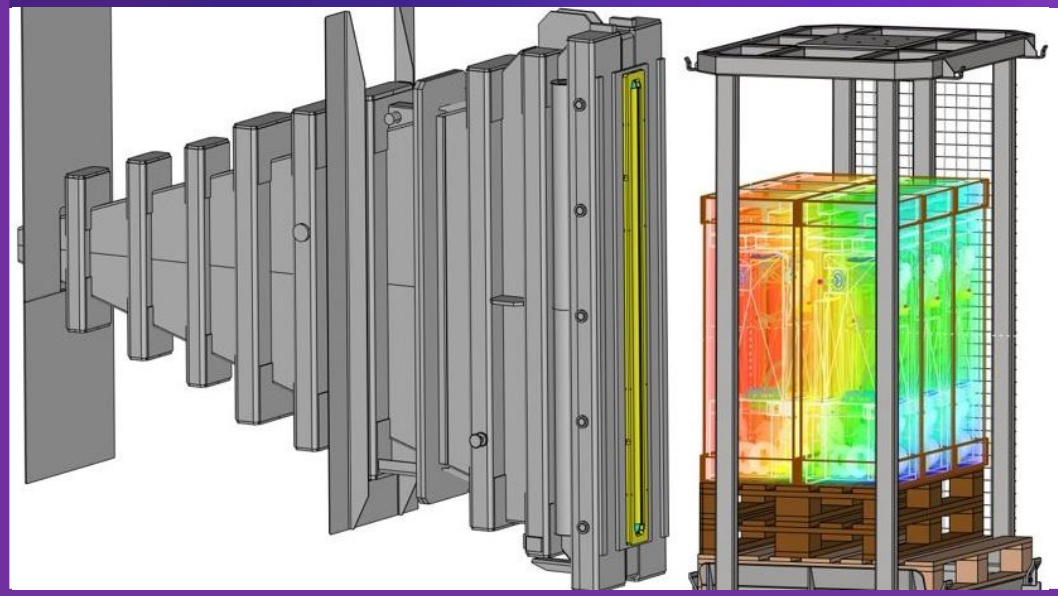
Medical Device Sterilization:
From Possibilities to Practice

September 21-23, 2022



Evaluation of Monte Carlo simulation in Radiation Processing

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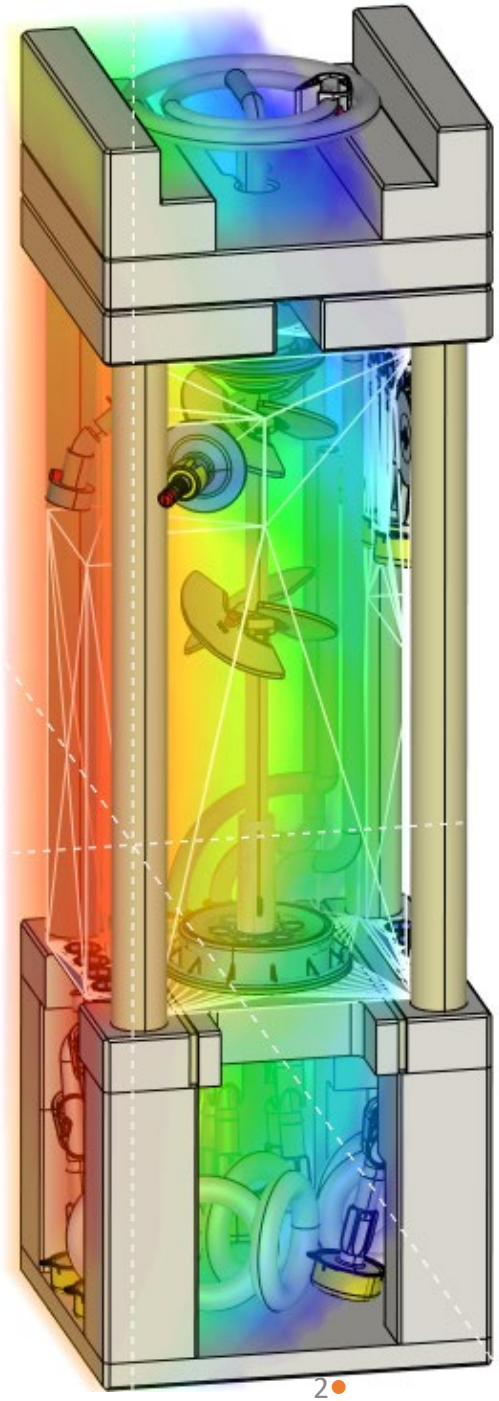
Florent KUNTZ - AERIAL CRT
Antoine GHILARDI – TRAD Tests & Radiations

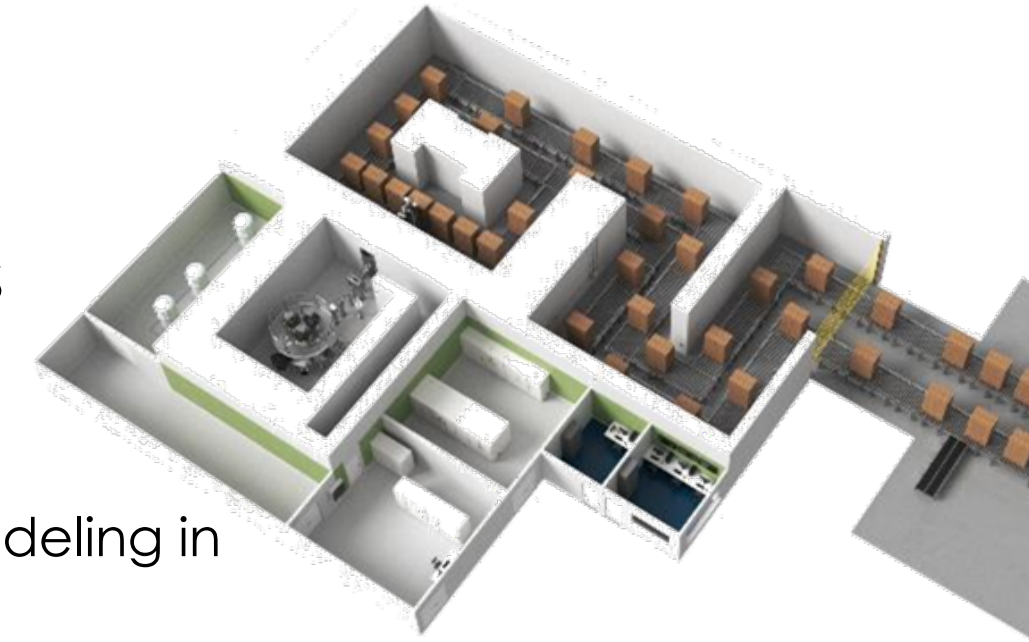
Purpose and Motivations

- Dose distribution evaluation is a key step to control radiation sterilization processes
- Are dose mappings the only way to validate dose distribution during sterilization?
- Can we predict overdosing on radiation sensitive parts?
- Monte Carlo modelling applied on SU products for biotech applications
- Comparison with real dose mapping with X-ray to check the good fit

Use in PQ realization, improving dose uniformity for complex products

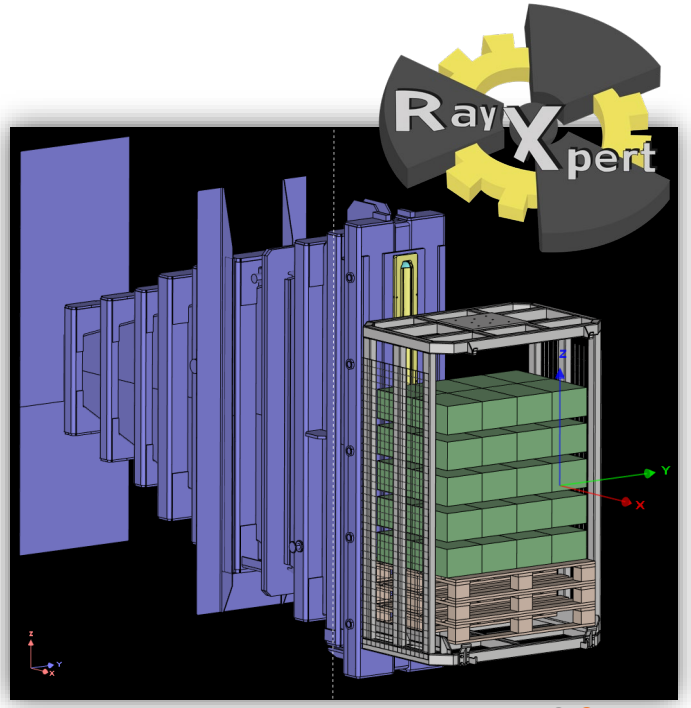


Consortium



- Product manufacturer
- Expertise and knowledge on the SUS applications

- Expertise and knowledge on the modeling in radiation processing
- RayXpert® software



- Expertise and knowledge on dosimetry and qualification process
- Ebeam/Xray facility feerix®

- Expertise and knowledge on the X-ray and Ebeam technologies
- Beam source information for the modeling

Product of interest in POC

- Sartorius STR 50L bags used in the POC (Proof of Concept)
- Complex SUS products with many components, tubing lines, magnetic stirrers, etc.

