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Practice for dosimetry in gamma irradiation facilities for food processing

Pratique de la dosimétrie dans les installations de traitement des produits alimentaires par irradiation gamma

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 15554 was prepared by the American Society for Testing and Materials (ASTM) Subcommittee E10.01 (as E 1204-93) and was adopted, under a special "fast-track procedure", by Technical Committee ISO/TC 85, *Nuclear energy*, in parallel with its approval by the ISO member bodies.

A new ISO/TC 85 Working Group WG 3, *High-level dosimetry for radiation processing*, was formed to review the voting comments from the ISO "Fast-track procedure" and to maintain these standards. The USA holds the convenership of this working group.

International Standard ISO 15554 is one of 20 standards developed and published by ASTM. The 20 fast-tracked standards and their associated ASTM designations are listed below:

ISO Designation	ASTM Designation	Title
15554	E 1204-93	*Practice for dosimetry in gamma irradiation facilities for food processing*
15555	E 1205-93	*Practice for use of a ceric-cerous sulfate dosimetry system*
15556	E 1261-94	*Guide for selection and calibration of dosimetry systems for radiation processing*
15557	E 1275-93	*Practice for use of a radiochromic film dosimetry system*
15558	E 1276-96	*Practice for use of a polymethylmethacrylate dosimetry system*
15559	E 1310-94	*Practice for use of a radiochromic optical waveguide dosimetry system*
15560	E 1400-95a	*Practice for characterization and performance of a high-dose radiation dosimetry calibration laboratory*
15561	E 1401-96	*Practice for use of a dichromate dosimetry system*

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15562	E 1431-91	*Practice for dosimetry in electron and bremsstrahlung irradiation facilities for food processing*
15563	E 1538-93	*Practice for use of the ethanol-chlorobenzene dosimetry system*
15564	E 1539-93	*Guide for use of radiation-sensitive indicators*
15565	E 1540-93	*Practice for use of a radiochromic liquid dosimetry system*
15566	E 1607-94	*Practice for use of the alanine-EPR dosimetry system*
15567	E 1608-94	*Practice for dosimetry in an X-ray (bremsstrahlung) facility for radiation processing*
15568	E 1631-96	*Practice for use of calorimetric dosimetry systems for electron beam dose measurements and dosimeter calibrations*
15569	E 1649-94	*Practice for dosimetry in an electron-beam facility for radiation processing at energies between 300 keV and 25 MeV*
15570	E 1650-94	*Practice for use of cellulose acetate dosimetry system*
15571	E 1702-95	*Practice for dosimetry in a gamma irradiation facility for radiation processing*
15572	E 1707-95	*Guide for estimating uncertainties in dosimetry for radiation processing*
15573	E 1818-96	*Practice for dosimetry in an electron-beam facility for radiation processing at energies between 80 keV and 300 keV*

Designation: E 1204 – 93

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

This standard is issued under the fixed designation E 1204; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice outlines dosimetric procedures to be followed in irradiator characterization, process qualification, and routine processing of food with ionizing radiation from isotopic gamma sources to ensure that all product has been treated within a predetermined range of absorbed dose. Other procedures related to irradiator characterization, process 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 Guides F 1355 and F 1356).

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—Practice E 1431 describes dosimetric procedures for electron beam and bremsstrahlung (X-ray) irradiation facilities for food processing.

1.2 For guidance in the selection, calibration, and use of specific dosimeters, and interpretation of absorbed dose in the product from dosimetry measurements, see Guide E 1261; Practices E 666, E 668, E 1026, E 1205, E 1275, E 1276, E 1310, and E 1401. For discussion of radiation dosimetry for gamma rays and X-rays see ICRU Report 14.

1.3 *This standard does not purport to address all of the safety problems, 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:*

E 170 Terminology Relating to Radiation Measurements and Dosimetry[2]

E 275 Practice for Describing and Measuring Performance of Ultraviolet, Visible, and Near Infrared Spectrophotometers[3]

E 666 Practice for Calculating Absorbed Dose from Gamma or X Radiation[2]

E 668 Practice for Application of Thermoluminescence-Dosimetry (TLD) Systems for Determining Absorbed Dose in Radiation-Hardness Testing of Electronic Devices[2]

E 925 Practice for the Periodic Calibration of Narrow Band-Pass Spectrophotometers[3]

E 958 Practice for Measuring Practical Spectral Bandwidth of Ultraviolet-Visible Spectrophotometers[3]

