An American National Standard

Standard Practice for Dosimetry in a Gamma Facility for Radiation Processing[1]

This standard is issued under the fixed designation ISO/ASTM 51702; 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 outlines the installation qualification program for an irradiator and the dosimetric procedures to be followed during operational qualification, performance qualification, and routine processing in facilities that process products with ionizing radiation from radionuclide gamma sources to ensure that product has been treated within a predetermined range of absorbed dose. Other procedures related to operational qualification, performance qualification, and routine processing that may influence absorbed dose in the product are also discussed.

NOTE 1—Dosimetry is only one component of a total quality assurance program for adherence to good manufacturing practices used in radiation processing applications.

NOTE 2—ISO/ASTM Practices 51818 and 51649 describe dosimetric procedures for low and high enery electron beam facilities for radiation processing and ISO/ASTM Practice 51608 describes procedures for X-ray (bremsstrahlung) facilities for radiation processing.

1.2 For the radiation sterilization of health care products, see ISO 11137-1. In those areas covered by ISO 11137-1, that standard takes precedence.

1.3 This document is one of a set of standards that provides recommendations for properly implementing and utilizing dosimetry in radiation processing. It is intended to be read in conjunction with ASTM Practice E2628.

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

2. Referenced documents

2.1 *ASTM Standards:*[2]

E170 Terminology Relating to Radiation Measurements and Dosimetry

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

E2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

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:*[2]

51261 Practice for Calibration of Routine Dosimetry Systems for Radiation Processing

51539 Guide for Use of Radiation-Sensitive Indicators

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

51649 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 KeV and 25 KeV

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

51818 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 keV

2.3 *International Commission on Radiation Units and Measurements (ICRU) Reports:*[3]

ICRU Report 85a Fundamental Quantities and Units for Ionizing Radiation

2.4 *ISO Standards:*[4]

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

2.5 *Joint Committee for Guides in Metrology (JCGM) Reports:*[5]

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

3. Terminology

3.1 *Definitions:*

3.1.1 *absorbed dose, D*—quantity of ionizing radiation energy imparted per unit mass of a specified material. The SI

[1] This practice is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.03 on Dosimetry Application, and is also under the jurisdiction of ISO/TC 85/WG 3.

Current edition approved Dec. 26, 2012. Published April 2013. Originally published as E 1702-95. Last previous ASTM edition E 1702–00. ASTM E 1702–95$^{\epsilon 1}$ was adopted by ISO in 1998 with the intermediate designation ISO 15571:1998(E). The present International Standard ISO/ASTM 51702:2013(E) replaces ISO 15571 and is a major revision of the last previous edition ISO/ASTM 51702–2004(E).

[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 International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland, http://www.iso.ch.

[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).

unit of absorbed dose is the gray (Gy), where 1 gray is equivalent to the absorption of 1 joule per kilogram of the specified material (1 Gy = 1 J/kg). The mathematical relationship is the quotient of $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass dm (see ICRU Report 85a).

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

3.1.2 *absorbed-dose mapping*—measurement of absorbed dose within an irradiation product to produce a one-, two- or three-dimensional distribution of absorbed dose, thus rendering a map of absorbed-dose values.

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

3.1.3.1 *Discussion*—In radiation processing standards, the term "dosimeter response" is generally used for "indication."

3.1.4 *compensating dummy*—See *simulated product*.

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

3.1.6 *dosimeter set*—one or more dosimeters used to measure the absorbed dose at a location and whose average reading is used as the absorbed-dose measurement at that location.

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

3.1.8 *installation qualification (IQ)*—process of obtaining and documenting evidence that equipment has been provided and installed in accordance with specifications.

3.1.9 *irradiation container*—holder in which product is placed during the irradiation process.

3.1.9.1 *Discussion*—"Irradiation container" is often referred to simply as "*container*" and can be a carrier, cart, tray, product carton, pallet, product package or other holder.

3.1.10 *operational qualification (OQ)*—process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.

3.1.11 *performance qualification (PQ)*—process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

3.1.12 *production run* (for continuous-flow and shuffle-dwell irradiations)—series of irradiation containers consisting of materials or products having similar radiation-absorption characteristics that are irradiated sequentially to a specified range of absorbed dose.

