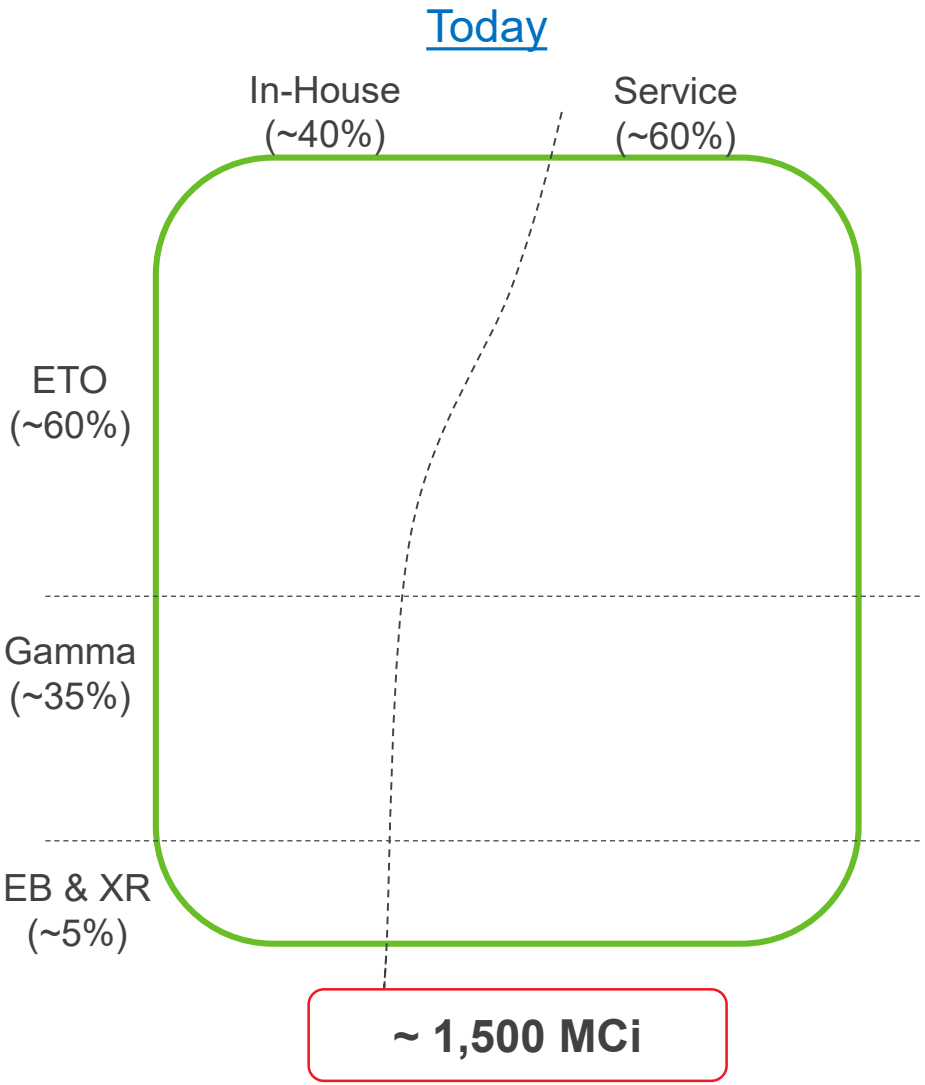
E-beam and X-ray: Why? What? How?

