Medical Device Sterilization:
From Possibilities to Practice
September 21-23, 2022

Design for Sterilization

Harnessing the power of virtual dose mapping tools

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TRIPLE RING technologies

DOSE INSIGHT

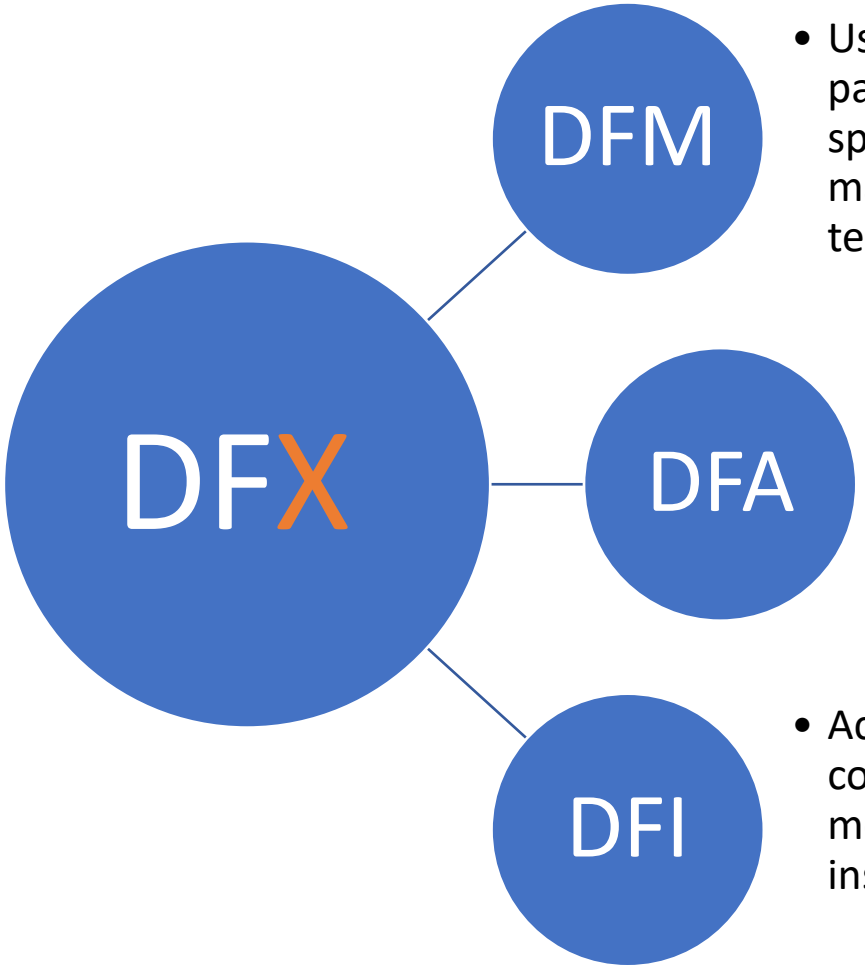
TRIPLE RING technologies

- Co-development company
- 100+ employees in Newark, CA and Boston
- Focus on life sciences and medical device development
- Internal R&D partially funded by government grants
- Spins out internal ideas as independent products

DOSE INSIGHT

- Develops a virtual dose mapping tool
- Seeks to deploy the tool with
  - Medical device developers
  - Sterilization vendors
- Visit us at: www.doseinsight.com

What is Design For X (DFX)?



- Use off-the-shelf parts, design for a specific manufacturing technique, etc.

- Reduce number of parts and assembly steps

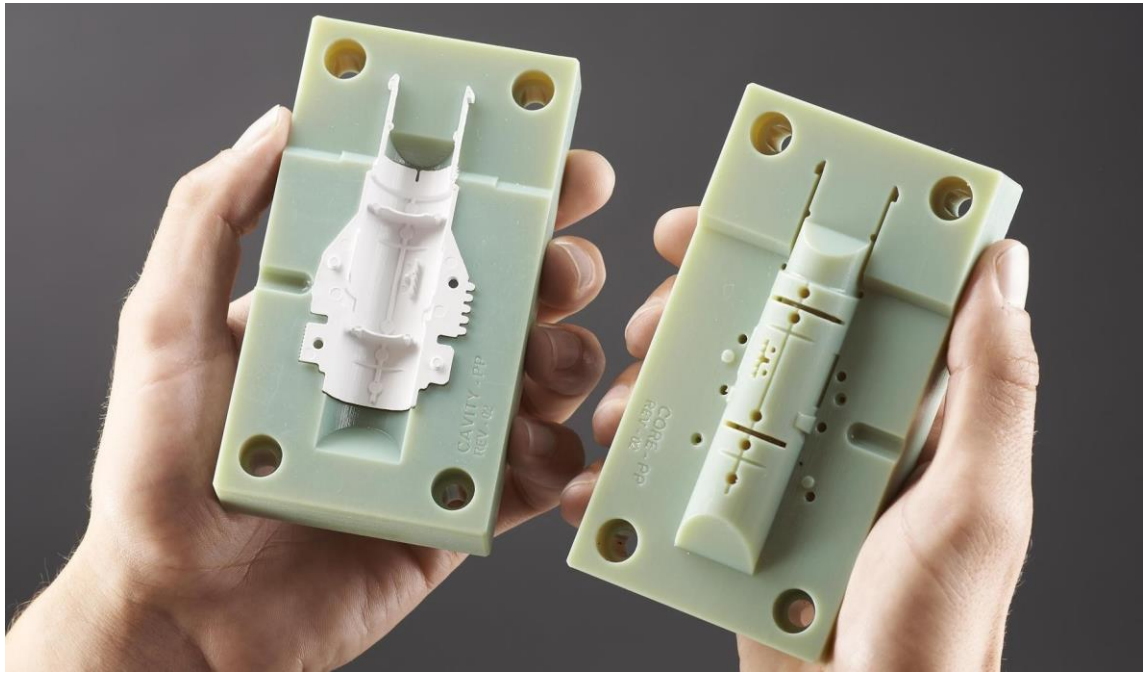
- Account for conventional measurement instruments

A medical component vendor used DFX to achieve[1]:

- **33%** reduction in # of parts
- **64%** reduction in # of assembly operations
- **53%** reduction in cost

[1]https://www.dfma.com/resources/southco.asp

The evolution of DFM for injection molding

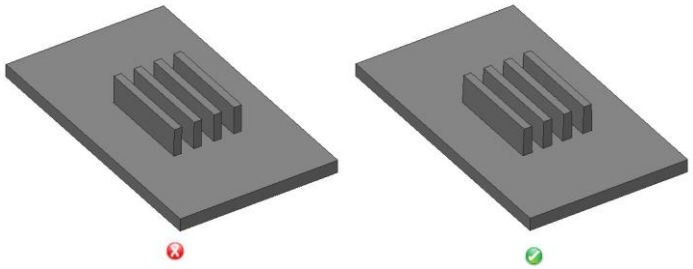


https://www.rapiddirect.com/blog/medical-injection-molding/

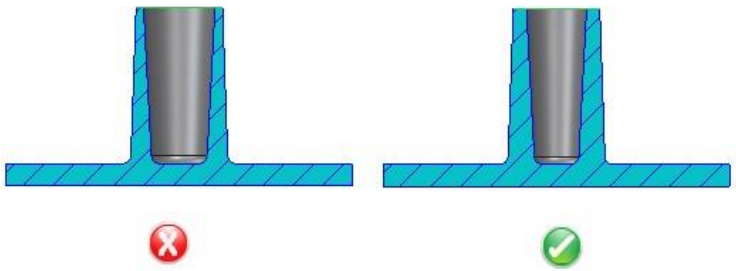
https://www.ennomotive.com/revolutionizing-injection-molding-process/

The evolution of DFM for injection molding

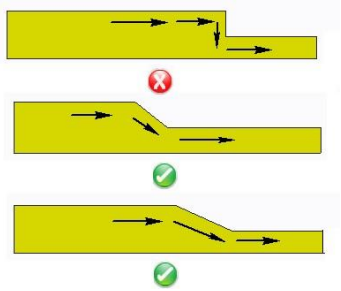
Conventional design guidelines reduce prototyping iterations



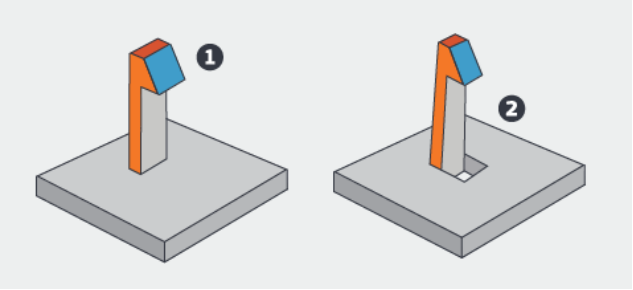
Ribs should have a ~1° draft angle to facilitate ejection and reduce contact pressure and friction[1]



Wall thicknesses of bosses should be <0.6x the wall thickness to minimize sinking[1]



Reduce sharp transitions in wall thickness to allow for smooth filling of the mold[1]



