ISO/ASTM 51204:2004(E)

Standard Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing[1]

This standard is issued under the fixed designation ISO/ASTM 51204; 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 food 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. Information about effective or regulatory dose limits for food products is not within the scope of this practice (see ASTM Guides F 1355, F 1356, F 1736, and F 1885).

NOTE 1—Dosimetry is only one component of a total quality assurance program for adherence to good manufacturing practices used in the production of safe and wholesome food.

NOTE 2—ISO/ASTM Practice 51431 describes dosimetric procedures for electron beam and X-ray (bremsstrahlung) irradiation facilities for food processing.

1.2 For guidance in the selection and calibration of dosimetry systems, and interpretation of measured absorbed dose in the product, see ISO/ASTM Guide 51261 and ASTM Practice E 666. For the use of specific dosimetry systems, see ASTM Practices E 1026 and E 2304, and ISO/ASTM Practices 51205, 51275, 51276, 51310, 51401, 51538, 51540, 51607, 51650, and 51956. For discussion of radiation dosimetry for gamma-rays and X-rays also see ICRU Report 14.

1.3 *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]

E 170 Terminology Relating to Radiation Measurements and Dosimetry

E 666 Practice for Calculating Absorbed Dose from Gamma or X Radiation

E 1026 Practice for Using the Fricke Reference Standard Dosimetry System

E 2232 Guide for Selection and Use of Mathematical Models for Calculating Absorbed Dose in Radiation-Processing Applications

E 2304 Practice for Use of a LiF Photo-Fluorescent Film Dosimetry System

F 1355 Guide for the Irradiation of Fresh Fruits as a Phytosanitary Treatment

F 1356 Guide for the Irradiation of Fresh and Frozen Red Meats and Poultry to Control Pathogens and Other Microorganisms

F 1736 Guide for the Irradiation of Finfish and Shellfish to Control Pathogens and Spoilage Microorganisms

F 1885 Guide for Irradiation of Dried Spices, Herbs, and Vegetable Seasonings to Control Pathogens and Other Microorganisms

2.2 *ISO/ASTM Standards:*[2]

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

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

51275 Practice for Use of a Radiochromic Film Dosimetry System

51276 Practice for Use of a Polymethylmethacrylate Dosimetry System

51310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System

51400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory

51401 Practice for Use of a Dichromate Dosimetry System

51431 Practice for Dosimetry in Electron Beam and X-ray bremsstrahlung Irradiation Facilities for Food Processing

51538 Practice for Use of an Ethanol-Chlorobenzene Dosimetry System

[1] This practice is under the jurisdiction of ASTM Committee E10 on Nuclear Technology and Applications and is the direct responsibility of Subcommittee E10.01 on Dosimetry for Radiation Processing and is also under the jurisdiction of ISO/TC 85/WG 3.

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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.

51539 Guide for the Use of Radiation-Sensitive Indicators
51540 Practice for the Use of a Radiochromic Liquid Dosimetry System
51607 Practice for the Use of the Alanine-EPR Dosimetry System
51650 Practice for the Use of a Cellulose Acetate Dosimetry System
51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing
51956 Practice for Use of Thermoluminescence-Dosimetry (TLD) Systems for Radiation Processing

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

ICRU Report 14 Radiation Dosimetry: X-Rays and Gamma Rays with Maximum Photon Energies Between 0.6 and 50 MeV
ICRU Report 60 Fundamental Quantities and Units for Ionizing Radiation

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 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 $d\bar{\epsilon}$ by d*m*, where $d\bar{\epsilon}$ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass d*m* (see ICRU Report 60).

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

3.1.2 *absorbed-dose mapping*—measurement of absorbed dose within a process load using dosimeters placed at specified locations to produce a one-, two- or three-dimensional distribution of absorbed dose, thus rendering a map of absorbed-dose values.

