SteriTek

Expert Sterilization Services

Routine Processing Overview

Service Order Forms Required – please see “SOF How To” or “DEA SOF How To” for help

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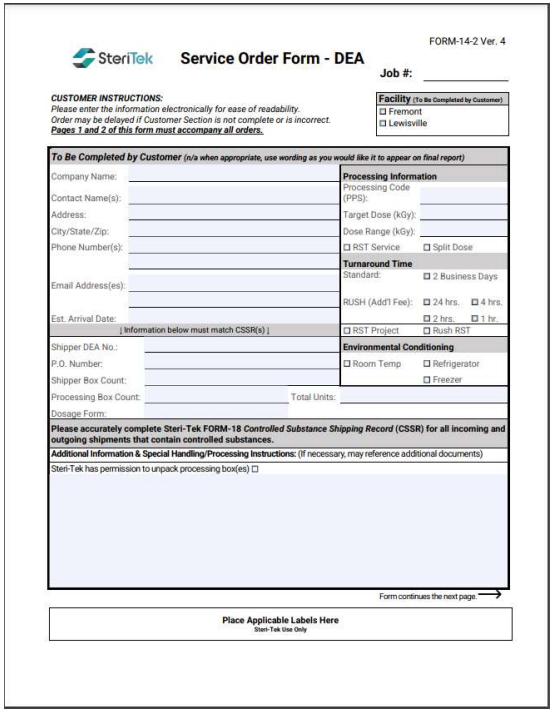
Expert Sterilization Services

SOF required for all Steri-Tek services



SteriTek **Service Order Form - DEA**

FORM-14-2 Ver. 4

Job #: _____

CUSTOMER INSTRUCTIONS:
Please enter the information electronically for ease of readability.
Order may be delayed if Customer Section is not complete or is incorrect.
Pages 1 and 2 of this form must accompany all orders.

Facility (To Be Completed by Customer)
☐ Fremont
☐ Lewisville

To Be Completed by Customer *(n/a when appropriate, use wording as you would like it to appear on final report)*

Company Name: _____
Contact Name(s): _____
Address: _____
City/State/Zip: _____
Phone Number(s): _____
Email Address(es): _____
Est. Arrival Date: _____

Processing Information
Processing Code (PPS): _____
Target Dose (kGy): _____
Dose Range (kGy): _____
☐ RST Service ☐ Split Dose

Turnaround Time
Standard: ☐ 2 Business Days
RUSH (Add'l Fee): ☐ 24 hrs. ☐ 4 hrs. ☐ 2 hrs. ☐ 1 hr.
☐ RST Project ☐ Rush RST

Environmental Conditioning
☐ Room Temp ☐ Refrigerator ☐ Freezer

↓ Information below must match CSSR(s) ↓

Shipper DEA No.: _____
P.O. Number: _____
Shipper Box Count: _____
Processing Box Count: _____ Total Units: _____
Dosage Form: _____

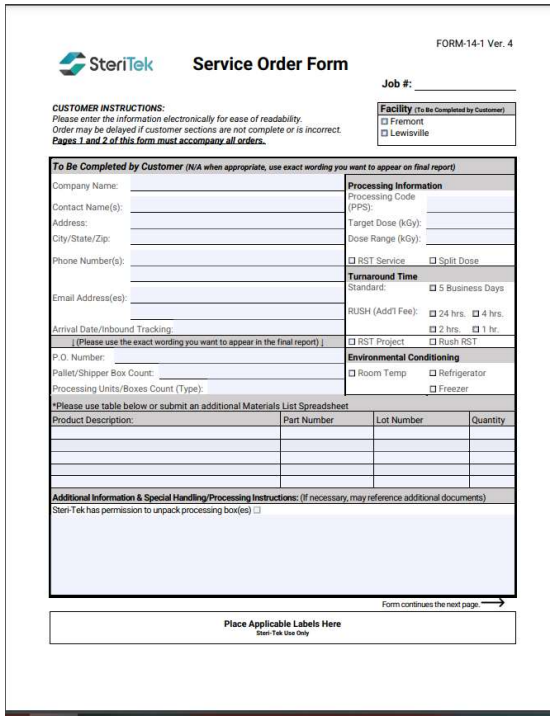
Please accurately complete Steri-Tek FORM-18 *Controlled Substance Shipping Record* (CSSR) for all incoming and outgoing shipments that contain controlled substances.

