INTERNATIONAL IRRADIATION ASSOCIATION

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IMRP2016 | VANCOUVER BC, CANADA

CAPA using Monte Carlo

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V2.2

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CAPA using Monte Carlo

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CAPA using Monte Carlo

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Corrective Action / Preventive Action:

- Organizational process improvement, based on the systematic investigation of root causes of identified problems to attempt to prevent their reoccurrence (corrective action) or prevent occurrence (preventive action)

Monte Carlo Modeling

- using randomness to solve problems that might be deterministic in principle
- Large number of events, CPU time
- Geometry modeling and beam source modeling used to be user-time intensive

Why Modelling?

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Packaging Planning

- Minor differences and movement inside the packaging
- Shadow effects by variations
- Packaging optimization
- Material change effects on dose

➔ Qualitative and Quantitative Analysis

➔ Reduce Risk

Medical Product Design

- Include sterilization early in the design
- Combination Products
- Electronic Components (10-500Gy)
- Complex Shadow effects

➔ Define energy range

➔ Design for radiation sensitive areas within the product

➔ Save development time

Why Modelling?

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CAPA

- Compare PQ data with Simulation
- Simulate many more dosimeters
  - Non-measurable locations
- Define & vary Critical Control Points

  Motion in packaging, materials, orientation, beam faults, MAD locations, min dose locations, product as dosimeter,…

➔ Really understand Complexity

➔ Reduce Risk & Time

➔ Predict & Prevent

Prototyping

- custom implants
- 3D-printed parts
- Create / avoid shadow regions
- Benchmark simulated product
- Use simulated dose map

➔ Sterilize Parts that exist only once

➔ Enable Conforming Process

Our Tool

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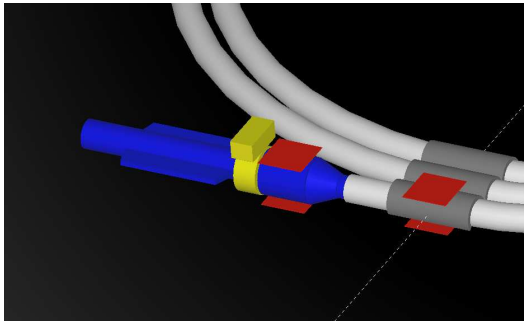
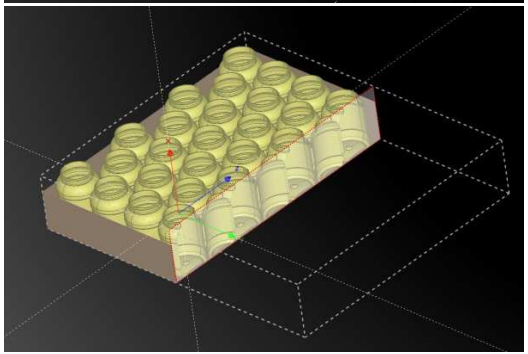
3D Geometry GUI

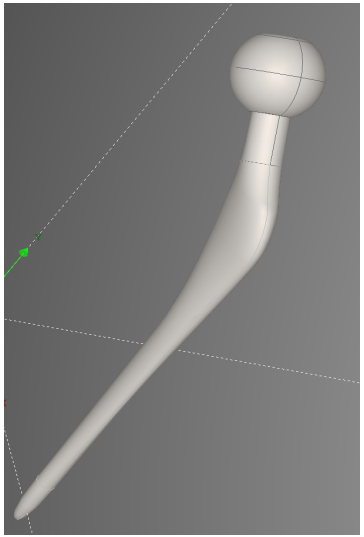
- Create geometry within tool – proprietary 3D CAD
- Import 3D files from other sources – and modify in GUI
- Simulate Dosimeters
  - Measurable locations (PQ)
  - Non-measurable locations
  - Parts of product as dosimeter