3.1.3 *calibration facility*—combination of an ionizing radiation source and its associated instrumentation that provides, at a specified location and within a specific material, a uniform and reproducible absorbed dose, or absorbed-dose rate, traceable to national or international standards and that may be used to derive the dosimetry system's response function or calibration curve.

3.1.4 *compensating dummy*—simulated product used during routine production runs in process loads that contain less product than specified in the product loading configuration, or simulated product used at the beginning or end of a production run, to compensate for the absence of product. Also see 3.1.18.

3.1.4.1 *Discussion*—Simulated product or phantom material may be used during operational qualification as a substitute for the actual product, material, or substance to be irradiated.

3.1.5 *dosimeter response*—reproducible, quantifiable radiation effect produced in the dosimeter by a given absorbed dose.

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

3.1.8 *installation qualification*—obtaining and documenting evidence that the irradiator, with all its associated equipment and instrumentation, has been provided and installed in accordance with specifications.

3.1.9 *irradiation time*—total time during which a process load is exposed to radiation.

3.1.10 *operational qualification*—obtaining and documenting evidence that installed equipment and instrumentation operate within predetermined limits when used in accordance with operational procedures.

3.1.11 *performance qualification*—obtaining and documenting evidence that the equipment and instrumentation, as installed and operated in accordance with operational procedures, consistently perform according to predetermined criteria and thereby yield product that meets specifications.

3.1.12 *primary–standard dosimeter*—dosimeter of the highest metrological quality, established and maintained as an absorbed-dose standard by a national or international standards organization (see ISO/ASTM Guide 51261).

3.1.13 *process load*—volume of material with a specified loading configuration irradiated as a single entity.

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

3.1.15 *reference-standard dosimeter*—dosimeter of high metrological quality, used as a standard to provide measurements traceable to and consistent with measurements made using primary-standard dosimeters (see ISO/ASTM Guide 51261).

3.1.16 *response function*—mathematical representation of the relationship between dosimeter response and absorbed dose for a given dosimetry system.

3.1.17 *routine dosimeter*—dosimeter calibrated against a primary-, reference-, or transfer-standard dosimeter and used for routine absorbed-dose measurements (see ISO/ASTM Guide 51261).

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

3.1.18.1 *Discussion*—Simulated product is used during operational qualification as a substitution for the actual product, material, or substance to be irradiated. When used in routine production runs, it is sometimes referred to as "compensating dummy." When used for absorbed-dose mapping, simulated product is sometimes referred to as "phantom material."

3.1.19 *transfer-standard dosimeter*—dosimeter, often a reference-standard dosimeter, suitable for transport between

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

different locations, used to compare absorbed-dose measurements (see ISO/ASTM Guide 51261).

3.2 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E 170. Definitions in E 170 are compatible with ICRU 60; ICRU 60, therefore, may be used as an alternative reference.

4. Significance and use

4.1 Food products may be treated with ionizing radiation, such as gamma-rays from ^{60}Co or ^{137}Cs sources, for numerous purposes, including control of parasites and pathogenic microorganisms, insect disinfestation, growth and maturation inhibition, and shelf-life extension. Food irradiation specifications almost always include a minimum or maximum limit of absorbed dose, sometimes both: a minimum limit is set to ensure that the intended beneficial effect is achieved and a maximum limit is set for the purpose of avoiding product or packaging degradation. For a given application, one or both of these values may be prescribed by government regulations that have been established on the basis of scientific data. Therefore, prior to the irradiation of the food product, it is necessary to determine the capability of an irradiation facility to deliver the absorbed dose within any prescribed limits. Also, it is necessary to monitor and document the absorbed dose during each production run to verify compliance with the process specifications at a predetermined level of confidence.

