

Medical device sustainable sterilization – Identifying E-beam opportunities with Monte Carlo Modelling

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1. Current status.



1. Current status.

Ethylene oxide (EO) sterilization

Issues with ethylene oxide:

- Regulation issues.
- Time efficiency (EO takes days).



Alternative methods:

- **Electron beam radiation (EB)**
- Vaporized hydrogen peroxide (VHP).
- Nitrogen dioxide.



Electron Beam (EB) radiation is a good alternative:

- More favorable regulations.
- EB sterilization takes seconds.
- More reliable supply chain.
- Wide range of use.

2. Project Inputs/Outputs.



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2.1. Project Inputs/Outputs.

Inputs



Outputs

- Material properties.
- Dimensions of products and product packaging.
- Infrastructure and irradiation conditions.
- Dosimetry systems.
- Regulation specifications.

- Dose uniformity ratios.
- Effects on the material properties.

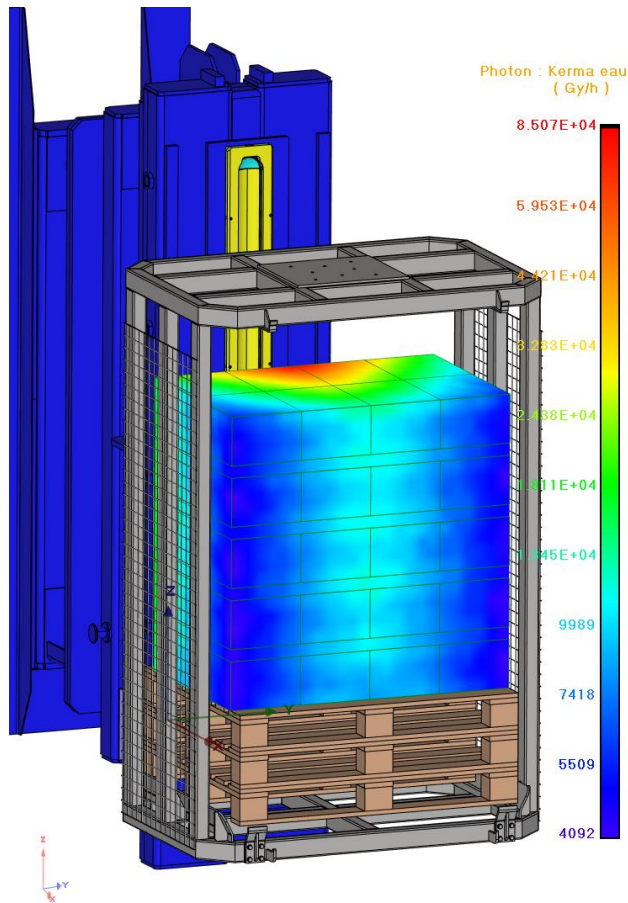
2.2. Monte Carlo Models.

Monte Carlo Model

Inputs



Outputs



RayXpert 3D

Statistical simulation technique to simulate physical events based on the generation of based on selected parameters.

- In irradiation this can be used to simulate dose distribution and irradiation scattering effects.



Asses the viability of the project using a Monte Carlo Model.

