Achieving Measurement Traceability Through Use of Dosimetry Standards

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Questions to Ask Yourself

1. **What product am I irradiating?**
2. **What is the intended effect to be achieved?**
3. **What standards should I follow?**
4. **What am I required to do to validate my process?**
5. **How do I maintain compliance?**

What is the intended effect to be achieved?

Phytosanitary Treatment of Produce

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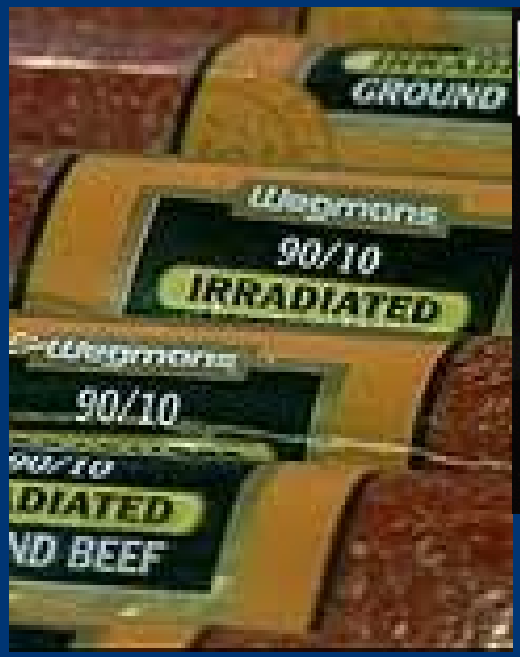
up to 1 kGy

What is the intended effect to be achieved?

Elimination of Pathogens



3 – 30 kGy

What is the intended effect to be achieved?

Sterilization of Healthcare Products / Medical Devices

STERILE R

25 kGy

What standards should I follow?

Industry Standard for Food:

ISO 14470 *"Food Irradiation- Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food"*

Twelve ASTM E10.01/E61 standards are referenced in ISO 14470: 2011

What standards should I follow?

Industry Standard for Health Care Products:

ISO 11137-1:2006 *"Sterilization of Healthcare Products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices"*

ISO 11137-2:2012 *"Sterilization of Healthcare Products – Radiation – Part 2: Establishing the sterilization dose"*

ISO 11137-3:2006 *"Sterilization of Healthcare Products – Radiation – Part 3: Guidance on dosimetric aspects"* [1]

[1] Fourteen ASTM E10.01/E61 standards are referenced in ISO 11137-3:2006

What am I required to do?

Define your sterilization equipment (ISO 11137-1 Section 6)

Define your product (ISO 11137-1 Section 7)

Define your process (ISO 11137-1 Section 8)

1. Maximum Acceptable Dose (8.1)
2. Sterilization Dose (8.2)

Validate your process (ISO 11137-1 Section 9)

1. Equipment Installation Qualification (9.1)
2. Equipment Operational Qualification (9.2)
3. Process / Performance Qualification (PQ) (9.3)

Monitoring & Control of your process (ISO 11137-1 Section 10)

QUESTION?

What is a CRITICAL component to your radiation sterilization validation?

DOSIMETRY

Why Dosimetry

Dosimetry is used in:

Maximum Dose Establishment - At what dose does the product fail?

Sterilization Dose Establishment - At what dose is the product SAL achieved?

Equipment Installation Qualification - Is the equipment delivering the dose required?

Equipment Operational Qualification - What is my equipment capable of delivering with respect to dose distribution?

Performance Qualification - What is the distribution of dose within my product?

Routine monitoring & control - How will I release my product?

How can I ensure the correct dose is delivered and the intended effect is achieved?

Measurement Traceability

DOSIMETRY


Designation: E2628 – 09

Standard Practice for Dosimetry in Radiation Processing


ISO/ASTM 51261:2002(E)

Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing

Dosimetry Standards – Measurement

ASTM E2628 *"Standard Practice for Dosimetry in Radiation Processing"*

ASTM E2701 *"Standard Guide for Performance Characterization of Dosimeters and Dosimetry Systems for Use in Radiation Processing"*

ISO/ASTM 51261 *"Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing"*

ISO/ASTM 51707 *"Standard Guide for Estimating Uncertainties in Dosimetry for Radiation Processing"*

Unbroken Calibration Chain

For traceability to national standards there must be an unbroken chain of measurements.

