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Practice for dosimetry in a gamma irradiation facility for radiation processing

Pratique de la dosimétrie dans une installation de traitement par irradiation gamma

Reference number
ISO 15571:1998(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 15571 was prepared by the American Society for Testing and Materials (ASTM) Subcommittee E10.01 (as E 1702-95) 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 15571 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*

For the purposes of this International Standard, the following amendments to the ASTM text apply.

Page 1, subclause 1.1, note 1, and subclause 1.2

Replace note 1 and subclause 1.2 by the following.

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

1.3 For the irradiation of food and the radiation sterilization of health care products, other specific ISO standards exist. For food irradiation, see ISO 15554:1998, *Practice for dosimetry in gamma irradiation facilities for food processing* (ASTM Practice E 1204). 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.

Page 1, subclauses 1.3 and 1.4

Renumber these subclauses as 1.4 and 1.5 respectively.

Designation: E 1702 – 95

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If not listed in the current combined index, will appear in the next edition.

Standard Practice for Dosimetry in a Gamma Irradiation Facility for Radiation Processing[1]

This standard is issued under the fixed designation E 1702; 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 outlines dosimetric procedures to be followed in irradiator characterization, process qualification, and routine processing in a gamma irradiation facility. These procedures ensure that all product processed with ionizing radiation from isotopic gamma sources receive absorbed doses within a predetermined range. Other procedures related to irradiator characterization, process qualification, and routine processing that may influence absorbed dose in the product are also discussed. Information about effective or regulatory dose limits is not within the scope of this document.

NOTE 1—Dosimetry is one component of a total quality assurance program for adherence to good manufacturing practices. Specific applications of gamma radiation processing may require additional controls.

1.2 This practice describes general procedures applicable to all gamma radiation processing requiring absorbed doses within a predetermined range. For procedures specific to food irradiation, see Practice E 1204. The sterilization of medical devices is a regulated irradiation process with specific process control requirements. These requirements, including specific dosimetry requirements for medical device sterilization, are given in Refs (**1**) and (**2**).[2] Guidelines for medical device sterilization are given in Refs (**3**) and (**4**).

1.3 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 and Practices E 666, E 668, E 1026, E 1205, E 1275, E 1276, E 1310, E 1400, E 1401, E 1538, E 1540, E 1607, and E 1650. For discussion of radiation dosimetry for gamma rays, see ICRU Report 14.

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

2. Referenced Documents

2.1 *ASTM Standards:*

E 170 Terminology Relating to Radiation Measurements and Dosimetry[3]
E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods[4]
E 456 Terminology Relating to Quality and Statistics[4]
E 666 Practice for Calculating Absorbed Dose from Gamma or X Radiation[3]
E 668 Practice for Application of Thermoluminescence-Dosimetry (TLD) Systems for Determining Absorbed Dose in Radiation Hardness Testing of Electronic Devices[3]
E 1026 Practice for Using the Fricke Reference Standard Dosimetry System[3]
E 1204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing[3]
E 1205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System[3]
E 1261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing[3]
E 1275 Practice for Use of a Radiochromic Film Dosimetry System[3]
E 1276 Practice for Use of a Polymethylmethacrylate Dosimetry System[3]
E 1310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System[3]
E 1400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory[3]
E 1401 Practice for Use of a Dichromate Dosimetry System[3]
E 1431 Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing[3]
E 1538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System[3]
E 1539 Guide for Use of Radiation-Sensitive Indicators[3]
E 1540 Practice for Use of a Radiochromic Liquid Dosimetry System[3]
E 1607 Practice for Use of the Alanine-EPR Dosimetry System[3]
E 1650 Practice for Use of a Cellulose Acetate Dosimetry System
E 1707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

2.2 *ICRU Reports:*

[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.
Current edition approved Sept. 10, 1995. Published November 1995.
[2] The boldface numbers in parentheses refer to a list of references at the end of this practice.

[3] *Annual Book of ASTM Standards*, Vol 12.02.
[4] *Annual Book of ASTM Standards*, Vol 14.02.

