SteriTek
Expert Sterilization Services

Dose Study Questionnaire

Fill out the questionnaire electronically to the best of your ability and sign at the end. If you have any questions, please email Steri-Tek (Fremont: dosemap@steri-tek.com/Lewisville: ltx_rst@steri-tek.com). Please note that this questionnaire must be filled out in full for every dose study; incomplete fields may cause delays to study turnaround time. The information in this questionnaire is used in the creation of your dose study report, and must be as accurate as possible to ensure all processing requirements are met by Steri-Tek.

	To be filled out by Steri-Tek:	
	Customer Code:	
	Steri-Tek Job Number/RST code:	
	Customer Contact:	
	Initial and Date:	
	To be filled out by the Customer (NA fields where applicable unless otherwise specified)	
1	Choose processing facility:	☐ Fremont, CA ☐ Lewisville, TX
2	Irradiation Mode:	☐ E-Beam ☐ X-Ray
3	Study Type:	☐ Dose Map ☐ Dose Map Verification ☐ Dose Distribution Study ☐ Single Layer Dose Map
4	Company name:	
5	Customer contact + email submitting the SOF and Questionnaire:	
6	Customer contact(s) approving the report:	
7	Approval customer(s) contact's email:	
	Product section: please enter to the best of your ability and if you have questions, Steri-Tek can help.	
8	What is the product name as it should appear in the final report?:	
9	Please provide a short explanation of the product:	
10	What is your product considered? (If "other" please provide explanation in the additional comment section.)	☐ Medical Device ☐ Labware ☐ Food ☐ Pharmaceutical ☐ HCT/P* ☐ Other*
11	What is your Validation Method if applicable?:	
12	Is the Dose Study product dunnage material?	☐ Yes ☐ No
13	Is the product a non controlled substance?	☐ Yes ☐ No
14	What is the requested **internal** minimum dose? (N/A for Single Layers):	
15	What is the requested **internal** maximum dose? (N/A for Single Layers):	
16	Has max dose testing been performed?	☐ Yes ☐ No
17	Does the product require split dosing?	☐ Yes ☐ No
18	How many devices/products are there per processing box?:	
19	What is the sterile barrier?:	
20	How many pages is the IFU? (N/A if no IFU included):	
21	Are there multiple product sizes or configurations (For Processing Groups only):	
22	Do you intend to send partial or mixed boxes?:	
23	Will the expected routine processing shipping method be on pallets? If so are there any pallet requirements? Please provide the requirements:	
	Environmental Conditioning section: if Ambient is checked, the rest of the section can be left blank.	
24	Does the product have any environmental conditioning specifications (Ambient/Refrigerated/Frozen/Dry Ice)/What is the temperature requirement for the product? (Attach IFU, SDS or other documents to evidence the required environmental conditioning):	☐ Ambient ☐ Refrigerated 2° to 8°C ☐ Dry Ice (not monitored) ☐ Frozen -26° to -16 °C
25	If other than ambient, what is the minimum dwell time for the product for pre/postprocessing?:	
26	Is there a maximum amount of time your product can be outside the controlled storage?:	
27	What is your specific environmental conditioning for HCT/P? Please provide short term/long term storage conditions if applicable? (Please provide applicable documentation)*	

DEA section: you are not a DEA customer, this section can be left blank and skipped.*		
28	Is the product a controlled substance? If so, please provide a DEA National Drug Code (NDC) official drug name:	
29	What schedule is the controlled substance?	☐ 2 ☐ 3 ☐ 3N ☐ 4 ☐ 5
30	Is the **Dose Study** product non-controlled?	☐ Yes ☐ No
Safety section: if your product is considered a Hazardous material, fill out this section. If not this section can be left blank and skipped. Information on what Steri-Tek considers hazardous can be see at the end of this questionnaire.**		
31	Does the **dose map** product contain Hazardous Material?	☐ Yes ☐ No
32	Does the product for **Routine Processing** contain Hazardous Material?	☐ Yes ☐ No
Miscellaneous Study section:		
33	For **Single Layer Dose Maps**, what is the verification dose, if available?:	
34	For a **Dose Map Verification**, what PPS is this product verifying against?:	
35	For a **Dose Map Verification**, what are the changes to the product and/or packaging?:	
36	For **Dose Maps** and **Dose Map Verifications**, what is your yearly projected/estimate production volume?:	
37	For **Dose Distribution Studies**, is there a R&D project waiting on this report?:	
38	Is there any additional information that you would like to included?:	
	Customer Signature and Date:	

It is the Customer's responsibility to provide all information/documentation needed for regulated products.**Hazardous includes skin irritants or flammable product as the units need to be physically handled to place internal dosimeters. Please provide a Safety Data Sheet, Material Safety Data Sheet (SDS, MSDS) if available. We always recommend using dunnage or representative product that is alike in density, geometry, orientation, and contains all components of the device.