Methodology
Product dose mapping

Placement of dosimeter on the product understanding hot/cold spots

Xray processing

Measurement of irradiated dosimeters

10 alanine dosimeters

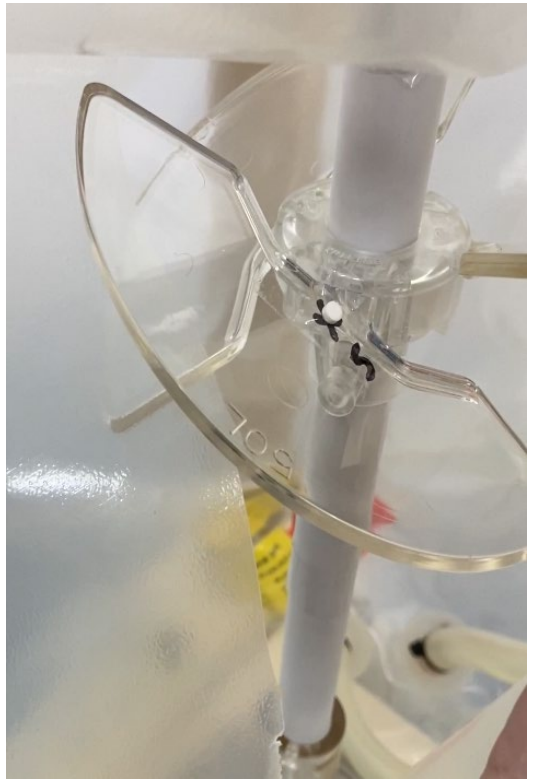
- sensitive compartments
- minimum dose zones

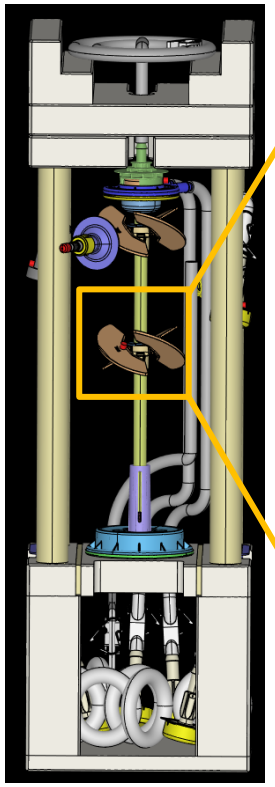
Dmin, Dmax location
DUR (= Dmax/Dmin)

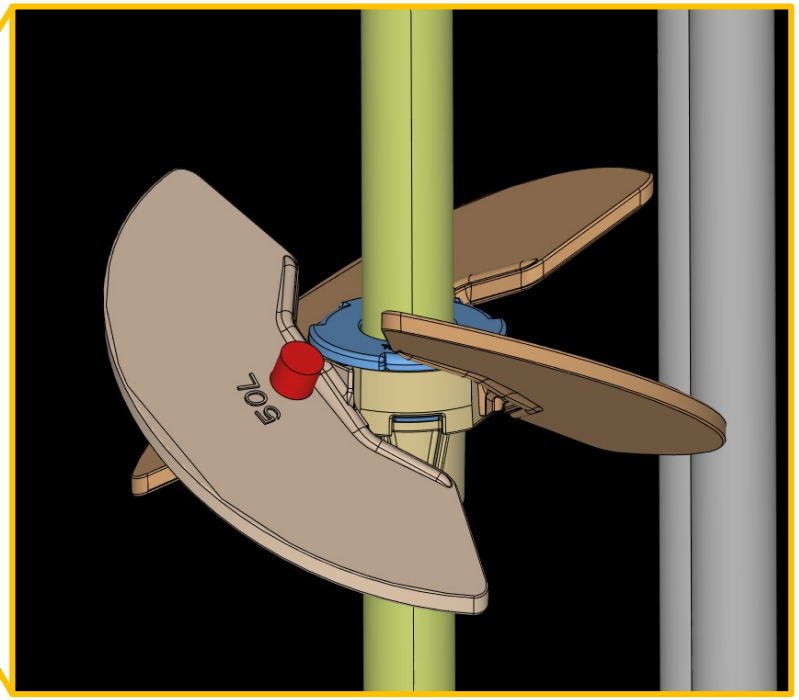
Dose mapping
Dosimeters positioning

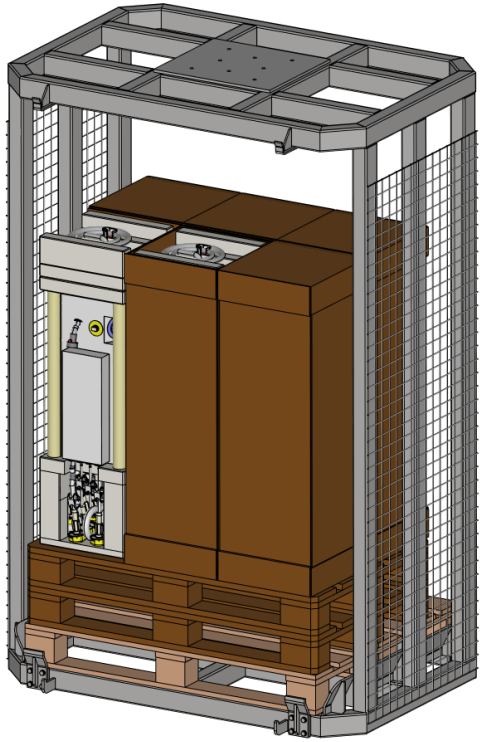
- 10 dosimeters were placed on each one of the six STR50.
- The 60 dosimeters were modelled in RayXpert®

Example: Dosimeter # 5 of STR # 1:

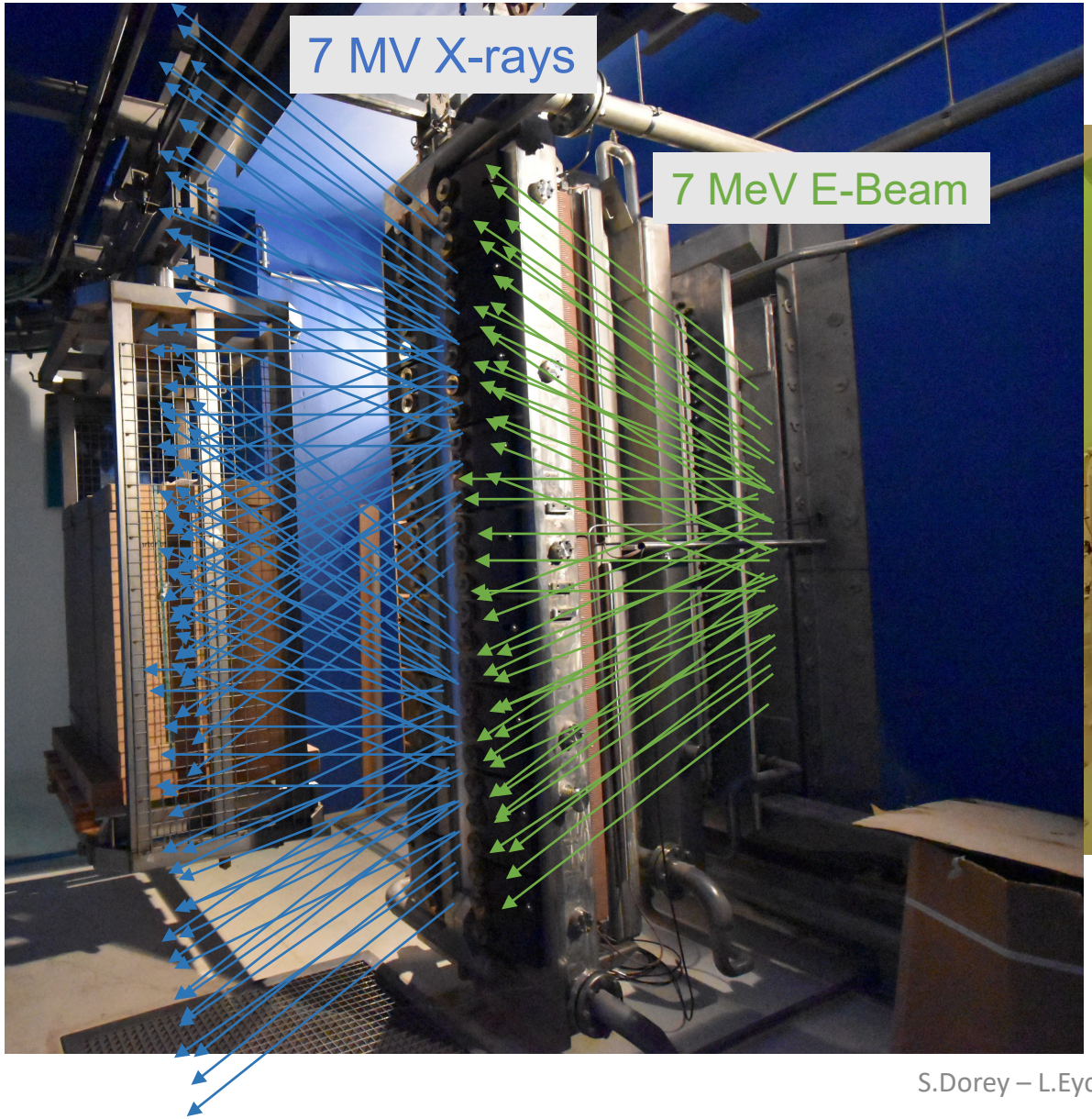


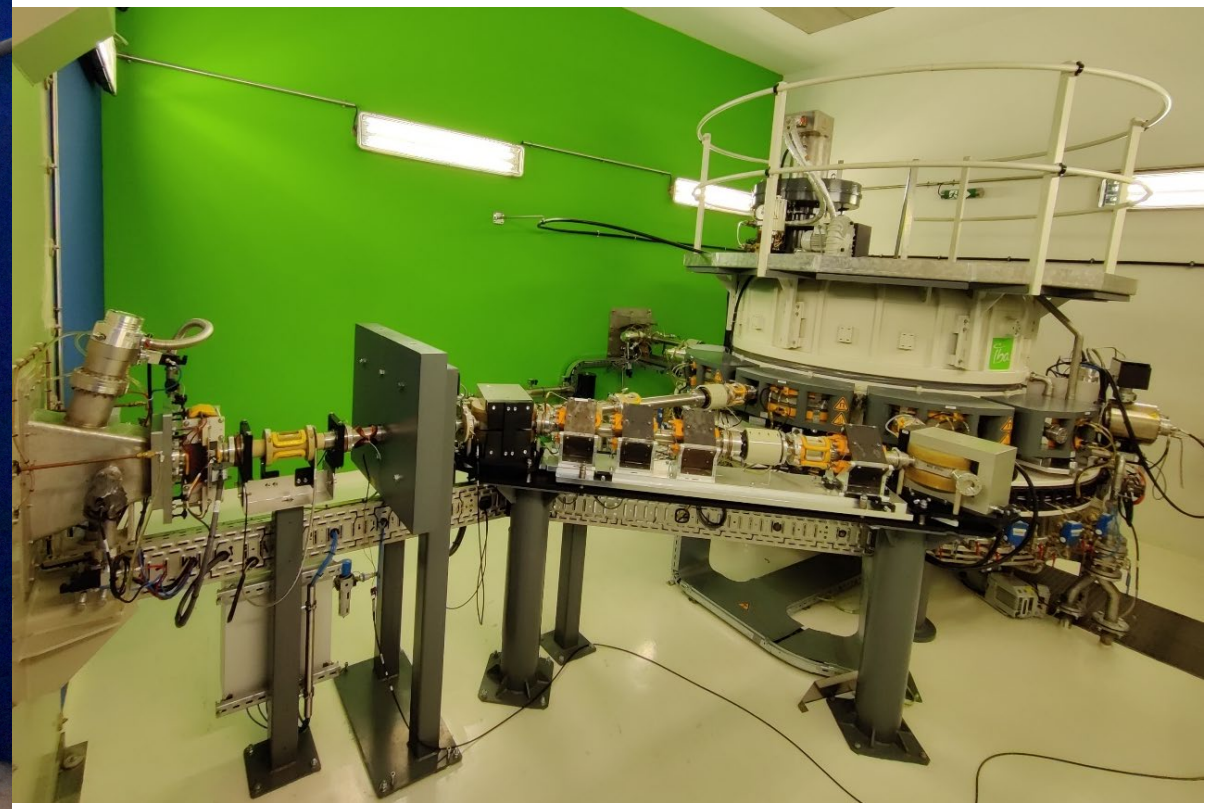






Dose mapping at Aerial



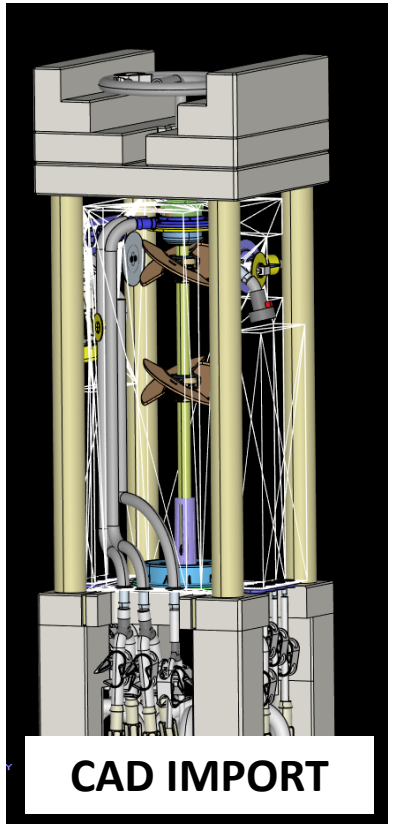


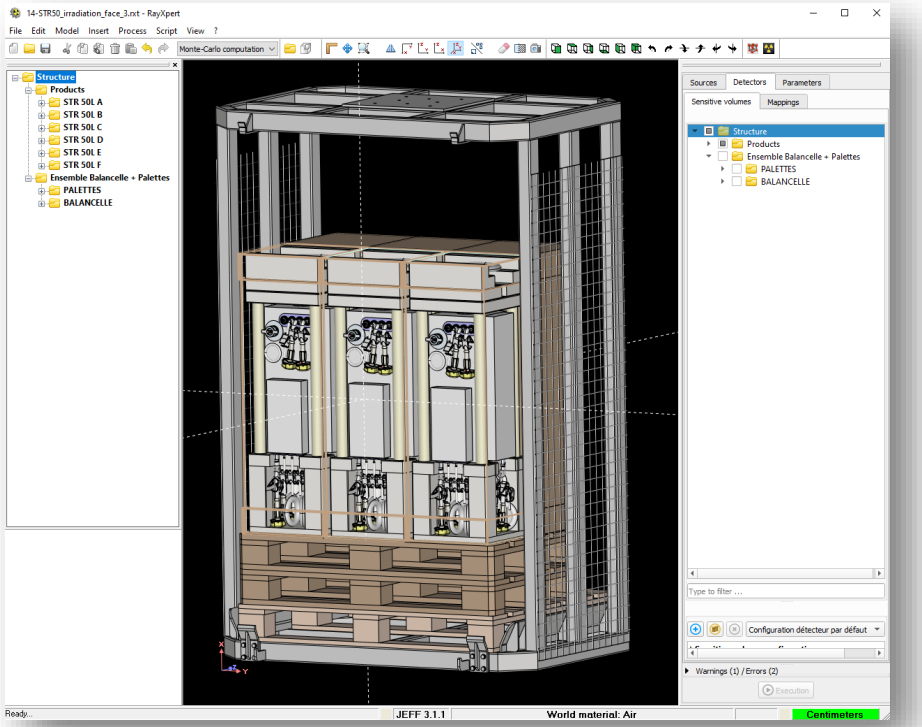
Methodology
Monte Carlo Simulation

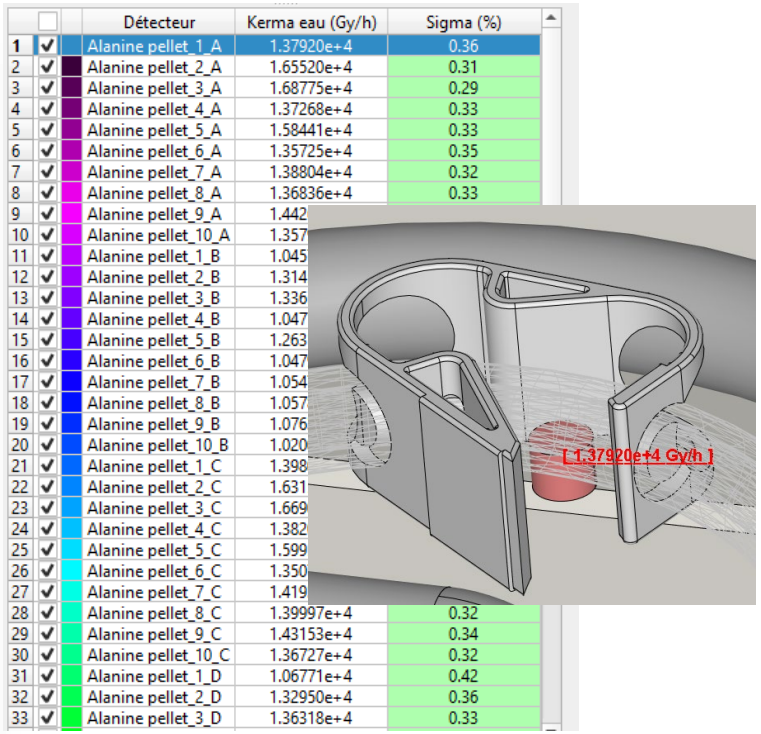
3D Modeling &
Virtual dose mapping

Monte Carlo
calculation

Result vizualisation





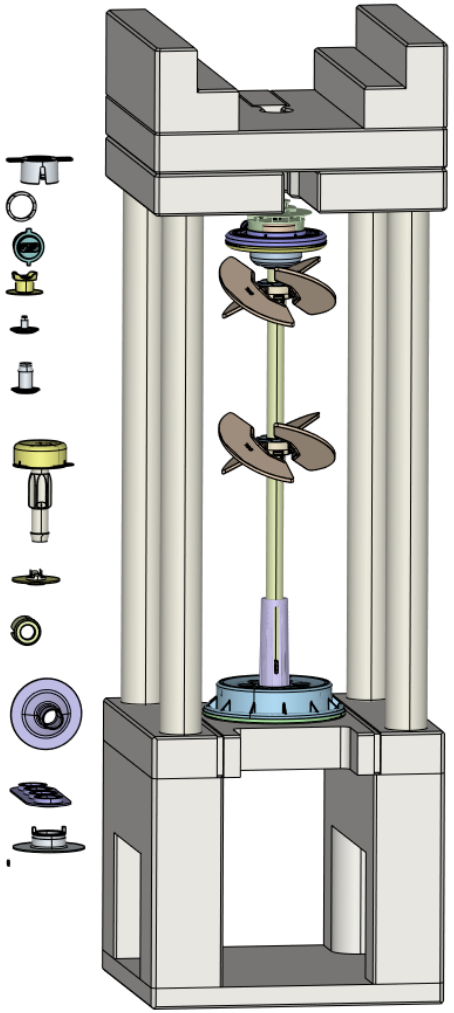


		Détecteur	Kerma eau (Gy/h)	Sigma (%)
1	✓	Alanine pellet_1_A	1.37920e+4	0.36
2	✓	Alanine pellet_2_A	1.65520e+4	0.31
3	✓	Alanine pellet_3_A	1.68775e+4	0.29
4	✓	Alanine pellet_4_A	1.37268e+4	0.33
5	✓	Alanine pellet_5_A	1.58441e+4	0.33
6	✓	Alanine pellet_6_A	1.35725e+4	0.35
7	✓	Alanine pellet_7_A	1.38804e+4	0.32
8	✓	Alanine pellet_8_A	1.36836e+4	0.33
9	✓	Alanine pellet_9_A	1.442	
10	✓	Alanine pellet_10_A	1.357	