NOTE 3—The Codex Alimentarius Commission has developed an international General Standard and a Code of Practice that address the application of ionizing radiation to the treatment of foods and that strongly emphasize the role of dosimetry for ensuring that irradiation will be properly performed **(1)**.[4]

4.2 Some food products are processed in the chilled or frozen state. Therefore, dosimeters used for routine processing should be selected for their functionality under those conditions. Moreover, the temperature of a dosimeter during irradiation should be sufficiently stable to allow correction for temperature effects on the dosimeter response. To avoid the influence of temperature gradients on dosimeter response and the subsequent need to correct for these effects, methods that isolate the dosimeter from temperature gradients may be employed.

NOTE 4—For more detailed discussions of radiation processing of various foods, see ASTM Guides F 1355, F 1356, F 1736, and F 1885 and Refs **(1-11)**.

4.3 To ensure that products are irradiated within a specified absorbed-dose range, routine process control requires routine product dosimetry, documented product handling procedures (before, during, and after irradiation), consistent orientation of the products during irradiation, monitoring of critical process parameters, and documentation of all relevant activities and functions.

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 **(12)**.

5.3 The half-lives for ^{60}Co and ^{137}Cs are approximately 5.2708 years and 30.07 years, respectively **(13, 14)**.

5.4 Between source replenishments, removals, or redistributions, the sole variation in the source output is 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 8-11.

6.2 Food processing facilities may be categorized by operating mode (for example, batch or continuous), conveyor system (for example, continuous or shuffle-dwell), and irradiator type (for example, container or bulk flow).

6.2.1 Food products may be moved to the location in the facility where the irradiation will take place, either while the source is fully shielded (batch operation) or while the source is exposed (continuous operation).

6.2.2 Food products may be transported past the source at a uniform and controlled speed (continuous conveyance), or may instead undergo a series of discrete controlled movements separated by controlled time periods during which the process load is stationary (shuffle-dwell).

6.2.3 For most commercial irradiators, the process load generally makes one or more passes on each side of the source array.

6.2.3.1 Process loads may move past a source array in a configuration in which the source either extends above and below the process load (source overlap) or the process load extends above and below the source (product overlap). In the latter configuration, the process load is usually moved past the source at two or more levels.

6.2.3.2 In bulk-flow irradiators, products such as grain or flour flow in loose form past the source.

6.3 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 systems

7.1 *Description of Dosimeter Classes*—Dosimeters may be divided into four basic classes according to their relative quality and areas of application: primary-standard, reference-standard, transfer-standard, and routine dosimeters. ISO/ASTM Guide 51261 provides information about the selection

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

of dosimetry systems for different applications. All classes of dosimeters, except the primary standards, require calibration before their use.

7.1.1 *Primary-Standard Dosimeters*—Primary-standard dosimeters are established and maintained by national standards laboratories for calibration of radiation environments (fields) and other classes of dosimeters. The two most commonly used primary-standard dosimeters are ionization chambers and calorimeters.

7.1.2 *Reference-Standard Dosimeters*—Reference-standard dosimeters are used to calibrate radiation environments and routine dosimeters. Reference-standard dosimeters may also be used as routine dosimeters. Examples of reference-standard dosimeters, along with their useful absorbed-dose ranges, are given in ISO/ASTM Guide 51261.

7.1.3 *Transfer-Standard Dosimeters*—Transfer-standard dosimeters are specially selected dosimeters used for transferring absorbed-dose information from an accredited or national standards laboratory to an irradiation facility in order to establish traceability for that facility. These dosimeters should be carefully used under conditions that are specified by the issuing laboratory. Transfer-standard dosimeters may be selected from either reference-standard dosimeters or routine dosimeters, taking into consideration the criteria listed in ISO/ASTM Guide 51261.

7.1.4 *Routine Dosimeters*—Routine dosimeters may be used for radiation process quality control, absorbed-dose monitoring, and absorbed-dose mapping. Proper dosimetric techniques, including calibration, shall be employed to ensure that measurements are reliable and accurate. Examples of routine dosimeters, along with their useful absorbed-dose ranges, are given in ISO/ASTM Guide 51261.