3.1.13 *simulated product*—mass of material with absorption and scattering properties similar to those of the product, material, or substance to be irradiated.

3.1.13.1 *Discussion*—Simulated product is used during irradiator characterization as a substitute for the actual product, material or substance to be irradiated. When used in routine production runs in order to compensate for the absence of product, simulated product is sometimes referred to as compensating dummy. When used for absorbed-dose mapping, simulated product is sometimes referred to as phantom material.

3.1.14 *timer setting*—defined time interval during which product is exposed to radiation.

3.1.14.1 *Discussion*—For a shuffle-dwell irradiator the timer setting is the time interval from the start of one shuffle-dwell cycle to the start of the next shuffle-dwell cycle. For a stationary irradiator, the timer setting is the total irradiation time.

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

4. Significance and use

4.1 Various products and materials routinely are irradiated at predetermined doses in gamma irradiation facilities to reduce their microbial population or to modify their characteristics. Dosimetry requirements may vary depending upon the irradiation application and end use of the product. Some examples of irradiation applications where dosimetry may be used are:

4.1.1 Sterilization of medical devices,

4.1.2 Treatment of food for the purpose of parasite and pathogen control, insect disinfestation, and shelf life extension,

4.1.3 Disinfection of consumer products,

4.1.4 Cross-linking or degradation of polymers and elastomers,

4.1.5 Polymerization of monomers and grafting of monomers onto polymers,

4.1.6 Enhancement of color in gemstones and other materials,

4.1.7 Modification of characteristics of semiconductor devices, and

4.1.8 Research on materials effects.

NOTE 3—Dosimetry is required for regulated irradiation processes such as sterilization of medical devices and the treatment of food. It may be less important for other industrial processes, for example, polymer modification, which can be evaluated by changes in the physical and chemical properties of the irradiated materials.

4.2 An irradiation process usually requires a minimum absorbed dose to achieve the intended effect. There also may be a maximum absorbed dose that the product can tolerate and still meet its functional or regulatory specifications. Dosimetry is essential to the irradiation process since it is used to determine both of these limits and to confirm that the product is routinely irradiated within these limits.

4.3 The absorbed-dose distribution within the product depends on the overall product dimensions and mass, irradiation geometry, and source activity distribution.

4.4 Before an irradiation facility can be used, it must be qualified to determine its effectiveness in reproducibly delivering known, controllable absorbed doses. This involves testing the process equipment, calibrating the equipment and

dosimetry system, and characterizing the magnitude, distribution and reproducibility of the absorbed dose delivered by the irradiator for a range of product densities.

4.5 To ensure consistent and reproducible dose delivery in a qualified process, routine process control requires documented product handling procedures before and after irradiation, consistent product loading configuration, control and monitoring of critical process parameters, routine product dosimetry and documentation of the required activities.

5. Radiation source characteristics

5.1 The radiation source used in a facility considered in this practice consists of sealed elements of ^{60}Co or ^{137}Cs which are typically linear rods or "pencils" arranged in one or more planar or cylindrical arrays.

5.2 A cobalt-60 source emits photons with energies of approximately 1.17 and 1.33 MeV in nearly equal proportions. A cesium-137 source emits photons with energies of approximately 0.662 MeV **(1)**.[6]

5.3 The radioactive decay half-lives for ^{60}Co and ^{137}Cs are regularly reviewed and updated. The most recent publication by the National Institute of Standards and Technology gave values of 1925.20 (± 0.25) days for ^{60}Co and 11018.3 (± 9.5) days for ^{137}Cs **(2)**.

5.4 Between source replenishments, removals, or redistributions, the variation in the source output is solely due to the steady reduction in the activity caused by the radioactive decay.

6. Types of facilities

6.1 The design of an irradiator affects the delivery of absorbed dose to a product. Therefore, the irradiator design should be considered when performing the absorbed-dose measurements described in Sections 9 through 11.

6.2 Products may be moved to locations where the irradiation will take place, either while the source is fully shielded (batch operation) or while the source is exposed (continuous operation).