- Absorbed Dose is transferred from a national standard to reference and transfer standard dosimetry systems within the calibration laboratory.
    - Absorbed Dose is then transferred to the user for a given set of conditions and performance characteristics.

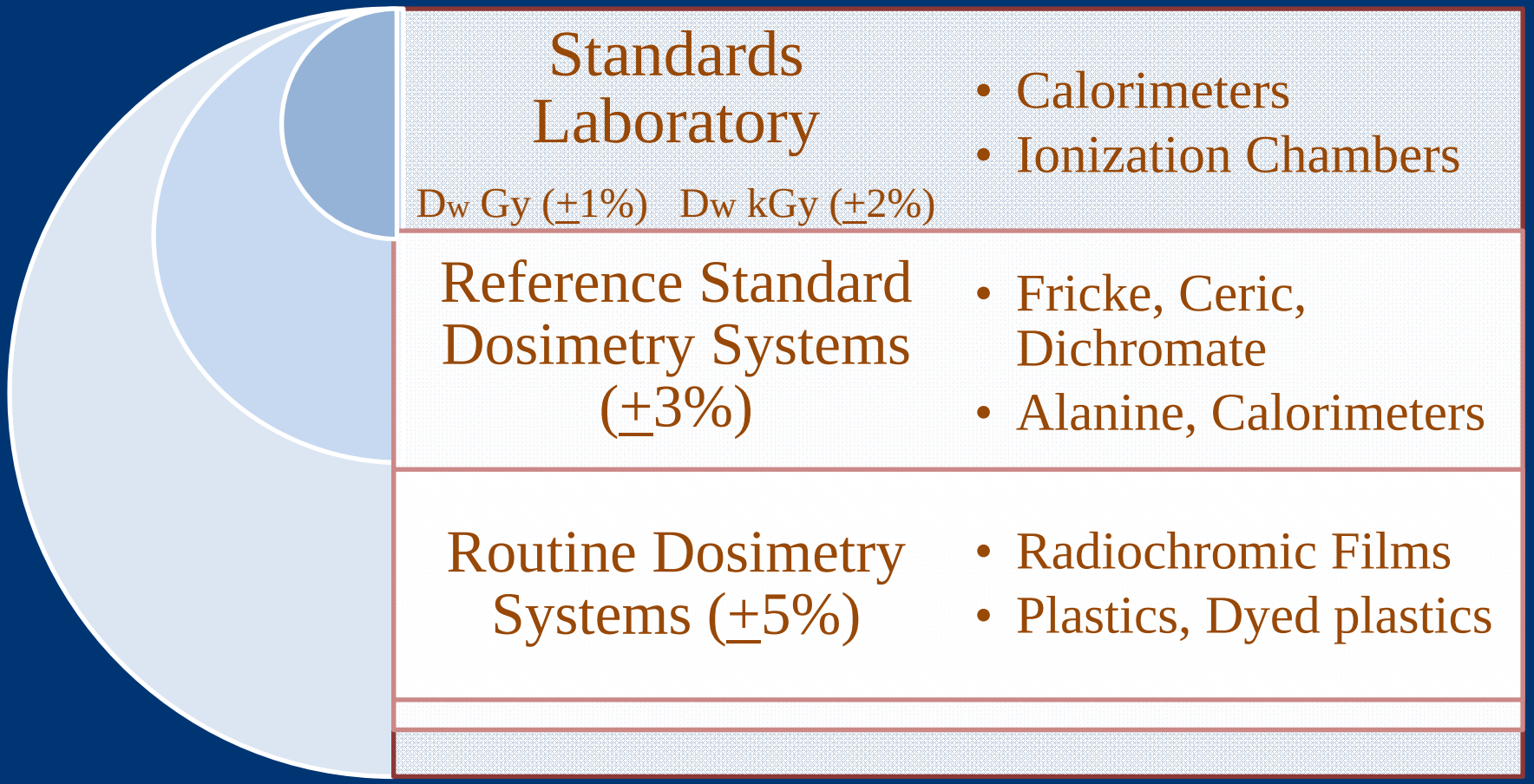
Traceability and Uncertainty

All aspects of the calibration procedure must be fully defined and documented and all possible influence quantities must be taken in to account.

