An American National Standard

Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV[1]

This standard is issued under the fixed designation ISO/ASTM 51649; 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 covers dosimetric procedures to be followed in Installation Qualification, Operational Qualification and Performance Qualifications (IQ, OQ, PQ), and routine processing at electron beam facilities to ensure that the product has been treated with an acceptable range of absorbed doses. Other procedures related to IQ, OQ, PQ, and routine product processing that may influence absorbed dose in the product are also discussed.

NOTE 1—For guidance in the selection and calibration of dosimeters, see ISO/ASTM Guide 51261. For further guidance in the use of specific dosimetry systems, and interpretation of the measured absorbed dose in the product, also see ISO/ASTM Practices 51275, 51276, 51431, 51607, 51631, 51650 and 51956. For use with electron energies above 5 MeV, see Practice E1026, and ISO/ASTM Practices 51205, 51401, 51538, and 51540 for discussions of specific large volume dosimeters. For discussion of radiation dosimetry for pulsed radiation, see ICRU Report 34.

1.2 The electron beam energy range covered in this practice is between 300 keV and 25 MeV, although there are some discussions for other energies.

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

1.4 Other specific ISO and ASTM standards exist for the irradiation of food and the radiation sterilization of health care products. For food irradiation, see ISO/ASTM Practice 51431. For the radiation sterilization of health care products, see ISO 11137. In those areas covered by ISO 11137, that standard takes precedence.

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
E1026 Practice for Using the Fricke Dosimetry System
E2232 Guide for Selection and Use of Mathematical Methods for Calculating Absorbed Dose in Radiation Processing Applications
E2303 Guide for Absorbed-Dose Mapping in Radiation Processing Facilities

2.2 *ISO/ASTM Standards:*[2]

51205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System
51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing
51275 Practice for Use of a Radiochromic Film Dosimetry System
51276 Practice for Use of a Polymethylmethacrylate Dosimetry System
51400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory
51401 Practice for Use of a Dichromate Dosimetry System
51431 Practice for Dosimetry in Electron and X-ray (Bremsstrahlung) Irradiation Facilities for Food Processing
51538 Practice for Use of an Ethanol-Chlorobenzene Dosimetry System
51539 Guide for the Use of Radiation-Sensitive Indicators
51540 Practice for Use of a Radiochromic Liquid Solution Dosimetry System
51607 Practice for Use of the Alanine–EPR Dosimetry System
51631 Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Measurements and Dosimeter Calibrations
51650 Practice for Use of a Cellulose Triacetate Dosimetry System
51707 Guide for Estimating Uncertainties in Dosimetry for

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[1] This practice is under the jurisdiction of ASTM Committee E61 on Radiation Processing and is the direct responsibility of Subcommittee E61.03 on Dosimetry Application, and is also under the jurisdiction of ISO/TC 85/WG 3.

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

Radiation Processing

51956 Practice for Thermoluminescence Dosimetry (TLD) Systems for Radiation Processing

2.3 *ISO Standard:*[3]

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

2.4 *International Commission on Radiation Units and Measurements (ICRU) Reports:*[4]

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 in the specified material (1 Gy = 1 J/kg). The mathematical relationship is the quotient of $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass dm.

$$D = d\bar{\varepsilon}/dm$$

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.

3.1.2 *average beam current*—time-averaged electron beam current; for a pulsed machine, the averaging shall be done over a large number of pulses (see Fig. 1).

3.1.3 *beam length*—dimension of the irradiation zone, perpendicular to the beam width and direction of the electron beam at a specified distance from the accelerator window (see Fig. 2).

3.1.4 *beam power*—product of the average electron beam energy and the average beam current.

3.1.5 *beam spot*—shape of the unscanned electron beam incident on the reference plane.

3.1.6 *beam width*—dimension of the irradiation zone in the direction that the beam is scanned, perpendicular to the beam length and direction of the electron beam at a specified distance from the accelerator window (see Fig. 2).

3.1.6.1 *Discussion*—For a radiation processing facility with a conveyor system, the beam width is usually perpendicular to the flow of motion of the conveyor (see Fig. 2). Beam width is the distance between two points along the dose profile, which are at a defined level from the maximum dose region in the

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[3] Available from International Organization for Standardization, 1 Rue de Varembé, Case Postale 56, CH-1211 Geneva 20, Switzerland.

