STERILIZATION METHODS & OVERVIEW

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Steri-Tek™
Expert Sterilization Services

GAMMA TECHNOLOGY

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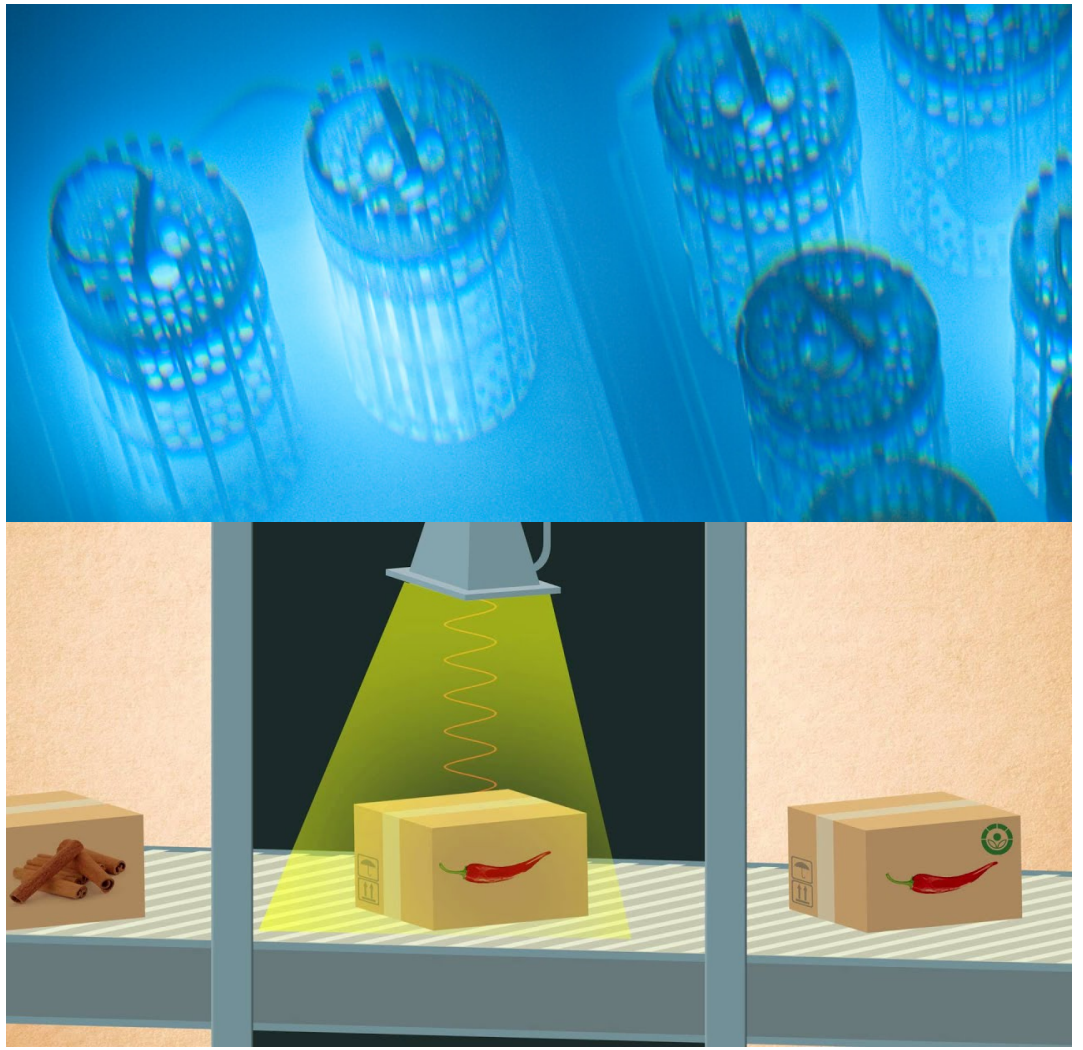
- Use of Cobalt-60
  - Produced through minimal carbon emission process using Cobalt-69, raw material
- Ionizing radiation in the form of gamma rays
- Around 60 years & about 200 large-scale commercial gamma irradiators are in operation in about 50 countries

