Mathematical Modeling of Dose Mapping in Electron-Beam Radiation Sterilization

Ayeh Jowzaee

STERIS Applied Sterilization Technologies

CIRMS Meeting, April 13th, 2026

STERIS

ELECTRON BEAM

X-RAY

GAMMA

EQUIPMENT & TECHNOLOGIES

TESTING SERVICES

ETHYLENE OXIDE

VHP

STEAM

CIRMS 2026 — Need

Annual Meeting · April 13–15, 2026

Progress in **the modeling** is currently blocked because we lack **regulatory guidance**, which prevents **establishing confidence in model-based dose mapping**.

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Overview

Presentation outline:

- Introduction to Monte Carlo Simulation
- Radiation Modeling Overview
- E-beam Radiation Modeling at STERIS
- Mock Phantom Modeling for E-beam processing
  - Design and simulation
  - Experimental setup
  - Model assessment and comparison
- Summary

Ayeh Jowzaee, Ph.D.
Scientist II
Applied Sterilization Technologies
STERIS
Texas, United States

Monte Carlo Simulation

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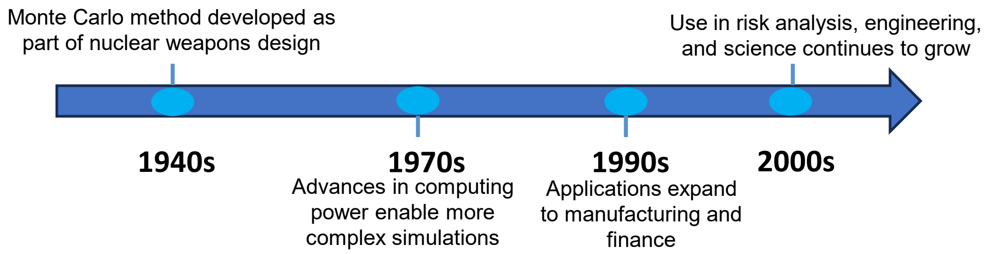
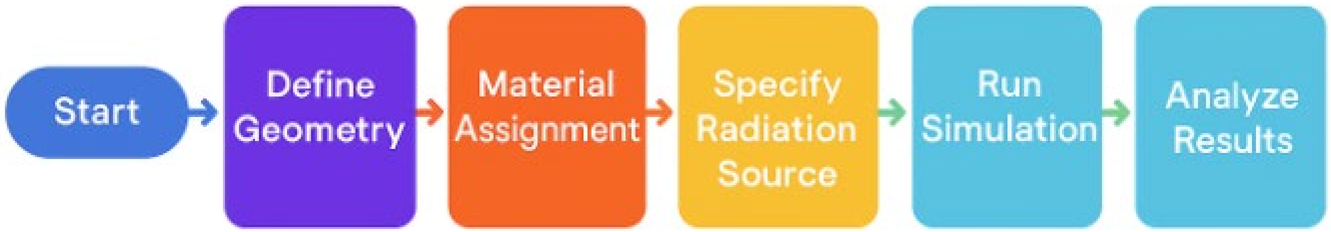
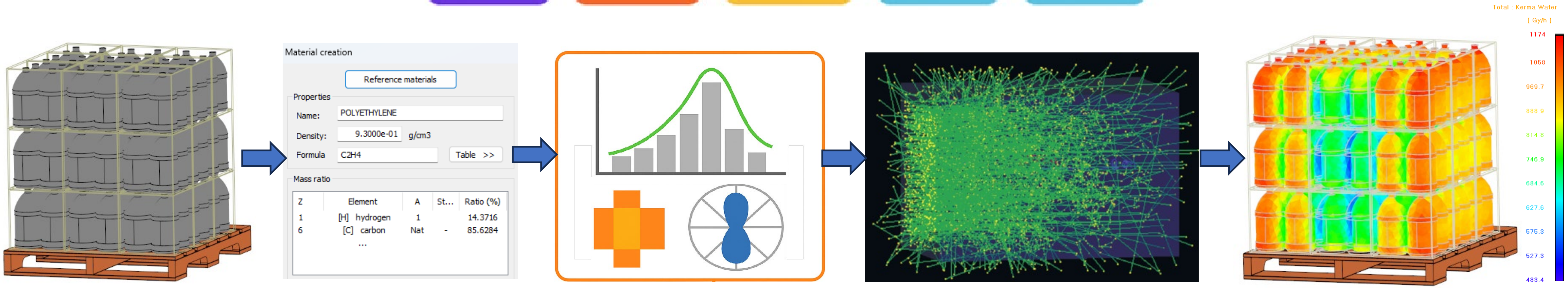
- Monte Carlo simulations, developed over many years, are now widely applied across diverse fields—including radiation processing



- Monte Carlo radiation simulation workflow





Monte Carlo GEANT4 simulation

Radiation Simulation Overview

- Simulation-Guided Strategies in Industrial Irradiation _ While Preserving Physical Dosimeter Evaluation
  - Simulation aligns with ISO 11137-1:2025

ISO 11137-1:2025(en)

NOTE 1 Guidance on dose mapping is given in ISO 11137-3, ASTM E3270 (gamma), and ISO/ASTM 52303. Guidance on the interpretation of dose mapping results is given in ISO/TS 11137-4.

NOTE 2 Mathematical models can be used to calculate dose distributions, and therefore supplement or complement the measurement of dose associated with dose mapping. See ASTM E2232, ISO 11137-3, and ISO/TS 11137-4 for guidance on the use of mathematical models.

  - STERIS AST aligns with ISO 11137-1:2025 by using validated mathematical models to supplement dosimetry, ensuring they reflect the performance of physical measurements
  - STERIS AST is currently developing a formal validation package of simulation modelling system

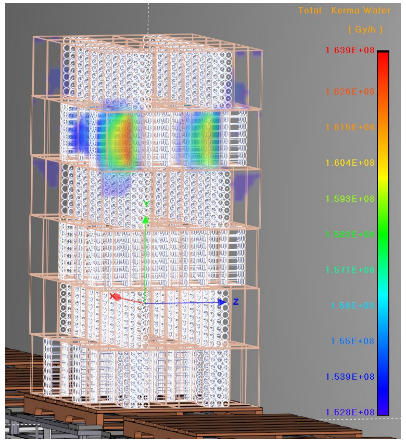
Simulation-Driven Irradiation

- Leveraging Simulation for Smarter Irradiation Processes _ <u>While Preserving Physical Dosimeter Evaluation</u>

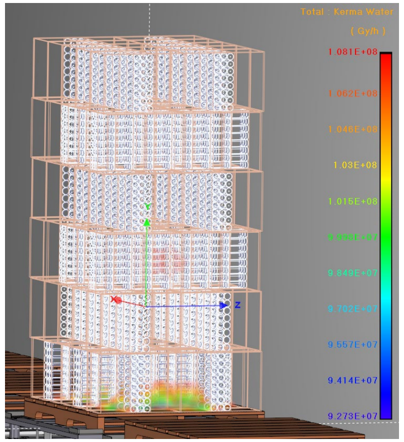
  - ➢ Reduce number of physical dosimeters in product performance qualification to save time