➔ Simplify Setup and Variations

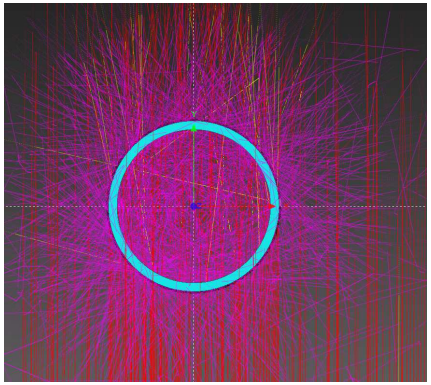
➔ Save User Time

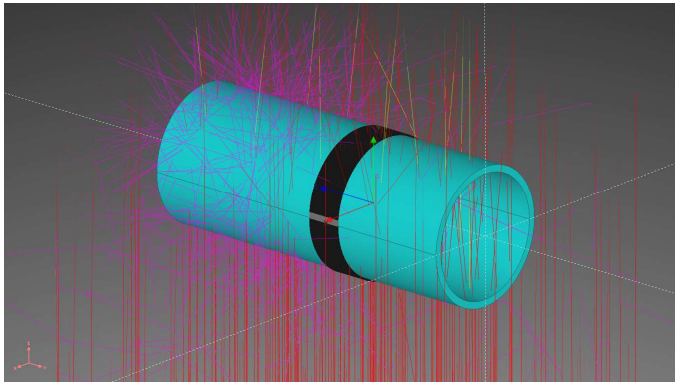


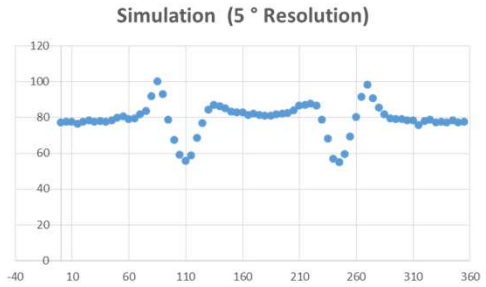


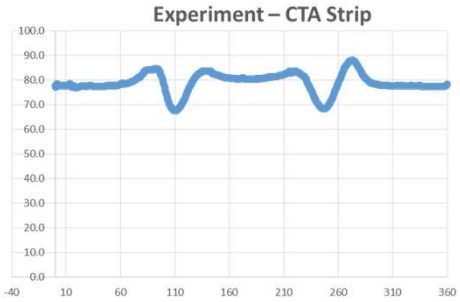


Project Specific Benchmarking Example









0° Direction

Tube: 2mm wall thickness, 4cm radius

Material: PC

Dosimeter: Water with 5° resolution

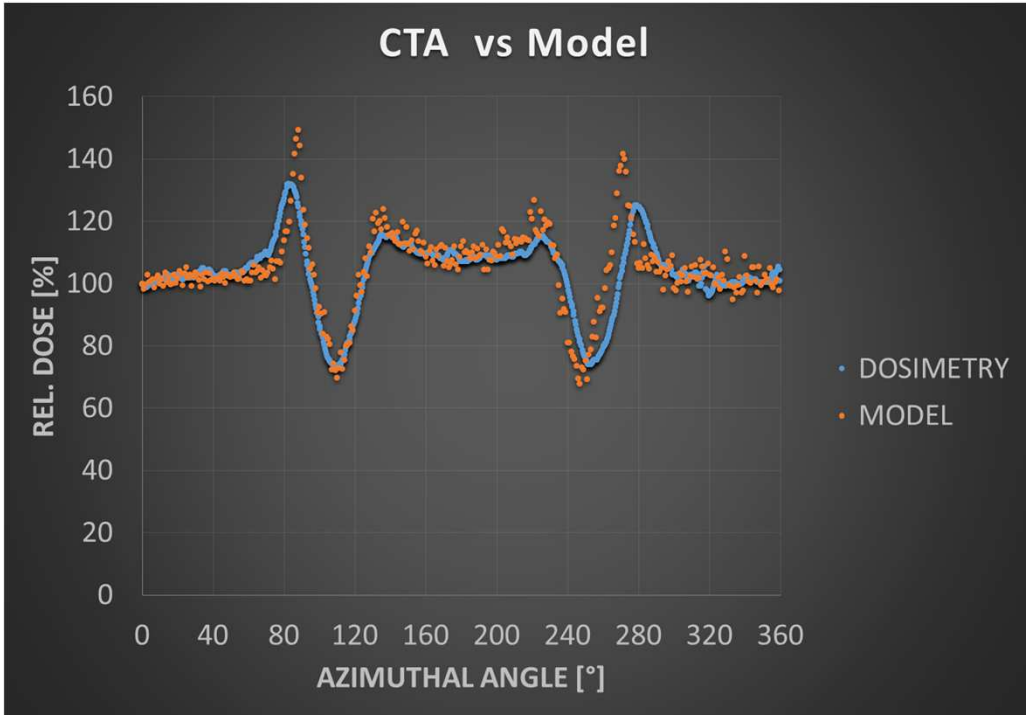
Single Sided Irradiation

Project Specific Benchmarking Example

PC Tube:
d=40mm d=2mm

Dosimeter:
CTA-Strip
d=125µm
1° Resolution

Work-In-Progress



Our Project

- Sterilization of Cardiovascular Stents
- Compliance Card must be inside the package
- Influence on Sterilization Dose Distribution
  - When parts (Compliance Card) inside the packaging move?
  - When the orientation of a stent package is different?

