

From: [Arribas-Colon, Maria](#)
To: jjmiller@intisoid.com
Cc: [Jankovich, John](#); [Poy, Stephen](#); [Kime, Traci](#)
Subject: Request for Additional Information, letter dated August 29, 2012
Date: Thursday, December 13, 2012 2:47:26 PM

Good Afternoon Mr. Miller,

This email is in reference to your amendment request dated August 29, 2012, to amend the Registry of Sealed Sources and Devices Safety Evaluation of Sealed Source number NR-1235-S-108-S to revise the Model designator from the BMNT57-YY to BMNT57-DDHH-YY and to replace the two drawings included in the current SS&DR. In reviewing your request, we find that additional information is required to complete our review.

Listed below is the information needed to complete the review.

1. Please provide complete information on when the 3 options listed on Attachment 2 of 3 are used.
2. Please clarify if the top lid would have similar options as the bottom lid, as specified on Attachment 2 of 3. If this is the case, please provide drawings.
3. The drawings on Attachment 2 of 3 do not specify the total number of fasteners used and their space allocation. Please provide drawings of the full top and bottom views. Electronic format for the drawings is preferred.

Please submit the requested information within 30 days of the date of this email. If we have not received complete information within 30 days of the date of this email, we will consider your application as having been abandoned by you. This is without prejudice to the submission of a complete application.

If you have any questions my contact information is listed below.

Thank you,

Maria del Mar Arribas-Colón, M.S.

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