

November 5, 2019

Director, Division of Spent Fuel Management
Office of Nuclear Materials Safety & Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

71-9310

Attn: Document Control Desk

Subject: Additional information and request to update renewed Certificate of Compliance No. 9310

References: Garcia Santos, Norma. "Action: Review of CoC, Rev. 7, Model No. F-431" Email message to Edna Sacay. 29 October 2019.

Best Theratronics would like to submit additional information for consideration regarding the Certificate of Compliance (CoC) renewal of Model No. F-431. Best Theratronics has owned the Gammacell product line since 2008, when the product and the manufacturing facility was purchased from MDS Nordion. Gammacell 1000 and Gammacell 3000 units have been manufactured for many years (Gammacell 1000 as early as 1969 and Gammacell 3000 as early as 1991). Throughout the years these units have been manufactured at the same facility, under the same name, but under different owners: AECL (Atomic Energy of Canada Limited), Nordion International, MDS Nordion and currently Best Theratronics. Best Theratronics uses the F-431 transport package to transports all of these Gammacell units.


Based on this information and considering the Safety Analysis Report (IN/TR 1913 F-431), Best Theratronics is requesting that the manufacturer's name preceding the Gammacell 1000 and Gammacell 3000 devices on the Model No. F-431 CoC, currently *MDS Nordion*, be removed and the devices listed as Gammacell 1000 and Gammacell 3000 without a manufacturer's name proceeding them.

Best Theratronics is requesting that the Certificate of Compliance renewal and this additional change be processed together. The information provided within the consolidated application (Safety Analysis Report) and in response to requests for addition information have not been affected by this request.

Issuance of the new certificate is requested by November 30, 2019 in order for Best Theratronics to obtain an endorsement certificated from the US DOT before expiry of the current certificate (December 31, 2019).

Thank you for your consideration on this matter. If you have any further questions please contact me at 613-591-2100 x 2766 or Edna Sacay (edna.sacay@theratronics.ca).

Sincerely,



Mojgan Soleimani
Director of Quality & Regulatory Affairs, RSO

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