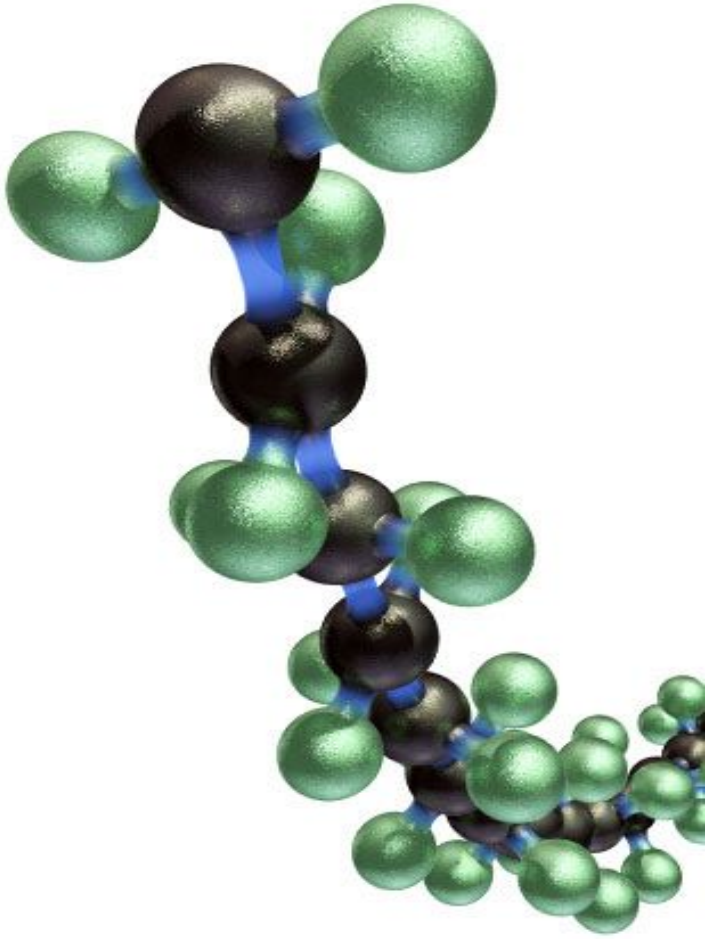
PHYSICAL DESCRIPTION

- **Energy:** measured at 1.17 MeV and 1.33 MeV
  - These high energy photons are emitted in all directions (isotopic)
  - High penetrating capability through materials
- **Power:** 1 MCi (curies) of Cobalt-60
  - Equivalent to 15 kW
- Not energetic enough to induce radioactivity in any material
- Cobalt-60, a radioactive material, needs to be replenished



SPECIFICATIONS

- Materials that are compatible with radiation
- Penetration of full pallets
  - Bulk density up to 0.40 g/cm^3
- Wide range of polymer compatibility
  - Some limitations due oxidation effects
    - PTFE and PVC
- Duration: < 24 hours typical but could process small batch quicker



ELECTRON BEAM TECHNOLOGY (E-BEAM)

ELECTRON BEAM TECHNOLOGY

- Through accelerated electrons
- Machine-generated electrons calibrated to a conveyor speed to achieve desired dose.
- Over 60 years, e-beam irradiation has made an essential contribution in meeting the sterilization needs for the global healthcare system
- Equivalent to or less expensive than gamma for certain products
- Quickest processing times

e^-

PHYSICAL DESCRIPTION

- **Energy:** relativistic speed and measured in MeV
  - 3 to 10 MeV
  - 10 MeV is typical energy since it provides the best penetration and dose uniformity.
- **Power:** product of the average electron beam energy (MeV) and the average beam current (mA)
  - Typically measured in kW
- Product materials may result in activation of radioactive isotopes
  - Not a significant concern using electron beam of 10 MeV or less