- The aim of the calibration is to ensure that dose measurements can be related to accepted standards through a series of known steps, each with a defined level of uncertainty.

ISO/ASTM 51707 "*Standard Guide for Estimating Uncertainties in Dosimetry for Radiation Processing*"

Traceability Chain



Traceability is achieved by:

Calibration based on measurements from a laboratory that itself can demonstrate traceability (an Approved Laboratory).

Ensure that all instrumentation is performing correctly.

Take account of influence quantities (temperature, dose rate, etc.) both at the time of calibration and during the whole period of use.

Fully document all steps and assess the associated uncertainty.

Traceability can be lost by:

Calibration based on measurements from a laboratory that cannot demonstrate traceability.

Not controlling the instrumentation and ensuring its correct performance.

Not taking all relevant influence quantities into account during the lifetime of the calibration.

Not maintaining adequate documentation (traceability needs to be demonstrated).

Not establishing full uncertainty budgets.

Dosimetry Standards - Application:

Designation: E 2303 – 03

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

ISO/ASTM 51649:2005(E)

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

ISO 11137-3:2006 "Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects"

ASTM E2303 "*Standard Guide for Absorbed Dose Mapping in Radiation Processing Facilities*"

ISO /ASTM 51608 "*Standard Practice for Dosimetry in an X-ray (Bremsstrahlung) Facility for Radiation Processing*"

ISO/ASTM 51649 "*Standard Practice for Dosimetry in an Electron Beam Facility for Radiation Processing at Energies Between 300 keV and 25 MeV*"

ISO/ASTM 51702 "*Standard Practice for Dosimetry in Gamma Irradiation Facilities for Radiation Processing*"

E2303 Dose Mapping Prerequisite

5.2 *Calibration of the Dosimetry System*:

5.2.1 Prior to use, the dosimetry system (consisting of a specific batch of dosimeters and specific measurement instruments) **shall be calibrated** in accordance with the user's documented procedure that specifies details of the calibration process and quality assurance requirements.

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.

What am I required to do?

Define your sterilization equipment

- Radiation source
- Irradiator and its characteristics
- Location of the Irradiator
- Process controls
- Product Pathway

Define your product

- What is it?
- What is it made of?
- How is going to be presented to the irradiation source?
- Will it be part of a family?

What am I required to do?

Define your process

Maximum Dose

- Ensure product is irradiated to a dose greater than the expected processing range and tested for functionality

Minimum Dose

- Establish the minimum sterilization dose through an appropriate method to achieve the desired SAL
  - Method 1, Method 2 or VD_{MAX}
    - ✓ Dose Map
    - ✓ Verification Dose

What am I required to do?

Validate your process

Equipment Installation Qualification

- Gamma Irradiator (ISO/ASTM 51702)
- Electron Beam Irradiator (ISO/ASTM 51649)
  - Beam Energy
  - Scan Width / Uniformity
- X-ray Irradiator (ISO/ASTM 51608)
  - Beam Energy
  - Scan Width / Uniformity

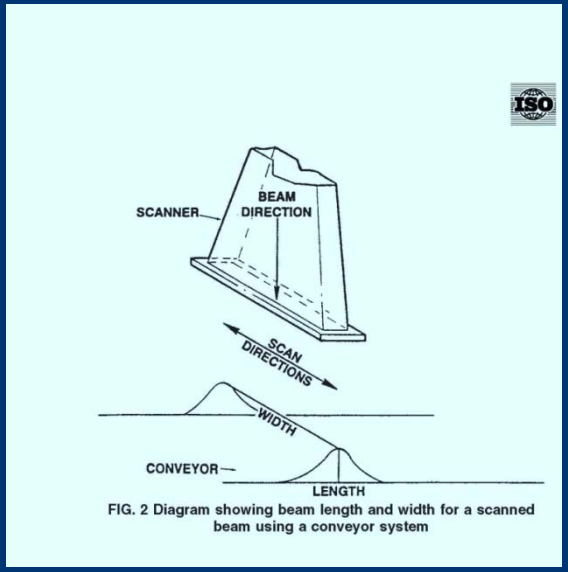


FIG. 2 Diagram showing beam length and width for a scanned beam using a conveyor system

E2303: Confirm installation is correct.

