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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

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ASTM International, 100 Barr Harbor Drive, PO Box C700,
West Conshohocken, PA 19428-2959, USA
Tel. +610 832 9634
Fax +610 832 9635
E-mail khooper@astm.org
Web www.astm.org

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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.

ASTM International is one of the world's largest voluntary standards development organizations with global participation from affected stakeholders. ASTM technical committees follow rigorous due process balloting procedures.

A pilot project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this pilot project, ASTM Subcommittee E10.01, Dosimetry for Radiation Processing, is responsible for the development and maintenance of these dosimetry standards with unrestricted participation and input from appropriate ISO member bodies.

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Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. Neither ISO nor ASTM International shall be held responsible for identifying any or all such patent rights.

International Standard ISO/ASTM 51204 was developed by ASTM Committee E10, Nuclear Technology and Applications, through Subcommittee E10.01, and by Technical Committee ISO/TC 85, Nuclear Energy.

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

1.2 For guidance in the selection and calibration of dosimeters, 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 668, E 1026 and ISO/ASTM Practices 51205, 51275, 51276, 51310, 51401, 51538, 51540, 51607, and 51650. 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:*

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

E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods[3]

E 275 Practice for Describing and Measuring Performance of Ultraviolet, Visible, and Near Infrared Spectrophotometers[4]

E 456 Terminology Relating to Quality and Statistics[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[4]

E 958 Practice for Measuring Practical Spectral Bandwidth of Ultraviolet-Visible Spectrophotometers[4]

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

F 1355 Guide for the Irradiation of Fresh Fruits as a Phytosanitary Treatment[2]

F 1356 Guide for the Irradiation of Fresh and Frozen Red Meats and Poultry to Control Pathogens and Other Microorganisms[2]

F 1736 Guide for the Irradiation of Finfish and Shellfish to Control Pathogens and Spoilage Microorganisms[2]

2.2 *ISO/ASTM Standards:*

51205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System[2]

51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing[2]

51275 Practice for Use of a Radiochromic Film Dosimetry System[2]

51276 Practice for Use of a Polymethylmethacrylate Dosimetry System[2]

51310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System[2]

51401 Practice for Use of a Dichromate Dosimetry System[2]

51431 Practice for Dosimetry in Electron Beam and Bremsstrahlung Irradiation Facilities for Food Processing[2]

51538 Practice for Use of an Ethanol-Chlorobenzene Dosimetry System[2]

51539 Guide for the Use of Radiation-Sensitive Indicators[2]

51540 Practice for the Use of a Radiochromic Liquid Dosimetry System[2]

51607 Practice for the Use of the Alanine-EPR Dosimetry System[2]

51650 Practice for the Use of a Cellulose Acetate Dosimetry System[2]

51707 Guide for Estimating Uncertainties in Dosimetry for

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

[3] *Annual Book of ASTM Standards*, Vol 14.02.

[4] *Annual Book of ASTM Standards*, Vol 03.06.

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Radiation Processing[2]

2.3 *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 60 Radiation Quantities and Units[5]

2.4 *Codex Alimentarius Commission Reports:*

CAC vol. 1, 2nd edition (1992), section 8.1: Recommended International Code of Practice for the Operation of Irradiation Facilities used for the Treatment of Foods (CAC/RCP 19-1979 (Rev. 1))[6]

3. Terminology

3.1 *Definitions*—Other terms used in this practice, in addition to those in 3.1.1-3.1.16, are defined in ASTM Terminology E 170 and in ICRU Report 60.

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

$$D = d\epsilon/dm \qquad (1)$$

3.1.2 *absorbed-dose mapping*—measurement of the 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.

3.1.5 *dosimeter response*—the reproducible, quantifiable radiation effect produced 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 of that location.

3.1.7 *dosimetry system*—a 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 *irradiation time*—total time during which a process load is exposed to radiation.

3.1.9 *primary–standard dosimeter*—a 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).

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

3.1.11 *production run* (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.

3.1.12 *reference–standard dosimeter*—a 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).

