Standard Practice for Dosimetry in Electron Beam and X-Ray (Bremsstrahlung) Irradiation Facilities for Food Processing[1]

This standard is issued under the fixed designation ISO/ASTM 51431; 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 high-energy electrons and X-rays (bremsstrahlung) 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, and appropriate energy limits for electron beams used directly or to generate X-rays is not within the scope of this practice (see ASTM Guides F1355, F1356, F1736, and F1885).

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 51204 describes dosimetric procedures for gamma 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 E666. For the use of specific dosimetry systems, see ASTM Practices E1026 and E2304, and ISO/ASTM Practices 51205, 51275, 51276, 51310, 51401, 51538, 51540, 51607, 51650 and 51956 For discussion of radiation dosimetry for electrons and X-rays also see ICRU Reports 35 and 14. For discussion of radiation dosimetry for pulsed radiation, see ICRU Report 34.

1.3 While gamma radiation from radioactive nuclides has discrete energies, X-rays (bremsstrahlung) from machine sources cover a wide range of energies, from low values (about 35 keV) to the energy of the incident electron beam. For information concerning electron beam irradiation technology and dosimetry, see ISO/ASTM Practice 51649. For information concerning X-ray irradiation technology and dosimetry, see ISO/ASTM Practice 51608.

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

2. Referenced documents

2.1 *ASTM Standards:*[2]

E170 Terminology Relating to Radiation Measurements and Dosimetry

E666 Practice for Calculating Absorbed Dose From Gamma or X Radiation

E1026 Practice for Using the Fricke Dosimetry System

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

E2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

E2304 Practice for Use of a LiF Photo-Fluorescent Film Dosimetry System

F1355 Guide for Irradiation of Fresh Agricultural Produce as a Phytosanitary Treatment

F1356 Practice for Irradiation of Fresh and Frozen Red Meat and Poultry to Control Pathogens and Other Microorganisms

F1736 Guide for Irradiation of Finfish and Aquatic Invertebrates Used as Food to Control Pathogens and Spoilage Microorganisms

F1885 Guide for Irradiation of Dried Spices, Herbs, and Vegetable Seasonings to Control Pathogens and Other Microorganisms

2.2 *ISO/ASTM Standards:*[2]

51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing

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

[1] This practice is under the jurisdiction of ASTM Committee E61 on Radiation Processingand is the direct responsibility of Subcommittee E61.04 on Specialty Application, and is also under the jurisdiction of ISO/TC 85/WG 3.

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

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
51538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System
51539 Guide for Use of Radiation-Sensitive Indicators
51540 Practice for Use of a Radiochromic Liquid Dosimetry System
51607 Practice for Use of the Alanine-EPR Dosimetry System
51608 Practice for Dosimetry in an X-ray (Bremsstrahlung) Facility for Radiation Processing
51631 Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Dose Measurements and Dosimeter Calibrations
51649 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV
51650 Practice for Use of a Cellulose Triacetate Dosimetry System
51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing
51956 Practice for 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 34 The Dosimetry of Pulsed Radiation
ICRU Report 35 Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV
ICRU Report 37 Stopping Powers for Electrons and Positrons
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 $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass dm (see ICRU 60).

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

3.1.1.1 *Discussion*—The discontinued unit for absorbed dose is the rad (1 rad = 100 erg/g = 0.01 Gy). Absorbed dose is sometimes referred to simply as dose. Water is frequently selected as the specified material for defining absorbed dose. In practice, dosimeters are most often calibrated in terms of dose to water. That is, the dosimeter measures the dose that water would absorb if it were placed at the location of the dosimeter. Water is a convenient medium to use because it is universally available and understood, and its radiation absorption and scattering properties are close to those of tissue. The requirement of tissue-equivalency historically originates from radiation-therapy applications. However, to determine the temperature increase in an irradiated material, it is necessary to know the absorbed dose in that material. This may be determined by applying conversion factors in accordance with ISO/ASTM Guide 51261.

3.1.2 *absorbed-dose mapping (for a process load)*—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 *average beam current*—time-averaged electron beam current.

3.1.3.1 *Discussion*—For a pulsed machine, the averaging shall be done over a large number of pulses.

3.1.4 *beam length*—dimension of the irradiation zone along the direction of product movement, at a specified distance from the accelerator window (see Fig. 1).

3.1.4.1 *Discussion—(1)* This term usually applies to electron irradiation. *(2)* Beam length is therefore perpendicular to beam width and to the electron beam axis. *(3)* In case of a low-energy, single-gap electron accelerator, beam length is equal to the active length of the cathode assembly in vacuum. *(4)* In case of product that is stationary during irradiation, 'beam length' and 'beam width' may be interchangeable.

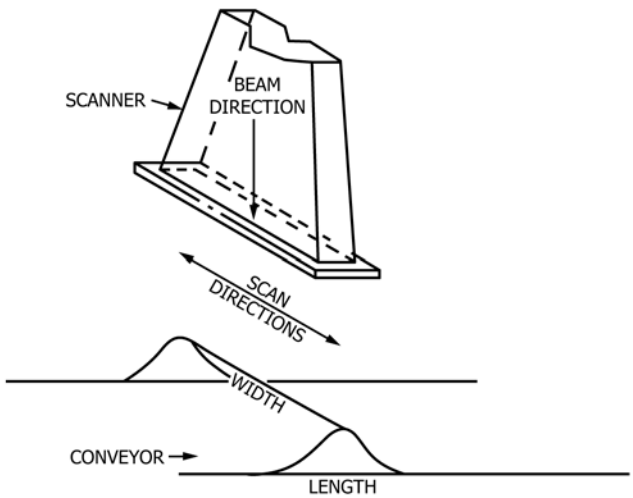


FIG. 1 Diagram showing beam length and width for a scanned beam using a conveyor system

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

3.1.5 *beam width*—dimension of the irradiation zone perpendicular to the direction of product movement, at a specified distance from the accelerator window (see Fig. 1).

3.1.5.1 *Discussion—(1)* This term usually applies to electron irradiation. *(2)* Beam width is therefore perpendicular to beam length and to the electron beam axis. *(3)* In case of product that is stationary during irradiation, 'beam width' and 'beam length' may be interchangeable. *(4)* Beam width may be quantified as the distance between two points along the dose profile, which are at a defined fraction of the maximum dose value in the profile (see Fig. 2). *(5)* Various techniques may be employed to produce an electron beam width adequate to cover the processing zone, for example, use of electromagnetic scanning of pencil beam (in which case beam width is also referred to as scan width), defocusing elements, and scattering foils.