Avoid undercuts where possible[2]

[1]dfmpro.com/manufacturing-processes/dfmpro-for-injection-molding
[2]https://www.protolabs.com/resources/design-tips/6-ways-to-achieve-undercut-success-in-molded-parts/

The evolution of DFM for injection molding

Modeling

Design guidelines

- Several companies sell modeling software for injection molding
- Able to simulate fluid dynamics and mechanical stress
- Case study[1] found using simulations resulted in:
  - **50%** reduction in development time
  - **95%** mold success rate

[1]https://www.solidworks.com/story/ambix-consulting-llc

Design for Sterilization (DFS)

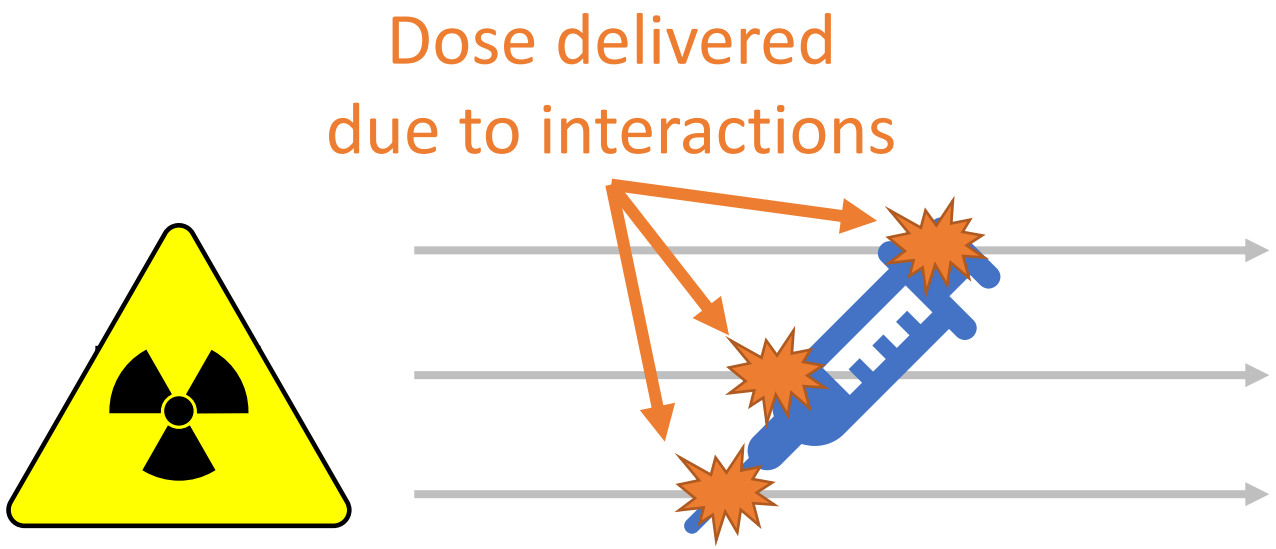
Modeling

Design guidelines

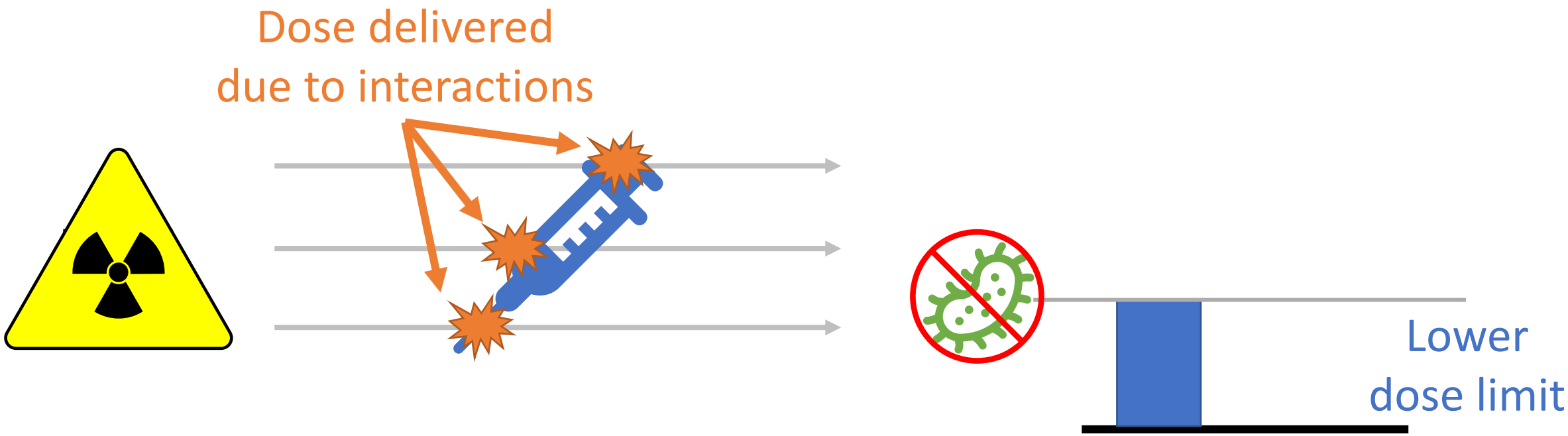
Design rules	EtO: consider breathability, avoid cavities where gas can get trapped, conformally coated circuit boards, etc.
Material compatibility	AAMI TIR17 *Compatibility of materials subject to sterilization*, 2017
Consulting with vendors	Leverage decades of experience