Additional Information & Special Handling/Processing Instructions: (If necessary, may reference additional documents)

Steri-Tek has permission to unpack processing box(es) ☐

Form continues the next page. ⟶

Place Applicable Labels Here
Steri-Tek Use Only



SteriTek **Service Order Form**

FORM-14-1 Ver. 4

Job #: _____

CUSTOMER INSTRUCTIONS:
Please enter the information electronically for ease of readability.
Order may be delayed if customer sections are not complete or is incorrect.
Pages 1 and 2 of this form must accompany all orders.

Facility (To Be Completed by Customer)
☐ Fremont
☐ Lewisville

To Be Completed by Customer *(N/A when appropriate, use exact wording you want to appear on final report)*

Company Name: _____
Contact Name(s): _____
Address: _____
City/State/Zip: _____
Phone Number(s): _____
Email Address(es): _____
Arrival Date/Inbound Tracking: _____

Processing Information
Processing Code (PPS): _____
Target Dose (kGy): _____
Dose Range (kGy): _____
☐ RST Service ☐ Split Dose

Turnaround Time
Standard: ☐ 5 Business Days
RUSH (Add'l Fee): ☐ 24 hrs. ☐ 4 hrs. ☐ 2 hrs. ☐ 1 hr.
☐ RST Project ☐ Rush RST

↓ (Please use the exact wording you want to appear in the final report) ↓

P.O. Number: _____
Pallet/Shipper Box Count: _____
Processing Units/Boxes Count (Type): _____

Environmental Conditioning
☐ Room Temp ☐ Refrigerator ☐ Freezer

*Please use table below or submit an additional Materials List Spreadsheet

Product Description:	Part Number	Lot Number	Quantity

Additional Information & Special Handling/Processing Instructions: (If necessary, may reference additional documents)

Steri-Tek has permission to unpack processing box(es) ☐

Form continues the next page. ⟶

Place Applicable Labels Here
Steri-Tek Use Only

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Routine Processing

What we need

SERVICE ORDER FORM (SOF)

PRODUCT

What you get

- Quick turnaround time
  - Standard turnaround 5 business days for devices/non-CS drugs
    - 2 business days for DEA customers
  - 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

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Validated vs. R&D

Validated Routine Processing

Product processing specification provided after dose map completion

- PPS: ###01, ###02, etc.
  - ### represents customers assigned code

Must match PPS exactly

- example provided

Results in a Certificate of Irradiation (COI) proving sterility

R&D (research and development)

General PPS for Fremont, CA: ###80

General PPS for Lewsiville, TX: ###80-T

- X-ray: ###80-X-T

No processing restrictions

Results in an external dosimetry report

Cannot be used to claim sterility

Target dose can be chosen with a dose range of +/- 10%. This is an external dose and the internal dose cannot be determined without internal dosimetry data

