrons.

NOTE 10—For gamma irradiations, both low, intermediate and high absorbed-dose rate conditions should be evaluated. For electron beams, the absorbed-dose rate depends on the type of electron beam. For a linear accelerator, the dose rate of interest could be either the average absorbed-dose rate or the instantaneous absorbed-dose rate in a pulse or both.

6.3.3 *Dose Fractionation*:

6.3.3.1 Absorbed dose may be delivered in two or more increments, due to either intentional or unintentional process interruption. The effects on the dosimeter response of this fractionation of the dose delivery should be investigated

NOTE 11—Dose fractionation testing may bring several influence quantities into play such as temperature effects and post irradiation fading or enhancement.

6.3.4 *Relative Humidity*:

6.3.4.1 The effect of relative humidity on the dosimeter response should be determined by irradiating dosimeters under different values of relative humidity.

NOTE 12—In general, the response of many dosimeter types is dependent on their water or oxygen content, or both, during irradiation, which might vary with the relative humidity. Changes in water or oxygen content might occur rapidly for thin films, requiring only a few minute, whereas changes for thick dosimeters might occur gradually, requiring hours or days. The water and oxygen content of the dosimeters can be controlled by storing them in an environmentally controlled chamber or over different saturated salt solutions for sufficiently long periods of time to establish equilibrium. The dosimeters should then be irradiated under these conditions (**1**).[5] A manufacturer may establish and implement specific manufacturing conditioning and packaging of the dosimeters to mitigate the effect of this influence quantity.

6.3.5 *Exposure to Light*:

6.3.5.1 The effect on dosimeter response from exposure to light during irradiation should be determined by irradiating some dosimeters in light-protective packages and some exposed to the light conditions expected during irradiation.

6.3.5.2 If a light-protective package is essential for consistent dosimeter performance, for example, for a film sensitive to ultraviolet light, then the packaging should be evaluated for light protection effectiveness.

6.3.6 *Radiation Energy*:

6.3.6.1 Possible effects of the radiation energy on the derived dose value should be taken into consideration.

6.4 *Influence Quantities Related to Post-Irradiation Conditions*—For all the testing described in this section, the response of the irradiated dosimeters should be measured under the same measurement conditions as used for the initial calibration curve. The effect of the influence quantity should be determined for both the dosimeter response and the derived absorbed dose calculated using the initial calibration curve.

6.4.1 *Storage Time*:

6.4.1.1 The post-irradiation stability can be determined by measuring the response of the same dosimeter(s) at different times over a period spanning the shortest and longest time expected between irradiation and measurement. If the process of measuring the dosimeter response alters its response or destroys the dosimeter, it is necessary to irradiate multiple dosimeter sets for each dose point sufficient to provide the data needed to determine the post-irradiation time stability of the dosimeter response.

NOTE 13—For liquid chemical dosimeters in sealed ampoules, the dosimeter material may be consumed in the measurement process. For dosimeters sealed in gas-impermeable pouches to control water or oxygen content, opening the pouch to take the measurement will alter the water or oxygen content of the dosimeter and thus may affect the subsequent dosimeter response measurements.

6.4.1.2 This testing should include the full range of absorbed dose expected to be encountered in routine use.

6.4.1.3 Preliminary measurements over a period of time may be useful for determining the time intervals to be used for the detailed measurements.

NOTE 14—For many dosimeters a rapid change in response can be observed immediately after irradiation followed by a gradual change over a period of time. In some dosimeters, the response can be stabilized by a heat treatment (see 6.4.3.1).

6.4.2 *Storage Temperature*:

6.4.2.1 The effect of the post-irradiation storage temperature on the dosimeter response may be determined by irradiating multiple sets of dosimeters to the same absorbed dose and storing them for specified time intervals at several different temperatures. The response for each set of dosimeters should be measured at the same time after irradiation.

6.4.3 *Conditioning Treatment*:

6.4.3.1 For some dosimeters, post-irradiation response can be stabilized by a conditioning treatment, for example, by exposing the irradiated dosimeters to a specified temperature for a specified time period. If heat treatment is to be utilized, the effects of different temperatures and time intervals after irradiation should be studied and appropriate requirements determined.