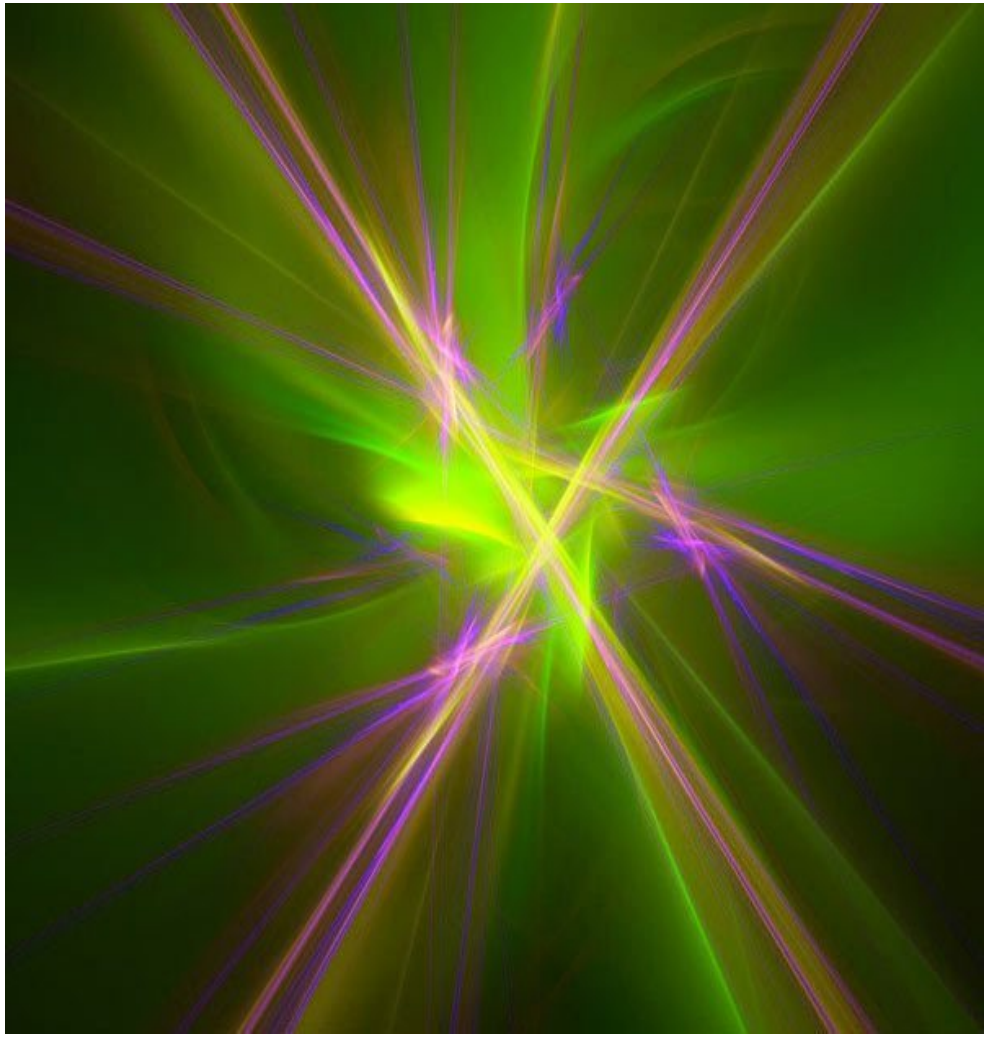
SPECIFICATIONS

- Materials are compatible with radiation
- Penetrate boxes with bulk densities up to 0.25 g/cm^3
- Wide range of polymer compatibility compared to gamma
  - Some limitation due to oxidation effects
- Duration: < 8 hours typical for smaller batches