3.1.6 *bremsstrahlung*—broad-spectrum electromagnetic radiation emitted when an energetic charged particle is influenced by a strong electric or magnetic field, such as that in the vicinity of an atomic nucleus.

3.1.6.1 *Discussion*—In radiation processing, bremsstrahlung photons with sufficient energy to cause ionization are generated by the deceleration or deflection of energetic electrons in a target material. When an electron passes close to an atomic nucleus, the strong coulomb field causes the electron to deviate from its original motion. This interaction results in a loss of kinetic energy by the emission of electromagnetic radiation. Since such encounters are uncontrolled, they produce a continuous photon energy distribution that extends up to the maximum kinetic energy of the incident electron. The bremsstrahlung spectrum depends on the electron energy, the composition and thickness of the target, and the angle of emission with respect to the incident electron. Even though bremsstrahlung has broad energy spectrum, the energy of the incident electron beam is referred to as the nominal bremsstrahlung energy.

3.1.7 *compensating dummy*—See *simulated product* (3.1.35).

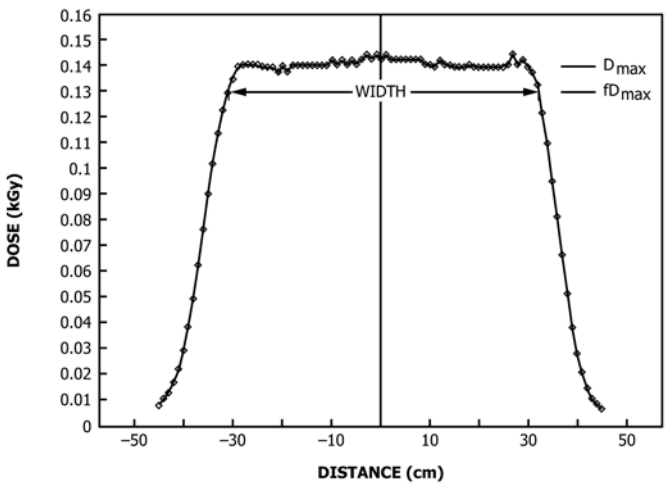


FIG. 2 Example of measured electron-beam dose distribution along the beam width, where the beam width is noted at some defined fractional level *f* of the average maximum dose D_{max}

3.1.8 *continuous-slowing-down-approximation range (CSDA range), r_0*—average path length traveled by a charged particle as it slows down to rest, calculated under the continuous-slowing-down approximation (see ICRU Report 35).

3.1.8.1 *Discussion*—Values of r_0 for a wide range of electron energies and for several materials are tabulated in ICRU Report 37.

3.1.9 *depth-dose distribution*—variation of absorbed dose with depth from the incident surface of a material exposed to a given radiation (see Fig. 3 for a typical distribution).

3.1.9.1 *Discussion*—Depth-dose distributions for several homogeneous materials produced by electron beams of different energies are shown in ISO/ASTM Practice 51649.

3.1.10 *dose uniformity ratio (for a process load)*—ratio of the maximum to the minimum absorbed dose within the process load. The concept is also referred to as the max/min dose ratio.

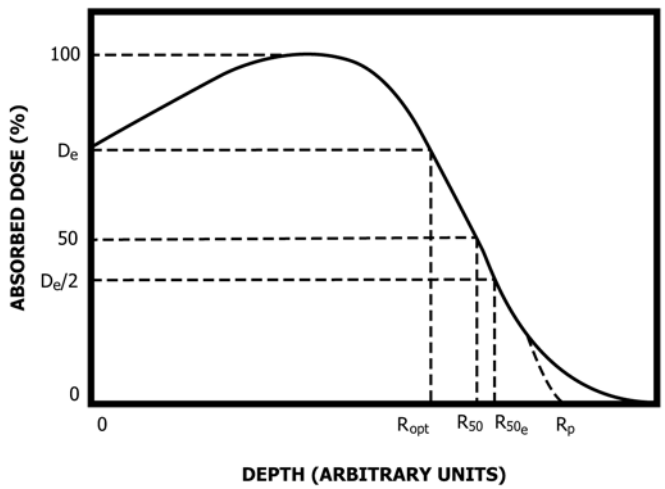
3.1.11 *dosimeter set*—one or more dosimeters used to measure absorbed dose at a location and whose average response is used to determine absorbed dose at that location.

3.1.12 *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.

3.1.13 *electron beam energy*—average kinetic energy of the accelerated electrons in the beam. Unit: J

3.1.13.1 *Discussion*—Electron volt (eV) or its multiples is often used as the unit for electron (beam) energy, where 1 eV = 1.602×10^{-19} J (approximately).

3.1.14 *electron beam range*—penetration distance of an electron beam along its axis in a specific, totally absorbing material.



NOTE 1—The peak-to-surface dose ratio depends on the energy of the incident electron beam (ICRU Report 35). The distribution shown here is typically for about 10 MeV electrons. For this case, $R_p = R_{ex}$, since X-ray background is negligible. For the case where R_p is not equal to R_{ex}, see ISO/ASTM Practice 51649, Annex A1.

FIG. 3 Typical (idealised) depth-dose distribution for an electron beam in a homogeneous material composed of elements of low atomic number

3.1.14.1 *Discussion*—This quantity may be defined and evaluated in several ways. For example, 'extrapolated electron beam range, R_{ex}' (see 3.1.16), 'practical electron beam range, R_p' (see 3.1.23), and 'continuous-slowing-down-approximation range, r_0' (see 3.1.8). R_p and R_{ex} can be determined from measured depth-dose distributions in a reference material (see Fig. 3). Electron range is usually expressed in terms of mass per unit area ($kg \cdot m^{-2}$), but sometimes in terms of thickness (m) of a specific material.

3.1.15 *electron energy spectrum*—particle fluence distribution of electrons as a function of energy.

3.1.16 *extrapolated electron beam range, R_{ex}*—depth from the incident surface of a reference material where the electron beam enters to the point where the tangent at the steepest point (the inflection point) on the almost straight descending portion of the depth-dose distribution curve meets the depth axis.

3.1.16.1 *Discussion*—Under certain conditions, $R_{ex} = R_p$, which is shown in Fig. 3. These conditions generally apply to foodstuff irradiated at electron energy equal to or less than 10 MeV. Also see 3.1.23.