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

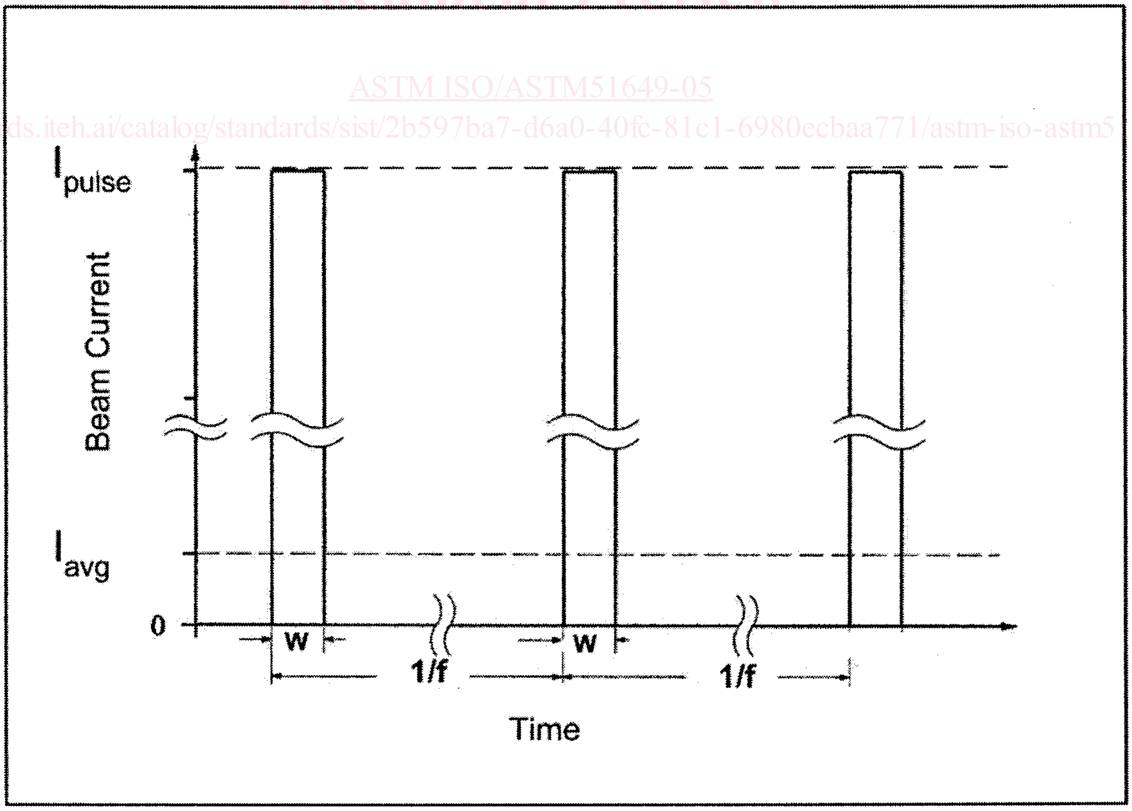


FIG. 1 Example pulse current (I_{pulse}), average beam current (I_{avg}), pulse width (W) and repetition rate (f) for a pulsed accelerator

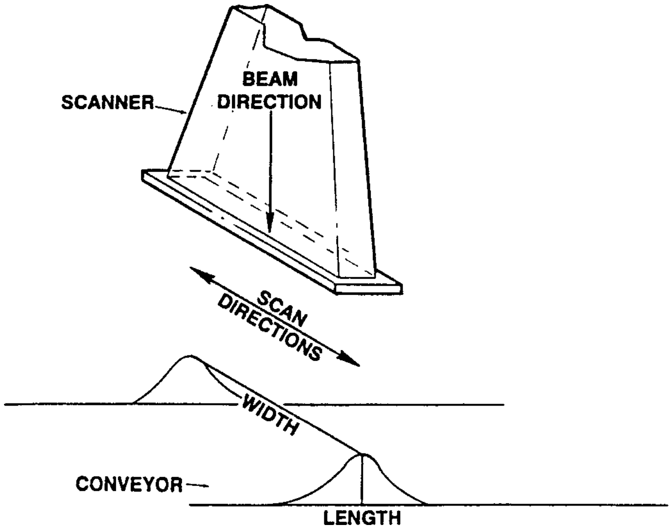


FIG. 2 Diagram showing beam length and width for a scanned beam using a conveyor system

profile (see Fig. 3). Various techniques may be employed to produce an electron beam width adequate to cover the processing zone, for example, use of electromagnetic scanning of a pencil beam (in which case beam width is also referred to as scan width), defocussing elements, and scattering foils.

3.1.7 *compensating dummy*—simulated product used during routine production runs in process loads that contain less product than specified in the documented product-loading configuration, or simulated product used at the beginning or end of a production run, to compensate for the absence of product.

3.1.7.1 *Discussion*—Simulated product or phantom material may be used during irradiator characterization as a substitute for the actual product, material or substance to be irradiated.

3.1.8 *continuous-slowing-down-approximation (CSDA) range (r_0)*—average pathlength traveled by a charged particle as it slows down to rest, calculated in the continuous-slowing-down-aproximation method.

3.1.8.1 *Discussion*—In this approximation, the rate of energy loss at every point along the track is assumed to be equal to the total stopping power. Energy-loss fluctuations are neglected. The CSDA range is obtained by integrating the reciprocal of the total stopping power with respect to energy. Values of r_0 for a wide range of electron energies and for many materials can be obtained from ICRU Report 37.