7.2 *Selection of Dosimetry Systems*—Select dosimetry systems suitable for the expected radiation processing applications at the facility using the selection criteria listed in ISO/ASTM Guide 51261. During the selection process, for each dosimetry system, take into consideration its performance behavior with respect to relevant influence quantities and the uncertainty associated with it.

7.3 *Calibration of Dosimetry Systems*—Prior to use, a dosimetry system shall be calibrated in accordance with the user's documented procedure that specifies details of the calibration process and quality assurance requirements. This calibration process shall be repeated at regular intervals to ensure that the accuracy of the absorbed-dose measurement is maintained within required limits. Calibration methods are described in ISO/ASTM Guide 51261. Irradiation is a critical component of the calibration of a dosimetry system.

7.3.1 *Calibration Irradiation of Reference- or Transfer-Standard Dosimeters*—Calibration irradiations shall be performed at an accredited calibration laboratory or in-house calibration facility meeting the requirements of ISO/ASTM Practice 51400. The laboratory or facility shall provide an absorbed dose (or absorbed-dose rate) having measurement traceability to nationally or internationally recognized standards.

7.3.2 *Calibration Irradiation of Routine Dosimeters*—Calibration irradiations may be performed per 7.3.1 or at a production or research irradiation facility together with reference- or transfer-standard dosimeters that have measurement traceability to nationally or internationally recognized standards. This statement also applies when reference-standard dosimeters are used as routine dosimeters.

7.3.3 *Measurement Instrument Calibration and Performance Verification*—Establish and implement procedures for calibrating the measurement instruments and for checking their performance periodically to ensure that the instruments are functioning according to performance specifications.

7.3.3.1 Document a calibration program to ensure that all measurement instruments used in the analysis of dosimeters are calibrated periodically. The calibrations shall be traceable to a national or international standards laboratory.

7.3.3.2 A performance check shall be made following any modification or servicing of the instruments and prior to their use for a dosimetry system calibration. This check can be accomplished by using standards, such as calibrated optical density filters, wavelength standards, and thickness gauges, supplied by the equipment manufacturer or by national or accredited standards laboratories.

7.3.3.3 See ISO/ASTM Guide 51261, the corresponding ISO/ASTM or ASTM standard for the dosimetry system, and instrument-specific operating manuals for instrument calibration and performance verification procedures.

8. Installation qualification

8.1 *Objective*—The purpose of an installation qualification program is to demonstrate that the irradiator and 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 food products during irradiation;

8.2.5 Description of the process control system;

8.2.6 Description of any modifications made during and after the irradiator 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.

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 conditions of operation for each set of irradiator parameters and process parameters expected to be used for irradiating product. The absorbed dose received by any portion of product in a process load depends on both the irradiator parameters and the process parameters.

9.1.1 Examples of irradiator parameters are the activity of the source of radiation, the source geometry, the source-to-product distance, the irradiation geometry (for example, 1- or 2-sided irradiation, multiple passes), and the process paths.

9.1.2 Examples of process parameters are the length of time product is irradiated, the conveyor speed, the product composition and density, and the product loading configuration.