Introduction & Agenda

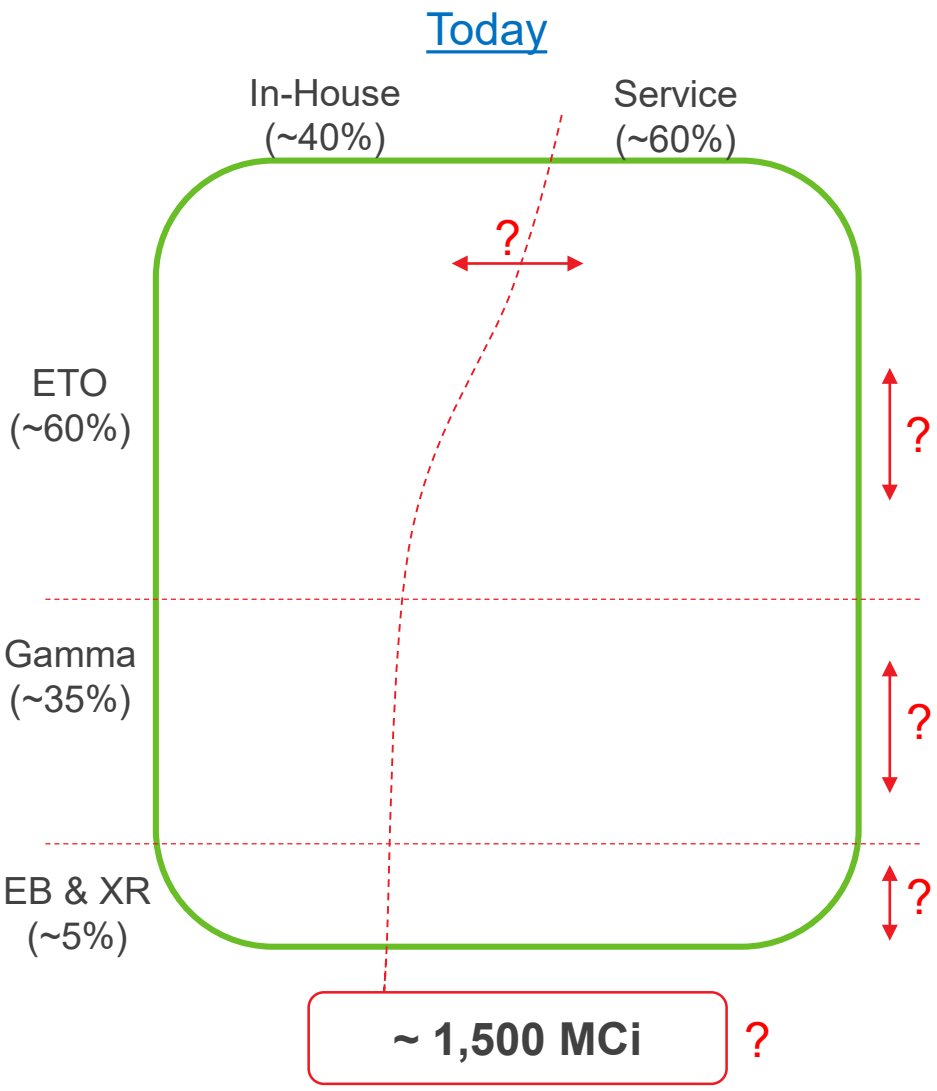
- Agenda:
  - We are investing to supply and service a growing market
  - E-Beam and X-ray are complementary solution that are financially viable
  - Mevex and IBA are there to help you to move from an idea to a real project
  - Still some challenges to adoption of E-beam and X-ray

WHY? Market Situation & Complication



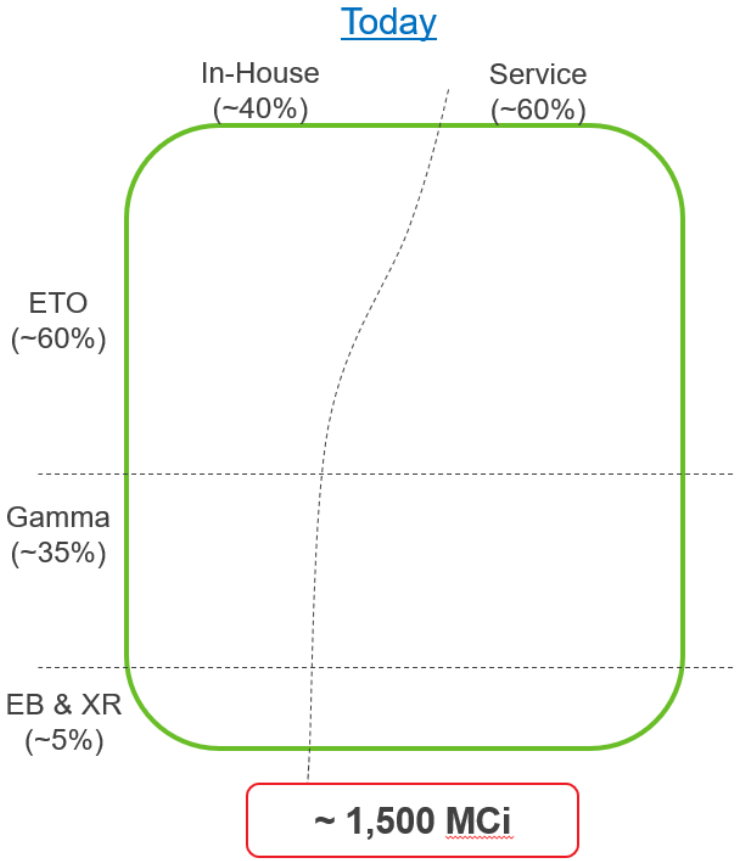
- Complication :
  - Increasing pressure on Co60 (Price, Supply, Security, …)
  - Increasing pressure on EtO (Environmental, residual, …)
  - Other (more specific): Product complexity, logistics, business model, …

Market Situation in 10 years…?



