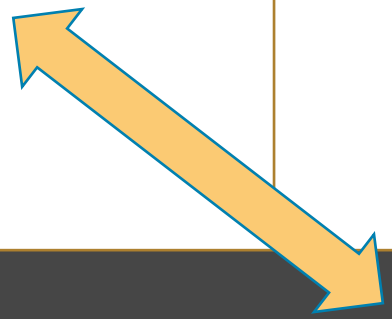
Dose Insight

Design for Sterilization –
Harnessing the power of a virtual dose mapping tool

Tobias Funk, PhD

TRIPLE RING technologies

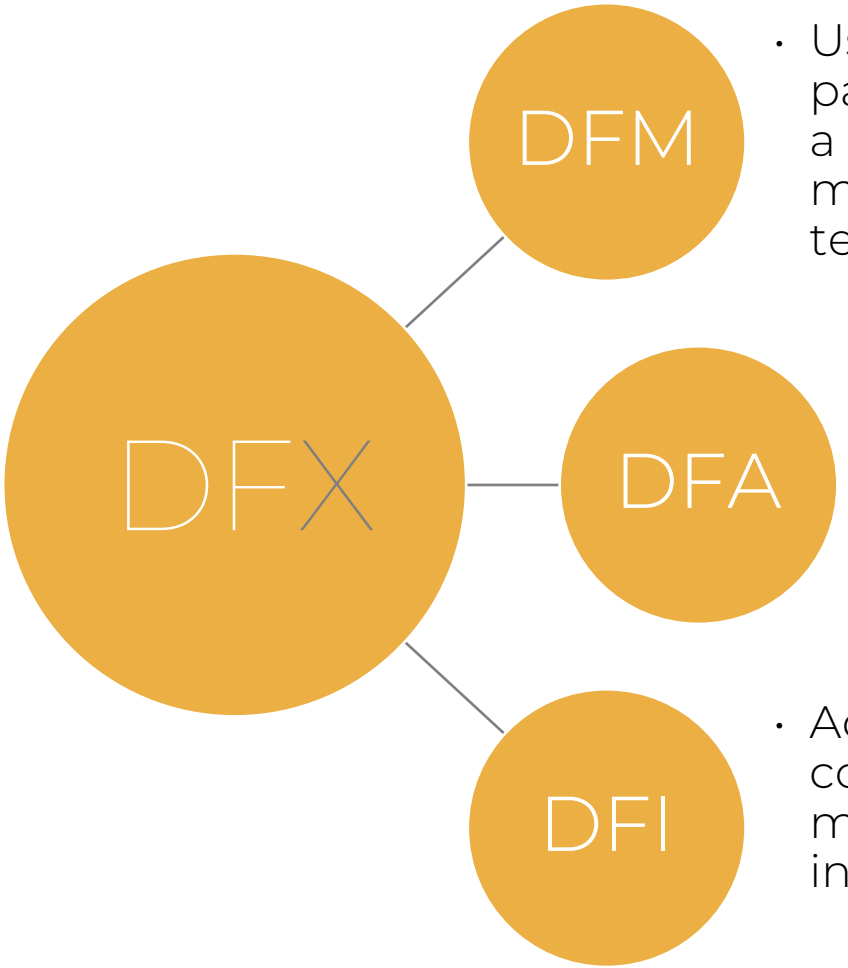
- Co-development company
- 100+ employees in Newark, CA and Boston
- Focus on life sciences and medical device development
- Internal R&D partially funded by government grants
- Spins out internal ideas as independent products



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)?



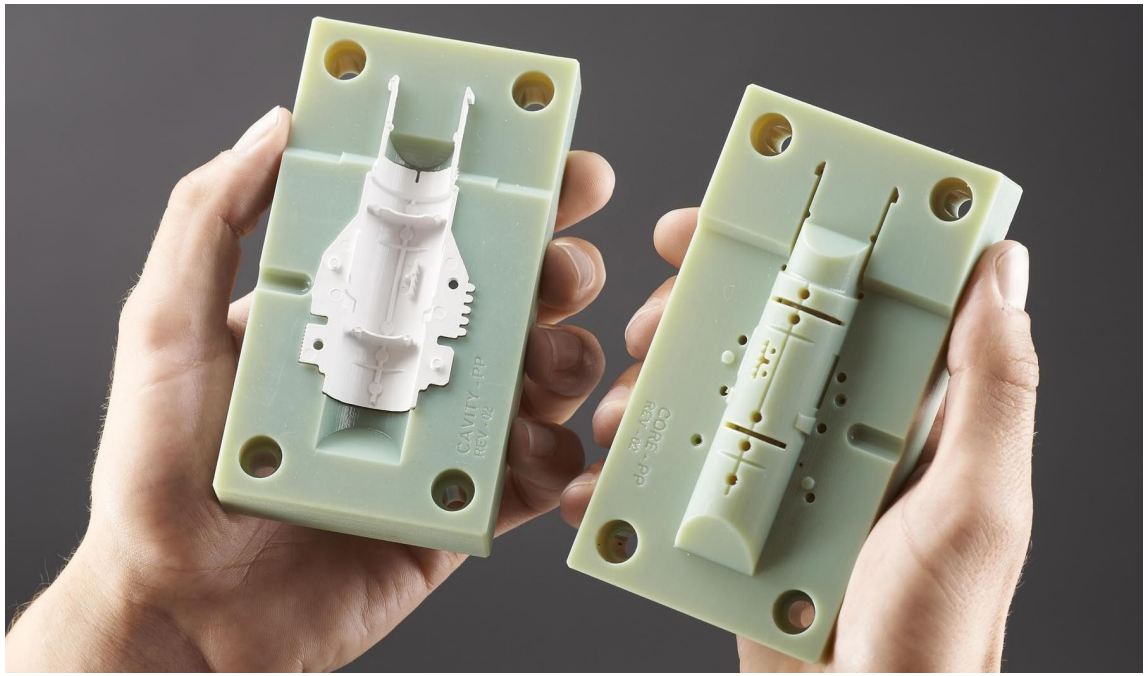
- Use off-the-shelf parts, design for a specific manufacturing technique, etc.
- Reduce number of parts and assembly steps
- Account for conventional measurement instruments

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

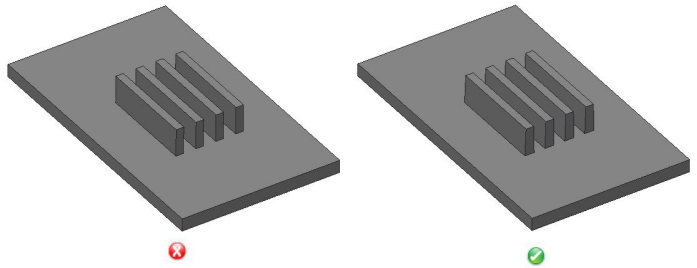


https://www.rapiddirect.com/blog/medical-injection-molding/

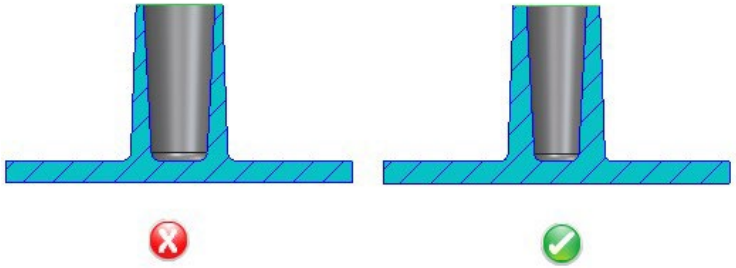
https://www.ennomotive.com/revolutionizing-injection-molding-process/

The evolution of DFM for injection molding

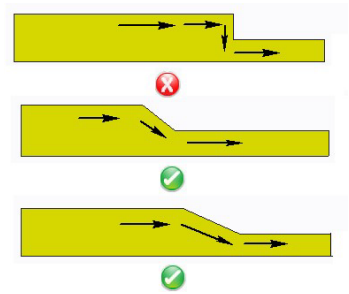
Conventional design guidelines reduce prototyping iterations



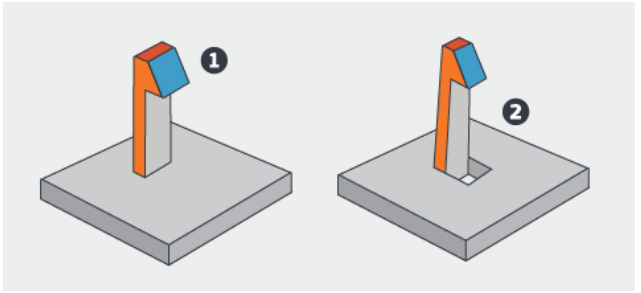
Ribs should have a ~1° draft angle to facilitate ejection, reduce contact pressure, and friction[1]



