

SAMPLE SUBMISSION FOR IRRADIATION AT THE RADIATION TECHNOLOGY CENTER: FAQS



Applied Sterilization Technologies

TECHNICAL TIP #25

The Radiation Technology Center (RTC) specializes in handling products requiring high precision irradiation dose delivery for validation, dose audit and research purposes. To help facilitate product submissions and improve product turn time this TechTip addresses questions that may arise when product is submitted for irradiation processing.

How do I submit samples?

For Customers that have not processed with STERIS Isomedix Services, Customer setup forms will need to be completed. These forms include: the Non-Sterile Shipping Agreement, Assignment of Responsibility, Terms & Conditions, Credit Application, and W9 forms. These forms must be signed by the Customer and a member of STERIS Isomedix Services management prior to processing. If these forms have been completed with another STERIS Isomedix Services facility, please inform the RTC staff of the previous set-up when establishing initial irradiation studies to streamline the process.

Samples are submitted using the Radiation Request Form (RRF). The RRF can be found and completed online at www.isomedix.com under the Gamma section. Once completed, the RRF is routed electronically for price quoting to a RTC Customer service representative. Following the completion of the quote, the RRF will be e-mailed back to the Customer. The returned quoted RRF will have the finalized information needed for your records, as well as the processing costs to initiate a Purchase Order (PO) or credit card order for payment. For credit card payment, simply type in "credit card" in the PO field on the RRF, and a RTC Customer service representative will contact you by phone to obtain the pertinent information. Alternately to electronic RRF submission, a manual RRF can be obtained by contacting the RTC if email submission is not possible. In this case, the manual form is completed by the Customer and then faxed to the RTC for a quote. Once the manual form is quoted it is then faxed back to the Customer.

On return to the Customer, the RRF, in electronic or manual form, should be reviewed, signed and returned to the RTC via fax or scan by the Customer with a hard copy of the purchase order or notification to the RTC that credit card will be used for payment. Product cannot be processed without both a signed RRF and a hardcopy of the PO available. It is also recommended that the original RRF, including the PO or credit

card request, should be included with the shipment of the product to help identify the product requirements upon receipt to the RTC. Once the RRF has been completed and maintained on file at the RTC, product can be immediately routed for processing.

What is the best way to package samples for irradiation?

It is best for samples to be packaged in corrugated cartons of no more than 2 cubic feet. Larger or irregular cartons can also be processed at a slightly higher fee. Please contact the RTC for your unique over-sized product requirements.

Outer shippers are sometimes utilized by Customers for protecting the inner cartons (e.g. the inner product is fragile) or to keep the product cool or frozen by surrounding it with ice or dry ice. In this case, it is the inner carton that should be irradiated and listed on the RRF. The RTC will remove the inner cartons for processing and repack them, as received, for return shipping.

Once an appropriate corrugate carton is chosen, product should be placed inside in a consistent (uniform density) manner to maximize the effectiveness of dose penetration during the irradiation process. If it is necessary, items such as bubble wrap, Styrofoam peanuts, bags of air, etc. should be used to avoid contents shifting, protect fragile product, and/or to ensure that there is little or no empty space in the package. Reducing empty space in a package is important as any density variations between low density packing material and high density product will be evident in the irradiation delivered dose. As with any item shipped, the corrugated carton should be sealed securely using packaging tape to assure containment of contents.

What other special handling options are available prior to irradiation?

Bundling is a service where limited numbers of smaller packages are bound together to create a larger cube of product. Bundling product cartons together allows one product irradiation to occur and not multiple product irradiations, thus saving the Customer money and increasing irradiation efficiency. There is no extra charge for bundling and requirements for bundling are as follows: 1) the cartons must be the same size and weight; 2) the total bundle volume must be less than or equal to 2 ft³ and 3) have a density of not more than 0.16 g/cm³.

Repacking is a service that is used to minimize the carton size shipped to the RTC (in the event the carton was too large or irregular in size to be effectively irradiated), if the shipped carton was damaged in transit, and/or if the carton contains excessive empty airspace. There is a minimum charge for performing this service.

What type of special instructions should be included when shipping dangerous goods?

Prior to shipping samples classified as dangerous goods, advance verbal notification is required. When you are shipping dangerous goods, ensure that all labeling, shipping, and any additional documentation requirements are met. It is required that a Material Data Safety Sheet (MSDS) be included with the packing slip for all materials shipped that are classified as dangerous goods. If you should have any questions regarding the shipment of dangerous goods, information can be obtained by contacting your shipping courier.

What if my samples are temperature sensitive?

Prior to shipping samples which are temperature sensitive, advanced prior notifications is required. For samples requiring dry ice, a Styrofoam container enclosed in a corrugate container is required. If dry ice needs to be added prior to irradiation, the Customer must notify the RTC at least 24 hours in advance of product arrival. All products either shipped or irradiated on dry ice must be processed as Same Day Processing or Priority. Routine processing on dry ice may be possible, but will need to be arranged with the RTC in advance. Dry ice can be added to containers as needed for an additional fee.

For samples requiring refrigeration or freezing, the shipper container and the Radiation Request Form must indicate this need and an additional fee will be assessed. The RTC maintains restaurant-grade refrigerators and freezers for product storage, and does not make claims to controlled conditions. If knowledge of shipping/storage conditions are important to your study, it is recommended a temperature data-logger be included with your product for monitoring. Please notify the RTC that a data-logger has been included, as it will need to be removed prior to irradiation to prevent damage to the instrument. All special instructions must be included on the submitted Radiation Request Form.

How can I check the status of my product one it has been received?

If you have any questions regarding the status of your product simply contact the RTC directly. The RTC will be able to check your product status by referencing your IRL#, (a unique tracking number provided to your product upon receipt) or PO number to identify the request.

If I am new to using Radiation Sterilization is there someone I can contact to help me understand the process?

The RTC is the home of the Gamma TechTeam and has a staff of full time Project Managers to assist Customers in understanding the radiation sterilization process. We welcome answering any questions you might have regarding the process. In addition, the RTC can provide full turnkey project management for establishing sterilization doses, dose audit handling, dose-mapping, and experimental design for your product requirements.

Contact Information:

The RTC and Gamma TechTeam is always available to discuss questions or concerns you may have specific to your product or the product submission process. Please feel free to contact the RTC - "We're here to Help!"

Location: 2500 Commerce Drive
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For more information, please contact:

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