Electron and X-ray Sterilization of Medical Devices

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Electrons and X-rays

- Overview of x-ray and e-beam; how is it different from gamma?
- Typical or representative devices sterilized with these modalities and material compatibility with this modality
- Description of the industrial infrastructure needed for e-beam and x-ray?
- What is the potential of accelerator technology in this area?
- Can x-ray/e-beam be an alternative to ethylene oxide sterilization?
What are we talking about?

- Ionizing Radiation
  - Electrons – directly ionizing radiation
    - Electrons do ~99.5% of the killing
  - Photons – indirectly ionizing radiation
    - X-ray and γ refer to how the photon is produced
    - But once produced, they are just photons
    - Photons have the penetration power, but electrons do the work
      - Compton Scattering
Photons – X-ray vs γ

• γ rays originate from the nucleus of an atom

• X-rays originate from transitions in the electrons from an atom or Bremsstrahlung

• Both are electro-magnetic energy
Photons – X-ray vs γ

• Caveat
  – γ rays are more monoenergetic
  – X-rays (Bremsstrahlung) have a spectra of energies

• Fundamentally, a photon is a photon
• (and an electron is an electron)
Remember – the electrons are the active ingredient!
The penetration characteristics of x-ray can be exploited to give better DUR.
Generating x-rays will always incur a significant inefficiency. Overcoming this requires high-power electron beams.
Generating X-rays

Much more directed than gammas from a cobalt array. Better utilization.
(Only ~ 30% of gamma rays are utilized)
What can be sterilized with E-beam and X-ray?

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Transitioning from Cobalt-60 to E-beam or X-ray for Sterilization – a Model for Collaboration

Presented at Fermilab on September 19, 2019

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8Johnson & Johnson, Raritan, NJ, USA
9Sterigenics Corp., Stittsville, Ontario, CANADA
Project Goals

- **Identify specific polymers/elastomers** used in medical products that present the greatest data gaps for radiation effects and would be of greatest industry impact if transitioned to e-beam or X-ray.
- **Measure any physical effects** that these materials exhibit when they are given sterilization-level radiation doses from e-beam or X-ray.
- Determine **whether these effects would preclude the use of E-beam or X-ray** for associated medical products.
- **Execute an industry and public outreach** component that will identify and fill knowledge and education gaps that impede the transition to E-beam and X-ray sterilization.
- **Encourage increased use of E-beam and X-ray** for sterilization of single-use medical products.
Five Selected Medical Products

- **#1**: Becton-Dickinson *Vacutainer™* tube.
  - Ultrahigh production volumes for the blood collection market at >5B products/year.

- **#2**: Becton-Dickinson *Vacutainer™* “Push Button” blood collection set.
  - Significant production volume for the blood collection market at ~260M products/year using multiple polymer families.

- These BD products involve over 6 separate polymers.

- All test measurements recently completed for these BD products.
The data indicate that Yellowness Index changed as much as 20 units for some polymers for the 0-90 kGy dose spread in the study; however, there was little to no discernible trend in the yellowness index between Cobalt-60, E-beam and X-ray samples.

Yellowness Index vs. dose for all 3 irradiation modalities.
Infrastructure

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Required Infrastructure

• Reliable electrical power
• Material handling systems are very similar
• Dosimetry, process control, etc. very similar
• Accelerator manufacturers report that on-site technical staff requirements are not significantly higher than gamma facilities
  – Technical skills required similar to well qualified auto mechanic
• Similar or slightly thicker shielding
  – But volume of irradiation room can be much less
  – Less total concrete?
• Less attractive target
Contract Electron Beam Facilities
Future potential

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Power

• 1 Mci = \(3.7 \times 10^{16}\) decays/second
  – Total energy released – 2.505 MeV/decay
  – 15 kW
  – Typical irradiation bunker – 30-60 kW of “beam” power

• Electron beam machines can provide this easily

• X-ray must overcome inefficiency of Bremsstrahlung process
  – 200 – 400 kW of electron beam power
  – Then must include efficiency of electron beam production
Capacity comparisons

• Gamma
  – ~10 kGy/hr
  – 3.4 m$^3$/h/MCi @ 25 kGy

• Electron Beam
  – ~20 MGy/hr

• X-ray
  – ~60 kGy/hr
  – 2.8 m$^3$/h/100 kW @ 25 kGy (including target losses)

1 MCi gamma ≈ 120 kW electron beam power to provide equivalent X-ray dose
Potential Accelerator Technology

- Linacs 10 – 50 kW
  - New machines being designed to > 100 kW
- Cyclotrons and Rhodotrons 50 - 350 kW
- Superconducting Linacs in development
  - 250 kW +
  - Direct equivalency to panoramic gamma irradiators
Alternative to EO?

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E-beam and X-ray as an alternative to EO

• Very similar to gamma as an alternative to EO
• Difference
  – Irradiation times are shorter with E-beam and X-ray
  – Less time for oxidative processes to occur

• Device manufacturers decide on sterilization modality
  – Education
  – Early planning in device design process can facilitate the use of alternative modalities
  – More “difficult” for established devices
Thank you
All materials have the same stopping power (scaled by density) between 1 and 10 MeV.