R&D Special Instruction Amendment Form

Document Number	FORM-77	Version	1
Document Owner	Operations	Department	All
Site	All		
Document Type	Form		

The purpose of this form is to provide guidance for customers in requesting special instructions for R&D (non-validated) processing orders (XXX80). Orders go through six (6) stages during processing at Steri-Tek; Receiving, Pre-Processing, Processing, Post- Processing, QA Approval/Product Release, and Shipping. All R&D orders that exceed three (3) special instructions must utilize this form.

1 Instructions

1.1 Form use

1.1.1 Steri-Tek personnel should provide this form to customers whenever they are aware of an incoming R&D (non-validated) order will contain more than three (3) special instructions, or if a FORM-14 Service Order Form (SOF) is received that meets the same criteria for special instructions. This form is also available on the Steri-Tek website.

1.2 Customer Section

1.2.1 Customers will enter information on this form in all the **green** fields and sign the authorized signature line.

1.2.1.1 Customers will enter the special instructions needed at each corresponding step. **Note:** *Please try to keep the form to one page.*

1.2.1.2 If there are any questions when filling out this form, contact the appropriate site-specific customer success and/or quality emails.

1.2.2 Customers must send this completed form (starting with page 2) to accompany all R&D (XXX80) FORM-14 and be sent to the appropriate site receiving and shipping emails.

1.2.2.1 If this order is tied to a past or current Dose Map/Validation Services project, fill out the “Dose Map/Validations information” section and copy the appropriate site-specific radiation services email.

1.2.2.1.1 If this order is tied to a Dose Map/Validations study, the Steri-Tek Dose Map team needs to verify the correct figure 4, product orientation and tote loading.

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

1.2.3 Customers must include a reference to this completed form on the SOF for traceability (e.g. “See attached R&D form/FORM-77 for special instructions”). **Note:** *Do not repeat instructions from this form on the FORM-14 (SOF).*

1.3 Steri-Tek Review/Approval

1.3.1 Upon receipt of this form, Steri-Tek will review the document for feasibility and understanding. Steri-Tek personnel will notify the customer contact listed on this form if instructions are not specific enough or if the request is not feasible.

1.3.2 If the form is acceptable, the receiver will complete the **blue** fields, then Initial and Date the Steri-Tek section and enter the order into the Steri-Tek ERP system.

1.3.3 Quality personnel will Initial & Date the appropriate **blue** fields if the form meets requirements.

R&D Special Instruction Amendment Form

Steri-Tek use only:	
Job #:	

Dose Map/Validations Project Information:	☐ N/A

	To be completed by customer: *(N/A when appropriate & be as specific as possible)*	*Steri-Tek Use Only:*
Receiving	*e.g. Repacking* instructions, Box orientation, Data loggers, Storage conditions (including dwell times), etc.*	**I/D:**
Pre-Processing	*e.g. Storage conditions (including dwell times), addition of internal dosimeters* (placement, quantity), etc.*	**I/D:**
Processing	*e.g. Cryotote*, split dose*, etc.*	**I/D:**
Post-Processing	*e.g. Post-processing storage requirements (dwell time before shipping), labeling processing boxes, etc.*	**I/D:**
Quality Approval	*Check the box below if you would like a copy of the processing report emailed.*	**I/D:**
	☐ Email a copy of the processing report to: ☐ N/A	
Shipping	*e.g. Split shipments, Shipping Restrictions (weekends), Repacking* (Insulated shipper instructions) Data loggers, etc.*	**I/D:**

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

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To be completed by customer (electronic signature is acceptable): *By signing below, I acknowledge that special instructions requested in this form require approval from Steri-Tek prior to processing, and that turnaround times may be impacted if all discrepancies/concerns are not resolved in a timely manner.*	
Company Name:	
Print Name:	
Email Address:	
Phone Number:	
Authorized Signature & Date:	

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

FORM-77 (DOC-173) Ver. 1

Approved By:

(CO-2601) Updating FORM-77 to Align With Current Document Format Template

Description

FORM-77 R&D Special Instructions Amendment: Reformatted the document to align with Steri-Tek's current template. Removed Quality from document owner section. Updated all mentions of "RST" to "Dose map/Validation Services." Updated opening statement to explain that orders go through six stages not five and that any order exceeding three special instructions should use FORM-77. Removed Scope and Responsibilities table. Updated section 1.1 to clarify when this form is to be used. Updated section 1.2 Customer section for clarity and instruct customers to contact their site-specific points of contact. Added sections 1.2.2, 1.2.2.1, 1.2.2.1.1, 1.2.2.1.2, and 1.2.3 to clarify how customers should use the form if the order has a corresponding Dose Map/Validation Services study. Added sections 1.3, 1.3.1, 1.3.2, and 1.3.3 for instructions regarding Steri-Tek Review/Approval. Updated table for clarity and added customer contact details section.

Justification

Updating the format of FORM-77 will align with Steri-Tek's approved template. Replacing "RST" with "Dose map/Validation Services" will reduce customer confusion. Removing procedure sections and updating the customer instructions will improve the customer's experience and utility when using FORM-77 and ensure customer products are handled appropriately. Adding the Steri-Tek Review/Approval instructions will ensure that the form is reviewed appropriately by the Quality department. Reformatting the table will improve the utility of the form and reduce customer confusion when utilizing FORM-77. Including a customer contact section will allow Steri-Tek receiving personnel or the RST team to address concerns about the content of FORM-77 with the appropriate customer contact.

Assigned To:	Initiated By:	Priority:	Impact:
Michelle Clopton	Michelle Clopton	Low	Minor

Version History:

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