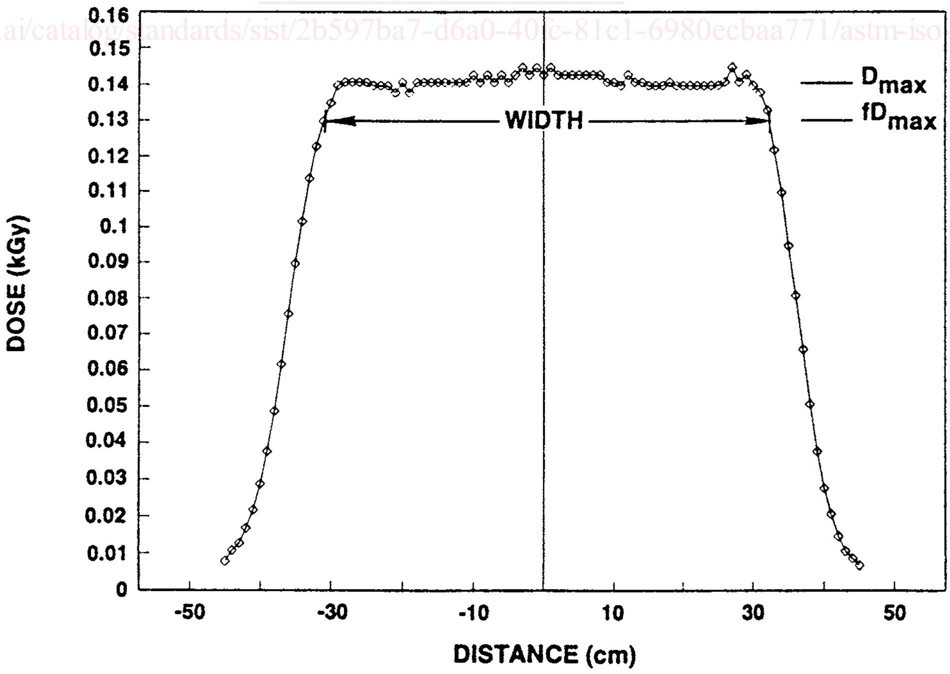
3.1.9 *depth-dose distribution*—variation of absorbed dose with depth from the incident surface of a material exposed to a given radiation.

3.1.9.1 *Discussion*—Typical distributions in homogeneous materials produced by an electron beam along the beam axis are shown in Figs. A1.1 and A1.2. See Annex A1.

3.1.10 *dose uniformity ratio*—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 *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.

3.1.12 *duty cycle—for a pulsed accelerator*, the fraction of time the beam is effectively on; it is the product of the pulse width in seconds and the pulse rate in pulses per second.



NOTE 1—McKeown, J., AECL Accelerators, private communication, 1993. Example of a beam width profile of an AECL Impela accelerator.

FIG. 3 Example of electron-beam dose distribution along the beam width with the width noted at some defined fractional level *f* of the average maximum dose D_{max}

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) is often used as the unit for electron beam energy where 1 eV = $1.602 \cdot 10^{-19}$ J (approximately). In radiation processing, where beams with a broad electron energy spectrum are frequently used, the terms *most probable energy* (E_p) and *average energy* (E_a) are common. They are linked to the *practical electron range*R_p and *half-value depth*R_{50} by empirical equations.

3.1.14 *electron beam facility*—establishment that uses energetic electrons produced by particle accelerators to irradiate product.

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

3.1.16 *electron range*—penetration distance in a specific, totally absorbing material along the beam axis of the electrons incident on the material (equivalent to practical electron range, R_P).

3.1.16.1 *Discussion*—R_P can be measured from experimental depth-dose distributions in a given material. Other forms of electron range are found in the dosimetry literature, for example, extrapolated range derived from depth-dose data and the continuous-slowing-down-approximation range (the calculated pathlength traversed by an electron in a material in the course of completely slowing down). Electron range is usually expressed in terms of mass per unit area ($kg \cdot m^{-2}$), but sometimes in terms of thickness (m) for a specified material.

3.1.17 *half-entrance depth* (R_{50e})—depth in homogeneous material at which the absorbed dose has decreased down to 50 % of the absorbed dose at the surface of the material (see Fig. 4).

3.1.18 *half-value depth* (R_{50})—depth in homogeneous material at which the absorbed dose has decreased down to 50 % of its maximum value (see Fig. 4).

3.1.19 *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. 4).

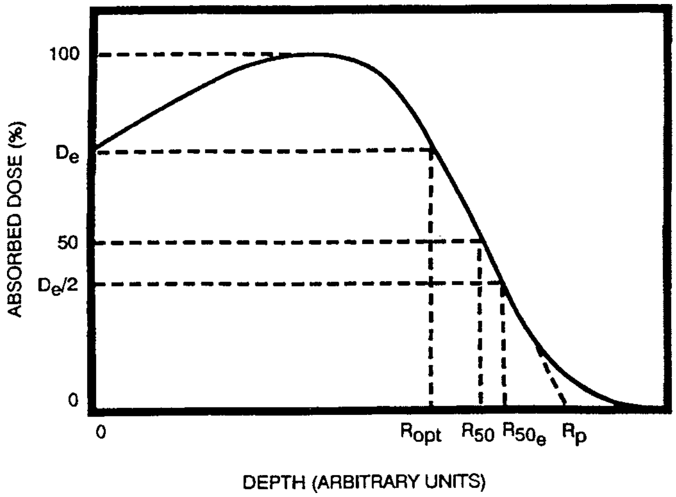


FIG. 4 A typical depth-dose distribution for an electron beam in a homogeneous material

3.1.20 *practical electron range* (R_p)—depth in homogeneous material 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. 4 and Fig. A1.6 in Annex A1).

