January 12, 2012

Richard Wassenaar, Ph.D.
Radiation Safety Officer
Best Theratronics
413 March Rd.
Ottawa, Ontario
Canada, K2K 0E4

SUBJECT: APPLICATION FOR F-431 TRANSPORTATION PACKAGE – REQUEST FOR ADDITIONAL INFORMATION

Dear Dr. Wassenaar:

By letter dated October 21, 2011, you submitted an application for amendment of the Model No. F-431 transportation package, Certificate of Compliance No. 9310. You requested approval of changes made to reflect modifications made to the Gammacell-1000 and Gammacell-3000 irradiators (GC-1000 and GC-3000). In the letter dated November 30, 2011, the application was accepted and a proposed schedule was provided for your review.

In connection with the staff's review, we need the information identified in the enclosure to this letter. We request that you provide this information by February 13, 2012. Inform us at your earliest convenience, but no later than January 30, 2012, if you are not able to provide the information by that date. To assist us in re-scheduling your review, you should include a new proposed submittal date and the reasons for the delay.

If you have any questions regarding this matter, please contact me at 301-492-3273.

Sincerely,

/RA/
Huda Akhavannik
Licensing Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-9310
TAC No. L24590

Enclosure: Request for Additional Information

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Enclosure: Request for Additional Information
Distribution: JPiotter, MCall, MRahimi, DPstrak, JChang, MSampson, MWaters, BBenney
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ADAMS Accession No.:

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OFC:						
NAME:	DPstrak	MWaters				
DATE:	1/5 /12	1/12/12				

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Request for Additional Information
Best Theratronics
Docket No. 71-9310
Certificate of Compliance No. 9310
Model No. F-431 Package

1.0 General Information

1-1 Provide a schematic drawing to illustrate the unmodified GC-1000 and GC-3000.

Figure 2 of Section 1.2.2 of the Safety Analysis Report (SAR) illustrates a detailed view of the modified GC-1000 and GC-3000, however, for comparison purposes, staff requests both the modified and unmodified be shown.

In addition, Section 1.1 of the SAR refers to two versions of the new design, a retrofit and new devices. The drawings and the schematics in the application should include all applicable design changes and indicate which changes are for retrofit and which are for a new device.

This information is needed to confirm compliance with 10 CFR 71.33.

1-2 Revise Drawing F643101-001, sheet 2 of 2.

The drawing of the GC-1000 and GC-3000 appears inconsistent with the detailed view of the modified GC-1000 and GC-3000 as illustrated in Figure 2 of Section 1.2.2. Furthermore, detail C also appears inconsistent with the detailed view of Figure 2.

Staff also requests that detail C (Alternate Mfg. Method) be revised to include increased detail of the area of consideration. If these alternate methods are indicative of retrofits or new installations, staff requests that this information be conveyed in the licensing drawings.

This information is needed to confirm compliance with 10 CFR 71.33.

1-3 Clarify the following regarding the description of the proposed changes, and modify the application, as necessary:

a. The description of the new features. Section 3.4 of the submittal indicates there are new steel and lead parts/features; however, the drawings indicate only new steel parts/features.
b. The sources are to be secured by 1 of 3 options, as indicated by the drawings. The text of the application is not clear that 3 options are available and acceptable for use (see Section 1.1, last paragraph).

The application, including the drawings, should be clear and consistent. Those aspects that are not consistent or clear, as discussed above, should be modified.

This information is needed to confirm compliance with 10 CFR 71.33.

1-4 Revise the licensing drawings to incorporate the following:

a. Modification of the "25.0 MAX" dimension in Drawing No. F643101-001, sheet 1 of 2, Revision G, to be consistent with the dimension for this item in Drawing No. F643101-001, sheet 2 of 2, Revision C, SAR Table 1.1 and the Certificate of Compliance (CoC), which indicate the correct dimension is "24.00 MAX."
b. Clarification that no change is needed to the depiction of the top bracing in Drawing No. F643101-001, sheet 2 of 2, Revision C, to account for the new Gammacell design. Modify the drawing as needed.
c. Removal of the GC-2000 from Item 8 in the Bill of Materials for Drawing No. F643101-001, sheet 1 of 2, Revision G. This Gammacell is not an authorized content.
d. Update to Drawing No. F643101-001, sheet 1 of 2, Revision G's "Weight of Components of F-431" table to be consistent with the text of the application. The weights for the Gammacells have increased and now differ between the two Gammacell contents. The table should list the new maximum weights for both Gammacells.
e. Modify the dimensions specifying the nominal lead thickness and the nominal steel shell thickness in Drawing No. F643101-001, sheet 2 of 2, Revision C, for both the GC-1000 and the GC-3000, to be consistent with the SAR Table 1.1 and the CoC. Table 1.1 of the SAR (IN/TR 1913 F432 (2)) and the CoC indicate that the nominal lead thickness is 6 inches for the GC-1000 and 4.35 inches for the GC-3000 and that the nominal steel shell thickness for both models is 0.375 inches. The correct dimensions should be specified in the drawing, consistent with the evaluations and descriptions in the SAR and the approval documented by the CoC.
f. Clarify which tolerance table is to be used for the dimensions of the shielding materials in Drawing No. F643101-001, sheet 2 of 2, Revision C. The drawing has two tables specifying tolerances, both of which state that they apply "unless otherwise specified."

This information is needed to confirm compliance with 10 CFR 71.33.

1-5 Provide additional dimensions and materials specifications on the proposed Drawing No. F643101-001, sheet 2 of 2, Revision C, which are necessary to capture the shielding performance of the package.

The package evaluation relies upon the contents (i.e., the GC-1000 and the GC-3000) to provide the shielding needed to comply with the dose rate limits in 10 CFR 71.47 and 71.51. The currently proposed drawing revision includes only a single dimension for the lead shielding in each Gammacell. It is not clear that this dimension applies all around the cavity of the source. It also appears that the shielding at the opening of the source cavity is composed of different materials. Thus, the drawing should be modified to include dimensions that clearly indicate the amount of shielding that is necessary around the source (e.g., above the source cavity, below the source cavity, in the direction of the rotating chamber, and in the direction away from the rotating chamber), addressing the specific items described above. Appropriate tolerances, or specifications of minimum values, should be included. In areas where more than one material is relied on for shielding, each material should be identified, along with the dimensions of that material that are relied on for shielding. If the shielding in the source holder is relied upon, information regarding that shielding should also be provided. NUREG/CR-5502 provides some additional guidance regarding information to be included in licensing drawings (e.g., see Sections 3.3, 3.3.1, and 3.3.7 of that document).

This information is needed to confirm compliance with 10 CFR 71.33, 71.47, and 71.51.

2.0 Structural

2-1 Provide reasonable assurance that the alternate manufacturing methods for source retention are sufficiently robust to survive a 30-foot drop.

It appears from the licensing drawing, F643101-001, sheet 2 of 2, detail C, that alternate manufacturing method (1) (retaining ring) is a slight protrusion above the top surface of the GC-1000 and GC-3000 outer shell.

It also appears that alternate manufacturing method (2) is a significant protrusion above the top surface of the GC-1000 and GC-3000 outer shell. It is not evident how this configuration is attached to the GC-1000 and GC-3000.

Given the statement that the packing braces provides “little protection,” staff does not have reasonable assurance that these design changes can perform as intended during a 30-foot drop, when compared to a groove welded recessed shield cover.

This information is needed to confirm compliance with 10 CFR 71.73(c)(1).