INTERNATIONAL STANDARD

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Practice for dosimetry in electron and bremsstrahlung irradiation facilities for food processing

Pratique de la dosimétrie electrons et Bremsstrahlung dans les installations de traitement des produits alimentaires irradiés

Reference number
ISO 15562:1998(E)

Foreword

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

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

International Standard ISO 15562 was prepared by the American Society for Testing and Materials (ASTM) Subcommittee E10.01 (as E 1431-91) and was adopted, under a special "fast-track procedure", by Technical Committee ISO/TC 85, *Nuclear energy*, in parallel with its approval by the ISO member bodies.

A new ISO/TC 85 Working Group WG 3, *High-level dosimetry for radiation processing*, was formed to review the voting comments from the ISO "Fast-track procedure" and to maintain these standards. The USA holds the convenership of this working group.

International Standard ISO 15562 is one of 20 standards developed and published by ASTM. The 20 fast-tracked standards and their associated ASTM designations are listed below:

ISO Designation	ASTM Designation	Title
15554	E 1204-93	*Practice for dosimetry in gamma irradiation facilities for food processing*
15555	E 1205-93	*Practice for use of a ceric-cerous sulfate dosimetry system*
15556	E 1261-94	*Guide for selection and calibration of dosimetry systems for radiation processing*
15557	E 1275-93	*Practice for use of a radiochromic film dosimetry system*
15558	E 1276-96	*Practice for use of a polymethylmethacrylate dosimetry system*
15559	E 1310-94	*Practice for use of a radiochromic optical waveguide dosimetry system*
15560	E 1400-95a	*Practice for characterization and performance of a high-dose radiation dosimetry calibration laboratory*
15561	E 1401-96	*Practice for use of a dichromate dosimetry system*

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15562	E 1431-91	*Practice for dosimetry in electron and bremsstrahlung irradiation facilities for food processing*
15563	E 1538-93	*Practice for use of the ethanol-chlorobenzene dosimetry system*
15564	E 1539-93	*Guide for use of radiation-sensitive indicators*
15565	E 1540-93	*Practice for use of a radiochromic liquid dosimetry system*
15566	E 1607-94	*Practice for use of the alanine-EPR dosimetry system*
15567	E 1608-94	*Practice for dosimetry in an X-ray (bremsstrahlung) facility for radiation processing*
15568	E 1631-96	*Practice for use of calorimetric dosimetry systems for electron beam dose measurements and dosimeter calibrations*
15569	E 1649-94	*Practice for dosimetry in an electron-beam facility for radiation processing at energies between 300 keV and 25 MeV*
15570	E 1650-94	*Practice for use of cellulose acetate dosimetry system*
15571	E 1702-95	*Practice for dosimetry in a gamma irradiation facility for radiation processing*
15572	E 1707-95	*Guide for estimating uncertainties in dosimetry for radiation processing*
15573	E 1818-96	*Practice for dosimetry in an electron-beam facility for radiation processing at energies between 80 keV and 300 keV*

Designation: E 1431 – 91

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Standard Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing[1]

This standard is issued under the fixed designation E 1431; 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 practice describes dosimetric procedures to be followed in characterizing, qualifying, and operating electron beam and bremsstrahlung irradiation facilities for food processing. Other procedures related to facility characterization, product qualification, and routine processing are also discussed.

1.2 The electron energy range covered in this practice is from 0.1 MeV to 10 MeV. Such electrons can be generated in continuous or pulse modes.

1.3 The maximum photon energy covered in this practice is 5 MeV. A photon beam can be generated by inserting a bremsstrahlung converter in the electron beam path.

1.4 For guidance in the selection, calibration, and use of specific dosimeters, and interpretation of absorbed dose in the product from dosimetry measurements, see Guide E 1261, Method E 1026, and Test Method E 1205. For discussion of radiation dosimetry for X rays and gamma rays, see ICRU Reports 14 and 17, and for pulsed radiation, see ICRU Report 34. For application of dosimetry in the characterization and operation of a gamma irradiation facility for food processing, see Practice E 1204, which also contains material relevant to the operation of an accelerator facility operated in a bremsstrahlung mode.