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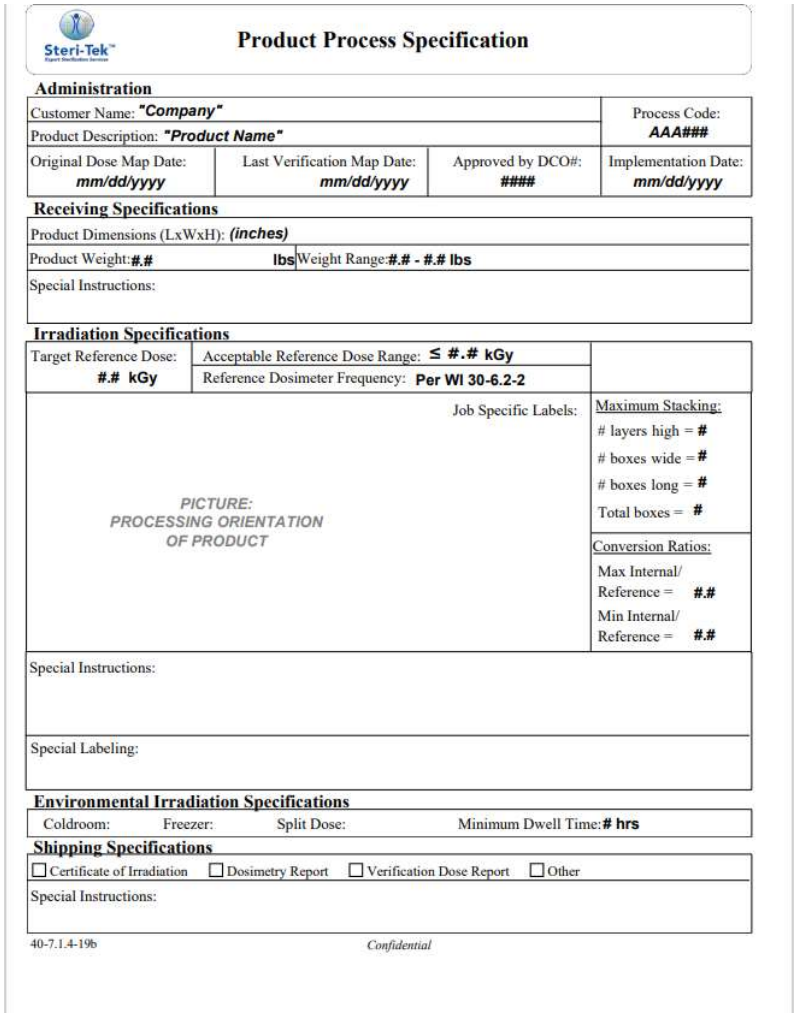
Product Processing Specifications

- Information submitted on the SOF MUST match the PPS
- If incorrect information, box dimensions, or box weight are received we will not be able to process your product as a validated run
  - Steri-Tek will contact you on how to proceed



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Product Process Specification

Administration

Customer Name: ***"Company"***			Process Code: ***AAA###***
Product Description: ***"Product Name"***			
Original Dose Map Date: ***mm/dd/yyyy***	Last Verification Map Date: ***mm/dd/yyyy***	Approved by DCO#: ***####***	Implementation Date: ***mm/dd/yyyy***

Receiving Specifications

Product Dimensions (LxWxH): ***(inches)***	
Product Weight: **#.# lbs**	Weight Range: **#.# - #.# lbs**
Special Instructions:	

Irradiation Specifications

Target Reference Dose: **#.# kGy**	Acceptable Reference Dose Range: **≤ #.# kGy** Reference Dosimeter Frequency: **Per WI 30-6.2-2**	
	Job Specific Labels:	Maximum Stacking: # layers high = **#** # boxes wide = **#** # boxes long = **#** Total boxes = **#**
PICTURE: PROCESSING ORIENTATION OF PRODUCT		Conversion Ratios: Max Internal/ Reference = **#.#** Min Internal/ Reference = **#.#**
Special Instructions:		
Special Labeling:		

