

From: [Miller, John](#)
To: "pds1@cdc.gov"
Subject: Request for Additional Information - Mail Control # 587023
Date: Wednesday, July 29, 2015 11:20:00 AM

Department of Health & Human Services
Centers for Disease Control and Prevention
License No. 10-06772-02
Docket No. 030-13108
Control No. 587023

Paul,

In your letter dated May 20, 2015, you have specified a difference in the Overall Diameter and Length Dimensions between the MDS Nordion C-198 (0.383 inches (D) x 8.265 inches (L)) source and the INIS-SF-1.0-20-J source (0.375 inches (D) x 8.00 inches (L)). The Gammacell 220 irradiator can use up to 48 Nordion C-198 source pencils. These pencils are spaced uniformly on the stainless steel source cage. Due to the differences in the dimensions, please describe what type of analysis was performed to determine that the International Isotope's source is compatible with the Gammacell 220 source holder. The analysis may include, but is not limited to:

1. An evaluation/explanation of how the International Isotope source is secured/installed in the source cage compared to the Nordion C-198 source.
2. Confirmation that no changes will be made to the design of the Gammacell 220 source holders/source cage in order to accommodate for the International Isotope sources.
3. Testing performed by International Isotopes to determine that the source and source holders/source cage are compatible.
4. Potential for vibrations that may affect a source with smaller dimensions in the source cage.

Please respond in writing with a signed letter. You may submit the signed response document by hard copy, or as a pdf copy attached to an email, or by facsimile to 610-337-5269. In addition, please be sure to include the Control No. 587023 on your response. We would appreciate a response within 20 days in order to expedite review of the license amendment request.

Thank you for your cooperation

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