6.4.4 *Storage Relative Humidty*:

6.4.4.1 If dosimeters are not supplied in environment secure factory sealed pouches, the effect of the post-irradiation storage relative humidity on the dosimeter response should be determined by storing irradiated sets of dosimeters at different values of relative humidity. The humidity can be controlled by storing the irradiated dosimeters in an environmentally controlled volume or over saturated salt solutions in enclosed containers (1).

6.4.4.2 Dosimeters should be returned to the humidity-controlled storage immediately after measurement if the dosimeter response is to be measured after different storage times.

6.4.5 *Exposure to Light*:

6.4.5.1 The magnitude of the effect of the post-irradiation exposure time to light sources on the dosimeter response should be determined. This can be accomplished by storing sets of irradiated dosimeters at ambient light conditions, such as room fluorescent light and sunlight through a laboratory

[5] The boldface numers in parentheses refer to the list of references at the end of this standard.

window, in addition to storage in the dark and measuring the response of the sets of dosimeters over controlled time periods to establish the impact of light exposure on the dosimeter response.

6.4.5.2 If the effect of light is significant, the dosimeter may be stored and used in a light-protective pouch. Measurement of the dosimeter response should be performed under conditions of minimal light or the measurement area can be modified using light-protective materials to mitigate the influence of light on the dosimeter response during the measurement process.

6.5 *Influence Quantities Related to Measurement Instruments* :

6.5.1 *Light*:

6.5.1.1 For dosimeters that require light for the measurement method, for example, ultraviolet or visible light beams in spectrophotometers, the effect of light from the measurement instrument on the response measurement should be determined.

NOTE 15—The magnitude of this potential effect may depend on the length of time the dosimeter is in the measurement beam.

6.5.1.2 If an effect of light is found, the maximum time the dosimeter can be left in the measurement beam prior to obtaining the measurement value should be determined.

6.5.2 *Temperature*:

6.5.2.1 The temperature of the dosimeter at the time of measurement can influence the measured response. This effect on the response measurement should be determined and, if required, the temperature should be controlled or monitored, or both.

NOTE 16—Some analysis parameters, such as the extinction coefficient for the ferric ion concentration used in the Fricke dosimetry system (see Practice E 1026) and the electropotential generated in the electrochemical cell used in the ceric-cerous dosimetry system (see ISO/ASTM Practice 51205), have a known temperature effect.

6.5.3 *Relative humidity*:

6.5.3.1 The effect of relative humidity on the measured response should be determined. This might be an effect on the measurement instrument or the dosimeter during the measurement.

NOTE 17—The response of some measurement instruments, such as EPR spectrometers, might be affected by the room relative humidity or the water content of the dosimeter

6.6 *Combined Effects*—Although combined effects may be difficult to quantify, the possibility of combined effects differing from summed individual effects should be investigated. By understanding the main contributors to the combined effects, a carefully designed and executed in-plant calibration method can be used to account for the multiple influence quantities to be encountered in actual use. By calibrating under the conditions of use, the combined effects may be minimized or eliminated (see ISO/ASTM Guide 51261).

6.6.1 *Combining Effects of Individual Influence Quantities*:

6.6.1.1 When the effects of influence quantities are evaluated one at a time, information on the combined effects of more than one influence quantity are not easily obtained. Two or more influence quantities could interact and the combined effect for the influence quantities, for example, temperature and absorbed-dose rate, might be different than the sum of the individual effects.

6.6.1.2 Consideration should be given to designing experiments that allow evaluation of the effects of combined influence quantities with the ability to evaluate the contributions of individual influences.

6.6.2 *Design of Experiments*:

6.6.2.1 When studying combined effects, a systematic approach called design of experiments using carefully planned, statistically-designed experiments can provide information not easily obtainable from experiments for which influence quantities are changed one at a time, thereby saving time and effort to obtain the same information (see Appendix X1 and Appendix X2).

7. Documentation

7.1 7.1 The experimental design used for performance characterization and all results from the characterization should be documented and the records maintained while the dosimeter or dosimetry system is being used.

7.2 The documentation should include a description of all experiments used for the characterization, the assumptions made, the experimental apparatus and conditions used, the raw and processed data, and the data analyses.