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



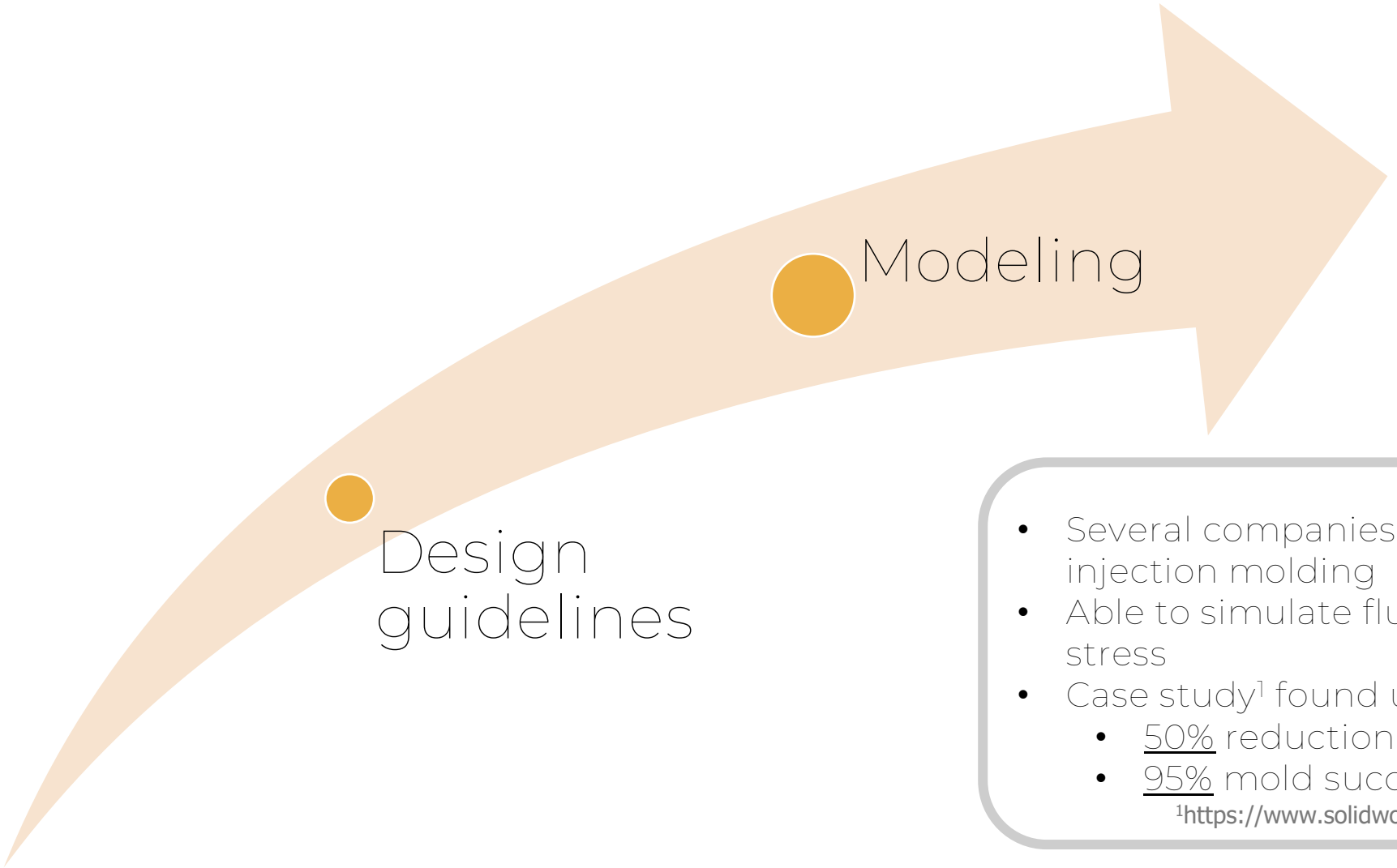
Reduce sharp transitions in wall thickness to allow for smooth filling of the mold[1]



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/

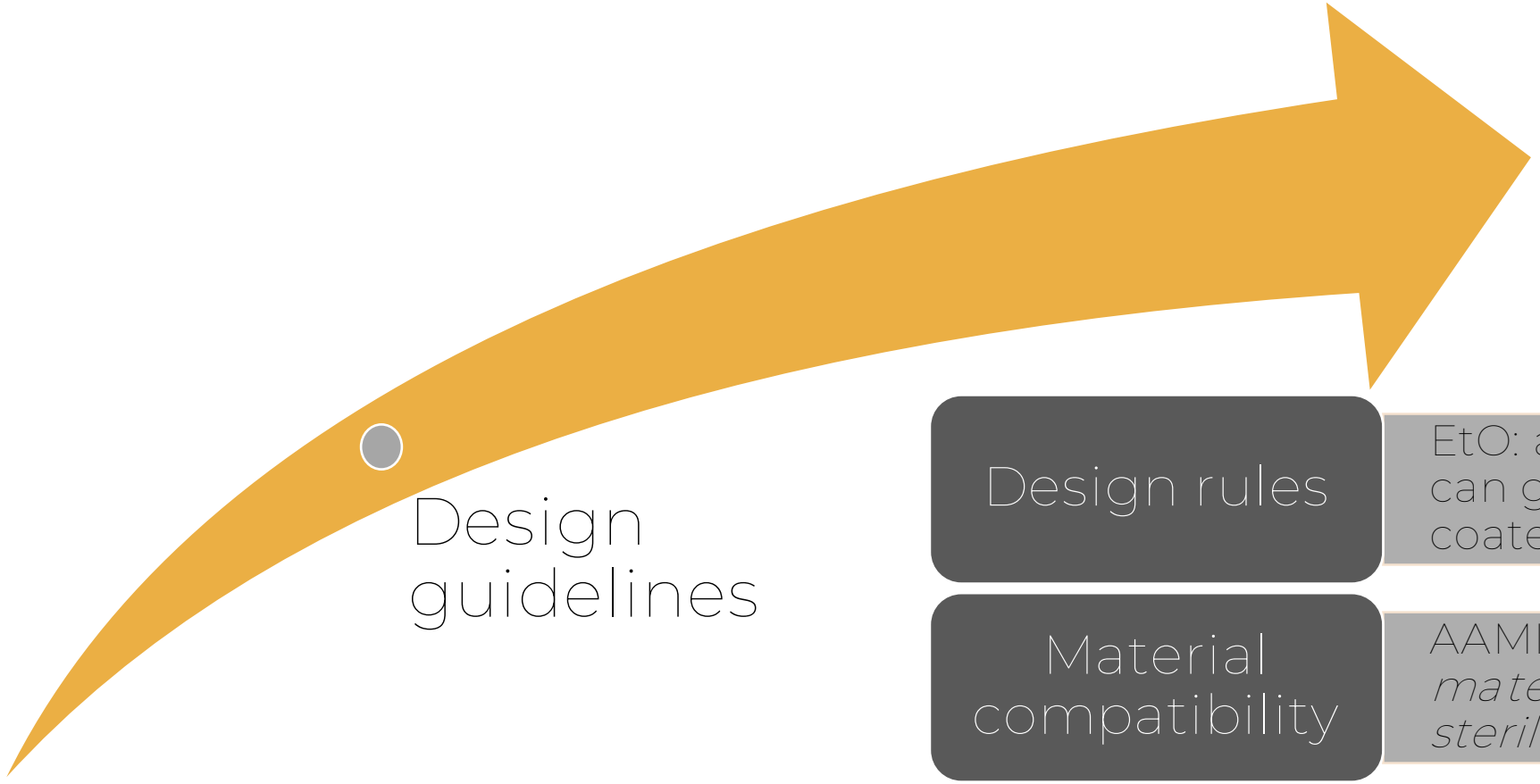
The evolution of DFM for injection molding



- 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

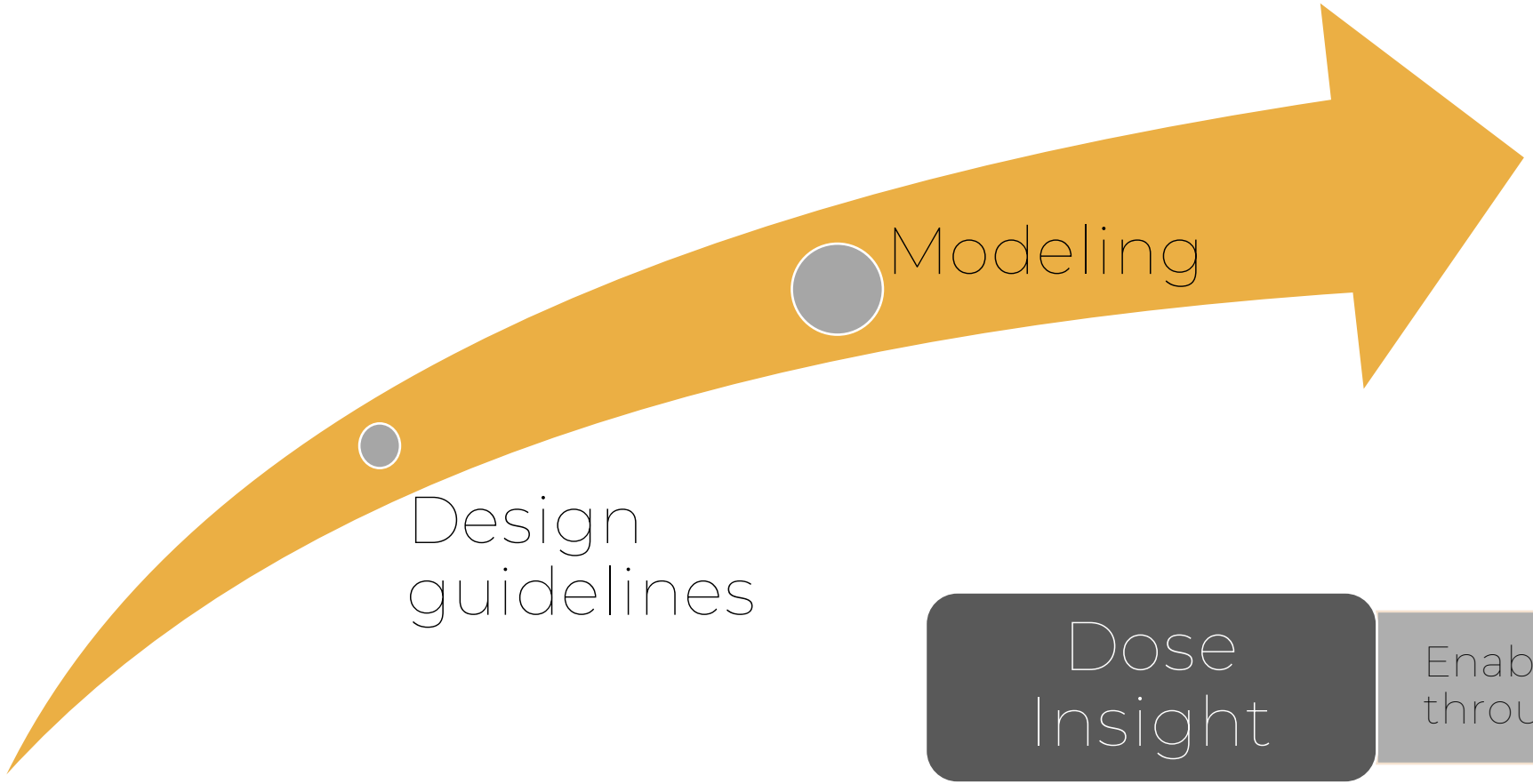
[1]https://www.solidworks.com/story/ambix-consulting-llc

From Design Guidelines to Design for Sterilization (DFS)



Design rules	EtO: 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

From Design Guidelines to Design for Sterilization (DFS)