Determine max, min zones for dosimeter placement

MAX

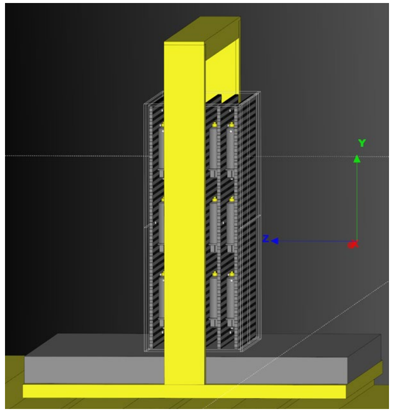


MIN

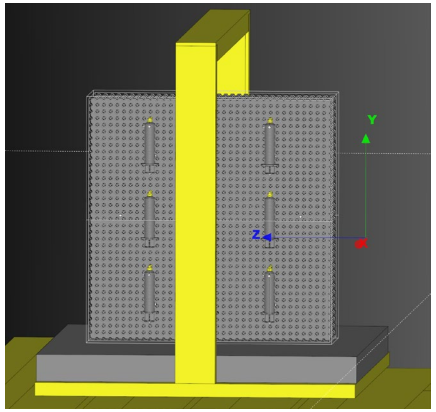


  - ➢ Reduce trial and error iterations to accelerate time to market

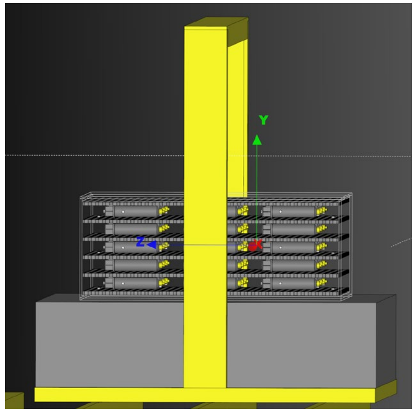
Try1
orientation 1
DUR1



Try2
orientation 2
DUR2



Try3
orientation 3
DUR3



Beam
Direction

Radiation Modeling of E-beam Processing

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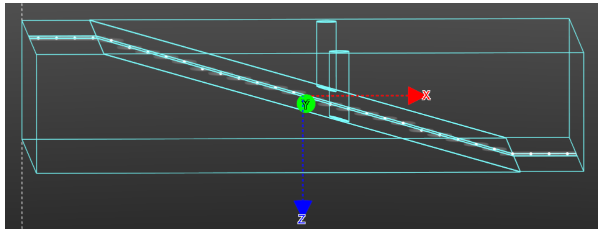
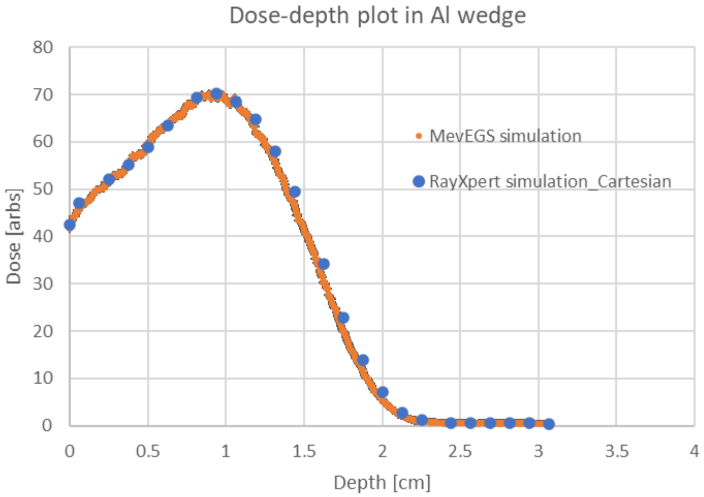
- STERIS simulation team are benchmarking the modeling of E-beam processing in IQ, OQ, and PQ levels

E-beam IQ

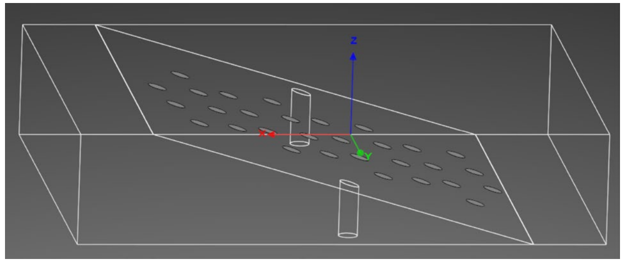
Cartesian mapping of CTA w/ cell deletion in RayXpert

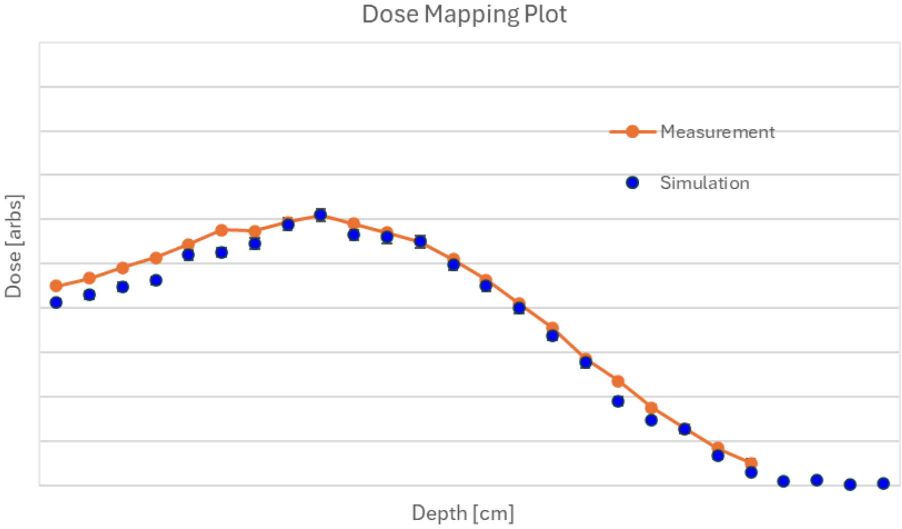


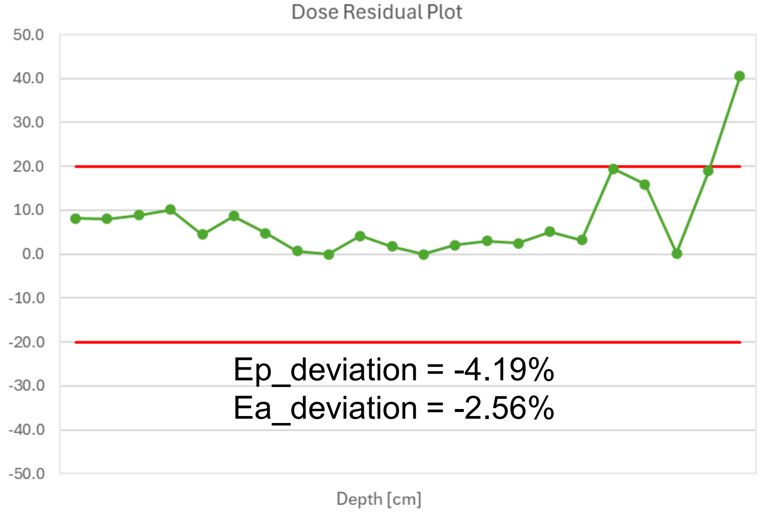


RayXpert physics algorithm (Geant4) compared to MevEGS (EGSnrc)

