PROTECT +
ENHANCE +
SAVE LIVES

IBA Industrial Sterilization Solutions

Radioactive Sources: Applications and Alternative Technologies

National Academy of Sciences

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INDUSTRIAL SOLUTIONS

Basics: Gamma vs E-beam vs X-ray

- All three modalities sterilizes via ionizing radiation
- Electrons are the source of energy deposition for all three modalities
- Accelerator based radiation is on-demand and directional
- E-beam has a lower characteristic penetration -> treats boxes, not pallets
- Gamma and E-beam have a long history of use for sterilization
  - First high-power x-ray sterilization facility commissioned 2011

	Electron Beam	X-rays	Gamma Rays for Co-60
Power Source	Electricity	Electricity	Radioactive isotope
Switch on-off	Electric on-off	Electric on-off	Not possible, half-live 5.27 years
Charge	1.6×10^{-19} coulombs	None	None
Emission Characteristic	Unidirectional beam, can be scanned and bent by magnets	Forward peaked	Isotropic
Penetration	Finite Range (build up and drop off) ≈ 35cm at density 0.1 g/cm³	Exponential attenuation Full pallet treatment possible	Exponential attenuation Full pallet treatment possible
Dose Rate	Up to 360,000 kGy/hour (in box load)	Up to 30,000 kGy/hour (in small volumes) Up to 60 kGy/hour (in pallet load)	Up to 10 kGy/h (in pallet load)
Heat Development	Room temperature is ambient Product temperature rise 5K for 10kGy (polymers)	Room temperature is ambient Product temperature rise appr. 5K for 10 kGy (polymers)	Room temperature is warm, appr. 30°C Product temperature rise appr. 5K for 10 kGy (polymers)
Average Dose Homogeneity (DUR)	1.4 to 2.8 for 2-sided box treatment	1.2 (boxes, totes) 1.4 (pallets)	1.3 (tote) 1.5 (pallets)

***Galloway, R., C. Malice, G. Massaro, and J. Mittendorfer (2021) X-ray's at service of health, security and environmental challenges** Ionizing Radiation Technologies: Managing and Extracting Value from Food and other Industrial Wastes (eds. Shima Shayanfar and Suresh D. Pillai) Wiley (in press)*