DFS for radiation sterilization

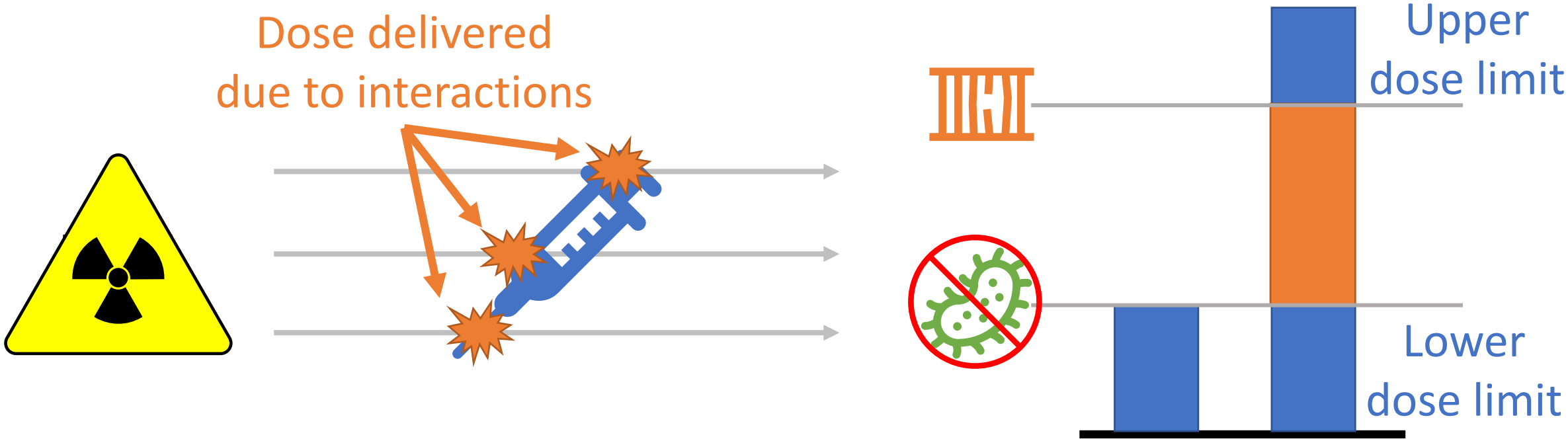
DFS for radiation sterilization



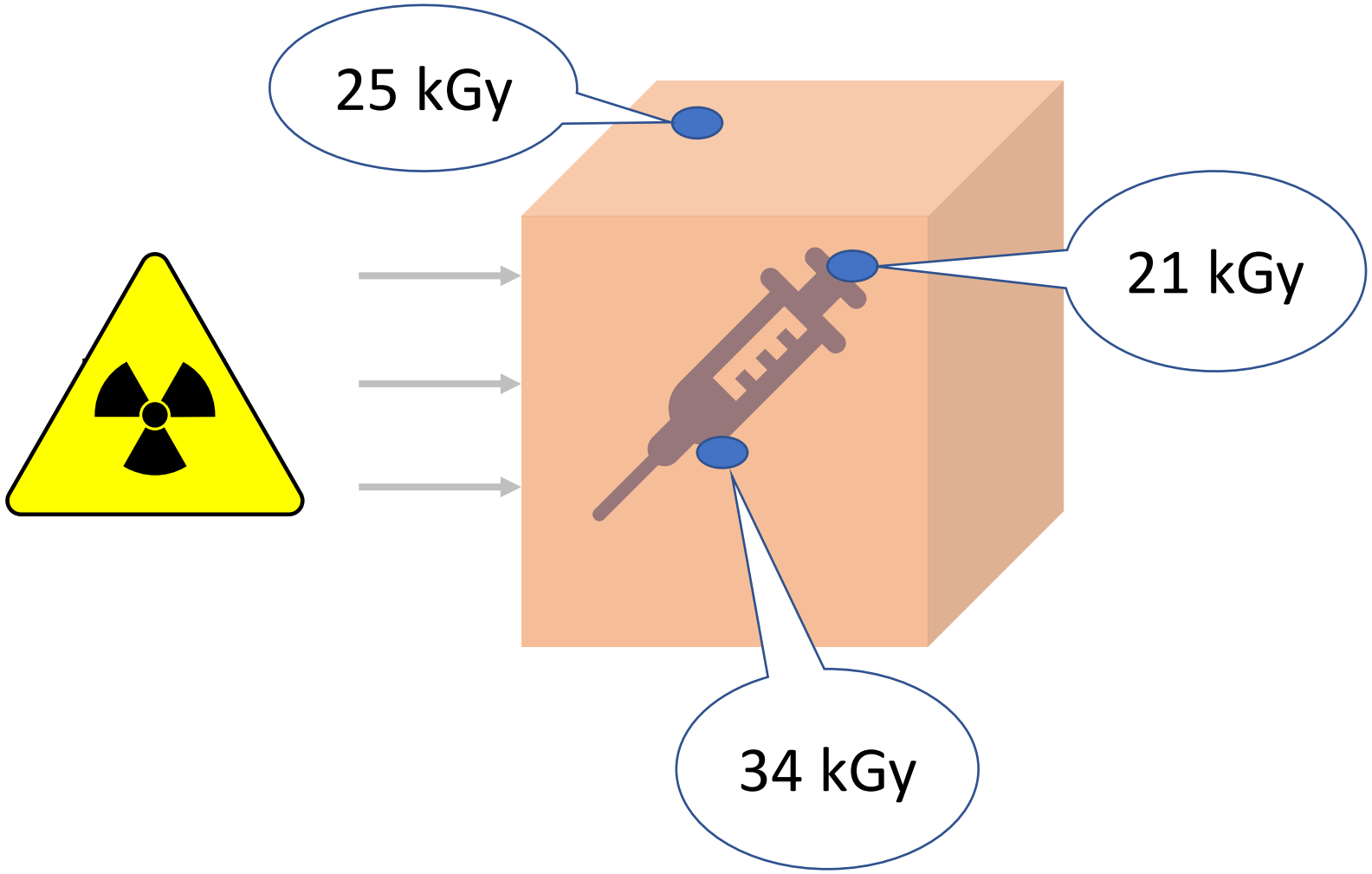
DFS for radiation sterilization



DFS for radiation sterilization

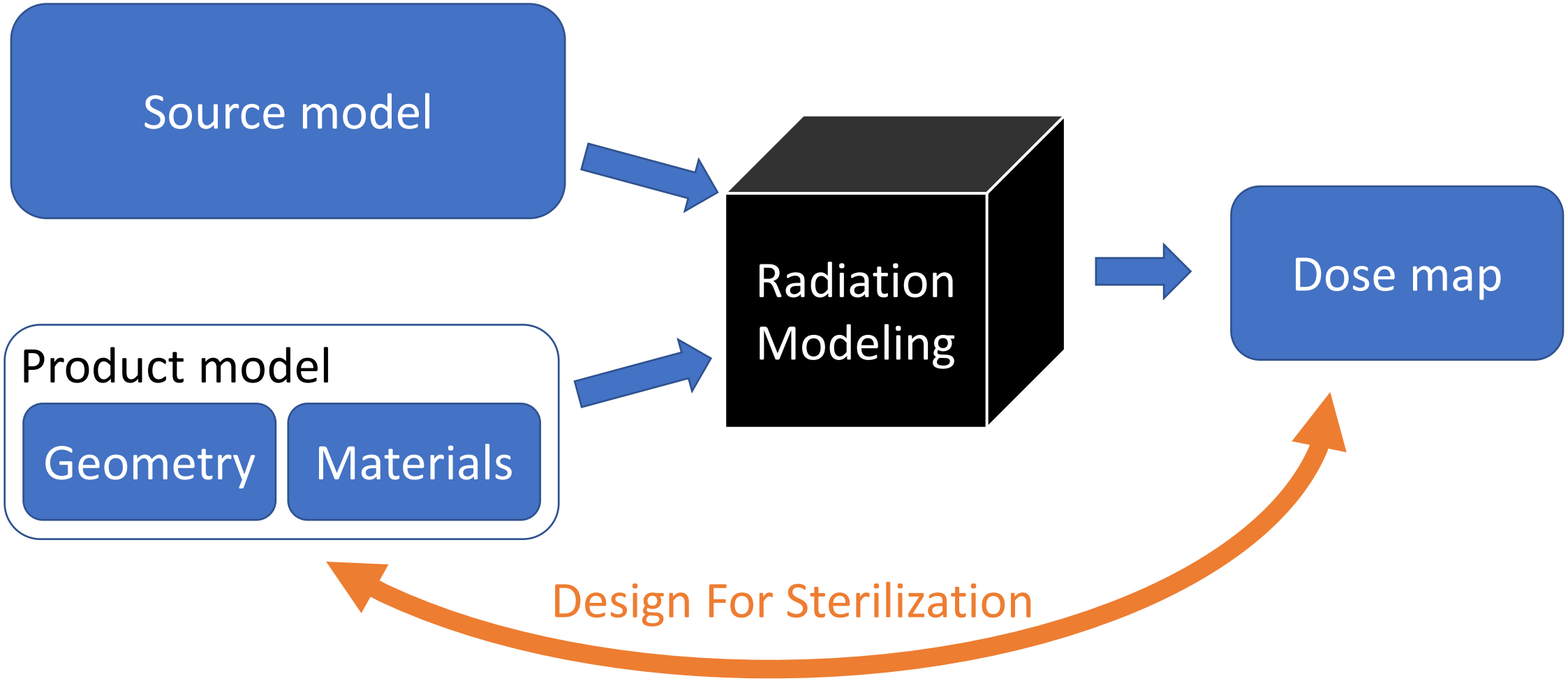


DFS for radiation sterilization



Predicting the full 3D dose map would enable DFS

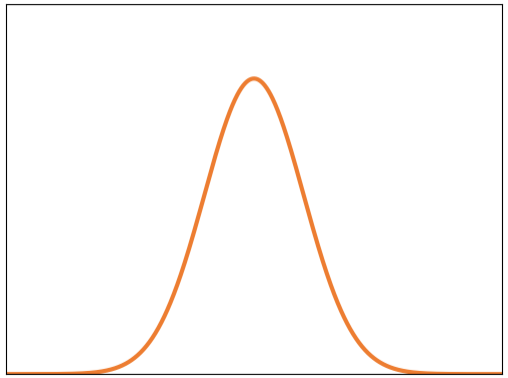
Predicting the dose map using modeling



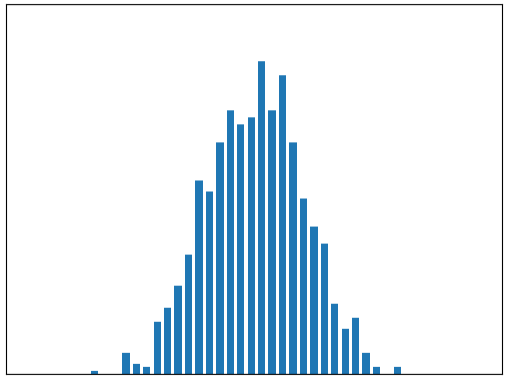
Types of radiation modeling

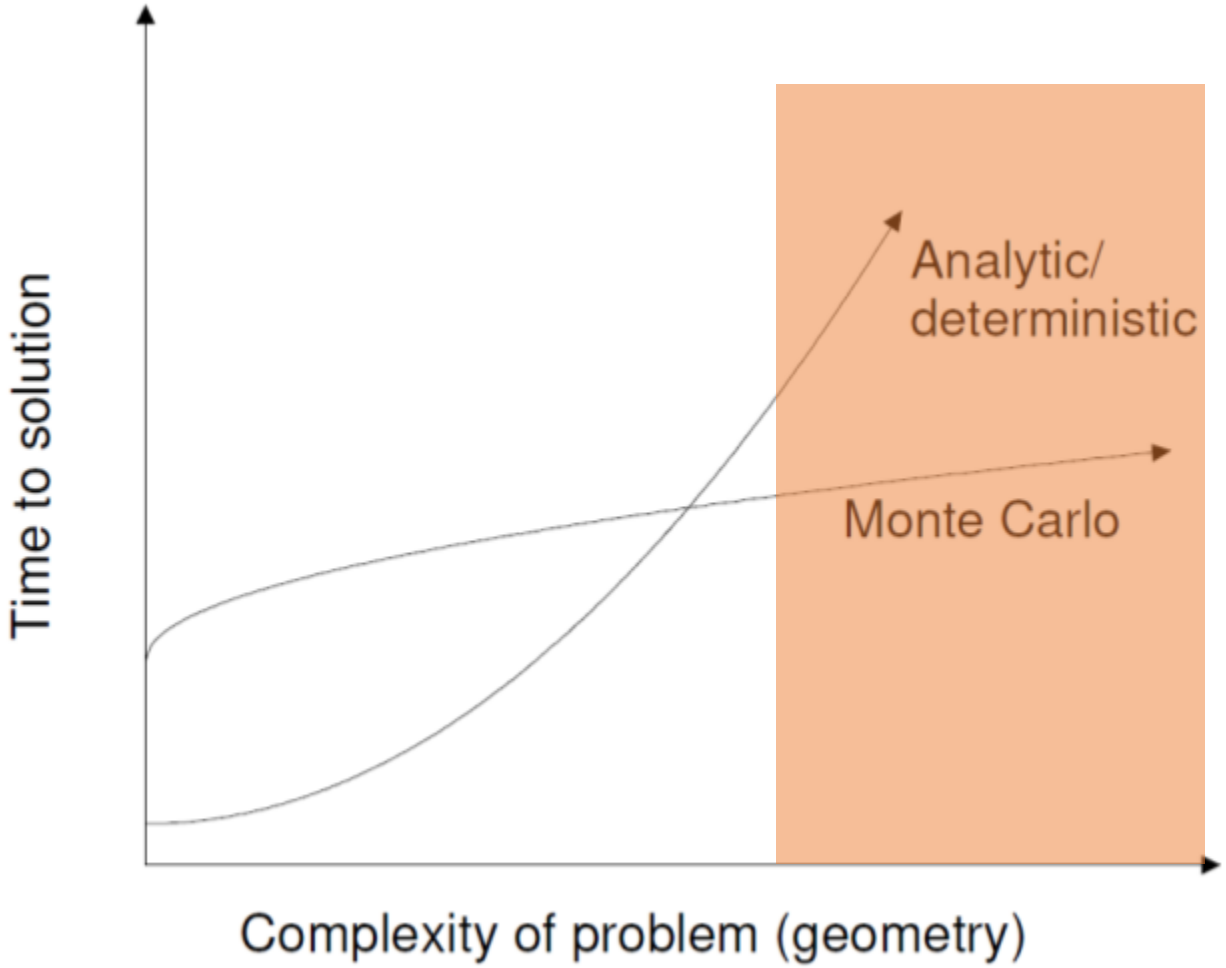
A.F. Bielajew "Fundamentals of the Monte Carlo method for neutral and charged particle transport", 2020

Analytic/ deterministic



Monte Carlo