IQ and OQ setup - Benchmarking

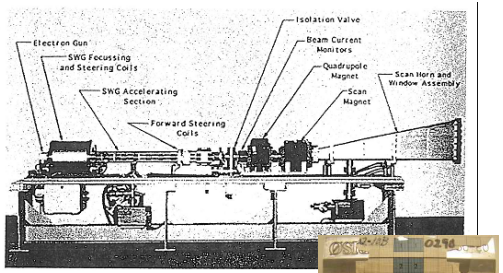
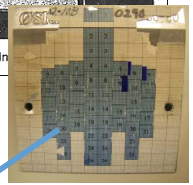
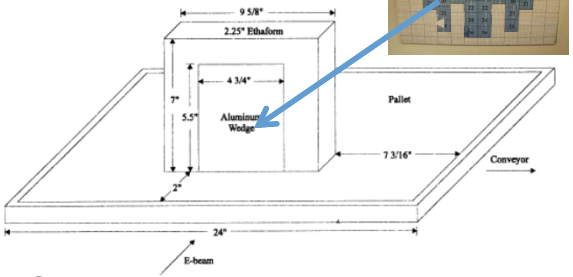
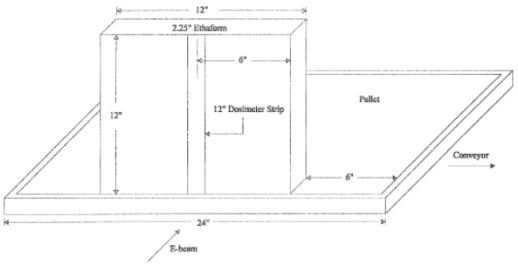
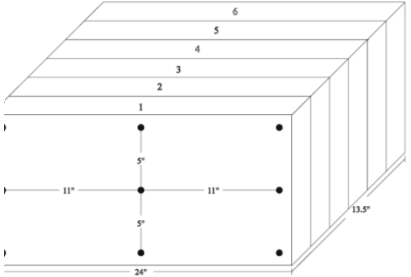


