X-Ray

SPENCER MICKUM | April 30TH, 2024

STERIS

Agenda

Presenter

Spencer Mickum

Principal Scientist

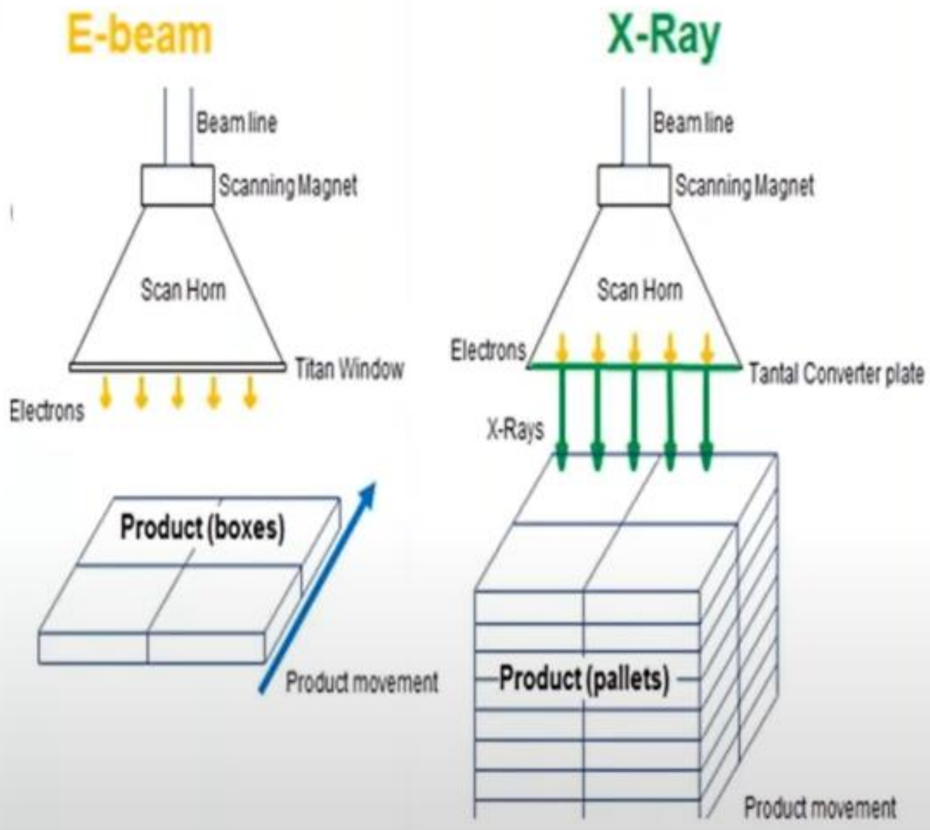
STERIS Applied Sterilization Technologies

Agenda

1. X-Ray Background
   - Why do we use x-ray?
2. X-Ray at STERIS
   - Model the Process
3. Radiation Simulation
   - Review Results
4. Conclusions
   - Visualize future goals

X-Ray Background

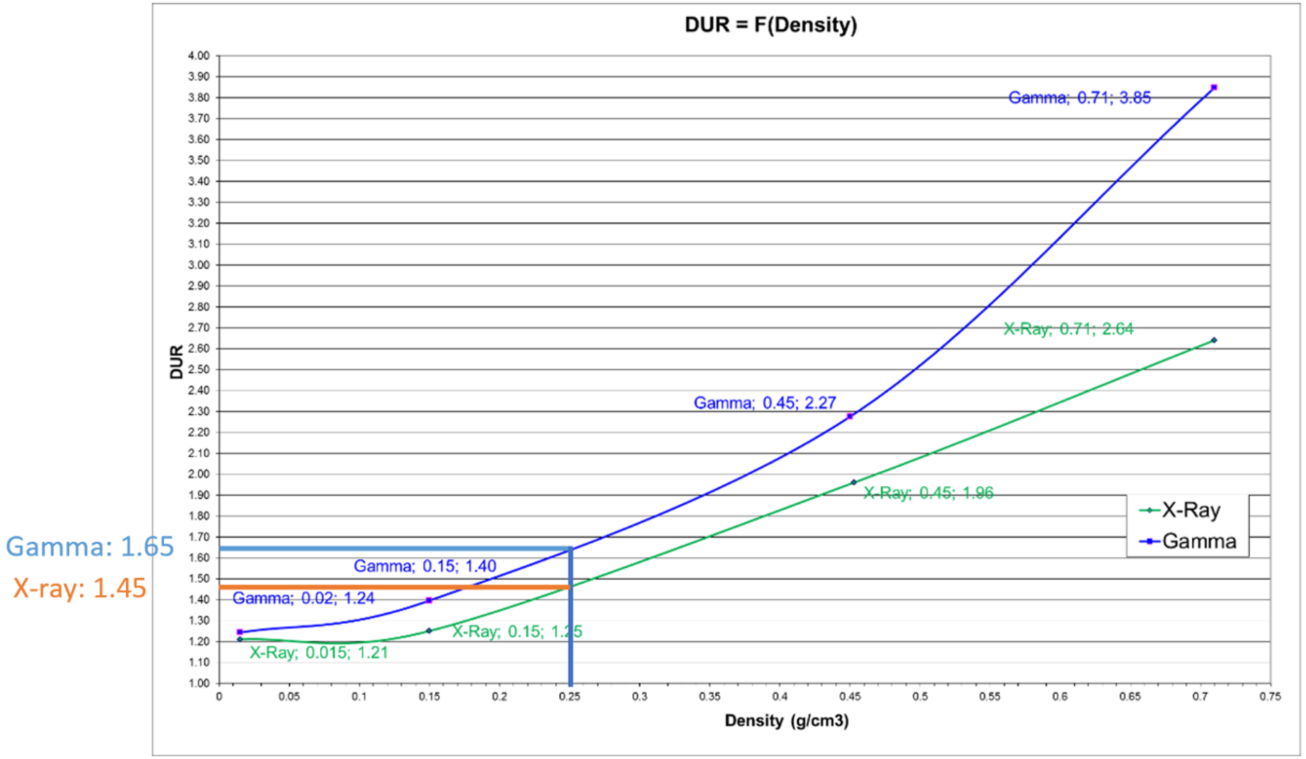
- X-ray starts as an E-beam, where electrons are generated and accelerated to gain energy
- Electrons are generated in a vacuum environment by the source (electron gun), located at the outer wall of the cavity
- The electrons are then drawn away and accelerated at the specified energy
- At the exit of the accelerator, the cylindrical-shaped beam of high-energy electrons is transported through the beam line from the accelerator to the radiation vault
- Electrons hit at the end a converter plate made of Tantalum where conversion into X-ray (photon) takes place and then hits the product



