SteriTek

Expert Sterilization Services

Dose Map Studies

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Dose Map Study

- Conducted to develop a validated process to allow the customer to process their routine product and receive a certificate of irradiation
- Need a minimum 2 shippers of dunnage/simulated product in its final configuration
- A minimum of 3 separate passes in the same configuration utilizing a minimum of 3 sets of data to develop a validated process to run routine production
- The dose map report provides the maximum and minimum dose delivered to the product during routine processing

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Single Layer Dose Map Study

- Conducted to develop a validated process to allow the customer to process their verification doses and receive a verification dose certificate
- Need 3 samples of dunnage/simulated product
- Product may need SIP
- A single pass utilizing a minimum of 3 sets of data to develop a validated process to establish a target dose to run verification doses

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Dose Map Verification Study

- Conducted to ensure changes to the product, packaging, configuration, product count, etc. fit within the original validated product specification
- A single pass utilizing a minimum of 1 set of data to determine the dose conversion are within the conversion ratios of 95% confidence dose conversion ratios from the validated specification
- If the change cannot process within the original specifications, a new specification can be generated by completing another Dose Map

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Dose Distribution Study

- Conducted to find the dose delivered to the product
- This is not a validated process and will not receive a certificate of irradiation
- This study will only receive a dose distribution study report
- A single pass utilizing a minimum of 1 set of data to determine the internal dose delivered to the product to establish an approximate internal dose range

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Sample/document requirements

- Dose map study: minimum 2 shippers of dunnage/simulated material in its final configuration
  - Questionnaire and SOF
- Single layer dose map study: 3 samples of dunnage/simulated material
  - Questionnaire and SOF
- Dose map verification study: the same number of shippers of dunnage/simulated material in its final configuration that was sent for the original dose map
  - Questionnaire and SOF
- Dose distribution study: 1-2 shippers of dunnage/simulated material in the same configuration you will use for your future R&D studies
  - Questionnaire and SOF

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Turnaround Times

*subject to change based on capacity
*turnaround times provided are for e-beam in Fremont, CA. Contact Steri-Tek Lewsiville for turnaround times
*rush options available based on capacity – please contact Steri-Tek

- Dose map study: 5 weeks
- Single layer dose map study: 2.5 weeks pending bioburden
- Dose map verification study: 3 weeks
- Dose distribution study: 2.5 weeks

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Frequently Asked Questions

- Why do you require dunnage/simulate material and not live product? Our dose mappers are working hands-on with the dunnage to place dosimeters. To keep our team safe, in cases of drugs/live product, we can only accept dunnage/simulated material. Our dosimeters can only be placed on ambient products which is also why dunnage/simulated material is needed. This will also reduce cost.
- During a sterilization validation, can the dose map study be started simultaneously with other testing? Yes, dose map can be done simultaneously.
- During a sterilization validation, can the single layer dose map study be started simultaneously? Yes, the single layer dose map study can be started simultaneously. However, cannot be completed until bioburden results are received from the lab.

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Frequently Asked Questions

- How do you determine what internal dosage the product is receiving at a certain reference dose? We use ratios to determine how much that spot gets for a given reference dose reading.
- When does my turnaround time start? Turnaround time starts once we have all required dunnage/simulated material, questionnaire(s), and SOF(s).
- What is my target dose for dose map studies? 25kGy for e-beam and 15kGy for x-ray.
- Is my validated code from my dose map valid at all Steri-Tek locations? No, the dose maps are not transferrable. If you would like to routine process and receive a Certificate of Irradiation (COI) at another/multiple Steri-Tek locations, the dose map will need to be repeated.
- I have made a change to my packaging, materials, configuration, manufacturing site, etc., what do I do? Contact your study director, customer success, and dose map department

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Frequently Asked Questions

- Can I use my product after a dose study? The product is considered destroyed after a dose study but can be used for material testing.
- Where can I find the questionnaire and SOF? On the website.
- Why would I do a dose distribution study vs. a full dose map study? A dose distribution study will guide you in R&D runs when you need a specific internal dose but are not ready for final packaging and configuration.

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Questions?

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