



*Science Advancing Health*

July 2, 1999

Mr. Frederick Sturz, Section Leader  
Materials Safety and Inspection Branch  
Division of Industrial and Medical Safety  
USNRC,  
11545 Rockville Pike Rockville Maryland  
20852-2738

**Subject:** Request for Sealed Source and Device Evaluation and Registration for TheraSphere®,  
Yttrium-90 Glass Microspheres

Dear Mr. Sturz,

Enclosed please find an application for sealed source and device evaluation and registration for TheraSphere®, Yttrium-90 Glass Microspheres.

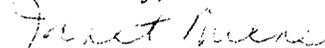
In accordance with the requirements for sealed source submissions specified in NUREG-1556, a report on the product has been compiled and is attached.

At our meeting in your office on May 5, 1999 we reviewed our dilemma, concerning our ability to fit TheraSphere® categorically to the definition of sealed source. As agreed, we have provided in this submission a description of the unique characteristics of TheraSphere® and have submitted all pertinent information on integrity testing (as per ISO 2919 1998) for this device which was deemed applicable and appropriate.

An application to the FDA for human use device exemption has been submitted and is pending. The safety data included in the FDA application was obtained through clinical use of the product. Additional history of use data exists for the product through licensed use of the product as a drug in Canada.

Enclosed is a cheque for \$910 USD as payment of the evaluation and registration fee.

Yours truly,

  
Ann Warbick Cerone  
Manager  
Regulatory Affairs

Encl.

**LICENSE FEE REQUIREMENTS**

ATTN: Sandra Kimberley, MS T-9E10  
U.S. Nuclear Regulatory Commission  
License Fee and Accounts Receivable Branch  
P. O. Box 954514  
St. Louis, MO 63195-4514

**MDS Nordion**  
ATTN: Ms Ann Warbick Cerone  
Manager, Regulatory Affairs  
447 March Road  
Kanata, Ontario, Canada K2K 1X8

**TYPE OF ACTION**

- NEW LICENSE
- RENEWAL OF LICENSE
- AMENDMENT TO LICENSE

REQUESTED DATE

07/02/1999

LICENSE NUMBER

New

CONTROL NUMBER

99-44

**I. APPLICATION FEE DUE**

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of 10 CFR Part 170. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
9A	\$ 3,600.00	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$
	\$	\$	\$

FEE(S) DUE	\$	3,600.00
PAYMENT RECEIVED	\$	910.00
AMOUNT DUE	\$	2,690.00

**II. FEE NOT REQUIRED**

- Check Number Enclosed is your check which accompanied your request. The fee is not required because:
- Check Number We received your check listed in payment of the fee.
- Date of Request The Licensing staff has informed us that your request is to be considered as a continuation of the request listed.
- Control Number
- Date of Request Your request was combined, prior to review, with the request listed.
- Control Number

**III. CHECK RETURNED**

- Check Number Enclosed is your check which was returned to us by the bank for:
- INSUFFICIENT FUNDS
- ACCOUNT CLOSED
- OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

**IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE**

- License Number Amendment Number Date Issued The listed license was issued without the required fee being collected. The fee required is noted in Section I of this form.
- The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).
- Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

SIGNATURE -- LICENSE FEE ANALYST

LFDCB	LFDCB
slk	
7/12/99	

Sandra Kimberley, 301-415-6096

Distribution:  
OC/DAF/LFARB S/F  
(LF-3.2.7)  
OC/DAF/LFARB RF  
OC/DAF R/F

Pending Cy

cc: SS&D

DATE

07/12/1999

## CONVERSATION RECORD

**TYPE:**

Outgoing Telephone x  
Incoming Telephone  
Meeting

**NAME OF PERSON CONTACTED:**

Ann Warbick Cerone

**ORGANIZATION:**

MDS Nordion

**TIME:**

2:30pm

**DATE:**

8/11/99

**SUBJECT:**

Request for additional information, Application No. 99-44

**SUMMARY:**

I called Ms. Cerone, after completing the acceptance review of their application, dated July 2, 1999. Douglas Beatty/Theratronics was in her office and was also on the phone. I asked for the following information not contained in the application:

1. Demonstration that the specimen which had been subjected to the leach test (dated 1993) are identical to those which are manufactured presently;
2. Information on Nordion's QA program, e.g. program summary, ISO certification, list of procedures;
3. Differences between ISO 2919-1998 and ANSI 43.10-1997.

She said that she will mail the information shortly.

**ACTION REQUIRED:**

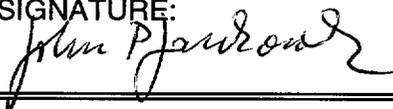
NRC to conduct safety evaluation when information arrives.

**PLACE THIS RECORD IN:**

Registration File NR-  
QA File  
Incident File  
General File 99-44

**PERSON DOCUMENTING THE CONVERSATION:**

John Jankovich

**SIGNATURE:****DATE:**

8/11/99