Dose mapping involves processing the product multiple times at a given dose, and the product should be regarded as destroyed once mapping is completed.

Document History

Document Number	FORM-96	Version	4
Document Owner	Radiation Services	Department	Radiation Services
Site	All		
Document Type	Form		

FORM-96 (DOC-196) Ver. 4

Approved By:

(CO-1989) Update to FORM-96 and FORM-113

Description

FORM-96: Updates include numbering to the individual questions, addition of “Irradiation Mode”. Removal of “date” from “Customer contact + email/date submitting the SOF and Questionnaire” Addition of “Is the Dose Study product dunnage material?” to the Product Section. Addition of “(For Processing Groups only):” to the question “Are there multiple product sizes or configurations:” Addition of “Please provide short term/long term storage conditions if applicable? (Please provide applicable documentation)*: to “What is your specific environmental conditioning for HCT/P?”. Added asterisk to DEA section: you are not a DEA customer, this section can be left blank and skipped. Section header. Updated question in DEA section from “Is the Dose Study product dunnage material (non-controlled):” to “Is the Dose Study product non-controlled?” In Safety Section “Is the Dose Study product dunnage or does the product contain Hazardous Material?:” to “Does the dose map product contain Hazardous Material?” Updated “For Dose Maps and Dose Map Verifications, what is your projected/estimate production volume?:” to include verbiage “yearly”. Addition of comment at end of dose study questionnaire “Dose mapping involves processing the product multiple times at a given dose, and the product should be regarded as destroyed once mapping is completed.” FORM-113: Format changes. Addition of instructions at the beginning of the questionnaire. Addition of numbering to the individual questions, updating version 1 to version 2. Addition of 13 new questions, including selection of answers. Addition of subsection for questions. Addition of disclaimer at the end of the questionnaire. Document table moved from the first page to the last page. Site location changed from “Fremont” to “All”.

Justification

FORM-96: Removal of “date” to customer contact submitting the form poses no risk to the document as the customer is required to sign and date on the second page of the Dose Study Questionnaire. Addition of “Is the Dose Study product dunnage material?” to the Product Section. To ensure the safety of the Radiation Services team member as well as proper storage. Addition of “(For Processing Groups only):” to the question “Are there multiple product sizes or configurations:” allows for the customer to list multiple product sizes for processing group dose maps. Addition of “Please provide short term/long term storage conditions if applicable? (Please provide applicable documentation)*:”, adding an asterisk to DEA section, updating “Is the Dose Study product dunnage material (non-controlled):” to “Is the Dose Study product non-controlled?” and “Is the Dose Study product dunnage or does the product contain Hazardous Material?:” to “Does the dose map product contain Hazardous Material?” Provides additional information for dose mapping and routine production, by providing the type of product that is being irradiated, the preferred storage conditions, the maximum time the product can be outside of its specific controlled storage for irradiation; if the controlled substance requires a higher degree of monitoring and if the product used for the dose map is dunnage to ensure the safety of the Radiation Services team member as well as proper storage of the product. Other changes listed on this document change order are documentation updates only and pose no risk to the dose studies nor to Steri-Tek's eQMS as they are formatting updates, corrections are to increase accuracy and consistency, and inclusion of more information to reduce human error. FORM-113: Changes to format, version number, site location, addition of numbering and moving of the document table from the first page to the last page are document changes and updates only and pose no risk to the validation study nor to Steri-Tek's eQMS as they are formatting updates are to increase accuracy and consistency. Instruction/disclaimers added to the document pose no risk as we are emphasizing that the customer must provide all pertinent information. The addition of 13 new questions regarding the customers’ product, report and protocol approvals, storage conditions and microbiological testing poses no risk to the document updates as the inclusion of more information regarding approval, handling and storage of products reduces human error, and confirmation of microbiology testing for increase documentation traceability. Changes made to FORM-113 properly allow for clarification for approvals, product detail and information for microbiology testing. Other changes listed on this document change order are documentation updates only and pose no risk to the validation/dose studies nor to Steri-Tek's eQMS as they are formatting updates, corrections are to increase accuracy and consistency within the document.

Assigned To:	Initiated By:	Priority:	Impact:
Sandra Ramirez	Sandra Ramirez	Low	Minor

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