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 Distribution Study	☐ Dose Map Verification ☐ 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/estimated production volume?	
37	For **Dose Distribution Studies**, is there an 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

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Document Owner	Radiation Services	Department	Radiation Services
Site	All		
Document Type	Form		

FORM-96 (DOC-196) Ver. 5

Approved By:

(CO-3564) Dose Study Questionnaire Format Imrovements

Description

FORM-96 is updated to expand fields vertically for ease of reading. Fillable fields on the PDF version of the document have had their fields set to auto font size to ensure that information remains contained and readable if it exceeds the expected size of the field. Question 36 typo has been fixed, "estimate" to "estimated". Question 37 grammar has been fixed, "a R&D" to "an R&D". Excess punctuation has been removed from the end of questions on multiple fields.

Justification

Revision of FORM-96 is low risk and improves customer usability. Please see CREQ-66 for reference.

Assigned To:	Initiated By:	Priority:	Impact:
Katrina Rasinouvong	Brian Wu	Medium	Minor

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