



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 26, 2019

Ms. Mojgan Soleimani
Best Theratronics
413 March Road
Ottawa, Ontario
Canada K2K 0E4

SUBJECT: CERTIFICATE OF COMPLIANCE NO. 9310, REVISION NO. 7, FOR THE MODEL NUMBER F-431 TRANSPORT PACKAGE (EPID NUMBER L-2019-RNW-0010)

Dear Ms. Soleimani:

As requested by your application dated May 23, 2019 (Agencywide Documents Access and Management System [ADAMS] No. ML19150A567), as supplemented on June 25, 2019 (ADAMS Accession No. ML19177A354), July 29, 2019 (ADAMS Accession No. ML19329A531), and November 5, 2019 (ADAMS Accession No. ML19312A446), enclosed is Certificate of Compliance No. 9310, Revision No. 7, for the Model No. F-431 transport package. Changes made to the enclosed certificate are indicated by vertical lines in the margin. The staff's safety evaluation report is also enclosed.

The approval constitutes authority to use the package for shipment of radioactive material and for the package to be shipped in accordance with the provisions of Title 49 of the *Code of Federal Regulations* (49 CFR) 173.471. Those on the attached list have been registered as users of the package under the general license provisions of 10 CFR 71.17 or 49 CFR 173.471.

Upon removal of Enclosure 3, this document is uncontrolled

M. Soleimani

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If you have any questions regarding this certificate, please contact me or Norma García Santos of my staff at 301-415-6999.

Sincerely,

/RA/

Daniel Doyle, Acting Chief
Storage and Transportation Licensing Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-9310
EPID No. L-2019-RNW-0010

Enclosures:

1. Certificate of Compliance
No. 9310, Revision No. 7
2. Safety Evaluation Report
3. Registered Users

cc w/encls 1 & 2:
R. Boyle, U.S. DOT
J. Shuler, U.S. DOE,
c/o L.F. Gelder

M. Soleimani

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MODEL NUMBER F-431 TRANSPORT PACKAGE (EPID NUMBER L-2019-
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DATE: November 26, 2019

DISTRIBUTION: SFST r/f

ADAMS Package Accession No.: ML19330F819, Letter: ML19330F966
This closes EPID No. L-2019-RNW-0010.

OFFICE/DIV	NMSS/DFM	NMSS/DFM	NMSS/DFM
NAME	N. García Santos	S. Figueroa by email	D. Doyle
DATE	11/25/19	11/26/19	11/26/19

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**SAFETY EVALUATION REPORT
Docket No. 71-9310
Model No. F-431 Transport Package
Certificate of Compliance No. 9310
Revision No. 7**

SUMMARY

By application dated May 23, 2019 (Agencywide Documents Access and Management System [ADAMS] No. ML19150A567), as supplemented on June 25, 2019 (ADAMS Accession No. ML19177A354), July 29, 2019 (ADAMS Accession No. ML19329A531), and November 5, 2019 (ADAMS Accession No. ML19312A446), Best Theratronics Ltd. (the applicant) requested the renewal of Certificate of Compliance (CoC) No. 9310, for the Model No. F-431 transport package. The applicant also requested to remove "MDS Nordion" in Gammacell-1000 and Gammacell-3000 from the "Description" section of the certificate, since the package can transport these types of gammacells from other manufacturers (ADAMS Accession No. ML19312A446).

The applicant did not request any changes to the package design or its authorized contents. The certificate has been renewed for a five-year term.

EVALUATION

The staff reviewed the applicant's requests to renew the CoC the Model No. F-431 and to remove "MDS Nordion" from the "Description" section of the certificate related to Gammacell-1000 and Gammacell-3000. Per the applicant's request dated November 5, 2019, these gammacells have been, through the years, "manufactured at the same facility" under the same name but different owners such as the following:

- 1) AECL (Atomic Energy of Canada Limited),
- 2) Nordion International,
- 3) MDS Nordion, and
- 4) Currently, Best Theratronics.

The Model No. F- 431 package is used to transport all these gammacell units (ADAMS Accession No. ML19312A446). Therefore, the removal of the phrase "MDS Nordion" does not affect the performance of the package.

In terms of the renewal, the staff reviewed the documents referenced in the CoC and determined that the documentation was available and complete. Given the number of supplements in the certificate for the Model No. F-431, the staff requested a consolidated application for this renewal. The staff verified that the information in the supplements listed in

Enclosure 2

Revision 6 of CoC No. 9310 was incorporated into the consolidated application (ADAMS Accession Nos. ML19177A354 and ML19329A531).

Based on the application and its supplements, the staff finds that the information provided by the applicant is adequate and the package continues to meet the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71.

CONDITIONS

The following conditions of the CoC were revised or added to the certificate:

- 1) In Condition No. 1.b., the revision No. of the certificate was increased to 7.
- 2) Condition 3.b. has been revised as follows:

Best Theratronics application dated July 29, 2019, as supplemented.
- 3) Condition 5.(a)(2) has been revised to delete the phrase “MDS Nordion.”
- 4) Condition 5.(a)(3) has been revised as follows to reflect different revision Nos. of the drawings:

The packaging is constructed in accordance with the Best Theratronics drawing F643101-001, “F-431/GC-1000/3000 Transportation Package Information Drawing,” Sheet 1, Revision K, and Sheet 2, Revision F.
- 5) Condition No. 9 has been added to allow using Revision 6 of the CoC until November 30, 2020.
- 6) Condition No. 9 was renumbered as Condition No. 10 and revised to reflect the new certificate expiration date.

The “REFERENCES” section has been updated to include the date of the last consolidated application submitted by the applicant for the renewal request (i.e., July 29, 2019) and the supplement requesting the removal of “MDS Nordion” from the “Description” of the certificate.

CONCLUSION

The certificate has been renewed for a five-year term, which expires on November 30, 2024. Based on the statements contained in the application, and the conditions listed above, the staff concludes that the changes to the certificate indicated by the applicant do not affect the ability of the package to meet the requirements of 10 CFR Part 71.

Issued with Certificate of Compliance No. 9310, Revision No. 7,
on 11/26/2019.