X-Ray Background

Benefits of X-ray include:

- Directional dose delivery, avoiding losses of isometric irradiation techniques
- Efficient dose delivery, reducing irradiation processing time and correlated temperature rise
- Rapid dose delivery limits oxidative degradation of polymers
- Ability to process to tight dose specifications through improved DUR
- Incremental lap-based dose delivery, offering flexible and precise process definition across a wide range of doses



From <[X-ray: An Effective Photon | STERIS AST (steris-ast.com)]>

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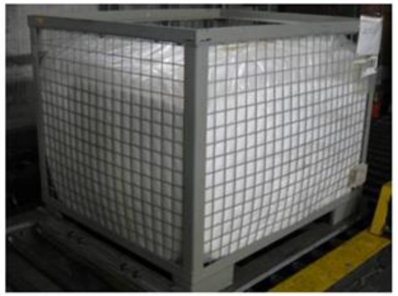
X-Ray Background

untreated

Gamma around 250 kGy



X-Ray around 250 kGy

Benefits of X-ray include:

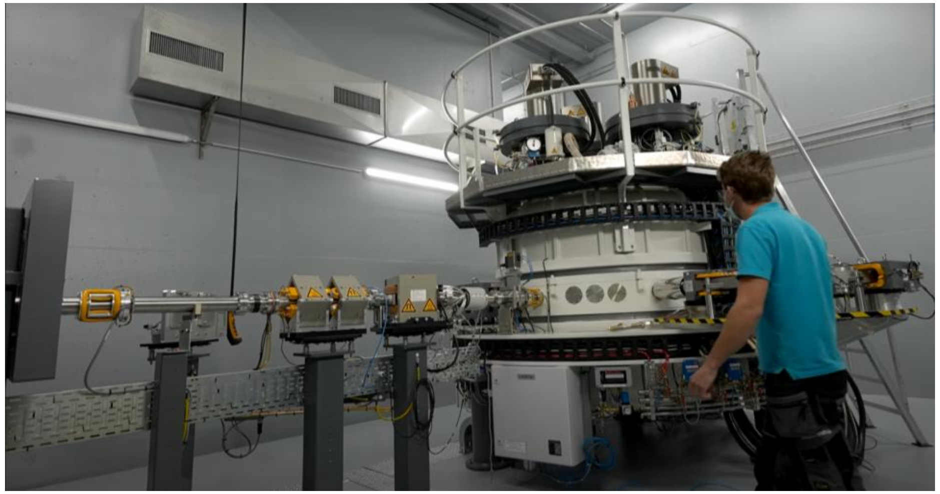
- Improved penetration ability of photon energy, like gamma
- Fast and efficient targeted processing that facilitates scale from carton to full pallets of product
- Flexibility – ability to mix different products with different dose requirements in the same irradiation cycle
- Ability to process to tight dose specifications through improved DUR
- Reduced material degradation with reduced processing times and reduce of the color modification when compared to Gamma irradiation.