E 1026 Practice for Using the Fricke Reference Standard Dosimetry System[2]

E 1205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System[2]

E 1261 Guide for Selection and Application of Dosimetry Systems for Radiation Processing of Food[2]

E 1275 Practice for Use of a Radiochromic Film Dosimetry System[2]

E 1276 Practice for Use of a Polymethylmethacrylate Dosimetry System[2]

E 1310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System[2]

E 1400 Practice for Characterization and Performance of a High-Dose Gamma-Radiation Dosimetry Calibration Laboratory[2]

E 1401 Practice for Use of a Dichromate Dosimetry System[2]

E 1431 Practice for Dosimetry in Electron Beam and Bremsstrahlung Irradiation Facilities for Food Processing[2]

E 1538 Practice for Use of an Ethanol-Chlorobenzene Dosimetry System[2]

E 1539 Guide for the Use of Radiation-Sensitive Indicators[2]

E 1540 Practice for the Use of a Radiochromic Liquid Dosimetry System[2]

F 1355 Guide for the Irradiation of Fresh Fruits for Insect Disinfestation as a Quarantine Treatment[4]

F 1356 Guide for the Irradiation of Fresh and Frozen Red Meats and Poultry (to Control Pathogens)[4]

2.2 *International Commission on Radiation Units and Measurements (ICRU) Reports:*

ICRU Report 14—Radiation Dosimetry: X-Rays and Gamma Rays with Maximum Photon Energies Between 0.6 and 50 MeV[5]

ICRU Report 33—Radiation Quantities and Units[5]

2.3 *Codex Alimentarius Commission Reports:*

CAC Vol XV (1984): Codex General Standard for Irradiated Foods and Recommended International Code of

[1] This practice is under the jurisdiction of ASTM Committee E-10 on Nuclear Technology and Applications and is the direct responsibility of Subcommittee E10.01 on Dosimetry for Radiation Processing.

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[2] *Annual Book of ASTM Standards*, Vol 12.02.

[3] *Annual Book of ASTM Standards*, Vol 14.01.

[4] *Annual Book of ASTM Standards*, Vol 15.07.

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

Practice for the Operation of Radiation Facilities Used for the Treatment of Foods[6]

3. Terminology

3.1 *Definitions*—Other terms used in this practice, in addition to those in 3.1.1 and 3.1.2, are defined in Terminology E 170 and in ICRU Report 33.

3.1.1 *absorbed dose, D*—quotient of $d\bar{\varepsilon}$ by d*m*, where $d\bar{\varepsilon}$ is the mean energy imparted by ionizing radiation to matter of mass d*m* (see ICRU Report 33).

$$D = d\bar{\varepsilon}/dm$$

The special name for the unit of absorbed dose is the gray (Gy):

$$1 \text{ Gy} = 1 \text{ J}\cdot\text{kg}^{-1}$$

Formerly, the special unit for absorbed dose was the rad:

$$1 \text{ rad} = 10^{-2} \text{ J}\cdot\text{kg}^{-1} = 10^{-2} \text{ Gy}$$

3.1.2 *absorbed-dose mapping*—measurement of the absorbed-dose distribution in an irradiation unit through the use of dosimeters placed at specified locations within the irradiation unit.

3.2 *Descriptions of Terms Specific to This Standard:*

3.2.1 *compensating dummy*—consists of material that matches the density and gamma attenuation characteristics of the actual product to the extent required to meet prescribed minimum or maximum absorbed doses. It is used during routine production runs within a partially filled irradiation unit or at the beginning and end of a production run to compensate for the absence of product. See also *simulated product*.

3.2.2 *irradiation time*—total time during which an irradiation unit is exposed to radiation.

3.2.3 *irradiation unit*—one or more containers of product, collectively transported through the irradiator as a whole, for example, box, tote, pallet, or carrier. This term is not relevant to bulk-flow processing.

3.2.4 *primary standard dosimeter*—a dosimeter that has the highest metrological quality in the field of radiation dosimetry and is recognized as such on a national or international basis.

3.2.5 *production run*—a series of irradiation units containing the same food product irradiated sequentially to nominally the same absorbed dose.

3.2.6 *reference standard dosimeter*—a dosimeter, generally of the highest metrological quality available at a facility, that is traceable to national primary standards.

3.2.7 *routine dosimeter*—a dosimeter calibrated against a primary, reference, or transfer standard dosimeter and used routinely to make dosimetry measurements.

