COLLEEN CAROL CASEY
MATERIALS LICENSING BRANCH
UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4352
OFFICE: (630)-829-9841 FAX: (630) 829-9782

5/17/05 - Tom K, Withdrew this request in 9 voicemail message to me. C. Casey

CONVERSATION RECORD	TIME	DATE
ACTUALLY FAXED? YES.	2:35 pm CT	May 4, 2005
	C left VM msg for Tom	
NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.

Thomas M. Kumpuris, M.S., consultant for Harper University Hospital 800-321-2207, fax, 313-662-9224

31Y284

SUBJECT
License No.: 21-04127-02 Control No.: ~~313798~~ 314235 - canceled

SUMMARY
We have reviewed your letter dated January 11, 2005, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

1. Please provide a copy of the IND application itself (from NeoRx to the FDA).

2. Please describe who will prepare the diagnostic and therapeutic dosages of the Holmium-166 (Ho-166) product (sponsoring vendor, commercial nuclear pharmacy, "in-house" staff, etc.).

3. Please describe the radiation safety handling precautions that will be employed for all personnel involved in each Ho-166 administration, including training, emergency procedures, "dry runs," spill procedures, use of remote handling tools and carts, security of the material etc. Please include copies of step-by-step emergency procedures and spill procedures that you will employ in the event of leakage, spills, patient interventions, etc. that result in Ho-166 contamination. Please describe the types and frequencies of surveys you will employ during and after each use of Ho-166.

4. Please describe the logistical and radiation safety considerations for the conduct of this study if any aspect of it will be "blind." Please refer to Information Notice IN 2000-19, previously sent to you, and note: "Licensees also need to be aware that participation in a "blind" study does not relieve the licensee from meeting the: labeling requirements in 10 CFR Part 35; written directive requirements; research subject release and the instruction requirements of 35.75; hospitalization requirements in 10 CFR Part 35; and misadministration (now called "medical events") notification and reporting requirements."

5. Please indicate the duration of time expected to be required for the infusion of the Ho-166 material therapeutically. Please indicate a minimum to maximum range of time as well as a typical/average time.

6. Please describe the radiation safety precautions that will be employed to prevent unnecessary exposure to the infusion tubing containing the Ho-166 product. For example, will the tubing be shielded with plexiglas and will the tubing bear a label reminding people to not touch it directly? Will only essential personnel/staff be physically present during the infusion and who will that be? Will family members and/or friends of the human research subject be physically present during the infusion? If so, why will they be present and how will they be protected from unnecessary radiation exposure?

7. Please submit a copy of the FDA IND application that contains radiation safety commitments suitable for public release. Please do not submit proprietary information subject to 10 CFR 2.390. The abbreviated response that accompanied your letter dated January 11, 2005, was marked "Confidential" but we must have a version that is complete and is suitable for public release.

8. Please confirm that Appendix U to NUREG 1556, or equivalent procedures will be employed for the release of human research subjects, in accordance with 10 CFR 35.75.

9. Please confirm that the sponsoring vendor will conduct onsite training with all essential personnel (authorized user, radiation workers, nurses, etc.) prior to commencement of the use of the Ho-166 products.

ACTION REQUIRED

Submit the requested information within 20 days (by May 24, 2005) by referencing control number **314235** to facilitate proper handling. Please note that this is a different control number than the one initially assigned to your letter dated January 11, 2005. The letter dated January 11, 2005, has been combined into another pending amendment request for you under control number 314235.

Upon receipt of your response we will resume our review. Address your written response to my attention at the above address.

PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT 630-829-9841.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. The enclosed license document is exempt from public disclosure in accordance with 10 CFR 2.390, because its disclosure to unauthorized individuals could present a security vulnerability.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Colleen Carol Casey	Colleen Carol Casey	May 4, 2005

TRANSMISSION VERIFICATION REPORT

TIME : 05/04/2005 14:38
NAME : USNRC
FAX : 6308299782
TEL : 6308299782

DATE,TIME	05/04 14:37
FAX NO./NAME	87346629224
DURATION	00:01:03
PAGE(S)	03
RESULT	OK
MODE	STANDARD ECM

(1-2002)

UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
801 Warrenville Road, Suite 255
Lisle, Illinois 60532-4351

TELEFAX TRANSMITTAL

DATE: 5/4/05

NUMBER OF PAGES: 3
(including this page)

SEND TO: TOM KUMPURIS

LOCATION: FOR HARPER UNIVERSITY HOSPITAL

FAX NUMBER: 734-662-9224 ☐ VERIFY BY CALLING SENDER

FROM: COLLEEN CAROL CASEY
(SENDER)

TELEPHONE NUMBER: 630-829-9841 FAX NUMBER: 630-829-9782

If you do not receive the complete fax transmittal, please contact the sender as soon as possible at the telephone number provided above.

MESSAGE

Please call me if you have any questions.

Thank you,

NRC FORM 366 (RIII)
(7-2001)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 Warrenville Road, Suite 255
Lisle, Illinois 60532-4351

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(SENDER) COLLEEN CAROL CASEY

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MESSAGE

Please call me if you have any questions.

Thank you,

Colleen Carol Casey

Revised to correct control no. on page 1 of fax record sheet and re-sent! Sorry about that!
- Colleen

NOTICE

TRANSMISSION VERIFICATION REPORT

TIME : 05/04/2005 14:29
NAME : USNRC
FAX : 6308299782
TEL : 6308299782

DATE,TIME	05/04 14:28
FAX NO./NAME	87346629224
DURATION	00:01:01
PAGE(S)	03
RESULT	OK
MODE	STANDARD ECM

(2-2002)

UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
801 Warrenville Road, Suite 255
Lisle, Illinois 60532-4351

TELEFAX TRANSMITTAL

DATE: 5/4/05

NUMBER OF PAGES: 3
(including this page)

SEND TO: TOM KUMPURIS

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(SENDER)

TELEPHONE NUMBER: 630-829-9841 FAX NUMBER: 630-829-9782

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MESSAGE

Please call me if you have any questions.

Thank you,

314135 copy

COLLEEN CAROL CASEY
MATERIALS LICENSING BRANCH
UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4352
OFFICE: (630)-829-9841 FAX: (630) 829-9782 or (630) 515-1259

CONVERSATION RECORD | TIME | DATE

ACTUALLY FAXED? YES. **February 7, 2005**

NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.
Richard Joyrich, M.D., RSO for Harper University Hospital		313-745-2007 Fax: 313-745-2314

SUBJECT
License No.: 21-04127-02 Control No.: 313558

SUMMARY
We have reviewed your letter dated November 1, 2004, requesting an amendment to your byproduct materials license and find that we need additional information as follows:

1. Please submit a copy of an acknowledgment of receipt from Nucletron showing that the vendor received your last active source. 10 CFR 30.41 and 30.51 require this information and we must review it before we can amend your license to remove this HDR source and device authority from your license. Nucletron should have sent this to you automatically when you returned the last source/device.

OK

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS.

The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

ACTION REQUIRED

As we cannot issue an amendment at this time, I am voiding your request to permit you to prepare a quality response without time constraints. This action is taken without prejudice to its resubmission at a later date. Please submit the requested information by referencing control number 313893 to facilitate proper handling. Upon receipt of your response we will resume our review. Address your written response to my attention at the above address.

PLEASE NOTE THAT A "VOID" IS AN ADMINISTRATIVE PROCEDURE THAT PUTS YOUR AMENDMENT REQUEST "ON HOLD" (TAKES IT OUT OF OUR ACTIVE CASEWORK DATABASE) UNTIL YOU REACTIVATE IT VIA A WRITTEN RESPONSE. IT "BUYS" YOU TIME TO PREPARE A QUALITY RESPONSE AND IS GENERALLY REGARDED AS A "GOOD THING."

PLEASE DIRECT ANY QUESTIONS YOU MAY HAVE TO ME AT 630-829-9841.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Colleen Carol Casey		February 7, 2005