X-RAY TECHNOLOGY

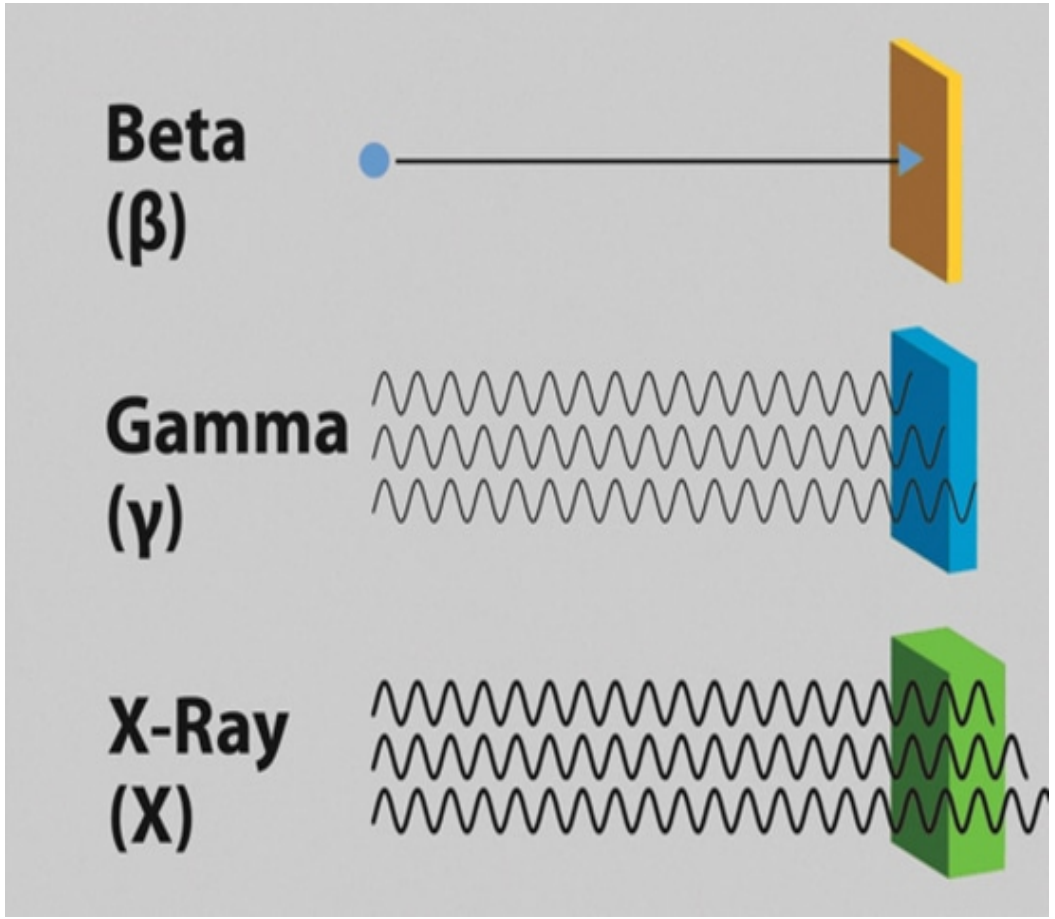
X-RAY TECHNOLOGY

- Available for several years, but first dedicated to sterilization was opened in 2010.
- X-ray uses electromagnetic energy (photons)
  - Wavelengths are similar to gamma
- Products sterilized by gamma radiation can be processed using x-ray technology
  - So as long as product characteristics are not affected by the increased energy level of x-rays
- < 5 facilities



PHYSICAL DESCRIPTION

- The heavier the element/product the greater the X-Ray's conversion efficiency
  - Very few plastics, while metal are very good X-Ray generator
- Deeper penetration than Gamma & E-Beam depending on energy
- 80 kW of more
  - Estimated 100 and 124 kW of beam power is 1 MCi Cobalt-60
- Smaller X-Ray systems with 30 and 40 kW