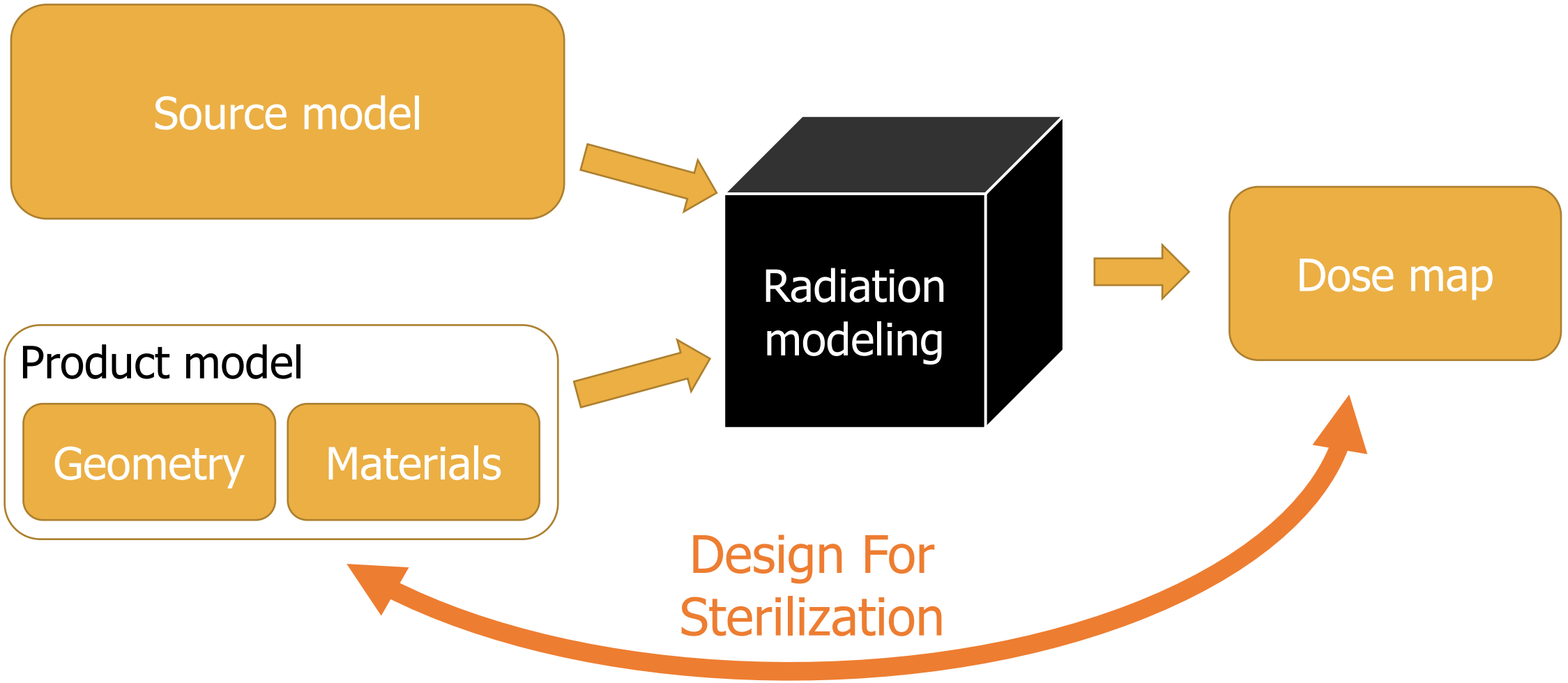


Dose Insight

Enables Design for Sterilization through modeling

Many industries went from design guidelines to modeling.
Examples: flow simulations for injection molding, data center design.

