



Industrial Sterilization Technologies

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Steri-Tek™
Expert Sterilization Services

Radiation

Gamma

E-beam

X-Ray

Gas

Ethylene Oxide

Revox

Nitrogen dioxide

Moist and Dry Heat

Industries served by Radiation

Medical Device

Lab Supplies

Pharmaceutical

Biologics

Food

Industries served

continued

Crosslinking

- Material Modification
- Tubing/Cable

Scission

Food

- Meat/Fruits/Vegetables
- In 2018, 200 million eggs were recalled

Electronics

Industrial capacity

Radiation contract facilities	~	40
In-house facilities	~	15

All facilities are at or near capacity

Industrial demands

- The industries served are growing at about 5 – 10 % per year
- 3 to 6 facilities are needed to meet growth in demand
- Covid testing kits, vials and syringes are additional demands on the terminal sterilization market

In-House Facility

Designed
around specific
products

VS.

Contract Facility

Flexibility is a
key to success

Facility Layout



Separation of incoming and outgoing product

Floor plan for product flow

Design around building

Design for shielding and machines

Facility Layout

continued 2

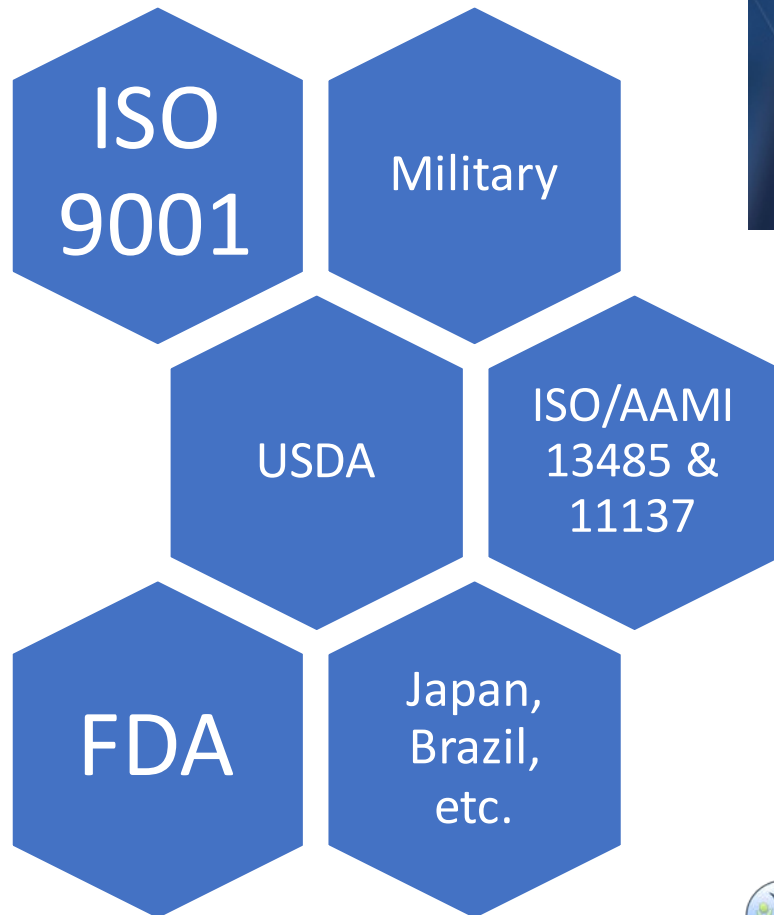
Presentation of the product to the beam:

- Horizontal vs. Vertical
- Single-Beam or Multiple Machines
- Rotating or Flipping Boxes

Conveyor

- Floor or Ceiling Mount
- Box Rotation Mechanism

Compliance Standards



Irradiation Services

Irradiation

Validation

Material Compatibility

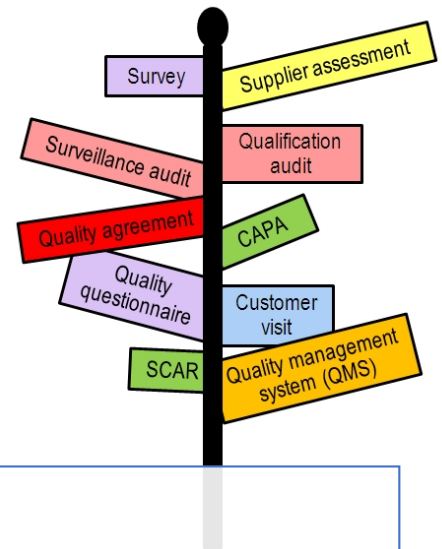
Material Testing

Innovation

- Cooling, split dosing, shielding, attenuation, etc.