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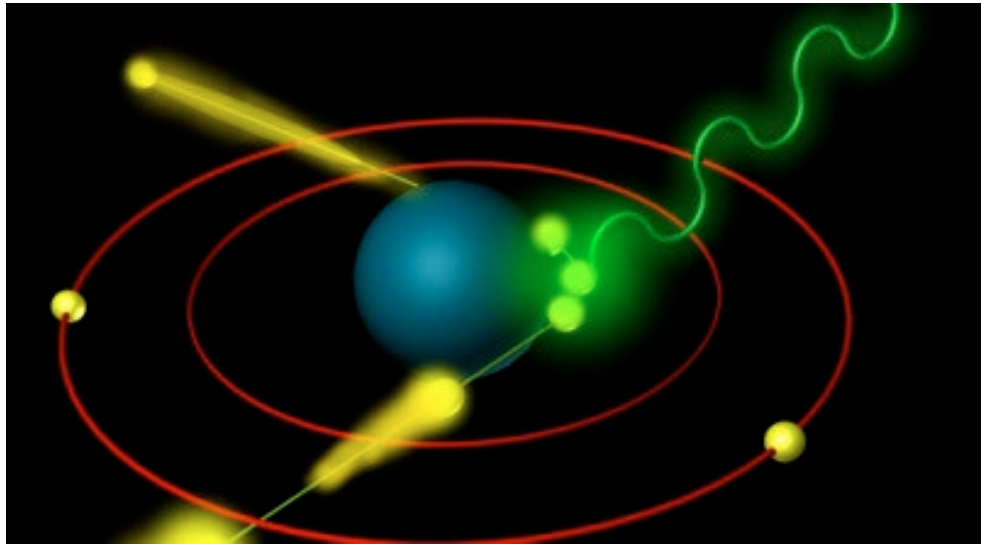
- Directional; Photons propagate from the converter in the same direction as the incident electrons.
  - Typically 10 MeV. Electron energy is related to their relativistic speed.

- Energy level for electron > 10 MeV -> induced radioactivity needs to be assessed, but < 7.5 do not cause significant activation



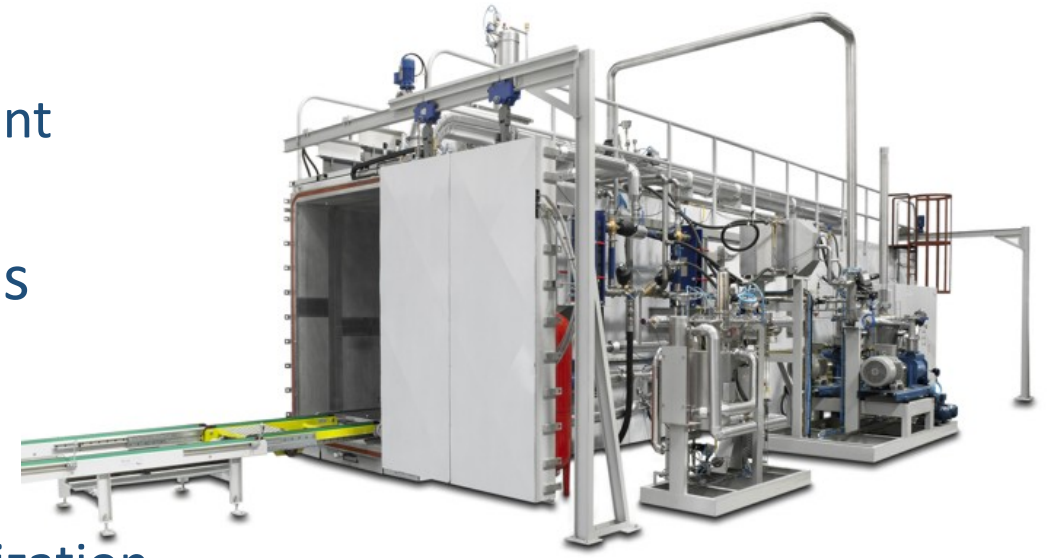
SPECIFICATIONS

- Materials are compatible with radiation, penetrate full pallets with densities up to 0.50 g/cm^3
- Wide range of polymer compatibility compared to gamma
  - Some limitations due to oxidation effects
- Duration: <24 hours typical but could process small batch quicker

ETHYLENE OXIDE TECHNOLOGY (EO)