IBA Rhodotron® – Platform Enablers

New TT50

2.0 to 10MeV
20kW
352MHz – 1.3m ∅
Pulsed
Efficiency ~20%

TT100

2.5 to 10MeV
40kW
215MHz – 1.6m ∅
Continuous wave
Efficiency ~20%

TT200/TT300

2 to 10MeV
100kW/245kW
107.MHz – 3.0m ∅
CW or pulsed
Efficiency **>25%**

TT1000

2 to 7MeV
560kW
107.5MHz – 3.0m ∅
CW or Pulsed
Efficiency **>50%**

High Energy

Up to 40MeV
125kW
107.5MHz – 3.0m ∅
Pulsed
Efficiency ~30%

Examples of IBA E-beam and X-ray Configurations

E-beam
Rhodotron
10 MeV E-beam

Boxes

E-beam top irradiation

X-ray
eXelis
5 or 7 MeV X-ray

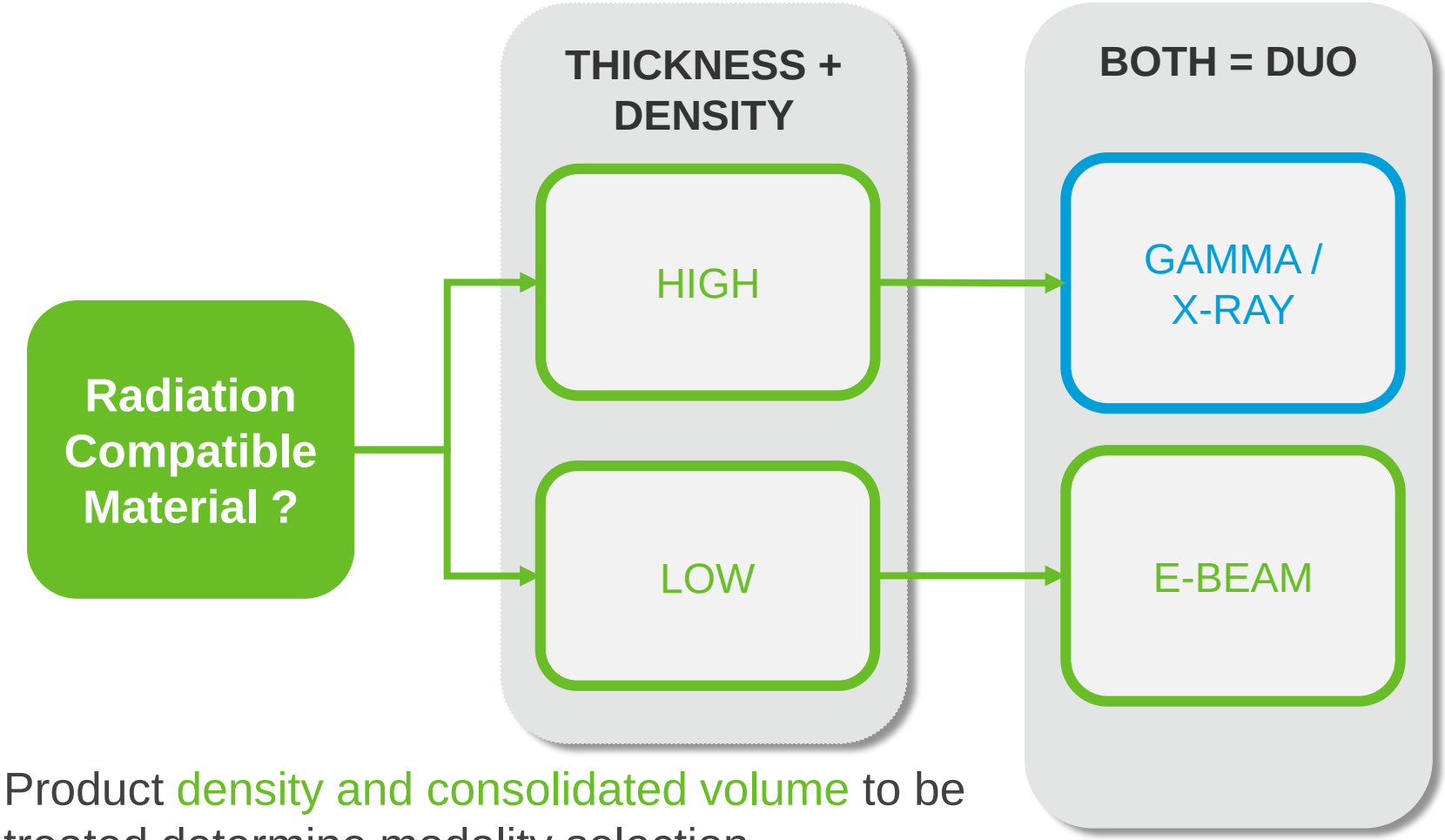
Pallets

X-ray lateral irradiation

E-beam + X-ray
Rhodotron Duo
10 MeV E-beam
+ 5 And/or 7 MeV X-ray
Boxes and pallets