11	✓	Alanine pellet_1_B	1.045	
12	✓	Alanine pellet_2_B	1.314	
13	✓	Alanine pellet_3_B	1.336	
14	✓	Alanine pellet_4_B	1.047	
15	✓	Alanine pellet_5_B	1.263	
16	✓	Alanine pellet_6_B	1.047	
17	✓	Alanine pellet_7_B	1.054	
18	✓	Alanine pellet_8_B	1.057	
19	✓	Alanine pellet_9_B	1.076	
20	✓	Alanine pellet_10_B	1.020	
21	✓	Alanine pellet_1_C	1.398	
22	✓	Alanine pellet_2_C	1.631	
23	✓	Alanine pellet_3_C	1.669	
24	✓	Alanine pellet_4_C	1.382	
25	✓	Alanine pellet_5_C	1.599	
26	✓	Alanine pellet_6_C	1.350	
27	✓	Alanine pellet_7_C	1.419	
28	✓	Alanine pellet_8_C	1.39997e+4	0.32
29	✓	Alanine pellet_9_C	1.43153e+4	0.34
30	✓	Alanine pellet_10_C	1.36727e+4	0.32
31	✓	Alanine pellet_1_D	1.06771e+4	0.42
32	✓	Alanine pellet_2_D	1.32950e+4	0.36
33	✓	Alanine pellet_3_D	1.36318e+4	0.33

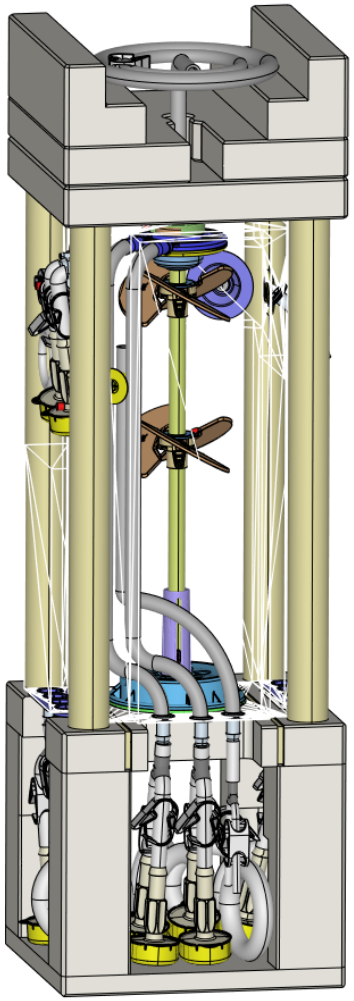
Dmin, Dmax location
DUR (= Dmax/Dmin)