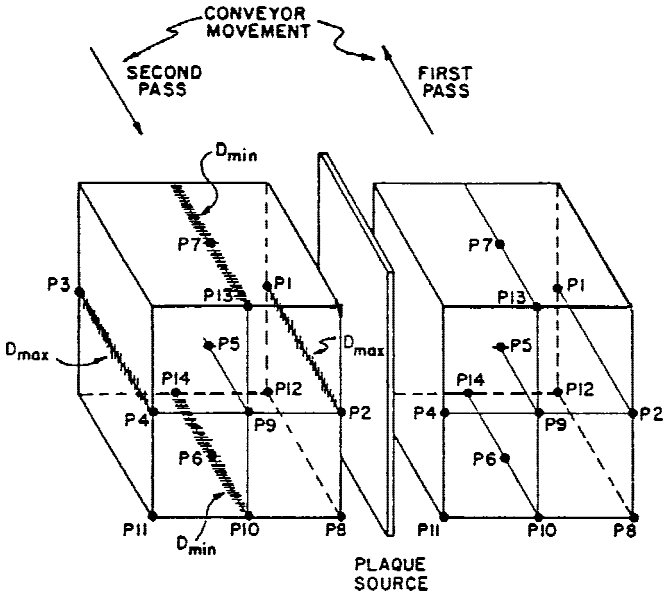
9.2 *Absorbed-dose Mapping*—Perform dosimetry *(1)* to establish relationships between the absorbed dose for homogeneous process loads and the irradiator and process parameters; *(2)* to characterize absorbed-dose variations when process parameters fluctuate statistically during normal operations; and *(3)* to measure absorbed-dose distributions in homogeneous materials, that is, with materials of uniform bulk density, such as grains (for example, wheat) or cardboard.

9.2.1 Map the absorbed-dose distribution by a three-dimensional placement of dosimeter sets in a process load containing homogeneous material **(15, 16)**. The amount of homogeneous material in this process load should be the amount expected during typical production runs or should be the maximum design volume for the process load.

9.2.1.1 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 absorbed doses. Dosimetry data from previously qualified irradiators of the same design or calculations using mathematical models (see ASTM Guide E 2232) may provide useful information for determining the number and location of dosimeters for this qualification process.

NOTE 5—Dosimeter strips or sheets may be used to increase spatial resolution of the absorbed-dose map, if the use of individual dosimeters is inadequate.

9.2.2 Map a sufficient number of process loads 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 process loads for this qualification.



NOTE—Two passes of a rectangular process load, one on each side of a stationary gamma-ray plaque source. Hatching indicates the probable regions of maximum and minimum absorbed dose after the second pass. The Ps indicate examples of locations for dosimeters that could be used for absorbed-dose mapping during operational qualification.

FIG. 1 An example of the maximum and minimum absorbed-dose locations in a typical process load (17)

9.2.3 The number of process loads preceding and following the dose-mapped process loads shall be sufficient to effectively simulate an irradiator filled with homogeneous product.

9.2.4 If the facility anticipates irradiating process loads spanning a range of densities, perform absorbed-dose mapping over the density range. This is necessary since differences in bulk density of the process load 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.

9.2.4.1 When products of different densities are in the irradiator at the same time, the absorbed-dose distribution in any one product may be influenced by the different attenuation and scattering properties of the other products. The magnitude of these effects can be estimated by absorbed-dose mapping of the first and last process loads of two sequential production runs for homogeneous products of different densities (see 11.2.2 and 11.2.3). The absorbed-dose map of the first process load entering an empty irradiator will provide information on the maximum absorbed dose expected when the irradiator is partially filled.

9.2.5 The absorbed-dose rate and absorbed-dose distribution in the product may vary for different timer settings as the process load traverses its path through the irradiation field. For some situations, for example, operating the irradiator at the maximum mechanical speed, a direct scaling from one absorbed dose to another by changing the timer setting may not be valid. This effect should be considered and quantified.

9.2.6 To ensure that product near the source is processed within pre-established absorbed-dose limits, contributions to the absorbed dose in the product during movement of the source to and from the irradiation position should be considered and quantified.

9.2.7 Repeat the dosimetry and absorbed-dose mapping (9.2.1-9.2.6) for each different irradiator parameter (see 9.1.1) 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. Enough dosimeters should be used to obtain statistically significant results. Calculations of minimum and maximum absorbed doses may be an appropriate alternative **(4, 7)**.

10. Performance qualification

10.1 *Objective*—Minimum and maximum absorbed-dose limits are almost always associated with food-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 process loads 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 process load shall be established for each product type. The documentation for this loading configuration shall include specifications for parameters that determine the process load homogeneity and thus influence the absorbed-dose distribution. Examples of such parameters include product size, product mass, product density, and product orientation with respect to the radiation environment.