From <https://www.steris-ast.com/solutions/x-ray-irradiation/>

X-Ray at STERIS

Overview of the x-ray irradiation processes at STERIS

- Several Sites:
  - Chonburi, Thailand,
  - Daniken, Switzerland,
  - Kuala Ketil, Malaysia,
  - Libertyville, Illinois Radiation Technology Center, USA,
  - Suzhou, China,
  - Venlo, The Netherlands
  - *Email ast_info@steris.com for more information*
- Using IBA Rhodotrons and MEVEX Linear Accelerators



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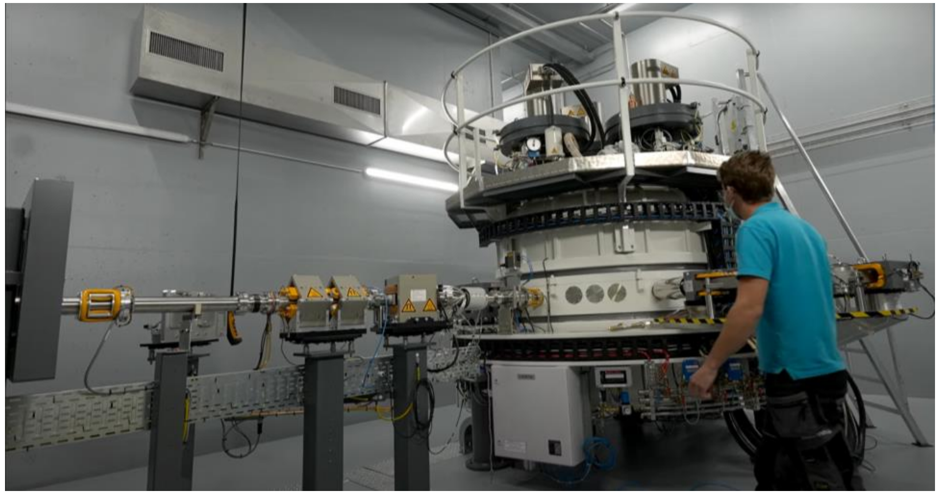
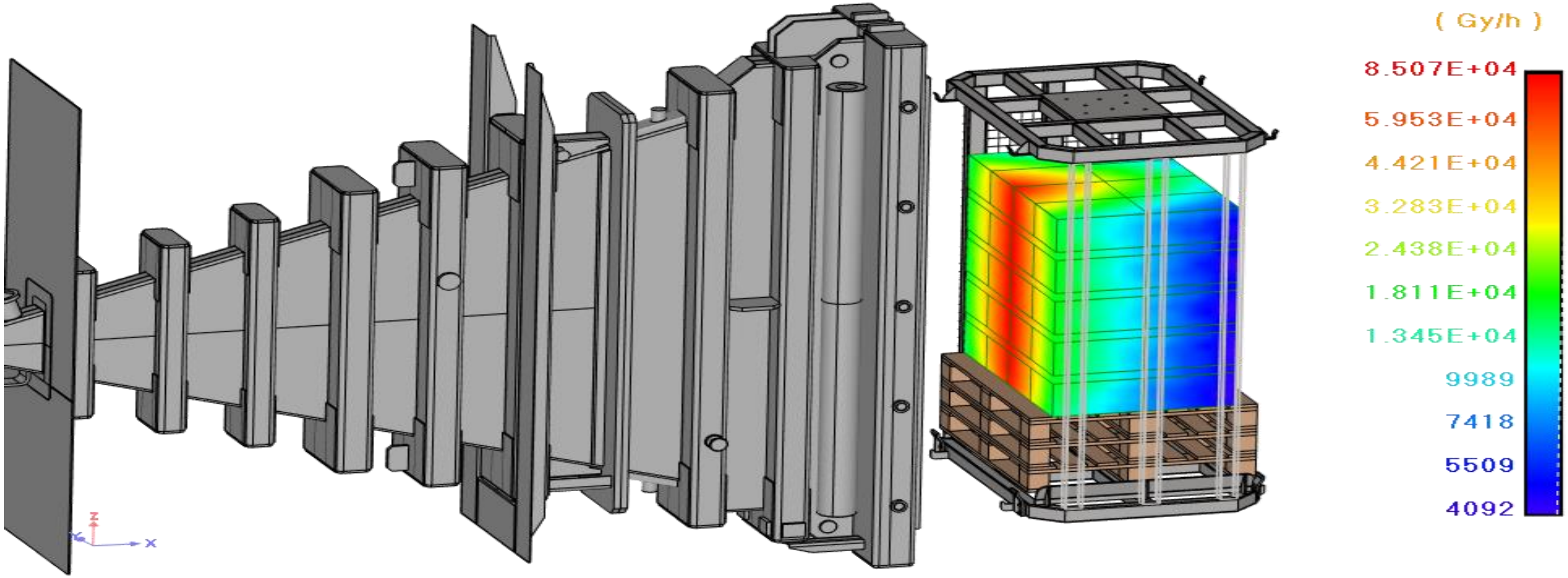


X-Ray at STERIS

Overview of the x-ray irradiation processes at STERIS Venlo

Radiation Simulation

X-ray simulation



- Courtesy of TRAD

Radiation Simulation

X-ray simulation Studies:

Using TRAD's RayXpert Version 1.9

1. Change in the magnitude of operating scan width required to bring a product's treatment to process capable

2. Review the importance for placing dosimetry within a certain area for repeatable dosimetric measurements.

- Courtesy of TRAD

Radiation Simulation

X-ray simulation 1

Experiment with adjusting the scan width:

Example single homogenous product pallet of 0.20 g/cc

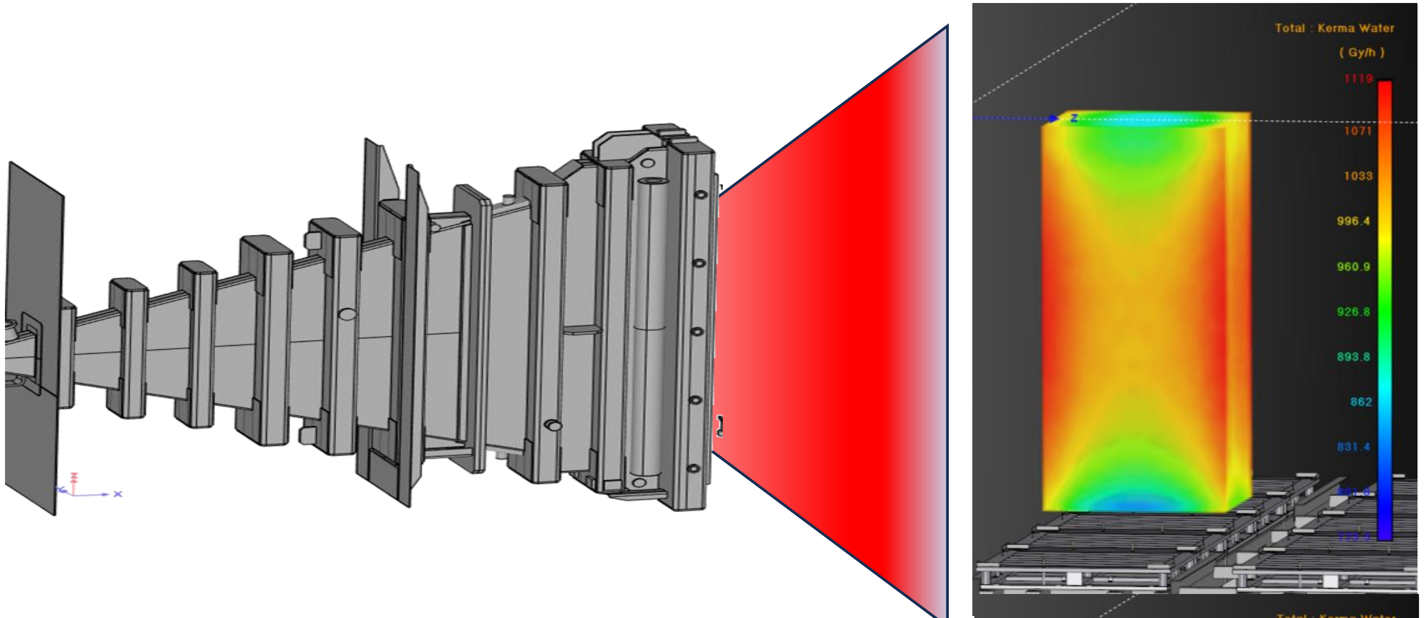
Range of Scan Widths Simulated:

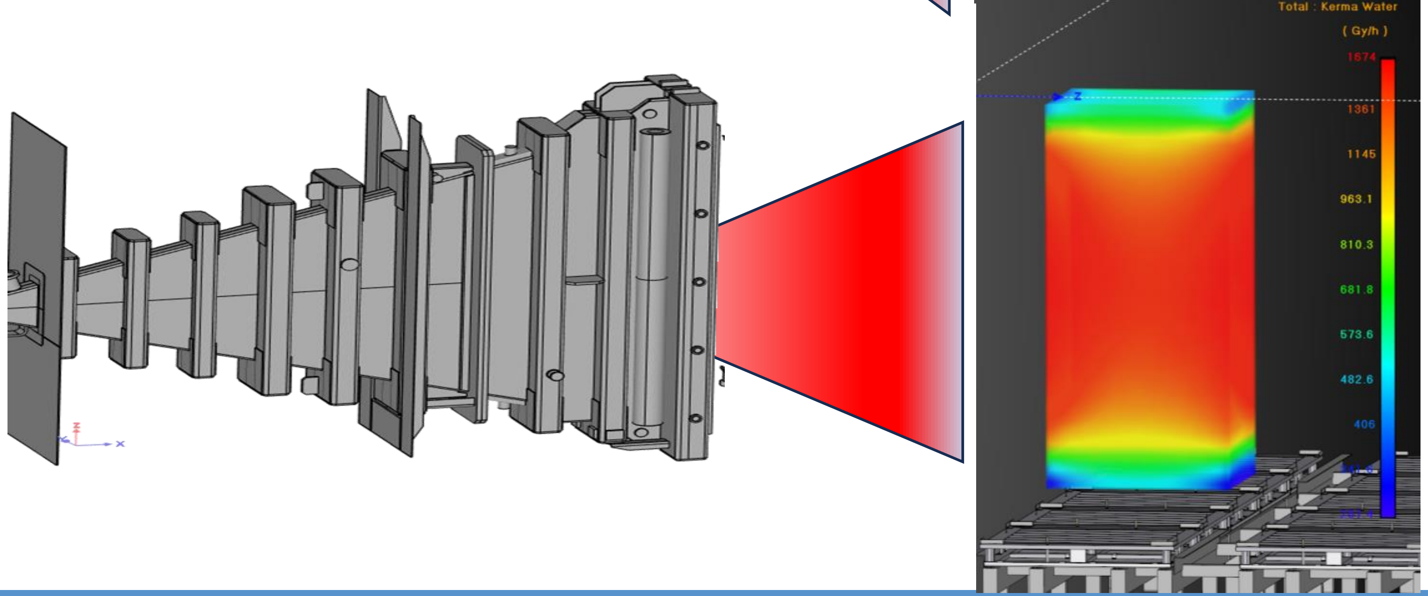
330 cm

300 cm

260 cm

210 cm





Radiation Simulation

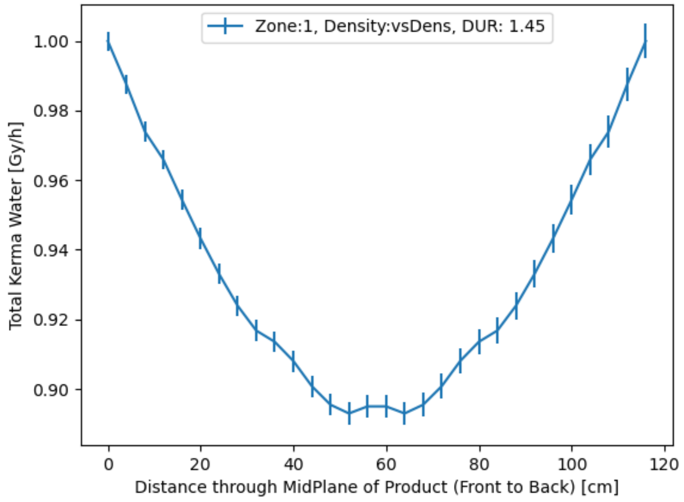
X-ray simulation 1

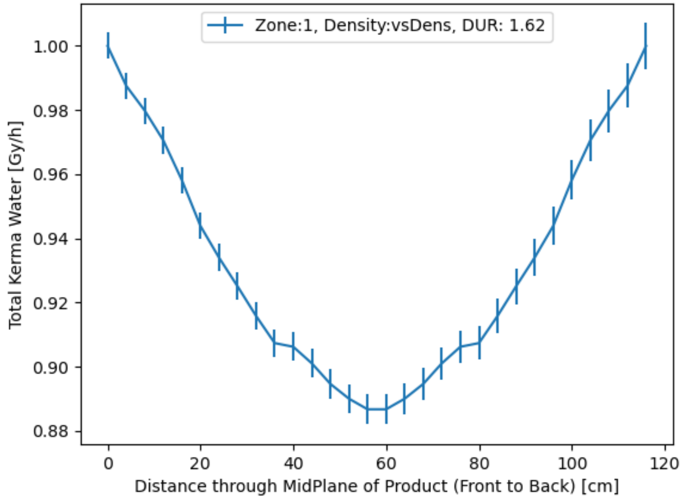
Experiment with adjusting the scan width:

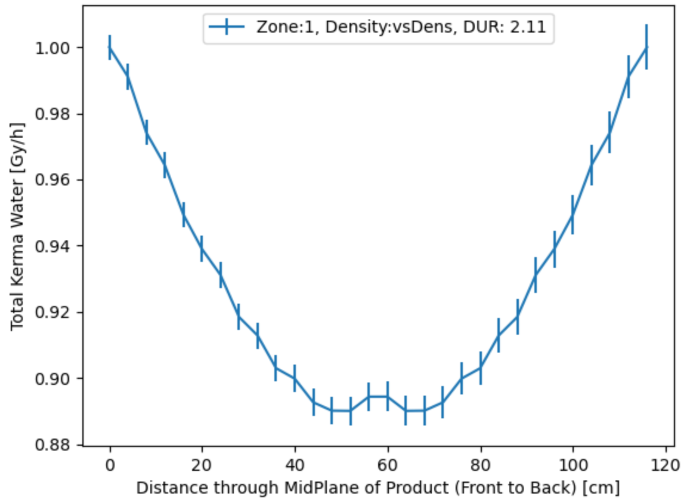
Example single homogenous product pallet of 0.20 g/cc