Virtual B3 dosimeter mapping in RayXpert



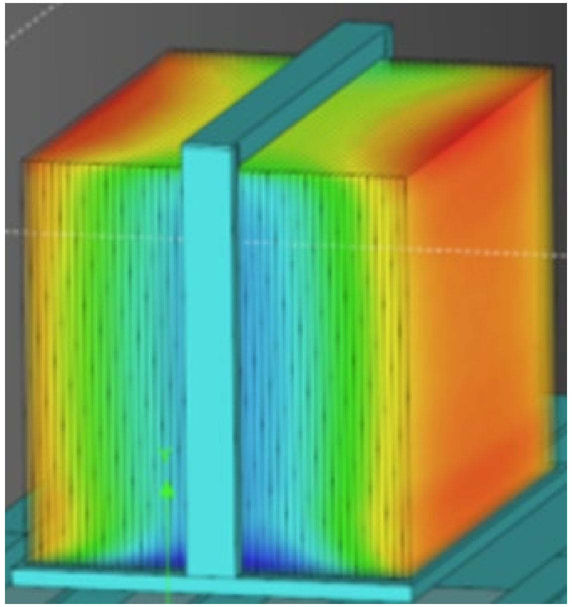


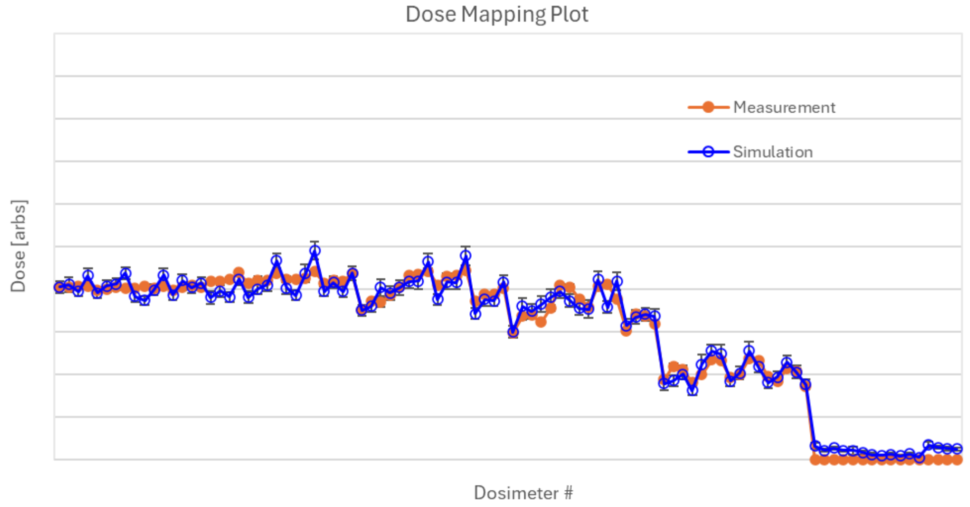


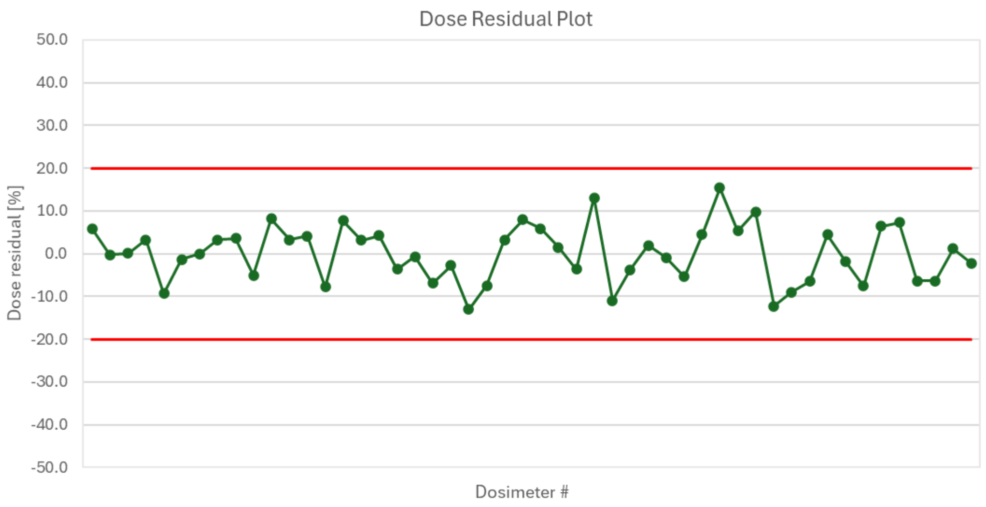
Radiation Modeling of E-beam Processing

- STERIS simulation team are benchmarking the modeling of E-beam processing in IQ, OQ, and PQ levels

E-beam OQ







Mock Phantom Design & Dosimeters Position

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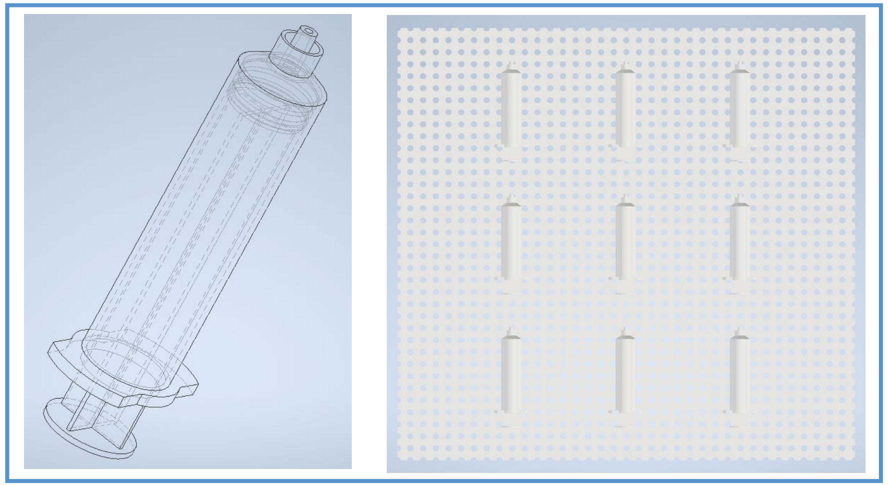
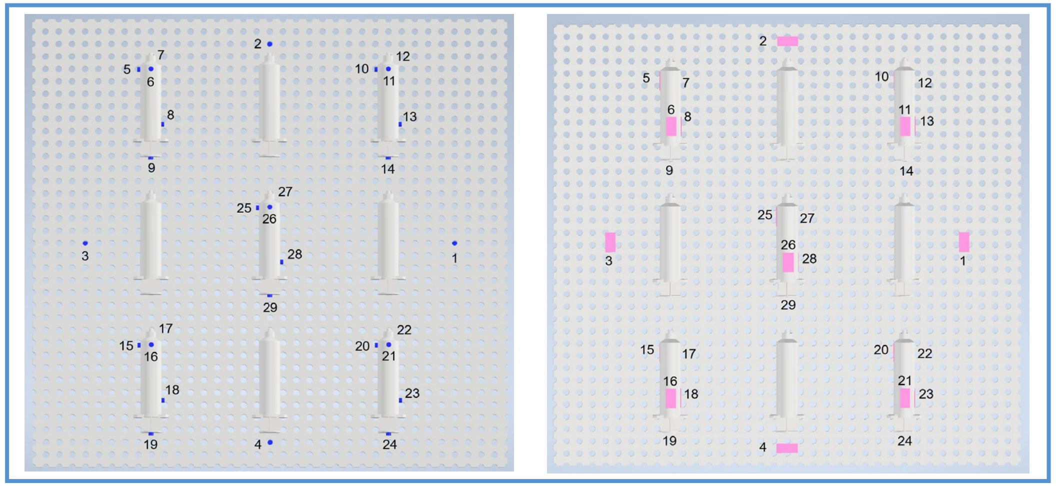
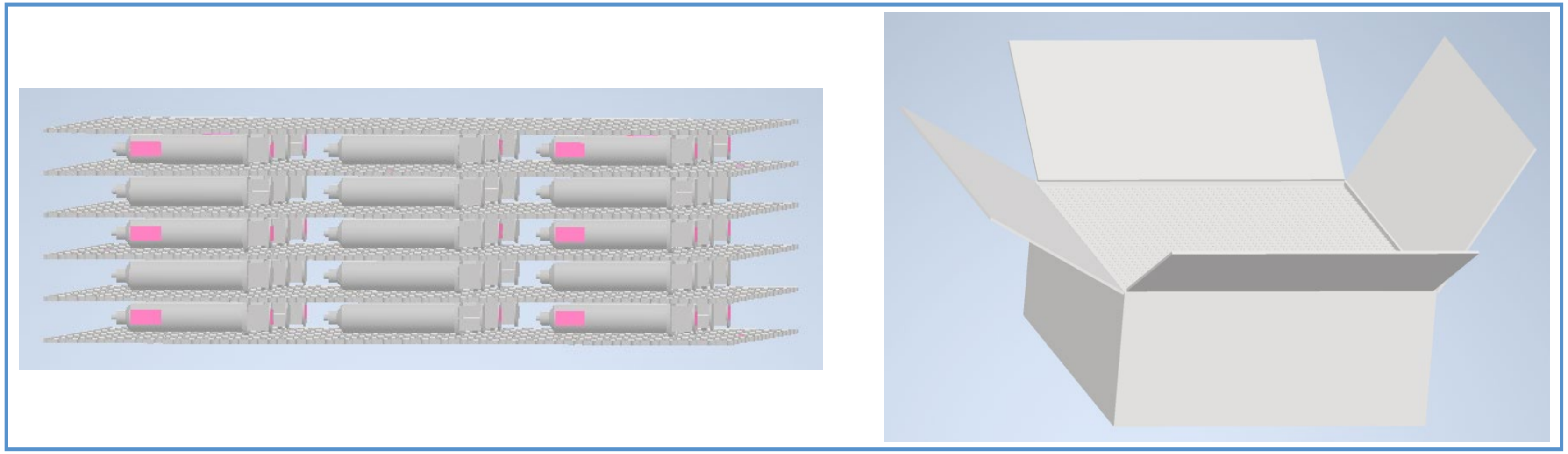
- The Steris simulation team has developed a mock PQ level phantom at RTC site to assess dose mapping