Predicting the dose map using modeling

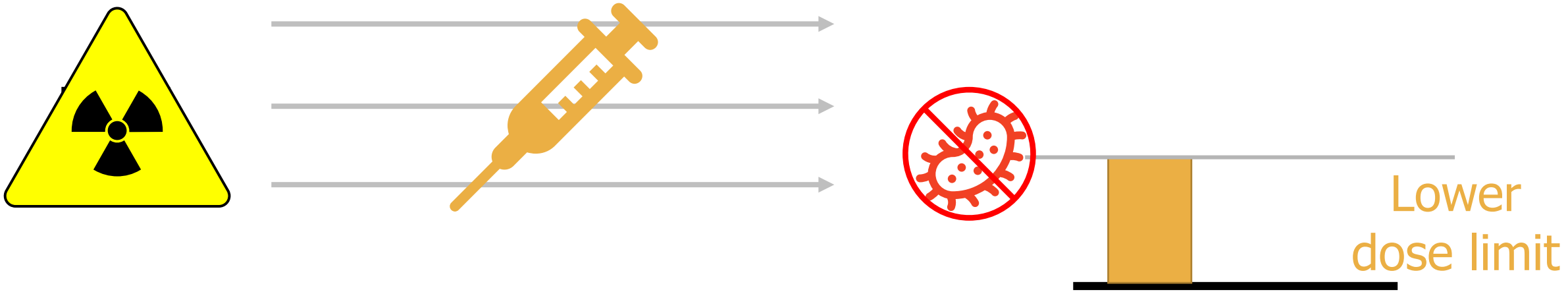


DFS for radiation sterilization

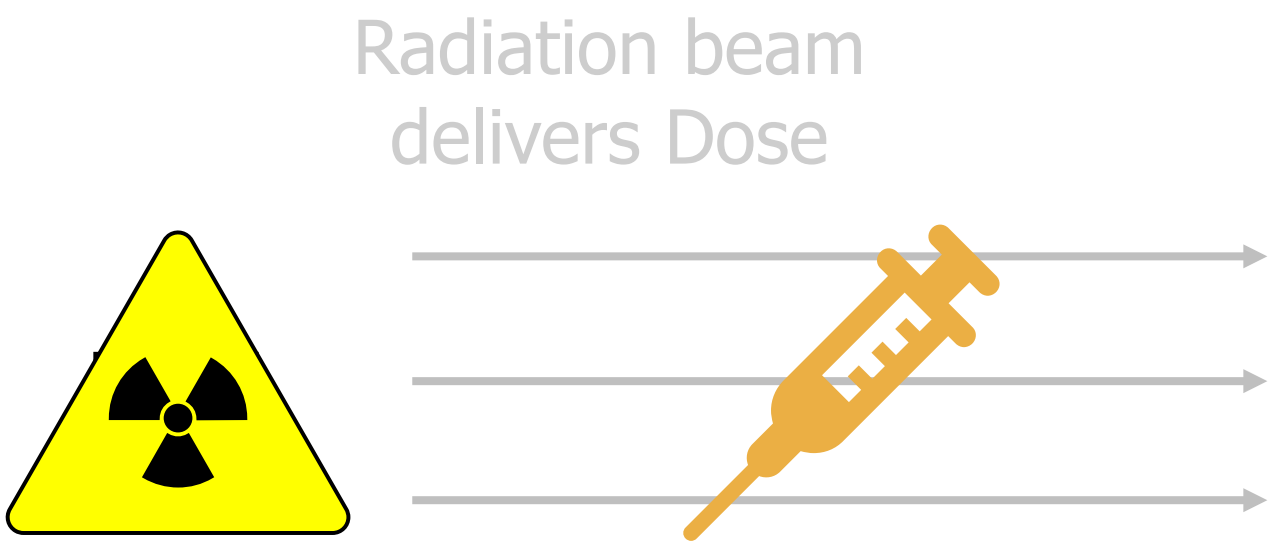
Radiation beam delivers Dose

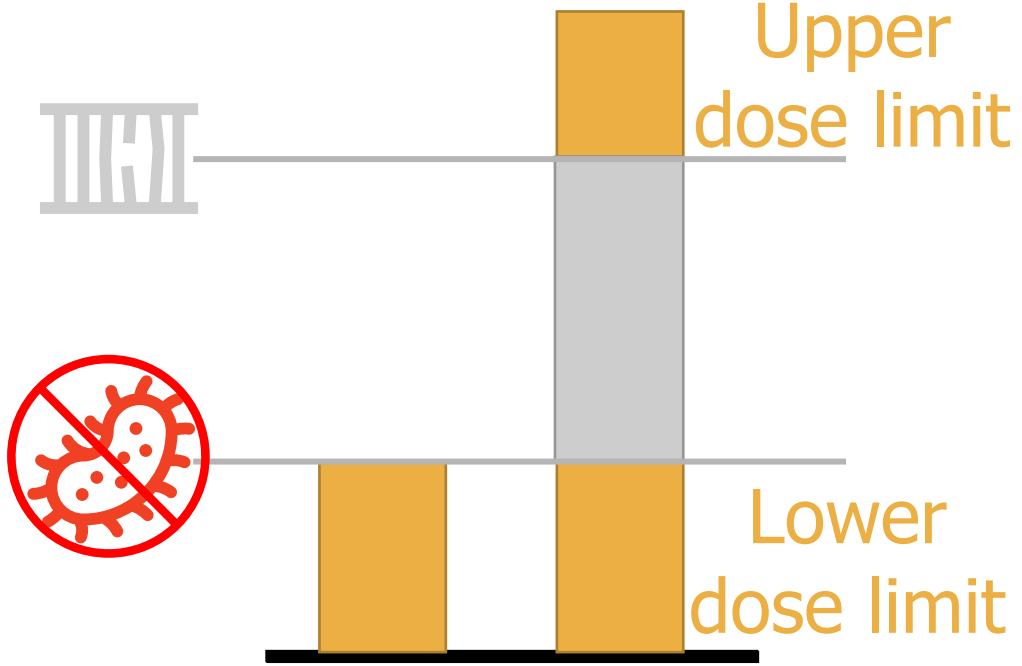
DFS for radiation sterilization

Radiation beam delivers Dose

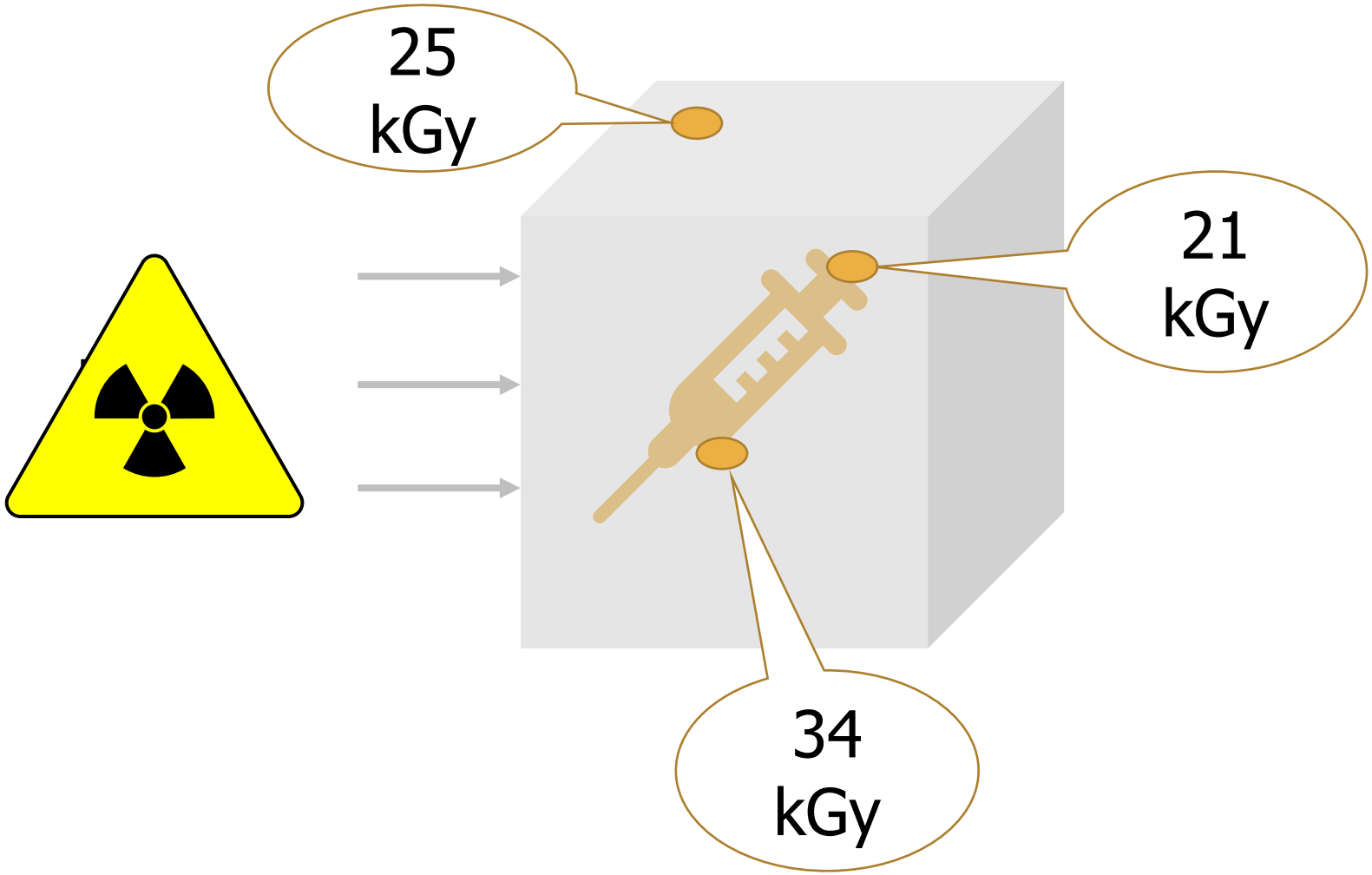


DFS for radiation sterilization





DFS for radiation sterilization



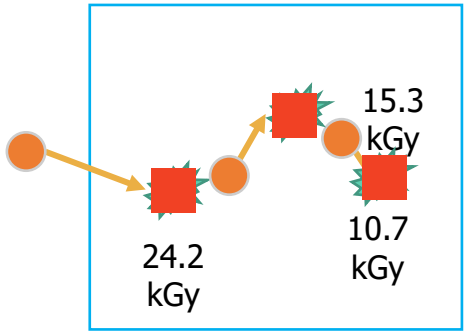
Predicting the full 3D dose map would enable DFS

What is dose?

Dose is the energy of electrons or photons absorbed in the medical device

Particles interact with matter

- Get absorbed
- Change direction
- Change energy
- Generate new particles



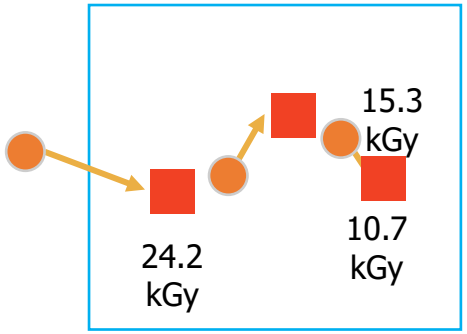
How do we model dose deposited in the device?

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

Source produces particles with random direction and energy

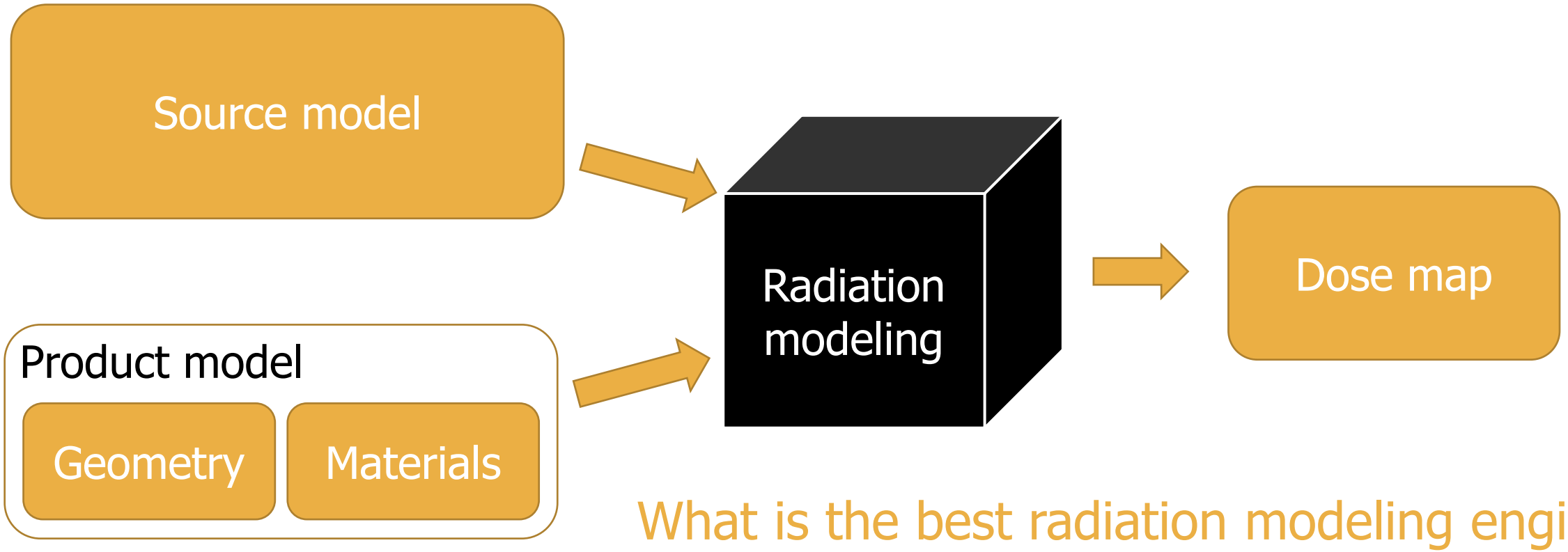
We model the particle interactions

Each particle's history is tracked
- Where did it get absorbed?
- How much energy did it deposit?



Monte Carlo simulations

Predicting the dose map using modeling

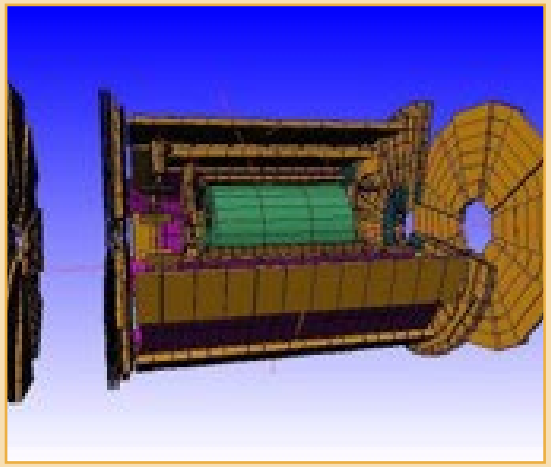


What is the best radiation modeling engine?

