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An American National Standard

Standard Guide for Absorbed-Dose Mapping in Radiation Processing Facilities[1]

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1. Scope

1.1 This document provides guidance in determining absorbed-dose distributions in products, materials or substances irradiated in gamma, X-ray (bremsstrahlung) and electron beam facilities.

NOTE 1—For irradiation of food and the radiation sterilization of health care products, other specific ISO and ISO/ASTM standards containing dose mapping requirements exist. For food irradiation, see ISO/ASTM 51204, Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing and ISO/ASTM 51431, Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing. For the radiation sterilization of health care products, see ISO 11137: 1995, Sterilization of Health Care Products Requirements for Validation and Routine Control Radiation Sterilization. In those areas covered by ISO 11137, that standard takes precedence. ISO/ASTM Practice 51608, ISO/ASTM Practice 51649, and ISO/ASTM Practice 51702 also contain dose mapping requirements.

1.2 Methods of analyzing the dose map data are described. Examples are provided of statistical methods that may be used to analyze dose map data.

1.3 Dose mapping for bulk flow processing and fluid streams is not discussed.

1.4 Dosimetry is only one component of a total quality program for an irradiation facility. Other controls besides dosimetry may be required for specific applications such as medical device sterilization and food preservation.

1.5 *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 requirements prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E170 Terminology Relating to Radiation Measurements and Dosimetry

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E178 Practice for Dealing With Outlying Observations

E666 Practice for Calculating Absorbed Dose From Gamma or X Radiation

E668 Practice for Application of Thermoluminescence-Dosimetry (TLD) Systems for Determining Absorbed Dose in Radiation-Hardness Testing of Electronic Devices

E1026 Practice for Using the Fricke Reference-Standard Dosimetry System

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

2.2 *ISO/ASTM Standards:*[3]

ISO/ASTM 51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing

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

ISO/ASTM 51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing

ISO/ASTM 51275 Practice for Use of a Radiochromic Film Dosimetry System

ISO/ASTM 51276 Practice for Use of a Polymethylmethacrylate Dosimetry System

ISO/ASTM 51310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System

ISO/ASTM 51400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory

ISO/ASTM 51401 Practice for Use of a Dichromate Dosimetry System

ISO/ASTM 51431 Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing

ISO/ASTM 51538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System

ISO/ASTM 51540 Practice for Use of a Radiochromic Liquid Dosimetry System

ISO/ASTM 51607 Practice for Use of the Alanine-EPR Dosimetry System

[1] This guide is under the jurisdiction of ASTM Committee E10 on Nuclear Technology and Application and is the direct responsibility of Subcommittee E10.01 on Dosimetry for Radiation Processing.

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[2] For referenced 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.

[3] Standards on Dosimetry for Radiation Processing. ASTM International 2002. For referenced 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.

ISO/ASTM 51608 Practice for Dosimetry in an X-ray (Bremsstrahlung) Facility for Radiation Processing
ISO/ASTM 51631 Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Dose Measurements and Dosimeter Calibrations
ISO/ASTM 51649 Practice for Dosimetry in an Electron beam Facility for Radiation Processing at Energies between 300 keV and 25 MeV
ISO/ASTM 51650 Practice for Use of Cellulose Acetate Dosimetry Systems
ISO/ASTM 51702 Practice for Dosimetry in a Gamma Irradiation Facility for Radiation Processing
ISO/ASTM 51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing
ISO/ASTM 51818 Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies between 80 and 300 keV

2.3 *International Commission on Radiation Units and Measurements Reports:*[4]

ICRU Report 14 Radiation Dosimetry: X-Rays and Gamma Rays with Maximum Photon Energies Between 0.6 and 50 MeV
ICRU Report 17 Radiation Dosimetry: X-Rays Generated at Potentials of 5 to 150 kV
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

2.4 *International Organization for Standardization:*[5]

ISO 11137 Sterilization of Health Care Products—Requirements for Validation and Routine Control—Radiation Sterilization

3. Terminology

3.1 *Definitions:*

3.1.1 *absorbed-dose mapping* —measurement of absorbed dose within a process load using dosimeters placed at specified locations to produce a one, two or three-dimensional distribution of absorbed dose, thus rendering a map of absorbed-dose values.

3.1.2 *calibration curve*—graphical representation of the dosimetry system's response function.

3.1.3 *container*—carrier, tote, cart, tray or other container in which product is loaded to traverse the irradiation field. In some instances, this may be the actual product package.

3.1.4 *dose map, dose mapping*—See *absorbed-dose mapping*.

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

3.1.6 *dose zone*—a volume or discrete point(s) within a process load that receives the same absorbed dose within the statistical uncertainty of the irradiation process and absorbed dose measurement(s).

3.1.7 *installation qualification (IQ)*—obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

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

3.1.9 *performance qualification (PQ)*—obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification.

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

3.1.11 *reference position*—dose measurement position with an established relationship to the minimum and/or maximum dose zones.