Phantom parts arrangement



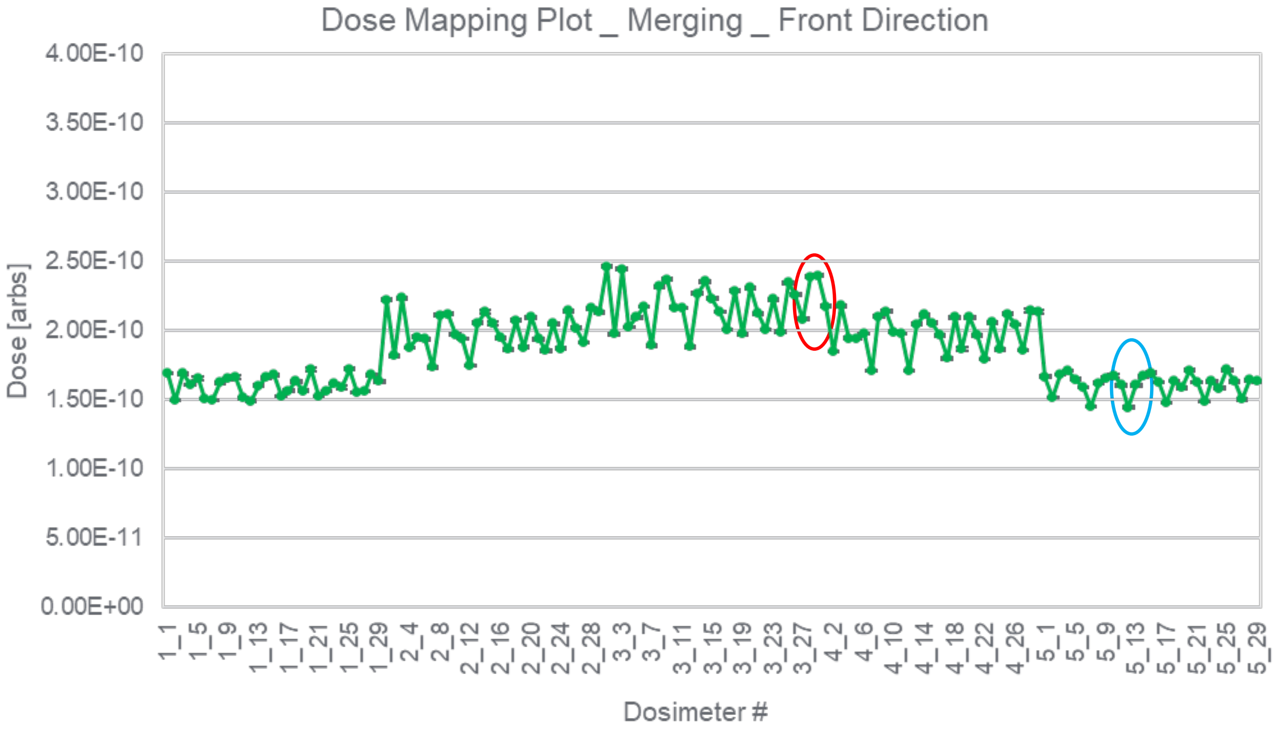
29 Alanine & B3 dosimeters position



Phantom layout

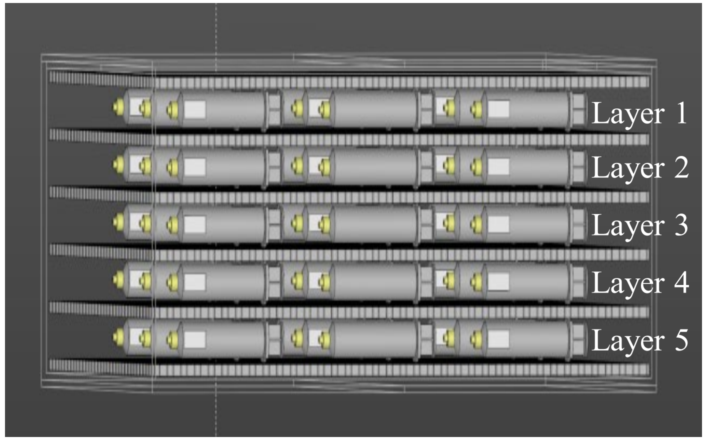
Dosimeters Placement

- A model of 29 B3 dosimeters in all 5 layers of phantom were developed to estimate the most probable layers for min and max dose position. In total, 145 B3 dosimeters were used in this model for dose mapping



Max and Min zones:

All dosimeters	Excluding PVC dosimeters
Max: 3_1	Max: 3_29
Min: 5_12	Min: 5_12



Front layer

Middle layer

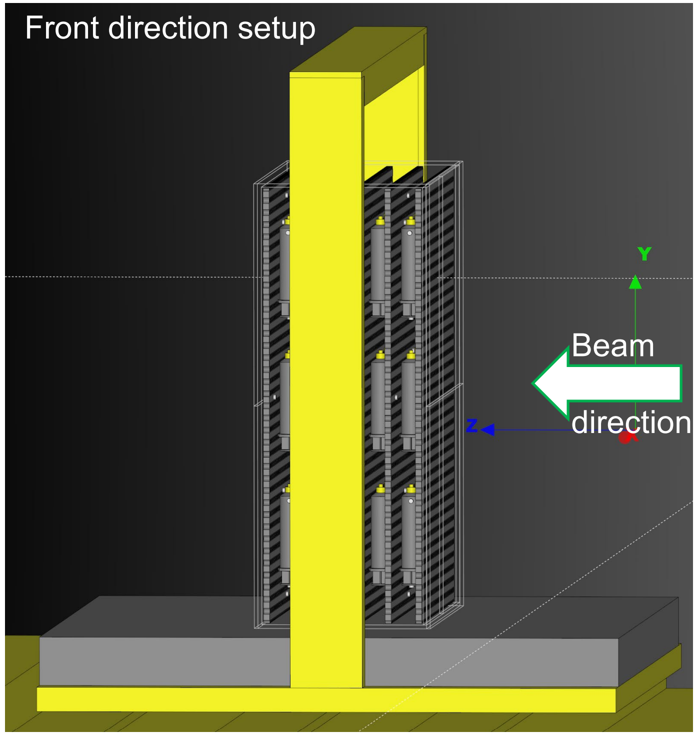
Back layer

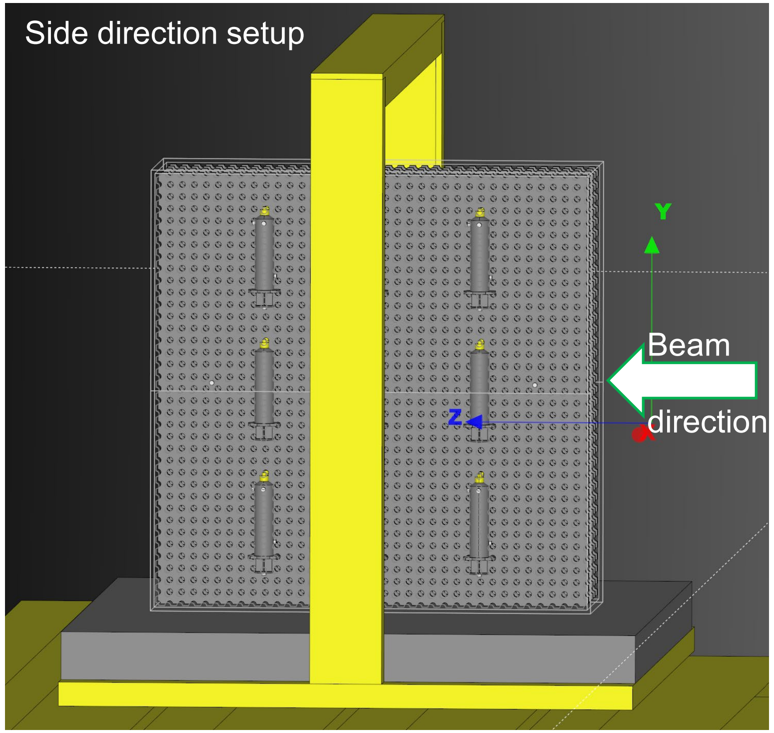
B3 dosimeters position in 5 layers of phantom