In 10 years

Market Situation in 10 years… **What if…**



In 10 years

What if, Only 40% in ETO, 25% in Gamma and 5% market growth?

→ **35**% of 2,400MCi = 840MCi …

~ 280 systems of 3 MCi

What if, Only 35% in ETO, 20% in Gamma and 7% market growth?

→ **45**% of 3,000MCi = 1.350MCi …

~ 450 systems of 3 MCi

What if, Only 30% in ETO, 30% in Gamma, 10% other modality and 5% market growth?

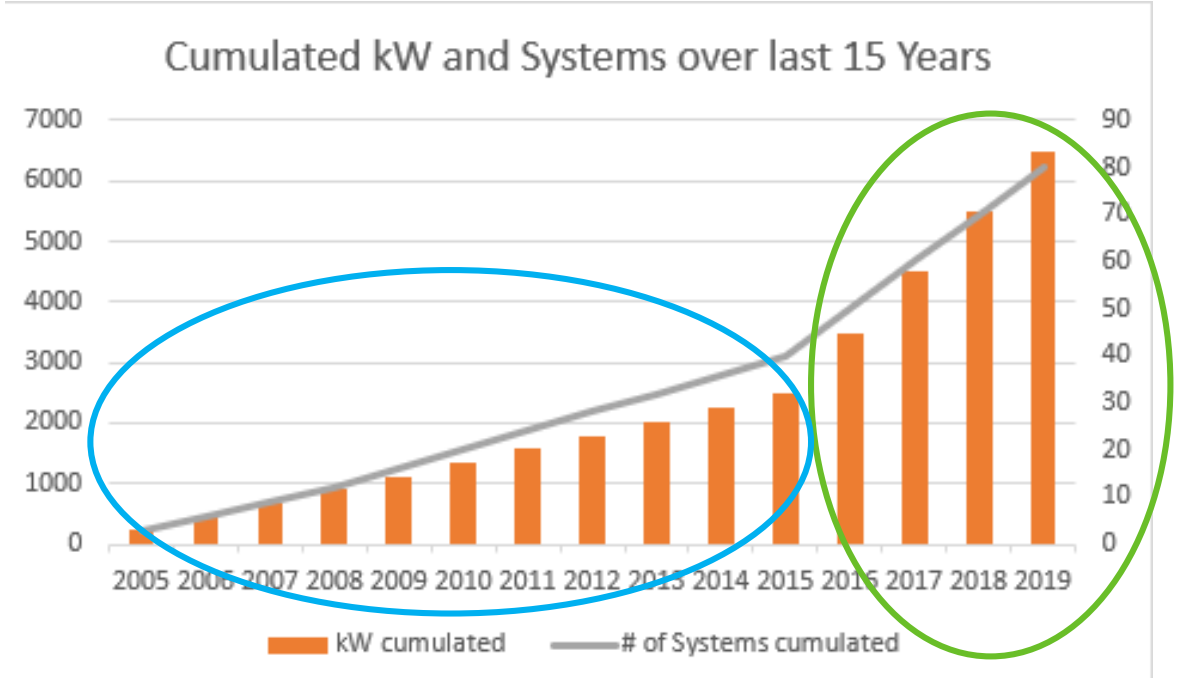
→ **25**% of 2,400MCi = 600 MCi …

~ 200 systems of 3 MCi

200 to 400 systems over the next 10 years

EB and XR adoption is accelerating over the last 4Y

Mevex and IBA Order Intake 5MeV+ for period of 2005-2015 and period of 2016-2019

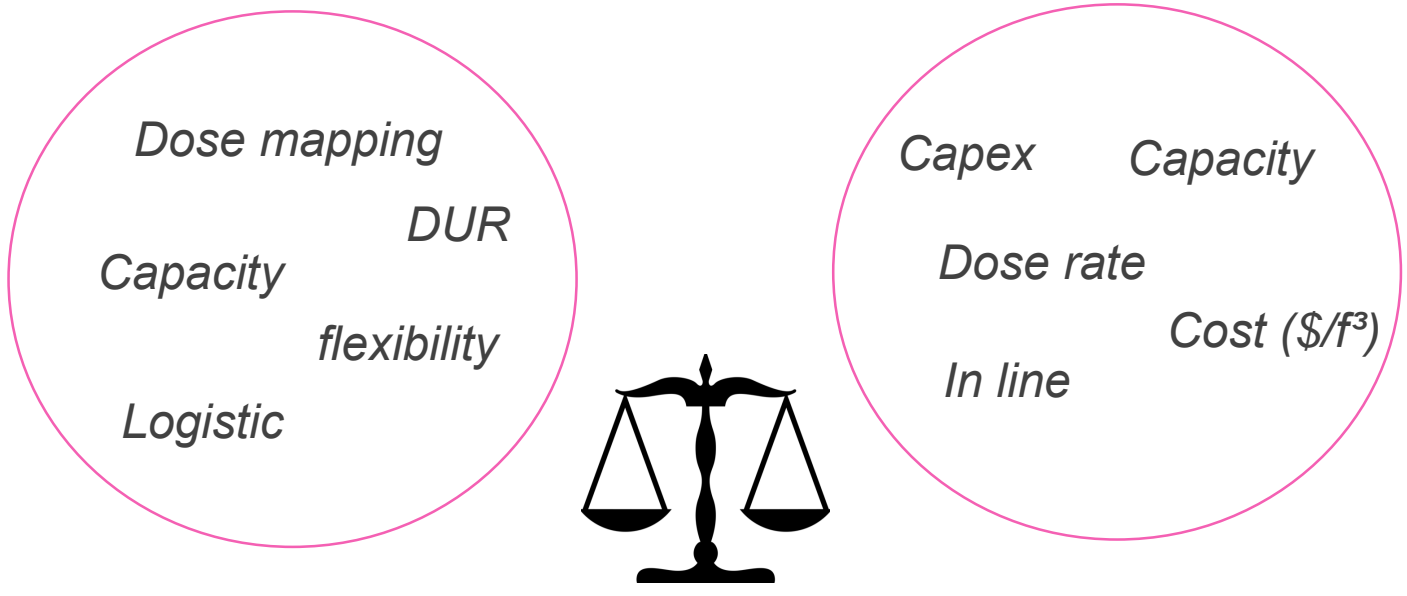


- 6.5 MW over the last 15 years
- **4 MW** over the last 4 years
- 2005-2015: Average of 4 Systems / year
- 2016-2019: Average of **12+ Systems / year**

Build up the capacity – Resources & Technology

X-ray and E-beam are complementary technologies

Different customer profile, with different products…



Each case has a preferred configuration

Is X-ray viable? Many parameters to consider…

- Some info:
  - For Medical devices:

Min dose	25 kGy	Average product density	0.15 g/cm3

*8000h; 0,1$/kW	210 kW	540kW
Electricity costs [$/h]	[40 – 60]	[90 - 110]
Throughput [m³/h]	[2 – 4]	[6 – 10]
$/m³	[60 - 130]	[30 - 60]

  - At 100kW Opex are spread as follow:
    - 25% Elec, 55% Labor, 20% Others
  - At 500kW Opex are spread as follow:
    - 60% Elec, 25% Labor, 15% Others