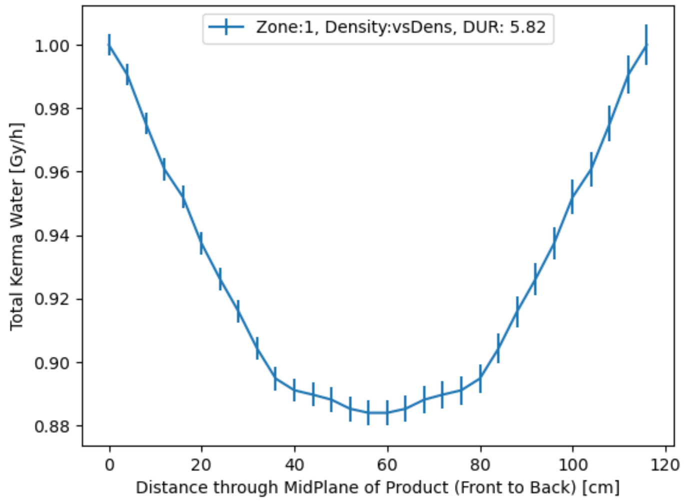
Range of Scan Widths Simulated:

	DUR
330 cm	1.45
300 cm	1.62
260 cm	2.11
210 cm	5.82

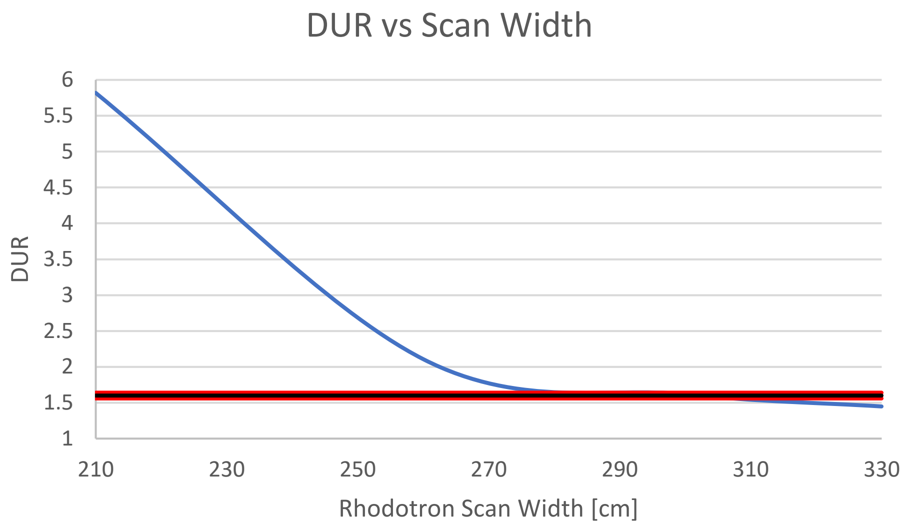








Radiation Simulation



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<u>Review a 5% Variation around DUR</u>

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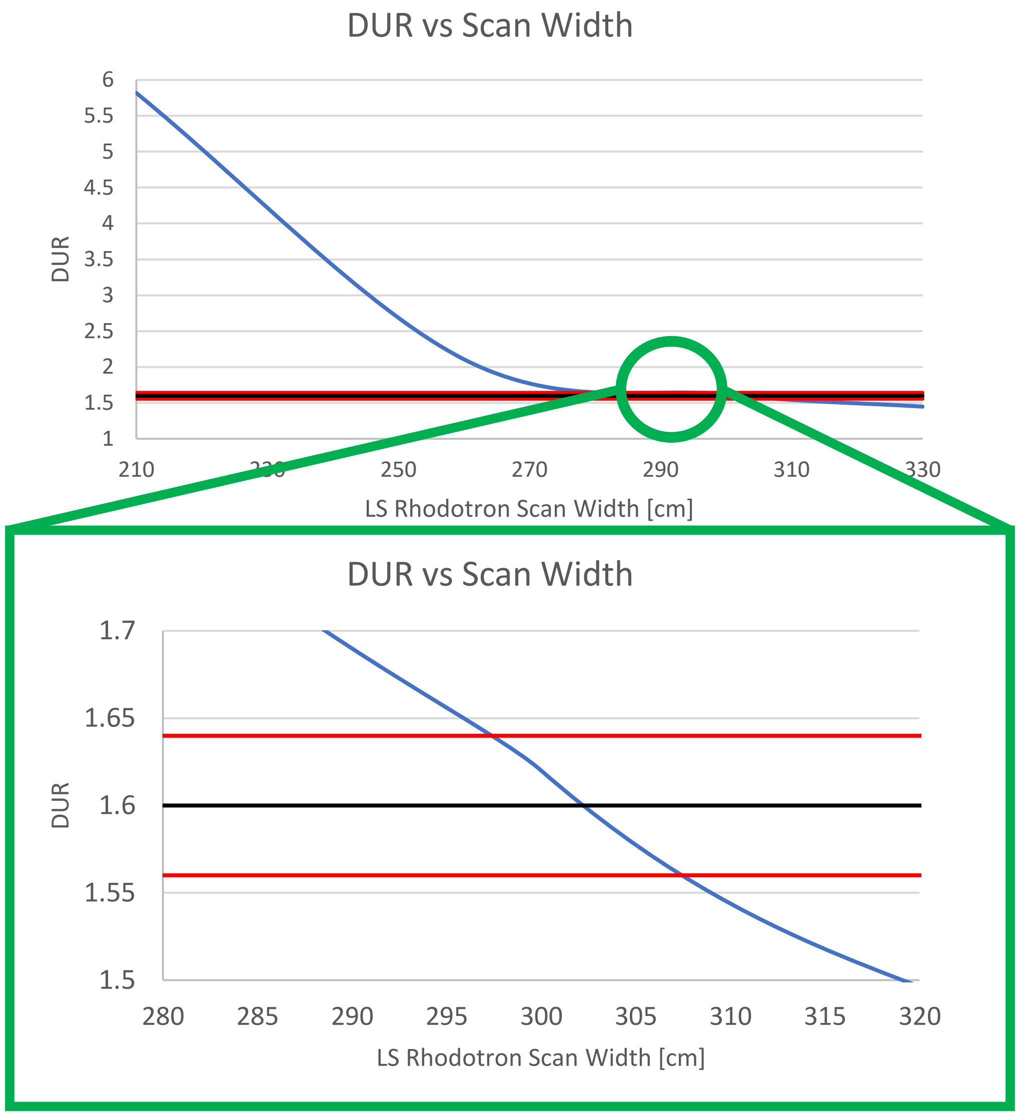