Select appropriate dosimetry system for dose mapping

What am I required to do?

Validate your process (cont.)

Equipment Operational Qualification

- Gamma Irradiator (ISO/ASTM 51702)
  - Dose Mapping (ASTM E2303)
- Electron Beam Irradiator (ISO/ASTM 51649)
  - Dose Mapping (ASTM E2303)
- X-ray Irradiator (ISO/ASTM 51608)
  - Dose Mapping (ASTM E2303)

Place a sufficient number of dosimeters in homogenous material to determine absorbed dose distribution.

Measure replicates at the same positions to determine variability.

Designation: E 2303 – 03

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

This standard is issued under the fixed designation E 2303; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

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

Note 1—For irradiation of food and the radiation sterilization of health care products, other specific ISO and ISO/ASTM standards containing dose mapping requirements exist. For food irradiation, see ISO/ASTM 51204, Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing and ISO/ASTM 51431, Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing. For the radiation sterilization of health care products, see ISO 11137: 1995, Sterilization of Health Care Products Requirements for Validation and Routine Control Radiation Sterilization. In those areas covered by ISO 11137, that standard takes precedence. ISO/ASTM Practice 51608, ISO/ASTM Practice 51649, and ISO/ASTM Practice 51702 also contain dose mapping requirements.

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

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

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

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

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E 170 Terminology Relating to Radiation Measurements and Dosimetry[3]

E 177 Practice for the Use of the Terms Precision and Accuracy Applied to Measurement of a Property of Material[4]

E 178 Practice for Dealing with Outlying Observations[4]

E 666 Practice for Calculating Absorbed Dose from Gamma or X Radiation[3]

E 668 Practice for the 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 2232 Guide for Selection and Use of Mathematical Methods for Calculating Absorbed Dose in Radiation Processing Applications[3]

2.2 *ISO/ASTM Standards:*[5]

ISO/ASTM 51204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing

ISO/ASTM 51205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System

ISO/ASTM 51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing

ISO/ASTM 51275 Practice for Use of a Radiochromic Film Dosimetry System

ISO/ASTM 51276 Practice for Use of a Polymethylmethacrylate Dosimetry System

ISO/ASTM 51310 Practice for Use of a Radiochromic Optical Waveguide Dosimetry System

ISO/ASTM 51400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory

ISO/ASTM 51401 Practice for Use of a Dichromate Dosimetry System

ISO/ASTM 51431 Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing

ISO/ASTM 51538 Practice for Use of the Ethanol-Chlorobenzene Dosimetry System

ISO/ASTM 51540 Practice for Use of a Radiochromic Liquid Dosimetry System

ISO/ASTM 51607 Practice for Use of the Alanine-EPR Dosimetry System

[1] This guide is under the jurisdiction of ASTM Committee E10 on Nuclear Technology and Applications and is the direct responsibility of Subcommittee E10.01 on Dosimetry for Radiation Processing.
Current edition approved July 10, 2003. Published August 2003

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

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

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

[5] "Standards on Dosimetry for Radiation Processing ASTM International 2002. See *Annual Book of ASTM Standards*, Vol 12.02.

What am I required to do?

Validate your process (cont.)

Process / Performance Qualification

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

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

[5] *Standards in Dosimetry for Radiation Processing* ASTM International 2002. See *Annual Book of ASTM Standards*, Vol 12.02.

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- Gamma Irradiator (ISO/ASTM 51702) Dose Mapping (ASTM E2303)
- Electron Beam Irradiator (ISO/ASTM 51649) Dose Mapping (ASTM E2303)
- X-ray Irradiator (ISO/ASTM 51608) Dose Mapping (ASTM E2303)

Replicate dose maps are performed for specific product and load configurations.

Correlation of dose at reference monitoring position to product dose are measured to document variability.

What am I required to do?

Monitoring & Control of your process

- Gamma Irradiator (ISO/ASTM 51702)
- Electron Beam Irradiator (ISO/ASTM 51649)
- X-ray Irradiator (ISO/ASTM 51608)

Dose measurement traceability and guidance from supporting standards, provides a way to ensure compliance to regulatory requirements.