Monte Carlo Simulation
Product and irradiation facility modelling

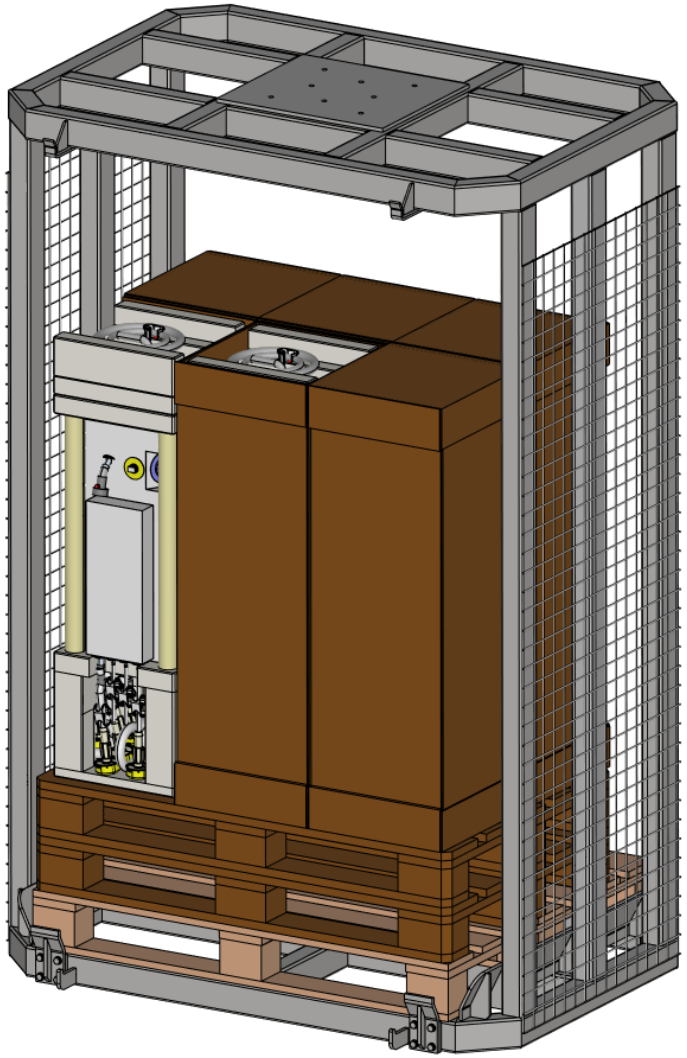
CAD import



Modelling



Final product

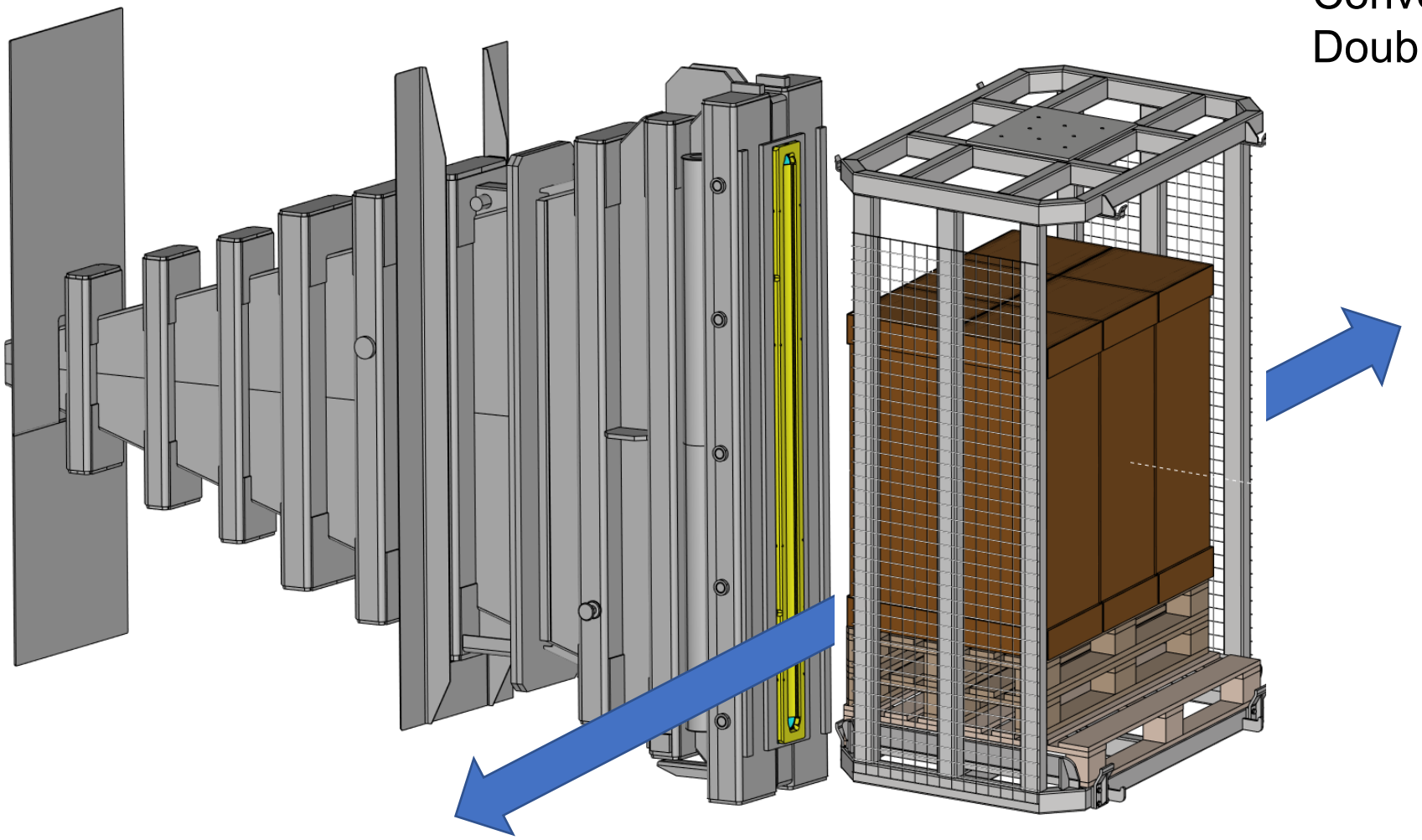


Monte Carlo Simulation

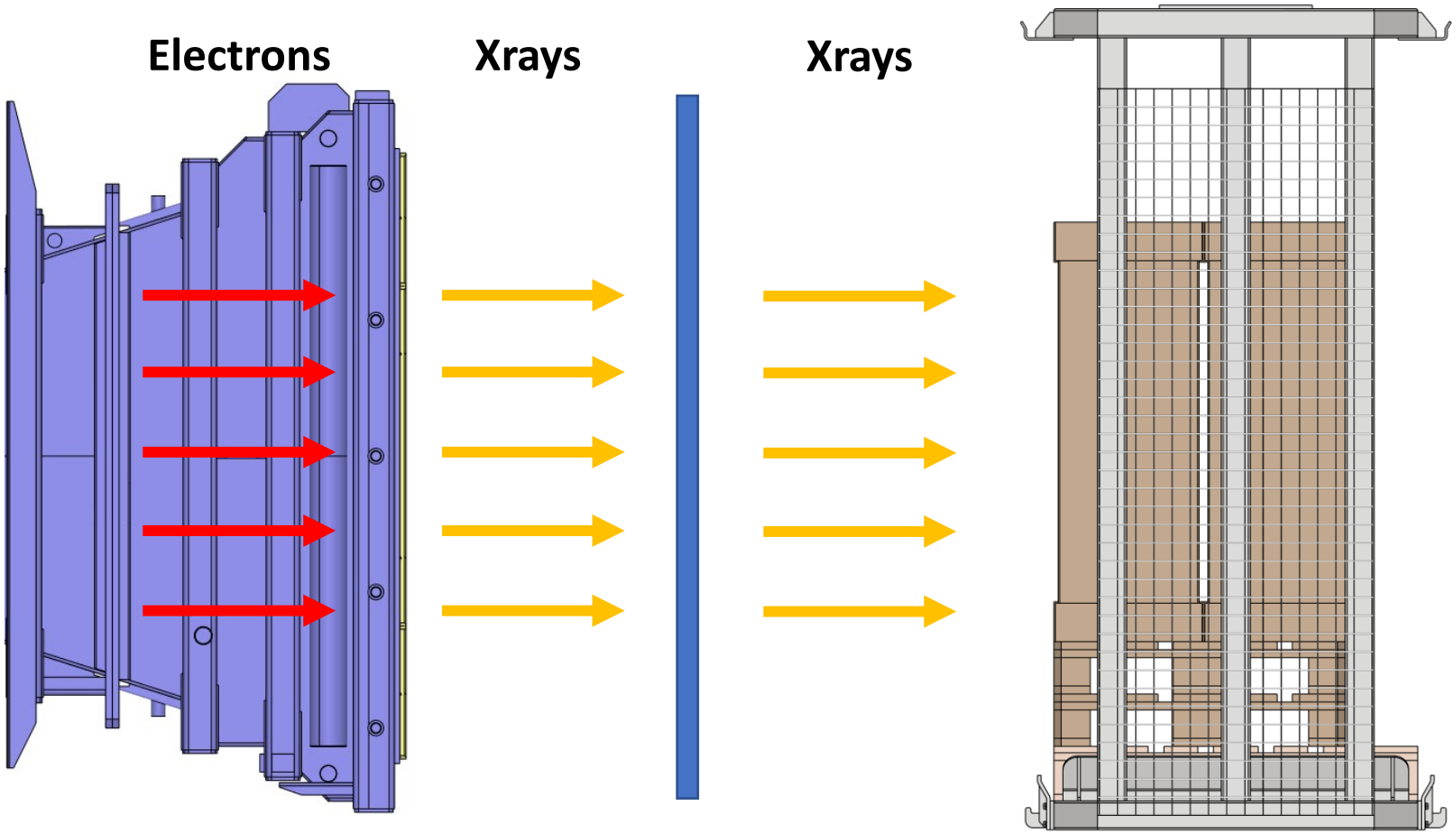
Source setup

7MV X-rays

Beam current = 13 mA
Scan width = 210 cm
Conveyor speed = 1 m/min
Double sided irradiation



Monte Carlo Simulation
Source setup



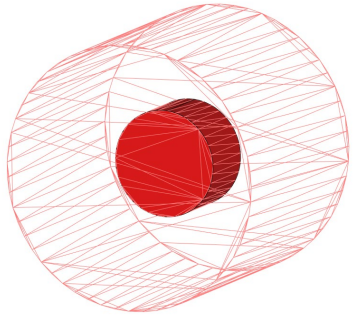
7MV X-rays

Beam current = 13 mA
Scan width = 210 cm
Conveyor speed = 1 m/min
Double sided irradiation