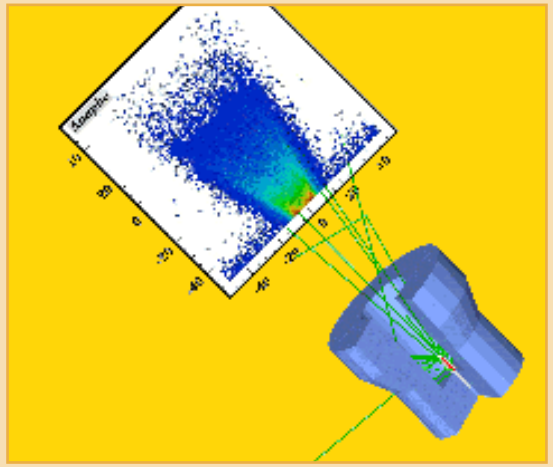
- Accuracy
- Speed

Geant4
A Monte Carlo toolkit for passage of particles through matter

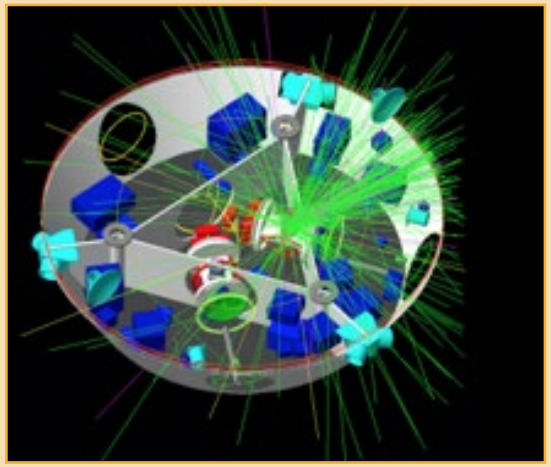
https://geant4.web.cern.ch/



High energy physics



Medical



Aerospace

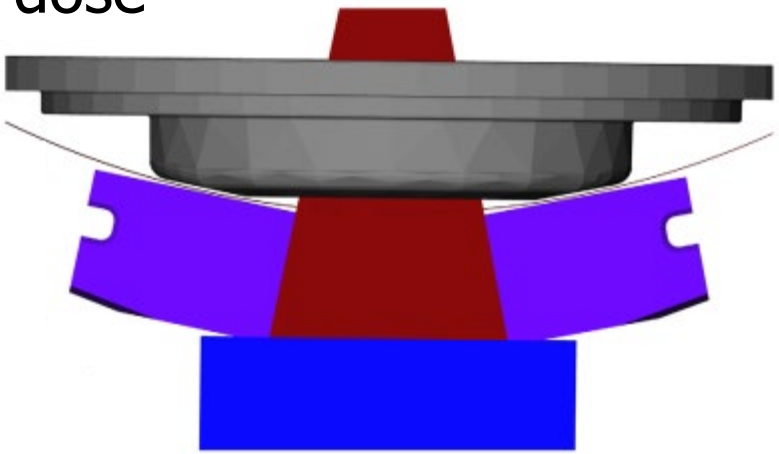
Strong institutional support

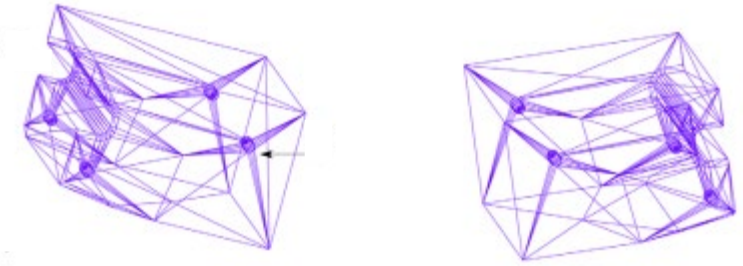
CERN SLAC NATIONAL ACCELERATOR LABORATORY TRIUMF Northeastern UNIVERSITY College of Computer Science CENBG Fermilab

Validation of Geant4 with a 6 MeV X-ray beam

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

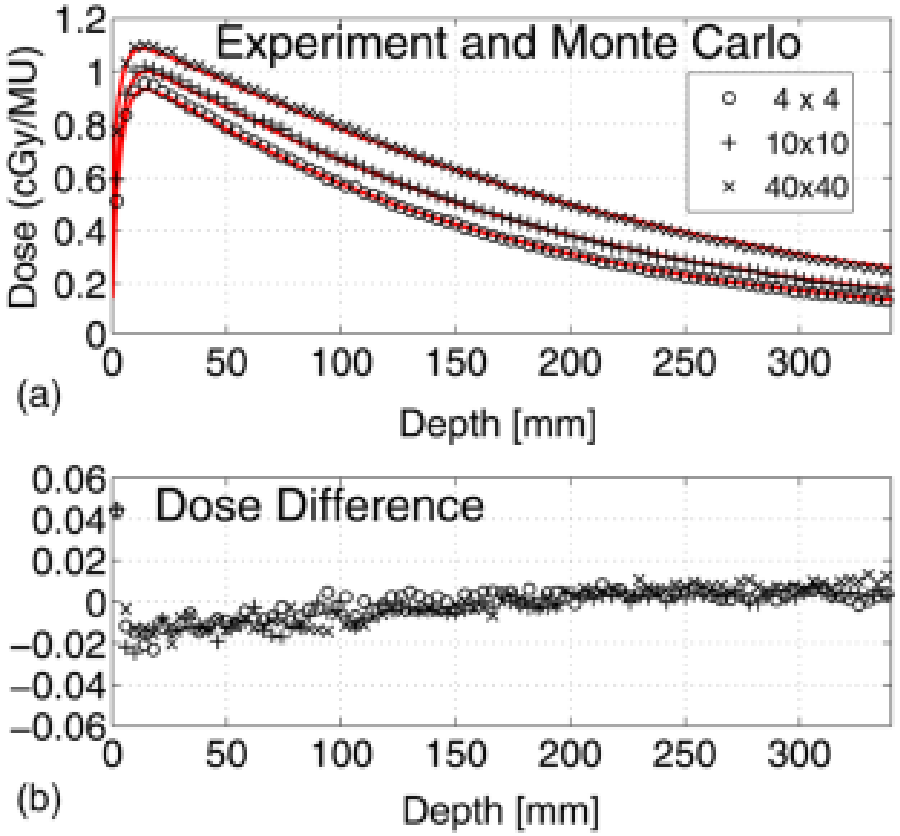
CAD model of treatment head





Collimator jaws

Measured (black) vs. simulated (red) dose



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

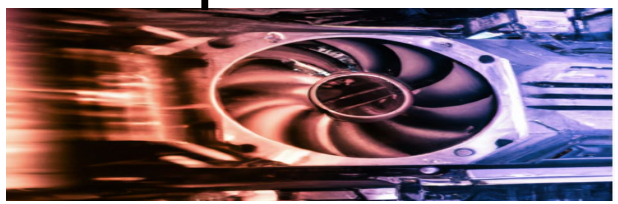
Radiation Modeling

fast and accurate

CPU

- Geant4
  - Open source software
  - Full physics model
  - Peer reviewed validation

Graphics Card



- Custom Monte Carlo
  - Implemented for photons
    - Currently no electron physics
  - Validation against Geant4

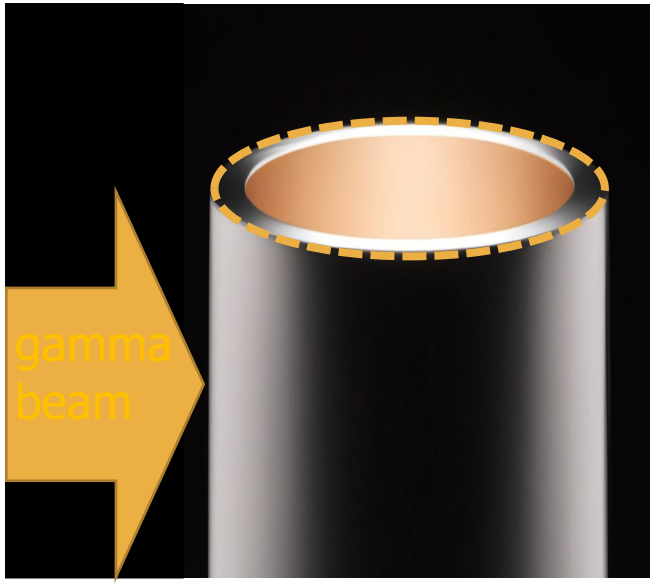
Cloud

- Cloud based Geant4
  - Speedup scales with number of nodes
    - E.g. 100 nodes deliver results 100x faster than 1 node

This work was partially funded by US FDA grants (1 R43FD007313-01, 1 R43FD007584-01). The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.

GPU-acceleration can speed up Monte Carlo

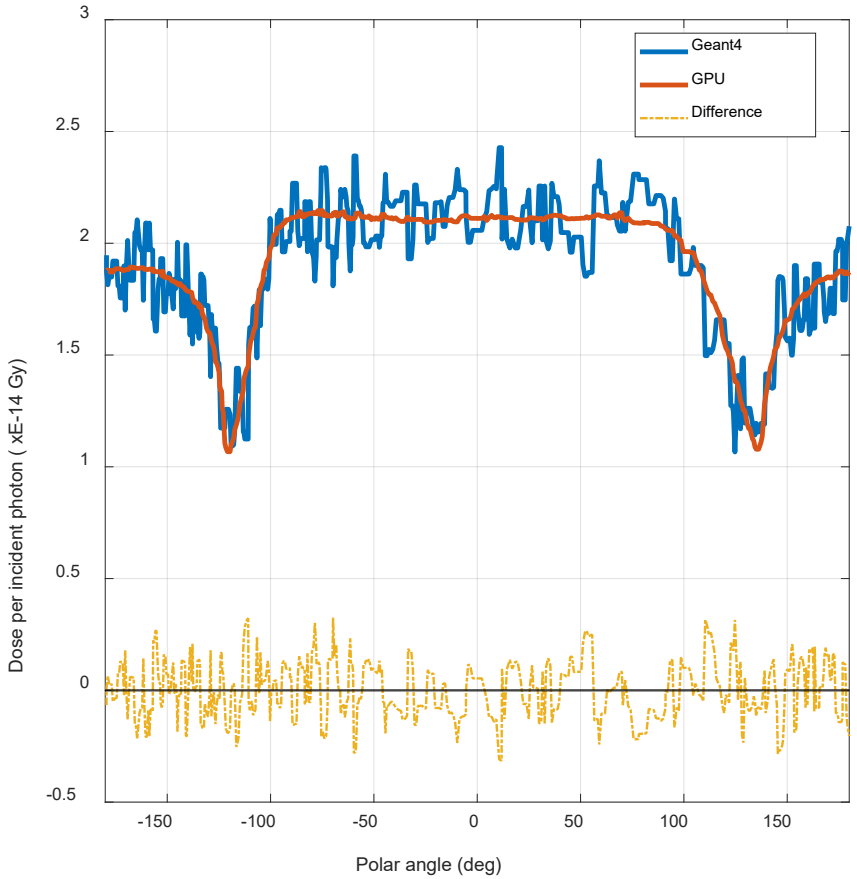
Set up: A hollow Aluminum cylinder is placed in a simplified gamma set up



Significant speedup over Geant4

- This example 900x
- More simple geometries up to 2500x
- Speedup depends on CAD model complexity