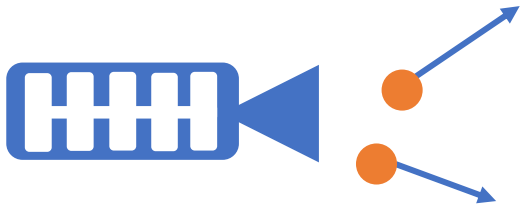




Monte Carlo simulations for radiation transport

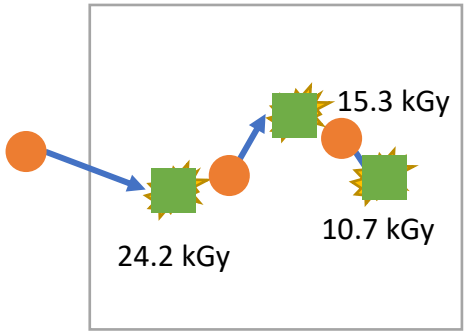
Emulate the real statistical nature of particle transport by simulating each particle's history

Source produces particles with random direction and energy



Particles interact with matter

- Get absorbed
- Change direction
- Change energy



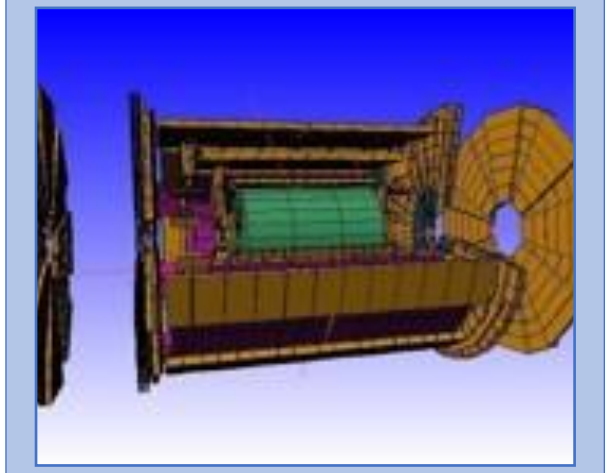
Each particle's history is tracked

- Where did it get absorbed?
- How much energy did it deposit?

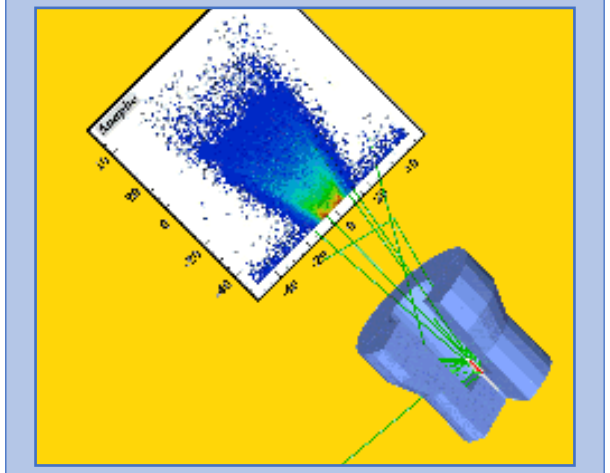
Geant4

https://geant4.web.cern.ch/

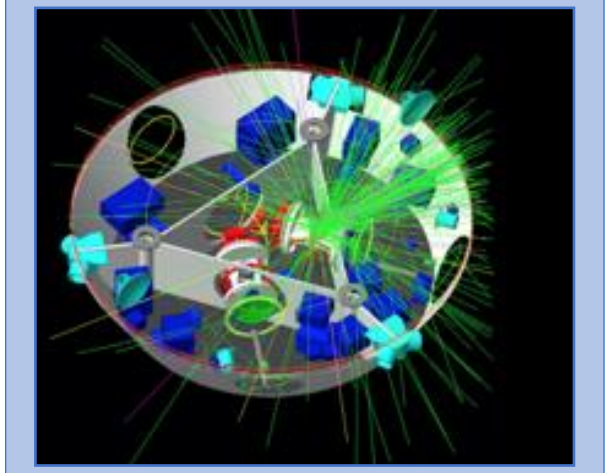
A Monte Carlo toolkit for passage of particles through matter