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

2. Referenced Documents

2.1 *ASTM Standards:*

E 170 Terminology Relating to Radiation Measurements and Dosimetry[2]

E 668 Practice for Application of Thermoluminescence-Dosimetry (TLD) Systems for Determining Absorbed Dose in Radiation-Hardness Testing of Electronic Devices[2]

E 1026 Method for Using the Fricke Dosimeter to Measure Absorbed Dose in Water[2]

E 1204 Practice for Application of Dosimetry in the Characterization and Operation of a Gamma Irradiation Facility for Food Processing[2]

E 1205 Test Method for Using the Ceric-Cerous Sulfate Dosimeter to Measure Absorbed Dose in Water[2]

E 1261 Guide for Selection and Application of Dosimetry Systems for Radiation Processing of Food[2]

E 1275 Practice for Use of a Radiochromic Film Dosimetry System[2]

E 1276 Practice for Use of a Polymethylmethacrylate Dosimetry System[2]

E 1310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System[2]

2.2 *International Commission on Radiation Units and Measurements (ICRU) Reports:*[3]

ICRU Report 14 Radiation Dosimetry: X Rays and Gamma Rays with Maximum Photon Energies Between 0.6 and 50 MeV

ICRU Report 17 Radiation Dosimetry: X Rays Generated at Potentials of 5 to 150 kV

ICRU Report 33 Radiation Quantities and Units

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

3. Terminology

3.1 *Definitions*—Other terms used in this practice may be found in Terminology E 170 and ICRU Report 33.

3.2 *Descriptions of Terms Specific to This Standard:*

3.2.1 *absorbed dose, D*—quotient of $d\bar{\epsilon}$ by dm, where $d\bar{\epsilon}$ is the mean energy imparted by ionizing radiation to matter of mass dm (see ICRU Report 33).

$$D = \frac{d\bar{\epsilon}}{dm}$$

The special name for the unit for absorbed dose is the gray (Gy):

$$1\ \text{Gy} = 1\ \text{J} \cdot \text{kg}^{-1}$$

Formerly, the special unit for absorbed dose was the rad:

$$1\ \text{rad} = 10^{-2}\ \text{J} \cdot \text{kg}^{-1} = 10^{-2}\ \text{Gy}$$

3.2.2 *average beam current*—time-averaged electron beam current. For a pulsed machine, the averaging shall be done over an integral number of pulses or a large number of pulses.

3.2.3 *beam width*—dimension of the irradiation zone

[1] This practice is under the jurisdiction of ASTM Committee E-10 on Nuclear Technology and Applications and is the direct responsibility of Subcommittee E10.01 on Dosimetry for Radiation Processing.

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[2] *Annual Book of ASTM Standards*, Vol 12.02.

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

perpendicular to the flow of the product. 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, extended emitting surface (cathode), defocusing elements, and scattering foils.

3.2.4 *bremsstrahlung*—broad-spectrum electromagnetic radiation emitted when an energetic electron is influenced by a strong electric field such as that in the vicinity of an atomic nucleus. Practically, bremsstrahlung is produced when an electron beam strikes any material (converter). The bremsstrahlung spectrum depends on the electron energy, the converter material and its thickness, and contains energies up to the maximum kinetic energy of the incident electrons **(1, 2)**.

3.2.5 *compensating dummy*—a mass of material with attenuation and scattering properties similar to those of a particular product, that may be placed adjacent to a product unit at the beginning and end of a production run, or within a partially filled product unit, to compensate for the absence of product.

3.2.6 *depth dose distribution*—variation of absorbed dose with depth from the incident surface of a material exposed to radiation. A typical distribution in homogeneous material produced by an electron beam along the beam axis perpendicular to the product is shown in Fig. 1.

3.2.7 *dose uniformity ratio*—ratio of the maximum to the minimum absorbed dose within the product. It is a measure of the degree of uniformity of the absorbed dose. This concept is also referred to as the max/min dose ratio.