ICRU Report 14 Radiation Dosimetry: X-Rays and Gamma Rays with Maximum Photon Energies Between 0.6 and 50 MeV
ICRU Report 33 Radiation Quantities and Units

3. Terminology

3.1 *Definitions*—Other terms used in this practice are defined in Terminology E 170 and ICRU Report 33.

3.1.1 *absorbed dose*—quantity of radiation energy imparted per unit mass of a specified material. The unit of absorbed dose is the gray (Gy), where 1 Gy is equivalent to the absorption of 1 J per kg (= 100 rad). The mathematical relationship is the quotient of $d\bar{\varepsilon}$ by dm, where $d\bar{\varepsilon}$ is the mean energy imparted by ionizing radiation to matter of mass dm (see ICRU 33).

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

3.1.2 *absorbed-dose mapping*—measurement of the absorbed-dose distribution within an irradiation unit through the use of dosimeters placed at specified locations.

3.1.3 *compensating dummy*—simulated product used during routine production runs with irradiation units containing less product than specified in the product loading configuration or used at the beginning or end of a production run to compensate for the absence of product.

3.1.4 *dosimeter set*—one or more dosimeters used to measure the absorbed dose at a location to a desired confidence level and whose average reading is used as the absorbed dose measurement at that location.

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

3.1.6 *irradiation unit*—a volume of material with a specified loading configuration irradiated as a single entity.

3.1.7 *production run (continuous-flow irradiation)*—a series of irradiation units consisting of materials or products having similar radiation-absorption characteristics that are irradiated sequentially to a specified range of absorbed dose.

3.1.8 *simulated product*—a mass of material with attenuation and scattering properties similar to those of a particular material or combination of materials. This term is sometimes referred to as dummy product.

3.1.9 *timer setting*—parameter varied to control the time during which an irradiation unit is exposed to radiation.

4. Significance and Use

4.1 Various products and materials routinely are irradiated at predetermined doses at gamma irradiation facilities to reduce their microbial population or to modify their characteristics. Dosimetry requirements may vary depending upon the irradiation application and end use of the product. Some examples of irradiation applications where dosimetry may be used are:

4.1.1 Sterilization of medical devices;

4.1.2 Treatment of food for the purpose of parasite and pathogen control, insect disinfestation, and shelf life extension;

4.1.3 Disinfection of consumer products;

4.1.4 Cross-linking or degradation of polymers and elastomers;

4.1.5 Polymerization of monomers and grafting of monomers onto polymers;

4.1.6 Control of pathogens in liquid or solid waste;

4.1.7 Enhancement of color in gemstones and other materials;

4.1.8 Modification of characteristics of semiconductor devices; and

4.1.9 Research on materials effects.

NOTE 2—Dosimetry is required for regulated irradiation processes such as the sterilization of medical devices and the treatment of food. It may be less important for other industrial processes, for example, polymer modification, which can be evaluated by changes in the physical and chemical properties of the irradiated materials.

4.2 Dosimeters are used as a means of quality control of the process by relating the measured response of the dosimeter to radiation to the absorbed dose in the product or in a specified material such as water.

4.3 An irradiation process usually requires a minimum absorbed dose to achieve the desired effect. There also may be a maximum absorbed dose that the product can tolerate and still meet its functional specifications. Dosimetry is essential to the irradiation process since it is used both to determine these limits and to confirm that the product is irradiated within these limits.

4.4 The absorbed-dose distribution within the product depends on the overall product dimensions and weight, irradiation geometry, and source activity distribution. The operating parameter that determines the absorbed dose is the timer setting. The timer setting must be controlled to obtain reproducible results.

4.5 Before an irradiation process can be used, the irradiator must be qualified to determine its effectiveness in reproducibly delivering known, controllable absorbed doses. This involves testing the process equipment, calibrating the equipment and dosimetry system, and characterizing the magnitude, distribution, and reproducibility of the absorbed dose delivered by the irradiator to a reference material.