10.3 *Product Absorbed-Dose Mapping*:

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 process loads. 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 E 2232). 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 useful information. The dosimeters used for the mapping procedure and for routine dose monitoring need not be of the same type.

10.3.1.2 In a process load 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 process loads. The variations in absorbed dose can be determined by mapping the absorbed-dose distribution in several process loads with the same product loading configuration and irradiation conditions.

10.3.2.2 To determine the variations in absorbed dose, place dosimeter sets in several process loads 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 process load during its movement through the irradiator), the bulk density of the process load, fluctuations in process parameter values, and the uncertainty in the dosimetry system.

10.3.3 *Transit Effects*—Determine whether the absorbed dose received during movement of the source or process loads is small compared to the total absorbed dose. If this requirement is met, the absorbed dose will be directly related to the timer setting and changes to the absorbed dose can be easily obtained by adjustment of the timer setting. If this requirement

cannot be met, the absorbed-dose mapping shall be performed using the timer setting estimated to be required for the routine production runs and repeated if there is a significant change in the timer setting.

NOTE 6—For low absorbed-dose applications, such as the inhibition of sprouting of onions and potatoes, the transit dose during the movement of the conveyer system might be significant and should be considered during the design of an irradiator intended for such applications.

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

10.3.5 *Setting the Timer or Conveyor Speed*:

10.3.5.1 Use the results of the absorbed-dose mapping measurements, to determine the timer setting or conveyor speed for the production run. This will ensure that the prescribed absorbed-dose requirements within the product are achieved.

10.3.5.2 Because of the statistical nature of the absorbed-dose measurement and the inherent variations in the radiation process (for example, see 10.3.2), set the process parameters, including the timer setting, to deliver an absorbed dose greater than any prescribed minimum dose and smaller than any prescribed maximum dose **(7, 17, 18)**.

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 limits, appropriate measures shall be taken to reduce the ratio to an acceptable value.

10.3.6.2 Some methods to improve absorbed-dose uniformity may include re-arranging source elements, using attenuators or compensating dummy, irradiating from four sides, rotating the process load during irradiation, and increasing source-to-product distance. In the case of bulk-flow irradiators, absorbed-dose uniformity can be improved by arranging baffles to control product flow through the irradiation zone.

10.3.6.3 It may be necessary to change the product loading configuration of the process load if an acceptable dose-uniformity ratio cannot be achieved by changing other parameters.

10.3.7 *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.

10.3.8 *Chilled or Frozen Foods*:

10.3.8.1 Absorbed-dose mapping may be performed with simulated product at room temperature. This requires that there be no change in any parameter (other than temperature) that may affect the absorbed dose during processing of the chilled or frozen food. Mapping of the simulated product includes placement of one or more dosimeters at a reference position known to be isolated from temperature gradients in the actual product. During routine processing of the chilled or frozen product, dosimeters are placed at this reference position.

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

10.3.8.3 The temperature dependence of the dosimeter response may be affected by the absorbed dose. 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 food will be irradiated.

10.3.9 *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 **(4)**. Enough dosimeters should be used to obtain statistically significant results. Calculation of the maximum and minimum absorbed doses may be an appropriate alternative **(4, 7)**.

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 product processing, set, control, monitor, and document the process parameters (for example, irradiation time, conveyor speed, product loading configuration) as established during performance qualification, taking into account source decay, to ensure that the product in each process load is processed within specifications. If the process parameters deviate outside prescribed processing limits, take appropriate actions.

11.2.2 *End Process Loads*—The absorbed-dose distributions and the magnitudes of the minimum and maximum absorbed doses in the first and last process loads (the “end” process loads) of a given production run may be affected by the process loads of adjacent production runs. These effects will be due to any differences between the radiation-absorption characteristics of the product in the end process loads of the given production run from the products in the adjacent production runs. To prevent an unacceptable absorbed-dose distribution resulting from these effects, it may be necessary to introduce, adjacent to the end process loads, additional process loads containing compensating dummy or material of density similar to the product.

