Validation and Dose Mapping

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Highly Appreciated Irradiation Service Provider since 1995

Three Technologies: E-Beam – Gamma – X-Ray

Devoted to Quality of Services and Innovation

TT-100 Rhodotron 10 MeV and TT-100 10 MeV/6.6 MeV E-Beam/X-Ray
TT-300 “Duo” E-Beam “Workhorse” X-Ray “Special Products”

190 kW Power E-Beam: 10 MeV 19 mA

X-Ray: 7 MeV 27 mA
• Fully Automatic

• Pallet Layers on Trays

• Separate E-Beam and X-Ray Process Conveyors
Depalletizer/Palletizer

Product Turning
Medical Device Example

- Medical Device in its Shipping Container
- Sterilized using Ionizing Radiation
- Electron Beam
Process Definition

\[ D_{\text{ster}} \] Minimum dose to ensure sterility (Dose Setting)

\[ D_{\text{max,acc}} \] Maximum dose not to harm the product (Material Qualification)
Electron Beam Treatment

Improve Penetration:

1\textsuperscript{st} Pass

2\textsuperscript{nd} Pass
Dose in PE-Foam Phantom

Standardized Depth: \( z \)

Build-Up Region

Fast Drop Off

\( z = \text{Depth [g/cm}^2\text{]} = \text{depth [cm]} \times \text{Density [g/cm}^3\text{]} \)
Double Sided Treatment to Improve Penetration

Z=8.5 g/cm²
**ISO 11137-1 PQ Requirements**

9.3 Performance qualification

9.3.1 Dose mapping shall be carried out using product loaded in irradiation containers in accordance with a specified loading pattern in order to

a) identify the location and magnitude of the minimum and maximum dose and

b) determine the relationships between the minimum and maximum dose and the dose(s) at the routine monitoring position(s).

9.3.5 Dose mapping shall be carried out on representative irradiation containers sufficient in number to determine the variability of dose between containers.
Product Validation- Dose Mapping

Dosimeters are placed inside the product to locate the minimum and maximum dose zones.

Quantify: \( D_{\text{min}}, D_{\text{max}}, D_{\text{mon}} \)

- \( D_{\text{min}} \): Dose at Minimum Position
- \( D_{\text{max}} \): Dose at Maximum Position
- \( D_{\text{mon}} \): Dose at Monitoring Position
Mapping in General - in 2 Dimensions
Dose Mapping  3-Dimensional

Evaluating dose in x-y-z inside the product:

Where?  → Locations/Grid

How?  → Dosimeter Modelling
Dosimeter

Radiochromic Films

Alanine Pellets
Dosimeter Placement

- Thin film dosimeter with poach (18-50 μm) with Al-pouch
- Alanine Pellets Cylinders R=2.4mm
- Plastic wrapping barcoded
Mathematical Modelling to assist Dose Mapping

- Established in Medical Physics
- New Possibilities with CAD input
- Place Dosimeters/Object is Dosimeter
- Simulate Changes to Product/Process
- Study Dose Effects
Visualisation - Example X-Ray Treatment
Example Shielding of Medical Devices

Mo 2 mm

Mo 10 mm
Deviation between Dose in Air and Dosimeter Measurement:

- Pellet horizontal: -0.3%
- Pellet vertical: -2%
- Film horizontal: -1.8%
- Film vertical: -14.4%

Example: Dosimeter Response and Dose
0.5mm Steel Wire in Tube

DUR ≈ 1.5
A ... outer E ... inner
Steel Needle  D=1mm  Thickness 100µm
Dose Mapping make synergistic use of:

- Alanine Dosimeter (averaging of microdose effects)
- Mathematical Modelling (validated by experiments) to study and interpret radiation physics phenomena
- No “hunt” for dose gradients

Understand - Interpret – Assess Risk
Routine Monitoring Position

- On-Product – Position Laser Guided
- Manual Placement
- Automatic Removal
- Alanine Dosimeter
PQ Run Summary

Color Indication:
- **Hot Spots** – Low Dose Region
- **Cold Spots** – High Dose Region

Variation between Runs: RSD
- RSD < 4%
- 4% < RSD < 8%
- RSD > 8%
Dose Mapping Summary

\[ D_{\text{mon}} \]

\[ D_{\text{min}} \]

\[ D_{\text{max}} \]

\[ R_{\text{min/mon}} = \frac{D_{\text{min}}}{D_{\text{mon}}} \]

\[ R_{\text{max/mon}} = \frac{D_{\text{max}}}{D_{\text{mon}}} \]

\[ \text{DUR} = \frac{D_{\text{max}}}{D_{\text{min}}} \]
Designing the Process

<table>
<thead>
<tr>
<th>Customer Requirements</th>
<th>$D_{\text{ster}}$ [kGy]</th>
<th>25</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$D_{\text{max, acc}}$ [kGy]</td>
<td>40</td>
</tr>
</tbody>
</table>

**Uncertainties:** Dose Mapping (R-factors), Machine, Dosimeter

- $D_{\text{ster}}$
- $D_{\text{max, acc}}$
- Process Parameter: $I,v,s$
- $[D_{\text{mon/lower}}, D_{\text{mon/upper}}]$
Setting Target Dose
(taking into account uncertainties)

\[
\begin{align*}
D_{\text{mon \ ster}} &= 15.4 \, \text{kGy} \\
D_{\text{target \ lower}} &= 16.2 \, \text{kGy} \\
D_{\text{target \ upper}} &= 18.6 \, \text{kGy} \\
D_{\text{mon \ max,acc}} &= 19.1 \, \text{kGy}
\end{align*}
\]
Product Doses

\[ D_{\text{ster}} = 25\text{kGy} \]
\[ D_{\text{min}} = 27.7\text{kGy} \]
\[ D_{\text{max}} = 35.6\text{kGy} \]
\[ D_{\text{max,acc}} = 40\text{kGy} \]
Dose vs. Process Parameter

\[ D = k \cdot \frac{I}{v \cdot s} \]

- **D**: Dose in kGy
- **I**: Beam Current
- **v**: Process Speed
- **s**: Scan Width

\[ k = D_e(0) \cdot F \]
Surface Dose – Beam Parameter Relationship

Reference Dose:
RSD ≈ 1.4 % (k=1)

Parametric Dose:
RSD ≈ 0.5 % (k=1)
Long Term Reference Dose Analysis
CONCLUSION

Dose Mapping is a core instrument to render a sterile product while sparing product from harm by preventing overdosing.

A fine-tuned, robust method, state-of-the-art dosimeters and advanced modelling are vital in achieving this goal.