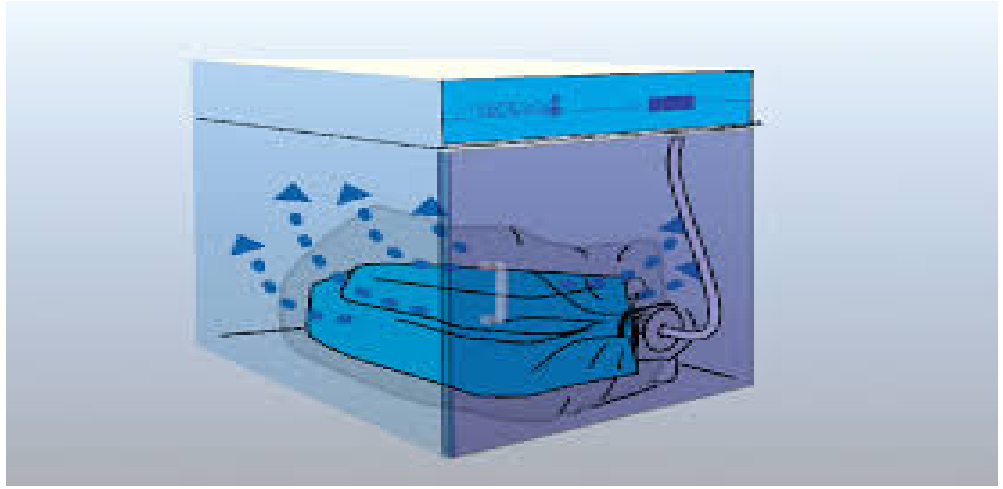
ETHYLENE OXIDE TECHNOLOGY

- Gaseous sterilization agent in the world
- Been around nearly 90 years
  - First patented 1928 by Cotton and Roark to prevent Japanese beetle dispersion.
- Highly effective at relatively low temperatures
- About 65 facilities
- Carcinogenic, volatile and explosive
  - Toxicity and byproducts cause limitation for sterilization
- Requires more employees to operate and maintain than other sterilizer.



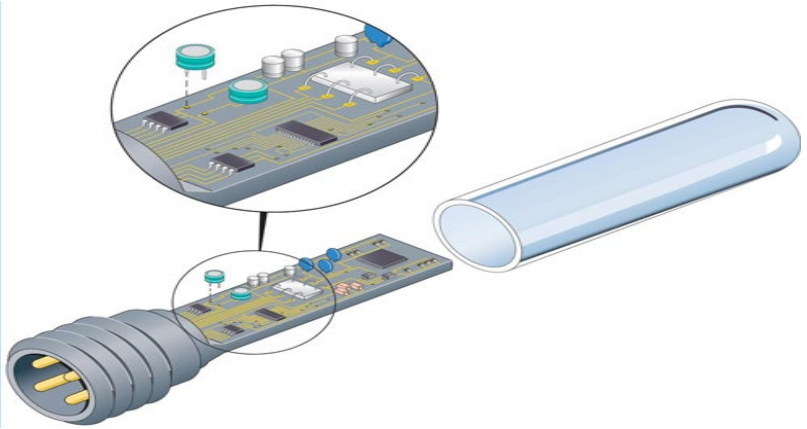
PHYSICAL DESCRIPTION

- Product exposed to EO penetrating gas
  - Defined moisture, pressure and temperature for a validated period or time
- Three phases:
  - Preconditioning
  - Sterilization
  - Aeration (1-7 days – allow desorption of EO and its by-products)



SPECIFICATIONS

- Package and all parts of product to be sterilized must be gas permeable (breathable), irrespective of density.
- Equipment with integrated-electronics
- Widest range of material compatibility
  - Except for moisture and temperature-sensitive materials
    - <30^{o}C and/or <30% RH (relative humidity)
- Pallets or boxes
- Duration: 1-7 days typical



