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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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Contents

Page

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 project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this 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.

Attention is drawn to the possibility that some of the elements of this document 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.

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
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

[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.

Current edition approved June 30, 2004. Published August 15, 2004. Originally published as ASTM E 1204 – 87. Last previous edition E 1204–97$^{\epsilon 1}$. ASTM E 1204 - 93 was adopted by ISO in 1998 with the intermediate designation ISO 15554:1998(E). The present International Standard ISO/ASTM 51204:2004(E) replaces ISO 15554 and is a major revision of the last previous edition ISO/ASTM 51204:2002(E).

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

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 dm, 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 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

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

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 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

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

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.

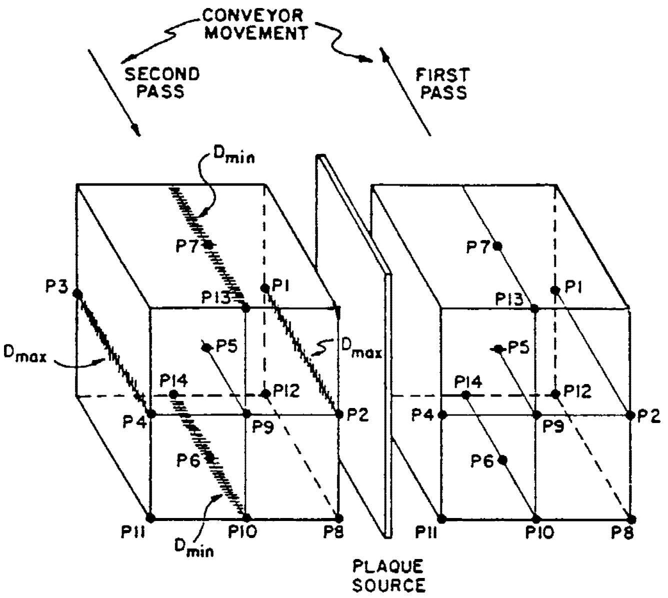
9.2.1.1 Select placement patterns to identify the locations of the absorbed-dose maxima and minima (for example, see Fig. 1). Place more dosimeter sets in these locations and fewer dosimeter sets in locations likely to receive intermediate absorbed doses. Dosimetry data from previously qualified irradiators 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.

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.



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)