1 Creation of an energy-angle spectrum

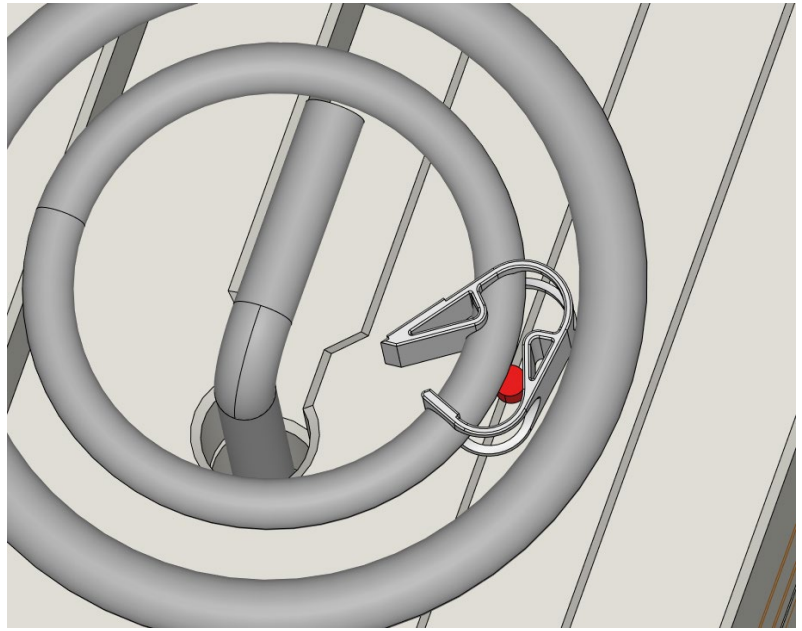
2 Direct emission of X-rays

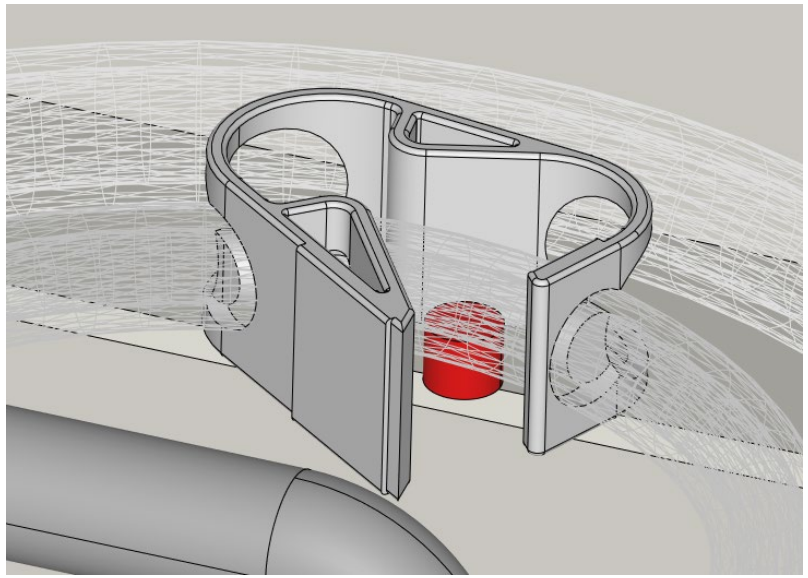
Monte Carlo Simulation
Detectors

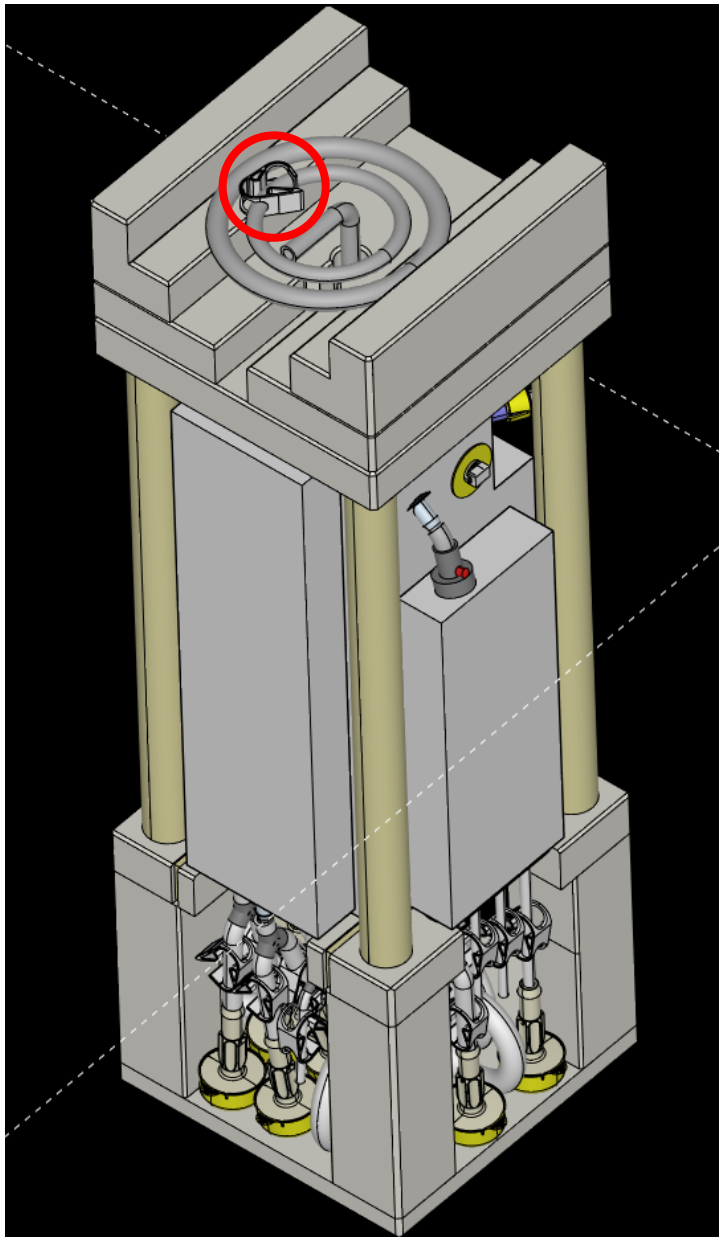


Alanine pellet

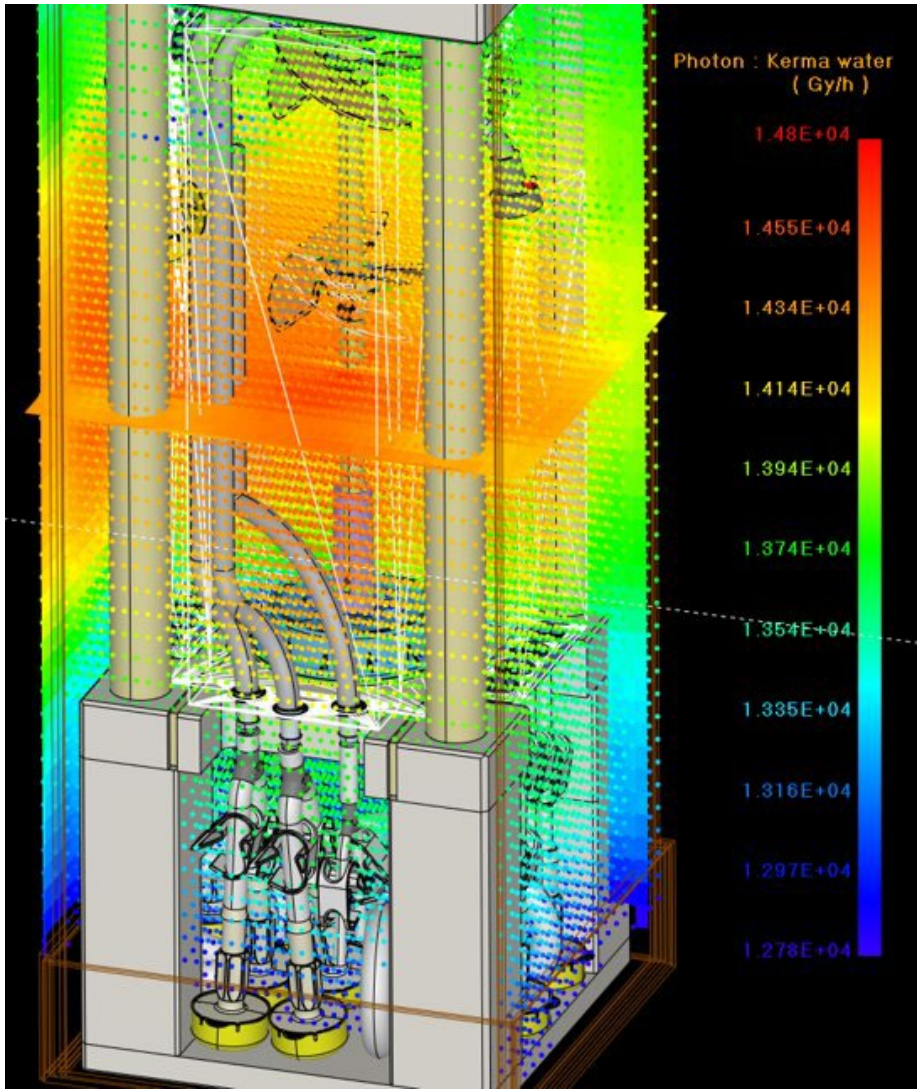
- 60 sensitive volumes
- Replicate alanine dosimeters response
- d = 1,25 g.cm^{-3}
- PE phantom
- Kerma water calculated
- Results in Gy/h







