Document Number	40-7.1.4-41	Revision	a
		Effective Date	02/16/2022
Document Owner	Quality/Operations	Department	All
Site	All		
Document Type	Form		

1 Objective

1.1 The purpose of this form is to provide guidance for customers in requesting special instructions for R&D processing orders (XXX80). Orders go through five (5) stages during processing at Steri-Tek; Receiving and Pre-Processing, Processing, Post-Processing, QA Approval/Product Release, and Shipping.

2 Scope

2.1 Upon review of orders from customers, special instructions must be reviewed by Steri-Tek personnel to determine feasibility and comprehensiveness. This form will be provided to customers and utilized to record all special instruction requests for a processing order.

2.2 By completing this form, customers acknowledge that R&D orders will not be considered "accepted" until all discrepancies are resolved. Turnaround times will be determined upon completion of order acceptance.

2.3 Responsibilities

Owner	Responsibility
Customer	To disseminate special instruction requests for each step of the Steri-Tek process.
Quality	To review the form for feasibility, completeness, and comprehensiveness.

3 Instructions

3.1 Complete Form

3.1.1 Customers will enter information on this form electronically for ease of readability and sign the authorized signature line.

3.1.1.1 Customers will enter the special instructions needed at each corresponding step (see form for examples).
Note: *Please try to keep the form to one page.*

3.1.1.2 If there are any questions when filling out this form, contact quality@steri-tek.com

3.1.2 Customers must send this completed form (starting with page 3) to accompany all R&D (XXX80) Service Order Forms (SOF) and be sent to receiving@steri-tek.com and shipping@steri-tek.com.

3.1.2.1 If this R&D order is tied to a past or current RST dose study project, DoseMap@steri-tek.com must be included in all correspondence.

3.1.2.1.1 Customers must include a reference to any associated job record number(s).

3.1.2.1.2 If the R&D order is tied to an RST dose study, the Steri-Tek Dose Map team needs to verify the correct figure 4, product orientation and tote loading.

3.1.2.1.3 The Steri-Tek Dose Map team must verify processing boxes, target dose, and internal dosimeter placement requests before the order is accepted.

3.1.3 Customers must include a reference to this completed form on the SOF for traceability (e.g. “See attached R&D form for special instructions.”

3.1.4 Steri-Tek personnel will notify the customer contact on the SOF if instructions are not specific enough or if the request is not feasible.

4 Document History

DCO	Revision	Author	Description of Change	Release Date
2157	a	KNR, KK	Initial release.	02/16/2022

Steri-Tek use only:	
Job#: **RST Project: ☐**	

	To be completed by customer: *(N/A when appropriate, be as specific as possible)*	*Steri-Tek Use Only:*
RST	**Radiation Services Instructions & Information:** **Note: This box to be used ONLY if this R&D study is tied to an RST project*** *e.g. Associated Job#, Attached Figure 4, Internal Dose Conversion ratios, Instruction Verification, etc*	*I/D*
Receiving	**Receiving Instructions & Information:** *e.g. Repacking* instructions, Box orientation, Storage conditions (including dwell times), etc.*	*I/D*
Pre-Processing	**Pre-Processing Instructions & Information:** *e.g. Storage conditions (including dwell times), addition of internal dosimeters* (placement, quantity), etc.*	*I/D*
Processing	**Processing Instructions & Information:** *e.g. Cryotote*, split dose*, etc.*	*I/D*
Post-Processing	**Post-Processing Instructions & Information:** *e.g. Post-processing storage requirements (dwell time before shipping), labeling processing boxes, etc.*	*I/D*
QA Approval	**Product Release Instructions & Information:** *e.g. Sending notification of run completion, request for soft copies of forms, etc.*	*I/D*
Shipping	**Shipping Instructions & Information:** *e.g. Split shipments, Shipping Restrictions (weekend deliveries), Repacking* (Quantity per shipper, Insulated shipper instructions), etc.*	*I/D*

**Additional charges will be determined by Steri-Tek, contact Jeffs@steri-tek.com for pricing*

To be completed by customer (electronic signature is acceptable):	
Authorized Signature & Date:	
Print Name:	

Steri-Tek use only:			
QA✓1 (I/D):		**QA Approval (I/D):**	
Comments:			