Environmental Irradiation Specifications

Coldroom:	Freezer:	Split Dose:	Minimum Dwell Time: **# hrs**

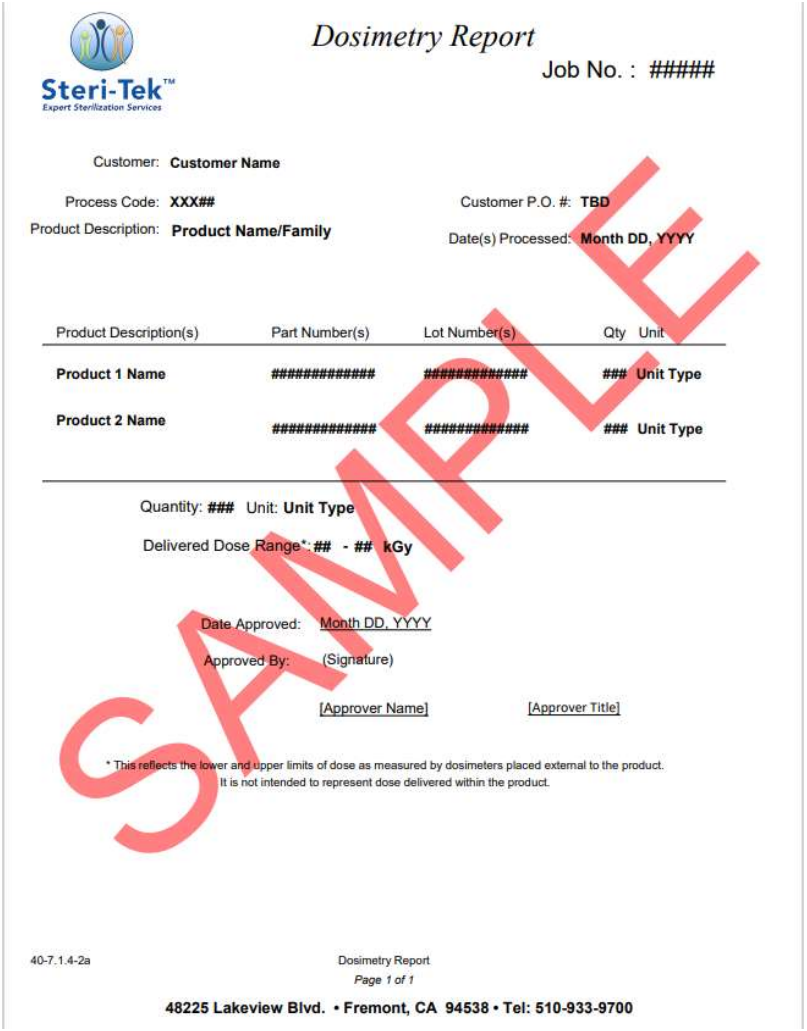
Shipping Specifications

☐ Certificate of Irradiation ☐ Dosimetry Report ☐ Verification Dose Report ☐ Other

Special Instructions:

40-7.1.4-19b *Confidential*

Dosimetry report provided after R&D/radiation tolerance study



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Dosimetry Report

Job No. : #####

Customer: **Customer Name**

Process Code: **XXX##**

Customer P.O. #: **TBD**

Product Description: **Product Name/Family**

Date(s) Processed: **Month DD, YYYY**

Product Description(s)	Part Number(s)	Lot Number(s)	Qty	Unit
Product 1 Name	############	############	###	**Unit Type**
Product 2 Name	############	############	###	**Unit Type**