6.3 Products may be transported past the source at a uniform and controlled speed (continuous conveyance), may undergo a series of shuffle-dwell cycles during which product movements are followed by periods of time during which the irradiation container is stationary (shuffle-dwell), or may be irradiated at fixed locations (stationary).

6.3.1 The desired absorbed dose for the product is obtained by controlling by the conveyor speed (continuous conveyance) or the timer setting (shuffle-dwell or stationary).

6.3.2 For many commercial irradiators, the irradiation containers move in one or more parallel rows on each side of a vertical rectangular source array. The irradiation containers may move past a source array in a configuration in which the source either extends above and below the irradiation container (source overlap) or the irradiation container extends above and below the source (product overlap). In the latter configuration, the irradiation container moves past the source at two or more levels.

6.3.2.1 In bulk-flow irradiators, products such as grain or flour flow in loose form past the source. The desired absorbed dose is obtained by controlling the flow rate.

6.4 Because of mechanical speed limitations, various techniques may be used to reduce the absorbed-dose rates for low absorbed-dose applications. These techniques include using only a portion of the source (for example, raising only one of several source racks to the irradiation position), using attenuators, and irradiating at greater distances from the source.

7. Dosimetry system calibration

7.1 The dosimetry system shall be calibrated in accordance with Practice 51261, and the user's procedures, which should specify details of the calibration process and quality assurance requirements.

7.2 The dosimetry system calibration is part of a measurement management system.

8. Installation qualification

8.1 *Objective*—The purpose of an installation qualification program is to demonstrate that the irradiator with its associated processing equipment and measurement instruments have been delivered and installed in accordance with their specifications. Installation qualification includes documentation of the irradiator and the associated processing equipment and measurement instruments, establishment of the testing, operation and calibration procedures for their use, and verification that they operate according to specifications. An effective installation qualification program will ensure consistent and correct operation of the irradiator so as to deliver the required absorbed dose to a product.

8.2 *Equipment Documentation*—Document descriptions of the irradiator and the associated processing equipment and measurement instruments installed at the facility. This documentation shall be retained for the life of the facility. At a minimum, it shall include:

8.2.1 Description of the location of the irradiator within the operator's premises in relation to the areas assigned and the means established for ensuring the segregation of un-irradiated products from irradiated products,

8.2.2 Description of the operating procedure of the irradiator,

8.2.3 Description of the construction and operation of the product handling equipment,

8.2.4 Description of the materials and construction of any containers used to hold products during irradiation,

8.2.5 Description of the process control system, and

8.2.6 Description of any modifications made during and after installation.

8.3 *Testing, Operation and Calibration Procedures*—Establish and implement standard operating procedures for the testing, operation and calibration (if necessary) of the installed irradiator and its associated processing equipment and measurement instruments.

[6] The boldface numbers in parentheses refer to the bibliography at the end of this practice.

8.3.1 *Testing Procedures*—These procedures describe the testing methods used to ensure that the installed irradiator and its associated processing equipment and measurement instruments operate according to specification.

8.3.2 *Operation Procedures*—These procedures describe how to operate the irradiator and its associated processing equipment and measurement instruments during routine operation.

8.3.3 *Calibration Procedures*—These procedures describe periodic calibration and verification methods that ensure that the installed processing equipment and measurement instruments continue to operate within specifications. The frequency of calibration for some equipment and instruments might be specified by a regulatory authority. Some equipment and instruments might be required to be traceable to a national or other accredited standards laboratory.

8.4 *Testing of Processing Equipment and Measurement Instruments*—Verify that the installed processing equipment and measurement instruments operate within their design specifications by following the testing procedures noted in 8.3.1. If necessary, ensure that the equipment and instruments have been calibrated according to the calibration procedures noted in 8.3.3.

8.4.1 Test all processing equipment to verify satisfactory operation of the irradiator within the design specifications. Document all testing results.

8.4.2 Test the performance of the measurement instruments to ensure that they are functioning according to performance specifications. Document all testing results.

8.4.3 If any modification or change is made to the processing equipment or measurement instruments during installation qualification, they shall be re-tested.

