

Gamma Dose Specification Authorization

Customer Name:					
Minimum Specified Dose:		kGy	Maximum Specified Dose:		kGy

1.0 Reason for Change: Addition of New Product Change to Existing Dose Range
 Removal of Product Code Other (Please specify): _____

2.0 Product Information:

If customer supplied document* will be used to provide dose and product codes, indicate the customer supplied document information in the space provided.

***Name of Customer Supplied Document:** _____ (attach signed/dated document to this form)

Product Code	Description

-Product codes must match customer label & customer packing list. If special post processing code is applicable, please indicate code in brackets.
 Note: The description may include proper name, registration name, generic description, and/or product weight and dimensions.

Check here if any of the above product codes are mixed density material.
 N/A

3.0 Product Classification:

Medical Device Pharmaceutical Active Pharmaceutical Ingredient Labware Botanicals Food / Spice
 Food Packaging Cosmetics Animal Food / Pet Treats Human Tissue (Complete Form 10)
 Blood (Complete Form 11) Other (define) _____
 Check here if any of the above listed codes is an implantable medical device.

4.0 Product Safety Information:

Check here if any of the above listed codes contain hazardous, flammable, corrosive, explosive, combustible, bio hazardous, or bio active materials. (If checked, STERIS management: Contact the Senior Radiation Safety Manager)
 Check here if any of the above listed codes are harmful, in anyway, to humans. (If checked, MSDS must be provided before processing)
 N/A

5.0 Process Interruption (Ref 11137-1:2006):

N/A
 Check here if your product will support microbial growth during an interruption of the irradiation process?

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If checked, must provide special handling instructions related to process interruption:

6.0 Storage Conditions

STERIS AST facilities do not provide special environmental conditions unless arranged with STERIS prior to accepting product.

N/A

Check here if any of the above listed codes contain environmental controlled requirements and list details below or in an attached document:

Customer Authorization:

Print Name: _____ Title: _____

Signature: _____ Date: _____

Note: Electronic signatures are not acceptable unless compliance to Part 11 can be demonstrated.
Form can be completed electronically, and printed and signed in ink.

STERIS Approval:

Production Signature: _____ Date: _____

QS/RC Signature: _____ Date: _____