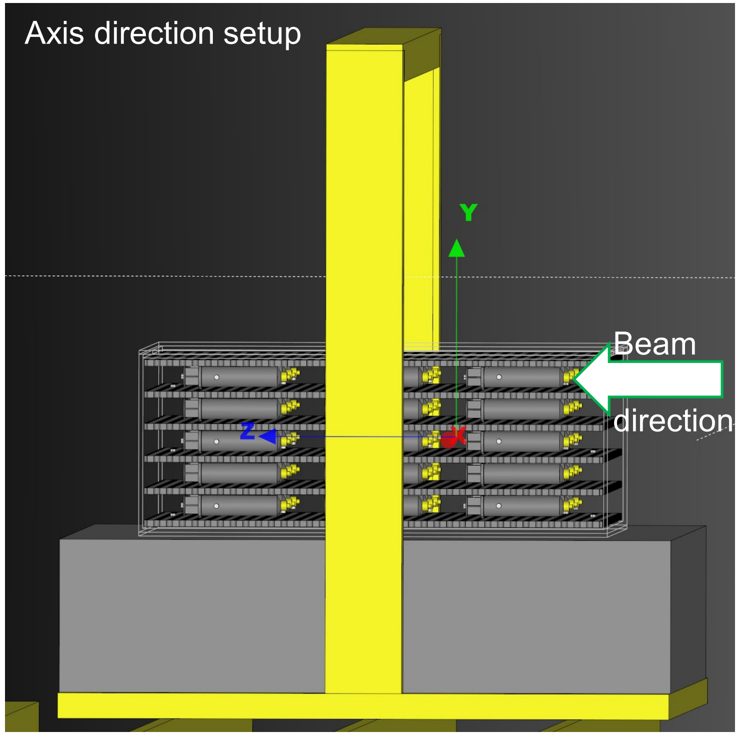
145 dosimeters → optimized & reduced → 87 dosimeters

Irradiation Directions

- A phantom product model was developed within the irradiator, evaluating three orientations of product box in a container relative to the electron beam direction
- Three orientations have been studied, including front, side, and along the syringe axis as shown bellow, respectively
- Processing condition: Electron beam energy 10 MeV, double sided passes, stretched source

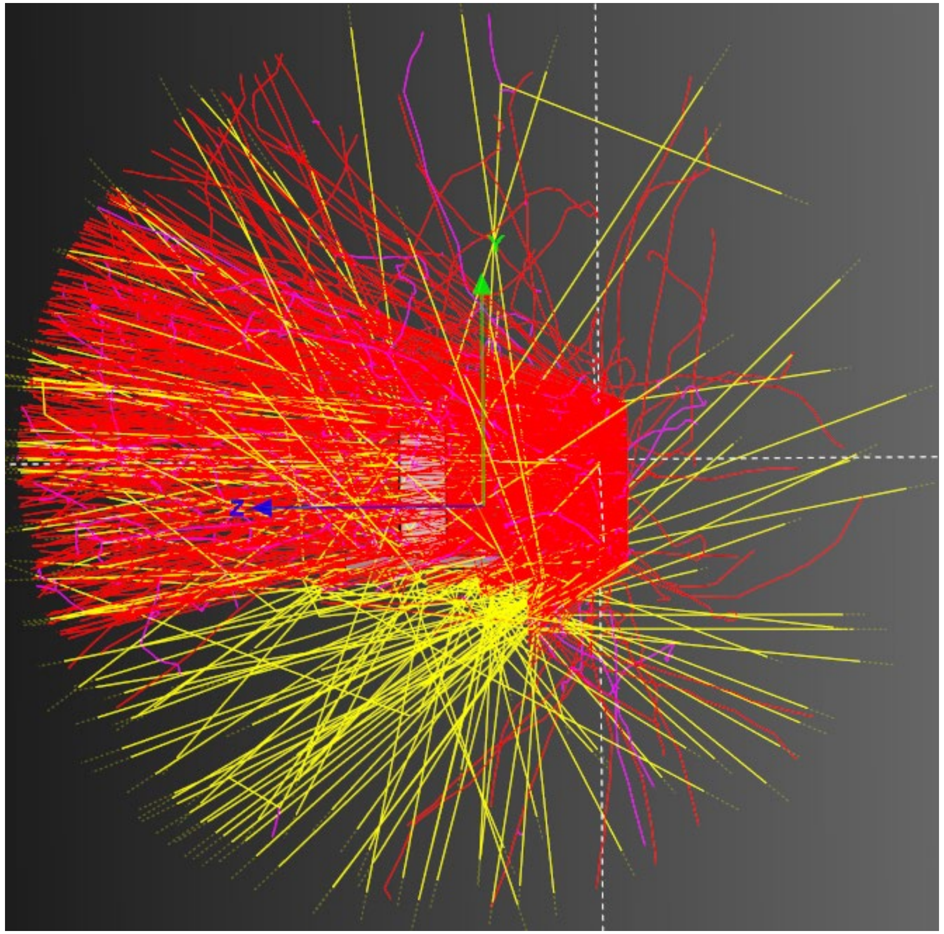






Phase 1: Simulation

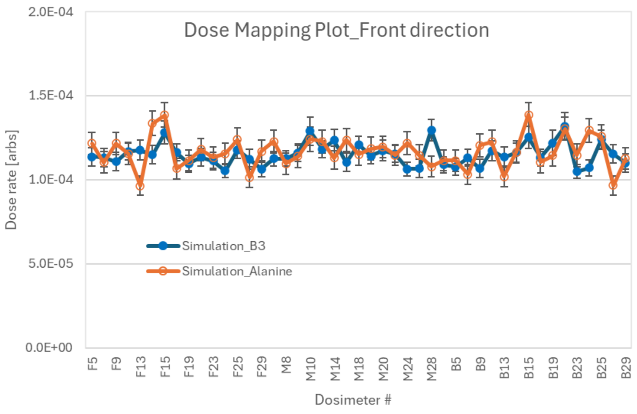
- Simulation Setup
  - **Radiation modeling Software:** RayXpert v1.9.3
  - **Physics Model:** GEANT4-based particle-matter interaction
  - **Particles:** 10^9 primary electrons
  - **Geometry:** Verified CAD model of the RTC irradiator
  - **Beam:** 10 MeV E-beam, using manufacturer-defined source specification
  - **Virtual dosimeters:** Sensitive elements of the model
  - **Threshold:** Secondary electrons ≥1 keV (default)
  - **Output:** Total absorbed dose rate