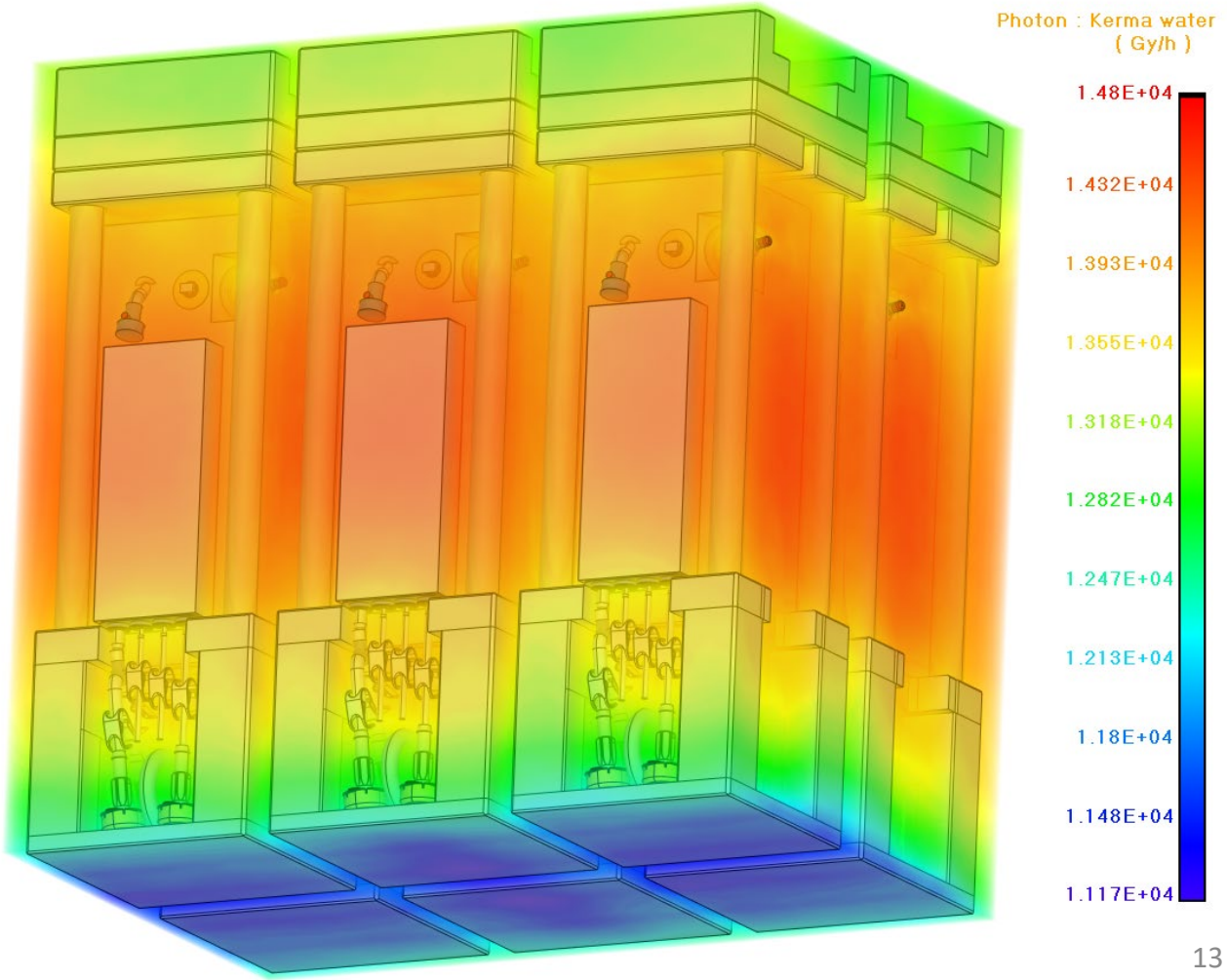
Monte Carlo Simulation
3D mapping



Virtual mapping in all the product

Results for kerma water in ***Gy/h***

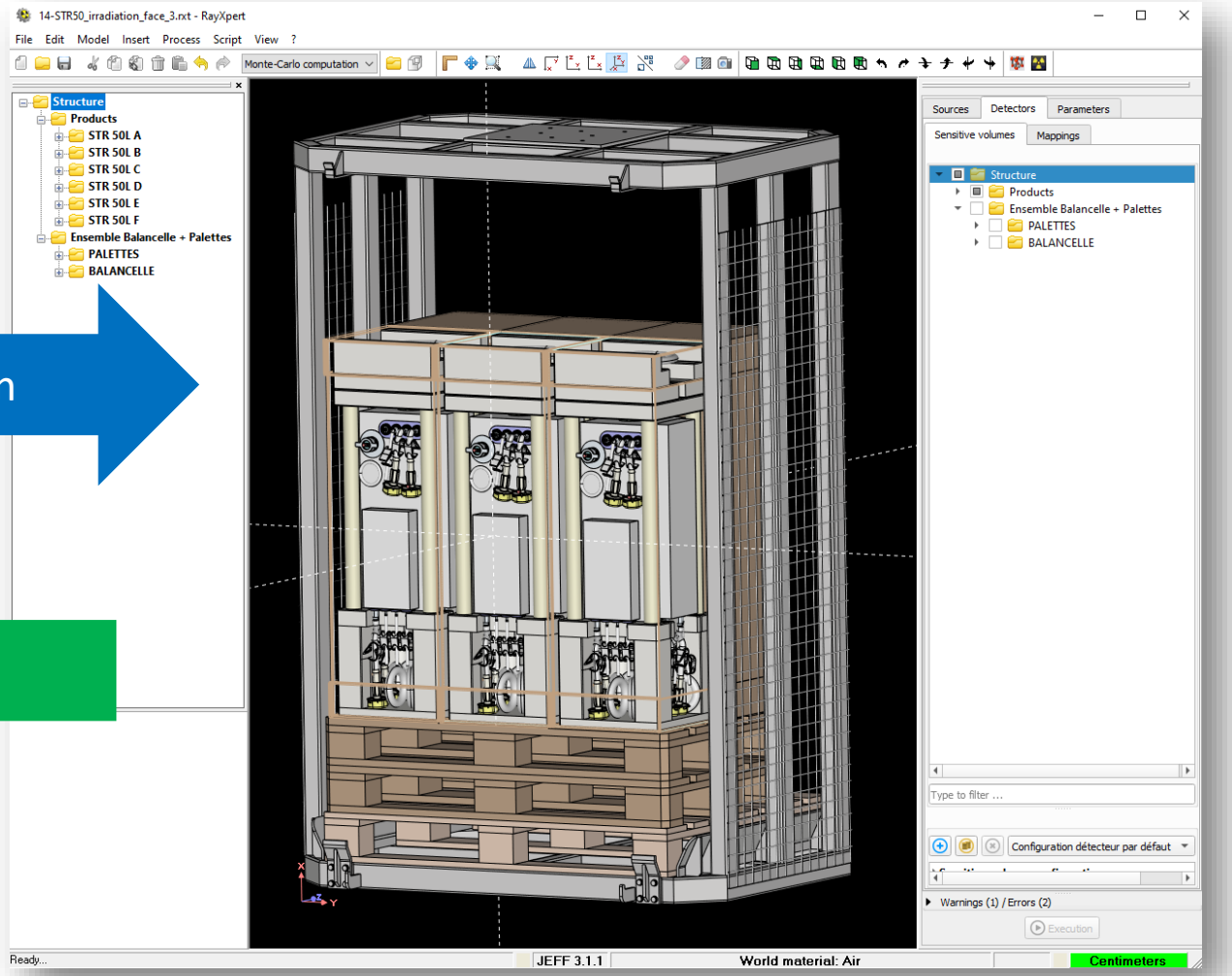
271 092 voxels in total



Simulations vs Dose mapping fit check

Dose mapping (8 kGy)

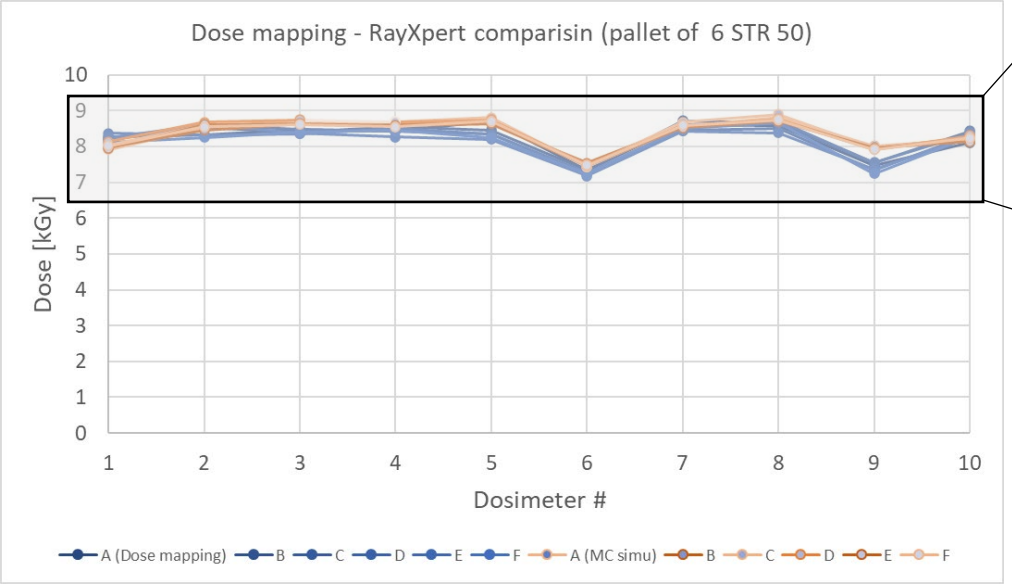
Simulation

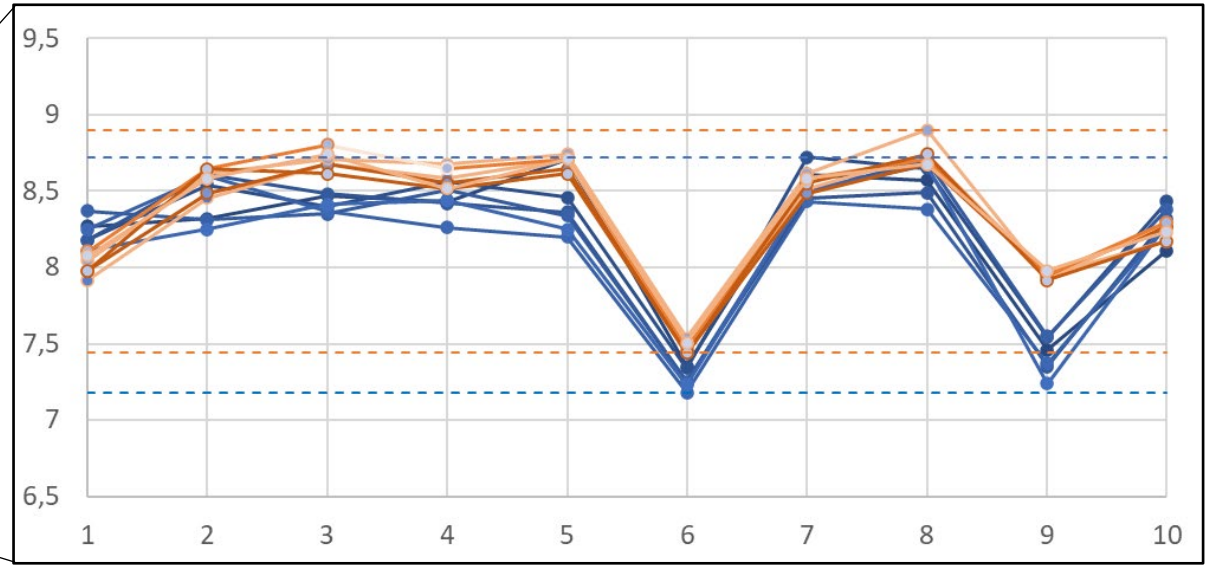


Comparison

Benefits

Very good matching between measurement and simulations!