High energy physics



Medical



Aerospace

Strong institutional support

CERN

SLAC NATIONAL ACCELERATOR LABORATORY

TRIUMF

Northeastern UNIVERSITY COLLEGE OF COMPUTER SCIENCE

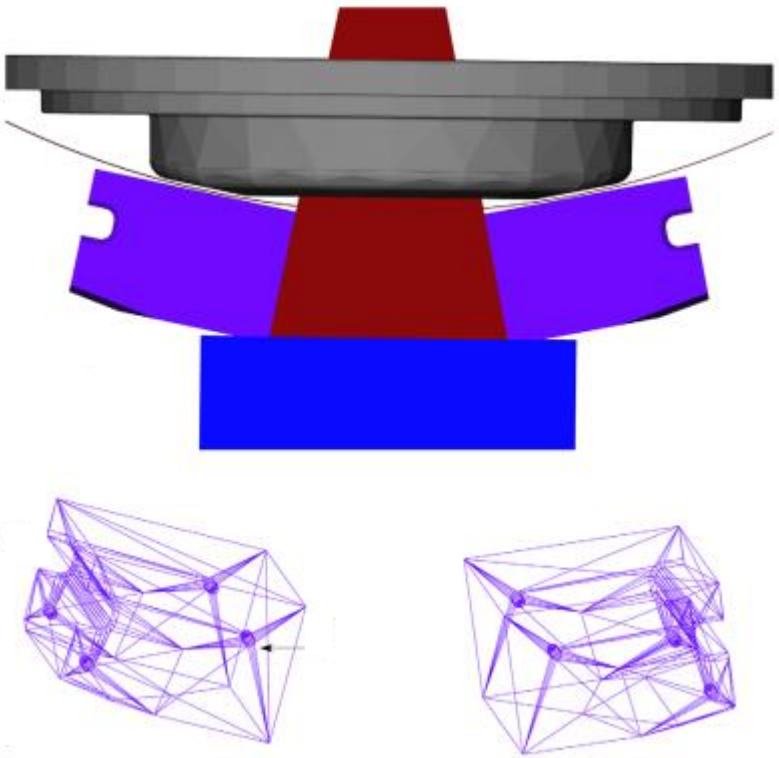
CENBG

Fermilab

Validation of Geant4 with a 6 MeV X-ray beam

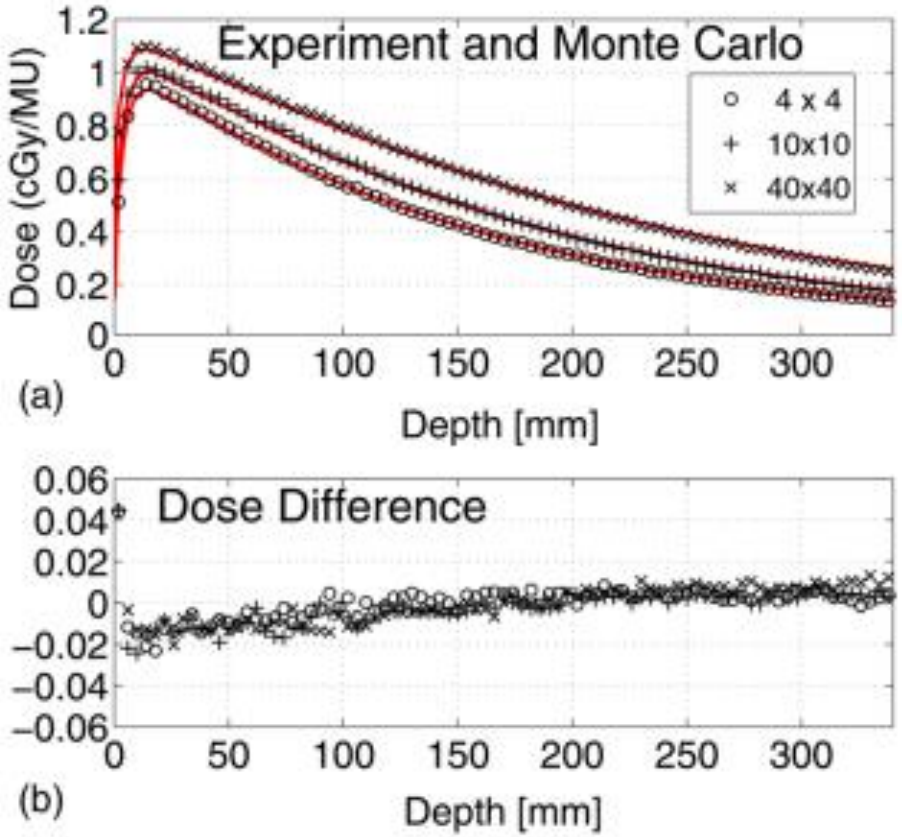
M. Constantin et al., Medical Physics, 38 (2011). Collaboration between Stanford and Varian

CAD model of treatment head



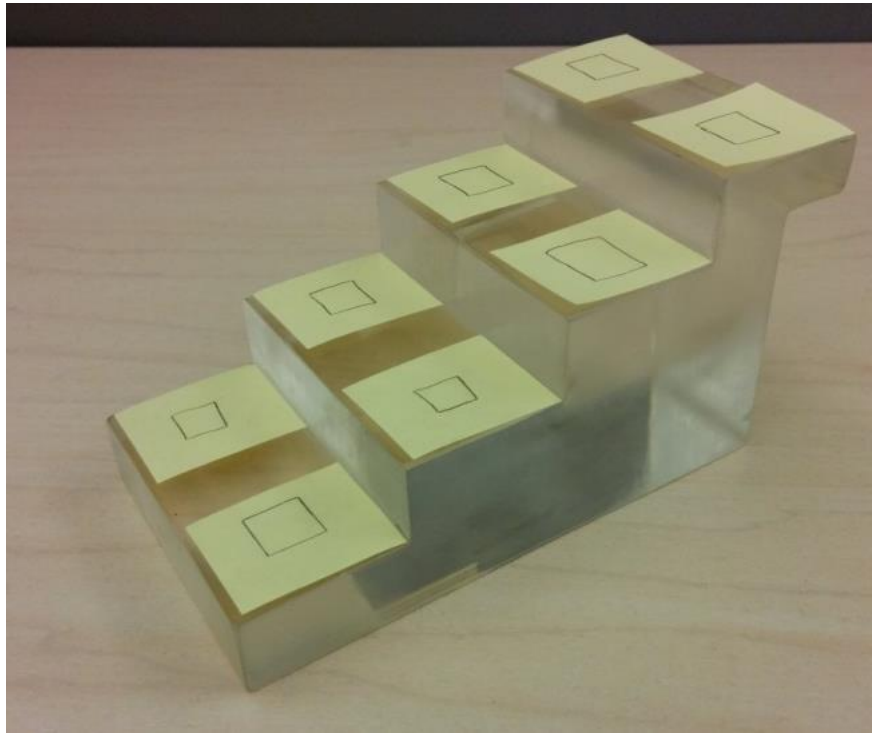
Collimator jaws

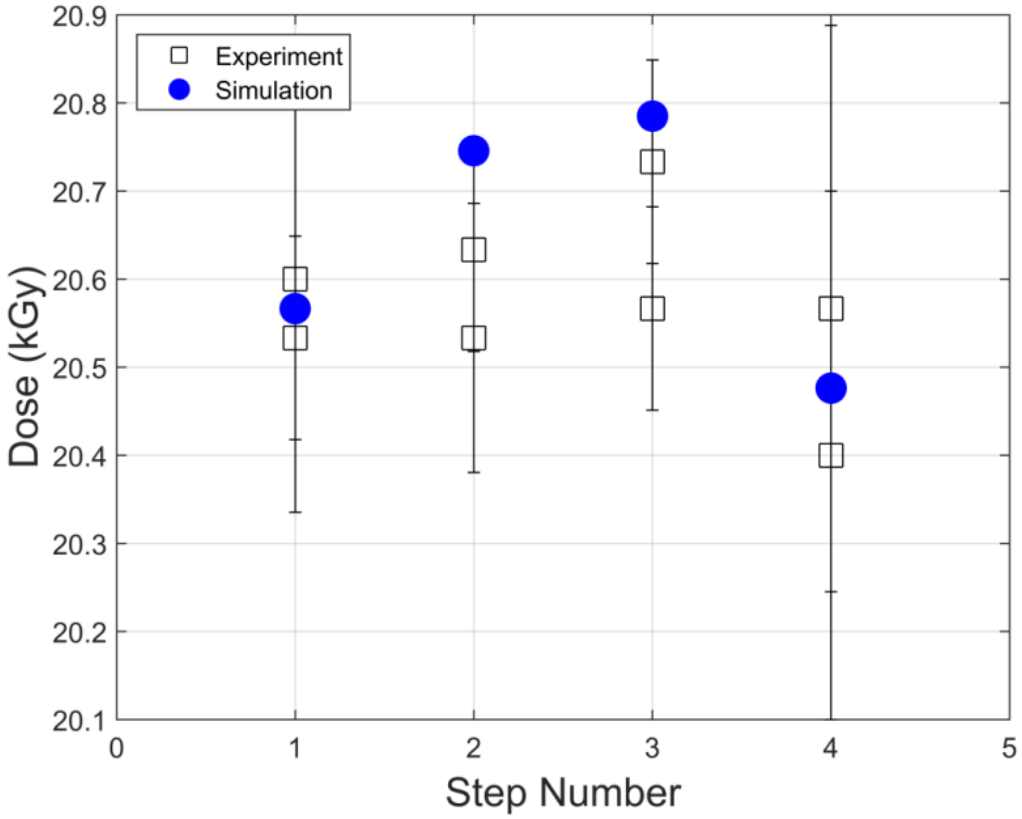
Measured (black) vs. simulated (red) dose