3.1.17 *half-entrance depth, (R_{50e})*—depth in homogeneous material at which the absorbed dose has decreased to 50 % of the absorbed dose at the entrance surface of the material (see Fig. 3).

3.1.18 *half-value depth (R_{50})*—depth in homogeneous material at which the absorbed dose has decreased 50 % of its maximum value (see Fig. 3).

3.1.19 *installation qualification (IQ)*—obtaining and documenting evidence that the irradiator, with all its associated equipment and instrumentation, has been provided and installed in accordance with specification.

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

3.1.21 *optimum thickness (R_{opt})*—depth in homogeneous material at which the absorbed dose equals the absorbed dose at the surface where the electron beam enters (see Fig. 3).

3.1.22 *performance qualification (PQ)*—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.

3.1.23 *practical electron beam range (R_p)*—depth from the incident surface of a reference material where the electron beam enters to the point where the tangent at the steepest point (the inflection point) on the almost straight descending portion of the depth-dose distribution curve meets the extrapolated X-ray background (see Fig. 3). See ISO/ASTM 51649 for more details.

3.1.23.1 *Discussion*—For energies below about 10 MeV, the X-ray background created by the incident electrons is insignificant for materials composed of elements with low atomic numbers (such as foodstuff). For this case, $R_p = R_{ex}$ (see 3.1.16).

3.1.24 *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).

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

3.1.26 *production run (for continuous-flow and shuffle-dwell irradiations)*—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.

3.1.27 *pulse rate*—pulse repetition frequency in hertz (Hz).

3.1.27.1 *Discussion—(1)* This is relevant to a pulsed accelerator. *(2)* It is also referred to as pulses per second or repetition (rep) rate.

3.1.28 *pulse width*—time interval between two points on the leading and trailing edges of the pulse beam current waveform where the current is 50 % of its peak value.

3.1.28.1 *Discussion*—This is relevant to a pulsed accelerator.

3.1.29 *reference material*—material with one or more properties, which are sufficiently well established to be used for calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

3.1.30 *reference plane*—selected plane in the radiation zone that is perpendicular to the electron beam axis.

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

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

3.1.33 *scanned beam*—electron beam that is swept back and forth with a varying magnetic field.

3.1.33.1 *Discussion*—This is most commonly done along one dimension (beam width); although two-dimensional scanning (beam width and length) may be used with high-current electron beams to avoid overheating the beam exit window, or the X-ray target.

3.1.34 *scan frequency*—number of complete scanning cycles per second expressed in Hz.

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

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

3.1.36 *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).

3.1.37 *X-radiation*—ionizing electromagnetic radiation, which includes both bremsstrahlung and the characteristic radiation emitted when atomic electrons make transitions to more tightly bound states. See 3.1.6.

3.1.38 *X-ray*—see *X-radiation*.

3.1.38.1 *Discussion*—In radiation processing applications, the principal X-radiation source is bremsstrahlung. The term X-radiation may be used to refer to X-ray.

3.1.39 *X-ray converter*—device for generating X-rays (bremsstrahlung) from an electron beam, consisting of a target, means for cooling the target, and a supporting structure.

3.1.40 *X-ray target*—that component of the X-ray converter that is struck by the electron beam.

3.1.40.1 *Discussion*—It is usually made of metal with high atomic number, high melting temperature, and high thermal conductivity.

3.2 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found in ASTM Terminology E170. Definitions in E170 are compatible with ICRU 60; therefore, ICRU 60 may be used as an alternative reference.

4. Significance and use

4.1 Food products may be treated with accelerator-generated radiation (electrons and X-rays) for numerous purposes, including control of parasites and pathogenic microorganisms, insect disinfestation, growth and maturation inhibition, and shelf-life extension. Food irradiation specifications almost always include a minimum or a maximum limit of absorbed dose, sometimes both: a minimum limit may be set to ensure that the intended beneficial effect is achieved and a maximum limit may be 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 consistently 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 For more detailed discussions of radiation processing of various foods, see Guides F1355, F1356, F1736, and F1885 and Refs (**2-15**).

4.3 Accelerator-generated radiation can be in the form of electrons or X-rays produced by the electrons. Penetration of radiation into the product required to accomplish the intended effect is one of the factors affecting the decision to use electrons or X-rays.

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

5. Radiation source characteristics

5.1 *Electron Facilities*—Radiation sources for electrons with energies greater than 300 keV considered in this practice are either direct-action (potential-drop) or indirect-action (microwave-powered or radiofrequency-powered) accelerators. The radiation fields depend on the characteristics and the design of the accelerators. Beam characteristics include the electron beam parameters, such as, electron energy spectrum, average electron beam current, pulse duration, beam cross section, and beam current distribution on the product surface. For a more complete discussion refer to ISO/ASTM Practice 51649.

5.2 *X-ray Facilities:*

5.2.1 A high-energy X-ray generator emits short-wavelength electromagnetic radiation (photons), whose effects on irradiated materials are generally similar to those of gamma radiation from radioactive nuclides. However, these kinds of radiation differ in their energy spectra, angular distribution and dose rates.

5.2.2 The characteristics of the X-rays depend on the design of the X-ray converter and the parameters of the electron beam striking the target, that is, electron energy spectrum, average beam current, and beam current distribution on the target.

5.2.3 The physical characteristics of an X-ray source and its suitability for radiation processing are further discussed in ISO/ASTM Practice 51608.

5.3 Codex Alimentarius Commission (**1**) as well as regulations in some countries currently limit the maximum electron energy and X-ray energy for the purpose of food irradiation.

6. Irradiation facilities

6.1 The design of an irradiation facility affects the delivery of absorbed dose to a product. Therefore, the facility design should be considered when performing the absorbed-dose measurements required in Sections 10 – 12.

6.2 *Facility Components*—Electron and X-ray irradiation facilities include the electron beam accelerator system; product handling system; a radiation shield with personnel safety system; product loading, unloading and storage areas as required by regulations; auxiliary equipment for power, cooling, ventilation, etc.; equipment control room; a laboratory for dosimetry; and personnel offices. An X-ray facility also includes an X-ray converter (see ISO/ASTM Practice 51608).

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

6.3 *Electron Accelerator*—The electron beam accelerator system consists of the radiation source, equipment to disperse the beam on product, and associated equipment. These aspects are further discussed in ISO/ASTM Practice 51649.

