
Johnson & Johnson

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Sterility Assurance

Low Energy Electron Beam

Industry Perspective

The need for absorbed dose measurements in low energy electron beam processing

Terminal Sterilization Perspective

Industry Perspective

A Change of Plans

Quotes (nearly 100 years ago)

Industry Perspective

1895 Röntgen discovered the x-ray (Crooks Tube)

1899 Rutherford observed,

there are two methods with which to observe x-rays; photographic plate & discharge of electrification

Industry Perspective

1899 Curie commented,

> of the two methods of observation, observation by conductivity acquired by air was fast and provided a quantifiable result that can be compared with others

These were measures of absorbed dose; dosimetry

Industry Perspective

Dr. Leupold Freund

“When we gain complete control of our apparatus, know which quantity of rays is appropriate, which best employed in the depths and on the surface of the body, and when our measurement is perfected, there will be an ever-widening field for our endeavors”

Industry Perspective

How do we demonstrate control of our apparatus

What quantity is appropriate

At surface and at depth

Measurement perfected

Industry Perspective

IQ & OQ of the irradiator

PQ of the processing application

Dosimetry, dosimetry calibration

“when our measurement is perfected”

Industry Perspective

Challenges

Calibration of dosimetry

OQ the irradiator

PQ the processing application

Industry Perspective

Calibration

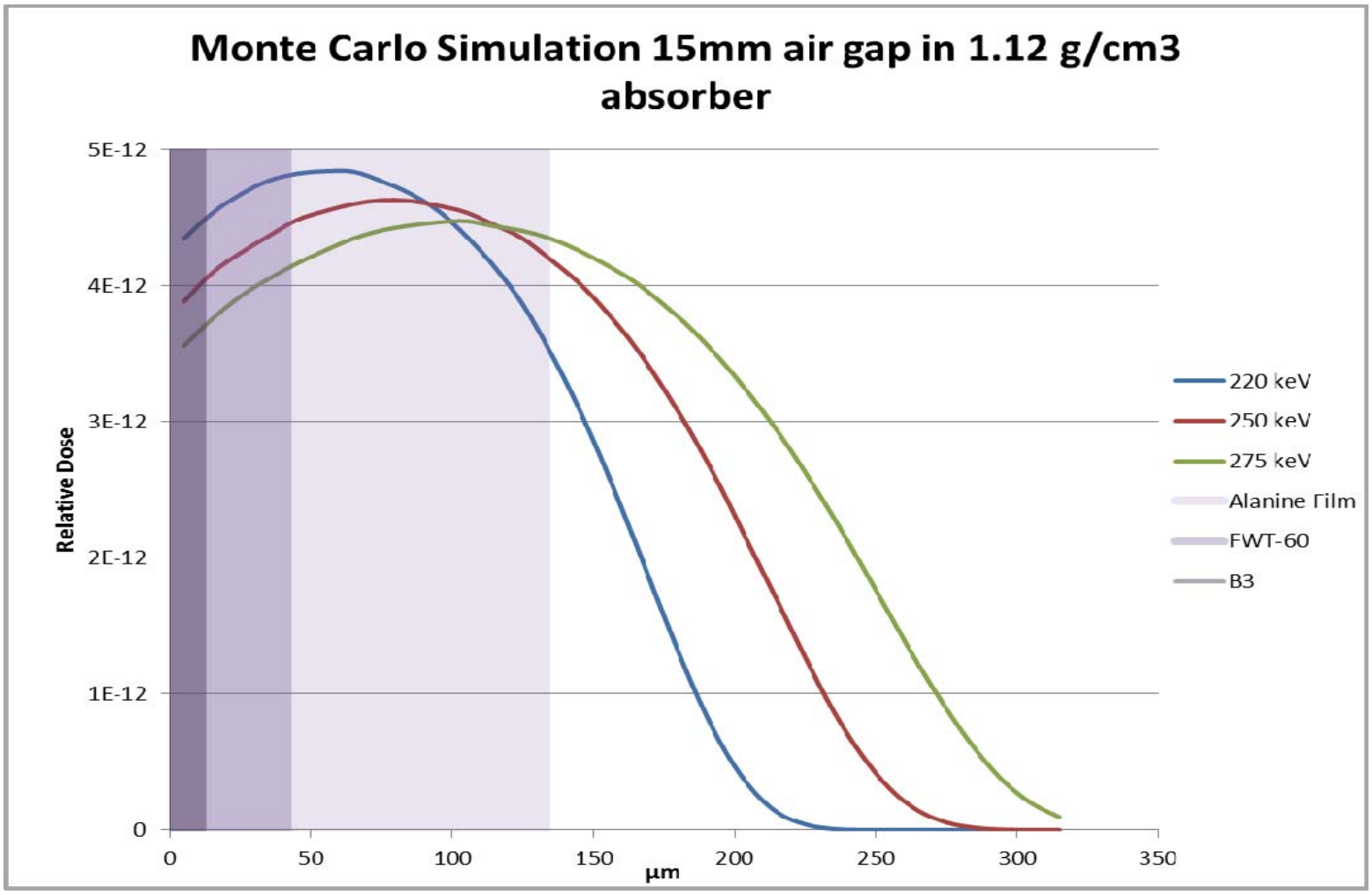
Establishing traceability

D_u calibration procedure

topical/surface – 1um

13-15% uncertainty at 2σ

Dose Depth Profiles



Industry Perspective

OQ - Qualification of the Irradiator

Uniformity of radiation field

Quantifying the energy

Demonstrating control (SPC)

Air Gap Models

Initial Energy	Air Gap			
240 keV	10mm	15mm	20mm	25mm
	220.4 keV	219.2 keV	217.8 keV	215.8 kEv
300 keV	10mm	15mm	20mm	25mm
	290.2 keV	289.1 keV	287.4 keV	286.3 keV

Industry Perspective

PQ – qualifying the process for a specific product

Dose Distribution

Min/Max dose

Precision: repeatability/reproducibility

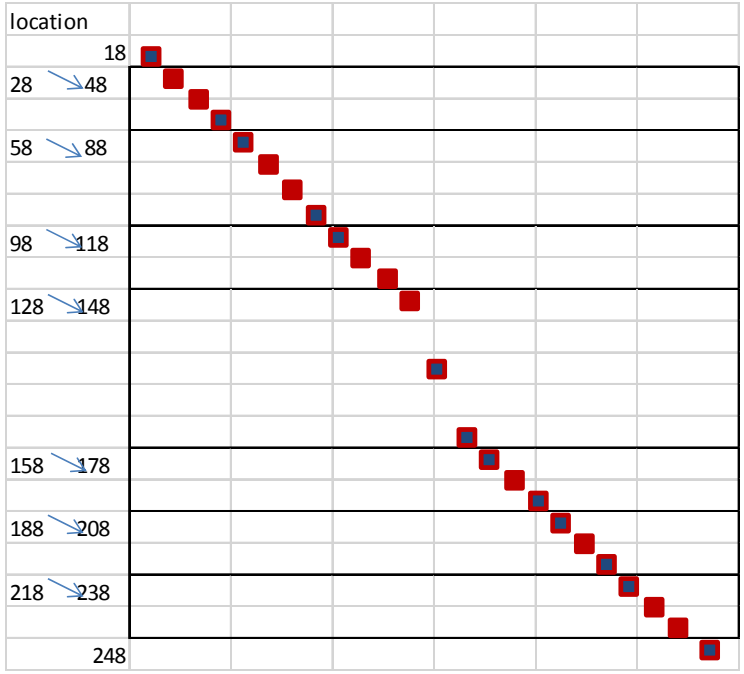
Process Capability: Cpk

Routine Process Monitoring

Dose Mapping Simulations

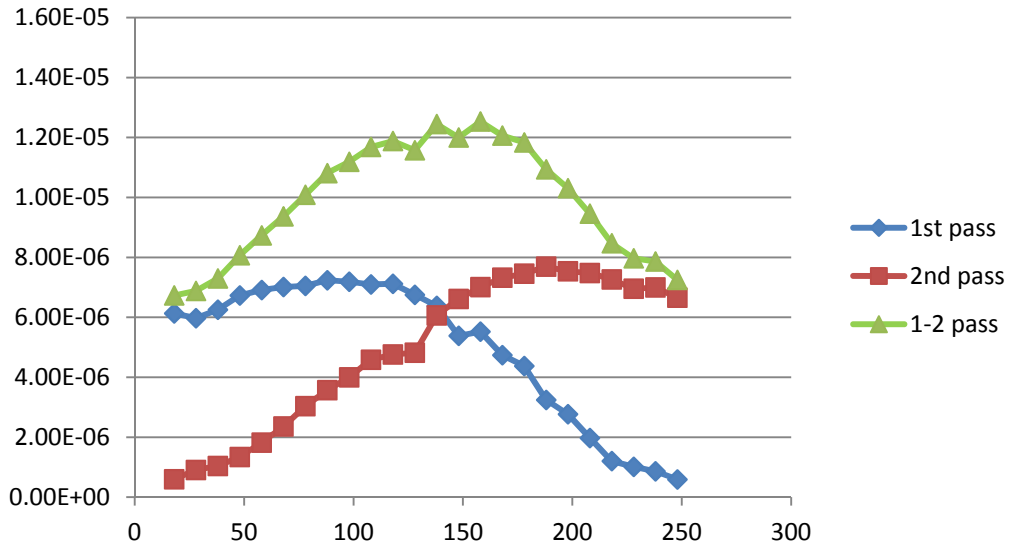
Dose mapping simulations using Monte Carlo