3.2.8 *dosimetry system*—system used for determining absorbed dose, consisting of the dosimeter, the calibration curve, appropriate instrumentation, and procedures for the system's use.

3.2.9 *electron energy*—kinetic energy of an electron (unit: electron volt (eV)).

3.2.10 *electron energy spectrum*—frequency distribution of electrons as a function of energy. The energy spectrum of the electrons impinging on the product depends on the type of the accelerator and the conditions of the radiation process.

3.2.11 *electron range*—penetration distance along the beam axis of electrons within a material. Several range parameters may be defined to describe the characteristics of the electron beam (see Fig. 1). For more discussion, refer to ICRU Report 35 and Ref **3**.

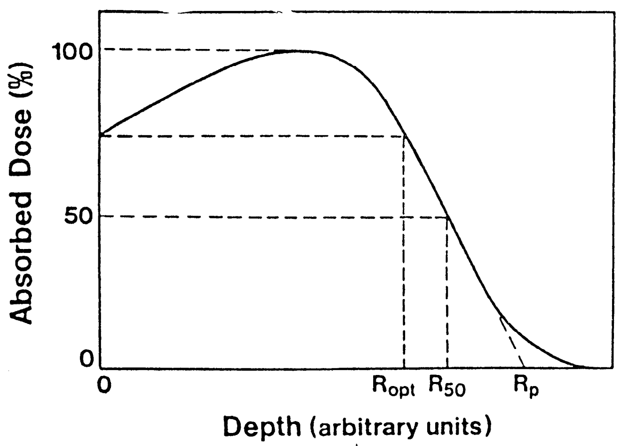


FIG. 1 A Typical Depth Dose Distribution for an Electron Beam

3.2.12 *half-value depth, R_{50}*—depth in a material at which the absorbed dose has decreased to 50 % of its maximum value (see Fig. 1).

3.2.13 *optimum thickness, R_{opt}*—depth within a material at which the absorbed dose equals the absorbed dose at the surface where the electron beam enters (see Fig. 1).

3.2.14 *practical range, R_p*—distance from the surface of the 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. 1).

3.2.15 *product unit*—one or more containers of a product, collectively transported through the irradiator as a whole, for example, box, tote, pallet, carrier. This term is not relevant to bulk-flow processing.

3.2.16 *production run*—series of product units containing the same product and irradiated sequentially to the same absorbed dose.

3.2.17 *reference material*—homogeneous material of known radiation absorption properties used to establish beam characteristics.

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

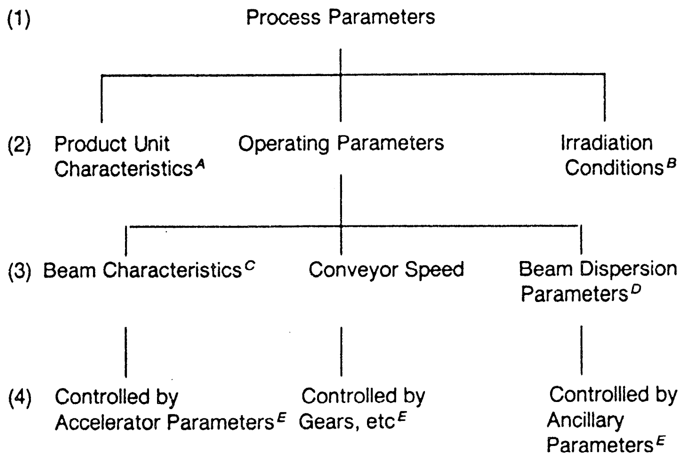
4. Significance and Use

4.1 Food products may be processed with accelerator-generated radiation to derive public health or economic benefits, or both. Examples include control of parasites, microorganisms, and insects, and extension of shelf-life. Food irradiation specifications usually include a pair of absorbed-dose limits: a minimum necessary to ensure the intended beneficial effect and a maximum to avoid product degradation. For a given application, one or both of these values may be prescribed by regulations. Therefore, it is necessary to determine the capability of an irradiation facility to process within these absorbed-dose limits prior to the irradiation of product for consumption. Once this capability is established, it is necessary to monitor the maximum and minimum absorbed dose in the irradiated product for each production run with an acceptable level of confidence to verify compliance with the process specifications.

