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Practice for dosimetry in gamma irradiation facilities for radiation processing

Pratique de la dosimétrie dans les installations de traitement par irradiation gamma

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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.

ASTM International is one of the world's largest voluntary standards development organizations with global participation from affected stakeholders. ASTM technical committees follow rigorous due process balloting procedures.

A project between ISO and ASTM International has been formed to develop and maintain a group of ISO/ASTM radiation processing dosimetry standards. Under this project, ASTM Subcommittee E10.01, Dosimetry for Radiation Processing, is responsible for the development and maintenance of these dosimetry standards with unrestricted participation and input from appropriate ISO member bodies.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. Neither ISO nor ASTM International shall be held responsible for identifying any or all such patent rights.

International Standard ISO/ASTM 51702 was developed by ASTM Committee E10, Nuclear Technology and Applications, through Subcommittee E10.01, and by Technical Committee ISO/TC 85, Nuclear energy.

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

This standard is issued under the fixed designation ISO/ASTM 51702; 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 outlines the installation qualification program for an irradiator and the dosimetric procedures to be followed during operational qualification, performance qualification, and routine processing in facilities that process product with ionizing radiation from radionuclide gamma sources to ensure that product has been treated within a predetermined range of absorbed dose. Other procedures related to installation qualification, operational qualification, performance qualification, and routine processing that may influence absorbed dose in the product are also discussed. Information about effective or regulatory absorbed-dose limits is not within the scope of this practice.

NOTE 1—Dosimetry is only one component of a total quality assurance program for adherence to good manufacturing practices.

NOTE 2—ISO/ASTM Practices 51649 and 51608 describe dosimetric procedures for electron beam and X-ray (bremsstrahlung) irradiation facilities for radiation processing.

1.2 For the irradiation of food and the radiation sterilization of health care products, other specific ISO/ASTM or ISO standards exist. For food irradiation, see ISO/ASTM Practice 51204. For the radiation sterilization of health care products, see ISO 11137. In those areas covered by ISO/ASTM Practice 51204 or ISO 11137, those standards take precedence.

1.3 For guidance in the selection and calibration of dosimetry systems, and interpretation of measured absorbed dose in the product, see ISO/ASTM Guide 51261 and ASTM Practice E 666. For the use of specific dosimetry systems, see ASTM Practices E 1026 and E 2304, and ISO/ASTM Practices 51205, 51275, 51276, 51310, 51401, 51538, 51540, 51607, 51650, and 51956. For discussion of radiation dosimetry for gamma-rays and X-rays also 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:* [2]

E 170 Terminology Relating to Radiation Measurements and Dosimetry

E 666 Practice for Calculating Absorbed Dose from Gamma or X Radiation

E 1026 Practice for Using the Fricke Reference Standard Dosimetry System

E 2232 Guide for Selection and Use of Mathematical Models for Calculating Absorbed Dose in Radiation-Processing Applications

E 2304 Practice for Use of a LiF Photo-Fluorescent Film Dosimetry System

2.2 *ISO/ASTM Standards:*[2]

51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing

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

51310 Practice for Use of a Radiochromic Optical Waveguide 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

51538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System

51539 Guide for Use of Radiation-Sensitive Indicators

51540 Practice for Use of a Radiochromic Liquid Dosimetry System

51607 Practice for Use of the Alanine-EPR Dosimetry System

51608 Practice for Dosimetry in an X-Ray (Bremsstrahlung) Facility for Radiation Processing

51649 Practice for Dosimetry at Energies Between 300 KeV and 25 KeV

51650 Practice for Use of a Cellulose Acetate Dosimetry System

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

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

51956 Practice for Use of Thermoluminescence-Dosimetry (TLD) Systems for Radiation Processing

2.3 *International Commission on Radiation Units and Measurements (ICRU) Reports:*

ICRU Report 14 Radiation Dosimetry: X-Rays and Gamma Rays with Maximum Photon Energies Between 0.6 and 50 MeV[3]

ICRU Report 60 Fundamental Quantities and Units for Ionizing Radiation[3]

2.4 *ISO Standard:*

ISO 11137 Sterilization of Health Care Products–Requirements for Validation and Routine Control-Radiation Sterilization[4]

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 of the specified material (1 Gy = 1 J/kg). The mathematical relationship is the quotient of $d\bar{\epsilon}$ by dm, where $d\bar{\epsilon}$ is the mean incremental energy imparted by ionizing radiation to matter of incremental mass dm (see ICRU Report 60).

$$D = d\bar{\epsilon}/dm \quad (1)$$

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

3.1.3 *calibration facility*—combination of an ionizing radiation source and its associated instrumentation that provides, at a specified location and within a specific material, a uniform and reproducible absorbed dose, or absorbed-dose rate, traceable to national or international standards and that may be used to derive the dosimetry system's response function or calibration curve.