Simulate 2-sided irradiation with sum of 2 single-sided models



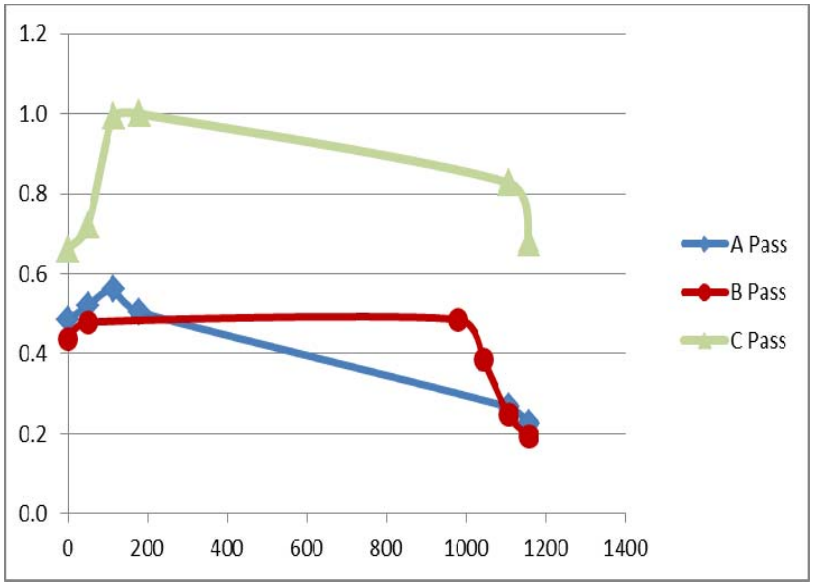
Dose Mapping Simulations

Dose mapping simulations using Monte Carlo

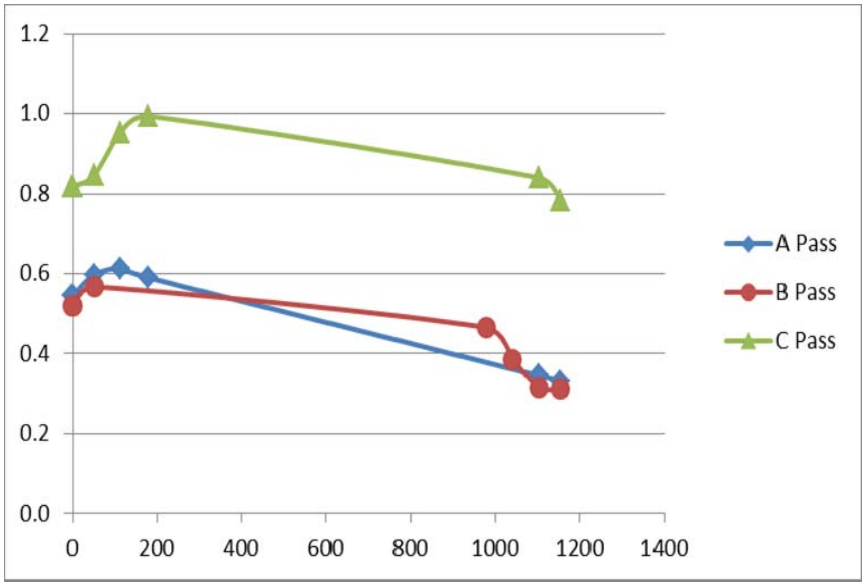


Dose Mapping Simulations

Dose Map vs. Monte Carlo 240 keV



Monte Carlo Prediction



Dose Map Data

Industry Perspective

Sterilization Processing

Minimum Dose Establishment Experiments
(ISO 11137)

Method I (bioburden based) verifications at ±10%
VDMax (bioburden based) verifications at ±10%
Method 2a & 2b (D_{10} value establishment) 2 kGy increments

Maximum Dose Establishment Experiments
(ISO 11137)

Industry Perspective

Standard under development for radiation processing (ASTM E61)

Operational Qualification (OQ)

Performance Qualification (PQ)

Re-qualification (test methods)

Statistical Process Control

Industry Perspective

Industrialization of low energy electron processing

-meet current standard requirements or may require development of new standards

ISO 11137 & ASTM E61

“When we perfect our measurement”

Precise Traceability of Absorbed Dose