3.2.8 *simulated product*—consists of material that closely matches the density and gamma attenuation characteristics of the foods of interest. It is used as a substitute for the actual product during irradiator characterization.

3.2.9 *transfer standard dosimeter*—a dosimeter prepared in a stable and rugged form, used by a nationally recognized standards calibration laboratory as an intermediary to compare absorbed-dose rates in radiation environments and check the calibration of routine dosimeters.

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 parasite and pathogen control, insect disinfestation, growth and maturation inhibition, and shelf-life extension. Food irradiation specifications usually include a pair of absorbed-dose limits. For a given application, one or both of these values may be prescribed by regulations based on available scientific data. Therefore, it is necessary to determine the capability of an irradiation facility to process within these absorbed-dose limits prior to the irradiation of the food product. Once this capability is established, it is necessary to monitor and record the absorbed dose during each production run to verify compliance with the process specifications within a predetermined level of confidence.

NOTE 3—The Codex Alimentarius Commission (**1**)[7] uses the term "overall average absorbed dose" in discussing broad concepts such as the wholesomeness of foods irradiated to an overall average absorbed dose of less than 10 kGy. The overall average dose should not, however, be used in place of minimum or maximum absorbed doses for specific applications. The CAC confirms this in the following statement from CAC/RCP 19-1979, Annex A: "(T)he design of the facility and the operational parameters have to take into account minimum and maximum dose values required by the process."

4.2 Some food products are processed in the chilled or frozen state. Therefore, it is necessary to confirm that the dosimeters used for routine monitoring are useable at low temperature and that the dosimeter temperature during irradiation is sufficiently stable to allow correction for temperature effects on the dosimeter response.

4.3 For more detailed discussions of radiation processing, see Guides F 1355 and F 1356 and Refs **1–10**.

5. Radiation Source Characteristics

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

5.2 Cobalt-60 emits photons with energies of approximately 1.17 and 1.33 MeV in equal proportions. Cesium-137 produces photons with energies of approximately 0.662 MeV (**11**).

5.3 The half-lives for ^{60}Co and ^{137}Cs are approximately 5.27 years and 30.2 years, respectively (**11**).

6. Types of Facilities

6.1 Food processing facilities may be categorized by irradiator type (for example, container or bulk flow), conveyor system (for example, shuffle-dwell or continuous), and operating mode (for example, batch or continuous). Food products may be moved to the location in the facility where the irradiation will take place, either while the source is shielded (batch operation) or while the source is exposed (continuous operation). Food products may be transported

[6] Available from the Joint FAO/WHO Food Standards Program, Joint Office, Food and Agriculture Organization of the United Nations, Via Della Terme de Caracalla, 00100 Rome, Italy.

[7] The boldface numbers in parentheses refer to the list of references at the end of this practice.

past the source at a uniform controlled speed (continuous conveyance), or may instead undergo a series of discrete controlled movements separated by controlled time periods (shuffle-dwell). For irradiators with rectangular source arrays, the irradiation unit generally makes one or more passes on each side of the source. Irradiation units may move past a rectangular source array in a configuration in which the source either completely overlaps the irradiation unit or the irradiation unit overlaps the source. In the latter configuration, the irradiation unit is moved past the source at one or more different levels. In bulk-flow irradiators, products such as grain or flour flow in loose form past the source.

6.2 Because of mechanical speed limitations, various techniques are used to reduce the absorbed-dose rates for low absorbed-dose applications. These techniques include using only a portion of the source, using attenuators, and irradiating at greater distances from the source.

6.3 The details of a particular irradiator design affect the delivery of absorbed dose to a product. They should, therefore, be considered when performing the absorbed-dose measurements required in Sections 8, 9, and 10.

7. Dosimetry Systems (see Guide E 1261, Practices E 1026, E 1205, E 1275, E 1276, E 1310, E 1401, E 1538, and E 1540)

7.1 *Dosimeter Classes and Applications:*

7.1.1 *Reference or Transfer Standard Dosimeters* are used to calibrate radiation fields (environments) and dosimeters employed in routine radiation processing. Reference or transfer dosimeters may also be used for the same purposes as routine dosimeters (7.1.2). Reference and transfer standard dosimeters are traceable to national standards.

7.1.2 *Routine Dosimeters* are used for monitoring and for quality assurance in food irradiation processing. They are calibrated against primary, reference, or transfer standard dosimeters.