4.2 Regulations in some countries limit the maximum electron energy to 10 MeV and photon energy to 5 MeV for the purpose of food irradiation to avoid induced radioactivity in the food.

NOTE 1—Electron beams from linear accelerators (linacs) may contain some electrons with energies above these prescribed limits. These higher energy electrons may be prevented from reaching the product by using a beam stop in combination with a magnetic deflection device.

4.3 There are various types of parameters that play essential roles in determining and controlling the absorbed dose in radiation processing at an irradiation facility. It is important to understand clearly the relationships among them. Figure 2 is a diagram of these relationships. The operating parameters (beam characteristics, conveyor speed, and beam dispersion parameters) are measurable parameters, and their values depend on the facility controlling parameters (shown in row 4 of Fig. 2). During the facility character-



^A For example, size, bulk density and heterogeneity.

^B For example, processing geometry, multi-sided exposure and number of passes.

^C For example, energy, current and pulse repetition rate.

^D For example, scan width and scan frequency.

^E These parameters control various operating parameters; the nature of their relationships depends on the type of irradiation facility.

FIG. 2 A Diagram of the Parameter Relationships for an Electron or Bremsstrahlung Facility

ization phase, absorbed dose characteristics over the expected range of the operating parameters (row 3, Fig. 2) are established for a reference material. The process parameters (row 2, Fig. 2) for a radiation process are established during the product qualification phase to achieve the absorbed dose within the set limits. During product processing, the facility controlling parameters (row 4, Fig. 2) are controlled and monitored to maintain the values of all the operating parameters that were set during the product qualification phase.

4.4 Accelerator-generated radiation can be in the form of electrons or photons (bremsstrahlung) produced by the electrons. Penetration into the product required to accomplish the intended effect is one of the factors affecting the decision to use electrons or photons. For a given electron energy, penetration of the bremsstrahlung radiation is substantially greater than that of the electrons. Penetration of 5-MeV bremsstrahlung radiation in water or plastic materials is slightly greater than that of Co-60 gamma rays (**4, 5, 6, 7**).

NOTE 2—More detailed discussion of food irradiation processing may be found in Refs **8 to 13**.

5. Facility Characterization

5.1 *Objective*—The purpose of dosimetry in commissioning a new or modified electron beam facility is to establish baseline data for monitoring the effectiveness, predictability, and reproducibility of the system under the range of conditions over which the facility will operate. For example, dosimetry shall be used *(1)* to establish relationships between absorbed dose in a reproducible geometry and the operating parameters of the facility, *(2)* to characterize the variation of dose when these parameters change within specified limits, and *(3)* to measure absorbed dose distributions in reference materials. The information gathered during this phase should assist in establishing process parameters during the product qualification phase.

5.2 *Operating Parameters:*

5.2.1 The absorbed dose within a product unit depends on beam characteristics, conveyor speed, and beam dispersion parameters. (It also depends on product unit characteristics and irradiation conditions. See Fig. 2.) These operating parameters are affected by various accelerator and other facility parameters. The variety of accelerators, conveyors, and beam dispersion systems and the possibility of new designs make it inappropriate to state general relationships between operating parameters and controlling facility parameters (see Fig. 2).

5.2.2 *Beam Characteristics:*

5.2.2.1 The two principal beam characteristics are the electron energy spectrum and the average beam current. The electron energy spectrum affects the depth dose distribution within a material. The average beam current, in addition to several other operating parameters, affects the dose rate.