9. Operational qualification

9.1 *Objective*—The purpose of dosimetry in the operational qualification of a gamma irradiation facility is to establish baseline data for evaluating facility effectiveness, predictability, and reproducibility for the range of operating conditions of the irradiator expected to be used for irradiating product. The absorbed dose received by any portion of product in an irradiation container depends on the irradiator design, the source activity and geometry and the process parameters.

9.1.1 Examples of irradiator design characteristics that affect the absorbed dose are the radiation source characteristics, source-to-product distance, the irradiation geometry (for example, 1- or 2-sided irradiation, multiple passes), and the irradiator pathways.

9.1.2 Examples of a process parameter are the timer setting or conveyor speed.

9.2 *Absorbed-dose Mapping*—Perform operational qualification absorbed-dose mapping to characterize the irradiator with respect to the dose distribution and reproducibility of absorbed-dose delivery. Map the absorbed-dose distribution by a three-dimensional placement of dosimeter sets in an irradiation container containing homogeneous simulated product. For guidance on performing absorbed-dose mapping see ASTM Guide E2303.

9.2.1 The amount of homogeneous simulated product in each irradiation container should be the amount expected during typical production runs or should be the maximum design volume for the irradiation container.

9.2.2 Select placement patterns to identify the locations of the absorbed-dose maxima and minima (for example, see Fig. 1). Place more dosimeter sets in these locations and fewer dosimeter sets in locations likely to receive intermediate

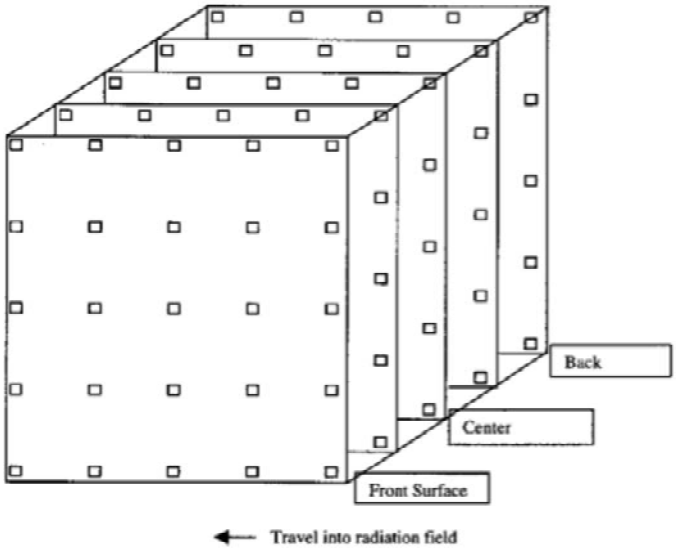

FIG. 1 An example of a dosimeter placement array in a three-dimensional grid pattern for an operational qualification dose mapping
In this drawing the small squares represent dosimeter positions. The "Front" is defined as the initial and in some cases only surface to directly face the radiation source during processing. The number of dosimeters and the number of planes (surfaces) to be mapped will depend on several factors, including but not limited to, the radiation type (electrons vs. photons), single- vs. double-sided irradiation, and resolution of absorbed dose required.

absorbed doses. Dosimetry data from previously qualified irradiators of the same design or calculations using mathematical models (see ASTM Guide E2232) may provide useful information for determining the number and location of dosimeters for this qualification process.

NOTE 4—Dosimeter strips or sheets may be used to increase spatial resolution of the absorbed-dose map, if the use of individual dosimeters is inadequate.

9.2.3 Map a sufficient number of irradiation containers to allow the estimation of the variability of the magnitude and distribution of the absorbed dose. Dosimetry data from previously qualified irradiators of the same design may provide useful information for determining the number of irradiation containers for this qualification.

9.2.4 The number of irradiation containers preceding and following the dose-mapped irradiation containers shall be sufficient to effectively simulate an irradiator filled with the product.

9.2.5 If the facility anticipates irradiating products spanning a range of densities, perform absorbed-dose mapping over the density range. This is necessary since differences in bulk density of the product in the irradiation container may result in changes in the magnitudes and locations of the minimum and maximum absorbed doses, which, in turn, could change the dose-uniformity ratio.

