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Practice for dosimetry in electron beam and X-ray (bremsstrahlung) irradiation facilities for food processing

Pratique de la dosimétrie dans les installations de traitement des produits alimentaires irradiés par faisceau d'électrons et de rayons X (bremsstrahlung)

Reference number
ISO/ASTM 51431:2005(E)

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Foreword

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

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

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

A 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 51431 was developed by ASTM Committee E10, Nuclear Technology and Applications, through Subcommittee E10.01, and by Technical Committee ISO/TC 85, Nuclear energy.

This second edition cancels and replaces the first edition (ISO/ASTM 51431:2002), which has been technically revised.

ISO/ASTM 51431:2005(E)

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 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 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 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 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]

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 2303 Guide for Absorbed-dose Mapping in Radiation Processing Facilities

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

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

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

F 1736 Guide for 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]

51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing

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

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

Current edition approved by ASTM Oct. 1, 2004. Published May 15, 2005. Originally published as E 1431–91. Last previous ASTM edition E 1431–98$^{\epsilon 1}$. ASTM E 1431–91 was adopted by ISO in 1998 with the intermediate designation ISO 15562:1998(E). The present International Standard ISO/ASTM 51431:2005(E) is a major revision of the last previous edition ISO/ASTM 51431:2002(E), which replaced ISO 15562.

[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.

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

$$D = \mathrm{d}\epsilon/\mathrm{d}m \tag{1}$$

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.

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

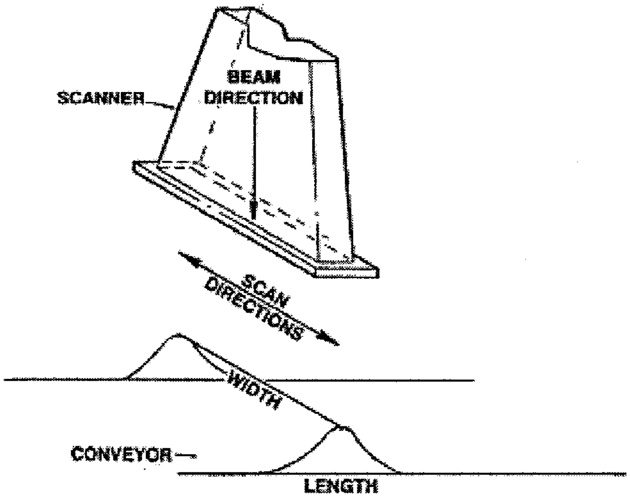

FIG. 1 Diagram showing beam length and width for a scanned beam using a conveyor system

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

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).

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).

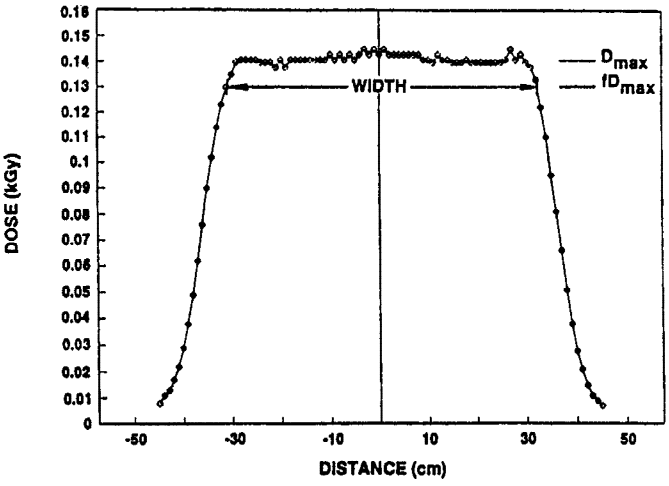


FIG. 2 Example of measured electron-beam dose distribution along the beam width, where the beam width is noted at some defined fractional level *f* of the average maximum dose D_{max}

3.1.8.1 *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.

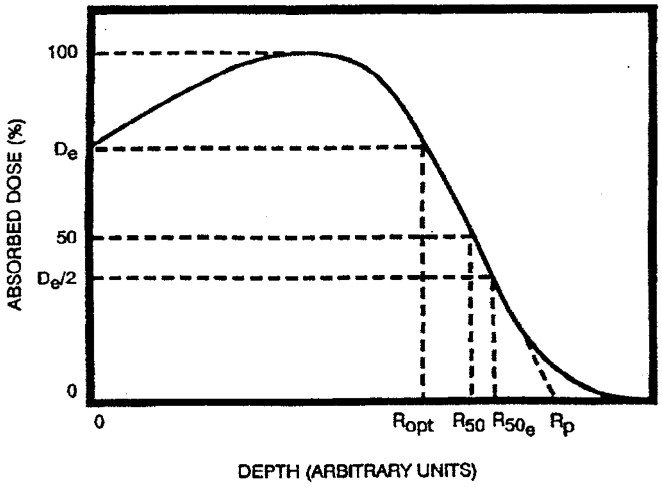
3.1.12 *dosimetry system*—system used for determining absorbed dose, consisting of dosimeters, measurement instruments and their associated reference standards, and procedures for the system’s use.

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.

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,



NOTE—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

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·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 E 170. Definitions in E 170 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 F 1355, F 1356, F 1736, and F 1885 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).

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

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

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 Practices E 1026 and E 2304, 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),