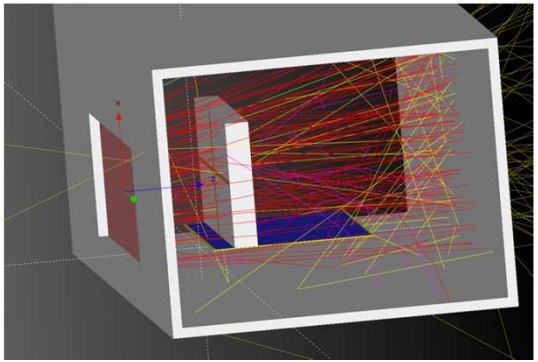
Figure G-1. TB-10/4 Beam Lin

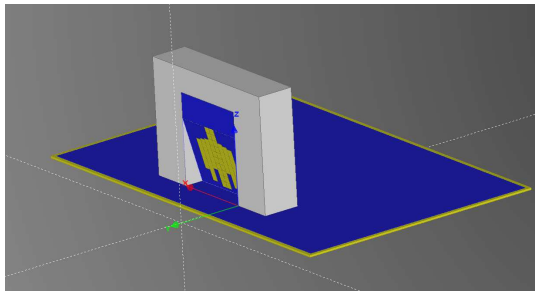










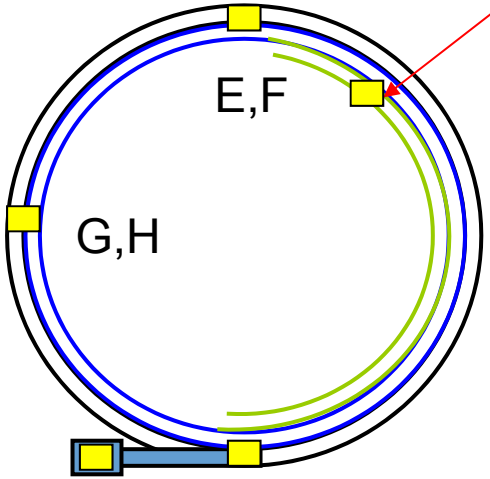


Courtesy: Abbott Vascular

Cardiovascular Stent Package

PQ setup

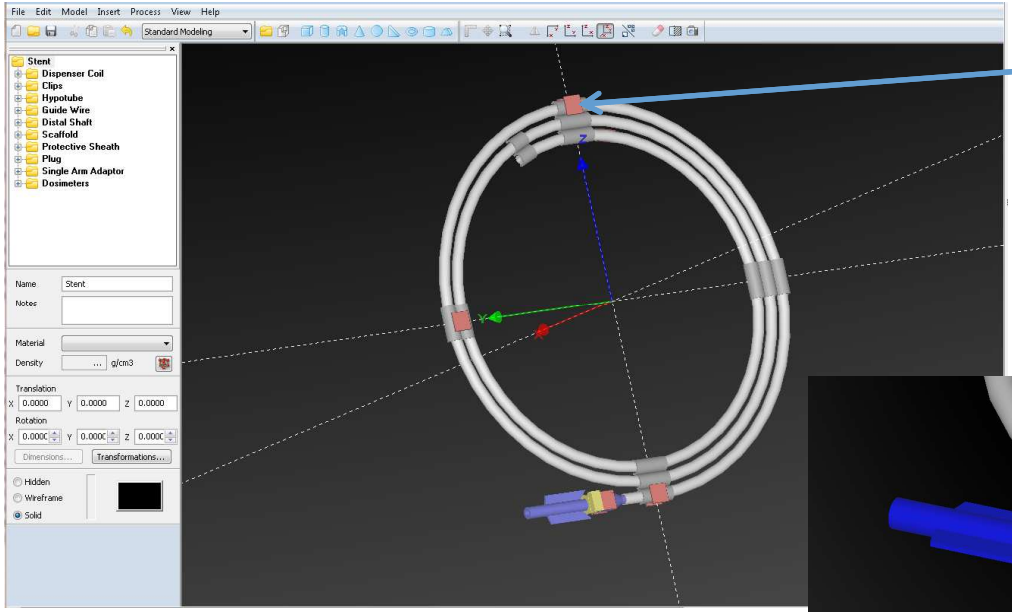
Courtesy: Abbott Vascular



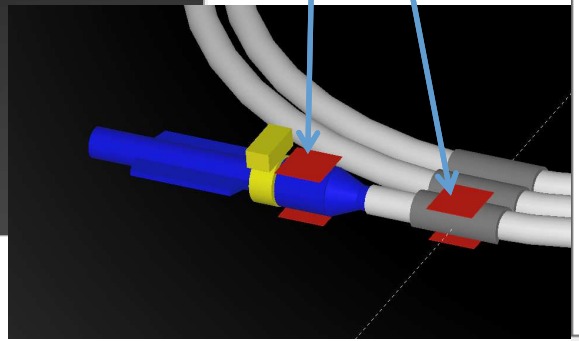
Stent Region

