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

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

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:


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)
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?
Dosimetry Standards – Measurement

ASTM E2628  “Standard Practice for Dosimetry in Radiation Processing”


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 into 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.

## Traceability Chain

<table>
<thead>
<tr>
<th>Standards Laboratory</th>
<th>Reference Standard Dosimetry Systems (+3%)</th>
<th>Routine Dosimetry Systems (+5%)</th>
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<tr>
<td>Dw Gy (+1%) Dw kGy (+2%)</td>
<td>• Fricke, Ceric, Dichromate • Alanine, Calorimeters</td>
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<td>• Calorimeters • Ionization Chambers</td>
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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:


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 51702  “Standard Practice for Dosimetry in Gamma Irradiation Facilities for Radiation Processing”
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

  o Method 1, Method 2 or $V_{D_{\text{MAX}}}$
    ✓ 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

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.
What am I required to do?

Validate your process (cont.)

Process / Performance 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)

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

Thank you for listening!
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