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

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

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

3.1.15.1 *Discussion*—Simulated product is used during irradiator characterization 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."

3.1.16 *transfer–standard dosimeter*—a dosimeter, often a reference–standard dosimeter, suitable for transport between different locations used to compare absorbed-dose measurements (see ISO/ASTM Guide 51261).

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 usually include an upper and lower limit of absorbed dose: a minimum to ensure the intended beneficial effect and a maximum to avoid product degradation. For a given application, one or both of these values may be prescribed by regulations that have been established on the basis of 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.

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

[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.

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: "The design of the facility and the operational parameters have to take into account minimum and maximum dose values required by the process."

NOTE 4—In some countries regulations require that the dose absorbed by a food item should not exceed some specified overall average dose in addition to minimum and maximum dose values. In this case, the overall averaged dose is the mean value of the lower and upper limits.

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 usable 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 of various foods, see ASTM Guides F 1355, F 1356, and F 1736 and References **(1-10)**.

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 Cobalt-60 emits photons with energies of approximately 1.17 and 1.33 MeV in nearly 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)**.

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

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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 fully shielded (batch operation) or while the source is exposed (continuous operation). 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). For irradiators with rectangular source arrays, the process load generally makes one or more passes on each side of the source. Process loads may move past a rectangular source array in a configuration in which the source either extends beyond the process load or the process load extends beyond the source. In the latter configuration, the process load is usually moved past the source at two 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 may be used to reduce the absorbed-dose rates for low absorbed-dose applications. These techniques include using only a portion of the source (e.g. raising only one of several source racks to the irradiation position), using attenuators, and irradiating at greater distances from the source.

6.3 The design of an irradiator affects the delivery of absorbed dose to a product. Therefore, the irradiator design must be considered when performing the absorbed-dose measurements required in Sections 8, 9, and 10.

7. Dosimetry Systems (see ASTM Practice E 1026, ISO/ASTM Practices 51205, 51275, 51276, 51310, 51401, 51538, 51540, 51607, 51650, and ISO/ASTM Guide 51261).

7.1 *Dosimeter Classes and Applications*:

7.1.1 *Reference– or Transfer–Standard Dosimeters* are used to calibrate radiation fields (environments) and dosimetry systems employed in routine radiation processing. Reference or transfer dosimeters may also be used as routine dosimeters (7.1.2).

7.1.2 *Routine Dosimeters* are used for monitoring and quality assurance in food irradiation processing.

7.1.3 Operational and technical criteria for the selection of a dosimetry system are given in ISO/ASTM Guide 51261.

7.2 *Calibration of Dosimetry Systems*:

7.2.1 Prior to use, dosimetry systems shall be calibrated in accordance with the user's documented procedure that specifies details of the calibration process and quality assurance requirements. This calibration procedure shall be repeated at regular intervals to ensure that the accuracy of the absorbed dose measurement is maintained within required limits. Irradiation is a critical component of the calibration of the dosimetry system. Detailed calibration procedures are provided in ISO/ASTM Guide 51261.

7.2.2 *Calibration Irradiation of Reference or Transfer Dosimeters*—Calibration irradiations shall be performed by irradiating the reference– or transfer—standard dosimeters using a calibration facility that provides an absorbed dose or an absorbed-dose rate having measurement traceability to nationally or internationally recognized standards.

7.2.3 *Calibration Irradiation of Routine Dosimeters*—Calibration irradiations shall be performed in several ways, including irradiating the routine dosimeters using:

7.2.3.1 A calibration facility that provides an absorbed dose or an absorbed-dose rate having measurement traceability to nationally or internationally recognized standards, or

7.2.3.2 An in-house calibration facility that provides an absorbed dose or an absorbed-dose rate having measurement traceability to nationally or internationally recognized standards, or

7.2.3.3 A production or research irradiation facility together with reference– or transfer–standard dosimeters that have

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

measurement traceability to nationally or internationally recognized standards.