NOTE 3—If the accelerator does not have an energy analyzing system (for example, an analyzing magnet) the electron energy spectrum of the beam can be specified in a practical way by two parameters: the average electron energy (E_a) and the most probable electron energy (E_p). The values of these two parameters at the surface of water-equivalent product are related to the electron range:

$$E_p\,(\mathrm{MeV}) = 0.22 + 1.98\,R_p + 0.0025\,R_p^2 \qquad \text{for } 1\ \mathrm{MeV} < E_p < 50\ \mathrm{MeV}$$

$$\text{and,}\quad E_a\,(\mathrm{MeV}) = 2.33\,R_{50} \qquad \text{for } 5\ \mathrm{MeV} < E_a < 35\ \mathrm{MeV}$$

where R_p and R_{50} are, respectively, the practical range and the half-value depth in water-equivalent material in cm (see 3.2.12 and 3.2.14). These expressions are valid for a very small angular spread of the beam. More discussion of these parametric relationships and procedures for measuring R_{50} and R_p for water-equivalent and other materials may be found in ICRU Reports 35 and 37, and Ref **14**. For lower energy beams ($E_p < 1$ MeV), the electron spectrum is affected by the accelerator window, intervening air, and any backing materials. However, reproducibility of the radiation process can be determined by routine measurements of the depth dose distribution.

5.2.2.2 For bremsstrahlung irradiators, absorbed dose rate is affected by the angular distribution of the bremsstrahlung beam, in addition to the electron energy spectrum and average beam current. Photon energy and angular distributions depend on the design and composition of the converter, and on the electron energy (**1, 6**).

5.2.3 *Conveyor Speed:*

5.2.3.1 For facilities utilizing continuously-moving conveyors to transport product through the irradiation zone, conveyor speed determines the irradiation time. Therefore, when other operating parameters are held constant, conveyor speed controls the absorbed dose in the product.

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

5.2.4 *Beam Dispersion Parameters*—Dispersion of the electron beam to produce a beam width adequate to cover the processing zone may be achieved by various techniques. These include electromagnetic scanning of a pencil beam, use of an extended emitting surface (cathode or plasma), use of defocusing elements and scattering foils. The beam width, in addition to several other operating parameters, affects the dose rate.

5.3 *Dose Characteristics Produced by the Accelerator:*

5.3.1 The dose on the surface of the product is primarily related to the average beam current, the beam width, and the conveyor speed (see 5.2). This dose is also affected by the electron energy. Over the expected range of these operating parameters, establish the absorbed dose characteristics for a reference plane using appropriate dosimetry (see Guide E 1261). Also, establish these relationships for those cases where dose uniformity varies with the distance between the beam exit window and the product unit.

5.3.1.1 Electron beam irradiators generally utilize continuously-moving conveyors. To ensure a uniform dose for a reference plane, the beam spot dimensions, the conveyor speed, and the scan frequency (for those irradiators that employ beam scanning) must be coordinated. In a pulsed-beam accelerator, all these parameters must also be coordinated with the pulse repetition rate. These considerations do not apply to extended cathode machines that do not employ scanning. Also, these considerations are less critical for a bremsstrahlung irradiator, because the photon beam is much more diffused than the incident electron beam.

NOTE 4—The conveyor speed and the beam current may be linked for some types of accelerators so that a variation in one causes a corresponding change in the other to maintain a constant value of the absorbed dose.

5.3.2 Using appropriate dosimetry and dose mapping techniques discussed in Practice E 1204 establish the depth dose distribution within a reference material for electrons and for bremsstrahlung photons as applicable. The exact shape of these distributions will be different for different facilities, since they depend on the energy spectrum of the electron beam, the irradiation geometry, and the bremsstrahlung target design **(15)**. In the case of electrons, the depth of penetration depends on electron energy. Increasing the electron energy increases the half-value depth (R_{50}), the practical range (R_p), and the optimum thickness (R_{opt}) (see Fig. 1). In comparison to electrons, bremsstrahlung radiation penetrates significantly deeper into the product. Thus, bremsstrahlung mode operation allows treatment of denser and thicker product units than in the case of electron mode operation.

5.3.3 Establish the capability of the facility to deliver a constant dose rate by measuring the fluctuations in the values of the accelerator parameters and the conveyor speed that may cause variation in absorbed dose. Estimate the magnitude of these variations, for example, by passing dosimeters through the irradiation zone on the product conveyor at time intervals appropriate to the frequency of the parameter fluctuations.