REGULATORY

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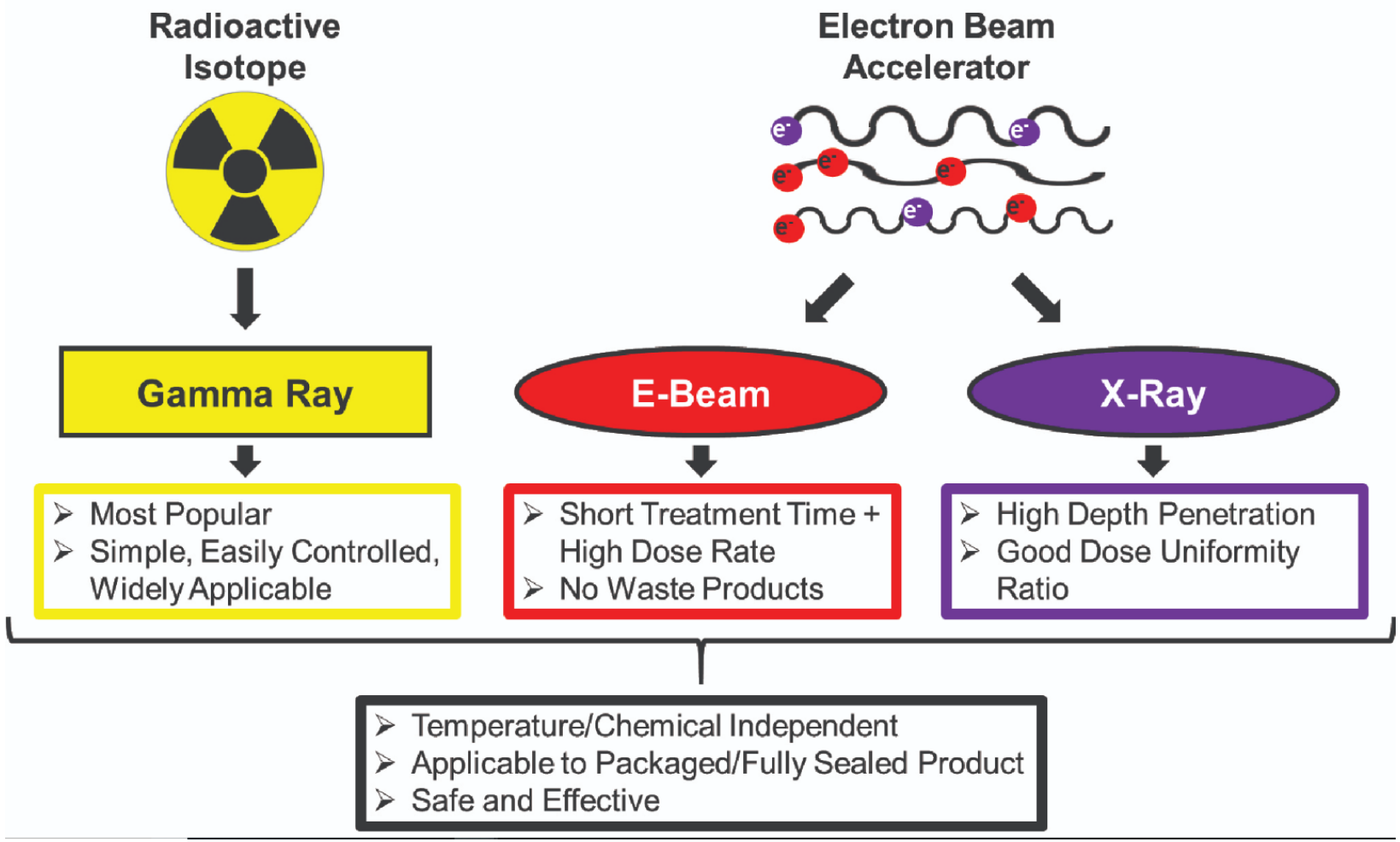
- Gamma, E-Beam, X-Ray (Radiation-based Sterilization):
  - Control of product manufacturing processes to ensure consistency with the validated radiation process
  - Validation requirements and methods are well described in ISO 11137-1
- EO (Gas-Based Sterilization):
  - Control of product manufacturing processes to ensure supply of material is consistent with the validated EO process
  - Compliance of the process parameters (time, temp, etc.) to the validated process specification

SUMMARY



EO Gas

> Versatile material compatibility

http://large.stanford.edu/courses/2018/ph241/goronzy2/

THANK YOU

Q&A

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