9.2.6 For some irradiator designs, when the irradiator is running near the maximum mechanical speed, the absorbed dose may not be directly related to the timer setting or conveyor speed. This effect should be considered and, if necessary, quantified.

9.2.7 Repeat the absorbed-dose mapping (9.2.1-9.2.6) for each different irradiator pathway to be used for routine product processing (Section 11).

9.2.8 The procedures for absorbed-dose mapping outlined in this section may not be feasible for some types of bulk-flow irradiators. In such cases, minimum and maximum absorbed doses should be estimated by using an appropriate number of dosimeters mixed randomly with and carried by product through the irradiation zone. A statistical model should be used to estimate the number of dosimeters required. Calculations of minimum and maximum absorbed doses may be an appropriate alternative **(3)**.

9.3 *Transit Effects*—Absorbed doses received during source or product movement should be considered.

9.3.1 To ensure that product near the source is processed within pre-established absorbed-dose limits, contributions to the absorbed dose to the product during movement of the source to and from the irradiation position should be considered and quantified. The absorbed dose received during movement of the source should be characterized and compared to the total absorbed dose. If the effects due to source movement are considered significant, adjustments should be made to the process to account for them.

9.3.2 For high throughput applications, the transit dose during the movement of the irradiation containers in a shuffle-dwell operation might be significant and should be considered (see 9.2.6).

9.4 *End Irradiation Containers*—The absorbed dose distributions and the magnitudes of the minimum and maximum absorbed dose in the first and last irradiation containers (the "end" irradiation containers) of a given production run may be affected by the irradiation containers of adjacent production runs. These effects will be due to any differences between the radiation-absorption characteristics of the product in the end irradiation containers of the given production run and those of the products in the adjacent production runs. Absorbed dose distribution studies should be conducted to evaluate this effect.

NOTE 5—To prevent an unacceptable absorbed-dose distribution resulting from these effects in routine processing, it may be necessary to introduce additional irradiation containers containing simulated product adjacent to the end irradiation containers.

9.5 *Partially Filled Irradiation Containers*—The absorbed dose distributions and the magnitudes of the minimum and maximum absorbed dose in partially filled irradiation containers in a given production run may be affected by or affect adjacent irradiation containers in the production run or in adjacent production runs. These effects will be due to any differences between the radiation-absorption characteristics and empty voids in the irradiation container of the given production run and those of the products in the adjacent production runs. Absorbed-dose distribution studies should be conducted to evaluate this effect.

NOTE 6—Changes to the absorbed-dose distribution arising from partially filled irradiation containers may be minimized by the use of simulated product placed at appropriate locations.

9.6 *Timer Setting or Conveyor Speed*—Dosimetry performed during operational qualification should also provide information for establishing the relationship between the absorbed dose for homogenous product of different densities and the required timer setting or conveyor speed, taking into account fluctuations in the process parameters during normal operation.

10. Performance qualification

10.1 *Objective*—Minimum and maximum absorbed-dose limits are almost always associated with irradiation applications. For a given application, one or both of these limits may be prescribed by government regulations. Dosimetry is used in performance qualification to determine the appropriate process parameters (including timer setting, conveyor speed, and product loading configuration) for ensuring that the absorbed-dose requirements for a particular product can be satisfied. This is accomplished by absorbed-dose mapping (see 10.3) of irradiation containers with specific product and product loading configurations. The purpose of the mapping is to determine the magnitudes and locations of the minimum and maximum absorbed doses and their relationships to the absorbed doses at locations used for monitoring during routine product processing.

10.2 *Product Loading Configuration*

10.2.1 A loading configuration of product within the irradiation container shall be established for each product. The documentation for this loading configuration shall include specifications for parameters that influence the absorbed-dose

distribution. Examples of such parameters include product size, product mass, product density/bulk density, and product orientation with respect to the radiation environment.

