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)	
Choose processing facility:	☐ Fremont, CA ☐ Lewisville, TX
Study Type:	☐ Dose Map ☐ Dose Map Verification ☐ Dose Distribution Study ☐ Single Layer Dose Map
Company name:	
Customer contact + email/date submitting the SOF and Questionnaire:	
Customer contact(s) approving the report:	
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.	
What is the product name as it should appear in the final report?:	
Please provide a short explanation of the product:	
What is your product considered?	☐ Medical Device ☐ Labware ☐ Food ☐ Pharmaceutical ☐ HCT/P* ☐ Other
What is your Validation Method if applicable?:	
What is the requested **internal** minimum dose? (N/A for Single Layers):	
What is the requested **internal** maximum dose? (N/A for Single Layers):	
Has max dose testing has been performed?	☐ Yes ☐ No
Does the product require split dosing (yes/no):	☐ Yes ☐ No
How many devices/products are there per processing box:	
What is the sterile barrier?:	
How many pages is the IFU? (N/A if no IFU included):	
Are there multiple product sizes or configurations:	
Do you intend to send partial or mixed boxes?:	
Will the expected routine processing shipping method be on pallets, if so are there any pallet requirements? If so, please provide the requirements	
Environmental Conditioning section: if Ambient is checked, the rest of the section can be left blank.	
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 enviormental conditioning):	☐ Ambient ☐ Refrigerated 2° to 8°C ☐ Dry Ice (not monitored) ☐ Frozen -26° to -16 °C
If other than ambient, what is the minimum dwell time for the product for pre/postprocessing?:	
Is there a maximum amount of time your product can be outside the controlled storage?	
What is your specific environmental conditioning for HCT/P?	

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

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

FORM-96 (DOC-196) Ver. 3

Approved By:

(CO-1692) Updates to FORM-96

Description

Updates to FORM-96 include: - Addition of separate emails for Steri-Tek Fremont and Lewisville site, and verbiage regarding the need of a completed dose map questionnaire for the creation of dose map projects to the top information line of the form. - Addition of "+email" on "Customer contact/date submitting the SOF and Questionnaire" and "Approval customer contact's email" line. Removal of "(If different from above)" from "Customer contact approving the report". - Addition of section headers. - Addition of "What is your product considered?" question with check box options (Medical Device, Pharmaceutical, Labware, HCT/P*, Food, and other) - Astrik added to HCT/P linking additional comment at the end of Dose Study Questionnaire. - Bolding of the word "Internal" for requested minimum and maximum dose. - Temperature ranges added to the environmental conditioning specifications: Frozen/Refrigerated - Additional comment on environmental conditioning - Dry Ice: not monitored. - Addition of question "What is the temperature requirement for the product?", "Is there a maximum amount of time your product can be outside the controlled storage?", and "What is your specific environmental conditioning for HCT/P?" - Addition of "What schedule is the controlled substance" and schedule levels "2, 3, 3N, 4, and 5" check boxes available to choose. - Addition of "Is the Dose Study product dunnage material (non-controlled):" with a Yes/No option. - Addition of Safety section verifying if the product sent in for Dose Study material/Routine production contains hazardous material. - Addition of customer signature and date of signature. - Addition of comment "It is the Customer's responsibility to provide all information/documentation needed for regulated products." And linking previous comment regarding Hazard to safety section All other changes are documentation changes only for clarity and classification of questions.

Justification

Addition of separate emails for Steri-Tek Fremont and Lewisville allows for customers to contact the correct facility for their dose maps, additional verbiage regarding the need for a completed Dose Study Questionnaire, lets customers know that this document is not optional for the start of a dose map. "+email" to customer contact/date submitting the report provides the correct email from the customer for the contact who is approving the documentation that is needed at the start of the dose map. Removal of "(If different from above)" from "Customer contact approving the report" provides additional confirmation and documentation for contacting the correct approver of the dose map report. This also shows separation of the customer contact who is submitting the report and the customer contact who will be approving the report at the end of the dose map study. Addition of section headers – group questions regarding product, storage, and overall processing requirements. Bolding of the word "internal" for requested minimum and maximum dose emphasizes the word internal for clarification for the customer. Addition of the temperature ranges to the Fridge and Freezer check boxes defines the temperature ranges for each of the storage conditions, these temperature ranges correspond to Steri-Tek's SOP-20 Preventive Maintenance. Dry Ice is specified that it is not monitored. Addition of questions "What is your product considered?", "Is there a maximum amount of time your product can be outside the controlled storage?", "What schedule is the controlled substance", "Is the Dose Study product dunnage material (non-controlled):" and "What is your specific environmental conditioning for HCT/P?" 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. Addition of the Safety section clearly defines if the dose map product and the routine production product is hazardous, this ensures the safety of the Radiation Services team member, who will be performing the dose map and handling the product as well as the Operations team members. Addition of customer signature and date of signature- confirms the information provided on the Dose Study questionnaire has been submitted and approved by the customer. Addition of comment "It is the Customer's responsibility to provide all information/documentation needed for regulated products." Linked to HCT/P option form "What is your product considered?" as we are emphasizing that the customer must provide all pertinent information regarding the HCT/P classified product. Additionally linking Hazardous material comment to safety section. Changes listed above do not impact customer product, the process, or Steri-Tek's eQMS as they provide additional clarification and information to both Steri-Tek and the customer. 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.

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

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