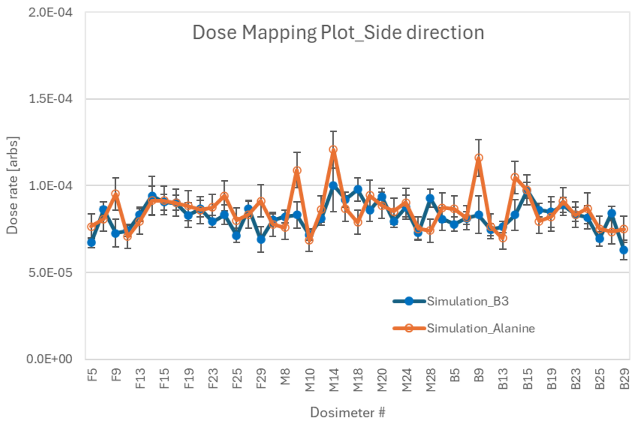


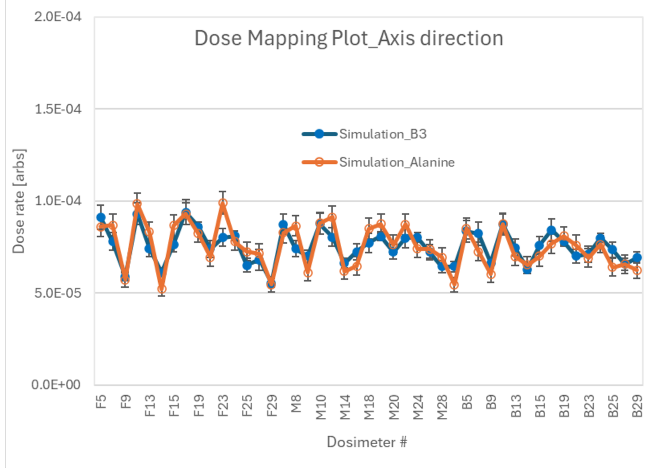
Simulation_B3 vs Alanine

- Total absorbed dose analysis of 45 B3 and Alanine dosimeters placed at the same position of phantom

Parameter	B3	Alanine	Deviation %
Front Direction			
DUR	1.26	1.44	12.57%
Max	1.32E-4 (B20)	1.39E-4 (B15)	4.97%
Min	1.05E-4 (B23)	9.64E-5 (F13)	-8.70%
Side Direction			
DUR	1.59	1.76	9.54%
Max	1.0E-4 (M14)	1.21E-4 (M14)	16.93%
Min	6.30E-5 (B29)	6.86E-5 (M10)	8.16%
Axis direction			
DUR	1.69	1.90	10.63%
Max	9.40E-5 (F18)	9.90E-5 (F23)	5.10%
Min	5.55E-5 (F29)	5.23E-5 (F14)	-6.18%

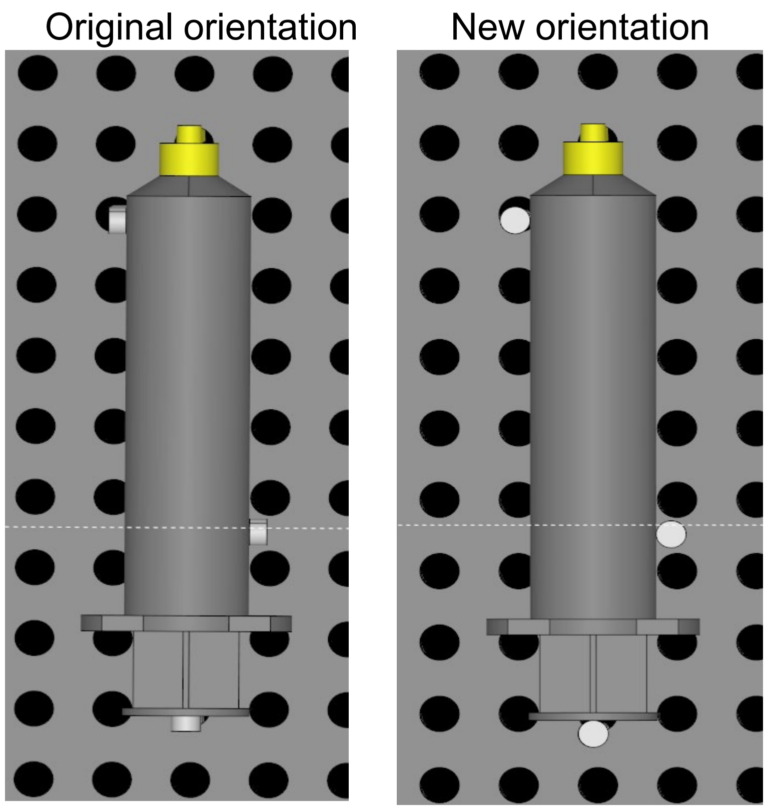


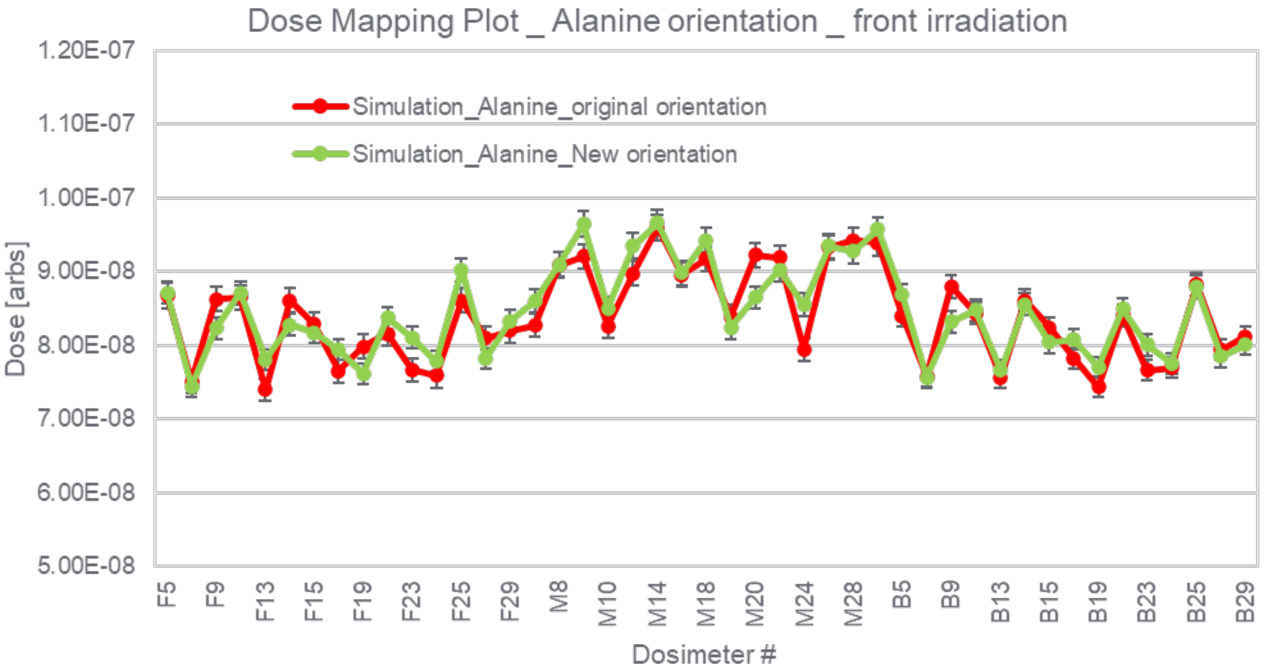




Alanine Orientation

- Different orientation of Alanine in 45 dosimeters have been studied and responses compared in DUR calculation





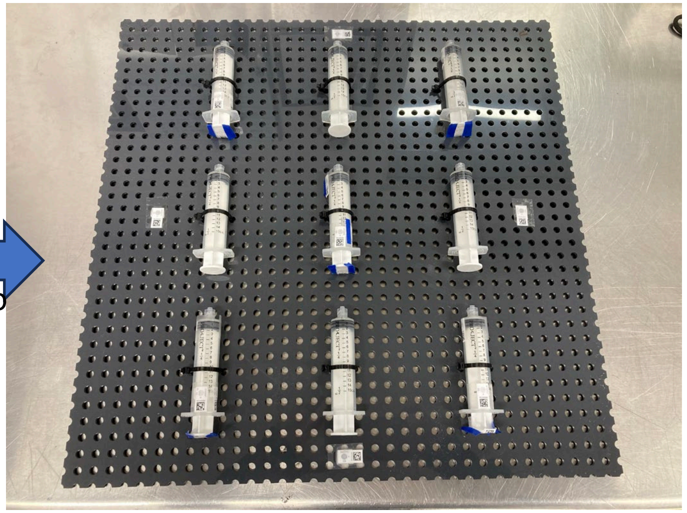
Deviation_DUR = 0.04%

- Simulation results indicate similar Alanine response across orientations, which will be verified experimentally