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

3.1.12.1 *Discussion*—Simulated product may be used during operational qualification as a substitute for the actual product, material or substance to be irradiated. When used in routine production runs, it is sometimes referred to as compensating dummy. When used for absorbed-dose mapping, simulated product is sometimes referred to as phantom material.

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

4. Significance and Use

4.1 Radiation processing is carried out under fixed path conditions where (*a*) a process load is automatically moved through the radiation field by mechanical means or (*b*) a process load is irradiated statically by manually placing product at predetermined positions before the process is started. In both cases the process is controlled in such a manner that the process load position(s) and orientation(s) are reproducible within specified limits.

4.2 Some radiation processing facilities that utilize a fixed conveyor path for routine processing may also characterize a region within the radiation field for static radiation processing, sometimes referred to as "Off Carrier" processing.

4.3 Radiation processing may require a minimum absorbed dose (to achieve a desired effect or to fulfill a legal requirement), and a maximum dose that can be tolerated (while the product, material or substance still meets functional specifications or to fulfill a legal requirement).

4.4 Dose mapping is used to characterize the radiation process and assess the reproducibility of absorbed-dose results, which may be used as part of operational qualification and performance qualification.

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

[5] Available from International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland.

4.5 Dose mapping is used to determine the spatial distribution of absorbed doses and the zone(s) of maximum and minimum absorbed doses throughout a process load, which may consist of an actual or simulated product.

4.6 Dose mapping is used to establish the relationship between the dose at a reference position and the dose within the minimum and maximum dose zones established for a process load.

4.7 Dose mapping is used to verify mathematical dose calculation methods. See Guide E2232.

4.8 Dose mapping is used to determine the process shutdown and startup transit dose effect on the distribution of absorbed dose and the magnitude of the minimum and maximum doses.

4.9 Dose mapping is used to assess the impact on the distribution of absorbed dose and the magnitude of the minimum and maximum doses resulting from the transition from one process load to another where changes, for example, in density or product loading pattern may occur.

5. Prerequisites

5.1 *Installation Qualification, Dosimetry and Other Prerequisites to Dose Mapping*:

5.1.1 Prior to performing the irradiator operational qualification (OQ) and performance qualification (PQ) dose mapping, confirm that installation qualification (IQ) is complete.

5.1.2 Select an appropriate dosimetry system(s) for the dose mapping experiments. See ISO/ASTM Guide 51261 for guidance.

NOTE 2—For requirements on the qualification of equipment and control systems, refer to ISO/ASTM Standard Practices 51204, 51431, 51608, 51649, 51702, and ISO 11137.

5.2 *Calibration of the Dosimetry System*:

5.2.1 Prior to use, the dosimetry system (consisting of a specific batch of dosimeters and specific measurement instruments) shall be calibrated in accordance with the user's documented procedure that specifies details of the calibration process and quality assurance requirements. This calibration process shall be repeated at regular intervals to ensure that the accuracy of the absorbed-dose measurement is maintained within required limits. Calibration methods are described in ISO/ASTM Guide 51261.

5.3 *Calibration Irradiation of Dosimeters*—Irradiation is a critical component of the calibration of the dosimetry system. Calibration irradiations shall be performed in one of three ways by irradiating the dosimeters at:

5.3.1 An accredited calibration laboratory that provides an absorbed dose (or an absorbed-dose rate) having measurement traceability to nationally or internationally recognized standards, or

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

5.3.3 A production or research irradiation facility together with reference- or transfer-standard dosimeters that have measurement traceability to nationally or internationally recognized standards.

5.4 *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 and/or instrument-specific operating manuals.

6. Dose Mapping

6.1 *Dose Mapping for Operational Qualification of the Irradiation Facility*:

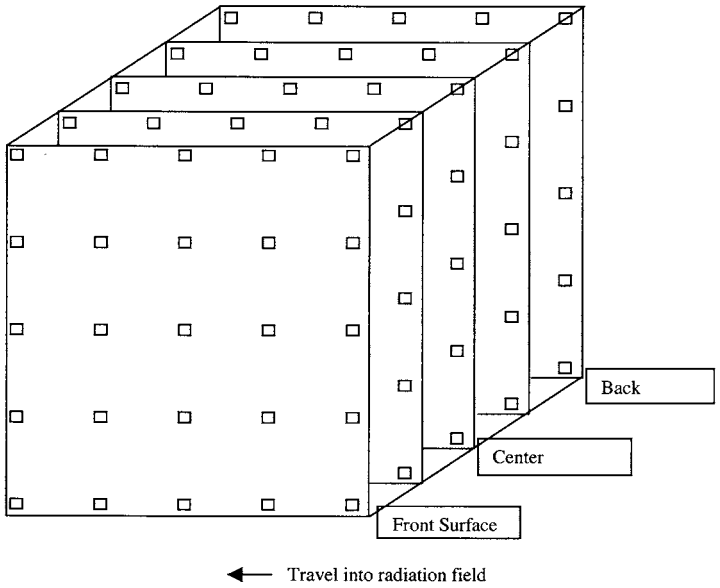
6.1.1 As specified in Practices ISO/ASTM 51204, ISO/ASTM 51431, ISO/ASTM 51608, ISO/ASTM 51649, ISO/ASTM 51702 and ISO 11137, perform irradiation facility dose mapping to characterize the irradiator with respect to the dose distribution and reproducibility of absorbed dose delivery. This should be performed in accordance with a formal validation program over the operational range that will be used in the irradiation of products.