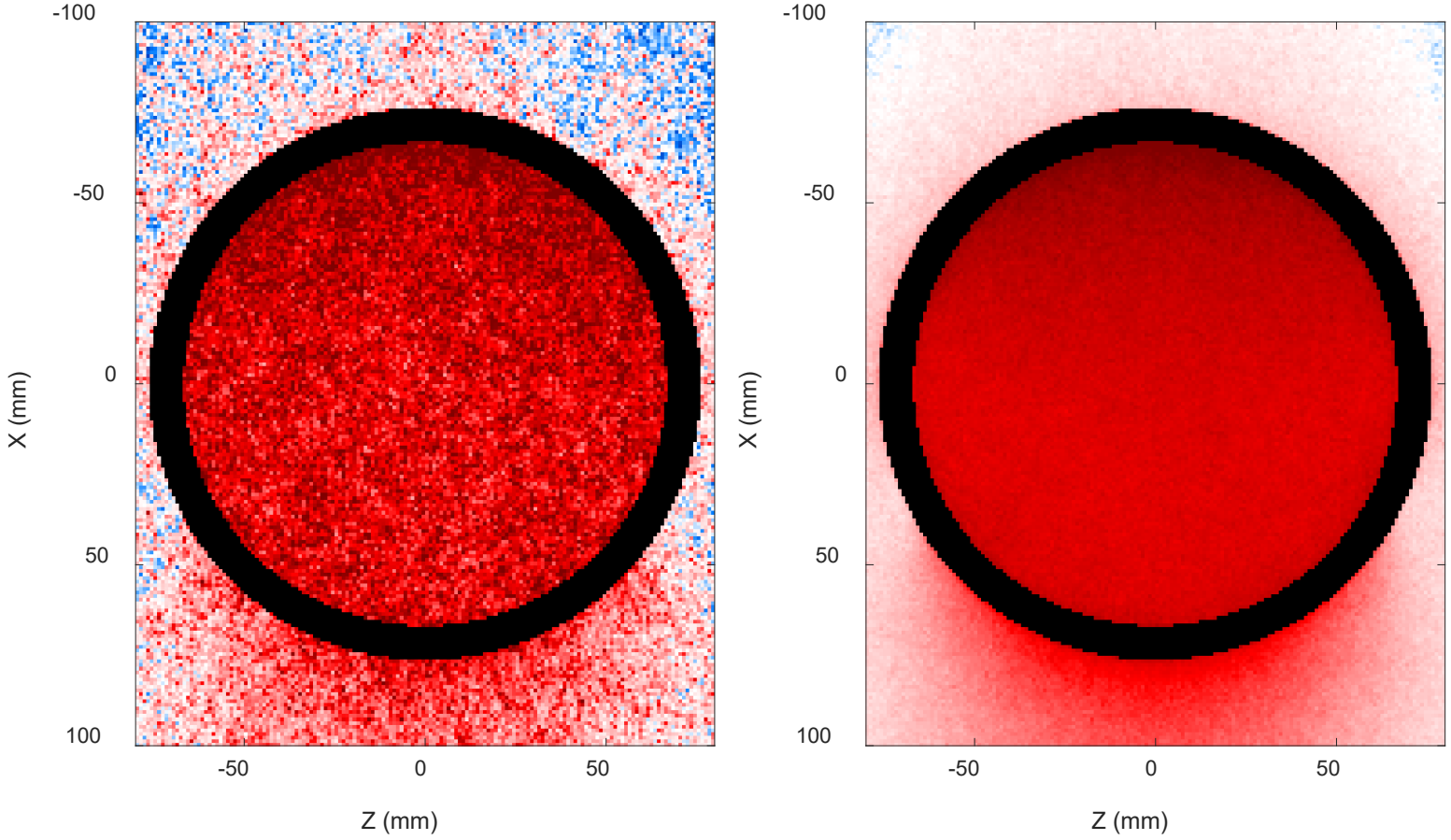
Dose along the outer circumference



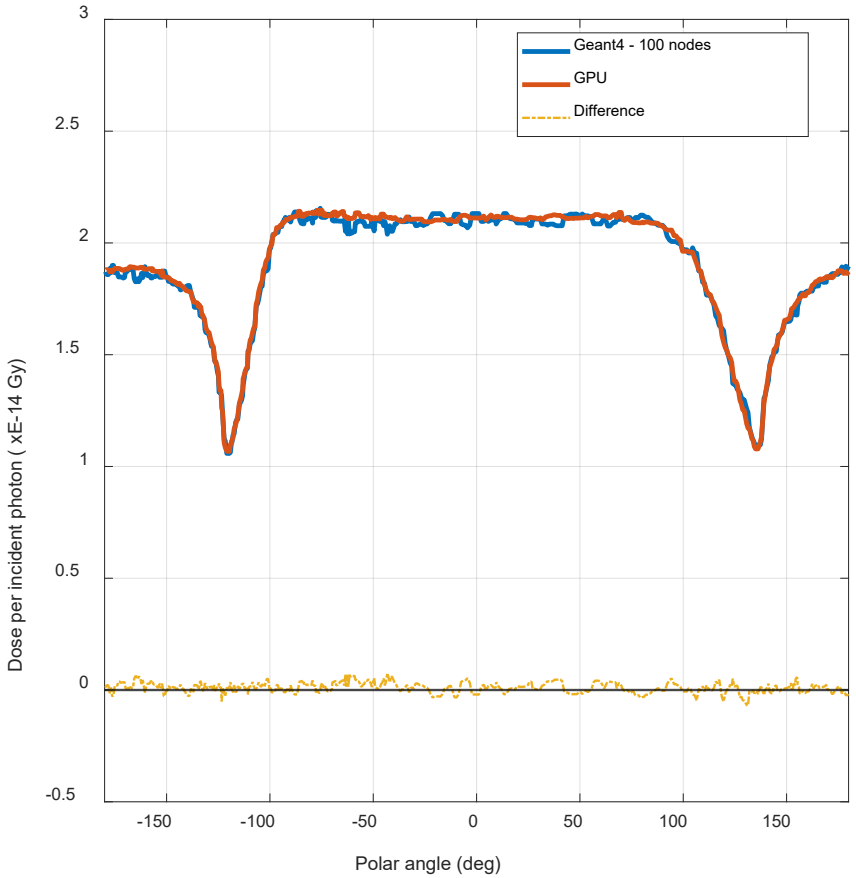
Cloud implementation can speed up Monte Carlo

Slice through the modeled 3d dose map

1 node vs. 100 nodes

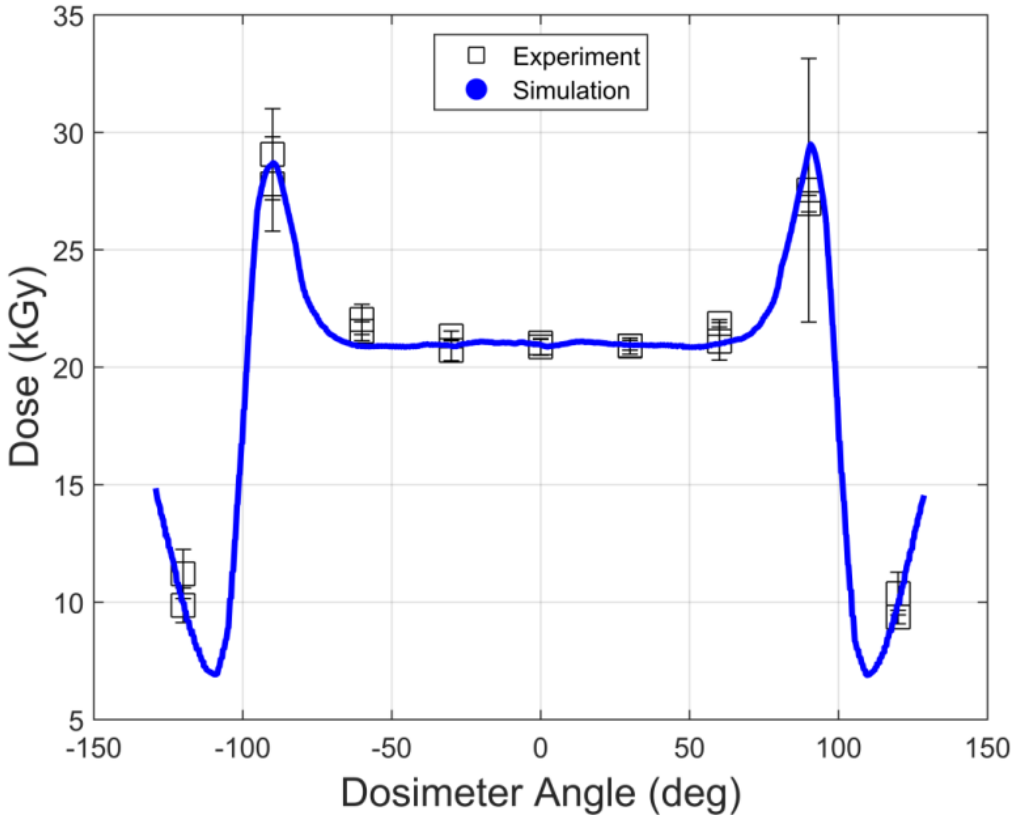


Dose along the outer circumference using Geant4 on 100 nodes in the cloud



Multi-node Geant4 has full physics model

Comparison: simulations vs. measurements at a 10MeV e-beam sterilization facility



Dose Insight

Dose Insight Web Interface

Select sterilization modality

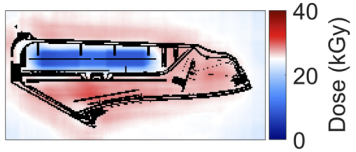
SOLIDWORKS · SIEMENS NX · creo · AUTODESK FUSION 360 · onshape · AUTOCAD

Upload CAD model

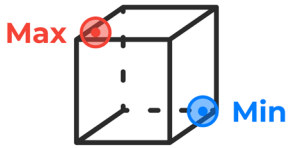
Position, orient & pattern the device in beam