7.2.4 When a reference– or transfer-standard dosimeter is to be used as a routine dosimeter, calibration may also be performed as stated in 7.2.3.2 or 7.2.3.3.

7.2.5 *Instrument Calibration*—Calibrations of the individual instruments used in the analysis of the dosimeters shall be verified at periodic intervals. These calibrations shall be traceable to nationally or internationally recognized standards. For example, if an optical absorbance-measuring instrument such as a spectrophotometer or densitometer is used, then appropriate standards shall be used to verify the accuracy of the optical absorbance at a specified wavelength(s). See ASTM Practices E 275, E 925, and E 958.

8. Installation Qualification

8.1 *Objective*:

8.1.1 Installation qualification includes the concepts of equipment documentation, testing and calibration as well as irradiator characterization.

8.1.2 The purpose of dosimetry in qualifying a gamma irradiation facility is to establish baseline data for evaluating facility effectiveness, predictability, and reproducibility for the range of conditions of operation. For example, dosimetry shall be used (1) to establish relationships between the absorbed dose for a reproducible geometry and the operating parameters of the facility, (2) to characterize absorbed-dose variations when facility and processing parameters fluctuate statistically and through normal operations, and (3) to measure absorbed-dose distributions in reference materials.

8.2 *Equipment Documentation*:

8.2.1 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 a predetermined specification. Documentation shall be retained for the life of the irradiator and shall include descriptions of instrumentation and equipment for ensuring the reproducibility, within specified limits, of the source-to-product geometry and the time the product spends at different locations in the irradiation zone **(12)**.

8.3 *Equipment Testing and Calibration*:

8.3.1 *Processing Equipment*—The absorbed dose in the product in a process load depends on the operating parameters of the irradiation facility which are controlled by the processing equipment and instrumentation.

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

8.3.1.2 Implement a documented calibration program to assure that all processing equipment and instrumentation that may influence absorbed dose are calibrated periodically.

8.3.2 *Analytical Equipment*—The accuracy of the absorbed-dose measurement depends on the correct operation and calibration of the analytical equipment used in the analysis of the dosimeters.

8.3.2.1 Check the performance of the analytical equipment periodically to ensure that the equipment is functioning according to performance specifications. Repeat this check following any equipment modification or servicing and prior to the use of the equipment for a dosimetry system calibration. This check can be accomplished by using standards such as calibrated optical density filters, wavelength standards, or calibrated thickness gauges supplied by the manufacturer or national or accredited standards laboratories.

8.3.2.2 Implement a documented calibration program to assure that all analytical equipment used in the analysis of dosimeters is calibrated periodically.

8.3.2.3 Prior to each use of an analytical instrument check the zero setting and, if applicable, the full scale reading.

8.4 *Irradiator Characterization*:

8.4.1 The absorbed dose received by any portion of product in a process load depends on facility parameters such as the activity and geometry of the source, the source to product distance, and the irradiation geometry, and on processing parameters such as the irradiation time, the product composition and density, and the product loading configuration.

8.4.2 The absorbed-dose rate and absorbed-dose distribution in the product will change during movement of the process load. Therefore, a direct scaling from one absorbed dose to another by simply changing the timer setting 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, contributions to the absorbed dose in the product during movement of the source to and from the irradiation position should be considered and quantified.

8.4.4 The irradiator characterization process shall include mapping the absorbed-dose distributions in process loads containing actual or simulated product (see 9.2). Dosimetry data from previously characterized irradiators of the same design or theoretical calculations may provide useful information for determining the number and location of dosimeters for this characterization process.

NOTE 5—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 isotropic point sources. The total absorbed dose at each dose point is obtained by summing the absorbed-dose contribution from each 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 surrounding and 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 and surrounding the source point and dose point.