7.3 Performance characterization results should be made available to potential users of the dosimeter or dosimetry system.

7.4 Performance characterization may be incorporated into a measurement management system.

8. Repeat of Performance Characterization

8.1 *Long-Term Effects after Manufacture of Dosimeters*:

8.1.1 Tests should be carried out to ensure that the performance characteristics found during the performance characterization are valid over the life of the dosimeters batch.

8.2 *New Batches of Dosimeters*:

8.2.1 An appropriate quality management system should be used to control changes to all aspects of the dosimeter manufacturing process to ensure that the dosimeter characteristics are maintained within specifications among different manufacturing batches.

8.2.1.1 Prior to the release of a new dosimeter batch, appropriate testing is recommended to verify the performance of the new batch.

8.2.1.2 The extent and frequency of batch performance testing can be based on previously determined batch-to-batch variations.

8.3 *User Continual Control*:

8.3.1 The user's measurement management system may include verification of continual control of performance characteristics for long-term use of dosimeters and for the introduction of new dosimeter batches.

9. Measurement Uncertainty

9.1 To be meaningful, measurements performed during performance characterization should be accompanied by an estimate of uncertainty.

9.2 Components of uncertainty should be identified as belonging to one of two groups:

9.2.1 Type A – those evaluated by statistical methods, or

9.2.2 Type B – those evaluated by other means.

9.3 Other ways of categorizing uncertainty have been widely used and might be useful for reporting uncertainty. For example, the terms *precision* and *bias* or *random* and *systematic* (non-random) are used to describe different categories of uncertainty.

NOTE 18—The identification of Type A and Type B uncertainties is based on methodology for estimating uncertainties published in 1995 by the International Organization for Standardization (ISO) in the Guide to the Expression of Uncertainty in Measurement (GUM). The purpose of using this type of characterization is to promote an understanding of how uncertainty statements are arrived at and to provide a basis for the international comparison of measurement results.

NOTE 19—ISO/ASTM Guide 51707 defines possible sources of uncertainty in dosimetry performed in radiation processing facilities, and offers procedures for estimating the magnitude of the resulting uncertainties in the measurement of absorbed dose using a dosimetry system. The guide defines and discusses basic concepts of measurement, including estimation of the measured value of a quantity, "true" value, error and uncertainty. Components of uncertainty are discussed and methods are provided for evaluating and estimating their values. Methods are also provided for calculating the combined standard uncertainty and estimating expanded (overall) uncertainty.

10. Keywords

10.1 absorbed dose; design of experiments; dosimeter; dosimetry system; electron beam; gamma radiation; influence quantity; ionizing radiation; irradiation; performance characterization; photons; radiation processing; X-radiation

APPENDIXES

(Nonmandatory Information)

X1. USE OF DESIGN OF EXPERIMENTS IN DOSIMETER CHARACTERIZATION

X1.1 Commonly used and easy to understand design of experiments are the fractional and full factorial designs for estimating the effects of multiple quantities simultaneously (2-6). Commercially available computer software may be used for designing the experiments and analyzing the data.

X1.2 The advantage of using an appropriate design of experiments over one-factor-at-a-time experiments comes from the use of the data from each experiment multiple times to estimate an effect. For example, a factorial design tests all possible combinations of the influence quantities (factors in statistical terminology). A 2^3 factorial design performs a test of each of 3 factors at 2 set values (levels), for example, irradiation temperature, absorbed-dose rate, and water content, as shown in Table X1.1.

X1.3 The 2^3 factorial design estimates the main effects (for example, the effect of temperature alone) by calculating the average difference between the four runs where the effect is high and the four runs where the effect is low. Two way interactions are estimated by calculating the average difference between the four runs where both effects are either high or low and the four runs where one effect is high and the other low. Thus, the estimates of all main and interaction effects are based on the difference between two sets of four replicates.

X1.4 A full factorial experiment provides an estimate of all interactions among factors. While it might seem desirable to characterize a dosimeter with one large factorial experiment, this is seldom practical or economically feasible. Often it is reasonable to assume that three-way and higher interactions are negligible. In this case, a fractional factorial experiment that uses a fraction of the full factorial experiments to estimate only the main and two-way effects is appropriate.