7.2 Operational and technical criteria for the selection of a dosimetry system are given in Guide E 1261.

7.3 *Calibration of Dosimetry Systems:*

7.3.1 Prior to use, a routine dosimetry system shall be calibrated in accordance with a documented procedure that specifies details of the calibration process and quality assurance requirements. Also, this calibration procedure shall be repeated at regular intervals to ensure that the accuracy of the absorbed dose measurement is maintained within required limits.

7.3.2 The instruments used in the analysis of the dosimeters shall be calibrated at periodic intervals using appropriate standards traceable to national standards. For example, if optical absorbance-measuring instruments (for example, spectrophotometer or densitometer) are used, then appropriate standards shall be used to verify the accuracy of the optical absorbance and specified wavelength(s). See Practices E 275, E 925, and E 958.

7.3.3 Each batch of dosimeters shall be calibrated at an irradiation facility that has a dose rate traceable to national standards. This irradiation facility should meet the requirements specified in Practice E 1400. Alternatively, each batch of dosimeters may be calibrated against a reference or transfer standard dosimeter (see 7.1.1) under the actual conditions of use in a product irradiation facility.

8. Installation Qualification

8.1 *Equipment Documentation*—Establish and document an irradiator qualification program to demonstrate that the irradiator, operating within specified limits, will consistently produce an absorbed-dose distribution in a given product to predetermined specification. Documentation shall include descriptions of instrumentation and equipment for ensuring the reproducibility, within specified limits, of the source-to-product geometry and of the time the product spends at different locations in the irradiation zone **(12)**.

8.2 *Equipment Testing*—Test all processing equipment and instrumentation that may influence absorbed dose in order to verify satisfactory operation of the irradiator within the design specifications.

8.3 *Equipment Calibration*—Implement a documented calibration program to assure that all equipment and instrumentation that may influence absorbed dose are calibrated within the specified limits.

8.4 *Irradiator Characterization*—Determine the overall performance of the irradiator in delivering absorbed dose to a product prior to routine processing.

8.4.1 The absorbed dose received by any portion of an irradiated product depends on facility parameters such as the activity and geometry of the source, and on processing parameters such as the source-to-product distance and geometry, the irradiation time, the product composition and density, and the product geometry.

8.4.2 The absorbed-dose rate and absorbed-dose distribution in the product will change during movement of the irradiation unit. Therefore, a direct scaling from one absorbed dose to another on the basis of irradiation time may not be valid and this effect should be considered during process qualification (see Section 9).

8.4.3 To ensure that product near the source is processed within specifications, changes in the absorbed dose caused by movement of the source to and from the irradiation position should be considered and quantified.

8.4.4 The irradiator characterization process includes mapping the absorbed-dose distributions in simulated or actual irradiation units. Theoretical calculations of absorbed-dose rates and absorbed-dose distributions at various locations within the irradiation unit may be used to define the number and placement of dosimeters needed for the mapping procedure. Dosimetry data from previously characterized irradiators of the same design also may be useful information for this characterization process.

NOTE 4—Theoretical calculations may be performed using the Monte Carlo method **(13)** or the point-kernel method **(14)**. In the point-kernel method, the radiation source is approximated by differential point isotropic sources. The total absorbed dose at each dose point is obtained by summing the absorbed-dose contribution from isotropic source point. The absorbed dose at a dose point depends mainly on the energy of the gamma radiation and the composition (for example, density and thickness) of the materials located between the source point and dose point (for example, source encapsulation material, other product units, and carrier wall material). In the Monte Carlo method, the total absorbed dose at a dose point is determined from the energy distribution at that point by modeling the trajectories of photons and electrons through the absorbing media. In order to obtain a good statistical representation of their interactions (for example, scattering or absorption) within the media, the paths of a sufficiently large number of photons and electrons are followed until the dose point is reached. Like the point-kernel method, the Monte Carlo method requires a knowledge

of all materials between the source and dose point.

8.4.4.1 Map the absorbed-dose distribution by a three-dimensional placement of dosimeters throughout an actual or simulated irradiation unit. Select placement patterns that can most probably identify the locations of the absorbed-dose maxima and minima (for example, see Fig. 1). Place more dosimeters in these locations, and fewer dosimeters in locations likely to receive intermediate absorbed doses. For further information on the use and placement of dosimeters see Refs **3**, **15**, **16**, and **17**.