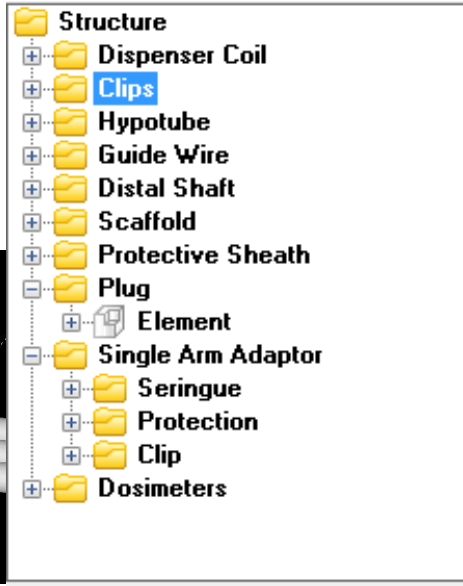
I wrapped around wire

Stent modeling in the GUI



Dosimeters, as in PQ





Compliance Card Moving

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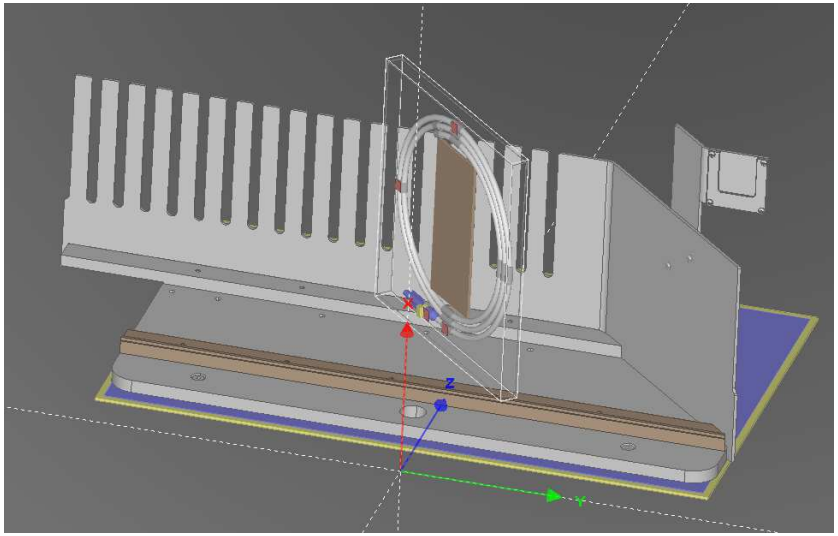
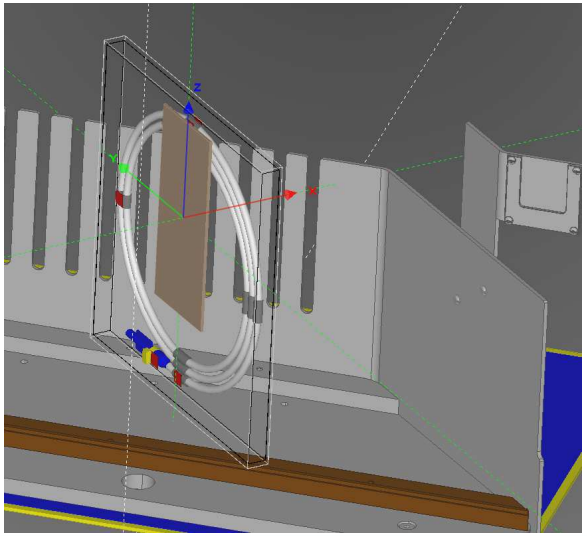
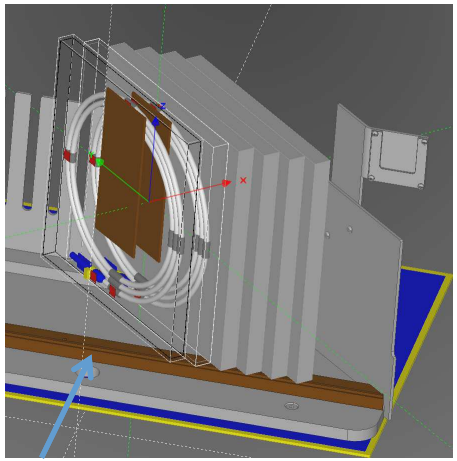
Compliance Card in Center