3.1.4 *compensating dummy*—simulated product used during routine production runs in process loads that contain less product than specified in the product loading configuration, or simulated product used at the beginning or end of a production run, to compensate for the absence of product. Also see 3.1.18.

3.1.4.1 *Discussion*—Simulated product or phantom material may be used during operational qualification as a substitute for the actual product, material, or substance to be irradiated.

3.1.5 *dosimeter response*—reproducible, quantifiable radiation effect produced by a given absorbed dose.

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

3.1.7 *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.

3.1.8 *installation qualification*—obtaining and documenting evidence that the irradiator, with all its associated equipment and instrumentation, has been provided and installed in accordance with specifications.

3.1.9 *irradiation time*—total time during which a process load is exposed to radiation.

3.1.10 *operational qualification*—obtaining and documenting evidence that installed equipment and instrumentation operate within predetermined limits when used in accordance with operational procedures.

3.1.11 *performance qualification*—obtaining and documenting evidence that the equipment and instrumentation, as installed and operated in accordance with operational procedures, consistently perform according to predetermined criteria and thereby yield product that meets specifications.

3.1.12 *primary-standard dosimeter*—dosimeter of the highest metrological quality, established and maintained as an absorbed-dose standard by a national or international standards organization (see ISO/ASTM Guide 51261).

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

3.1.14 *production run* (applicable to continuous-flow and shuffle-dwell irradiations)—a 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.

3.1.15 *reference-standard dosimeter*—dosimeter of high metrological quality, used as a standard to provide measurements traceable to and consistent with measurements made using primary-standard dosimeters (see ISO/ASTM Guide 51261).

3.1.16 *response function*—mathematical representation of the relationship between dosimeter response and absorbed dose for a given dosimetry system.

3.1.17 *routine dosimeter*—dosimeter calibrated against a primary-, reference-, or transfer-standard dosimeter and used for routine absorbed-dose measurements (see ISO/ASTM Guide 51261).

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

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

3.1.19 *transfer-standard dosimeter*—dosimeter, often a reference-standard dosimeter, suitable for transport between different locations, used to compare absorbed-dose measurements (see ISO/ASTM Guide 51261).

3.2 Definitions of other terms used in this standard that pertain to radiation measurement and dosimetry may be found

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

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

in ASTM Terminology E 170. Definitions in E 170 are compatible with ICRU 60; ICRU 60, therefore, may be used as an alternative reference.

4. Significance and use

4.1 Various products and materials may be treated with ionizing radiation, such as gamma rays from ^{60}Co or ^{137}Cs sources, for numerous purposes, including microbial reduction and material modification. Dosimetry requirements may vary depending upon the irradiation application and the end use of the product.

4.2 For many products, the irradiation specifications include a minimum or maximum limit of absorbed dose, sometimes both: a minimum is set to ensure that the intended beneficial effect is achieved and a maximum limit is set for the purpose of avoiding product degradation.

4.2.1 For a given application, one or both of these values may be prescribed by regulations that have been established on the basis of available scientific data. Therefore, it is necessary to determine the capability of an irradiation facility to deliver the absorbed dose within prescribed limits prior to the irradiation of the product. Also, it is necessary to monitor and document the absorbed dose during each production run to verify compliance with the process specifications within a predetermined level of confidence.

4.2.2 Some examples of irradiation applications where dosimetry requirements are similar to those required for food irradiation or for radiation sterilization of health care products are:

4.2.2.1 Disinfection of consumer product;

4.2.2.2 Control of pathogens in liquids or solids; and

4.2.2.3 Research on material effects.

4.3 For other products, the irradiation specifications may depend on the evaluation of changes in the physical and chemical properties of the irradiated materials.

4.3.1 For these products, the requirements for dosimetry may be less stringent, but dosimetry data may be useful for quality control, transfer of the process to another facility or for comparison with data from other facilities.

4.3.2 Some examples of radiation applications where all of the dosimetry requirements stated in this practice may not be required are:

4.3.2.1 Cross-linking or degradation of polymers and elastomers;

4.3.2.2 Polymerization of monomers and grafting of monomers onto polymers; and

4.3.2.3 Enhancement of color in gemstones and other materials.

4.4 For some products, the requirements for dosimetry may be different.

4.4.1 An example of a radiation application with different requirements is:

4.4.1.1 The requirement to determine the absorbed dose in silicon or other materials different from water in radiation hardness testing of semiconductors or the modification of characteristics of semiconductor devices.