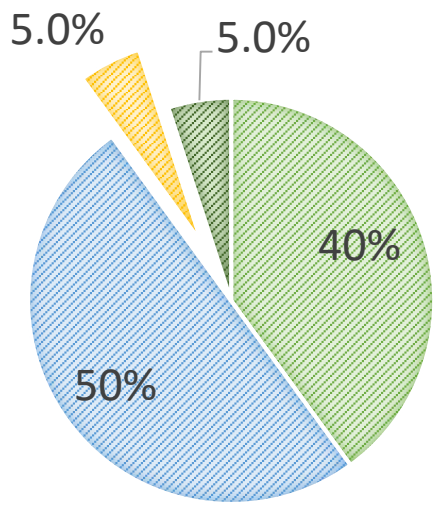
E-beam and X-ray top irradiation

Modality Selection

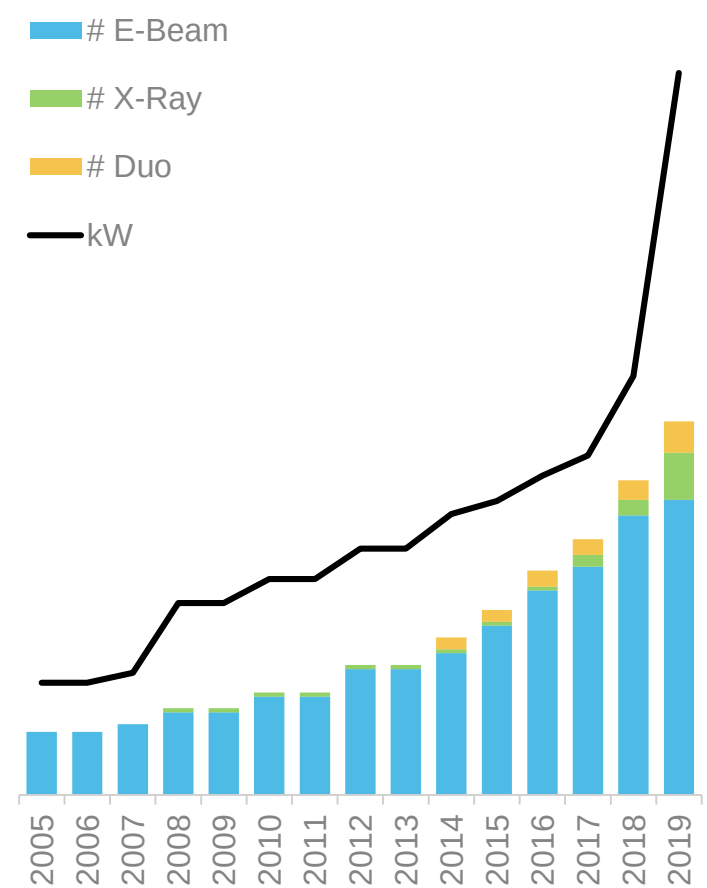


- Product density and consolidated volume to be treated determine modality selection
- Gamma and X-ray treat similar consolidated products

E-Beam & X-Ray adoption has accelerated over the last 5 years



- Global **cobalt scarcity** has led to increased prices and delays in product sterilization
- Strict regulations for cobalt irradiator licensing (safety concerns)
- **EtO** under **increased scrutiny**
- 5 to 7% global MD sterilization market growth
- Average yearly **E-beam and X-ray orders have tripled** since 2015

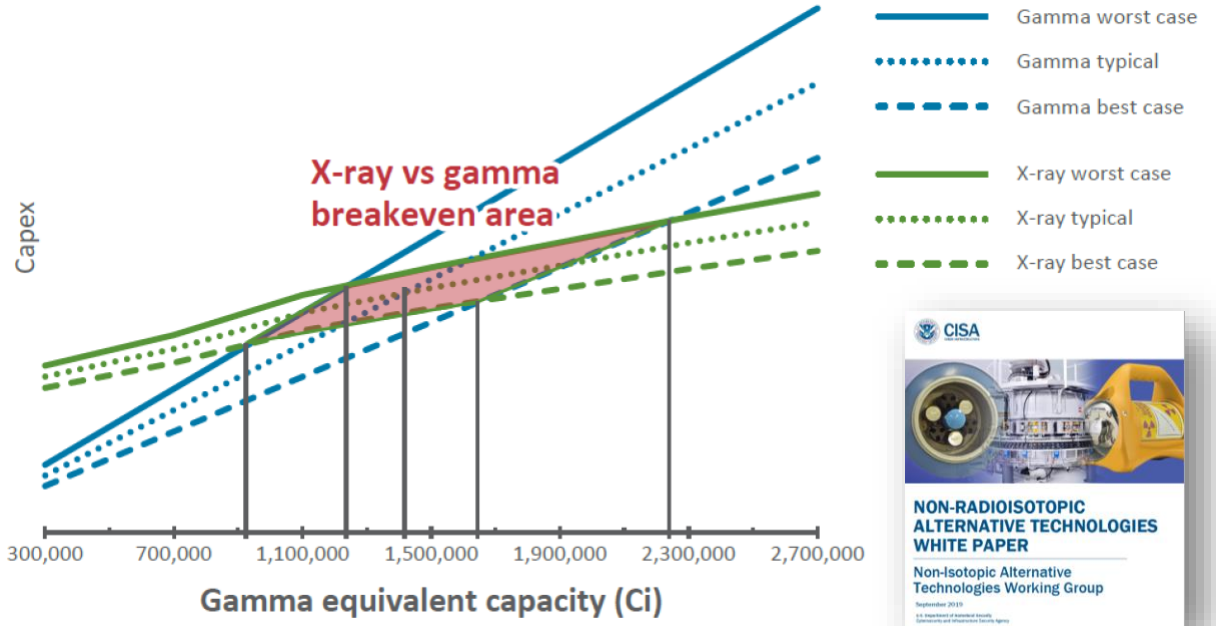


Cost of Sterilization

- Accelerator based sterilization is a cost competitive modality
  - *DHS White Paper at right*
- Cost of treatment is similar or lower than gamma
- Ability to treat higher volumes enables potential for greater ROI
- Reduces risk of ^{60}Co scarcity

Processing Costs

For example, one large, multinational medical device manufacturer, utilizes both in-house and contract sterilization services for its products, including gamma, e-beam, and EtO processing. It identifies similar processing volume and costs for gamma and EtO overall, although these costs vary significantly among processing locations, depending on the volume processed. Although the company only uses e-beam sterilization on a proportionally limited basis—for roughly a third of the volume as each of the other two technologies—it estimates that its e-beam processing costs per volume are roughly half of those for gamma and EtO. The company does not use x-ray sterilization for its products.