10.3 *Product Absorbed-Dose Mapping (see ASTM Guide* E2303*)*

10.3.1 *Minimum and Maximum Dose Locations*

10.3.1.1 Establish the locations of the regions of minimum and maximum absorbed dose for the selected product loading configuration. This is accomplished by placing dosimeter sets throughout the volume of interest for one or more irradiation containers. Select placement patterns to identify the locations of the absorbed-dose extremes, using data obtained from the absorbed-dose mapping studies during operational qualification (see 9.2) or from theoretical calculations (see ASTM Guide E2232). Concentrate dosimeter sets in the expected regions of minimum and maximum absorbed dose with fewer dosimeter sets placed in areas likely to receive intermediate absorbed dose. Dosimeter films in sheets or strips may also be employed to obtain additional useful information.

10.3.1.2 In an irradiation container containing voids or non-uniform product, include dosimeter sets at locations where discontinuities in composition or density may affect the regions of maximum or minimum absorbed dose.

10.3.2 *Variations in Absorbed Dose*

10.3.2.1 When dose mapping a specific product loading configuration, consideration should be given to possible variations in the absorbed doses measured in similar locations in different irradiation containers. These variations in absorbed dose can be determined by mapping the absorbed-dose distribution in several irradiation containers with the same product-loading configuration and irradiation conditions.

10.3.2.2 Place dosimeter sets in several irradiation containers at the expected regions of the minimum and maximum absorbed doses. The variations in the measured absorbed-dose values reflect the variations in, for example, the product loading configuration (due to shifts in the contents of the irradiation container during its movement through the irradiator), the bulk density of the product in the irradiation container, fluctuations in process parameter values, and the uncertainty in the dosimetry system calibration.

10.3.3 *Routine Monitoring Positions*—If the locations of absorbed-dose extremes identified during the absorbed-dose mapping procedure of 10.3.1 are not readily accessible during routine production runs, alternative positions may be used for absorbed-dose monitoring during routine product processing. The relationships between the absorbed doses at these alternative monitoring positions and the absorbed-dose extremes shall be established, be reproducible, and be documented.

10.3.4 *End Irradiation Containers*—The effect of end irradiation containers on the expected absorbed dose distribution in the product should be evaluated (see 9.4).

10.3.5 *Partially Filled Irradiation Containers*—The effect of partially filled irradiation containers on the expected absorbed dose distribution in the product should be evaluated (see 9.5).

10.3.6 *Unacceptable Dose-uniformity Ratio*

10.3.6.1 If the dose-mapping procedure of 10.3.1 reveals that the dose-uniformity ratio for the product is unacceptably large, that is, larger than the ratio between prescribed maximum and minimum absorbed-dose specifications, appropriate measures shall be taken to reduce the ratio to an acceptable value.

10.3.6.2 If changes are made to the product loading configuration, repeat the absorbed-dose mapping (see 10.3.1).

NOTE 7—It may be necessary to change the product loading configuration of the irradiation container if an acceptable dose uniformity ratio cannot be achieved by changing other parameters.

10.3.7 *Timer Setting or Conveyor Speed*

10.3.7.1 Use the results of the product absorbed-dose mapping measurements and known process variability to determine the timer setting or conveyor speed for the production runs.

10.3.7.2 Because of the statistical nature of the absorbed-dose measurement and the inherent variations in the radiation process (for example, see 10.3.2), use a timer setting or conveyor speed that will deliver an absorbed dose greater than any prescribed minimum dose and smaller than any prescribed maximum dose **(4)**.

10.3.8 *Irradiator Changes*—If changes that could affect the magnitudes or locations of the absorbed-dose extremes are made to the facility or mode of operation, repeat the absorbed-dose mapping to the extent necessary to establish the effects. The dosimetry data obtained during operational qualification (Section 9) should serve as a guide in determining the extent of these absorbed-dose-mapping studies.

10.3.9 *Processing at High or Low Temperatures*

10.3.9.1 For applications where product is irradiated at a temperature significantly different from the dosimeter calibration temperature, absorbed-dose mapping may be performed with simulated product at a temperature where dosimetry results will not be significantly affected. This requires that there be no change in any parameter (other than temperature) that may affect the absorbed dose during processing of the heated or cooled product. Mapping of the simulated product includes placement of one or more dosimeters at a routine monitoring position known to be isolated from temperature gradients in the actual product. During routine processing of product (at higher or lower temperatures) dosimeters are only placed at this routine monitoring position.