98% of measurement values are within 2% of simulated dose

Example of validation at a 10 MeV e-beam facility





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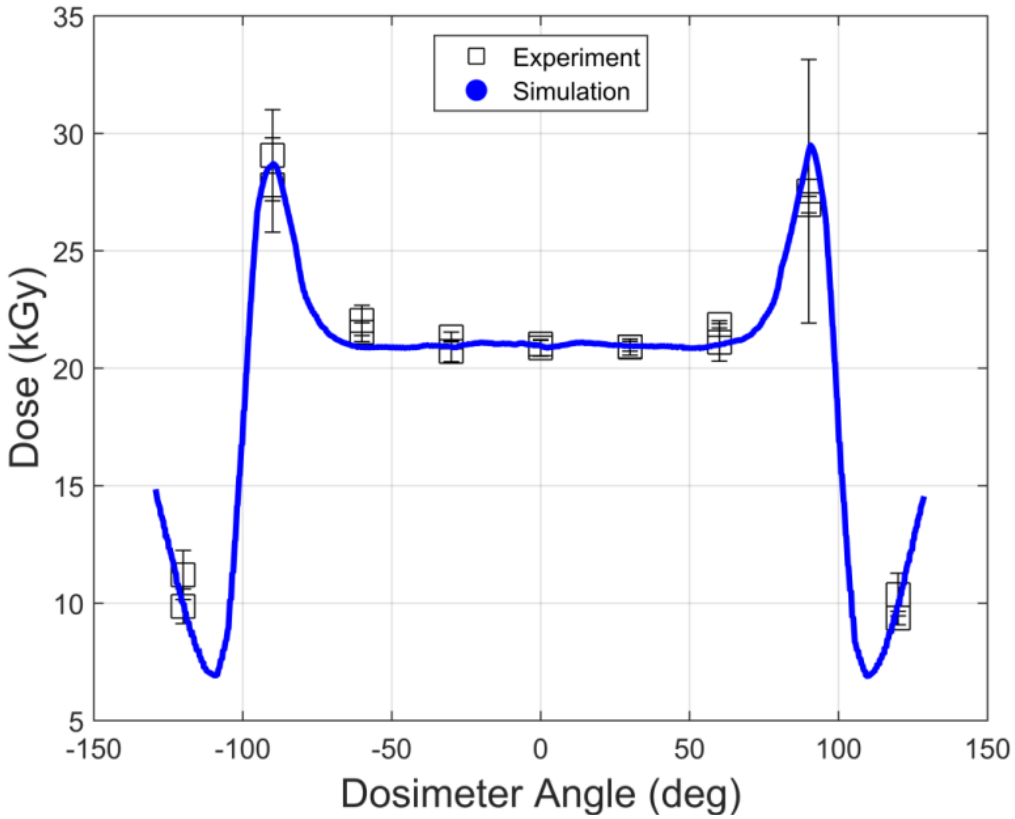
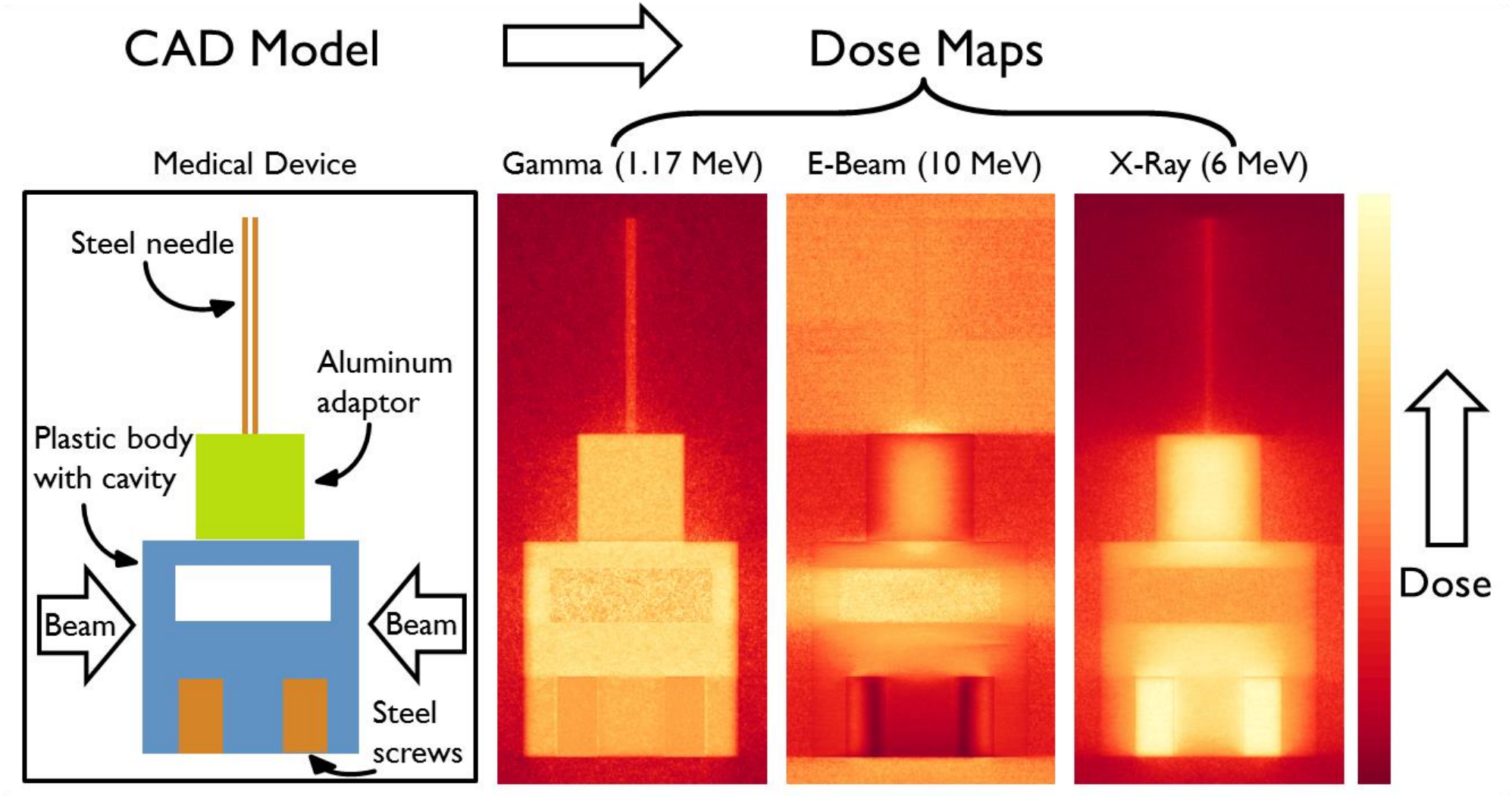


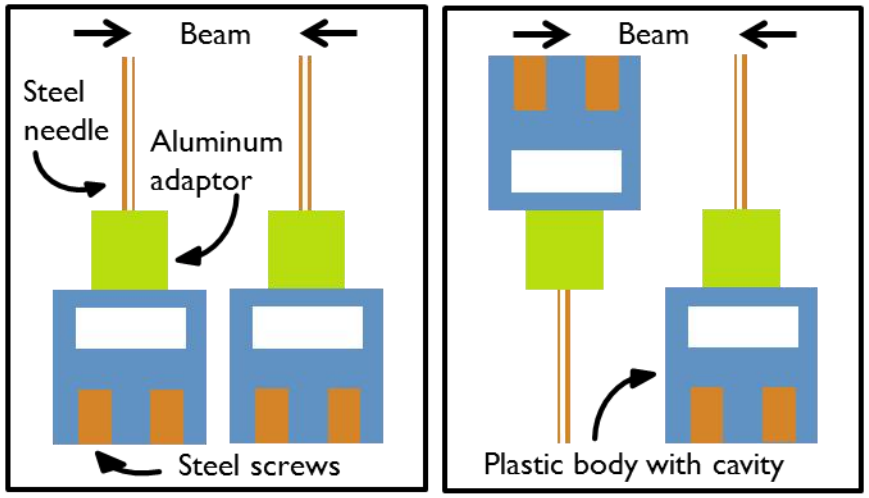
I have a dose map modeling tool, now what?