IQ/OOQ/PO



Facility Validation

- Installation Qualification
- Operational Qualification

Process Qualification

- Customer Product Validation
- Dose Mapping → Dose Map Images

Facilities are audited by ISO, FDA, State, Japan, Customers

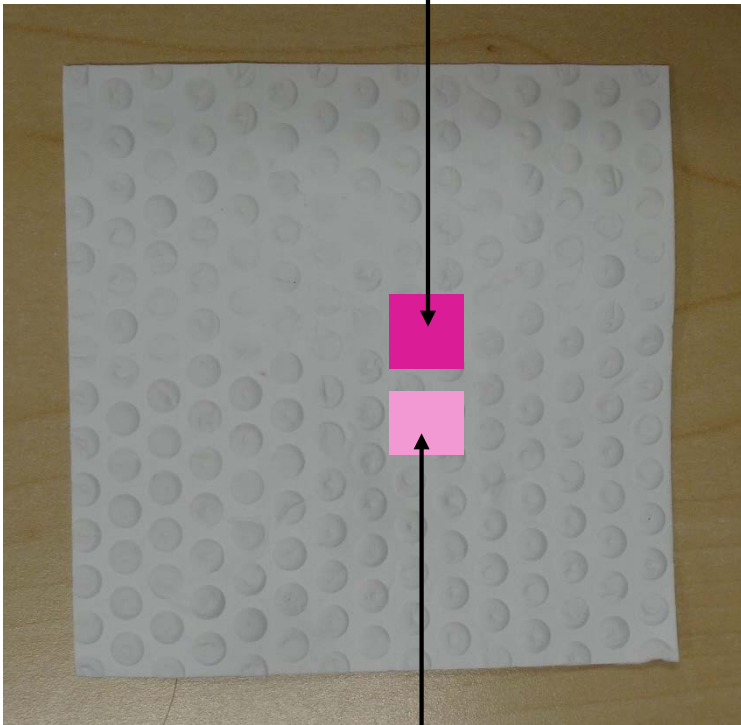
Process Qualification



- Determination of product loading pattern
- Product dose mapping
 - Dosimeters are placed throughout the packaging.
 - There are anywhere from 24 to 150 dosimeters, depending on the complexity of the device.
 - 3 passes are run to confirm the reproducibility of the process.

