



# SteriTek

Expert Sterilization Services



# Company Background

Steri-Tek was formed by employees from Nutek, an E-beam facility that had been established for 25 years

They have over 100 years of experience in the E-beam industry

Our flagship facility is 42,000 sq. ft. and located in the SF Bay Area in Fremont CA providing e-beam sterilization

The newest 100,000 sq. ft. facility is in Lewisville, TX

# Certificates & Licenses

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ISO 11137

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ISO 13485

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DEA Manufacturing Registration

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FDA Medical Device Manufacturing Registration

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FDA medical Drug Manufacturing Registration in

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State of California Medical Device Manufacturing License

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State of Texas Medical Device Manufacturing License

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State of California Drug Manufacturing License

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State of Texas Drug Manufacturing License

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MedAccred Accredited

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FDA Tissue manufacturing registration

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Japanese Ministry of Health



# Technology



10 MeV Linear Accelerator  
(2)



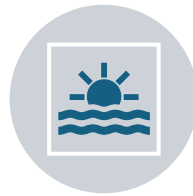
The Beams are mounted  
horizontally on either side  
of the conveyor



Redundancy – if one  
machine is out for  
servicing, the boxes are  
automatically rotated



20 KW in E-Beam (2) CA  
30KW in E-Beam (2) TX



80 KW in the X-Ray mode  
(2) TX



Mevex manufactures the  
most state-of-the-art  
machines in the industry



# E-Beam

Electrons are accelerated to about 99.7% the speed of light

10 million pound concrete bunker to contain the radiation

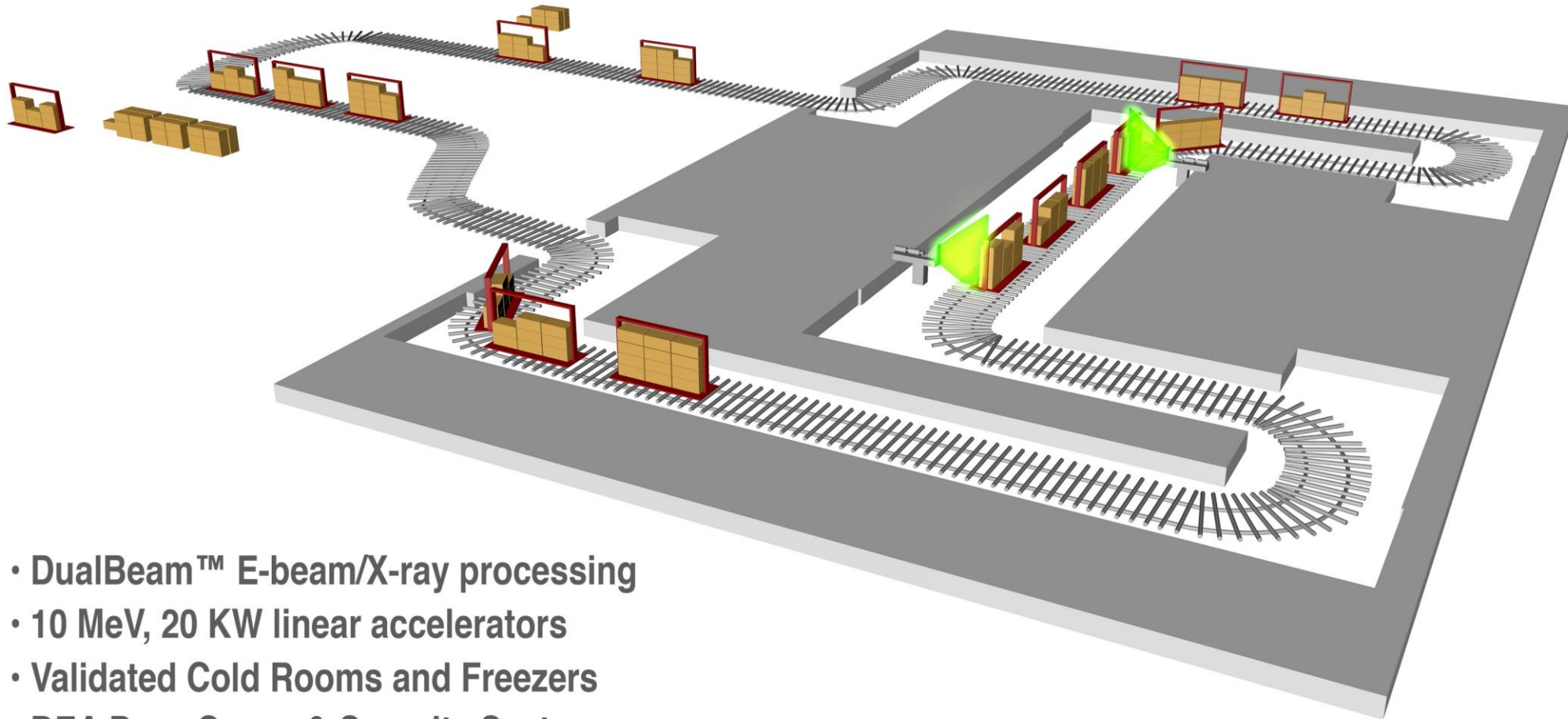
Conveyer system

- Product travels between 1 and 5 feet per minute past the beam
- Dual beam system

Penetration of 7.7 g/cm squared

Minimal exposure to Ozone





- DualBeam™ E-beam/X-ray processing
- 10 MeV, 20 KW linear accelerators
- Validated Cold Rooms and Freezers
- DEA Drug Cages & Security System



# Capabilities

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Scalable E-beam irradiation from one box to truckloads

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Ultra low dose processing down to 0.4 kGy