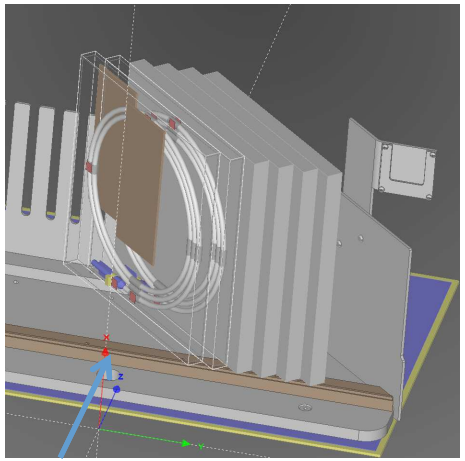


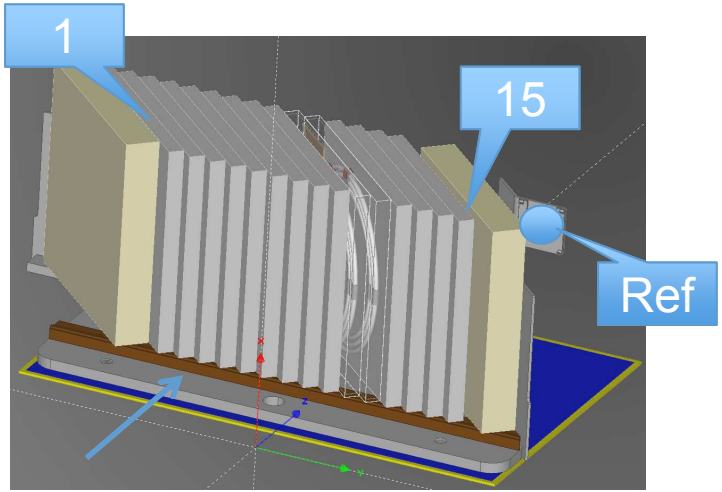
Variation of Position



Compliance Card Moving



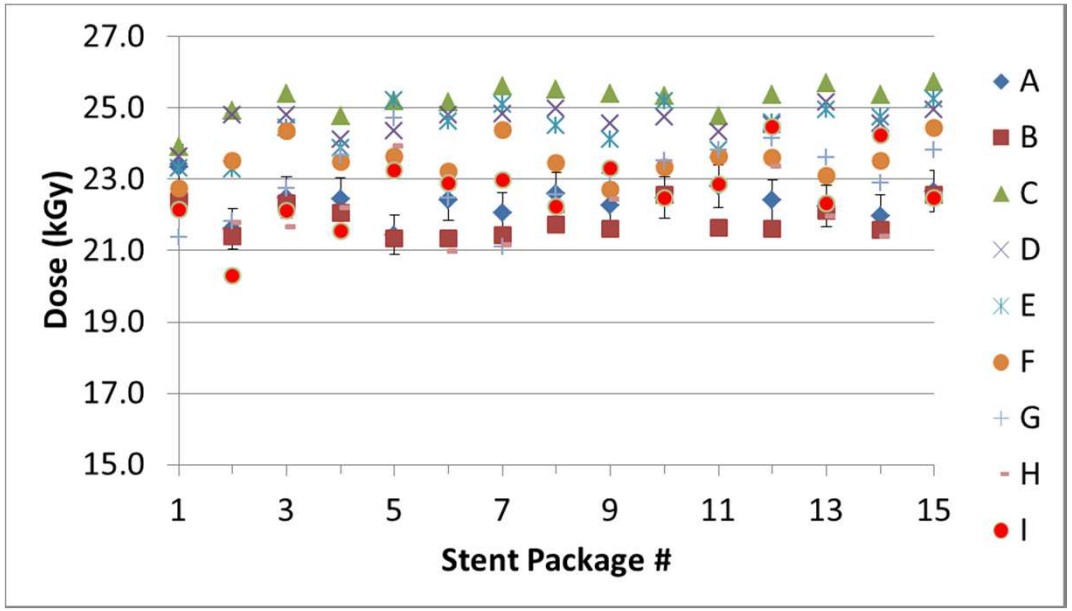




Beam Direction →

Reference Dose Monitoring ●

Compliance Card - Baseline Scenario

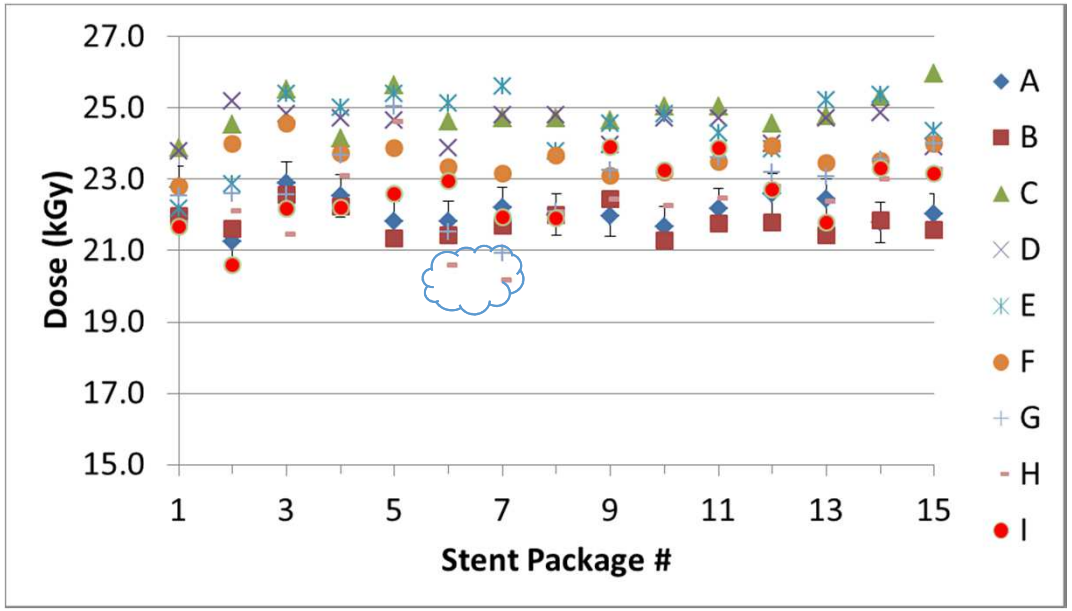


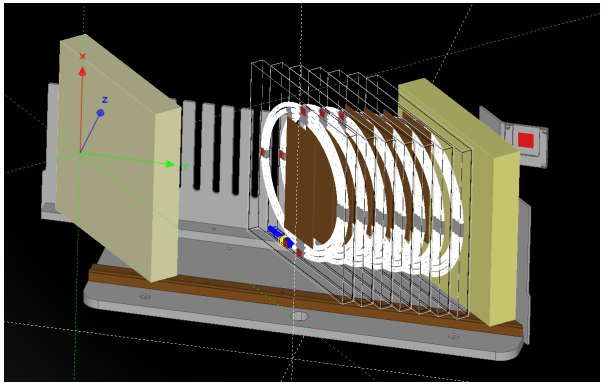
- Reference Dose: 23.6 kGy
- ± 2.2% - 5% at 1σ
- ~ 6hrs on high performance workstation