6.1.2 Perform irradiation facility dose mapping by placing dosimeters in a process load of homogeneous density material that fills the container to its design volume limits. Material densities should be within the density range for which the irradiator is to be used. In electron beam facilities, a single material density may be used provided the maximum and minimum process settings that affect dose are demonstrated (for example, conveyor speed, beam current, scan frequency and scan height or width). Determine absorbed dose distribution throughout the process load for each product path through the irradiation field.

Discussion—Electron beam irradiation facilities may satisfy the dose mapping requirements described in 6.1.2 using a two dimensional surface grid dose map with a separate penetration test performed in a homogenous density material. Appropriate methods should be used (see ISO/ASTM Practice 51649) to determine the electron beam energy. For process load fringe or edge effect studies in electron beam, several different densities of homogeneous material should be used. The maximum electron beam process area limits may be determined by demonstrating the uniformity of absorbed dose in both the direction of scan and direction of travel under the maximum and minimum process settings that affect dose (for example, conveyor speed, beam current, scan frequency and scan height or width). Different product paths through the radiation process field need not be a physical transport path but may be created by variation(s) made to irradiator process settings that affect the absorbed dose distribution (for example, single- and double-sided irradiations in electron beam facilities, changes made to electron beam energy, use of multiple source rack(s) or a source rack positioning change in gamma irradiators, etc.). The impact of process interruptions and process transit doses for each product path should also be demonstrated.

6.1.2.1 Place a sufficient number of dosimeters in an array to determine the absorbed dose distribution. Dosimeter strips or sheets may be used to increase the spatial resolution of the dose map. An example dosimeter placement array is given in Fig. 1.

6.1.2.2 Measure the dose at the same positions in three or more replicate process loads to determine the variability of the measured absorbed dose.



NOTE—In this drawing the small squares represent dosimeter positions. The "Front" is defined as the initial and in some cases only surface to directly face the radiation source during processing.

FIG. 1 An Example of a Dosimeter Placement Array in a Three-Dimensional Grid Pattern for a Facility Dose Mapping

6.1.2.3 Following irradiation, retrieve and read the dosimeters, and evaluate the data in accordance with established procedures (see Section 7).

6.1.3 If changes that could affect the magnitude or location of the absorbed-dose extremes are made to the irradiator or mode of operation, repeat the absorbed-dose mapping to the extent necessary to establish the effects. The dose mapping may be repeated in its entirety or a reduced dosimeter placement grid can be justified. A single density of homogeneous material may be used to demonstrate equivalence to the original dose mapping.

6.1.4 The use of mathematical models in determining dosimeter locations for dose mapping or in predicting dose map results may be appropriate. See Guide E2232 for guidance.

6.2 *Dose Mapping for Performance Qualification of Process Loads*:

6.2.1 Perform dose mapping for specific products and load configurations to determine the dose distribution expected during the routine processing of process loads. Products, materials or substances should be actual product or may be simulated product of materials with similar densities and distributions as the actual products.

NOTE 3—Different products with similar densities and distribution may be considered as a single processing category and the dose map data can be applied to all products in this group.

6.2.2 If a reference position is used for routine process monitoring, the relationship between these dose distributions and the reference position shall be established. Facilities that process only product loads exhibiting the same dose distribution characteristics as those used in the operational qualification (OQ) dose mapping(s) discussed in 6.1 can be considered to have met the product dose mapping requirements for performance qualification (PQ).

6.2.3 Specify a loading pattern that describes the products, materials or substances contained within the process load, including dimensions, mass or density, and if applicable, the orientation of the product within the process load as well as the orientation of the process load itself with respect to the radiation field.

6.2.4 Specify or determine the location of the dosimeters used in the dose map, taking into consideration voids, density variations or any material interfaces that may cause significant localized dose gradients that could affect the location of minimum and/or maximum dose within the process load.

6.2.4.1 Use dosimeters capable of measuring any localized dose gradients and of a size that does not significantly influence the radiation field or the interpretation of absorbed-dose measurements. The magnitude of dose gradients is also dependent on the type of radiation source; that is, gamma, x-ray, electron beam.

6.2.4.2 Process loads containing voids, density variations or materials interfaces that could cause localized dose gradients require that the dosimeters be placed directly on the material surfaces. Selection of the dosimeter positions to be monitored in the map shall include areas of suspected high dose gradients based on a physical assessment of the materials and their composition that make up the process load being dose mapped. These positions may be concentrated in the expected zones of minimum and/or maximum dose known from the irradiator operational qualification (OQ) dose map. Heterogeneous products such as metal implants or certain foods may require placement of appropriately sized dosimeters positioned at internal locations within the individual products. This can involve cutting open the individual product inside the package to permit dosimeter positioning and retrieval.