3.1.21 *extrapolated electron range* (R_{ex})—depth in homogeneous material 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 (see Fig. A1.6 in Annex A1).

3.1.22 *process load*—volume of product with a specified loading configuration processed as a single entity; this term is not relevant to bulk-flow processing.

3.1.23 *production run*—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.

3.1.24 *pulse beam current, for a pulsed accelerator*—beam current averaged over the top ripples (aberrations) of the pulse current waveform; this is equal to I_{avg}/wf, where I_{avg} is the average beam current, w is the pulse width, and f is the pulse rate (see Fig. 5).

3.1.25 *pulse rate, for a pulsed accelerator*—pulse repetition frequency in hertz, or pulses per second; this is also referred to as the repetition (rep) rate.

3.1.26 *pulse width, for a pulsed accelerator*—time interval between two points on the leading and trailing edges of the pulse current waveform where the current is 50 % of its peak value (see Fig. 5).

3.1.27 *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.

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

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

3.1.29.1 *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 of the accelerator or product under the scan horn.

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

3.1.31 *scan uniformity*—degree of uniformity of the dose measured along the scan direction.

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

3.1.32.1 *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, it is sometimes referred to as compensating

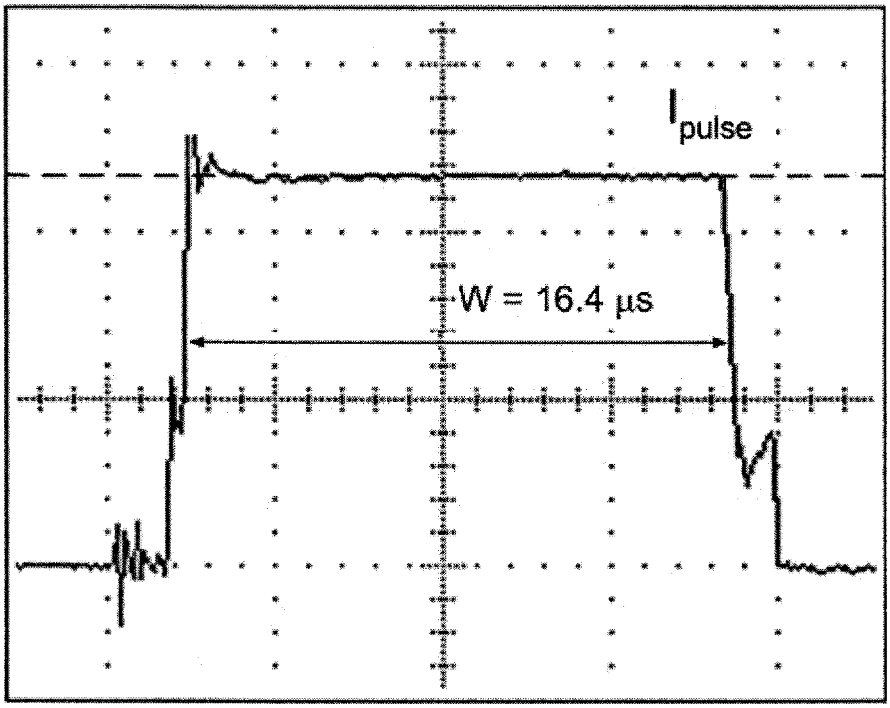


FIG. 5 Typical pulse current waveform from an S-Band linear accelerator

dummy. When used for absorbed-dose mapping, simulated product is sometimes referred to as phantom material.

3.1.33 *standardized depth (z)*—thickness of the absorbing material expressed as the mass per unit area, which is equal to the depth in the material t times the density ρ. If m is the mass of the material beneath that area and A is the area of the material through which the beam passes, then:

$$z = m/A = t\rho$$

If t is in meters and ρ in kilograms per cubic meter, then z is in kilograms per square meter.

3.1.33.1 *Discussion*—It is common practice to express t in centimeters and ρ in grams per cm^3, then z is in grams per square centimeter. Standardized depth may also be referred to as surface density or area density.

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

4. Significance and use

4.1 Various products and materials are routinely irradiated at pre-determined doses at electron beam facilities to preserve or modify their characteristics. Dosimetry requirements may vary depending on the radiation process and end use of the product. For example, a partial list of processes where dosimetry may be used is given below.