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Split dose processing

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Walk-in Freezers -16 to -26 C and -80

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Walk-in Refrigerator 2-8 C

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CryoTote for continuous cold processing

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Shielding

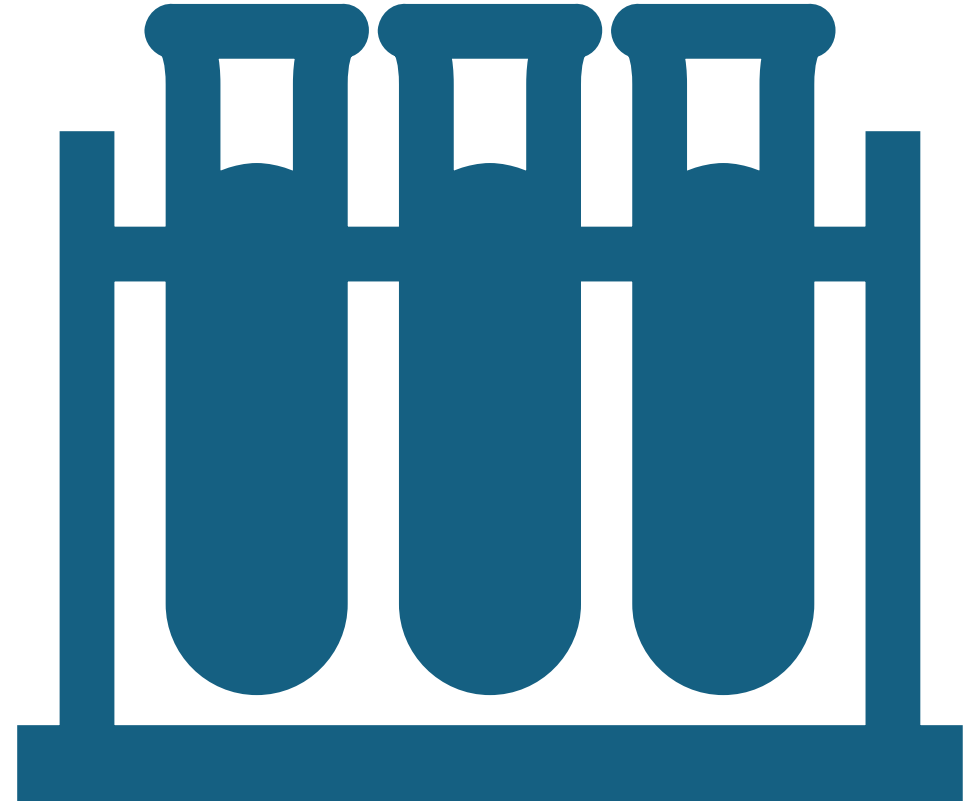
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Steri-Tek offers turnkey  
Sterilization Validation to  
claim Sterility

# Sample Requirements

- 30 samples (10 from 3 separate batches) for bioburden analysis/enumeration
  - 10 samples for single batch release
- 3 samples for bioburden recovery (any batch)
- 3 samples for bacteriostasis/fungistasis
- 3 samples for additional method development (dependent on lab)
- 10 samples for sterility
- 10 samples for confirmatory
- 2 shippers + 3 samples of dunnage/simulated material for dose mapping activities



# Sterilization Validation Steps (14- 20 weeks including dose map studies)

\*turnaround time subject to change



Protocol creation



R&D (research and development)



Microbiology testing



Dose map studies



Verification dose



Final report



# Microbiology Tests

Bioburden recovery

Bioburden enumeration/analysis

Bacteriostasis/Fungistasis

Sterility



# Dose Audit Requirements

4 quarterly for at least one year



Semi annual for at least one year



Annual



# Dose Audit Process



Protocol creation



Bioburden enumeration/analysis (10 unprocessed samples)



Verification dose/DVS (10 samples to be processed)



Sterility using the verification dose samples



Dose audit report



# Dose Map Studies

# Dose Map Study

- Conducted to develop a validated process to allow the customer to process their routine product and receive a certificate of irradiation
- Need a minimum 2 shippers of dunnage/simulated product in its final configuration
- A minimum of 3 separate passes in the same configuration utilizing a minimum of 3 sets of data to develop a validated process to run routine production
- Dose map report provides the maximum and minimum dose delivered to the product on routine processing



# Single Layer Dose Map Study

- Conducted to develop a validated process to allow the customer to process their verification doses and receive a verification dose certificate
- Need 3 samples of dunnage/simulated product
- A single pass utilizing a minimum of 3 sets of data to develop a validated process to establish a target dose to run verification doses
- Product may need SIP



# Dose Map Verification Study

- Conducted to ensure changes to the product, packaging, configuration, product count, etc. fit within the original validated product specification
- A single pass utilizing a minimum of 1 set of data to determine the dose conversion are within the conversion ratios of 95% confidence dose conversion ratios from the validated specification
- If the change cannot process within the original specification, a new specification can be generated by completing another Dose Map



# Dose Distribution Study

- Conducted to find the dose delivered to the product
- This is not a validated process and will not receive a certificate of irradiation
- This study will only receive a dose distribution study report
- A single pass utilizing a minimum of 1 set of data to determine the internal dose delivered to the product to establish an approximate internal dose range



# Routine Processing

## What we need



SERVICE ORDER  
FORM (SOF)



PRODUCT

## What you get

- Quick turnaround time
  - Standard turnaround 5 business days
  - 24hr RUSH at 2x standard pricing
  - 4hr/same day RUSH at 4x standard pricing
- Certificate of Irradiation (COI) for validated run
- Dosimetry report for R&D





THANK YOU