5.4 *Methods of Dose Measurement*—For selection and application of dosimetry systems for use in food irradiation, see Guide E 1261. For description of various dosimeter systems, see Test Method E 1205, and Practices E 1275, E 1276, and E 1310.

6. Product Qualification

6.1 *Objective:* Minimum and maximum dose limits are almost always associated with food irradiation applications. For a given application, one or both of these values may be prescribed by regulations. Therefore, the objective of product qualification is to ensure that the absorbed dose at every point is within the two limits. This is accomplished by mapping the dose distribution throughout the product unit using dosimetry procedures described in this section. This exercise also establishes all the process parameters, namely, electron energy, beam current, conveyor speed, beam width, product unit characteristics, and irradiation conditions necessary to achieve the absorbed dose within the set limits.

6.2 *Dose Uniformity Ratio:*

6.2.1 Establish the value of the dose uniformity ratio and the location of the maximum and the minimum dose values for each product type and geometry. This can be accomplished by placing dosimeters throughout the volume of interest for several product units. Select placement patterns that can most probably identify the locations of the dose extremes; place more dosimeters in those areas, with fewer dosimeters placed in areas likely to receive intermediate absorbed dose. Films in sheets or strips may also be employed to provide useful information. Because of variations in packaging geometry or product distribution, dosimeters placed in similar locations in several product units may produce a range of absorbed dose measurements. Select a sufficient number of product units for mapping to determine the variability of the absorbed dose distributions among product units (refer to Practices E 668 and E 1204 for discussions).

6.2.2 Ensure that the process parameters that affect the absorbed dose in the product are the same during both mapping and routine production runs.

NOTE 5—This requirement is necessary to avoid altering the magnitudes (and perhaps locations) of maximum and minimum absorbed dose because a change in process parameters might cause the doses to lie outside the prescribed upper or lower absorbed dose limits.

6.2.3 If there is a change in process parameters that could affect the magnitudes or locations of maximum and minimum absorbed dose, repeat the dose mapping to the extent necessary to establish the effects. The irradiator performance characterization (see Section 5) should serve as a guide in determining the extent of these absorbed-dose mapping studies.

6.2.4 If the locations of minimum or maximum absorbed dose identified during the dose mapping procedure of 6.2.1 are not readily accessible during production runs, alternative positions may be used. The relationships between the absorbed doses at these alternative reference positions and the maximum and minimum absorbed dose shall be established, shown to be reproducible, and documented.

6.2.5 For bulk-flow irradiators, absorbed-dose mapping as described in 6.2.1 may not be feasible. In this case, minimum and maximum absorbed doses may be estimated by using an appropriate number of dosimeters mixed randomly with and carried by the product through the irradiation zone. Enough dosimeters should be used to obtain statistically significant results **(16, 17)**. Calculation of the maximum and minimum absorbed dose may be an appropriate alternative **(14)**.

6.2.6 If the dose mapping procedure of 6.2.1 reveals that the measured dose uniformity ratio is too large, for example, larger than the ratio between the maximum and minimum absorbed-dose limits prescribed by regulators, change the process parameters to reduce the ratio to an acceptable level.

6.2.6.1 Changing the beam characteristics, for example, by optimizing the electron energy, can reduce the dose uniformity ratio (see 5.2.2). Other means to reduce the dose uniformity ratio may be employed, such as use of attenuators, scatterers, and reflectors.

6.2.6.2 Depending upon the density, thickness, and heterogeneity of a product unit, some processes may require a double-sided irradiation to achieve an acceptable dose uniformity ratio. For double-sided irradiation, the regions of maximum and minimum dose may be quite different from those for single-sided irradiation. For electron irradiation, caution is necessary for a double- (or multiple-) sided irradiation because slight variations in thickness or density of the product unit or in electron energy can lead to extreme over- or under-exposure in the middle of the product unit.

6.2.6.3 If the dose uniformity ratio still is not acceptable, a redesign of the product unit may be needed to achieve an acceptable ratio.