X1.5 Experiments might be done sequentially. Early experiments would be used to map out large main effects and interactions. These results would be used in subsequent experiments to refine estimates of minor interactions.

X1.6 The analysis of data obtained from an experiment is intimately connected with the experimental design. An additional consideration when performing the analysis is the designation of the factors (influence quantities) as having either fixed effects or random effects.

X1.6.1 A fixed effect factor is one where the experimenter chooses possible values of the factor. For example, if the two possible choices for the dosimeter packages are paper or polyester, then the effect of dosimeter packaging is a fixed effect because all possible choices are covered by the experiment.

TABLE X1.1 Example of 2^3 Factorial Design

Experiment	Irradiation Temperature	Absorbed-Dose Rate	Water Content
1	Low	Low	Low
2	High	Low	Low
3	Low	High	Low
4	High	High	Low
5	Low	Low	High
6	High	Low	High
7	Low	High	High
8	High	High	High

X1.6.2 A random effect factor is one where the experiment samples the population of possible values. For example, if the irradiation temperature of the dosimeter can span 20°C to 60°C, then the effect of temperature tested at 30°C and 50°C is a random effect because the effect of a 20 Celsius degree difference is assumed to be representative of all 20 Celsius degree differences in the range from 20°C to 60°C.

X2. EXAMPLE OF USE OF A FACTORIAL EXPERIMENT FOR PERFORMANCE CHARACTERIZATION OF A NEW DOSIMETER

X2.1 Consider a new dosimeter being developed for use in the absorbed-dose range from 5 to 50 kGy.

X2.2 Preliminary tests have determined that the manufacturing conditions provide dosimeters that give reproducible results after storage under ambient room conditions for two months after production. To determine if the water and oxygen content resulting from storage at low or high values of relative humidity might influence the response, some of the dosimeters were stored at low relative humidity (20 %) and some of the dosimeters were stored at high relative humidity (80 %).

X2.3 An initial calibration curve has been obtained for dosimeters stored under ambient room conditions and irradiated using ^{60}Co gamma rays under a set of irradiation conditions (absorbed-dose rate of 8 kGy/h, irradiation temperature of 25°C) with measurement of the absorbance at a wavelength of 450 nm.

X2.4 To determine if irradiation temperature, absorbed-dose rate, and relative humidity during storage are significant influence quantities with possible combined effects, a 2^3 factorial experiment, as described in Appendix X1, is planned. These experiments are performed at a low absorbed-dose level of 10 kGy and repeated at a high absorbed-dose level of 45 kGy to determine the effect of the absorbed-dose level on the effects.

X2.5 Table X2.1 shows the influence quantities to be used in the irradiation experiments.

X2.6 The example factorial design uses the results from 8 experimental runs. The three main effects: temperature, absorbed-dose rate, and relative humidity; are all measured with four experimental runs at a low level and four experimental runs at a high level. To duplicate this using a one factor at a time design would take 24 experimental runs. The 3 factor factorial design is one-third the cost of the one factor design.

X2.7 The results from the experimental runs are given in Table X2.2 and Table X2.3.

X2.8 An analysis of variance (ANOVA) of the data might be performed to test the significance of the main effects and the two-way interactions. Three-way interactions are assumed to be negligible; the three-way interaction term might then be used to provide an error term.

NOTE X2.1—The analysis of the data could be performed using multiple regression software and indicator variables. However, while this type of analysis would provide similar results, the use of regression analysis for an ANOVA problem is both less efficient and more complicated to set up correctly. Virtually all statistical software has the capability of performing both regression and analysis of variance calculations. Further discussion can be found in Ref (**3**).

X2.8.1 The results of the ANOVA are shown in Table X2.4 and Table X2.5.

X2.8.2 In Table X2.4 and Table X2.5, the meaning of the columns is as follows:

• *Sum Sqrs* is the sum of the squared differences between the factor values and the factor mean. The total of the Sum Sqrs column is the total sum of squared differences between individual responses and the overall mean response.

• *Degr. of Freedom* is the number of free parameters. For example, if you have two unknown numbers and their mean, knowing one of the numbers and the mean will determine the remaining number – one degree of freedom.

• *Mean Square* is the sum of squares divided by the degrees of freedom. It is the contribution to the overall variance under the null hypothesis of no factor effects.