10.3.9.2 Absorbed-dose mapping with a product may be performed at the temperature to which the product will be heated or cooled during actual product processing, using a dosimetry system that can be characterized at the intended processing temperature. The temperature of the product during irradiation must be maintained relatively constant (for example, by using insulated product containers).

10.3.9.3 The temperature dependence of the dosimeter response may affect the absorbed-dose measurement. For such cases, the error introduced when correcting for the temperature dependence may be significant. To avoid introducing error, routine dosimetry systems should be calibrated at the temperature at which the product will be irradiated.

10.3.10 *Bulk-Flow Irradiators*—Absorbed-dose mapping as described in 10.3.1 may not be feasible for products flowing

through the irradiation zone. In this case, minimum and maximum absorbed doses should be estimated by using an appropriate number of dosimeters mixed randomly with and carried by the product through the irradiation zone **(3)**. Enough dosimeters should be used to obtain statistically significant results. Calculation of the maximum and minimum absorbed doses may be an appropriate alternative **(3)**.

11. Routine product processing

11.1 *Process Control*—Demonstrating that an irradiation process is under control requires attention to all process parameters that can affect absorbed dose (11.2) and to the use of routine production dosimetry (11.3). Additionally, the application of radiation-sensitive indicators to product(s) may be of assistance in inventory control (see 11.4).

11.2 *Process Parameters*

11.2.1 *General*—For routine product processing, set the critical process parameters (for example, timer setting, conveyor speed, product loading configuration) as established during performance qualification, taking into account source decay. Control, monitor, and document their values to ensure that the product in each irradiation container is processed within specifications. If the process parameters deviate outside prescribed processing limits, take appropriate actions.

11.3 *Routine Production Dosimetry*

11.3.1 Routine dosimetry is part of a verification process for establishing that the irradiation process is under control.

11.3.2 Ensure that the product receives the required absorbed dose by employing proper dosimetry procedures, with appropriate statistical controls and documentation, as described below.

11.3.2.1 *Dosimeter Location*—Place dosimeter sets in or on the irradiation containers at predetermined locations of the maximum and/or minimum absorbed dose (see 10.3.1) or, alternatively, at the routine monitoring positions (see 10.3.3).

11.3.2.2 *Placement Frequency*—Select a sufficient number of irradiation containers, on which to place dosimeter sets at the locations described in 10.3.3, in order to verify that the absorbed doses for the entire production run fall within specified limits. For each production run, place dosimeter sets in or on the first and last irradiation containers and in selected intermediate irradiation containers to ensure that at least one irradiation container containing a dosimeter set is being irradiated at all times. Available dosimetry data may be useful in determining the necessity of placing dosimeter sets in intermediate irradiation containers. For operation in a batch mode, place dosimeter sets on at least one irradiation container for each product.

NOTE 8—The absorbed-dose distribution in the irradiation container is already known from the dose-mapping effort described in Section 10. However, the use of a sufficient number of strategically placed dosimeter sets serves to confirm that the absorbed doses have been achieved within the specified range. More frequent placement of dosimeter sets during the production run could result in less product rejection, in case of operational uncertainty or failure.

11.3.2.3 *Environmental Effects*—A change in the environment (for example, temperature, humidity) of a dosimeter during the irradiation process may affect the dosimeter response. If required, apply a correction factor to the dosimeter response to account for any such effect. Care must also be taken in handling and storage of dosimeters before and after irradiation (see ISO/ASTM 51261 and Practices for individual dosimetry systems listed in ASTM Practice E2628).

11.3.2.4 *Processing at High or Low Temperatures*—If the response of dosimeters used for routine process control is temperature dependent, exercise care when determining the temperature of the dosimeter during irradiation of heated or cooled products and when applying the appropriate temperature correction (see 10.3.9). Dosimeters that exhibit a highly temperature-dependent response should not be placed in locations with large temperature gradients (see Practices for individual dosimetry systems listed in ASTM Practice E2628).