6.4 *Product Handling System:*

6.4.1 The absorbed-dose distribution within the food product being irradiated may be affected by the configuration of the product handling system.

6.4.2 *X-ray Facilities*—The penetrating quality of high-energy photons permits the treatment of large containers or full pallet loads of food products. For optimum photon power utilization and dose uniformity, the container size depends on the maximum energy and product density. The narrow angular distribution of the radiation favors the use of continuously moving conveyors rather than shuffle-dwell systems to enhance dose uniformity.

6.4.3 *Electron Facilities*—For optimum beam power utilization and dose uniformity, the process load size depends on the beam energy and product density. Two different configurations are commonly used.

6.4.3.1 *Conveyors or Carriers*—Process loads containing food products are placed upon carriers or conveyors for passage through the electron beam. The speed of the conveyor or carriers is controlled so that the required dose is delivered. Also see Note 13.

6.4.3.2 *Bulk-flow System*—For irradiation of liquids or particulate foodstuff like grain, bulk-flow transport through the irradiation zone may be used.

7. Dosimetry systems

7.1 Dosimetry systems are used to measure absorbed dose. They consist of dosimeters, measurement instruments and their associated reference standards, and procedures for the system's use (see ASTM Practice E1026 and Guide E2304 and ISO/ASTM Practices 51205, 51275, 51276, 51310, 51401, 51538, 51540, 51607, 51650, 51956 and ISO/ASTM Guide 51261.

NOTE 4—For a comprehensive discussion of various dosimetry methods applicable to the radiation types and energies discussed in this practice, see ICRU Reports 14, 34 and 35, and Ref (**16**).

7.2 *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.

7.2.1 *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.

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

7.2.3 *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.

7.2.4 *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.

7.3 *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. For accelerator applications, it is also essential to consider the influences of absorbed-dose rate (average and peak dose rate for pulsed accelerators), pulse rate and pulse width (if applicable) on dosimeter performance. Some of the dosimetry systems that are suitable for gamma radiation from radioactive nuclides (such as those from ^{60}Co) may also be suitable for X-rays (**17**).

NOTE 5—Dosimeters consisting mainly of water or hydrocarbon materials are generally suitable for both gamma radiation from radioactive nuclides and X-rays. Some exceptions are dosimeters containing substantial amounts of material with elements of high atomic numbers which are highly sensitive to the low-energy photons in the X-ray spectrum. Also, the X-ray dose rate may be higher than that for an isotopic gamma-ray source used for radiation processing, especially in products passing near the converter. The dose-rate dependence of the dosimeters should be considered in their calibration procedure (**18,19**).

7.4 *Calibration of Dosimetry Systems:*

7.4.1 A dosimetry system shall be calibrated prior to use and at intervals thereafter, in accordance with the user's documented procedure that specifies details of the calibration process and quality assurance requirements. Calibration requirements are given in ISO/ASTM Guide 51261.

7.4.2 *Calibration Irradiation*—Irradiation is a critical component of the calibration of the dosimetry system. Acceptable ways of performing the calibration irradiation depend on whether the dosimeter is used as a reference-standard, transfer-standard or routine dosimeter.

7.4.2.1 *Reference- or Transfer-Standard Dosimeters*—Calibration irradiations shall be performed at a national or accredited laboratory using criteria specified in ISO/ASTM Practice 51400.

7.4.2.2 *Routine Dosimeters*—The calibration irradiation may be performed by irradiating the dosimeters at *(a)* a national or accredited laboratory using criteria specified in

ISO/ASTM Practice 51400, *(b)* 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 *(c)* a production irradiator under actual production irradiation conditions, together with reference- or transfer-standard dosimeters that have measurement traceability to nationally or internationally recognized standards. In case of option *(a)* or *(b)*, the resulting calibration curve shall be verified for the actual conditions of use.

7.4.3 *Measurement Instrument Calibration and Performance Verification*—For the calibration of the instruments, and for the verification of instrument performance between calibrations, see ISO/ASTM Guide 51261, the corresponding ISO/ASTM or ASTM standard for the dosimetry system, and/or instrument-specific operating manuals.

8. Process parameters

8.1 Parameters characterizing the components of the irradiation facility, the process load and the irradiation conditions are referred to as process parameters. The establishment and control of these parameters will determine the absorbed dose received by a product.

8.2 For irradiation facilities with accelerator-generated radiation (electrons and X-rays) process parameters include:

8.2.1 Beam characteristics (for example, electron beam energy, beam current, pulse frequency, pulse duration, beam cross section, X-ray converter design),

8.2.2 Beam dispersion (for example, scan width, scan frequency, collimator aperture),

8.2.3 Product handling characteristics (for example, conveyor speed),

8.2.4 Product loading characteristics (for example, size of the process load, bulk density, orientation of product), and

8.2.5 Irradiation geometry (for example, 1- or 2-sided irradiation, multiple passes, reflectors).

8.3 The first three sets of parameters (8.2.1, 8.2.2 and 8.2.3) are used to characterize the irradiation facility without reference to the product or the process. These parameters are referred to as operating parameters.

NOTE 6—Procedures during operational qualification (OQ) deal with operating parameters. The objective of performance qualification (PQ) is to establish the values of all process parameters (including operating parameter) for the radiation process under consideration. During routine product processing, operating parameters are continuously controlled and monitored for process control.

9. Installation qualification

9.1 *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 help ensure correct operation of the irradiator.

9.2 *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:

9.2.1 Description of the location of the irradiator (accelerator) 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,

9.2.2 Accelerator specifications and characteristics,

9.2.3 Description of the operating procedure of the irradiator,

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

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

9.2.6 Description of the process control system, and

9.2.7 Description of any modifications made during and after the irradiator installation.

9.3 *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.

9.3.1 *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.

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

9.3.3 *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. Calibration of some equipment and instruments might be required to be traceable to a national or other accredited standards laboratory.

9.4 *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 9.3.1. If necessary, ensure that the equipment and instruments have been calibrated according to the calibration procedures noted in 9.3.3.

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

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

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

10. Operational qualification

10.1 *Objective*—The purpose of dosimetry in the operational qualification (OQ) is to establish baseline data for evaluating facility predictability, and reproducibility over the expected range of conditions of operation for the key operating parameters that affect absorbed dose in the product **(20)**. Thus, dosimetry is used:

10.1.1 To measure absorbed-dose distributions in reference material(s) – this process is sometimes referred to as 'dose mapping' (see 10.3),

10.1.2 To measure absorbed-dose characteristics over the expected operational range of the operating parameters for reference conditions (see 10.4),

10.1.3 To characterize absorbed-dose variations when operating parameters fluctuate statistically during normal operations (see 10.5), and

10.1.4 To establish the effect of a process interruption/restart (see 10.6).

10.2 *Dosimetry Systems*—Calibrate the dosimetry systems to be used at the facility as discussed in Section 7.