8.4.4.2 For a given process irradiation time or product dwell time, an increase in the product density generally results in a decrease in a minimum absorbed dose. The maximum absorbed dose may not change appreciably or it may also decrease, but to a lesser degree than the minimum absorbed dose; therefore, the dose uniformity ratio increases.

8.4.5 Changes in the source loading, source geometry, or product transport system can affect the absorbed-dose distributions. If such a change is made, repeat the irradiator characterization procedure of 8.4.4, with emphasis on measurements in the regions of expected maximum and minimum absorbed dose, to the extent necessary to establish the effects.

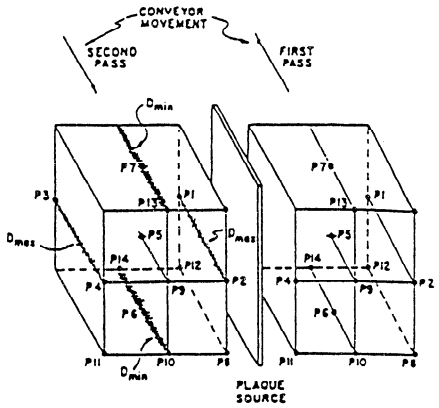
8.4.6 Use the results of the irradiator characterization as a guide for dosimeter placement for process qualification as discussed in Section 9.

8.4.7 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. Calculations may be an appropriate alternative (**4**, **7**).

9. Process Qualification

9.1 *Processing Parameters:*

9.1.1 The absorbed dose requirements for each product type to be processed in the irradiation facility must be known. The processing parameters required to achieve absorbed doses within the specified limits are determined from the product absorbed-dose mapping studies (see 9.2).



NOTE—Two passes of a rectangular package, one on each side of a stationary gamma-ray plaque source. The probable regions of maximum and minimum absorbed dose after the second pass are indicated by hatching. The recommended locations for dosimeters during irradiator characterization are indicated by the Ps.

FIG. 1 An Example of the Maximum and Minimum Absorbed-Dose Locations in a Typical Product (17)

9.1.2 The prescribed maximum and minimum absorbed dose limits determine the upper limit for the dose uniformity ratio for the product. At times, it may be necessary to take measures to improve the uniformity of absorbed dose. In some facilities, this may be accomplished by having the source extend beyond the boundaries of the irradiation unit, or the irradiation unit may move past the source at several different levels. Other methods to improve absorbed-dose uniformity may include arranging source elements so that those with greater activity are near the perimeter of the source array, using attenuators, irradiating from four sides, rotating the irradiation unit during irradiation, increasing source-to-product distance, and reducing product thickness. In the case of bulk-flow irradiators, absorbed-dose uniformity can be improved by arranging baffles to control product flow through the irradiation zone.

9.2 *Product Absorbed-Dose Mapping:*

9.2.1 Map the absorbed-dose distribution for each product and geometry to determine the regions of maximum and minimum absorbed dose within the irradiation unit (**1**, **7**, **16**, **18**). Also, determine the locations for routine placement of dosimeters during production runs (see 9.2.3).

NOTE 5—Theoretical calculations or dosimetry data obtained for similar products and geometries may be useful in defining the number and placement of dosimeters (see 8.4.4).

9.2.1.1 In an irradiation unit that contains voids or heterogeneous product, the absorbed-dose mapping shall include placement of dosimeters at locations where discontinuities in composition or density may affect the regions of maximum or minimum absorbed dose.

9.2.1.2 The number of irradiation units selected for mapping shall be sufficient to determine the variability of the absorbed-dose distribution among irradiation units.

9.2.2 Absorbed-dose mapping (see 9.2.1) shall be required whenever an irradiator characterization indicates a significant change in absorbed-dose distributions (see 8.4.5). The criteria for determining whether a change is significant shall be established and documented.

9.2.3 *Reference Dose Position*—As a consequence of absorbed dose mapping, a relationship can be established between absorbed doses at a reference position relative to the maximum or minimum absorbed-dose positions. This relationship is most useful for dosimeter placement during routine processing when the minimum or maximum absorbed-dose position is inaccessible. This relationship shall be reproducible and documented.

9.2.4 *Chilled or Frozen Foods*—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.

9.2.5 *Bulk-Flow Irradiators*—Absorbed-dose mapping as described in 9.2.1 may not be feasible. 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 min-

imum absorbed doses may be an appropriate alternative (**4, 7**).