6.3 *Process Parameters*—After establishing the dose uniformity ratio, determine the average beam current and conveyor speed (or time of exposure for stationary irradiations, see 5.2.3.2 to be used in the product processing phase. Due to the uncertainties of the dose measurement system and the inherent variations in the radiation process, it is advisable to set these operating parameters so as to deliver a dose greater than the required minimum and smaller than the required maximum **(17)**. This procedure, in effect, establishes all the controlling parameters (see Fig. 2).

7. Product Processing

7.1 *Process Parameters:*

7.1.1 For product processing, set the controlling parameters (and thus the operating parameters) as established during product qualification. Control, monitor, and document these parameters to ensure that each product unit that passes through the irradiator is processed in accordance with specifications.

7.1.2 If these parameters deviate outside the processing limits, take appropriate actions, for example, immediate interruption of the process.

7.2 *Routine Production Dosimetry:*

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

7.2.1.1 *Dosimeter location*—Place dosimeters either within or on the selected product units (see 7.2.1.2) at predetermined locations of the maximum and minimum absorbed dose (see 6.2.1), or at the reference positions determined in 6.2.4.

7.2.1.2 *Placement frequency*—Place dosimeters at locations described in 7.2.1.1 at or near the start, middle, and end of the production run. For monitoring during long production runs (exceeding 16 h), employ additional dosimeters so that absorbed-dose measurements are made at least once every eight hours.

NOTE 7—More frequent placement of dosimeters during the production run could result in less product rejection should some operational uncertainty or failure arise.

7.2.1.3 *End units*—The first and last units of a contiguous series of product units may experience dose distributions different from the other units. If prior dosimetry data indicate an unacceptable dose distribution exists for these two end units, place compensating dummies adjacent to these units to make their dose distributions acceptable.

7.2.1.4 *Partial loading*—If processing partially-loaded product units is necessary, use the same measurement requirements as for fully-loaded product units. Perform the dose mapping procedures of 6.2.1 to ensure that the absorbed-dose distributions are adequately characterized. Changes 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 product unit.

7.2.1.5 *Bulk-flow*—For some types of bulk-flow irradiators (for example, fluids or grains), where it may not be feasible during routine production to place dosimeters at the locations of minimum and maximum absorbed dose, add several dosimeters to the product stream at the beginning, the middle, and near the end of the production run. Each set of absorbed-dose measurements requires several dosimeters to ensure, within a specified level of confidence, that the minimum and maximum absorbed doses are known. This procedure requires that the total irradiation time and rate of flow of the dosimeters are the same as those of the product.

7.2.1.6 *Environmental changes*—A change in the environment (for example, temperature, humidity) of a dosimeter during the irradiation process may affect its response. If required, correct the dosimeter response for any such effect (see Guide E 1261 and Practices E 1275 and E 1276).

7.3 *Radiation-sensitive Indicators*—For some dose levels, radiation-sensitive indicators may be available that can be used for process control and for inventory purposes. A radiation-sensitive indicator may be affixed on each unit to help ensure that the product unit has passed through the irradiation zone. For multiple irradiation, one indicator should be affixed before each pass on each side facing the electron beam to give visual evidence of the number of passes the product unit has traversed. However, the use of radiation-sensitive indicators is not a substitute for the dosimetry procedures described in 7.2.

7.4 *Documentation:*

7.4.1 *Irradiation control record:*

7.4.1.1 Record and document the dosimetry for all phases of irradiator operation, from initial characterization through production irradiation of specific products, including date, time, product type, loading diagrams, and absorbed doses for all products processed (see Guide E 1261).

7.4.1.2 Record the process parameters affecting absorbed dose together with sufficient information identifying these parameters with specific product batches or production runs.

7.4.1.3 Record or reference the calibration and maintenance of equipment and instrumentation used to control or measure the absorbed doses delivered to the product (see Guide E 1261).

7.4.2 *Facility log:*

7.4.2.1 Record the date the product is processed and the beginning and the ending times of the irradiation. Record the name of the operator as well as any special conditions of the accelerator or the facility that could affect the dose.

7.4.2.2 For each lot that is processed, record the identifi-