10.3 *Dose Mapping:*

10.3.1 Map the absorbed-dose distribution by a three-dimensional placement of dosimeter sets in a process load containing homogeneous reference material (such as grains, cardboard or sheets of plastics) as discussed in ASTM Guide E2303 (also see Refs **16,21**). The amount of 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.

NOTE 7—Dosimeter strips or sheets may be used to increase spatial resolution of the absorbed-dose map (especially for electron beam irradiations), if the use of individual dosimeters is inadequate.

10.3.2 The procedure for absorbed-dose mapping outlined in 10.3.1 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 the product through the irradiation zone. Enough dosimeters should be used to obtain statistically significant results.

NOTE 8—Theoretical calculations may be performed using the Monte Carlo methods **(22)**, and applied to industrial radiation processing **(23)**. The use of the point-kernel method is not recommended for electron beam but can be considered for X-ray facilities **(24)**. Both these methods require accurate radiation interaction cross-sections for all materials between and surrounding the source point and dose point. General-purpose software packages are available for these types of calculations (see ASTM Guide E2232). Models built using these codes should be validated against dosimetry data for their predictions to be meaningful. Empirically derived models built directly from dosimetry data may be satisfactory but should be applied within the boundaries of experiments at a specific facility.

10.3.3 For electron facilities, establishment of the depth-dose distribution in a homogeneous reference material is a special type of 1-dimensional dose mapping. This can be achieved with either a stack geometry or a wedge; both in conjunction with a film dosimetry system (see ISO/ASTM Practice 51649). The exact shape of the dose distribution will be different for different facilities since it depends on the energy spectrum of the electron beam and the irradiation geometry **(25)**. The depth of penetration depends on electron energy.

NOTE 9—For electron beam, Fig. 3 illustrates a typical depth-dose distribution in a homogeneous material. The range parameters, R_{opt}, R_{50}, and R_{50e} may be used for designing a suitable process load. For an X-ray facility, the depth-dose distribution in a homogeneous material with low atomic number is approximately exponential, and penetration for 5 MeV X-rays is slightly greater than that for cobalt-60 gamma radiation (see ISO/ASTM Practice 51608, Fig. A1.7).

10.4 *Absorbed Dose and Operating Parameters:*

10.4.1 *Objective*—The dose in the product depends on several operating parameters (such as, conveyor speed, beam current, beam energy, scan width). Over the expected range of these parameters, establish the absorbed-dose characteristics in a reference material using appropriate dosimetry.

10.4.1.1 The depth-dose distribution depends on beam energy and the reference material characteristics.

10.4.1.2 Surface dose and its uniformity depend on conveyor speed, beam characteristics and beam dispersion.

10.4.2 *Depth-dose Distribution*—For electron beam facilities, establish depth-dose distributions for the expected ranges of beam energy and the reference material bulk density, for 1-sided and 2-sided irradiation.

NOTE 10—For X-ray irradiators, photon energy spectrum and angular distribution depend on the design and composition of the X-ray converter and on the electron energy spectrum (see ISO/ASTM Practice 51608). Higher energy electrons will increase forward focus of the photon distribution and therefore improve penetration in the product **(26)**.

10.4.3 *Surface Dose*—Establish the relationships between surface dose (or dose in a reference plane) and conveyor speed, beam characteristics and beam dispersion parameters over the expected range of operation (see ISO/ASTM Practice 51649).

10.4.3.1 Establish the range of uniform surface dose that can be delivered to reference material. This will set the range of operation for the conveyor speed, pulse rate and scan frequency.

NOTE 11—Electron beam and X-ray irradiators generally utilize continuously moving conveyors. Dose uniformity in a reference plane is strongly influenced by the coordination of the beam spot dimensions, conveyor speed and scan frequency (for those irradiators that employ beam scanning). For a pulsed-beam accelerator, all these parameters must also be coordinated with the pulse width and pulse rate. Improper coordination of these parameters can cause unacceptable dose variation in the reference plane.

NOTE 12—Indirect-action accelerators may deliver higher dose rates during the pulse compared to direct-action accelerators with the same average beam current. Also, scanning of a small-diameter beam can produce dose pulses at points along the beam width. This can influence the dosimeters' performance if they are sensitive to dose rate.

10.4.3.2 Establish relationship between surface dose and conveyor speed, where all other operating parameters are held constant. Generally, surface dose should be inversely proportional to the conveyor speed.

NOTE 13—The conveyor speed and the beam current may be linked during routine product processing so that a variation in one causes a corresponding change in the other to maintain a constant value of the surface (or reference plane) dose.

10.4.3.3 For X-ray irradiators, absorbed dose rate also depends on the incident electron energy spectrum and the design of the X-ray converter.

10.5 *Dose Variability:*

10.5.1 Establish the capability of the facility to deliver a reproducible dose in a reference geometry. Measure the fluctuations in the operating parameter values that may cause variation in absorbed dose. Estimate the magnitude of the corresponding dose variations in a reference material, for example, by passing dosimeters in the reference geometry through the irradiation zone on the product conveyor at time intervals appropriate to the frequency of the parameter fluctuations. The irradiation geometry for the reference material should be selected so that the placement of the dosimeters on and within the material will not affect the reproducibility of the measurements.

10.5.2 Following the procedure of 10.3, map a sufficient number of nominally identical process loads containing reference material 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.

10.6 *Process Interruption/Restart:*

10.6.1 In the event of a process interruption, for example stoppage of the conveyor system due to power failure, the implication of a restart on the process (for example, uniformity of dose in a reference plane) shall be investigated.

10.6.1.1 Expose an array of dosimeters or a strip of dosimeter film in a reference plane through a stop/start sequence of the conveyor system.

10.6.1.2 The delivery of dose within specifications through the stop/start sequence would suggest that the conveyor could be restarted after the failure to continue the process. The effect of the process interruption (for example, time delay) on the product itself is discussed in 12.6.

10.6.1.3 If the dose is found to be significantly non-uniform through the stop/start sequence, the subsequent impact on the process shall be evaluated.