Use case: Modality selection

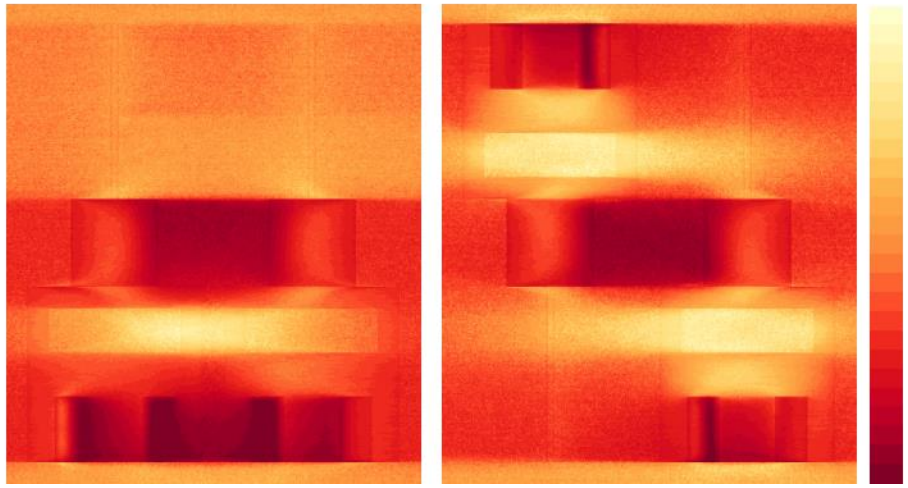


Use case: Optimizing packaging configuration

CAD Model

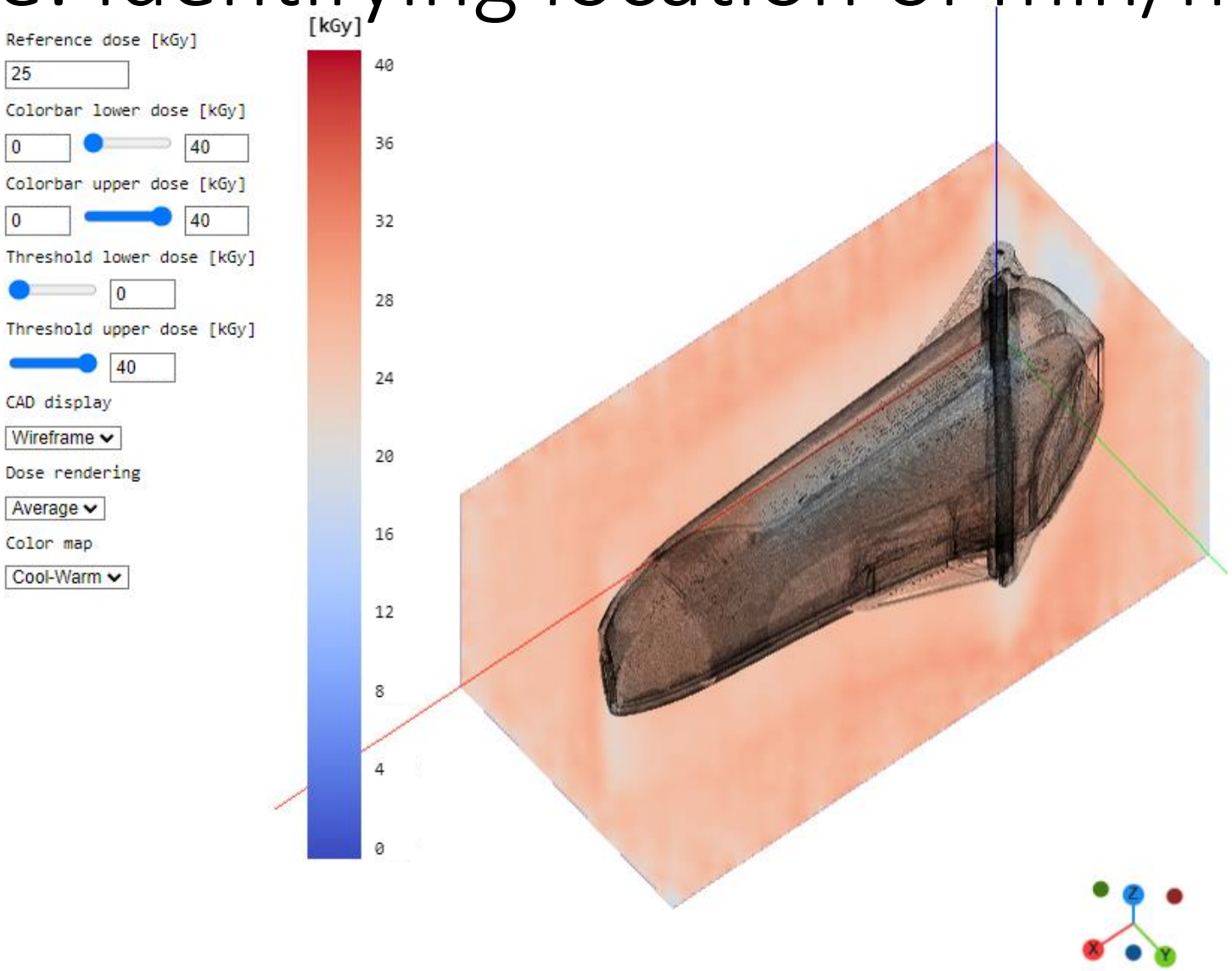


Dose Maps

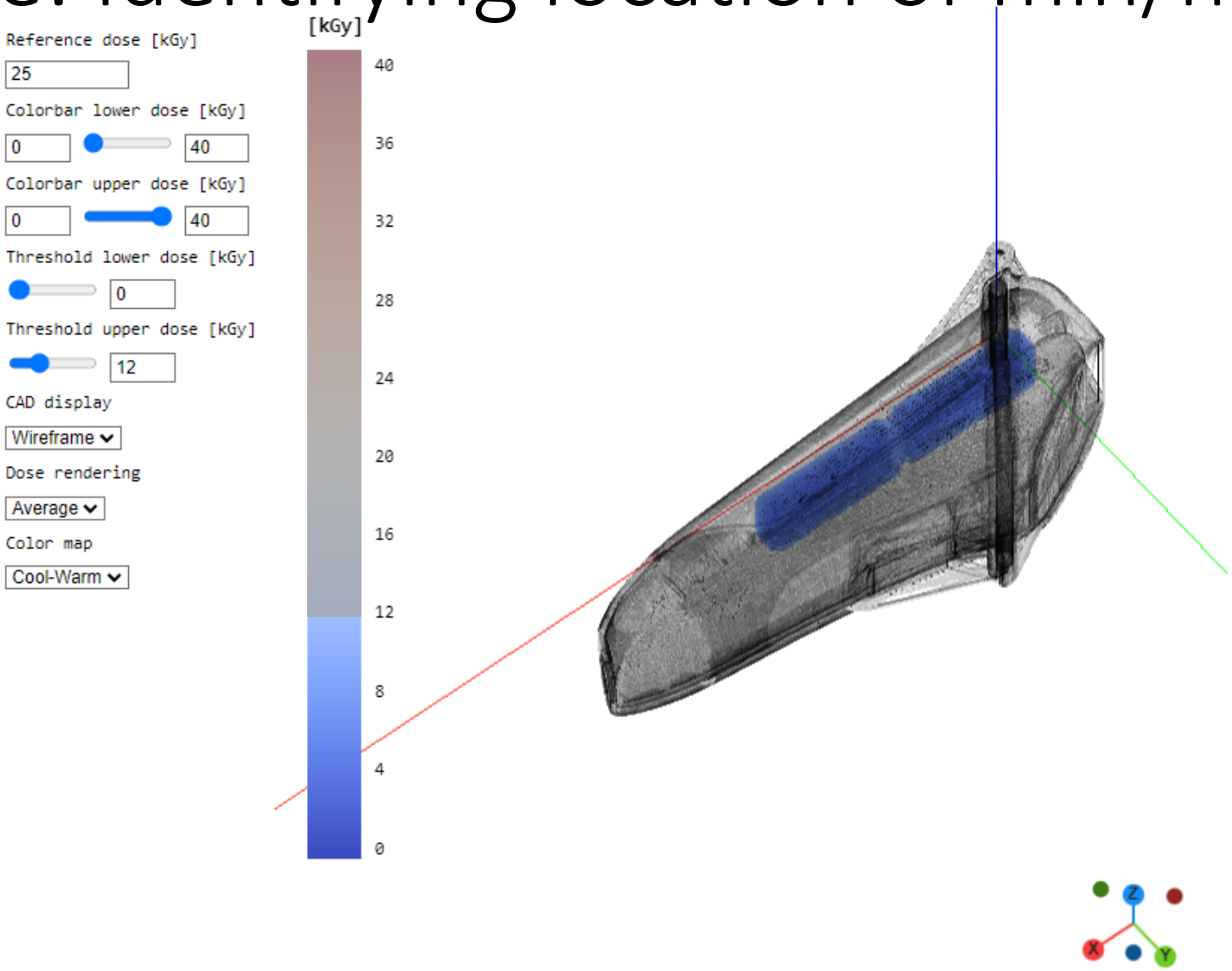


Dose

Use case: Identifying location of min/max dose



Use case: Identifying location of min/max dose



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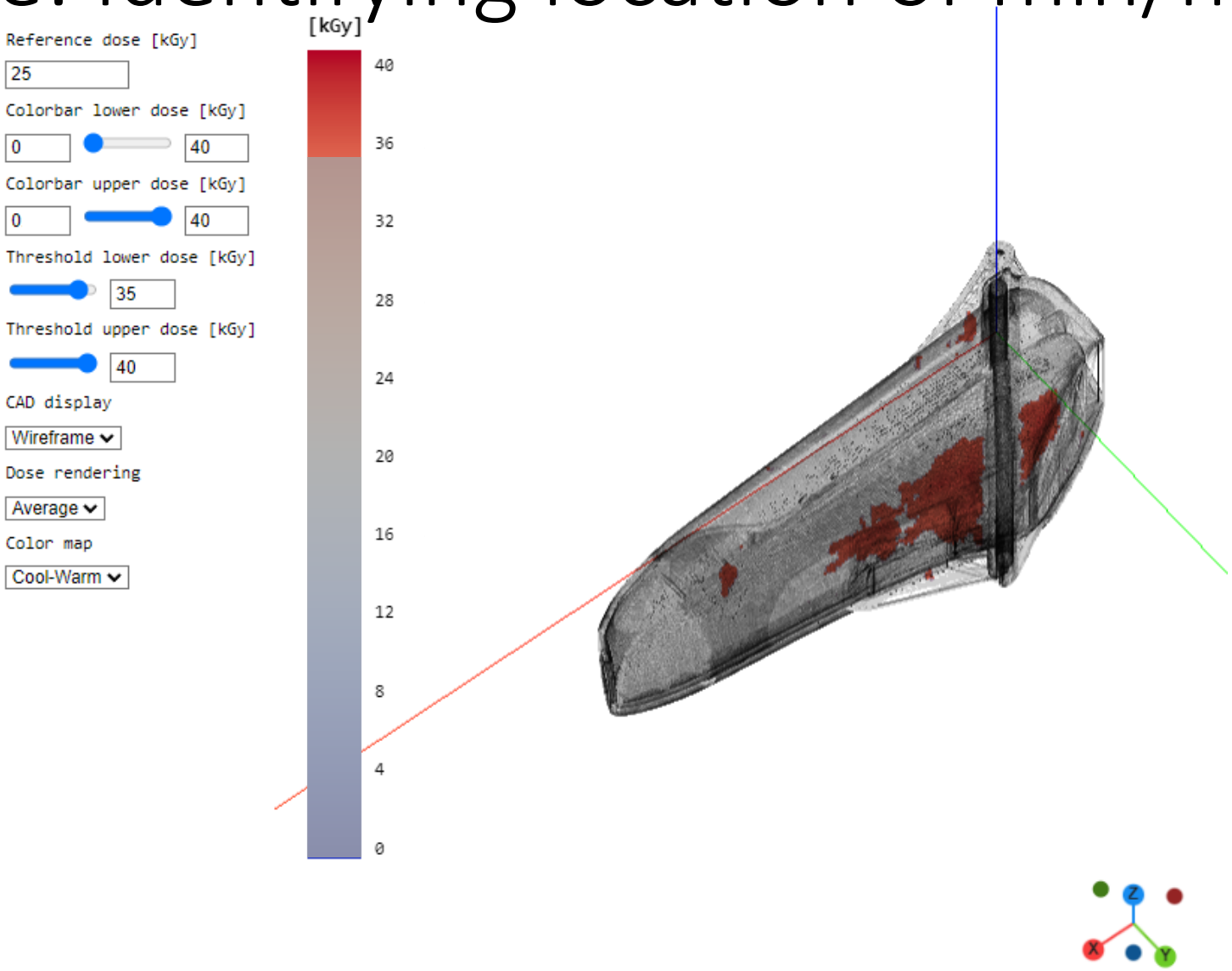