Validated Monte Carlo simulations in the cloud

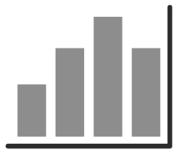
Dose Report



Dose map



Max / min dose location

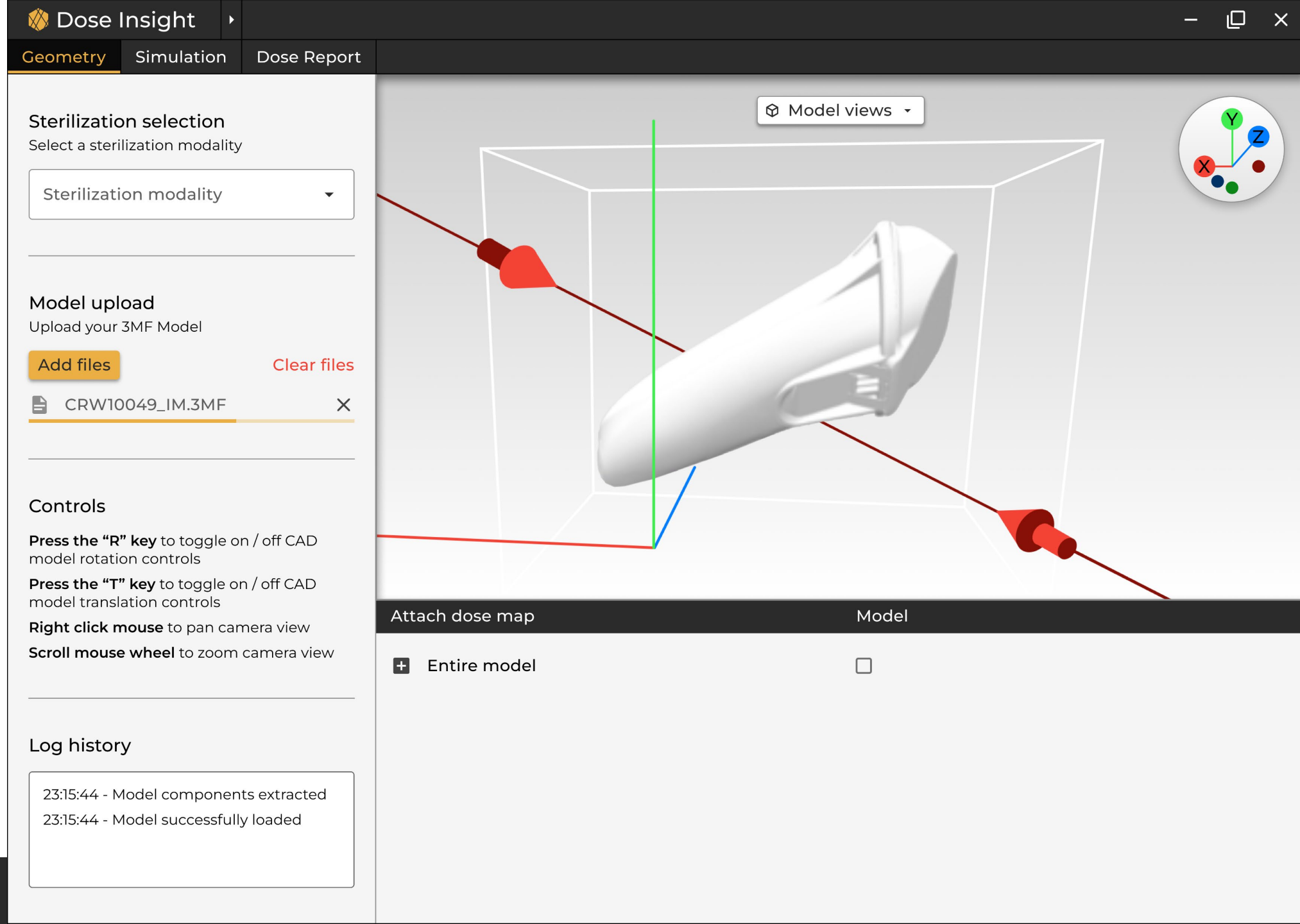


DUR = 1.5

Dose histogram

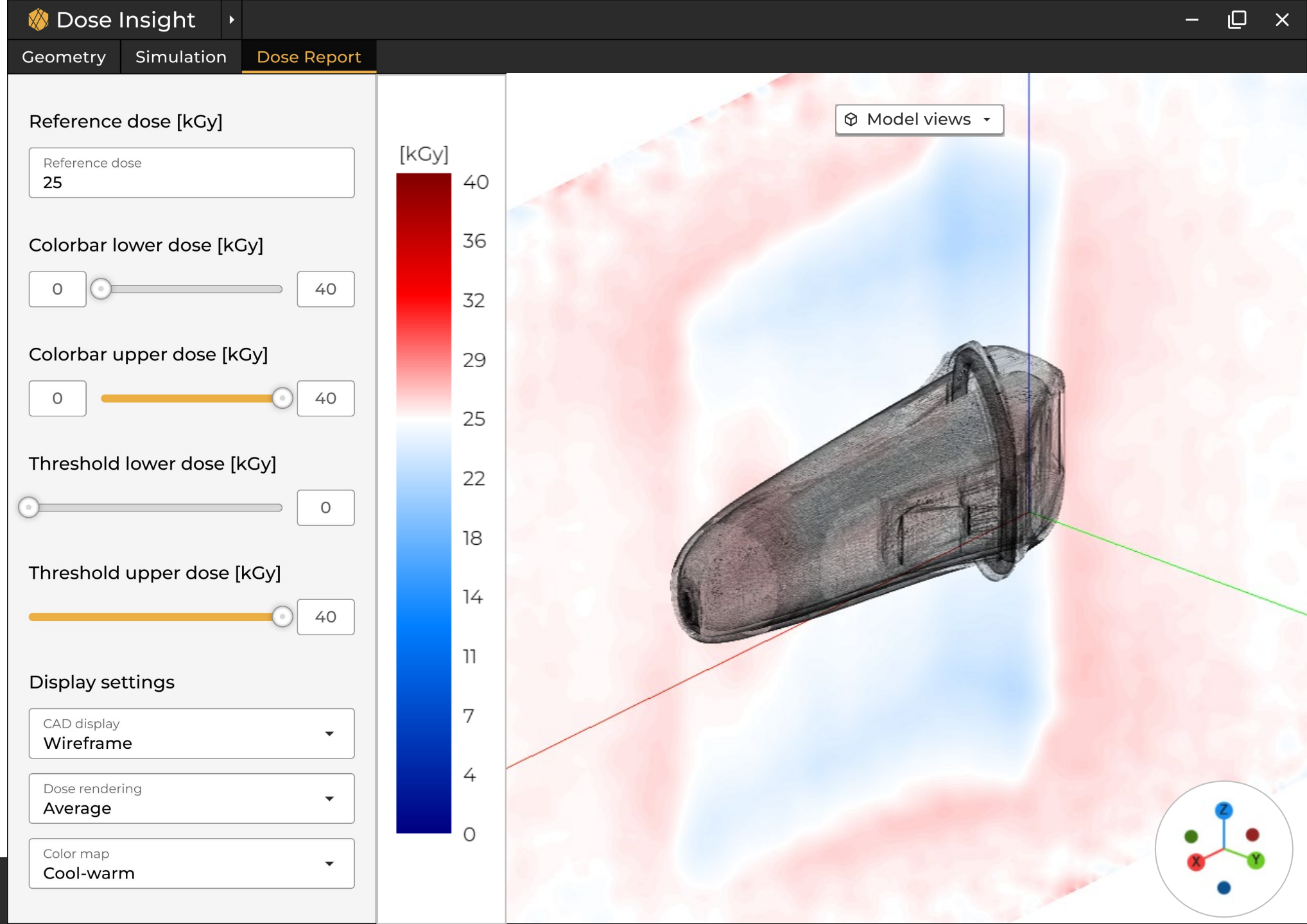
User friendly GUI:

- Choose sterilizer beamline
- Choose and upload CAD model
- Orient device in respect to beam
- Choose parts to be included in the dose map
- Submit simulation job

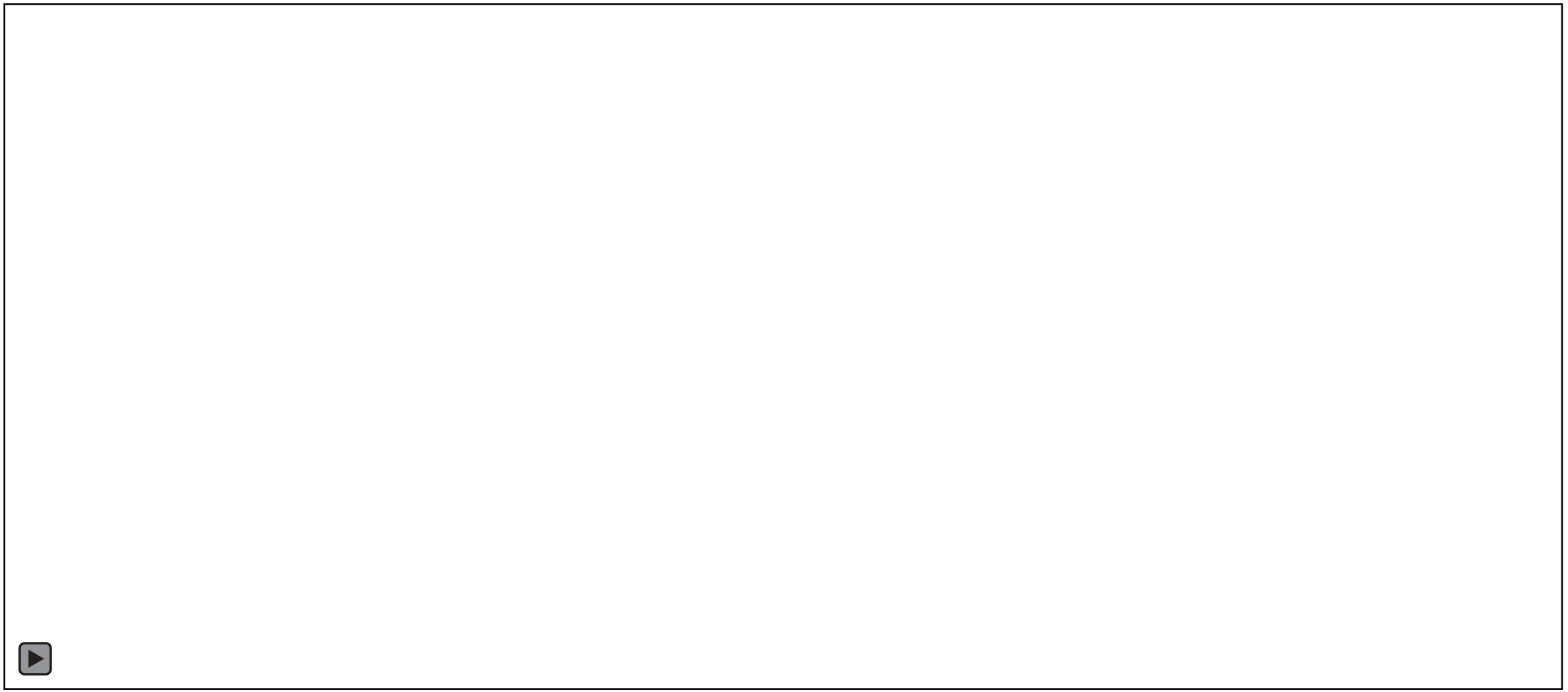


Visualization tool:

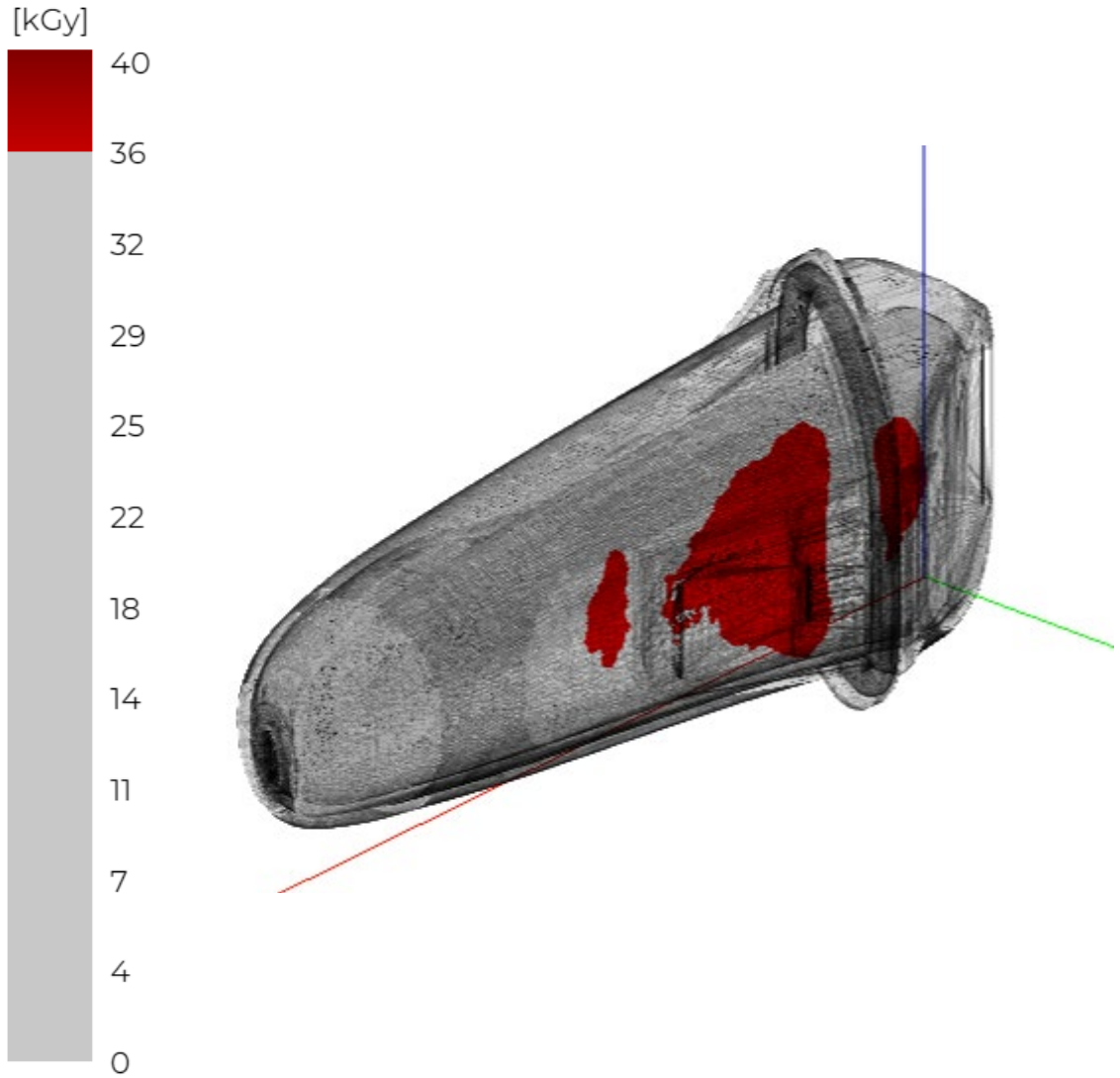
- Set reference dose
- Choose lower and upper dose in colorbar
- Choose display settings

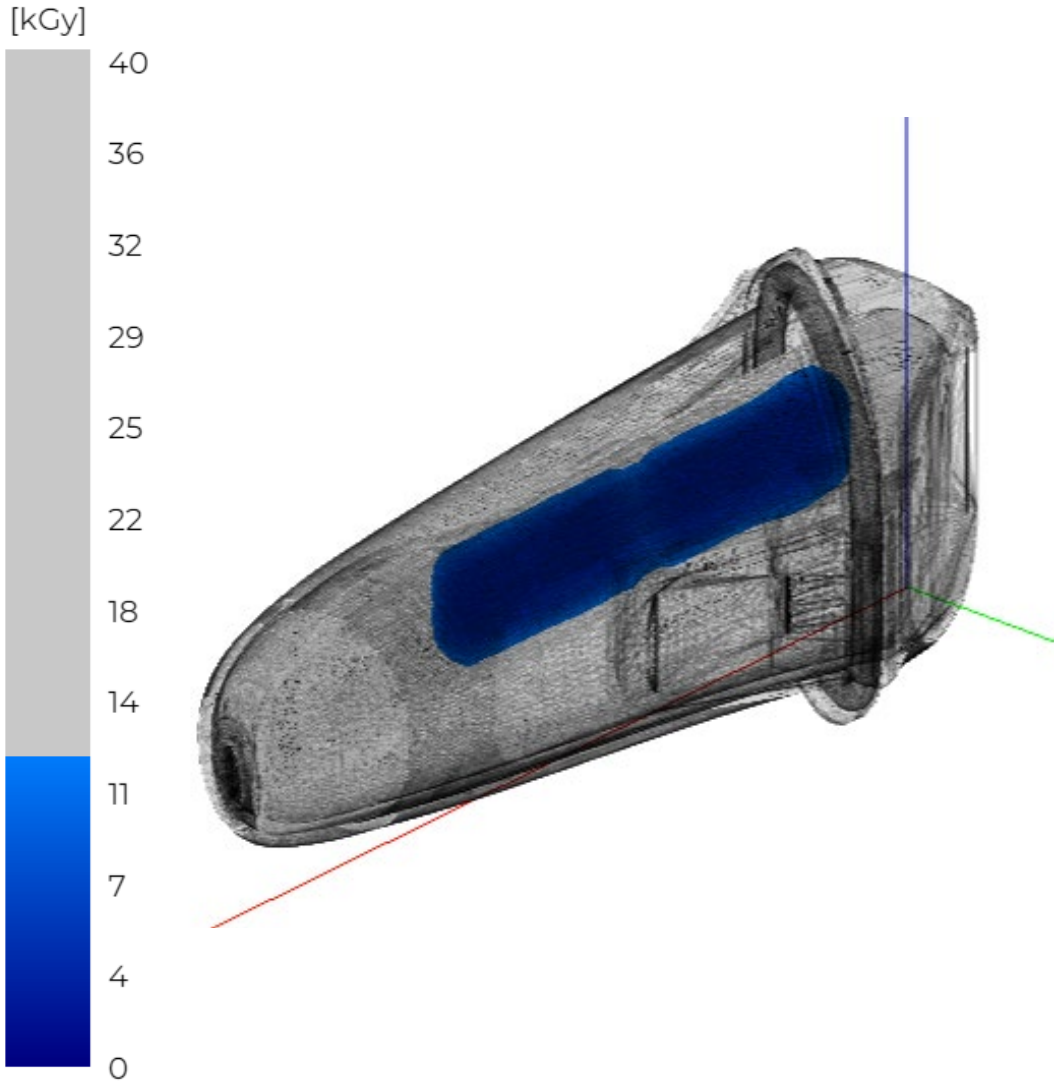


Dose Insight's dose visualization tool

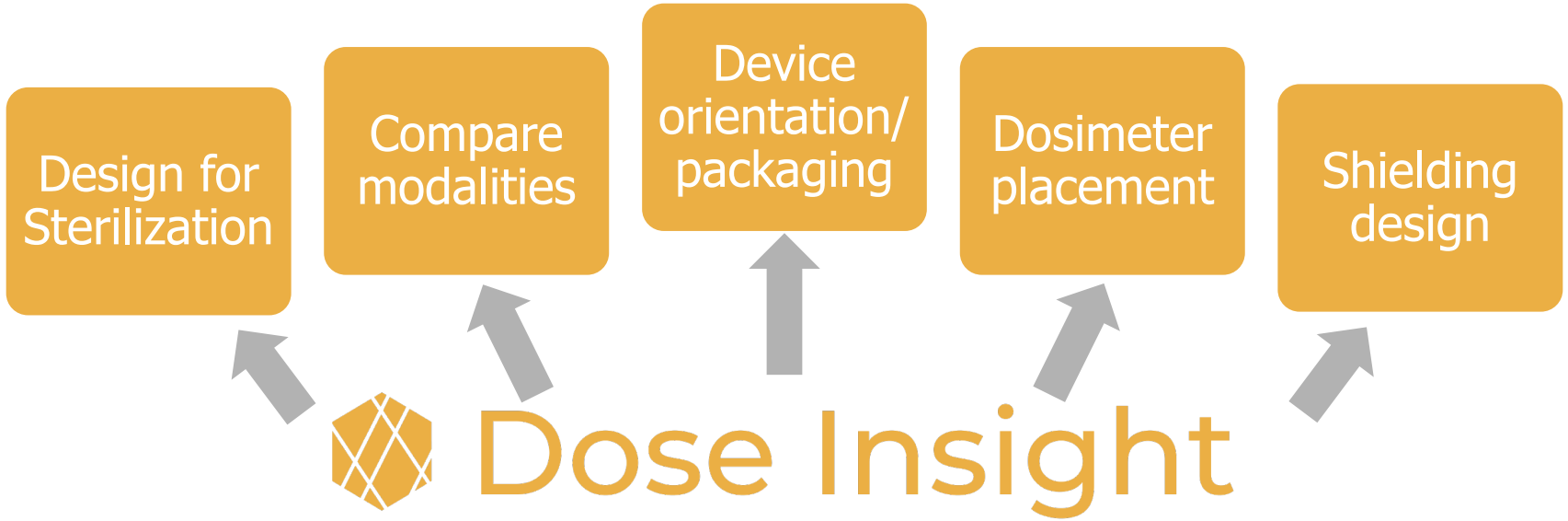


Maximum and Minimum Dose





Dose Insight's approach



- Dose Insight enables any engineer to produce virtual dose maps
- Collaborate with us to use modeling in your development process
- Get in touch today! https://doseinsight.com or info@doseinsight.com