Quantity: **###** Unit: **Unit Type**

Delivered Dose Range*: **## - ## kGy**

Date Approved: Month DD, YYYY

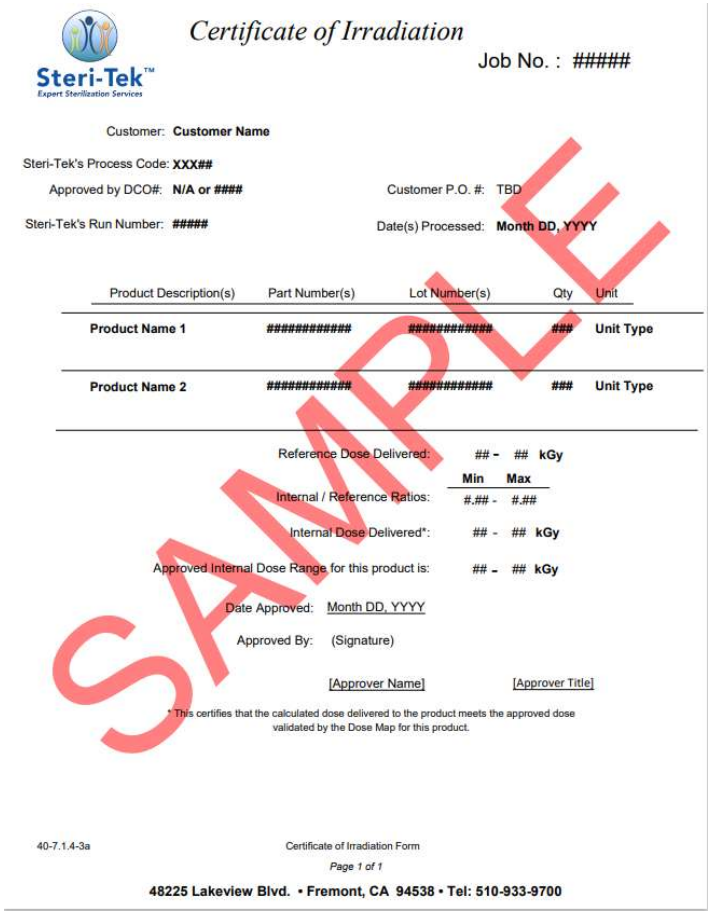
Approved By: (Signature)

[Approver Name] [Approver Title]

* This reflects the lower and upper limits of dose as measured by dosimeters placed external to the product. It is not intended to represent dose delivered within the product.

SAMPLE

48225 Lakeview Blvd. • Fremont, CA 94538 • Tel: 510-933-9700



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Certificate of Irradiation

Job No. : #####

Customer: **Customer Name**

Steri-Tek's Process Code: **XXX##**

Approved by DCO#: **N/A or ####**

Customer P.O. #: TBD

Steri-Tek's Run Number: **#####**

Date(s) Processed: **Month DD, YYYY**

Product Description(s)	Part Number(s)	Lot Number(s)	Qty	Unit
Product Name 1	**########**	**########**	**###**	**Unit Type**
Product Name 2	**########**	**########**	**###**	**Unit Type**

	Min	Max
Reference Dose Delivered:	## -	## kGy
Internal / Reference Ratios:	#.## -	#.##
Internal Dose Delivered*:	## -	## kGy
Approved Internal Dose Range for this product is:	## -	## kGy

Date Approved: Month DD, YYYY

Approved By: (Signature)

[Approver Name] [Approver Title]

* This certifies that the calculated dose delivered to the product meets the approved dose validated by the Dose Map for this product.

SAMPLE

40-7.1.4-3a Certificate of Irradiation Form

Page 1 of 1

48225 Lakeview Blvd. • Fremont, CA 94538 • Tel: 510-933-9700

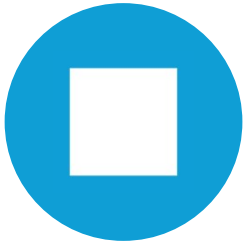
Certificate of Irradiation

- Provided after routine processing of a validated PPS
- Used to claim sterility

Frequently Asked Questions

Can I change my target dose from my PPS on a validated run? No, target dose needs to match exactly. If you need to test a different dose, please do an R&D with PPS ###80

Can I change my dose range from my PPS on a validated run? No, dose range needs to match exactly. If you need to test a different dose range, please do an R&D with PPS ###80



Can I use a different box (dimension/weight) than what we sent for dose map for a validated run? No, box dimensions needs to match exactly. If you need to test a different box dimension please do an R&D with PPS ###80

Why was my project placed on hold? Project may be placed on hold if incorrect/incomplete paperwork is received, missing product from what is on the SOF, etc.

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Questions?

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THANK YOU