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An American National Standard

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

This standard is issued under the fixed designation E2303; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

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

~~NOTE1—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.~~

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

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

~~1.4Dosimetry 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~~ *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 Beam and X-Ray (Bremsstrahlung) Irradiation Facilities for Food Processing. For the radiation sterilization of health care products, see ISO 11137-1, Sterilization of Health Care Products Radiation – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices. In those areas covered by ISO 11137-1, that standard takes precedence. ISO/ASTM 51608, Practice for Dosimetry in an X-ray (Bremsstrahlung) Facility for Radiation Processing, ISO/ASTM 51649, Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies between 300 keV and 25 Mev, ISO/ASTM 51702, Practice for Dosimetry in a Gamma Irradiation Facility for Radiation Processing, and ISO/ASTM 51818, Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 80 and 300 KeV also contain dose mapping requirements.*

1.2 This guide is one of a set of standards that provides recommendations for properly implementing dosimetry in radiation processing. it is intended to be read in conjunction with ASTM Practice E2628.

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

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

1.5 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.

1.6 *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

[1] This guide 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.~~ on Radiation Processing: Dosimetry and Applications.

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Current edition approved July 1, 2011. Published August 2011. Originally approved in 2003. Last previous edition approved in 2003 as E2303-03. DOI: 10.1520/E2303-11.

[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.

E177Practice for Use of the Terms Precision and Bias in ASTM Test Methods
E178 Practice for Dealing With Outlying Observations
E666Practice for Calculating Absorbed Dose From Gamma or X Radiation
E668Practice for Application of Thermoluminescence-Dosimetry (TLD) Systems for Determining Absorbed Dose in Radiation-Hardness Testing of Electronic Devices
E1026Practice 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 Guide for Selection and Use of Mathematical Methods for Calculating Absorbed Dose in Radiation Processing Applications
E2628 Practice for Dosimetry in Radiation Processing

2.2 *ISO/ASTM Standards:*[2]

ISO/ASTM 51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing
ISO/ASTM 51205Practice 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 51275Practice for Use of a Radiochromic Film Dosimetry System
ISO/ASTM 51276Practice for Use of a Polymethylmethacrylate Dosimetry System
ISO/ASTM 51310Practice for Use of a Radiochromic Optical Waveguide Dosimetry System
ISO/ASTM 51400Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory
ISO/ASTM 51401Practice for Use of a Dichromate Dosimetry System
ISO/ASTM 51431Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing
ISO/ASTM 51538Practice for Use of the Ethanol-Chlorobenzene Dosimetry System
ISO/ASTM 51540Practice for Use of a Radiochromic Liquid Dosimetry System
ISO/ASTM 51607Practice for Use of the Alanine-EPR Dosimetry System
Practice for Dosimetry in Electron Beam and X-Ray (Bremsstrahlung) Irradiation Facilities for Food Processing
ISO/ASTM 51608 Practice for Dosimetry in an X-ray (Bremsstrahlung) Facility for Radiation Processing
ISO/ASTM 51631Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Dose Measurements and Dosimeter Calibrations
ISO/ASTM 51649Practice for Dosimetry in an Electron beam Facility for Radiation Processing at Energies between 300 keV and 25 MeV
ISO/ASTM 51650Practice for Use of Cellulose Acetate Dosimetry Systems
Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies between 300 keV and 25 MeV
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:*
ICRU Report 14Radiation Dosimetry: X-Rays and Gamma Rays with Maximum Photon Energies Between 0.6 and 50 MeV
ICRU Report 17Radiation Dosimetry: X-Rays Generated at Potentials of 5 to 150 kV
ICRU Report 34The Dosimetry of Pulsed Radiation
ICRU Report 35Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV
ICRU Report 37Stopping Powers for Electrons and Positrons
International Commission on Radiation Units and Measurements Reports:[3]
ICRU Report 60Fundamental Quantities and Units for Ionizing Radiation Fundamental Quantities and Units for Ionizing Radiation
ICRU Report 80 Dosimetry Systemes for Use in Radiation Processing

2.4 *International Organization for Standardization:*
ISO 11137Sterilization of Health Care Products—Requirements for Validation and Routine Control—Radiation Sterilization International Organization for Standardization:[4]
ISO 11137-1 Sterilization of health care products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
GUM Guide to the Expression of Uncertainty in Measurement, 1995, ISBN 92-6710188-9
VIM International Vocabulary of Basic and General Terms in Metrology

[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.
[3] Available from International Commission on Radiation Units and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814.
[4] Available from International Commission on Radiation Units and Measurements, 7910 Woodmont Ave., Suite 800, Bethesda, MD 20814.
[4] Available from International Organization for Standardization (ISO), 1 rue de Varembé, Case postale 56, CH-1211, Geneva 20, Switzerland.

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.~~ —measurement of absorbed dose within an irradiated product to produce a one-, two- or three-dimensional distribution of absorbed dose, thus rendering a map of absorbed-dose values.

3.1.1.1 *Discussion*—For a process load, such a dose map is obtained using dosimeters placed at specified locations within the process load.