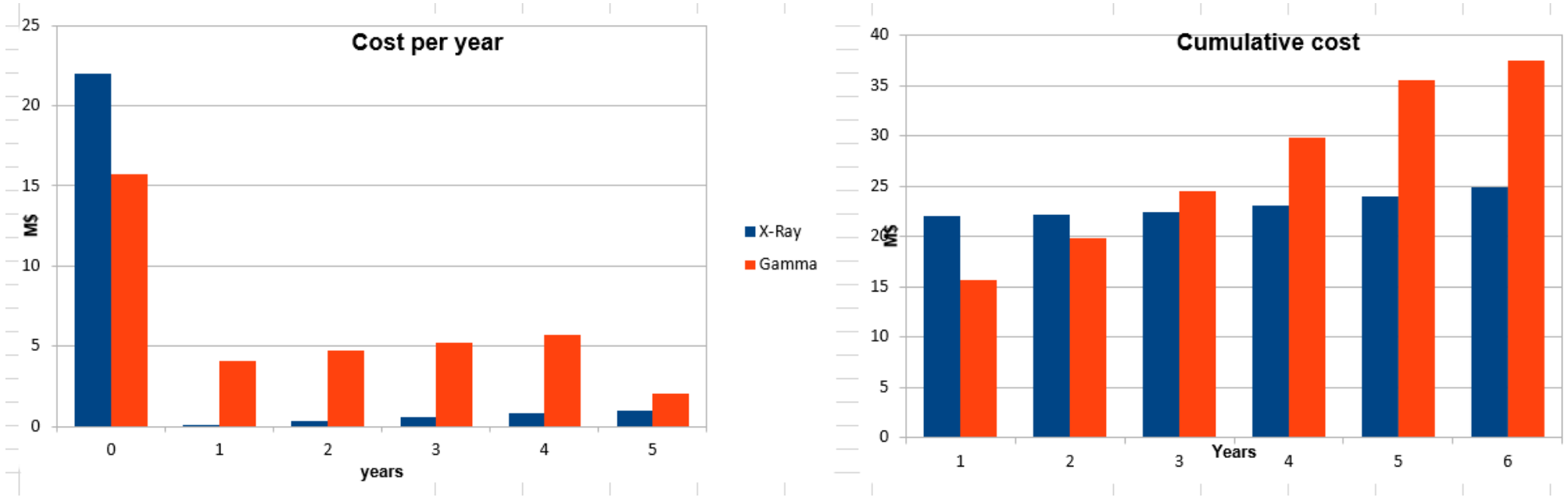
- Some question:

For a 200 kW to 500 kW X-ray facility, Over a period of 10 years, what's the **impact on the cost per m³** of:

- A CAPEX increase of $ 5M ?
  → **$2 to 3**
- A extension of the ramp-up period from 3 to 7 years?
  → **$5 to 15**
- An increase of the kW/h from 0.1 to 0.2?
  → **$10 to 15**
- Running the plant in 2 shifts instead of 3 shifts?
  → **$15 to 35**

X-ray versus Gamma – Is the Capex higher?

- For a 5MCi equivalent



Hurdles to adoption

- **Real** hurdles
  - Existing gamma infrastructure
  - Lack of x-ray infrastructure
  - Lack of experience within medical device companies
- **Perceived** hurdles
  - Regulatory hurdles – standards already exist, FDA has pathways for transition
  - Experience with equipment - Daniken has been running 10 years, x-ray uses e-beam which has been in use decades more

Keys to success

- Leverage existing infrastructure where possible
  - Ramp up machine source with decay
- Leverage multiple modalities when possible
  - Use e-beam for efficiency
  - Use x-ray for products that can’t be treated in e-beam due to penetration
- Compatibility needs to be established
  - X-ray will be gamma compatible 99.99% of the time
  - E-beam may have differences in material properties and heating

What is happening today

- X-ray capacity is being built in Europe and North America
  - Multiple sites will allow for more adoption vs single source
  - More opportunities for product testing
- Mevex and IBA are investing in new technologies and capacity in order to meet current and future demand for equipment
  - Risk is mitigated because high power solutions already exist or are built on existing platforms
  - Industry “ramp-up” requirement due to lack of cobalt availability is matched by Mevex and IBA capabilities

What are we doing as an industry?

- Support collaborations like Team Nablo (IBA and Mevex both members)
- Partnering with service providers to make more testing facilities/resources available
- New guidance being written on transitions between radiation modalities through AAMI WG2
- Follow up from Kilmer collaboration on Modality Changes and Process Optimization
    - Support for publications
    - Identify training gaps and opportunities
    - Provide support for FDA tools
- FDA challenge to spur alternatives to EO

Conclusions

- The market has spoken – e-beam and x-ray capacity is growing
- There is a value proposition for each sterilization technology, but availability trumps economics in a supply constrained market
- The transition is happening now – and we can all help to make it easier

THANK YOU

Where can I learn more about e-beam and x-ray?

- ASTM Dosimetry workshop, June 21-25 2020, Prague, CZ www.astm.org/E61_June_2020_Workshop
- Texas A&M eBeam Workshop, College Station, TX ebeam-tamu.org/ebeam-workshop
- Riso High Dose Reference Laboratory Course – Validation and Process Control for EB Sterilization, September 2019 www.nutech.dtu.dk/english/products-and-services/industrial-dosimetry/hdrl/hdrl_courses/
- GEX training workshops – www.gexcorp.com
- STERIS Education and Events www.steris-ast.com/education-and-events/
- Sterigenics and Nelson Labs training sterigenics.com/events/,
- IMRP (International Meeting on Radiation Processing), 2021 Bangkok, Thailand imrp-iia.com/
- iia Membership/ website www.iiaglobal.com

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