4.6 To ensure consistent and reproducible dose delivery in a qualified process, routine process control requires documented product handling procedures before and after the irradiation, consistent product loading configurations, monitoring of critical processing parameters, routine product dosimetry, and documentation of the required activities and functions.

5. Radiation Source Characteristics

5.1 The radiation source used in a facility considered in this practice consists of sealed linear elements (rods or "pencils") of cobalt-60 or cesium-137 arranged in one or more planar or cylindrical arrays. Cobalt-60 and cesium-137 sources decay at known rates, emitting photons with known energies. Between source additions, removals, or redistributions, the only variation in the source output is the steady reduction in the activity due to the radioactive decay.

6. Types of Facilities and Modes of Operation

6.1 Radiation processing facilities may be categorized by irradiator type (for example, container or bulk flow), conveyor system (for example, shuffle-dwell or continuous), and operating mode (for example, batch or continuous). Product may be moved to the location in the facility where the

irradiation will take place either while the source is shielded (batch operation), or while the source is exposed (continuous operation). Product may be transported in irradiation containers past the source at a uniform controlled speed (continuous conveyance), or instead may undergo a series of discrete controlled movements separated by controlled time periods during which the irradiation container is stationary (shuffle-dwell). The source may extend above and below the product (overlapping source) or the product may extend above and below the source (overlapping product). For the overlapping product configuration, the irradiation unit is moved past the source at two or more different levels. For irradiators with rectangular source arrays, the irradiation container generally makes one or more passes on each side of the source. In bulk-flow irradiators, products such as grain or flour flow in loose form past the source.

6.2 For low absorbed-dose applications that may require particularly high mechanical speed, various techniques are used to reduce the absorbed-dose rates. These may include use of only a portion of the source, use of attenuators, and irradiation at greater distances from the source.

6.3 The details of a particular irradiator design and the mode of operation affect the delivery of absorbed dose to a product. They therefore should be considered when performing the absorbed-dose measurements required in Sections 8, 9, and 10.

7. Dosimetry Systems

7.1 Dosimetry systems used to determine absorbed dose shall cover the absorbed dose range of interest and shall be calibrated before use.

7.2 *Dosimetry System Selection*—It is important that the dosimetry system be evaluated for those parameters associated with gamma irradiation facilities that may influence the dosimeter response, for example, gamma-ray energy, absorbed-dose rate, and environmental conditions such as temperature, humidity, and light. Guidance as to desirable characteristics and selection criteria can be found in Guide E 1261. Details for individual dosimetry systems are given in Practices E 1026, E 1205, E 1275, E 1276, E 1310, E 1401, E 1538, E 1540, E 1607, and E 1650.

7.3 *Dosimetry System Calibration*—It is important that the dosimetry system used is properly calibrated with calibration traceable to a recognized national or international standard. Guidance for calibration can be found in Guide E 1261.

8. Installation Qualification

8.1 *Objective:*

8.1.1 The purpose of dosimetry in qualifying a gamma irradiation facility is to establish baseline data for evaluating 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 dose variations when these conditions fluctuate statistically and through normal operations, and (*3*) to measure absorbed dose distributions in reference materials.

8.2 *Equipment Documentation:*

8.2.1 Establish and document the irradiator qualification program that demonstrates that the irradiator, operating within specified limits, will consistently produce an absorbed-dose distribution in a given product to predetermined specification. Such documentation shall be retained for the life of the irradiator, and shall include:

8.2.1.1 A description of the instrumentation and equipment for ensuring the reproducibility, within specified limits, of the source-to-product geometry and of the time the product spends at different locations in the irradiation zone.

8.3 *Equipment Testing and Calibration:*

8.3.1 *Processing Equipment*—The absorbed dose in the product in an irradiation container depends on the operating parameters of the irradiation facility, which are controlled by the processing equipment and instrumentation.

8.3.1.1 Test all processing equipment and instrumentation that may influence absorbed dose in order to verify satisfactory operation of the irradiator within the design specifications.

8.3.1.2 Implement a documented calibration program to ensure that all processing equipment and instrumentation that may influence absorbed dose are calibrated periodically.

8.3.2 *Analytical Equipment*—The accuracy of the absorbed-dose measurement depends on the correct operation and calibration of the analytical equipment used in the analysis of the dosimeters.

8.3.2.1 Check the performance of the analytical equipment periodically to ensure that the equipment is functioning in accordance with performance specifications. Repeat this check following equipment modification or servicing and prior to the use of the equipment for a dosimetry system calibration. This check can be accomplished by using standards such as calibrated optical density filters, wavelength standards, or calibrated thickness gages supplied by the manufacturer or national or accredited standards laboratories. The correct performance of dosimetry analysis equipment also can be demonstrated by showing that the analysis results from dosimeters, given known absorbed doses, are in agreement with the expected results within the limits of the dosimetry system uncertainty. However, this method is only applicable to reference standard dosimetry systems where the long-term stability of the response has been demonstrated and documented.

8.3.2.2 Implement a documented calibration program to ensure that all analytical equipment used in the analysis of dosimeters is calibrated periodically.

8.3.2.3 Prior to each use of an analytical instrument, check the zero setting and, if applicable, the full scale reading.

8.4 *Irradiator Characterization:*

8.4.1 The absorbed dose received by any portion of product in an irradiation unit depends on facility parameters such as the activity and geometry of the source, the source-to-product distance, and the irradiation geometry, and on processing parameters such as the irradiation time, the product composition and density, and the product loading configuration.

8.4.2 The absorbed-dose rate and absorbed-dose distribution in the product will change during movement of the irradiation unit. Therefore, changing from one absorbed dose

to another by direct scaling of the time setting may or may not be valid (see 9.3.3).

8.4.3 To ensure that product near the source is processed within specifications, additions to the absorbed dose resulting from the movement of the source to and from the irradiation position should be considered and quantified.

8.4.4 The irradiator characterization process includes mapping the absorbed-dose distributions in irradiation units containing actual or simulated product. Dosimetry data from previously characterized irradiators of the same design or theoretical calculations may provide useful information for determining the number and location of dosimeters for this characterization process.

NOTE 3—Theoretical calculations may be performed using an analytical method such as the point-kernel method (5) or the Monte Carlo method (6). In the point-kernel method, the radiation source is approximated by differential isotropic point sources. The total absorbed dose at each dose point is obtained by summing the absorbed-dose contribution from each isotropic source point. The absorbed dose at a dose point is dependent mainly upon the energy of the gamma radiation and the effective atomic number, density, and thickness of the materials located between the source point and dose point (for example, source encapsulation material, product, and metal containers or supports). In the Monte Carlo method, the total absorbed dose at a dose point is determined from the energy distribution at that point by modelling the trajectories of photons and electrons through the absorbing media. In order to obtain a good statistical representation of their interactions (for example, scattering or absorption) within the media, the paths of a sufficiently large number of photons and electrons are followed until the dose point is reached. Like the point-kernel method, the Monte Carlo method requires a knowledge of relevant properties of all materials between the source and dose points.

8.4.4.1 Map the absorbed-dose distribution by a three-dimensional placement of dosimeters throughout the actual or simulated product. For this general characterization, the amount of product in the irradiation units should be the amount expected during typical irradiation runs. Select placement patterns that can most probably identify the locations of the absorbed-dose maxima and minima. Place more dosimeters in these locations, and fewer dosimeters in locations likely to receive intermediate absorbed doses. For further information on the use and placement of dosimeters, see Refs (7–13).

8.4.4.2 For a given process irradiation time or product dwell time, an increase in the product density generally results in a decrease in the minimum absorbed dose. The maximum absorbed dose may not change appreciably or it may decrease, but to a lesser degree than the minimum absorbed dose; therefore, the dose uniformity ratio increases.

8.4.5 Changes in the source loading, source geometry, or product transport system can affect the absorbed-dose distribution. If such a change is made, perform sufficient dosimetry to confirm that the change has not affected the absorbed-dose distribution, or to determine the new absorbed-dose distribution.