4.1.1 Polymerization of monomers and grafting of monomers onto polymers,

4.1.2 Cross-linking or degradation of polymers,

4.1.3 Curing of composite materials,

4.1.4 Sterilization of medical devices,

4.1.5 Disinfection of consumer products,

4.1.6 Food irradiation (parasite and pathogen control, insect disinfestation, and shelf-life extension),

4.1.7 Control of pathogens and toxins in drinking water,

4.1.8 Control of pathogens and toxins in liquid or solid waste,

4.1.9 Modification of characteristics of semiconductor devices,

4.1.10 Color enhancement of gemstones and other materials, and

4.1.11 Research on radiation effects on materials.

NOTE 2—Dosimetry is required for regulated radiation processes such as sterilization of medical devices (see ISO 11137 and Refs **(1-4)**[5] and preservation of food (see ISO/ASTM 51431 and Ref **(5)**. It may be less important for other processes, such as polymer modification, which may be evaluated by changes in the physical and chemical properties of the irradiated materials. Nevertheless, routine dosimetry may be used to monitor the reproducibility of the treatment process.

4.2 Dosimeters are used as a means of monitoring the radiation process.

NOTE 3—Measured dose is often characterized as absorbed dose in water to have a traceable standard reference. Moreover, materials commonly found in disposable medical devices and food are approximately equivalent to water in the absorption of ionizing radiation. Absorbed dose in materials other than water may be determined by applying conversion factors in accordance with ISO/ASTM Guide 51261.

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

4.3 A beneficial irradiation process is usually specified by a minimum absorbed dose to achieve the desired effect and a maximum dose limit that the product can tolerate and still be functional. Dosimetry is essential, since it is used to determine these limits, and dosimetry is essential in the evaluation and monitoring of the radiation process.

4.4 The dose distribution within the product depends on process load characteristics, irradiation conditions, and operating parameters. The operating parameters consist of beam characteristics (such as electron energy and beam current), beam dispersion parameters, and product material handling. These critical parameters must be controlled to obtain reproducible results.

4.5 Before a radiation facility is used, it must be qualified to demonstrate its ability to deliver specified, controllable doses in a reproducible manner. This involves testing the process equipment, calibrating the equipment and dosimetry system, and characterizing the magnitude, distribution and reproducibility of the dose absorbed by a reference material.

4.6 To ensure that products are irradiated with reproducible doses, routine process control requires documented product handling procedures before, during and after the irradiation, consistent orientation of the products during irradiation, monitoring of critical process parameters, routine product dosimetry and documentation of the required activities and functions.

5. Radiation source characteristics

5.1 Electron radiation sources considered in this practice are either direct-action (potential-drop) or indirect-action (RF- or microwave-powered) accelerators. These are discussed in Annex A4.

6. Types of irradiation facilities

6.1 *Irradiation Facility Design:*

6.1.1 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 8 to 11.

6.1.2 An electron beam facility includes the electron beam accelerator system; material handling systems, a radiation shield with personnel safety system, product staging, loading and storage areas; auxiliary equipment for power, cooling, ventilation, etc.; equipment control room; laboratories for dosimetry and product testing; and personnel offices. The electron beam accelerator system consists of the radiation source (see Annex A4), equipment to disperse the beam on product, control system, and associated equipment (**2**).

6.2 *Configuration of Material Handling*—The absorbed dose distributions within product may be affected by the material handling system. Examples of systems commonly used are:

6.2.1 *Conveyors or Carriers*—Material is placed upon carriers or conveyors for passage through the electron beam. The speed of the conveyor or carriers is controlled in conjunction with the electron beam current and beam width so that the required dose is applied.

6.2.2 *Roll-to-Roll Feed System*—Roll-to-roll (also referred to as reel-to-reel) feed systems are used for tubing, wire, cable, and continuous web products. The speed of the system is controlled in conjunction with the electron beam current and beam width so that the required dose is applied.

6.2.3 *Bulk-flow System*—For irradiation of liquids or particulate materials like grain or plastic pellets, bulk-flow transport through the irradiation zone may be used. Because the flow velocity of the individual pieces of the product cannot be controlled, the average velocity of the product in conjunction with the beam characteristics and beam dispersion parameters determines the average absorbed dose.

6.2.4 *Stationary*—For high-dose processes, the material may be placed under the beam and not moved. Cooling may be required to dissipate the heat accumulated by the product during processing. The irradiation time is controlled in conjunction with the electron beam current, beam length, and beam width to achieve the required dose.

7. Dosimetry systems

7.1 *Description of Dosimeter Classes:*

7.1.1 Dosimeters may be divided into four basic classes according to their relative quality and areas of application: primary-standard, reference-standard, transfer-standard, and routine dosimeters. ISO/ASTM Guide 51261 provides information about the selection of dosimetry systems for different applications. All classes of dosimeters, except the primary standards, require calibration before their use.

7.1.1.1 *Primary-Standard Dosimeters*—Primary-standard dosimeters are established and maintained by national standards laboratories for calibration of radiation environments (fields) and other classes of dosimeters. The two most commonly used primary-standard dosimeters are ionization chambers and calorimeters.

7.1.1.2 *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 dose ranges, are given in ISO/ASTM Guide 51261.