Radiation Simulation

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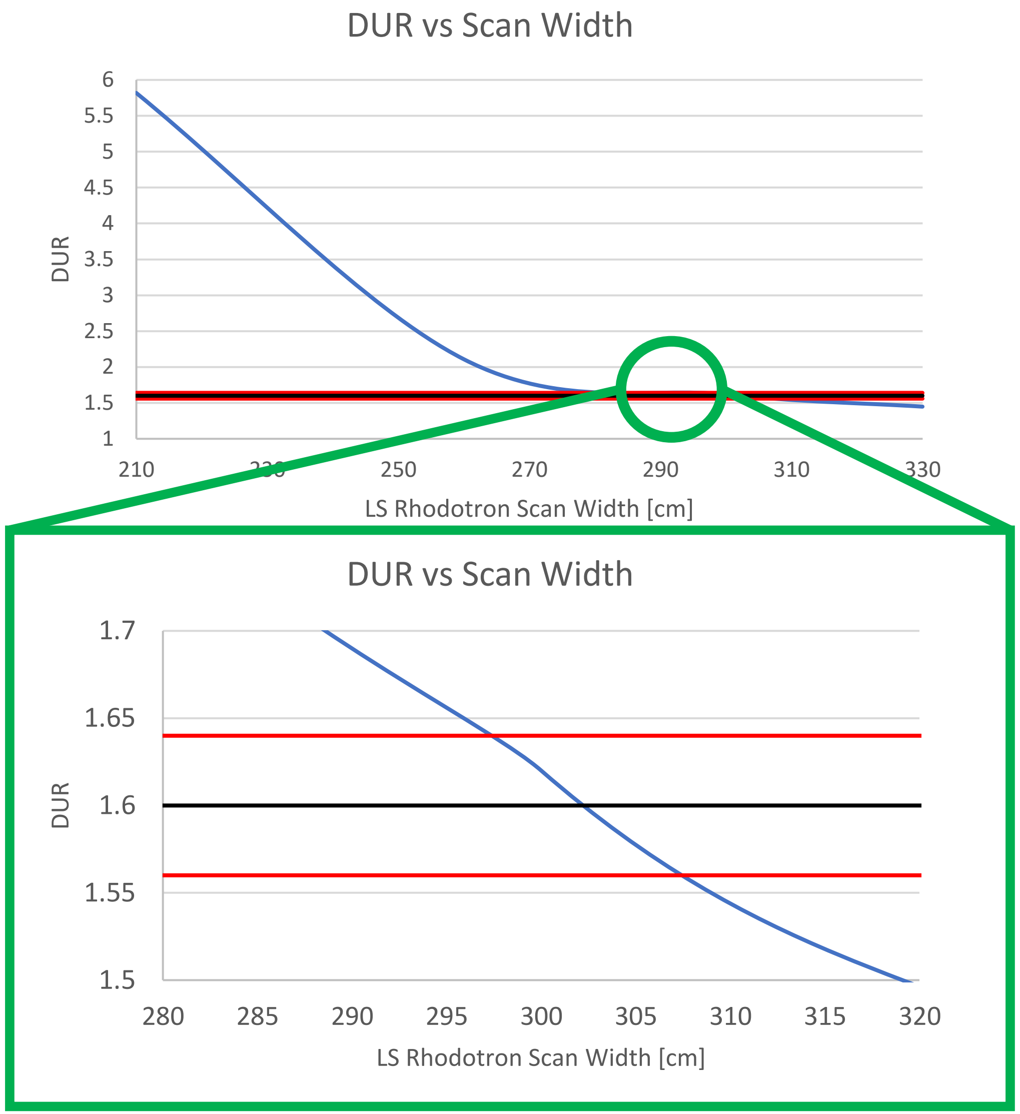

Range of 8 cm to accurately simulate DUR

Radiation Simulation

X-ray simulation 1

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Knowledge of the treatment conditions for the product is critical to reproducing the expected uniformity in simulation

Radiation Simulation

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X-ray simulation 2

Experiment with adjusting the position of routine monitoring dosimeter.