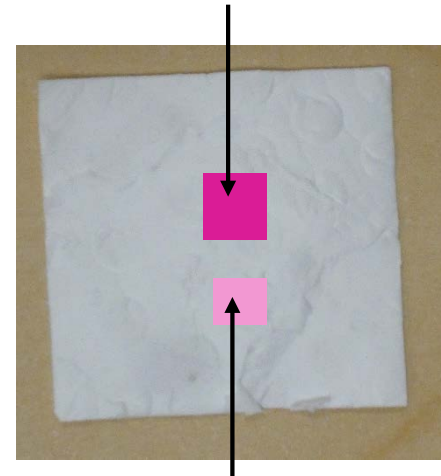
IQ/OOQ/PO

1. On center of Wound matrix - front

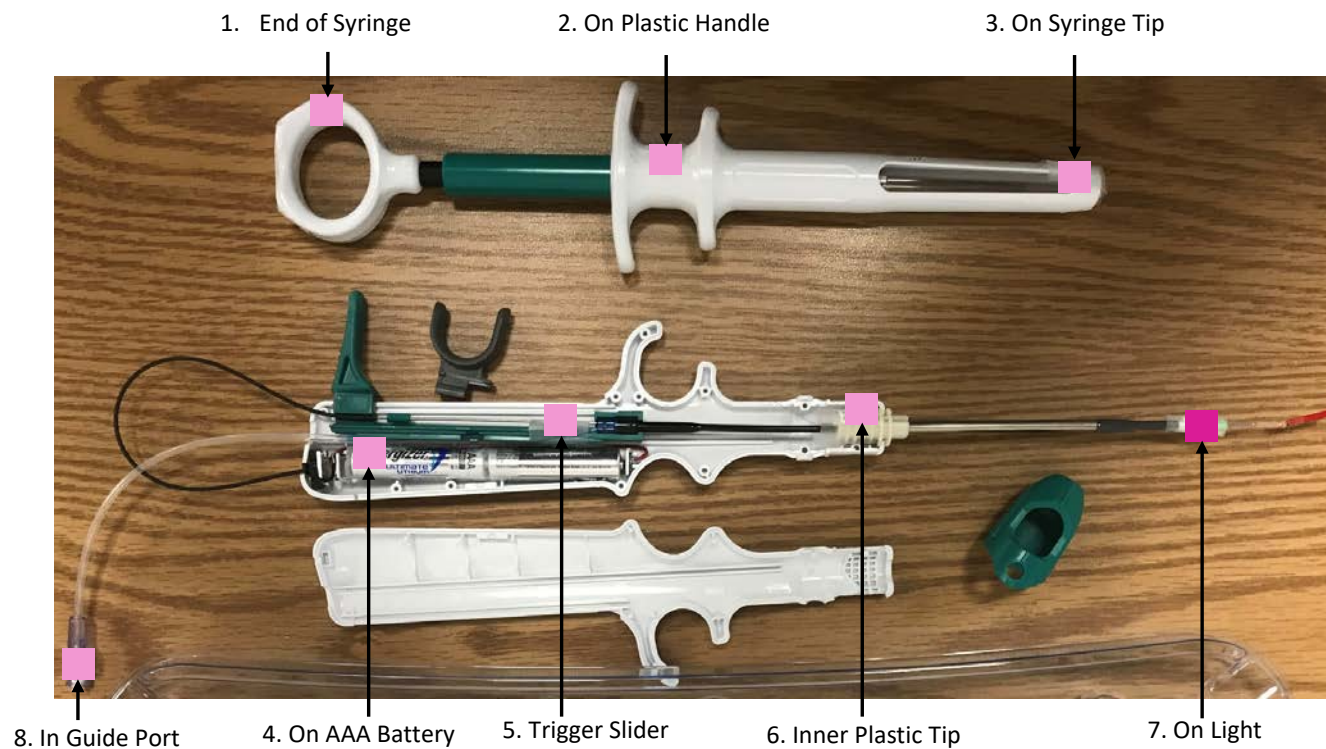


2. On back of Wound matrix

1. On center of Wound matrix - front



2. On back of Wound matrix



Outside - ■

Inside or hidden - ■