Ingredients of a DFS radiation modeling tool

Accurate

- Validated with measurements
- Report statistical uncertainty

Fast

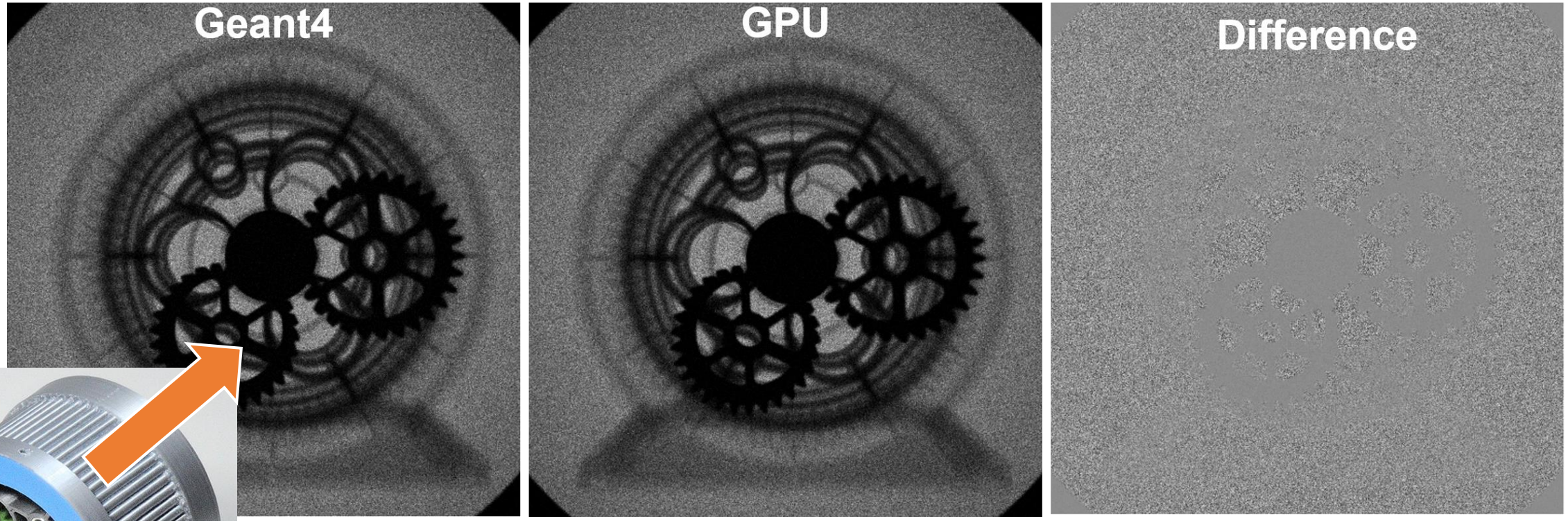
- Enable iterations on design and configurations

User friendly

- Support for CAD models
- Easily configurable

GPU-acceleration can speed up Monte Carlo

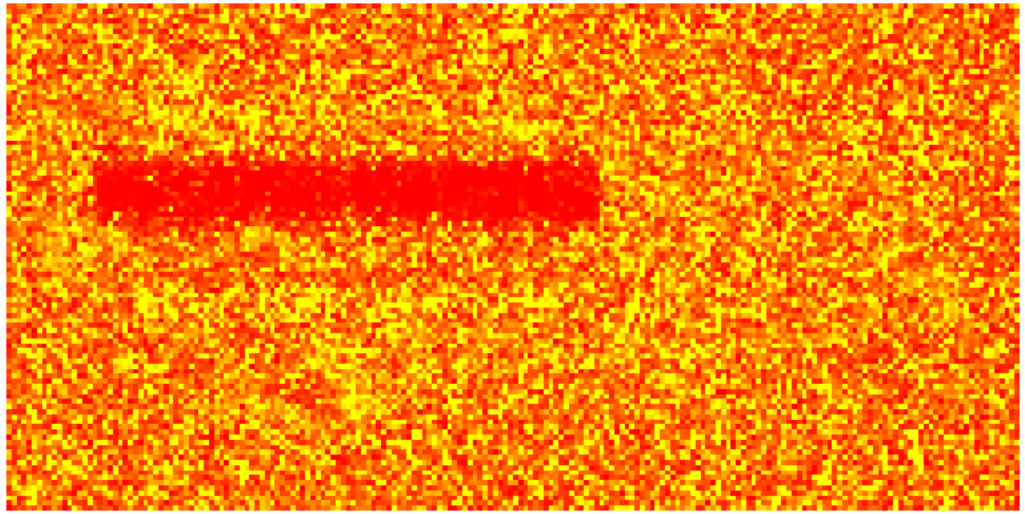
A recent FDA grant enables us to harness this power for virtual dose mapping



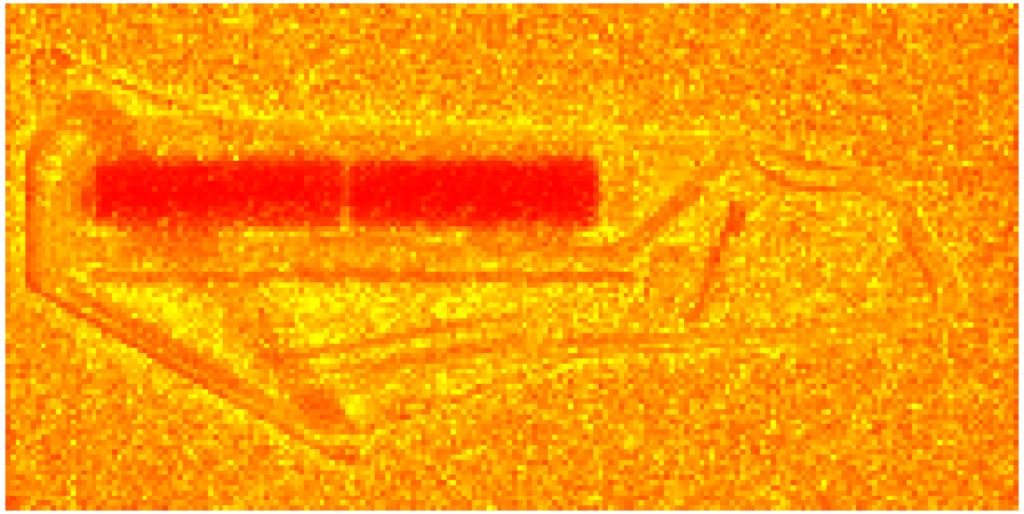
900x speedup over Geant4

Speedup of modeling with cloud computing

Multiple nodes in the cloud can get better statistics for the same turnaround time



1 node (local computer)



30 nodes in parallel in the cloud

User friendly workflow

DOSE INSIGHT

Export file with mesh and material info

SOLIDWORKS
SIEMENS NX
creo
AUTODESK FUSION 360
onshape
AUTOCAD

Select sterilization vendor from list of validated source models

Upload to web app

Validated Monte Carlo simulations in the cloud

Location of min/max dose

$\mathrm{DUR} = 1.5$ Dose Uniformity Ratio

Dose histogram

Dose Insight’s approach

- We are developing a software tool for modelling virtual dose maps
- We aim at seamless integration with modern CAD tools
- We envision that a medical device engineer can use the tool without specialized physics training
- We are looking for collaborators who will help us to achieve these goals
- Visit us at https://doseinsight.com or contact info@doseinsight.com