11.3.2.5 *Bulk-Flow Irradiators*—For some types of bulk-flow irradiators (for example, those treating fluids or grains), it might not be feasible during routine product processing to place dosimeters at the locations of minimum and maximum absorbed dose. In such cases, add several dosimeters to the product stream at the beginning, the middle, and near the end of the production run. Each set of absorbed-dose measurements requires several dosimeters to ensure that, at a specified level of confidence, the minimum and maximum absorbed doses are known. This procedure requires that the dosimeters flow in the same path through the irradiation zone and at the same rate as the product. See, for example, Ref **(3)**.

11.4 *Radiation-Sensitive Indicators (see ISO/ASTM Guide 51539)*—In some applications, radiation-sensitive indicators (sometimes known as "go/no go" indicators) may be used to show that product has been exposed to a radiation source. However, these indicators provide only a qualitative indication of radiation exposure. In addition, the color change of radiation-sensitive indicators is not always stable and may be affected by, for example, light or heat. Thus, their use is neither a substitute for nor a complement to the dosimetry procedures described in 11.3. Also, while radiation-sensitive indicators can conveniently be used to assist in production inventory control, they shall not be used to replace other administrative inventory control procedures.

12. Certification

12.1 *Documentation*

12.1.1 *Equipment Documentation*—Record or reference the calibration and maintenance of equipment and instrumentation used to control or measure the absorbed doses delivered to the product (see ISO/ASTM Guide 51261).

12.1.2 *Process Parameters*—Record the process parameter values (see 11.2) affecting absorbed dose together with sufficient information identifying these parameters with specific product lots or production runs.

12.1.3 *Dosimetry*—Record and document all dosimetry data for operational qualification (see Section 9), performance qualification (see Section 10), and routine product processing (see Section 11). Include date, time, product type, product loading diagrams, and absorbed doses for all product processed. Record the time of dosimeter analysis if the post-irradiation stability of the dosimeters under the conditions of

use requires time-dependent corrections of the dosimetry system calibration curve.

12.1.4 *Dosimetry Uncertainty*—Include estimates of the measurement uncertainty of absorbed dose (see Section 13) in records and reports, as appropriate.

12.1.5 *Facility Log*—Record the date the product is processed and the starting and ending times of the irradiation. Record the name of the operator, as well as any special conditions of the irradiator or the facility that could affect the absorbed dose to the product.

12.1.6 *Product Identification*—Ensure that each product lot that is processed bears an identification that distinguishes it from all other lots in the facility. This identification shall be used on all documents related to that product lot.

12.2 *Review and Certification*

12.2.1 Prior to release of irradiated product, review dosimetry results and recorded values of the process parameters to verify compliance with specifications.

12.2.2 Approve and certify the absorbed dose to the product for each production run, in accordance with an established facility quality assurance program. Certification shall be performed by authorized personnel, as documented in the quality assurance program.

12.2.3 Audit all documentation at time intervals specified in the quality assurance program to ensure that records are accurate and complete. If deficiencies are found, ensure that corrective actions are taken.

12.3 *Retention of Records*—File all information pertaining to each production run (for example, copies of the shipping document, certificates of irradiation, and the irradiation control record (see 12.1.1-12.1.6)). Retain the files for the period of time specified in the quality assurance program. Keep the files available for inspection as required by the relevant government authorities.

13. Measurement uncertainty

13.1 All dose measurements need to be accompanied by an estimate of uncertainty. Appropriate procedures are recommended in ISO/ASTM Guide 51707 and Practice 51261 (see also GUM).

13.1.1 All components of uncertainty should be included in the estimate, including those arising from calibration, dosimeter variability, instrument reproducibility, and the effect of influence quantities. A full quantitative analysis of components of uncertainty is referred to as an uncertainty budget, and is then 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.

14. Keywords

14.1 absorbed dose; cesium-137; cobalt-60; dose mapping; dosimeter; dosimetry; food irradiation; food processing; gamma; installation qualification; ionizing radiation; irradiated food; irradiation; operational qualification; performance qualification; radiation; radiation processing; ICS 17.240; ICS 67.020

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