Challenges Holding Back Adoption

- Product qualification
  - An involved, costly process
  - Requires available testing facilities
- Regulation
  - Fragmented international regulation
  - Establishing gamma and x-ray equivalence
- Available information
  - Material effects
  - Operational guidance

IAEA
International Atomic Energy Agency
Atoms for Peace

Economical Feasibility of Transitioning from Gamma Sterilization to Accelerator-based Sterilization

REPORT OF A CONSULTANTS MEETING

IAEA Headquarters, Vienna, Austria

19 – 22 August 2019

4. RECOMMENDATIONS

- The IAEA should continue to provide platforms for sharing information and experiences on the use of all radiation modalities that are available for radiation sterilization of healthcare product. This could be done through:
- The IAEA should support Member States' initiatives to evaluate compatibility of existing products to all three technologies, in order to facilitate the transition from one technology to the other if required.
- The IAEA should support harmonization of existing standards and Member State regulation, for instance the acceptance of radiation processing using X-Ray technology with energy up to 7.5 MeV. This may be done by organizing technical meetings or workshops supporting studies in this area.

Where Government Could Help

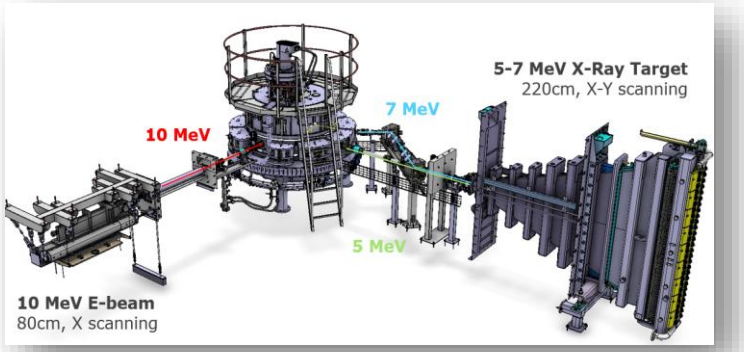
- Working to harmonize international regulations
- Facilitating product qualification
  - Material effect studies and publicly available data
    - NABLO ongoing through NNSA
  - Support for facility/facilities that would enable users to qualify products
    - Texas A&M E-beam research facility

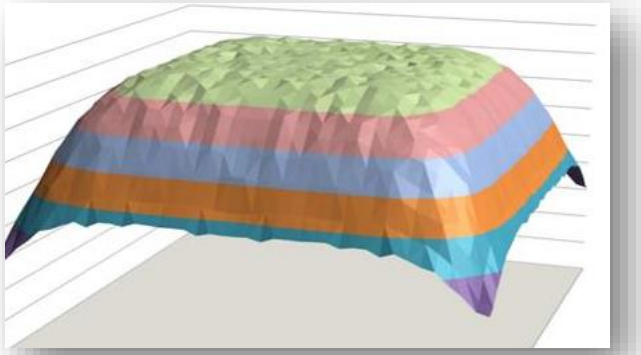
National Center for Electron Beam Research

National Center for Electron Beam Research

High power x-ray version?

Aerial – A Public/Private User Facility Model



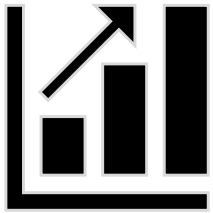


- **Example: FEERIX in Strasbourg, France**
  - 10 MeV E-Beam & 5, 7 MeV X-Ray, and low energy beams
  - Dose mapping
  - Material compatibility
  - Process optimization
  - Dosimetry study
  - Hands-on training

And a lot more…

Summary

Accelerator-based sterilization is a reliable, cost-competitive, industrialized process



Uptake of E-Beam and X-Ray over the last 5 years

Increase in cobalt prices brings down the capacity for break-even in X-Ray

Validating in X-ray is challenging and time consuming

What can be done to help adopters?