7.1.1.3 *Transfer-Standard Dosimeters*—Transfer-standard dosimeters are specially selected dosimeters used for transferring absorbed-dose information from an accredited or national standards laboratory to an irradiation facility in order to establish traceability for that facility. These dosimeters should be carefully used under conditions that are specified by the issuing laboratory. Transfer-standard dosimeters may be selected from either reference-standard dosimeters or routine dosimeters taking into consideration the criteria listed in ISO/ASTM Guide 51261.

7.1.1.4 *Routine Dosimeters*—Routine dosimeters may be used for radiation process quality control, dose monitoring and 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 dose ranges, are given in ISO/ASTM Guide 51261.

7.2 It is important that the dosimeter be evaluated for those parameters which may influence the dosimeter's response; for example, average and peak absorbed dose rate (particularly for pulsed accelerators), environmental conditions (for example, temperature, humidity, and light) and electron energy. Guidance as to desirable characteristics and selection criteria for dosimetry systems can be found in ISO/ASTM Guide 51261, Practice E1026, and ISO/ASTM Practices 51205, 51275, 51276, 51401, 51538, 51540, 51607, 51631 and 51650.

7.3 *Calibration of Dosimetry Systems:*

7.3.1 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 51261.

7.3.2 *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.

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

7.3.2.2 *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.

7.3.3 *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.

NOTE 4—For some dosimetry systems, the dosimeter response at different absorbed-dose rates for the same given absorbed dose may differ over portions of the system's working range. Accelerator systems are available which operate from about 1 kW to many hundred kW average beam power. Some are DC, others are pulsed with low duty cycles. So, dose rates (average and peak) can be very different from one system to the next. Because of this, it may be difficult to match the dose rate characteristics of the processing plant to that of the calibration facility. For this reason, calibration irradiation using the production irradiator (in-situ calibration) should be strongly considered (see ISO/ASTM Guide 51261).

8. Process parameters

8.1 There are various processing parameters that play essential roles in determining and controlling the absorbed dose in radiation processing. They should, therefore, be considered when performing the absorbed-dose measurements required in Sections 8 to 11.

8.2 Processing parameters include process load characteristics (for example, size, bulk density, and heterogeneity), irradiation conditions (for example, processing geometry, multi-sided exposure, and number of passes through the beam), and operating parameters.

8.2.1 Operating parameters include beam characteristics (for example, energy, average beam current, and pulse rate), performance characteristics of material handling (see 6.2), and beam dispersion parameters (for example, beam width and frequency at which the beam is scanned across product). Operating parameters are measurable and should be monitored. During irradiation facility qualification (see Sections 9 and 10), absorbed dose characteristics over the expected range of the operating parameters are established for a reference material.

8.2.2 Processing parameters for a radiation process are established during performance qualification (see Section 11) to achieve the absorbed dose within the specified limits.

8.2.3 During routine product processing (see Section 12), the facility operating parameters are controlled and monitored to maintain values that were set during performance qualification.

8.2.4 Different product types may require different values of operating and processing parameters.

9. Installation qualification

9.1 *Objective*—The purpose of the electron beam facility installation qualification is to obtain and document evidence that equipment has been provided and installed in accordance with its specifications.

9.2 *Equipment Documentation*—Documentation of an installation qualification program shall be retained for the life of the irradiator, and shall include:

9.2.1 The accelerator specifications and characteristics,

9.2.2 A description of the construction and the operation of any associated material handling equipment,

9.2.3 A description of the process control system and personnel safety system,

9.2.4 A description of the location of the irradiator within the operator's premises in relation to the means provided for the segregation of non-irradiated products from irradiated products, if required,

9.2.5 Description of the materials and the construction dimensions of containers used to hold products during irradiation, if used,

9.2.6 A description of the manner of operating the irradiator, and

9.2.7 Any modifications made during and after installation. Such documentation is necessary to ensure the reproducibility of absorbed dose in the reference material within specified limits.

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 *Conditions Affecting Absorbed Dose*—The absorbed dose within a process load depends in part on the operating parameters: beam characteristics, beam dispersion parameters, material handling, and their inter-relationships. It also depends on process load characteristics and irradiation conditions. These operating parameters are controlled by various accelerator and other facility parameters.

9.4.1 *Beam Characteristics:*

9.4.1.1 The two principal beam characteristics that affect absorbed dose are the electron energy spectrum, and average beam current. The electron energy spectrum affects the depth-dose distribution within the product (see Annex A1). The average beam current, in addition to several other operating parameters, affects the average dose rate.

9.4.1.2 Beam characteristic measurements of importance include:

(1) Electron beam energy,
(2) Average beam current,
(3) Peak beam current (for pulsed machines),
(4) Average beam power,
(5) Peak beam power (for pulsed machines),
(6) Duty cycle (for pulsed machines),
(7) Pulse (or Repetition or rep) Rate,
(8) Pulse width (for pulsed machines), and
(9) Beam cross-section.

NOTE 5—The electron energy spectrum of the incident electron beam may be characterized by the average electron beam energy (E_a) and the most probable electron beam energy (E_p) (see Annex A3). An energy-analyzing magnet may be used for a detailed analysis of the energy spectrum.

9.4.2 *Beam Dispersion:*

9.4.2.1 Dispersion of the electron beam to obtain a beam width adequate to cover the processing zone may be achieved by various techniques. These include electromagnetic scanning of a pencil beam or use of defocussing elements or scattering foils.

9.4.2.2 Beam dispersion measurements of importance include:

(1) Scan width,
(2) Scan length,
(3) Variation of dose along the scan width and length, and
(4) Beam centering with respect to the irradiation zone.

NOTE 6—The beam width, in addition to several other operating parameters, affects the dose rate. Scanning of a pencil beam can produce pulsed dose at points along the beam width. This can influence the dosimeters' performance when they are sensitive to dose rate variations (see Annex A2).

9.4.3 *Material Handling:*

9.4.3.1 For facilities utilizing continuously-moving conveyors (including, for example, roll-to-roll feed systems and bulk flow systems to transport product through the irradiation zone), conveyor speed determines the irradiation time. Therefore, when other operating parameters are held constant, conveyor speed governs the absorbed dose in the product.

NOTE 7—The conveyor speed and the beam current may be linked so that a variation in one causes a corresponding change in the other to maintain a constant value of the absorbed dose.

9.4.3.2 For those facilities that irradiate products while they are stationary in the irradiation zone, irradiation time governs the absorbed dose in the product when other operating parameters are held constant.

9.4.4 *Measurement Instruments*—The accuracy of the absorbed-dose measurements depends on the correct operation and calibration of the measurement instruments used in the analysis of the dosimeters.

9.4.4.1 Check the performance of the measurement instruments to ensure that the instruments are functioning according to performance specifications. Repeat this check following any modification or servicing of the instruments and prior to their use for a dosimetry system calibration. This check can be accomplished by using standards, such as calibrated optical density filters, wavelength standards, or calibrated thickness gauges, supplied by the equipment manufacturer or by national or accredited standards laboratories.

10. Operational qualification

10.1 *Objective*—The purpose of qualifying an electron beam facility is to establish baseline data for evaluating the ability of the facility to accurately and reproducibly deliver doses over the range of conditions at which the facility will operate (**2, 3**). Dosimetry can be used *(1)* to establish relationships between measured absorbed dose distributions in reference material under reference irradiation geometries and operating parameters of the facility, and *(2)* to characterize dose variations when these conditions fluctuate statistically through normal operations (**4**).

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

10.3 *Dose Mapping:*

10.3.1 Map the absorbed-dose distribution by a three-dimensional placement of dosimeter sets in a process load containing homogeneous material as discussed in ASTM Guide E2303. The amount of homogeneous material in this process load should be the amount expected during typical production runs or should be the maximum design volume for the process load.

10.3.2 Using appropriate dosimetry, establish the depth-dose distribution within a reference material under reference irradiation geometry (see Annex A1 and Annex A3). The exact shape of the distribution will be different for different facilities since it depends on the energy spectrum of the electron beam and the irradiation geometry (**6**). The depth of penetration depends on electron energy.

10.4 *Absorbed Dose and Operating Parameters:*

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

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

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

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

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

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

NOTE 8—Electron beam irradiators generally utilize continuously-moving conveyors. Dose uniformity in a reference plane is strongly influenced by the coordination of the beam spot dimensions, conveyor speed and scan frequency (for those irradiators that employ beam scanning). For a pulsed-beam accelerator, all these parameters must also be coordinated with the pulse width and pulse rate. Improper coordination of these parameters can cause unacceptable dose variation in the reference plane.

NOTE 9—Indirect-action accelerators may deliver higher dose rates during the pulse compared to direct-action accelerators with the same average beam current. Also, scanning of a small-diameter beam can produce dose pulses at points along the beam width. This can influence the dosimeters' performance if they are sensitive to dose rate.

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

NOTE 10—The conveyor speed and the beam current may be linked during routine product processing so that a variation in one causes a corresponding change in the other to maintain a constant value of the surface (or reference plane) dose.

10.5 *Dose Variability:*

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

10.5.2 Following the procedure of 10.3, map a sufficient number of nominally identical process loads containing reference material to allow the estimation of the variability of the magnitude and distribution of the absorbed dose. Dosimetry data from previously qualified irradiators of the same design may provide useful information for determining the number of process loads for this qualification.

10.6 *Process Interruption/Restart:*

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

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

10.6.1.2 The delivery of dose within specifications through the stop/start sequence would suggest that the conveyor could be restarted after the failure to continue the process. The effect of the process interruption (for example, time delay) on the product itself is discussed in 12.4.

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

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

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

10.8 *Facility Changes*—If changes that could affect the magnitudes or locations of the absorbed-dose extremes are made to the facility (for example, beam characteristics, beam dispersion parameters, material handling, etc.) or its mode of operation, repeat the operational qualification procedures to the extent necessary to establish the effects.