4.5 For some radiation applications, the irradiations may be performed at low or high temperatures, causing difficulties in dosimetry. For these applications, it may be necessary to perform dosimetry at ambient room temperatures and rely on process control to ensure that the absorbed dose is within the desired limits. In some cases it may be possible to use dosimeters for routine monitoring at the temperature used for the irradiation application if the dosimeter temperature during irradiation is sufficiently stable to allow correction for temperature effects on the dosimeter response.

5. Radiation source characteristics

5.1 The radiation source used in a facility considered in this practice consists of sealed elements of ^{60}Co or ^{137}Cs which are typically linear rods or "pencils" arranged in one or more planar or cylindrical arrays.

5.2 Cobalt-60 emits photons with energies of approximately 1.17 and 1.33 MeV in nearly equal proportions. Cesium-137 emits photons with energies of approximately 0.662 MeV **(1)**.[5]

5.3 The half-lives for ^{60}Co and ^{137}Cs are approximately 5.2708 years and 30.07 years, respectively **(2, 3)**.

5.4 Between source replenishments, removals, or redistributions, the sole variation in the source output is the steady reduction in the activity caused by the radioactive decay.

6. Types of facilities

6.1 The design of an irradiator affects the delivery of absorbed dose to a product. Therefore, the irradiator design should be considered when performing the absorbed-dose measurements described in Sections 8-11.

6.2 Radiation processing facilities may be categorized by operating mode (for example, batch or continuous), conveyor system (for example, continuous or shuffle-dwell), and irradiator type (for example, container or bulk flow).

6.2.1 Product may be moved to the location in the facility where the irradiation will take place, either while the source is fully shielded (batch operation) or while the source is exposed (continuous operation).

6.2.2 Product may be transported past the source at a uniform and controlled speed (continuous conveyance), or may instead undergo a series of discrete controlled movements separated by controlled time periods during which the process load is stationary (shuffle-dwell).

6.2.3 For most commercial irradiators, the process load generally makes one or more passes on each side of the source array.

6.2.3.1 Process loads may move past a source array in a configuration in which the source either extends above and below the process load (source overlap) or the process load extends above and below the source (product overlap). In the latter configuration, the process load is usually moved past the source at two or more levels.

6.2.3.2 In bulk-flow irradiators, product flows in loose form past the source.

6.3 Because of mechanical speed limitations, various techniques may be used to reduce the absorbed-dose rates for low

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

absorbed-dose applications. These techniques include using only a portion of the source (for example, raising only one of several source racks to the irradiation position), using attenuators, and irradiating at greater distances from the source.

7. Dosimetry systems

7.1 *Description of Dosimeter Classes*—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 *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.

7.1.2 *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 absorbed-dose ranges, are given in ISO/ASTM Guide 51261.

7.1.3 *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.

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

7.2 *Selection of Dosimetry Systems*—Select dosimetry systems suitable for the expected radiation processing applications at the facility using the selection criteria listed in ISO/ASTM Guide 51261. During the selection process, for each dosimetry system, take into consideration its performance behavior with respect to relevant influence quantities and the uncertainty associated with it.

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

7.3.1 *Calibration Irradiation of Reference- or Transfer-Standard Dosimeters*—Calibration irradiations shall be performed at an accredited calibration laboratory or in-house calibration facility meeting the requirements of ISO/ASTM Practice 51400. The laboratory or facility shall provide an absorbed dose (or absorbed-dose rate) having measurement traceability to nationally or internationally recognized standards.

7.3.2 *Calibration Irradiation of Routine Dosimeters*—Calibration irradiations may be performed per 7.3.1 or at a production or research irradiation facility together with reference- or transfer-standard dosimeters that have measurement traceability to nationally or internationally recognized standards. This statement also applies when reference-standard dosimeters are used as routine dosimeters.

7.3.3 *Measurement Instrument Calibration and Performance Verification*—Establish and implement procedures for calibrating the measurement instruments and for checking their performance periodically to ensure that the instruments are functioning according to performance specifications.

7.3.3.1 Document a calibration program to ensure that all measurement instruments used in the analysis of dosimeters are calibrated periodically. The calibrations shall be traceable to a national or international standards laboratory.

7.3.3.2 A performance check shall be made 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, and calibrated thickness gauges, supplied by the equipment manufacturer or by national or accredited standards laboratories.

7.3.3.3 See ISO/ASTM Guide 51261, the corresponding ISO/ASTM or ASTM standard for the dosimetry system, and instrument-specific operating manuals for instrument calibration and performance verification procedures.