3.1.2 ~~*calibration curve*—graphical representation of the dosimetry system's response function.~~ calibration curve (VIM:2008)—expression of the relation between indication and corresponding measured quantity value.

3.1.2.1 *Discussion*—In radiation processing standards, the term "dosimeter response" is generally used for "indication."

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~~ —*see absorbed-dose mapping.*

~~3.1.5~~

3.1.4 *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—~~*ratio of the maximum to the minimum absorbed dose within the irradiated product.*

3.1.4.1 *Discussion*—The concept is also referred to as the max/min dose ratio. Product generally refers to the "process load."

3.1.5 *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~~3.1.6 *installation qualification (IQ)*—~~obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.~~ —process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

3.1.7 *irradiation container*—holder in which process load is transported through the irradiator.

3.1.7.1 *Discussion*—"Irradiation container" is often referred to simply as "container" and can be a carrier, cart, try, product carton, pallet, product package or other holder.

3.1.8 *operational qualification (OQ)*—process of 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)*—process of 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 product 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.~~ processing category—group of different product that can be processed together.

3.1.11.1 *Discussion*—Processing categories can be based on, for instance, composition, density or dose requirements.

3.1.12 *reference material*—homogeneous material of known radiation absorption and scattering properties used to establish characteristics of the irradiation process, such as scan uniformity, depth-dose distribution, throughput rate, and reproducibility of dose delivery.

3.1.13 *routine monitoring position*—position where absorbed dose is monitored during routine processing to ensure that the product is receiving the absorbed dose specified for the process.

3.1.13.1 *Discussion*—This position may be a location of minimum or maximum dose in the process load or it may be an alternate convenient location in, on or near the process load where the relationship of the dose at this position with the minimum and maximum dose has been established.

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

~~3.1.12.1~~

3.1.14.1 *Discussion*—Simulated product ~~may be~~ is used during ~~operational qualification~~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.

3.2 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 Report 60; that document, therefore, may be used as an alternative reference.

4. Significance and Use

~~4.1Radiation processing is carried out under fixed path conditions where (~~

4.1 This guide is one of a set of guides and practices that provide recommendations for properly implementing dosimetry in

radiation processing. In order to understand and effectively use this and other dosimetry standards, consider first "Practice for Dosimetry in Radiation Processing," ASTM Practice E2628, which describes the basic requirements that apply when making absorbed dose measurements in accordance with the ASTM E10.01 series of dosimetry standards. In addition, ASTM Practice E2628 provides guidance on the selection of dosimetry systems and directs the user to other standards that provide information on individual dosimetry systems, calibration methods, uncertainty estimation and radiation processing applications.

4.2 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.

NOTE 2—Static irradiation encompasses irradiation of the process load using either manual rotation, no rotation or automated rotation.

~~4.2Some~~4.3 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.

~~4.3Radiation~~ 4.4 Many radiation processing ~~may~~applications 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).

~~4.4Dose~~4.5 Dose mapping is used to ~~e~~:

4.5.1 Characterize the radiation process and assess the reproducibility of absorbed-dose ~~results,~~values, which may be used as part of operational qualification and performance qualification.

~~4.5Dose mapping is used to determine~~ 4.5.2 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.

~~4.6Dose mapping is used to establish~~ 4.5.3 Establish the relationship between the dose at a ~~reference~~ routine monitoring position and the dose within the minimum and maximum dose zones established for a process load.

~~4.7Dose mapping is used to verify~~ 4.5.4 Verify mathematical dose calculation methods. See ASTM Guide E2232.

~~4.8Dose mapping is used to determine the~~ 4.5.5 Determine the effect of process ~~shutdown and startup transit dose effect~~ interruptions on the distribution of absorbed dose and the magnitude of the minimum and maximum doses.

~~4.9Dose mapping is used to assess~~ 4.5.6 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 product density or product loading pattern may occur.

5. Prerequisites

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

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

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

~~NOTE2—For requirements on the qualification of equipment and control systems, refer to ISO/ASTM Standard Practices 51204, 51431, 51608, 51649, 51702, and ISO 11137~~

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

5.1.1.1 For electron beam and X-ray irradiation facilities, IQ includes dosimetric testing to confirm the characteristics of the beam (electron energy, average beam current, and if applicable, scan width and scan uniformity). Refer to ISO/ASTM 51431, 51608, 51818, 51649 and ISO 11137-1.

5.1.1.2 For gamma irradiation facilities, dosimetric testing is not required during IQ; however, the activity of the source and location of the individual components of the source should be confirmed and documented. Refer to ISO/ASTM 51204, 51702 and ISO 11137-1.

5.1.2 Select an appropriate dosimetry system(s) for the dose mapping exercises. See 6.2.4.1 and ASTM Practice E2628 for guidance.

5.2 *Calibration of the Dosimetry System*:

~~5.2.1Prior 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~~

5.2.1 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. Calibration methods are described in ISO/ASTM 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:~~

~~5.3.1An accredited calibration laboratory that provides an absorbed dose (or an absorbed-dose rate) having measurement~~

~~traceability to nationally or internationally recognized standards, or~~

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

~~5.3.3A 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.~~

NOTE 3—A generic dosimetry system calibration may be used for relative dose measurement applications.