3. Process flow.



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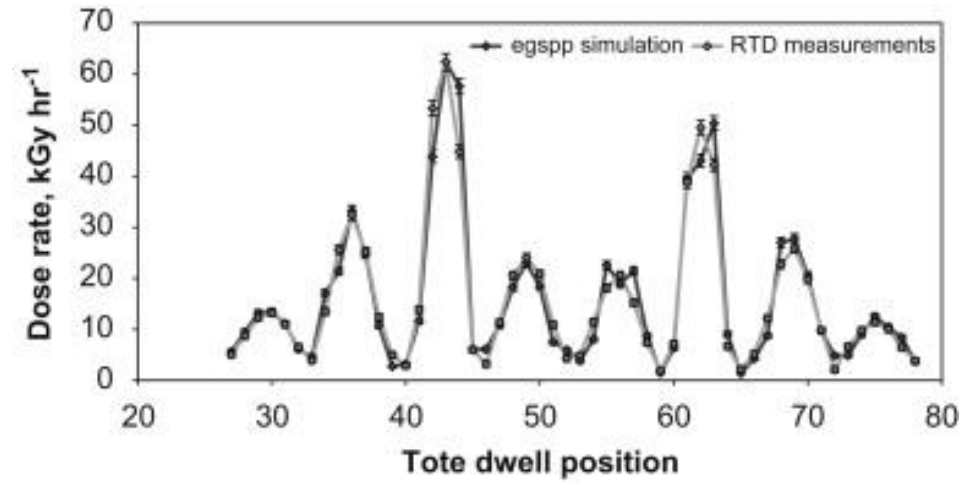
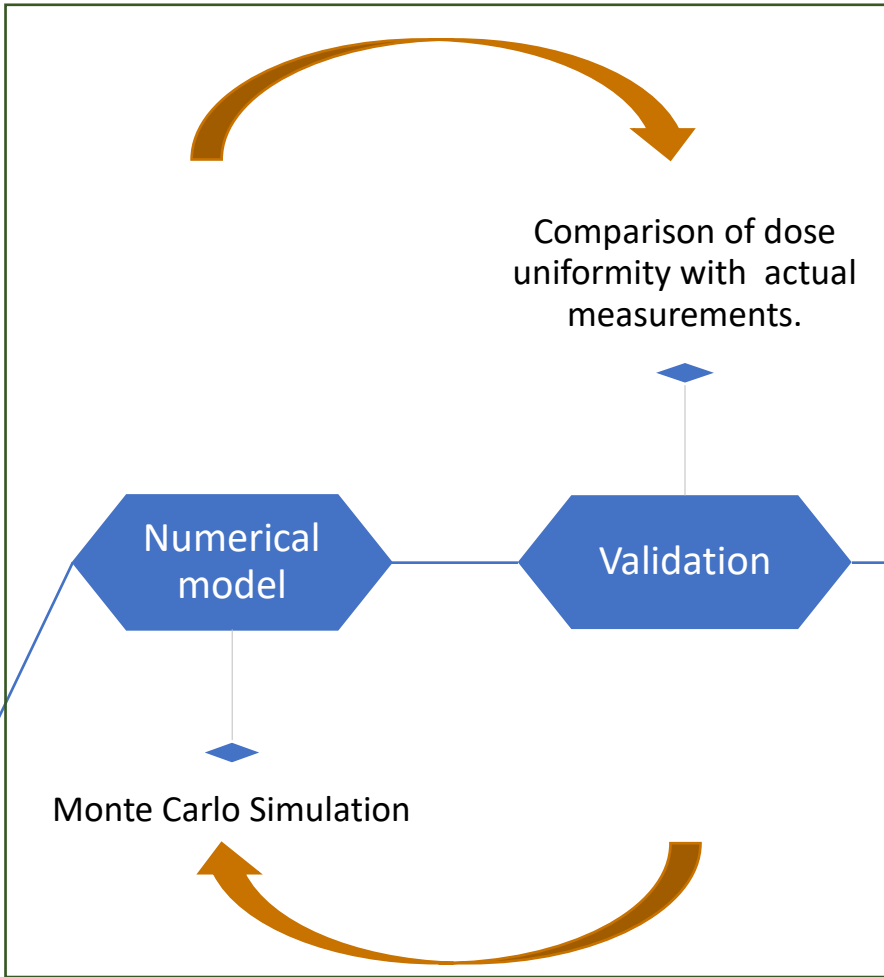
3. Process flow.

Iterative process

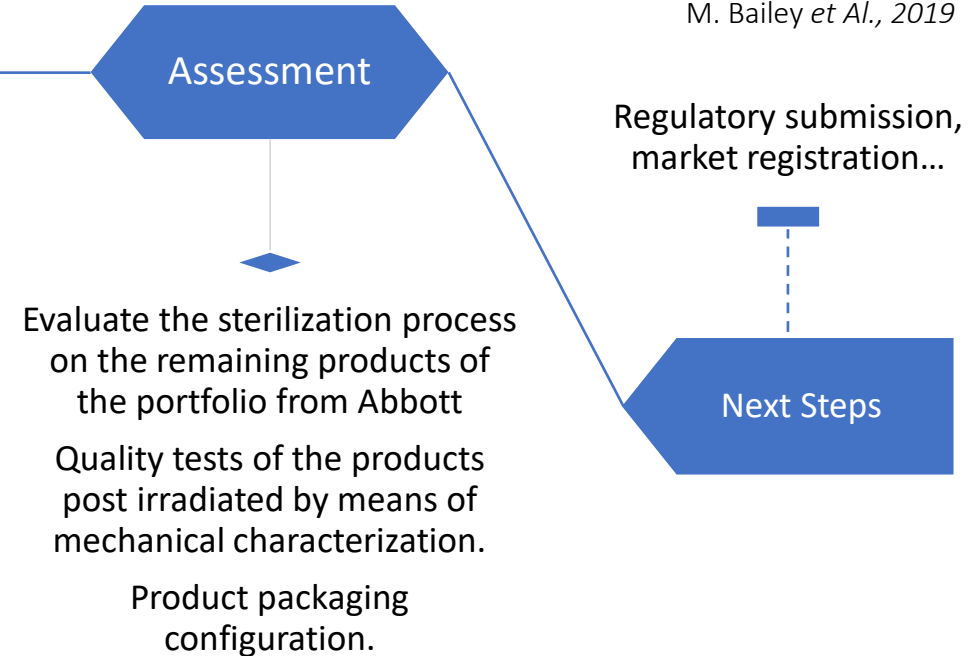
95% (2σ) confidence

Material properties.
 Dimensions of products and product packaging.
 Infrastructure and irradiation conditions.
 Dosimetry systems.
 Regulation specifications.

Inputs



M. Bailey *et Al.*, 2019



4. Requirements/prerequisites.



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4. Requirements/prerequisites.

- Training on software: CAD Software, Monte Carlo simulations



Proposed software:

CAD software	Solid Edge
Monte Carlo Simulations	RayXpert

- EB facility for testing and validation.
- Geometry modelling of the products.
- Cost estimation.

5. Next steps.



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5. Next steps.

- Assessment of future costs.
- Regulatory submission.
- Risk assessment.
- Guidelines generation (protocols).
- Packaging optimization.
- Implementation in the supply chain (end user perspective).

Questions?





Thank you for
you attention!



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