NOTE 7—For some batch irradiators, there might be no end process loads when the irradiator is filled with product from one production run.

11.2.3 *Partially Filled Process Loads*—For process loads containing less product than specified in the product loading configuration (see 10.2), ensure that absorbed-dose mapping data exist to confirm that the absorbed doses will be within the specified limits. If absorbed-dose-mapping data are not available, perform the dose-mapping procedure of 10.3.1 to ensure that the absorbed-dose distributions are adequately characterized. Changes to the absorbed-dose distribution arising from partial loading may in some cases be minimized by the use of compensating dummy placed at appropriate locations in the partially filled process load.

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 Dosimeters used for routine dosimetry need not be of the same type as those used for the absorbed-dose mapping procedure.

11.3.3 Ensure that the product receives the required absorbed dose by employing proper dosimetric measurement procedures, with appropriate statistical controls and documentation. These procedures involve the use of routine in-plant dosimetry performed as described below.

11.3.3.1 *Dosimeter Location*—Place dosimeter sets in or on the process loads at predetermined locations of the maximum and minimum absorbed dose (see 10.3.1) or, alternatively, at the reference dose positions (see 10.3.4 and 10.3.8.1).

11.3.3.2 *Placement Frequency*—Select a sufficient number of process loads on which to place dosimeter sets at the locations described in 11.3.3.1 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 process loads and in selected intermediate process loads to ensure that at least one process load 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 process loads. For operation in a batch mode, place dosimeter sets on at least one process load for each product type.

NOTE 8—The absorbed-dose distribution in the process load 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, should some operational uncertainty or failure arise.

11.3.3.3 *Environmental Effects*—A change in the environment (for example, temperature, humidity) of a dosimeter during the irradiation process may affect its 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 Guide 51261 and practices for individual dosimetry systems listed in 2.1 and 2.2.)

11.3.3.4 *Chilled or Frozen Foods*—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 chilled or frozen food products and when applying the appropriate temperature correction (see 10.3.8). Dosimeters that exhibit a highly temperature-dependent response should not be placed in locations with large temperature gradients. (See ISO/ASTM Guide 51261, and Practices for individual dosimetry systems listed in 2.1 and 2.2.)

11.3.3.5 *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 **(9)**.

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 Accumulation*:

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 parameters (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 to the dosimeter response function.

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 lot of product that is processed bears an identification that distinguishes it from all other lots in the facility. This identification shall be used on all lot documents.

12.2 *Review and Certification*:

12.2.1 Prior to release of 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 To be meaningful, a measurement of absorbed dose shall be accompanied by an estimate of uncertainty.

13.2 Components of uncertainty shall be identified as belonging to one of two categories:

13.2.1 *Type A*—those evaluated by statistical methods, or

13.2.2 *Type B*—those evaluated by other means.

13.3 Other ways of categorizing uncertainty have been widely used and may 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 9—The identification of Type A and Type B uncertainties is based on the methodology for estimating uncertainties published in 1995 by the International Organization for Standardization (ISO) in the Guide to the Expression of Uncertainty in Measurement **(19)**. The purpose of using this type of characterization is to promote an understanding of how statements of uncertainty are developed and to provide a basis for the international comparison of measurement results.

NOTE 10—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 dosimetry. The document 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 estimating their values. Methods are also provided for calculating the combined standard uncertainty and estimating expanded (overall) uncertainty.

13.4 The level of uncertainty in the absorbed-dose measurement that is acceptable should take into account both regulatory and commercial requirements pertaining to the specific product being irradiated.

14. Keywords

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

Bibliography

(**1**) "Codex General Standard for Irradiated Foods" (CODEX STAN 106-1983, Rev.-2003) and "Recommended International Code of Practice for the Radiation Processing of Food (CAC/RCP 19-1979, Rev.-2003)." *Codex Alimentarius Commision*, Food and Agriculture Organization and World Health Organization, Rome, 2003.