ISO/ASTM 51649:2005(E)

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

This standard is issued under the fixed designation ISO/ASTM 51649; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision.

1. Scope

1.1 This practice covers dosimetric procedures to be followed in Installation Qualification, Operational Qualification and Performance Qualifications (IQ, OQ, PQ), and routine processing at electron beam facilities to ensure that the product has been treated with an acceptable range of absorbed doses. Other procedures related to IQ, OQ, PQ, and routine product processing that may influence absorbed dose in the product are also discussed.

NOTE 1—For guidance in the selection and calibration of dosimeters, see ISO/ASTM Guide 51261. For further guidance in the use of specific dosimetry systems, and interpretation of the measured absorbed dose in the product, also see ISO/ASTM Practices 51275, 51276, 51431, 51607, 51631, 51650, and 51956. For use with electron energies above 5 MeV, see Practice E 1026, and ISO/ASTM Practices 51205, 51401, 51538, and 51540 for discussions of specific large volume dosimeters. For discussion of radiation dosimetry for pulsed radiation, see ICRU Report 34.

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

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

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

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

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2.1 *ASTM Standards:* [2]

E 170 Terminology Relating to Radiation Measurements and Dosimetry

E 1026 Practice for Using the Fricke Reference Standard Dosimetry System

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

E 2303 Guide to Dose Mapping in Radiation Processing Facilities

2.2 *ISO/ASTM Standards:*[2]

51205 Practice for Use of a Ceric-Cerous Sulfate Dosimetry System

51261 Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing

51275 Practice for Use of a Radiochromic Film Dosimetry System

51276 Practice for Use of a Polymethylmethacrylate Dosimetry System

51400 Practice for Characterization and Performance of a High-Dose Radiation Dosimetry Calibration Laboratory

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51538 Practice for Use of an Ethanol-Chlorobenzene Dosimetry System

51539 Guide for the Use of Radiation-Sensitive Indicators

51540 Practice for Use of a Radiochromic Liquid Solution Dosimetry System

51607 Practice for Use of the Alanine–EPR Dosimetry System

51631 Practice for Use of Calorimetric Dosimetry Systems for Electron Beam Measurements and Dosimeter Calibrations

51650 Practice for Use of a Cellulose Triacetate Dosimetry System

51707 Guide for Estimating Uncertainties in Dosimetry for Radiation Processing

[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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ASTM E61 Radiation Processing

Standards that provide guidance to end users in developing and maintaining a TRACEABLE DOSE MEASUREMENT SYSTEM

Thank you for listening!

ASTM INTERNATIONAL

E61 STANDARDS

Subcommittee E61.01
Dosimetry

- E2628 Use of Dosimeters
- E2701 Performance Characterization
- 51261 Calibration
- 51707 Measurement Uncertainty

Subcommittee E61.02
Dosimetry Systems

- 51205 Ceric Cerous
- 51275 Radiochromic Film
- 51276 PMMA
- 51310 Optical Waveguide
- 51401 Dichromate
- 51538 Ethanol Chlorobenzene
- 51540 Radiochromic Liquid
- 51607 Alanine
- 51631 Calorimetry
- 51650 CTA
- 51956 TLD
- E2304 LiF
- E1026 Fricke

Subcommittee E61.03
Dosimetry Application

- E2303 Dose Mapping
- NEW Process Control
- 51702 Gamma Irradiators
- 51608 X-ray Irradiators
- 51649 High E-beam Irradiators
- 51818 Low E-beam Irradiators

Subcommittee E61.04
Specialty Application

- 51539 Radiation Indicators
- 51900 Agricultural Research
- 51939 Blood Irradiation
- E2116 Self Contained Dry Storage
- E2232 Mathematical Methods
- E2381 Fluidized Beds

Subcommittee E61.05
Food Irradiation

- F1355 Phytosanitary
- F1356 Red Meat and Poultry
- F1640 Food Irradiation Packaging
- F1736 Finfish & Aquatic Invertebrates
- F1885 Spices
- E2449 Processed Meat & Poultry