9.2.6 If the dose mapping procedure of 9.2.1 reveals that the dose uniformity ratio for the product is too large, for example, larger than the ratio between the maximum and minimum absorbed-dose limits prescribed by government regulations, change the appropriate processing parameters to reduce the ratio to an acceptable value (see 9.1.2). It may be necessary to redesign the irradiation unit if an acceptable value cannot be achieved by changing other processing parameters. If changes are made, repeat the absorbed-dose mapping (see 9.2.1).

9.2.7 A change in a processing parameter, for example, product composition or density, may affect the locations or prescribed magnitudes of maximum and minimum absorbed doses. If a change occurs that could affect these locations and magnitudes, repeat the absorbed-dose mapping (see 9.2.1) to the extent necessary to establish the effects. The dosimetry data obtained during irradiator characterization (see 8.4) should serve as a guide in determining the extent of these absorbed-dose mapping studies.

10. Routine Production Processing

10.1 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 dosimetric measurements performed as described in the following paragraphs.

10.1.1 *Dosimeter Location*—Place dosimeters either within or on the selected irradiation units (see 10.1.2) at predetermined locations of the maximum and minimum absorbed dose (see 9.2.1), or at the reference positions determined in 9.2.3.

10.1.2 *Placement Frequency*—When operating in the continuous mode, place dosimeters at locations described in 10.1.1 at or near the start, middle, and end of the production run. For monitoring during long production runs (exceeding 16 h), employ additional dosimeters so that absorbed-dose measurements are made in an irradiation unit at least once every 8 h. When operating in the batch mode, place dosimeters at locations described in 10.1.1 on at least one irradiation unit for each product type.

NOTE 6—More frequent placement of dosimeters during the production run could result in less product rejection should some operational uncertainty or failure arise.

10.1.3 *End Units*—The first and last units of a contiguous series of irradiation units may experience absorbed-dose distributions different from the other units. If prior dosimetry data indicate the existence of an unacceptable absorbed-dose distribution for the end units, place compensating dummies adjacent to these units to make their absorbed-dose distributions acceptable.

10.1.4 *Partial Loading*—If processing partially loaded units is necessary, use the same measurement requirements as for fully loaded irradiation units. Perform the dose mapping procedure of 9.2.1 to assure that the absorbed-dose distributions are adequately characterized. Changes to the absorbed-dose distribution arising from partial loading may in some cases by minimized and made acceptable by the use of compensating dummy material placed at appropriate locations within the irradiation unit.

10.1.5 *Environmental Effects*—A change in the environment (for example, temperature, humidity) of a dosimeter during the irradiation process may affect its response. If required, correct the dosimeter response for any such effect. Care must also be taken in handling and storage of dosimeters before and after irradiation. (See Guide E 1261 and practices for individual dosimetry systems listed in 2.1.)

10.1.6 *Chilled or Frozen Food Products*—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. Dosimeters that exhibit a highly temperature-dependent response should not be placed in locations with large temperature gradients. (See Guide E 1261 and practices for individual dosimetry systems listed in 2.1.)

10.1.7 *Bulk-Flow Irradiators*—For some types of bulk-flow irradiators (for example, those treating fluids or grains), where it may not be feasible during routine operation to place dosimeters at the locations of minimum and maximum absorbed dose, 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, within a specified level of confidence, that the minimum and maximum absorbed doses are known. This procedure requires that the dosimeters flow in the same manner and at the same rate as the product to ensure that the irradiation time of the dosimeters is the same as that of the product. See, for example, Ref. **19**.

10.2 Radiation-sensitive indicators (see Guide E 1539) may be available for some absorbed-dose levels. The use of radiation-sensitive indicators is neither a substitute for nor a complement to the dosimetry procedures described in 10.1.

11. Certification

11.1 *Documentation Accumulation:*

11.1.1 *Irradiation Control Record:*

11.1.1.1 Record and document all dosimetry data for irradiator characterization, product absorbed-dose mapping, and routine production processing. Include date, time, product type, loading diagrams, and absorbed doses for all product processed (see Guide E 1261).

11.1.1.2 Record the processing parameters (see 9.1) affecting absorbed dose together with sufficient information identifying these parameters with specific product batches or production runs.

11.1.1.3 Record or reference the calibration and maintenance of equipment and instrumentation used to control or measure the absorbed doses delivered to the product (see Guide E 1261).

11.1.2 *Facility Log:*

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

11.1.2.2 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.