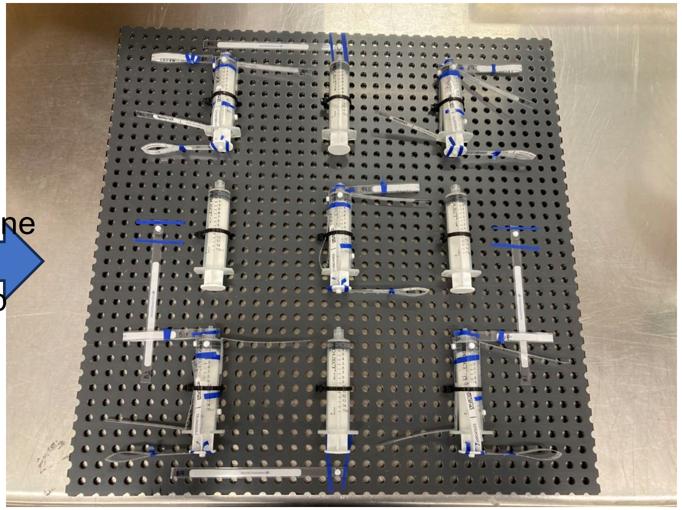
Phase 2: Experiment

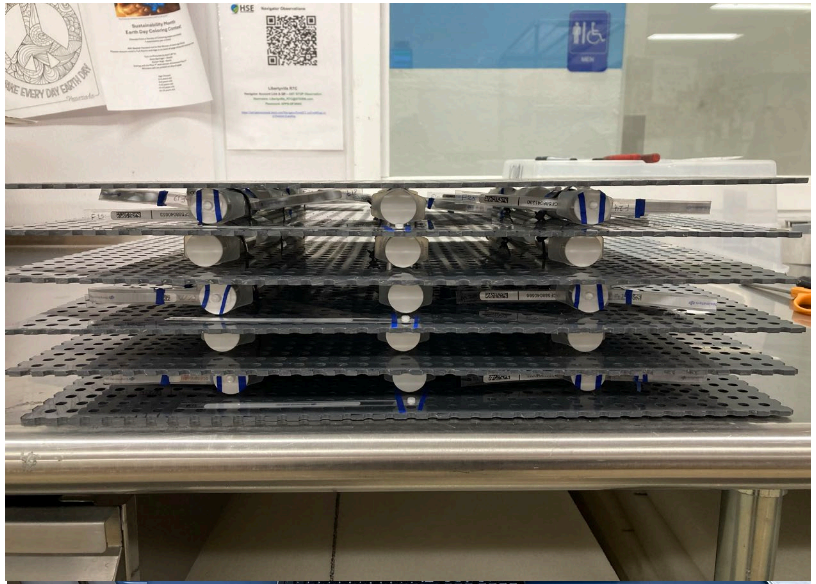
- Phantoms with Alanine and B3 dosimeters were prepared at the RTC lab for irradiation testing

B3 setup



Alanine setup

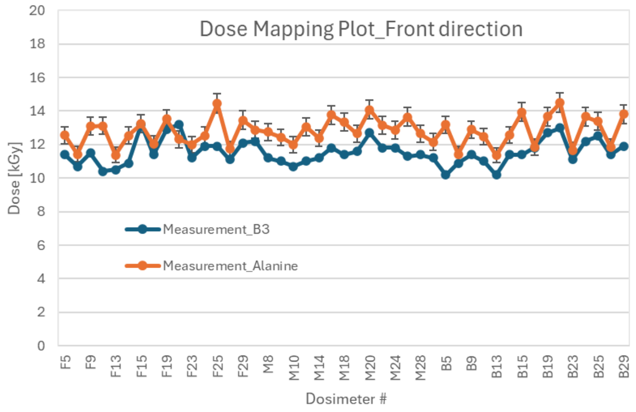


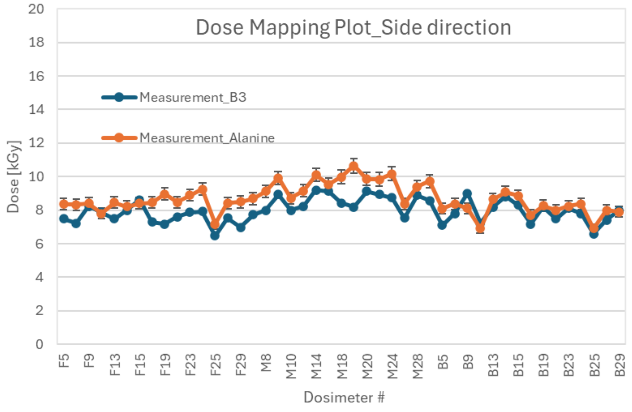


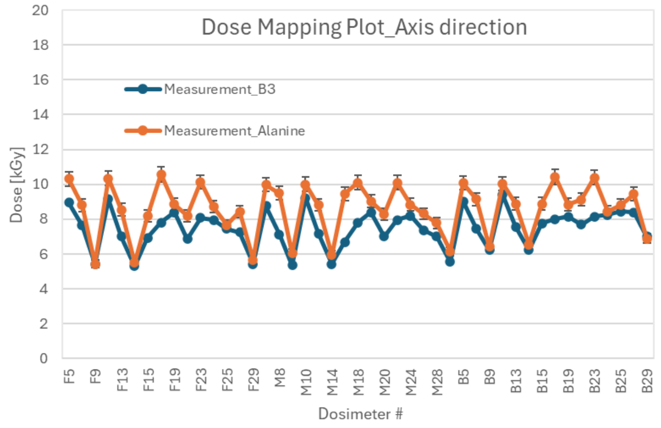
Experiment_B3 vs Alanine

- Total absorbed dose analysis of 45 B3 and Alanine dosimeters placed at the same position of phantom

Parameter	B3	Alanine	Deviation %
Front Direction			
DUR	1.29	1.27	-1.6%
Max	13.20 (F15)	14.48 (B20)	8.8%
Min	10.20 (B5)	11.36 (B13)	10.2%
Side Direction			
DUR	1.42	1.54	7.8%
Max	9.2 (M14)	10.64 (M19)	13.5%
Min	6.46 (F25)	6.9 (B10)	6.4%
Axis direction			
DUR	1.77	1.95	9.2%
Max	9.40 (B10)	10.58 (F18)	11.1%
Min	5.30 (F14)	5.42 (F9)	2.2%

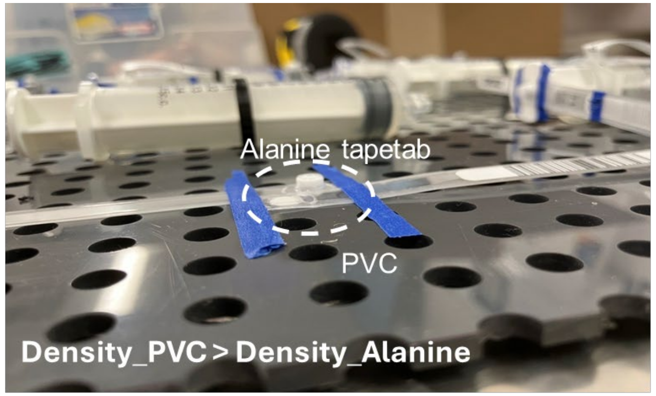


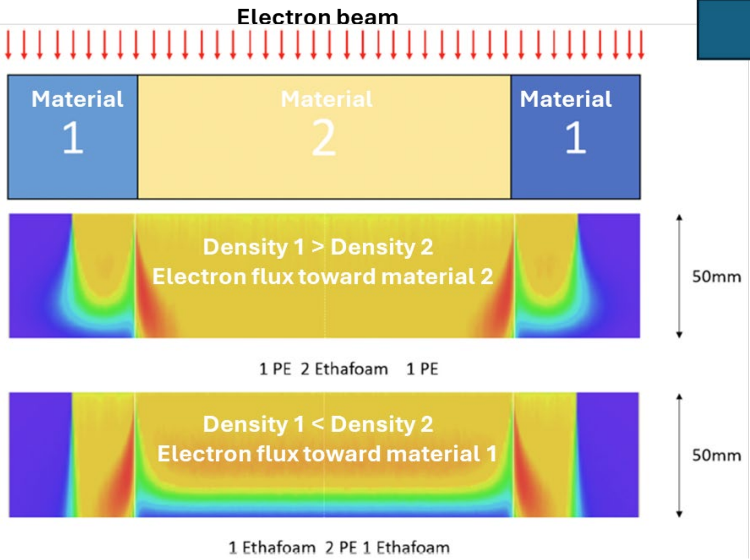




Dosimeter Location

- Electron-flux behavior compared for dosimeters inside PVC holes (R5, R6) vs. surface locations (F1, M1)
- Simulation and measurements show similar trend, driven by PVC–dosimeter density differences affecting electron transport & flux