Scenario

All compliance cards shadow locations E,F,I

Compliance Card - Scenario Variation



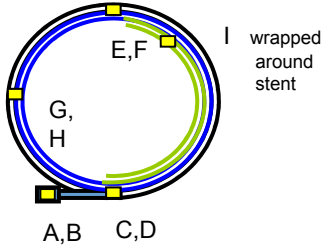


Scenario

All compliance cards shadow locations E,F,I

Except package 4, 5 and 6

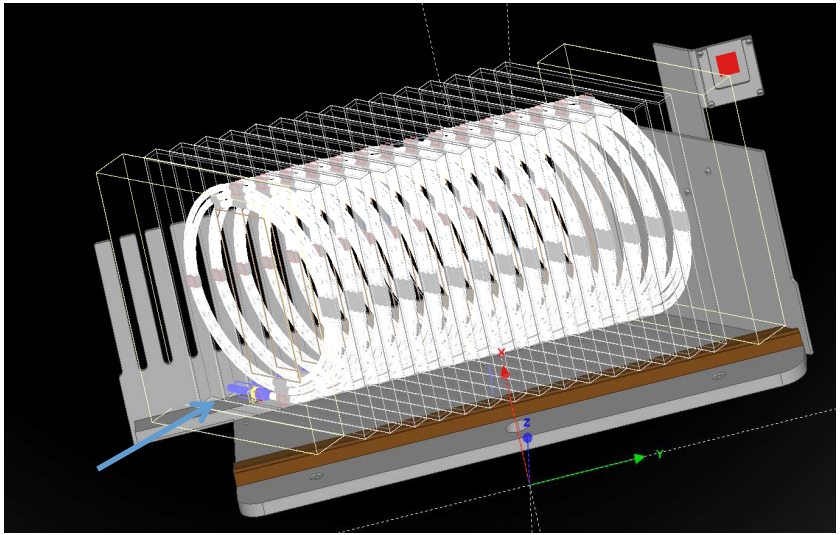
First results – still Work-In-Progress



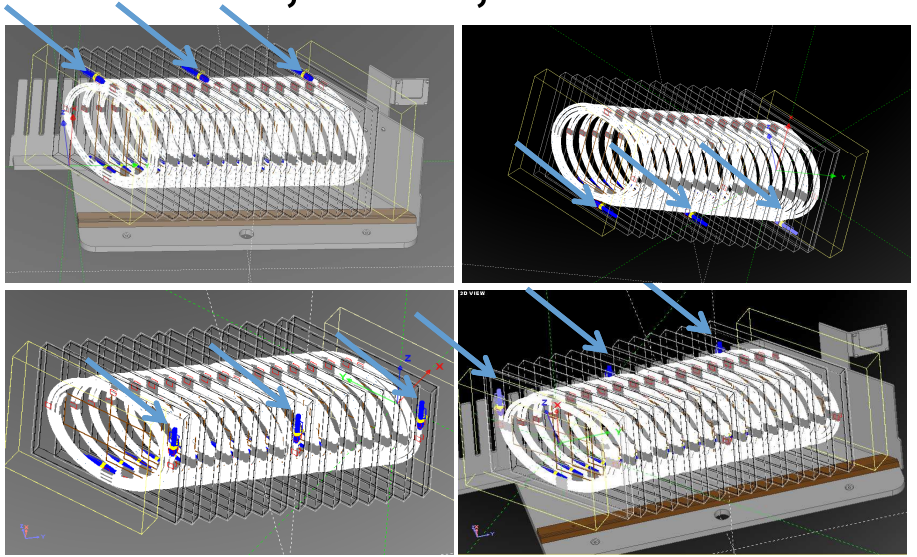
- Multi-parameter
  - We would have predicted an change for locations E,F and I
  - We saw a change at location H
  - Due to multi stentpackage, 45°
- Simulations provide
  - input for verification/benchmarking scenarios
  - Trends
  - Ideas for more critical control points (➔prevent)