5.2.2 For the calibration of the instruments, and for the verification of instrument performance between calibrations, see ISO/ASTM 51261 or instrument-specific operating manuals, or both.

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, ISO/ASTM 51818 and ISO ~~11137~~11137-1, 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.

~~6.1.2Perform 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.~~

~~6.1.2.1Place 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~~

6.1.2 Perform irradiation facility dose mapping by placing dosimeters in a number of process loads of reference material that fills the container to its design volume limits. The number of process loads to be dose mapped should be large enough (3 or more) to determine the variability of dose. For those irradiation facilities that vary operating parameters which impact dose distribution, dose mapping should be carried out over a range of selected operating parameters which cover the operational limits to be used in the irradiation of products.

6.1.2.1 Specific to photon-based facilities (gamma or X-ray), material densities should be within the density range for which the irradiator is to be used. When processing multiple densities, dose mapping should be done for at least two densities close to the minimum and maximum density to be processed to assess the impact density has on the magnitude and distribution of the absorbed dose. A user may consider dose mapping for additional intermediate densities to gain additional performance information.

6.1.2.2 *Specific to Electron Beam Facilities*—For irradiation facility dose mapping, use one or more reference materials having densities within the density range for which the irradiator is to be used.

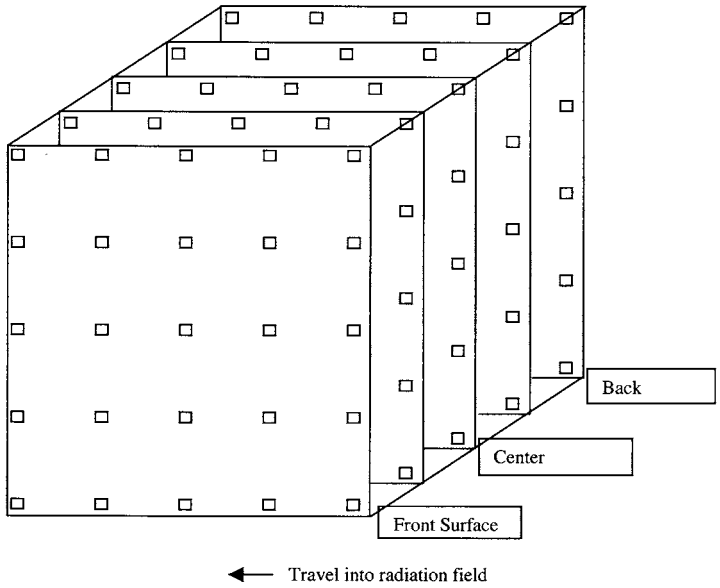
6.1.2.3 Determine absorbed-dose distribution throughout the process load for each product path through the irradiation field and each set of process parameters.

NOTE 4—Additional ways to influence the absorbed-dose distribution within a given process load include: performing single- versus double-sided irradiation in electron beam and X-ray facilities, or using multiple source rack(s) or source rack positioning changes in gamma irradiators.

6.1.2.4 For each process load, 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 of dosimeter placement array is given in Fig. 1.

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

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



NOTE 1—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. The number of dosimeters and the number of planes (surfaces) to be mapped will depend on several factors, including but not limited to, the radiation type (electrons versus photons), single- versus double-sided irradiation, and resolution of absorbed dose required.

FIG. 1 An Example of a Dosimeter Placement Array in a Three-Dimensional Grid Pattern for a ~~F~~n Operational Qualification Dose Mapping

6.1.2.5 Measure the dose at the same positions in three or more replicate process loads to determine the variability of the measured absorbed dose and absorbed-dose distribution for each product path and set of process parameters.

(1) For process loads transported through the irradiation field, a sufficient number of similar process loads should precede and follow those being dose mapped to minimize variations on the absorbed-dose distribution in the dose-mapped process loads.

(2) Depending on the irradiator design, additional dose map studies may be needed to determine effects on dose and dose distribution associated with changes during processing in process loading configurations and their density (sometimes referred to as "phase-in and phase-out" effects). The effect of density changes on dose and dose distribution can be evaluated by irradiating two different density process loads sequentially and dose mapping the last process load of the one density and the first process load of the second density and comparing these results against the results obtained from the uniform density dose map described in 6.1.2.5, (1).

6.1.2.6 Following irradiation, retrieve and measure the response of each dosimeter, and evaluate the data in accordance with established procedures (see Section 7).

~~6.1.3If 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.~~

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

6.1.3 If changes are made to the irradiation system that could affect the absorbed-dose or absorbed-dose distribution, it may be necessary to repeat the dose mapping.

NOTE 5—ISO 11137-1 provides additional guidance regarding changes to the irradiation system and recommended post-change qualification activities.

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

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

~~6.2.1Perform 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.~~

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 density, distributions and packaging configuration as the actual products.

6.2.2 If a routine monitoring position is used for process monitoring, the relationships between minimum dose, maximum dose and the dose at the routine monitoring position should be established.