10.6.2 The procedure described in 10.6.1.1 – 10.6.1.3 should be conducted for the extremes of the operating parameters.

10.7 *Documentation and Maintenance of OQ*—The baseline data collected during the procedures described in 10.2 – 10.6 shall be documented. These procedures shall be repeated periodically as specified in the quality assurance program to update the baseline data from the previous operational qualification.

10.8 *Facility Changes*—If changes that could affect the magnitudes or locations of the absorbed-dose extremes are made to the facility (for example, accelerator, X-ray converter, conveyor) or its mode of operation, repeat the operational qualification procedures to the extent necessary to establish the effects.

11. Performance qualification

11.1 *Objective*—Minimum and maximum absorbed-dose limits are almost always associated with food-irradiation applications. For a given application, one or both of these limits may be prescribed by government regulations. Dosimetry is used in performance qualification to determine the appropriate values of process parameters for ensuring that the absorbed-dose requirements for a particular product can be satisfied. This is accomplished by absorbed-dose mapping (see 11.3) of process loads with specific product and product loading configurations using dosimetry procedures described in this section.

11.2 *Product Loading Configuration:*

11.2.1 A loading configuration of product within the process load shall be established for each product type. The specification for this loading pattern shall document the following:

11.2.2 Product type, product size, product density and bulk density of the process load, and if applicable, description of the orientation of the product within its package.

11.2.3 Orientation of the product or its package with respect to the beam axis.

11.3 *Product Absorbed-Dose Mapping:*

11.3.1 The purpose of product dose mapping is to determine the magnitudes and locations of the regions of minimum and maximum absorbed dose for the selected product loading configuration. This is accomplished by placing dosimeter sets throughout the volume of interest for one or more process loads (see ASTM Guide E2303). Select placement patterns to identify the locations of the absorbed-dose extremes, using data obtained from the absorbed-dose mapping studies during operational qualification (see 10.3) or from theoretical calculations (see ASTM Guide E2232). Concentrate dosimeter sets in the expected regions of minimum and maximum absorbed dose with fewer dosimeter sets placed in areas likely to receive intermediate absorbed dose.

11.3.1.1 In a process load containing voids or non-uniform product, include dosimeter sets at locations where discontinuities in composition or density may affect the regions of maximum or minimum absorbed dose.

11.3.1.2 Dosimeters used for dose mapping must be capable of responding to doses and dose gradients likely to occur within irradiated products. For electron irradiation, dosimeter films in sheets or strips may be useful for obtaining this information. The dosimeters used for this dose mapping procedure and for routine dose monitoring (12.4) need not be of the same type.

11.3.1.3 *End Process Loads*—For a production run with contiguous process loads, the first and last process loads may experience dose distributions different from the other units. Perform dose mapping for process loads for this geometry to verify that the dose distribution is acceptable. If it is not, compensating dummies will need to be placed adjacent to these end units, during routine product processing (see 12.1.3).

11.3.1.4 *Partial Loading*—For partially-loaded process loads, follow the same performance qualification requirements as for fully-loaded process loads. Perform the dose mapping procedure of 11.3.1 to ensure that the absorbed-dose distributions are adequately characterized and are acceptable. Variations to the dose distribution from a partial loading may in some cases be minimized by the use of compensating dummy material placed at appropriate locations within the process load.

11.3.2 *Chilled or Frozen Food Products:*

11.3.2.1 The response of nearly all dosimeters is temperature-dependent, and this dependence often varies with absorbed dose. Thus, for chilled and frozen food applications, dosimetry may be performed following one of two methods:

11.3.2.2 Absorbed-dose mapping may be performed with the actual product or simulated product at room temperature. This requires that there be no change in any parameter that may affect the absorbed dose during processing of the chilled or frozen food. Dose mapping at room temperature includes placement of one or more dosimeters at a reference dose location (11.3.4) that would be isolated from temperature gradients in the actual product during routine processing. Routine dosimeters should be placed at this reference dose location during routine processing of the chilled or frozen product.

11.3.2.3 Absorbed-dose mapping may be performed at the temperature to which the food will be chilled or frozen during actual product processing, using a dosimetry system that can be characterized at the intended processing temperature or whose response is not significantly affected by temperature. The temperature of the food and the dosimeter during irradiation must be maintained relatively constant (for example, by using insulated totes).

11.3.3 *Bulk-Flow Irradiators*—Absorbed-dose mapping as described in 11.3.1 may not be feasible for products flowing through the irradiation zone in bulk. 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 (**5**). Enough dosimeters should be used to obtain statistically significant results.

11.3.4 *Reference Dose Locations*—If the locations of absorbed dose extremes identified during the dose mapping procedure of 11.3.1 are not readily accessible during production runs, alternative locations (external or internal to the process load) may be used for routine product processing dosimetry. The relationships between the absorbed doses at these alternative reference dose locations and the absorbed-dose extremes shall be established, shown to be reproducible, and documented.

11.4 *Dose Variability:*

11.4.1 When dose mapping a specific product loading configuration, consideration should be given to possible variations in the absorbed doses measured at similar locations in different process loads.

11.4.2 To evaluate the extent of this dose variability, place dosimeter sets in the expected regions of the minimum and maximum absorbed doses in several process loads and irradiate them under the same conditions. The measured variations in the absorbed-dose values reflect, for example, variations in product loading configuration (due to shifts in the contents of the process load during its movement through the irradiator), small differences in bulk density of the process loads, fluctuations in operating parameter values, and the uncertainty in the routine dosimetry system.

11.4.3 *Target Dose Values*—Because of this statistical nature of the absorbed-dose measurement and the inherent variations in the radiation process, select the operating parameters to deliver an absorbed dose to product greater than any prescribed minimum dose and smaller than any prescribed maximum dose (**8**,**27**). This requirement in effect modifies the process dose limits; these modified dose limits may be referred to as 'target dose values.' Select these target dose values so that there is an acceptably low probability of irradiating the product or part of the product with doses lower than the required minimum or higher than the allowed maximum, and that this probability is known and documented. For further discussion on determination of the target dose values, see Refs (**3**,**28**).

11.5 *Unacceptable Dose Uniformity Ratio:*

11.5.1 If the dose mapping procedure of 11.3 reveals that the measured dose uniformity ratio is unacceptably large, for example, larger than the ratio between the modified values of the maximum and minimum absorbed-dose limits (such as target dose values), change the process parameters (operating parameters, process load characteristics or irradiation conditions) to reduce the ratio to an acceptable level.