8. Installation qualification

8.1 *Objective*—The purpose of an installation qualification program is to demonstrate that the irradiator with its associated processing equipment and measurement instruments have been delivered and installed in accordance with their specifications. Installation qualification includes documentation of the irradiator and the associated processing equipment and measurement instruments, establishment of the testing, operation and calibration procedures for their use, and verification that they operate according to specifications. An effective installation qualification program will ensure consistent and correct operation of the irradiator so as to deliver the required absorbed dose to a product.

8.2 *Equipment Documentation*—Establish and document descriptions of the irradiator and the associated processing equipment and measurement instruments installed at the facility. This documentation shall be retained for the life of the facility. At a minimum, it shall include:

8.2.1 Description of the location of the irradiator within the operator's premises in relation to the areas assigned and the means established for ensuring the segregation of un-irradiated products from irradiated products;

8.2.2 Description of the operating procedure of the irradiator;

8.2.3 Description of the construction and operation of the product handling equipment;

8.2.4 Description of the materials and construction of any containers used to hold food products during irradiation;

8.2.5 Description of the process control system;

8.2.6 Description of any modifications made during and after installation.

8.3 *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.

8.3.1 *Testing Procedures*—These procedures describe the testing and validation methods that ensure that the installed irradiator and its associated processing equipment and measurement instruments operate according to specification.

8.3.2 *Operation Procedures*—These procedures describe how to operate the irradiator and its associated processing equipment and measurement instruments during routine operation.

8.3.3 *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. Some equipment and instruments might be required to be traceable to a national or other accredited standards laboratory.

8.4 *Verification of Processing Equipment and Measurement Instruments*—Verify that the installed processing equipment and measurement instruments operate within their design specifications by following the testing procedures noted in 8.3.1. If necessary, ensure that they have been calibrated according to the calibration procedures noted in 8.3.3.

8.4.1 Test all processing equipment to verify satisfactory operation of the irradiator within the design specifications. Document all testing results.

8.4.2 Test the performance of the measurement instruments to ensure that they are functioning according to performance specifications. Document all testing results.

8.4.3 If any modification or change is made to the processing equipment or measurement instruments during installation qualification, they shall be re-tested.

9. Operational qualification

9.1 *Objective*—The purpose of dosimetry in the operational qualification of a gamma irradiation facility is to establish baseline data for evaluating facility effectiveness, predictability, and reproducibility for the range of conditions of operation for each set of irradiator parameters and process parameters used for irradiating product. The absorbed dose received by any portion of product in a process load depends on both the irradiator parameters and the process parameters.

9.1.1 Examples of irradiator parameters are the activity of the source of radiation, the source geometry, the source-to-product distance, the irradiation geometry (for example, 1- or 2-sided irradiation, multiple passes), and the process paths.

9.1.2 Examples of process parameters are the length of time product is irradiated, the conveyor speed, the product composition and density, and the product loading configuration.

9.2 *Absorbed-dose Mapping*—Perform dosimetry *(1)* to establish relationships between the absorbed dose for homogeneous process loads and the irradiator and process parameters; *(2)* to characterize absorbed-dose variations when process parameters fluctuate statistically during normal operations; and *(3)* to measure absorbed-dose distributions in homogeneous materials, that is, with materials of uniform bulk density, such as grains (for example, wheat) or cardboard.

9.2.1 Map the absorbed-dose distribution by a three-dimensional placement of dosimeter sets in a process load containing homogeneous material **(4, 5)**. 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.

9.2.1.1 Select placement patterns that can most probably identify the locations of the absorbed-dose maxima and minima (for example, see Fig. 1). Place more dosimeter sets in these locations and fewer dosimeter sets in locations likely to receive intermediate absorbed doses. Dosimetry data from previously qualified irradiators of the same design or calculations using mathematical models (see ASTM Guide E 2232) may provide useful information for determining the number and location of dosimeters for this qualification process.

NOTE 3—Dosimeter strips or sheets may be used to increase spatial resolution of the absorbed-dose map, if the use of individual dosimeters is inadequate.

9.2.2 Map a sufficient number of process loads 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.

9.2.3 The number of process loads preceding and following the dose-mapped process loads shall be sufficient to effectively simulate an irradiator filled with homogeneous product.

9.2.4 If the facility anticipates irradiating process loads spanning a range of densities, perform absorbed-dose mapping over the density range. This is necessary since differences in bulk density of the product may result in changes in the magnitudes and locations of the minimum and maximum absorbed doses, which, in turn, could change the dose-uniformity ratio.

9.2.4.1 When products of different densities are in the irradiator at the same time, the absorbed-dose distribution in any one product may be influenced by the different attenuation and scattering properties of the other products. The magnitude of these effects can be estimated by absorbed-dose mapping of the first and last process loads of two sequential production