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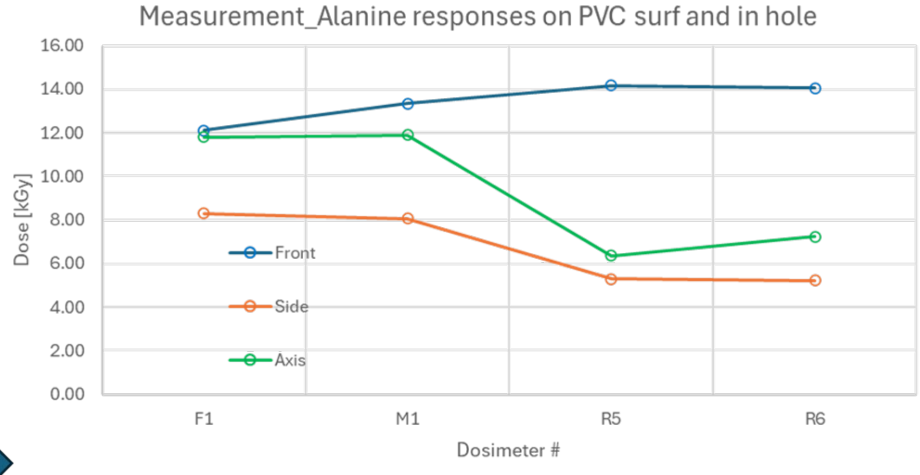
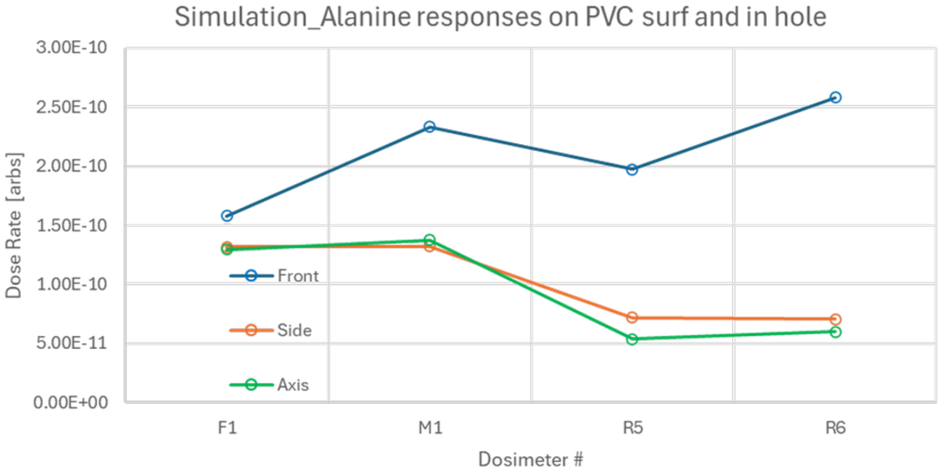




Front: F1,M1 < R5, R6
(surf. Dose < hole dose)

Side: F1, M1 > R5, R6
Axis: F1, M1 > R5, R6
(surf. Dose > penetrated dose)

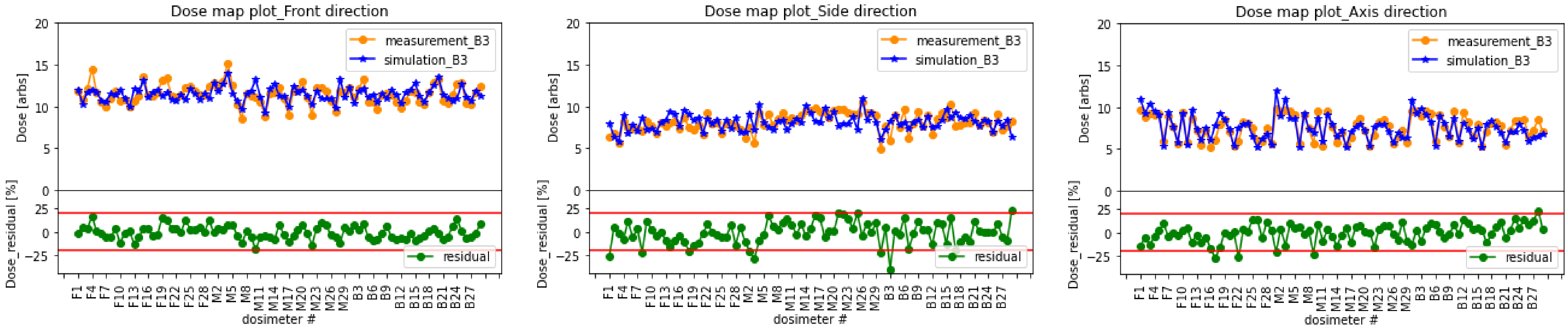
Phase 3: Model Assessment

- Validation serves as a critical step for model assessment, confirming that the mock phantom model behaves consistently with experimental benchmarks

- Sensitivity analysis enhances validation by identifying which model parameters have the greatest impact on simulation outcomes, including:

Models Accuracy Assessment

- Simulated doses from dosimeters and experimental measurements across three irradiation orientations were comparatively analyzed



A variation of less than 20% among most individual doses was achieved

Dose Comparison

- Simulated dose distribution in syringes compared with measured values across three irradiation orientations

Parameter	B3_sim.	B3_meas.	Deviation %
Front Direction			
DUR	1.46 ± 0.1	1.58 ± 0.0	7.59%
Max	13.53 ± 0.83	13.60 ± 0.0*	0.5%
Min	9.24 ± 0.28	8.58 ± 0.0	-7.68%
Side Direction			
DUR	1.75 ± 0.23	1.72 ± 0.0	-1.92%
Max	11.03 ± 1.04	10.60 ± 0.0	-4.09%
Min	6.31 ± 0.57	6.18 ± 0.0	-2.13%
Axis direction			
DUR	1.85 ± 0.18	1.84 ± 0.0	-0.52%
Max	9.62 ± 0.52	9.53 ± 0.0	-1.00%
Min	5.19 ± 0.41	5.17 ± 0.0	-0.48%

* The measurement error is from three-time readings of dosimeters in single irradiation

Both simulation and experimental measurements demonstrated a consistent trend in DUR following the order:

DUR_Front < DUR_Side < DUR_Axis

Summary

- Development of a formal validation package for the simulation service is underway at STERIS to further strengthen confidence in model-based dose mapping
- Simulation results show IQ, OQ-level agreement with measurements, supporting their use for process characterization and dose-distribution assessment in E-beam processing
- Simulations proved effective for optimizing product orientation within irradiators, enabling more efficient and precise processing
- Agreement between simulated and measured mock-phantom data demonstrates consistency and supports confidence in the simulation model for predicting dose distribution across varying irradiation orientations
- STERIS AST is aligned with ISO 11137-1(2025) through the use of validated mathematical models to supplement dosimetry, provided they demonstrate functional equivalence to physical measurements

THANK YOU

www.steris-ast.com

For more information:

Ayeh Jowzaee

Tel: +1 224-331-1026

Email: Ayeh_Jowzaee@steris.com

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