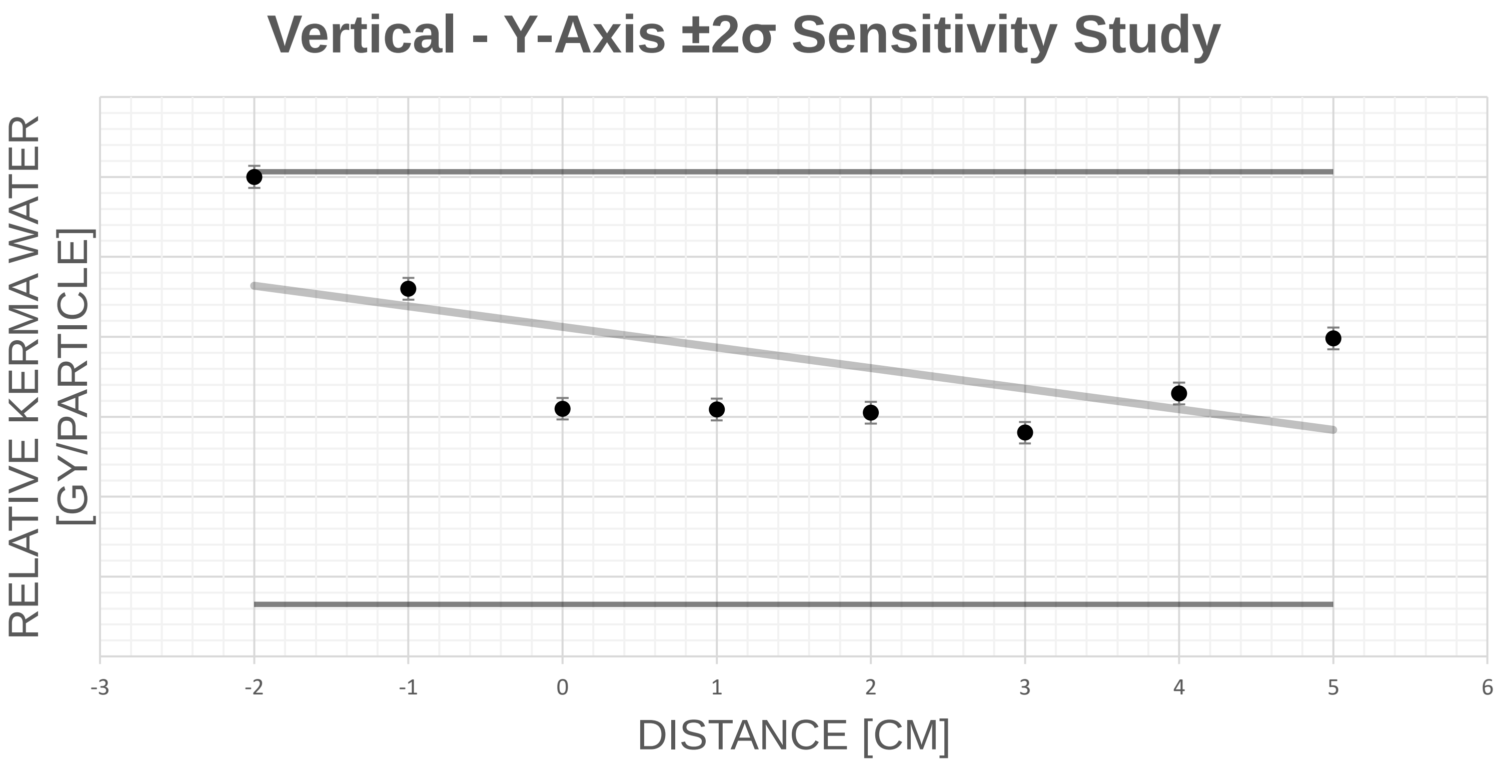
Preparation to adopt automation

Also allowing for optimizing position and sensitivity of placement.

Radiation Simulation

X-ray simulation 2

Experiment with adjusting the position of routine monitoring dosimeter.



Conclusions

X-ray promises some improvements in economics, material response and processing efficiency.

Some parameters need to be well understood to develop appropriate relationship between processing parameters and operational goals.

- highlighted importance of mirroring

Use of radiation simulation provides STERIS a powerful tool to predict sterilization performance and inform upon the importance of standard operating procedures.

- enhanced flexibility in placement of dosimeters.

Thank You

Questions?

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