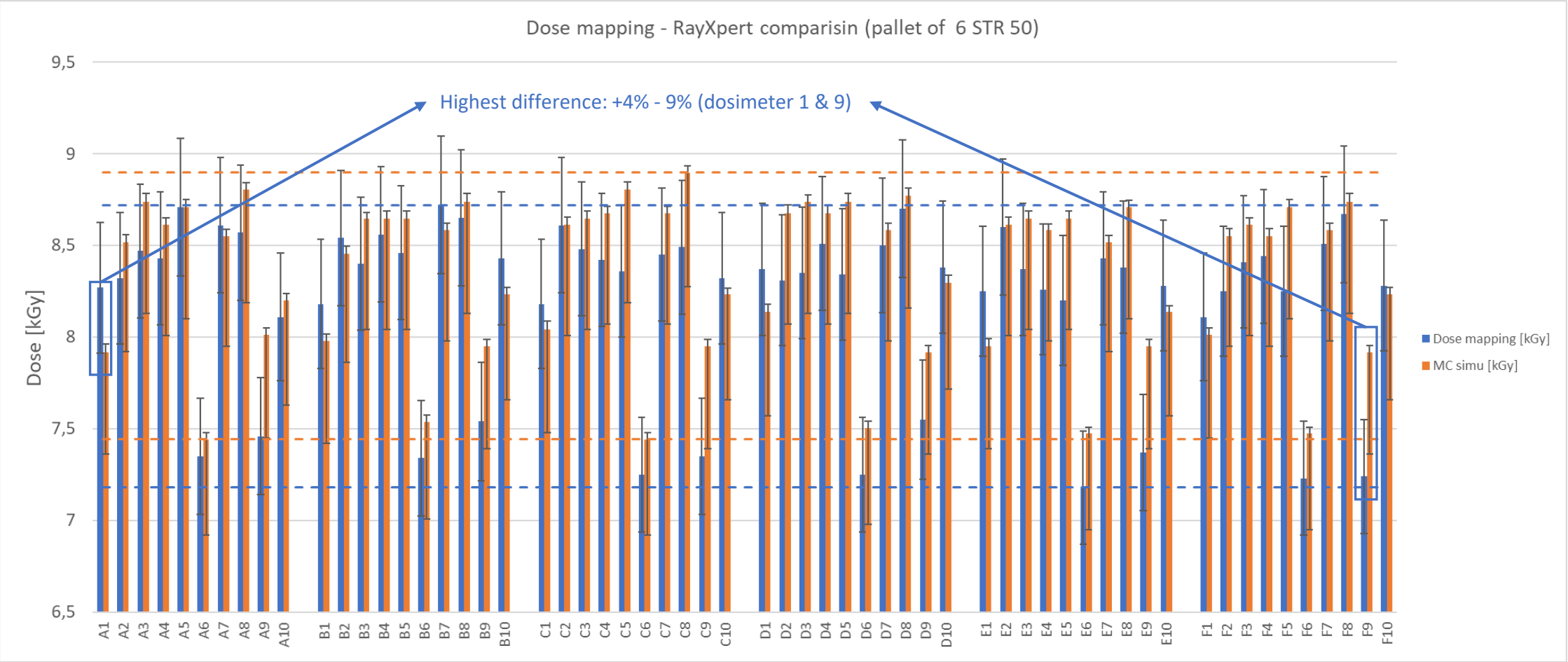




	Dose mapping	RayXpert®	
Average dose [kGy]	8,20	8,35	**-1,8%**
D_{min} [kGy]	7,18	7,44	-3,6%
D_{max} [kGy]	8,72	8,90	-2,0%
DUR	**1,21**	**1,20**	**1,6%**

- D_{min} located on dosimeter # 6 & #9. / D_{max} spread on dosimeter #5, # 7 & # 8.
- The measured dose matches with RayXpert to 1.8% on average (absolute value) .
- The DUR also matches very well (1.6%)
- RayXpert overestimates the dose at location # 9 by 9% (under investigation)

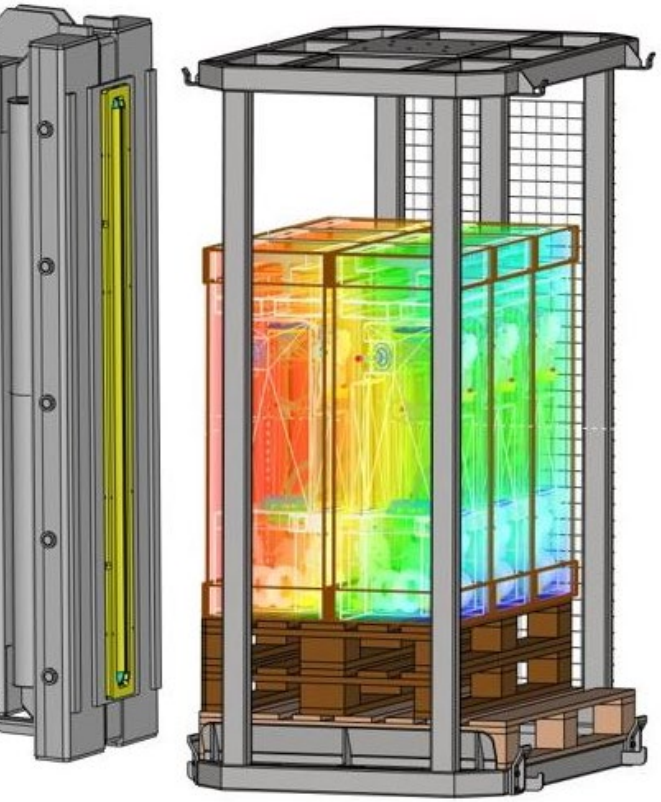
The matching is better than the uncertainties!



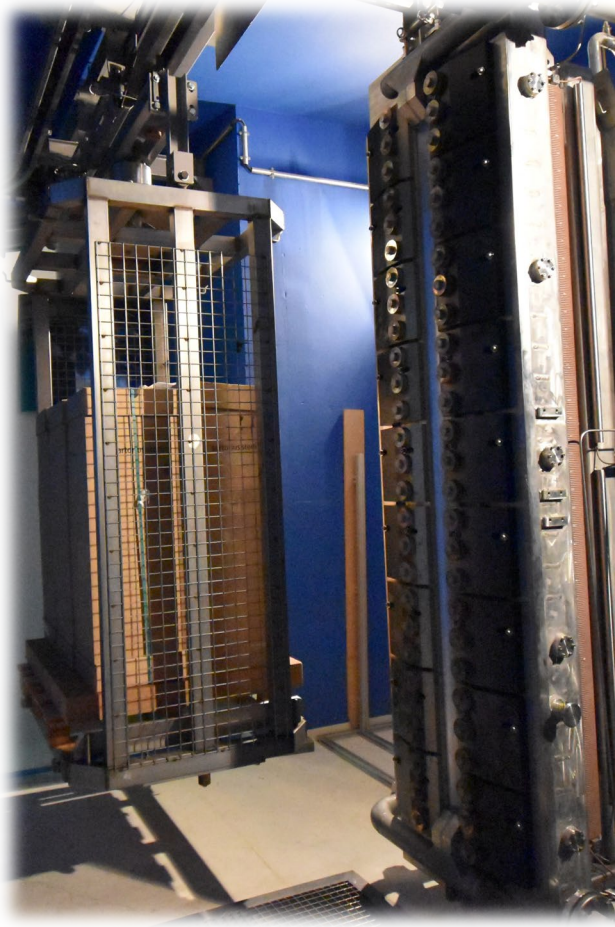
- Dose measurement uncertainty : 4.3% (k = 2)
- RayXpert computes the dose in Kerma water. Error linked : +0.5% / - 7%

The difference between the dose mapping and simulated dose *expressed in Kerma water* is well below those uncertainties

Conclusion



- Monte Carlo tools now suitable to model complex products and for industrial application
- Good matching between Monte Carlo simulation and dose mapping on a complex product processed with X-rays
- Monte Carlo can be used to ease the PQ of products requiring radiation processing
- Monte Carlo can be used to evaluate the dose distribution in a product in a specific X-Ray site without requiring such site to perform a dose mapping or to have the prototype in hand
- Simulation would allow a significant gain in time when transferring a product PQ from one site to another
- Can Monte Carlo be a tool to help the transition from Cobalt-60 to X-Ray processing?



Questions?

Input your questions for speakers at any time via the Q&A function at the bottom of your screen: