January 12, 2012

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

SUBJECT: APPLICATION FOR F-430 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-430 transportation package, Certificate of Compliance No. 9290. You requested approval of changes made to reflect modifications made to the Gammacell-40 irradiator (GC-40). 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. 71-9290
TAC No. L24591

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.:

OFC:						
NAME:	HAkhavannik	MDeBose	JPiotter	MCall	JPearson	MRahimi
DATE:	1/5/12	1/ 5/12	1/5/12	1/6/12	1/5/12	1/12/12
OFC:						
NAME:	DPstrak	MWaters				
DATE:	1/5 /12	1/12/12				

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Request for Additional Information
Best Theratronics
Docket No. 71-9290
Certificate of Compliance No. 9290
Model No. F-430 Package

1.0 General Information

1-1. Clarify that the two versions of the new design described in the last paragraph of Section 1.1 of the supplemental Safety Analysis Report (SAR) will conform to the proposed drawings.

The last paragraph in Section 1.1 of the submittal indicates there are two versions of the new design. Per the proposed drawings, there is only one version. Thus, it is unclear what is meant by there being two versions of the new design and whether the drawings accurately reflect the proposed design(s).

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

1-2. Revise the licensing drawings to incorporate the following:

a. Identify the differences between Revision M and Revision K (the currently approved revision) of Drawing No. F643001-001, sheet 1 of 2. The differences are not clear, and the drawing doesn't appear to have any change markings.
b. Modify the weights in the table in the upper right of Drawing No. F643001-001, Revision M, for "Gammacell GC-40 Upper Head" and "Lower Head" to be consistent with the weights in the proposed amendment. The weights of these two items have increased per Table 2-1 of the submittal.

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

1-3. Clarify that the intent is to only ship heads with the new configuration or to ship heads with both the new configuration and the current configuration, and modify Drawing No. F643001-001, sheet 2 of 2, Revision F, and the package operations in Chapter 7 of the submittal accordingly.

Item 1 in the drawing's bill of materials is shown as "optional." However, per the submittal, Item 1 is not, and cannot be, used with the new configuration, and so can't be an "optional" item. Thus, if only heads with the new configuration are shipped, there is no Item 1 and it should be deleted. Also, Chapter 7 of the submittal indicates that both the current and the new source head configurations are to be shipped. If only the new configuration is acceptable, the operations should be modified to be consistent with this intention (e.g., delete current descriptions that address use of a shipping tube/spacer/tube spacer). If the intent is to ship both the new and the current configurations, then the drawing should be modified to include both configurations and the word "optional" should be removed from Item 1 (since it would be required for one of the configurations).

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

1-4. Provide additional dimensions on proposed Drawing No. F643001-001, sheet 2 of 2, Revision F, which are necessary to capture the shielding performance of the package.

The package evaluation relies upon the contents (i.e., the GC-40 upper and lower heads) 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 the head. It is not clear that this dimension applies all around the cavity for the source drawer. The minimum distance between the opening in the head's cone and the position of the source during transport, as well as the amount of lead shielding between the source position and the cone wall, are also not clear from the drawings. Additionally, the lead in the source drawer is relied on for shielding on either side of the source. The drawings do not indicate the amount of lead that is present on each side of the source in the source drawer. The drawings should be modified to include dimensions that clearly indicate the amount of shielding that is necessary around the source, addressing the specific items described above. Appropriate tolerances, or specifications of minimum values, should be included. 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 procedures are in place that ensure proper thread engagement of the ½-20 socket head cap screw such that the G-loads realized during the 30-foot drop are accounted for.

If the cap screw is installed incorrectly, there is the potential that a 30-foot drop will be sufficient to disengage the source drawer from the cap screw. Staff does not have reasonable assurance that procedures are in place to prevent this unanalyzed condition.

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

Editorial Requests:

Please provide a revised SAR which incorporates the changes resulting from previous supplements indicated in the Certificate of Compliance (CoC) No. 9290, Revision 6. A revised SAR incorporating these changes facilitates a smoother review process. Additionally, applicants are normally requested to provide a consolidated SAR when applying for a renewal of their CoC when the certificate contains more than five substantive supplements, per 10 CFR 71.38(c).