Orientation Defects

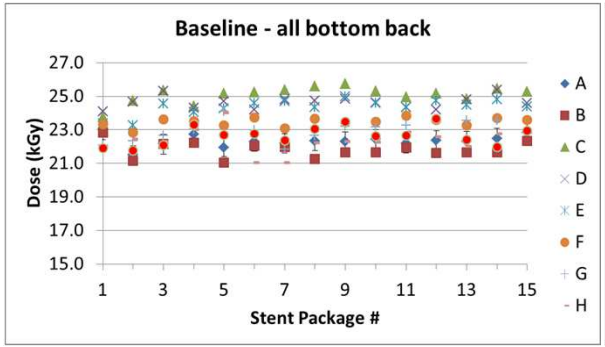
Standard Orientation

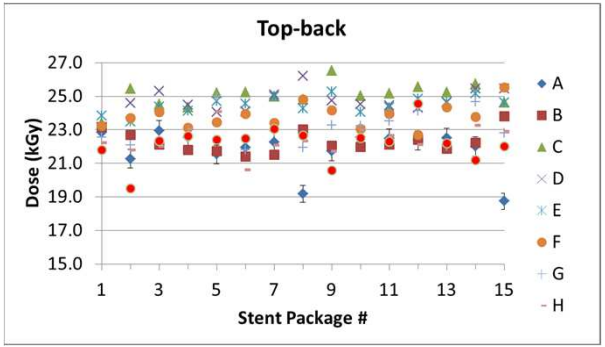


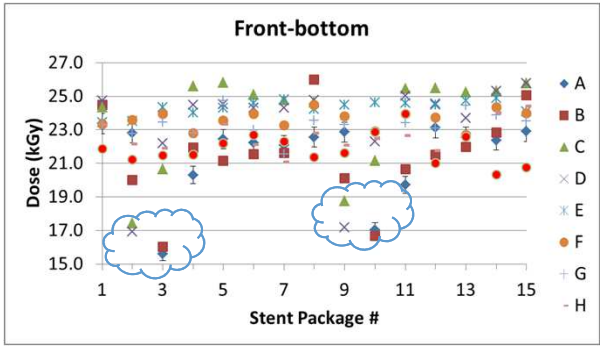
Variations, unit 1, 8 and 15



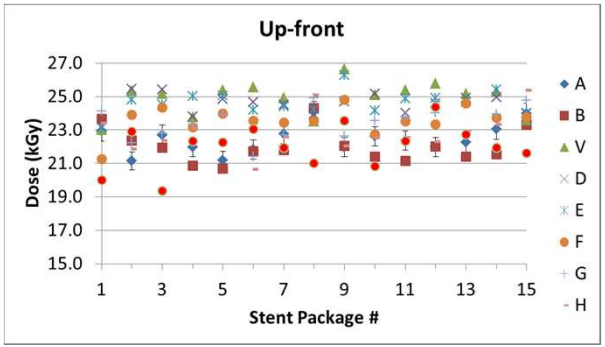
Orientation Defects - Scenario Variation

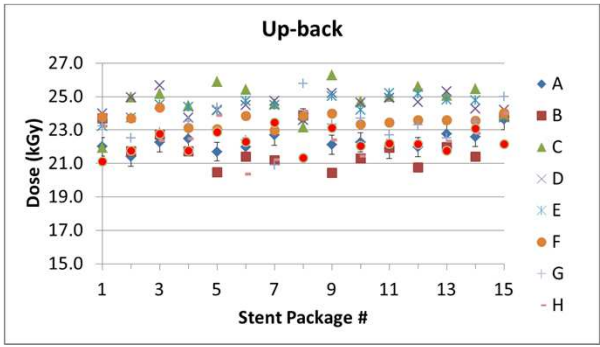






D_{min}/D_{ref} – D_{max}/D_{ref}	
Baseline:	**0.89 – 1.09**
Front-bottom:	**0.60 – 1.82**
Top-Back:	**0.80 – 1.11**
Up-Front:	**0.80 – 1.11**
Up-Back:	**0.80 – 1.09**





First results – still Work-In-Progress

- Overall dose distribution homogeneous for each location; within statistical uncertainties
- Worst case defect: Front-Bottom
- Manageable defects

➔ Preventive Action

  ➔ Reset range slightly for D_{min}/D_{ref} – D_{max}/D_{ref}

Conclusions - CAPA

- Today we presented a Method and a Tool
  - 3D geometry input, easy adaptation, quick to add complexity
- The results shown today are very preliminary, but
  - Demonstrate the Effectiveness for Variance Analysis
  - Provide additional data to Support Defect Resolution
  - Help identify cases where Corrective Actions are likely required
  - Help set limits for Preventive Actions
- Performance Qualification Benchmarking
  - Verify measurable locations, determine uncertainties
  - Trust non-measurable locations

Conclusions - Business

- Understand complexity
  - Gain Predictability
  - Reduce Risk
- Simulate vs. Experiment
  - Many more dose maps than one would perform experimentally
  - Much less resource use (people, beam time, preparation time, travel, analysis)
  - Reduced development time and cost
- 3D interface to Monte Carlo
  - Quick Iterations: Maintain focus of development team
  - Allow to quickly increase complexity

THANK YOU!