11.5.1.1 *Operating Parameters*—Changing the beam characteristics, for example, by optimizing the electron energy, can reduce the dose uniformity ratio. Other means to reduce the dose uniformity ratio may be employed, such as the use of attenuators, scatterers, and reflectors (**29**,**30**).

11.5.1.2 *Irradiation Conditions*—Depending on the bulk density, thickness, and heterogeneity of a process load, some processes may require a double-sided irradiation to achieve an acceptable dose uniformity ratio (**3**), also see ISO/ASTM Practice 51649. For double-sided irradiation, the regions of maximum and minimum dose may be quite different from those for single-sided irradiation (see Figs. 4 and 5 for electron beam irradiation). For electron irradiation therefore, caution is necessary for a double- (or multiple-) sided irradiation because slight variation in the thickness or bulk density of the process load or in the electron energy can lead to an unacceptable dose near the middle of the process load. In the case of bulk-flow irradiators, absorbed-dose uniformity can be improved by arranging baffles to control product flow through the irradiation zone.

11.5.1.3 *Process Load Characteristics*—For some cases, a redesign of the process load may be needed to achieve an acceptable dose uniformity ratio.

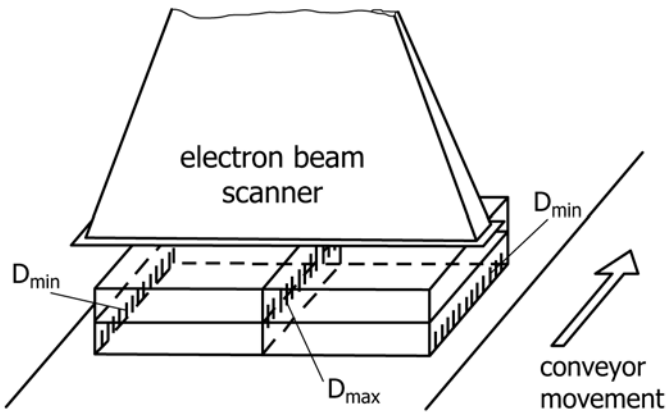


FIG. 4 Regions of D_{max} and D_{min} (indicated by hatching) for a rectangular process load after one-sided irradiation using an electron beam

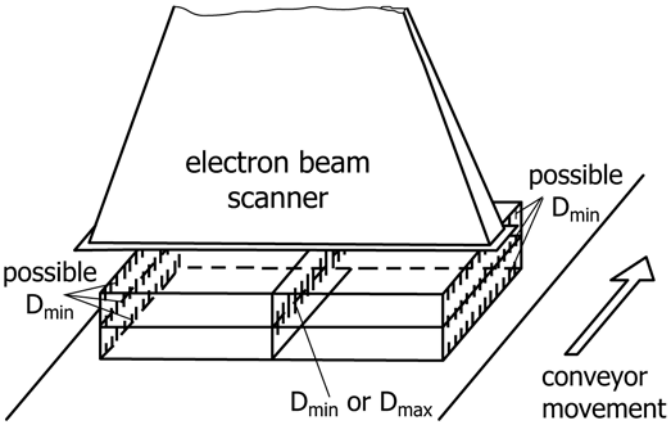


FIG. 5 Regions of D_{max} and D_{min} (indicated by hatching) for a rectangular process load after two-sided irradiation using an electron beam

11.5.2 If any process parameter that affects the magnitudes or locations of maximum and minimum absorbed dose is changed (for example, for the purpose of improving the dose uniformity ratio), repeat the dose mapping to the extent necessary to establish the effects. The information gathered during operational qualification (Section 10) should serve as a guide in determining the extent of these absorbed-dose mapping studies.

11.6 The procedures described above should yield the appropriate values of all process parameters (namely, all key operating parameters, process load characteristics and irradiation conditions) that would satisfy the dose requirements for all types of process loads that have been mapped. Document these values for future use.

12. Routine product processing

12.1 *Routine Procedure:*

12.1.1 Before commencing routine product processing, set all process parameters as established during performance qualification to ensure that the product in each process load will be processed within specifications (see 11.6).

NOTE 14—The average beam current *I* and the conveyor speed *v* may be set in such a way that the quotient *I/v* has the same value in performance qualification and in routine product processing. For example, if the beam current is lowered by 20 %, the conveyor speed should be decreased by the same percentage for the same absorbed dose to be delivered.

12.1.2 Ensure that product loading configuration remains the same for all process loads, and constant for the bulk-flow irradiation.

12.1.3 *End Process Loads*—For a production run with contiguous process loads, the first and last process loads may experience dose distributions different from the other units. As determined during performance qualification (see 11.3.1.3), it may be necessary to place compensating dummies adjacent to these units so as to make their dose distributions acceptable.

12.1.4 *Partial Loading*—For partially-loaded process loads, ensure that the product loading configuration conforms to that established during performance qualification (see 11.3.1.4).

12.2 *Process Control*—Demonstrate that the irradiation process is continuously under control through these process control elements: (*1*) continuously controlling and monitoring during product processing all operating parameters that affect dose (see 12.3), and (*2*) use of routine production dosimetry (see 12.4). Additionally, the application of radiation-sensitive indicators to process loads or product packages may be a convenient means to show that they have been irradiated and to assist in inventory control (see 12.5).

12.3 *Operating Parameters:*

12.3.1 Control, monitor and document the relevant operating parameters as evidence to show the continuity of the process, and thus to ensure that each process load is processed in accordance with specifications.

12.3.2 If these parameters deviate outside the tolerance limits prescribed during performance qualification, take appropriate actions. For example, immediately interrupt the process to evaluate and correct the cause of the deviations.

12.4 *Routine Production Dosimetry:*

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

NOTE 15—Dosimeters used for routine dosimetry need not be of the same type as those used for the absorbed-dose mapping procedure.

12.4.2 *Dosimeter Location*—Place dosimeter sets either in or on the selected process loads at predetermined locations of the maximum or minimum absorbed dose (see 11.3), or alternatively, at the reference dose locations discussed in 11.3.4.

12.4.3 *Placement Frequency*—It is not necessary to have routine dosimeters on every process load. Select a sufficient number of process loads on which to place dosimeter sets at the locations described in 12.4.2 in order to verify that the absorbed doses for the entire production run fall within specified limits. Always place dosimeter sets at the start of the run. For long production runs, place dosimeter sets at other intervals as appropriate. Available dosimetry data may be useful in determining this.