8.4.6 Use the results of the irradiator characterization as a guide for dosimeter placement for process qualification as discussed in Section 9.

8.4.7 The procedures for absorbed-dose mapping outlined in this section may not be feasible for some types of bulk-flow irradiators. In this case, minimum and maximum absorbed doses should 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. Calculation of the minimum and maximum absorbed doses may be an appropriate alternative (10, 13).

9. Process Qualification

9.1 *Objective:*

9.1.1 Absorbed-dose requirements vary depending upon the application and type of product being irradiated. Irradiation application is usually associated with a minimum absorbed-dose requirement and sometimes a maximum absorbed-dose requirement. For a given application, one or both of these limits may be prescribed by regulations. Therefore, the objective of process qualification is to ensure that absorbed dose requirements are satisfied. This is accomplished by absorbed-dose mapping of specific products and product loading configurations to determine the minimum and maximum absorbed doses, the locations of the minimum and maximum absorbed-dose regions, and the timer setting necessary to achieve absorbed dose within the set requirements.

9.2 *Determination of Product Loading Configuration:*

9.2.1 A product loading configuration for irradiation shall be established for each product type. The documentation for this loading configuration shall include specifications for parameters that influence the radiation processing such as product size, product mass, or product density.

9.3 *Product Absorbed-Dose Mapping:*

9.3.1 Establish the locations of the regions of minimum and maximum absorbed dose for the selected product and product loading pattern. This is accomplished by placing dosimeters throughout the volume of interest for one or more irradiation units. Select placement patterns that can most probably identify the locations of the absorbed dose extremes using data obtained from other absorbed-dose mapping studies or from theoretical calculations. Concentrate dosimeters in regions of minimum and maximum absorbed dose with fewer dosimeters placed in areas likely to receive intermediate absorbed dose. Dosimeter films in sheets or strips also may be employed to obtain useful information.

9.3.2 Consideration should be given to possible variations in the absorbed doses measured in similar locations in different irradiation units caused by variations in the product or product distributions. Timer settings chosen for routine processing should take this variation into account.

9.3.3 Ensure that the absorbed dose received during movement of the source or irradiation units during the absorbed-dose mapping is small compared to the total absorbed dose. If this requirement is met, the absorbed dose will be related directly to the timer setting, and changes to the absorbed dose can be obtained by adjustment of the timer setting. If this requirement cannot be met, the absorbed-dose mapping shall be performed using the timer setting estimated to be required for the routine production runs and repeated if there is a significant change in the timer setting.

9.3.4 If changes that could affect the magnitude or location of the absorbed dose extremes are made to the facility or mode of operation, repeat the absorbed-dose mapping to the extent necessary to establish the effects.

9.3.5 If the locations of absorbed-dose extremes identified during the absorbed-dose mapping procedure of 9.3.1 are not readily accessible during production runs, alternative positions may be used for routine 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.

9.3.6 Results from the absorbed-dose mapping measurements will determine the timer setting to be used in the production run to ensure that prescribed absorbed-dose requirements within the product are achieved. Because of the uncertainties in the absorbed-dose measurement and the inherent variations in the radiation process, it is advisable to set the operating parameters to deliver an absorbed dose greater than the prescribed minimum and smaller than the prescribed maximum, if applicable **(13, 14)**.

9.3.7 For bulk-flow irradiators, absorbed-dose mapping as described in 9.3.1 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. Calculation of the absorbed-dose extremes may be an appropriate alternative **(10, 13)**.

9.3.8 If the absorbed-dose mapping procedure of 9.3.1 reveals that the measured absorbed-dose extremes are unacceptable, it may be possible to alter these values by changing the operating parameters or by using attenuators or compensating dummy. Alternatively, it may be necessary to change the product loading pattern of the irradiation unit.

10. Routine Product Processing

10.1 *Processing Parameters:*

10.1.1 For product processing, set the operating parameters as established during process qualification, taking into account source decay.