11. Performance qualification

11.1 *Objective*—Absorbed dose requirements vary depending on the process and type of product being irradiated. A radiation process is usually associated with a minimum absorbed dose requirement and sometimes a maximum absorbed dose limit. For a given process, one or both of these limits may be prescribed by regulations. Therefore, the objective of performance qualification is to establish all processing parameters so that absorbed dose requirements are satisfied. This is accomplished by mapping the dose distribution throughout the process load for a specific product loading pattern. Such processing parameters include electron energy, beam current, material handling parameters (conveyor speed or irradiation time), beam width, process load characteristics and irradiation conditions (see, for example, Refs **2**, **4**, **7**, **8**).

11.2 *Product Loading Configuration*—A loading pattern for irradiation shall be established for each product type. The specification for this loading pattern shall document the following:

11.2.1 Product specifications that influence the absorbed dose distribution (such as dimensions and composition) and, if applicable, description of the orientation of the product within its package, and

11.2.2 Orientation of the product with respect to the material handling system. This may include a further description of the orientation of the product within another container used during irradiation.

11.3 *Process load Absorbed-Dose Mapping:*

11.3.1 Determine the locations and values of absorbed dose extremes for the selected product loading pattern. This can be accomplished by placing dosimeters throughout the volume of interest for several process loads (see ASTM Guide E2303). Select placement patterns that can most probably identify the locations of the dose extremes; concentrate dosimeters in those areas, with fewer dosimeters placed in areas likely to receive intermediate absorbed dose. Dosimeters used for dose mapping must be selected to be able to detect doses and dose gradients likely to occur within irradiated products. For electron irradiation, dosimeter films in sheets or strips may be most useful for obtaining this information (**9**, **10**). Measured values of dose extremes will vary between process loads because of variations in packaging geometry or product distribution, uncertainty in dosimetry system performance and minor fluctuations in the values of the operating parameters. Thus, dosimeters placed in similar locations in several process loads may produce a range of absorbed dose measurements. Select a sufficient number of process loads for mapping to determine the variability in the extreme dose values among process loads.

NOTE 11—The irradiation of tubing, wire, cable, continuous web, and other products may not require absorbed dose mapping studies. Desired effects from absorbed dose may be attained through control of the operating parameters and monitoring the desired effects in the product.

11.3.2 Results from the dose mapping measurements will determine the values of the processing parameters to ensure that prescribed dose requirements within the product are achieved. The uncertainties of the dosimetry system, the uncertainties from the measurement of the dose distribution, and the variations of the radiation process lead to an overall uncertainty of the minimum and maximum doses within the product. This uncertainty must be taken into account when the process parameters are chosen. Generally, the parameters must be chosen so that there is a low probability of irradiating the product or part of the product with doses lower than the required minimum or higher than the allowed maximum and this probability is known and documented (**4**, **7**).

11.3.3 *Partial Loading*—For partially-loaded process loads, follow the same process qualification requirements as for fully-loaded process loads. Perform the dose mapping procedures of 11.3 to ensure that the absorbed-dose distributions are adequately characterized and are acceptable. Variations to the dose distribution from a partial loading may in some cases be minimized by the use of compensating dummy material placed at appropriate locations within the process load.

11.3.4 *Bulk-Flow Irradiators*—For irradiators used in a bulk flow mode, absorbed-dose mapping as described in 11.3.1 may not be feasible. In this case, absorbed dose extremes may be estimated by using an appropriate number of dosimeters mixed with and carried by the product through the irradiation zone. Enough dosimeters should be used to obtain statistically significant results (**8**, **10**). Calculation of the absorbed dose extremes may be an appropriate alternative (**8**).

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

11.4 *Dose Variability:*

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

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

11.5 *Unacceptable Dose Uniformity Ratio:*

11.5.1 If the dose mapping procedure of 11.3.1 or 11.3.4 reveals that the measured dose extremes are unacceptable, it may be possible to change the processing parameters to improve the dose uniformity ratio to an acceptable level. Alternatively, it may be necessary to change the product configuration within the process load or the shape, size, or flow pattern of the process load itself.

11.5.2 *Operating Parameters*—Changing the beam characteristics, for example, by optimizing the electron energy, can change the dose extremes. Other means to change the dose extremes may be employed, such as use of attenuators, scatterers and reflectors.

11.5.3 *Irradiation Conditions*—Depending upon the density, thickness, and inhomogeneity of a process load and electron beam energy of the irradiator, many processes require double-sided irradiation to achieve an acceptable dose distribution. For double-sided irradiation, the magnitudes and locations of dose extremes are usually quite different from those for single-sided irradiation. Slight fluctuations in density or thickness of product within the process load or fluctuations in electron beam energy may cause more pronounced changes in absorbed dose within the product for double-sided irradiation as compared to single-sided irradiation.

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

11.5.5 If any process parameter that affects the magnitudes or locations of maximum and minimum absorbed dose is changed (for example, for the purpose of improving the dose uniformity ratio), repeat the dose mapping to the extent