

January 24, 2000

ASSIGNMENT NUMBER: 00-04

MDS Nordion
447 March Road
Kanata, Ontario, Canada K2K 1X8

SUBJECT: ACKNOWLEDGMENT OF REQUEST FOR SAFETY EVALUATION

Dear Ms. Warbick Cerone:

This letter acknowledges the receipt of your January 19, 2000, application that requested a safety evaluation for a TheraSphere device. We have performed a cursory review of your application and determined that enough information has been provided to allow a technical reviewer to initiate the evaluation process. Applications are assigned to technical reviewers on a first-in basis. Therefore, your application will be assigned in turn. Please note that the technical reviewer may contact you to request information that was omitted from your application or to obtain clarification of technical issues concerning your application. If you have any questions concerning the status of your application, please contact me at (301) 415-8140. Please reference the assignment number listed above in your questions or correspondence.

Please be aware that your request may be subject to the NRC's application fees in accordance with 10 CFR Part 170. Therefore, a copy of your application has been forwarded to the License Fee and Debt Collection Branch for approval of the fee category and amount. If you have any questions concerning the fees associated with your application, please contact the License Fee and Debt Collection Branch at (301) 415-7554.

Sincerely,

/s/

Traci Kime, Registration Assistant
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

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SSD-00-04 *JK*

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CONVERSATION RECORD

TYPE:

Outgoing Telephone
Incoming Telephone x
Meeting

NAME OF PERSON CONTACTED:
Ann Warbick Cerone

ORGANIZATION:
MDS Nordion

TIME:
8:30 am

DATE:
12/22/99

SUBJECT:

Requested extension to respond to deficiency letter

SUMMARY:

Ms. Cerone called and requested a long term extension to respond to NRC's deficiency letter dated November 23, 1999. There are two reasons for the request:

1. MDS Nordion received NRC's letter extremely late, i.e. on December 17, 1999. The delay could have been caused by NRC's Mail Room putting insufficient postage on the letter (\$0.25) and, thus, the letter was sent as 3rd class mail; and
2. To respond to NRC's No. 7 deficiency question, MDS Nordion needs to conduct additional testing. For the tests Nordion needs to order yttrium and to design/conduct the test. Therefore, at this time Ms. Cerone was not able to define the exact duration for an extension to the response time. She estimated that by the end of January or the middle of February, 2000, they will be able to provide the information.

ACTION REQUIRED:

NRC to close SSD 99-44 at this time based on this telephone request. NRC is to resume the review when Nordion's response is received.

PLACE THIS RECORD IN:

Registration File NR-0220-D-113-S
QA File
Incident File
General File SSD 99-44

PERSON DOCUMENTING THE CONVERSATION:
John Jankovich

SIGNATURE:



DATE:
12/22/99

cc: FSturz/IMNS
SKime/IMNS