Dose Map Job #: 11929

Process Code #: INT04

Intersect ENT

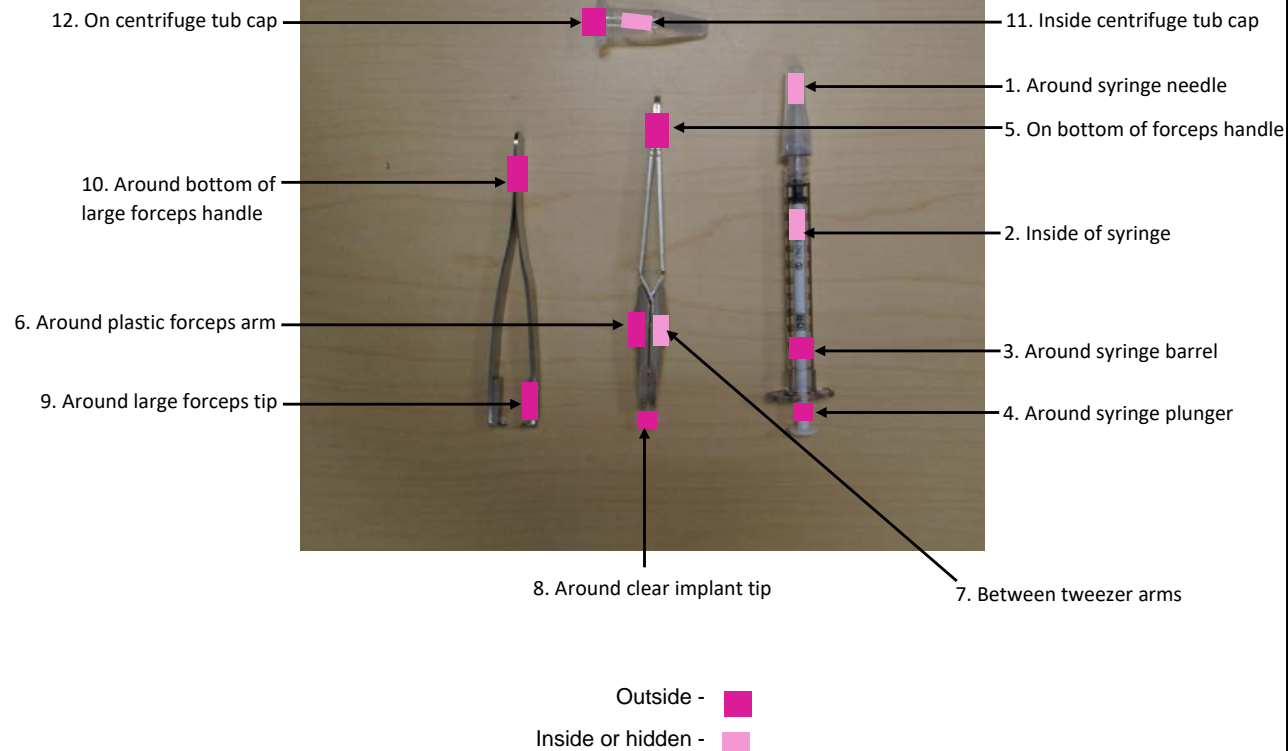
Figure 2a

UP Commercial System

Drawn By: _____

Approved By: _____





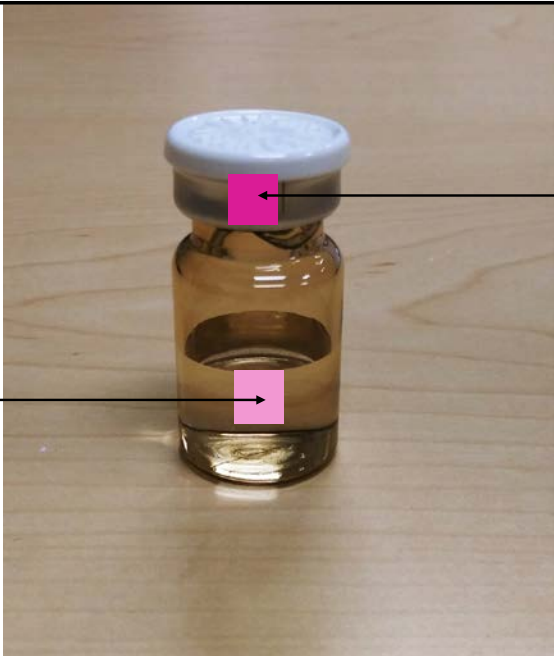


Dose Map Job #: 00445

Process Code #:


Figure 2

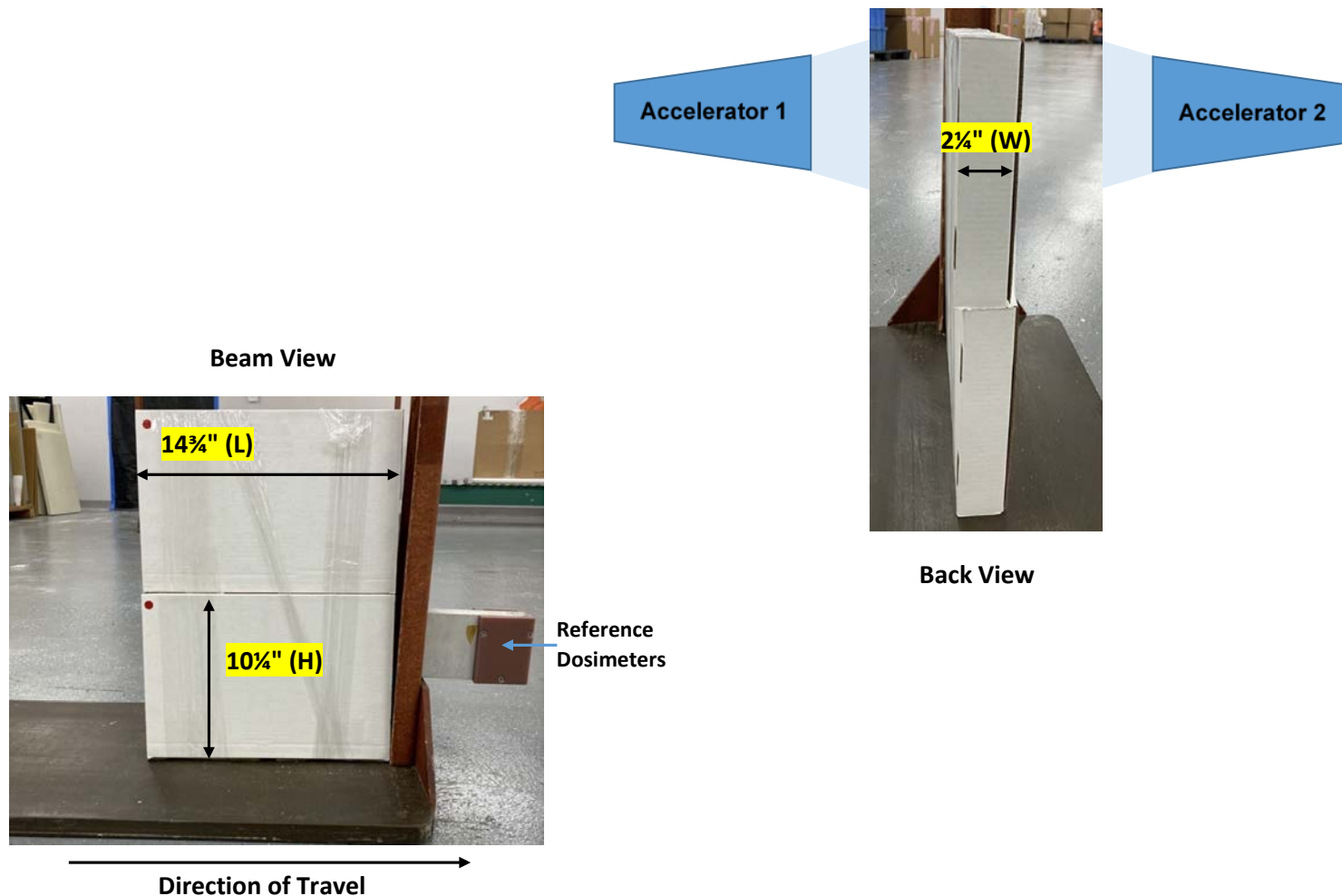
Drawn By: _____


Approved By: _____

<div><p>1. Outside on metal lid</p><p>2. Inside vial</p><p>Outside - </p><p>Inside or hidden - </p></div>			

10. Inside blister pack with pellet	5. Inside blister pack with pellet	1. Inside blister pack with pellet
10. Inside empty blister pack	5. Inside empty blister pack	1. Inside empty blister pack
<div style="border: 1px solid black; background-color: #4a86e8; color: white; padding: 5px; text-align: center;"> Box A contains empty blister packs. Box B contains blister packs with pellets. </div>		
		Outside - Inside or hidden -

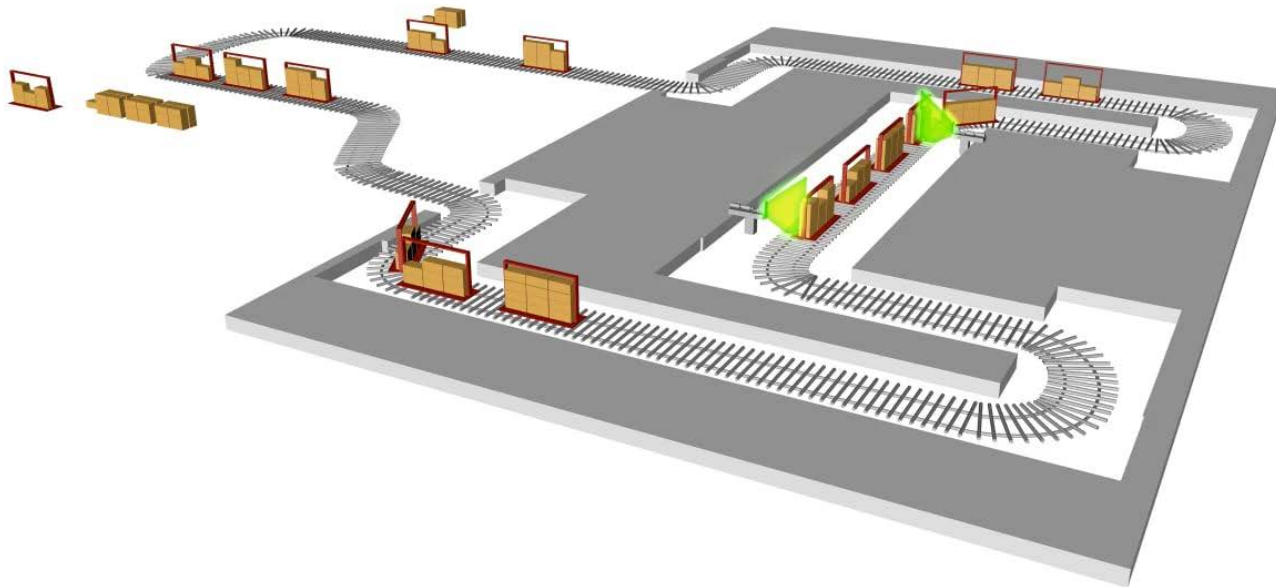
 Steri-Tek <small>Expert Sterilization Services</small>	Dose Map Job #:		Figure 2	Drawn By: _____
	Process Code #:			Approved By: _____



	<u>Job #:</u>		Figure 1b Drawn By: _____ Approved By: _____
	<u>Process Code #:</u>		

Process Qualification

- Routine processing of customer's product completes the process validation



THANK YOU

Q&A



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