

Sterilization
Methods
Overview



SteriTek
Expert Sterilization Services

Electron Beam Technology

E-Beam

Technology

Through accelerated electrons

Machine-generated electrons calibrated to a conveyor speed to achieve desired dose

Equivalent to or less expensive than gamma for certain products

Quickest processing times

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 compatible with radiation



Penetrate boxes with bulk densities up to 0.25g/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



Technology

Available for several years, but first dedicated to sterilization was opened in 2010

X-ray uses electromagnetic energy (photons)

- Wavelengths similar to gamma

Products sterilized by gamma radiation can be processed using x-ray technology

- So 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

80kW or more

- Estimated 100 and 124kW of beam power is 1 Mci Cobalt-60

Smaller X-Ray systems with 30 and 40kW

Directional; Photons propagate from the converter in the same direction as the incident electrons

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

Gamma Technology



Technology



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 and 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 (isotropic)

High penetrating capability through materials



Power: 1 MCi (curies) of Cobalt-60

Equivalent to 15kW



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 to oxidation effects
 - PTFE and PVC

Duration: < 24 hours typical but could process small batch quicker

Ethylene Oxide Technology (EO/ETO)

Technology



Gaseous sterilization agent in the world



Been around nearly 90 years

Frist patented in 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 limitations for sterilization



Requires more employees to operate and maintain than other sterilizer

Physical Description

Product exposed to EO/ETO 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/ETO 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°C and/or <30% RH (relative humidity)



Pallets or boxes



Duration: 1-7 days typical

Regulatory

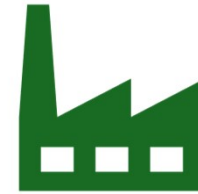
Regulatory



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 ISO11137-1



EO/ETO (Gas-Based Sterilization)

Control of product manufacturing processes to ensure supply of material is consistent with the validated EO/ETO process

Compliance of the process parameters (time, temperature, etc.) to the validated process specifications

Thank you

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