8.4.4.1 Map the absorbed-dose distribution by a three-dimensional placement of dosimeter sets in the process loads. The amount of actual or simulated product in these process loads shall be the amount expected during typical production runs. Select placement patterns that can most probably identify the locations of the absorbed-dose maxima and minima (for

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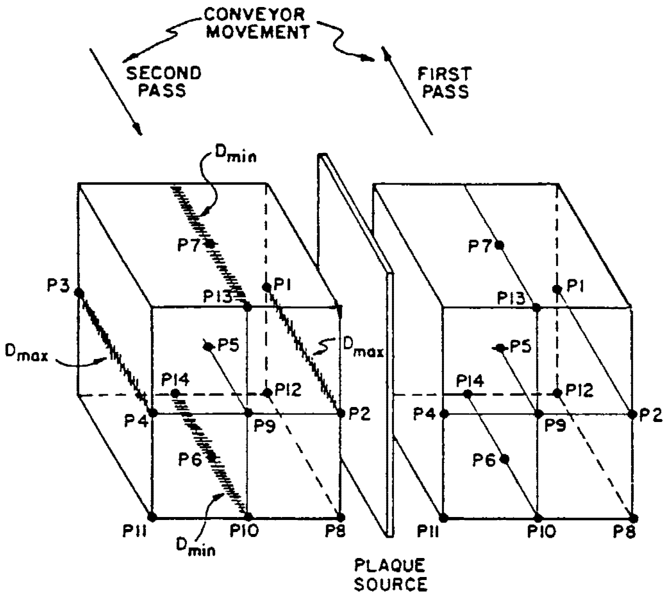
example, see Fig. 1). Place more dosimeter sets in these locations, and fewer dosimeter sets in locations likely to receive intermediate absorbed doses. For further information on the use and placement of dosimeters see Refs (**3,15-17**).

8.4.4.2 For a given process irradiation time or product dwell time, a change in the product density 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. Unacceptable changes in the dose uniformity ratio that may be revealed during product absorbed-dose mapping (see 9.3) may be corrected using measures such as described in 9.3.6.

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, perform dosimetry (see 8.4.4) to confirm that the change has not affected the absorbed-dose distribution or to determine the new absorbed-dose distribution.

8.4.6 Use the results of the irradiator characterization as a guide for placement of dosimeter sets 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. Enough dosimeters should be used to obtain statistically significant results. Calculations of minimum and maximum doses may be an appropriate alternative (**4,7**).



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. Process Qualification

9.1 *Objective*:

9.1.1 Minimum and maximum absorbed-dose limits are almost always associated with food irradiation applications. For a given application, one or both of these values may be prescribed by regulations. Therefore, the purpose of dosimetry in process qualification is to ensure that the absorbed-dose requirements for a particular product can be satisfied. This is accomplished by absorbed-dose mapping (see 9.3) of a process load with a specific product and product loading configuration to determine the minimum and maximum absorbed doses, the locations of the minimum and maximum absorbed-dose regions, and the irradiator timer setting necessary to achieve the absorbed doses within the set requirements.

9.2 *Product Loading Configuration*:

9.2.1 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 and product density.

9.2.2 All process loads for a given production run shall have the same product loading configuration.

9.3 *Product Absorbed-Dose Mapping*:

9.3.1 Establish the locations of the regions of minimum and maximum absorbed dose for the selected product and product loading configuration. This is accomplished by placing dosimeter sets throughout the volume of interest for one or more process loads. Select placement patterns that can most probably identify the locations of the absorbed–dose extremes using data obtained from other absorbed-dose mapping studies or from theoretical calculations. Concentrate dosimeter sets in 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.

9.3.1.1 In a process load that contains 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.

9.3.2 When dose mapping a specific product and product loading configuration, consideration should be given to possible variations in the absorbed doses measured in similar locations in different process loads caused, for example, by variations in the product density or by shifts in the contents of the process load during loading or during its movement through the irradiator. The variations in absorbed dose can be determined by mapping the absorbed-dose distribution in several process loads with the same product loading configuration under the same irradiation conditions. Data obtained from other absorbed-dose mappings or theoretical calculations can be useful in determining the magnitude of the effects caused by such variations. Timer settings chosen for routine processing should take these variations into account (see 10.2.2.3).

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