(**2**) *Dosimetry for Food Irradiation*, Technical Reports Series No. 409, International Atomic Energy Agency, Vienna, 2002.

(**3**) Ehlermann, D. A. E., "The Use of Various Dosimeters for the Measurement of Random Fluctuations of the Dose Distribution in Commercial Scale Food Irradiation," *Dosimetry in Agriculture, Industry, Biology and Medicine*, International Atomic Energy Agency, Vienna, 1973, pp. 77–83.

(**4**) Ehlermann, D. A. E., "Dose Distribution and Methods for Its Determination in Bulk Particular Food Materials," *Health Impact, Identification, and Dosimetry of Irradiated Food*, Bogl, K. W., Regulla, D. F., and Suess, M. J., eds., A World Health Organization Report, Institut fur Strahlenhygiene des Bundesgesund-heitsamtes, Munchen, 1988, pp. 415–419.

(**5**) Farkas, J., *Irradiation of Dry Food Ingredients*, CRC Press Inc., Boca Raton, Florida, 1988, chap. 8.

(**6**) "Food Irradiation, a Technique for Preserving and Improving the Safety of Food," A World Health Organization Report, Geneva, 1988.

(**7**) McLaughlin, W. L., Jarrett, Sr., R. D., and Olejnik, T. A., chap. 8, "Dosimetry," *Preservation of Food by Ionizing Radiation*, Vol. 1, CRC Press, Boca Raton, FL, 1983.

(**8**) *Preservation of Food by Ionizing Radiation*, Vols 1–3, Josephson, E. S. and Peterson, M. S., eds., CRC Press, Boca Raton, FL, 1983.

(**9**) Stenger, V., Sipos, T., Laszlo, L., Hargittai, P., Kovacs, A., and Horvath, I., "Experiences with a High Capacity Industrial Scald Pilot Onion Irradiator," *Radiation Physics and Chemistry*, Vol 22, 1983, pp. 717–732.

(**10**) Urbain, W. M., *Food Irradiation*, Academic Press, Inc., New York, 1986.

(**11**) *Food Irradiation: Principles and Applications*, Molins, R.A., ed., John Wiley & Sons, New York, 2001.

(**12**) *Handbook of Chemistry and Physics*, 71st ed., Lide, D. R., ed., CRC Press, Boca Raton, FL, 1990.

(**13**) Unterweger, M. P., Hoppes, D. D., and Schima, F. J., "New and Revised Half-life Measurement Results," *Nuclear Instrument Measurements*, Vol A312, 1992, pp. 349-352.

(**14**) Tuli, J. K., "Nuclear Data Sheets Update for A=137," Nuclear Data Sheets, Vol 72, No. 3, July 1994, p. 366.

(**15**) McLaughlin, W. L., "Radiation Measurements and Quality Control," *Radiation Physics and Chemistry*, Vol 9, 1977, pp. 147-181.

(**16**) McLaughlin, W. L., Boyd, A. W., Chadwick, K. H., McDonald, J. C., and Miller, A., *Dosimetry for Radiation Processing*, Taylor and Francis, New York, 1989.
(**17**) Vas, K., Beck, E. R. A., McLaughlin, W. L., Ehlermann, D. A. E., and Chadwick, K. H., "Dose Limits Versus Dose Range," *Acta Alimentaria*, Vol 7, No. 2, 1978, p. 343.
(**18**) Mehta, K., "Process Qualification for Electron-Beam Sterilization," *Medical Device and Diagnostic Industry*, June 1992, pp. 122-134.
(**19**) "Guide to the Expression of Uncertainty in Measurement," International Organization of Standardization, 1995, ISBN 92-67-10188-9. Available from the International Organization for Standardization, 1 rue de Varembé, Case Postale 56, CH-1211, Geneva 20, Switzerland.