10.1.2 Control, monitor, and document the operating parameters to ensure that the product in each irradiation unit is processed in accordance with specifications.

10.1.3 If these operating parameters deviate from prescribed processing limits, take appropriate action.

10.1.4 *End Units*—The first and last irradiation units of a production run may undergo changes in absorbed-dose distributions, including changes in the location and magnitude of the minimum and maximum absorbed dose, which are caused by differences in the radiation-absorption characteristics of product in the preceding and following production run. If prior dosimetry data indicate the existence of an unacceptable absorbed-dose distribution for the end units, place compensating dummy in adjacent units to make the absorbed-dose distributions acceptable.

NOTE 4—For some batch irradiators, there may be no end units when the irradiator is filled with product from one production run.

10.1.5 *Partially Loaded Units*—For irradiation units containing less product than specified in the product loading pattern (see 9.2.1), ensure that absorbed-dose mapping data exist to confirm that the absorbed doses will be within the specified limits. If absorbed-dose mapping data are not available, perform the dose mapping procedure of 9.3.1 to ensure that the absorbed-dose distributions are characterized adequately. Changes to the absorbed dose distribution arising from partial loading in some cases may be minimized by the use of compensating dummy placed at appropriate locations in the irradiation unit.

10.2 *Routine Production Dosimetry:*

10.2.1 Routine production dosimetry is part of the verification process for establishing that the irradiation process is under control.

10.2.2 Ensure that the product receives the required absorbed dose within the specified limits by employing proper dosimetry procedures, with appropriate statistical controls and documentation. These procedures involve the use of routine in-plant dosimetry performed as described in 10.2.2.1 through 10.2.2.5.

10.2.2.1 *Dosimeter Location*—Place dosimeter sets in or on the product in selected irradiation units at predetermined locations of the maximum and minimum absorbed dose (see 9.3.1), or at the alternative reference positions determined in 9.3.5.

10.2.2.2 *Placement Frequency*—Select a sufficient number of irradiation units to which to place dosimeter sets in order to verify that the dose absorbed by the product falls within specified limits. Place dosimeter sets at locations described in 10.2.2.1 in the first and last irradiation units of the production run to confirm that the absorbed doses at these locations are within the specified limits. Dosimeter locations or interpretations of results should take into consideration possible changes in absorbed dose distributions in these units (10.1.4). For short production runs, available dosimetry data may be useful in determining if it is actually necessary to place dosimeter sets in intermediate irradiation units.

NOTE 5—The absorbed dose distribution in the irradiation unit is already known from the dose mapping effort described in Section 9 and from the equipment operating parameters (dwell time, etc). However, the use of a sufficient number of strategically placed dosimeter sets serves to confirm that the absorbed doses within the specified range have been achieved. Some examples of acceptable dosimeter placement frequency are the use of sufficient dosimeter sets so that the absorbed-dose measurements are made in an irradiation unit at least once every 8 hours, or the use of sufficient dosimeter sets so that there is at least one irradiation unit containing a dosimeter set being irradiated at all times. For operation in the batch mode, it is desirable to place dosimeter sets on at least one irradiation unit for each product type in each batch. More frequent placement of dosimeters during the production run could result in less product rejection should some operational uncertainty or failure arise.

10.2.2.3 *Environmental Effects*—A change in the environment (for example, temperature or humidity) of a dosimeter before, during, and after the irradiation process may affect its response. If required, correct the dosimeter response for any such effect. See Guide E 1261 and Practices for individual dosimetry systems listed in 2.1.

10.2.2.4 *Radiation Processing at High or Low Temperatures*—If the response of dosimeters used for routine process control is temperature-dependent, exercise care when determining the temperature of the dosimeter during irradiation and apply the appropriate temperature correction. Dosimeters that exhibit a highly temperature-dependent response should not be placed in locations with large temperature gradients.

10.2.2.5 *Bulk-Flow Irradiators*—For some types of bulk-flow irradiators such as those treating fluids or grains, where