• *F Stat* is the ratio of the mean square to the error term. Under the null hypothesis both the numerator and denominator are both estimates of random (error) variability and the ratio should be about one.

• *P* is the probability that the *F* ratio statistic differs from 1.0 by random chance alone. Values less than 0.05 (1 in 20 probability) are usually considered significant.

X2.8.3 Table X2.4 shows that at 10 kGy, the irradiation temperature, the absorbed-dose rate, and the relative humidity all have a significant effect on the dosimeter response. There are no interactions of temperature, absorbed-dose rate, and relative humidity.

X2.8.4 Table X2.5 shows that at 45 kGy, the irradiation temperature, the absorbed-dose rate, and the relative humidity all have a significant effect on the dosimeter response. At this absorbed-dose level, there is also an interaction between the absorbed-dose rate and the relative humidity.

X2.8.5 These results indicate that the performance of the dosimeter might be improved by conditioning the dosimeters to

TABLE X2.1 Influence Quantities to be Used in the Irradiation Experiments

Influence Quantity	Low Level	High Level
Irradiation temperature	15°C	45°C
Absorbed-dose rate	1 kGy/h	20 kGy/h
Relative humidity	20 %	80 %

TABLE X2.2 Irradiations to 10 kGy

Experiment	Irradiation Temperature (°C)	Absorbed Dose-Rate (kGy/h)	Relative Humidity (%)	Measured Response (A@450 nm)
1	15	1	20	1.080
2	45	1	20	1.140
3	15	20	20	1.137
4	45	20	20	1.200
5	15	1	80	0.960
6	45	1	80	1.020
7	15	20	80	1.017
8	45	20	80	1.077

TABLE X2.3 Irradiations to 45 kGy

Experiment	Irradiation Temperature (°C)	Absorbed Dose-Rate (kGy/h)	Relative Humidity (%)	Measured Response (A@450 nm)
1	15	1	20	2.920
2	45	1	20	2.983
3	15	20	20	2.699
4	45	20	20	2.753
5	15	1	80	2.581
6	45	1	80	2.638
7	15	20	80	2.913
8	45	20	80	2.976

TABLE X2.4 ANOVA of Experimental Effects for 10 kGy

		Significance of Influence Factor Effects			
Effect	Sum Sqrs	Degr. of Freedom	Mean Square	*F* Stat	*P*
Intercept	9.311770	1	9.311770	8277129	0.000221
Temperature	0.007381	1	0.007381	6561	0.007859
Dose-Rate	0.006670	1	0.006670	5929	0.008267
Relative Humidity	0.029161	1	0.029161	25921	0.003954
Temperature*Dose-Rate	1.12E-06	1	1.12E-06	1	0.500000
Temperature*Relative Humidity	1.13E-06	1	1.13E-06	1	0.500000
Dose-Rate*Relative Humidity	1.13E-06	1	1.13E-06	1	0.500000
Error	1.13E-06	1	1.13E-06		

TABLE X2.5 ANOVA of Experimental Effects for 45 kGy

		Significance of Influence Factor Effects			
Effect	Sum Sqrs	Degr. of Freedom	Mean Square	*F* Stat	*P*
Intercept	63.07245	1	63.07245	2288110	0.000421
Temperature	0.00703	1	0.00703	255	0.039812
Dose-Rate	0.00594	1	0.00594	216	0.043289
Relative Humidity	0.00765	1	0.00765	278	0.038159
Temperature*Dose-Rate	0.00000	1	0.00000	0	0.879288
Temperature*Relative Humidity	0.00000	1	0.00000	0	0.879288
Dose-Rate*Relative Humidity	0.15684	1	0.15684	5690	0.008439
Error	0.00003	1	0.00003		

obtain consistent water content and sealing them in gas-impermeable pouches to maintain this water content.

X2.8.6 The interaction between the absorbed-dose rate and the relative humidity would not have been observed with the one factor at a time design. Instead, different results for the absorbed-dose rate effect would have been obtained, depending on the selected constant relative humidity. Likewise, the relative humidity effect would have been different depending on the selected constant absorbed-dose rate. The interaction between factors could have led to contradictory and confusing results from a one factor at a time design.

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