NOTE 16—More frequent (than suggested in 12.4.3) placement of dosimeters during the production run will provide more dosimetry information that could result in less product rejection if some operational uncertainty or failure arises (such as malfunction of the conveyor speed measurement equipment).

12.4.4 *Bulk-flow*—For some types of bulk-flow irradiators (for example, where fluids or grains continuously flow during irradiation), it may not be feasible during routine production to place dosimeters at the locations of minimum and maximum absorbed dose. In this case, add several dosimeters mixed randomly with and carried by the product through the irradiation zone at the beginning of the production run. For a long irradiation run, also add dosimeters at the middle and near the end of the production run or as required by regulations. Each set of absorbed-dose measurements requires several dosimeters to ensure, at a specified level of confidence that the minimum and maximum absorbed doses are known. This procedure requires that the dosimeters flow in the same path through the irradiation zone and at the same rate as the product **(5,10)**.

NOTE 17—In case it is not feasible to measure dose during the routine processing of bulk materials, it may be acceptable to rely on operating parameter control. For some processes, it may be sufficient to determine the average dose and the maximum and minimum doses in process experiments using samples of food to be irradiated or simulated products. Calculation of dose extremes may also be acceptable (ASTM Guide E2232). The consistency of the dose distribution can be ensured by monitoring all of the critical operating parameters and by repeating the performance qualification procedure at appropriate intervals.

12.4.5 *Chilled or Frozen Food Products*—Use a dosimetry system that is characterized at the processing temperature, or that has insignificant temperature dependence. If a dosimetry system is used that is significantly temperature dependent, place the dosimeter(s) at a reference dose location(s) that is isolated from the temperature gradient (see 11.3.2). See ISO/ASTM Guide 51261 and practices for individual dosimetry systems listed in 2.1 and 2.2.

12.4.6 *Environmental Effects*—A change in the environment (for example, temperature, humidity) of a dosimeter during the irradiation process may affect its response. If required, apply a correction factor to the measured value of the dosimeter response to account for any such effect. Care must also be taken in handling and storage of dosimeters before and after irradiation. (See ISO/ASTM Guide 51261 and practices for individual dosimetry systems listed in 2.1 and 2.2.)

12.5 *Radiation-sensitive Indicators:*

12.5.1 In some applications, radiation-sensitive indicators (sometimes known as "go/no go" indicators) may be used to visually confirm that product packages or process loads have been exposed to a radiation source (see ISO/ASTM Guide 51539). These indicators provide only a qualitative indication of radiation exposure.

12.5.2 The color change of radiation-sensitive indicators is not always stable and may be affected by, for example, light or heat. Thus, they are useful only within the irradiation facility where these conditions are controlled.

12.5.3 For multiple irradiations, one indicator may be affixed before each pass on the side facing the radiation beam to give visual evidence of the number of passes the process load has traversed.

12.5.4 Their use is not a substitute for the dosimetry procedures described in 12.4.

12.5.5 While radiation-sensitive indicators can be used conveniently to assist in product inventory control, they shall not be used to replace other administrative inventory control procedures.

12.6 *Process Interruption*—If there is a process failure, for example due to power loss, its implication on the process (for example, dose uniformity) and the product (for example, impact of time delay) shall be evaluated before re-starting the process.

12.6.1 Based on the data collected during operational qualification (see 10.6), determine if the dose when the process is re-started would be adequately uniform for the process under consideration. If not, it may be necessary to discard those process loads affected by the process interruption.

12.6.2 Generally in food irradiation, the radiation-induced effect is additive as in the case of elimination/reduction of microorganisms and insect pests, and the process can be re-started from where it was interrupted.

12.6.3 However for some processes, such as delay of ripening/maturation, the effect of prolonged process interruption should be critically evaluated before re-starting the process.

12.6.4 If the product is irradiated at low temperatures or under frozen state, care should be taken to maintain those conditions throughout the interruption.

13. Measurement uncertainty

13.1 To be meaningful, a measurement of absorbed dose shall be accompanied by an estimate of uncertainty.

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

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

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

13.3 Other ways of categorizing uncertainty have been widely used and may be useful for reporting uncertainty. For example, the terms *precision* and *bias* or *random* and *systematic* (non-random) are used to describe different categories of uncertainty.

NOTE 18—The identification of Type A and Type B uncertainties is based on the methodology for estimating uncertainties published in 1995 by the International Organization for Standardization (ISO) in the Guide to the Expression of Uncertainty in Measurement (**31**). The purpose of using this type of characterization is to promote an understanding of how statements of uncertainty are developed and to provide a basis for the international comparison of measurement results.

NOTE 19—ISO/ASTM Guide 51707 defines possible sources of uncertainty in dosimetry performed in radiation processing facilities and offers procedures for estimating the magnitude of the resulting uncertainties in the measurement of absorbed dose using dosimetry. The document defines and discusses basic concepts of measurement, including estimation of the measured value of a quantity, "true" value, error, and uncertainty. Components of uncertainty are discussed and methods are provided for estimating their values. Methods are also provided for calculating the combined standard uncertainty and estimating expanded (overall) uncertainty.

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

14. Certification

14.1 *Documentation Accumulation:*

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

14.1.2 *Operating Parameters*—Record the values of the operating parameters (see 12.3) affecting absorbed dose together with sufficient information identifying these parameters with specific product lots or production runs.

14.1.3 *Dosimetry*—Record and document all dosimetry data for performance qualification (Section 11) and routine product processing (see 12.4). Include name of the operator, date, time, product type, loading diagrams, and absorbed doses for all product processed. Record the time of dosimeter analysis if the

post-irradiation stability of the dosimeters under the conditions of use requires time-dependent corrections to the dosimeter response.

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

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

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

14.2 *Review and Certification:*

14.2.1 Prior to release of product for use, review dosimetry results and recorded values of the operating parameters to verify compliance with specifications.

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

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

14.3 *Retention of Records*—File all information pertaining to each production run together (for example, copies of the shipping document, certificates of irradiation, and the irradiation control record (see 14.1.1 – 14.1.6). Retain the records for the period of time specified in the quality assurance program and have them available for inspection as needed.

15. Keywords

15.1 absorbed dose; bremsstrahlung; dose mapping; dosimeter; dosimetry; electron beam; food irradiation; food processing; ionizing radiation; irradiated food; irradiation; installation qualification; operational qualification; performance qualification; radiation; X-rays

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