

MAY 10 1985

File

Holy Cross Parkview Hospital
ATTN: Martin P. Braaksma
Executive Director
1401 North Michigan Street
Plymouth, IN 46563

Gentlemen:

Enclosed is Amendment No. 05 renewing your NRC License No. 13-18880-01 in accordance with your request.

Several new conditions have been incorporated in your license. In view of this, please review your license carefully to assure that you understand and are in compliance with the terms and conditions contained therein. If you have questions, please contact our office by dialing (312) 790-5625.

Thyroid uptake can occur by breathing volatile iodine which is released when the cap is first removed from vials containing therapeutic liquid iodine-131. Personnel should be instructed to wear gloves and to open the vials in a fume hood or to take alternative precautionary measures.

A bioassay program should be established for personnel who handle therapeutic liquid iodine-131. As a minimum, thyroid counts should be obtained approximately twenty-four (24) hours after exposure. Refer to the enclosed bioassay guide.

License Condition No. 15. requires that you establish a bioassay program in accordance with Regulatory Guide 8.20 (enclosed). License Condition No. 16. requires that you follow procedures found in Appendix K, "Radiation Safety Procedures for Therapeutic Use of Radiopharmaceuticals" of Regulatory Guide 10.8, October, 1980 (enclosed). If you wish to develop alternative procedures that are at least equivalent to those found in Regulatory Guide 8.20 or Appendix K of Regulatory Guide 10.8, your license can be amended accordingly.

Please review the enclosed document carefully and be sure that you understand all conditions. You must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Possess radioactive material only in the quantity and form indicated in your license.

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3. Use radioactive material only for the purpose(s) indicated in your license.
4. Notify NRC in writing of any change in mailing address.
5. Request and obtain appropriate amendment if you plan to change ownership of your organization, change locations of radioactive material, or make any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any supplemental correspondence with NRC. Any amendment request should be accompanied by the appropriate fee specified in 10 CFR Part 170.
6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.
7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material prior to your expiration date.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions and representations in your license application will result in enforcement action against you in accordance with the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

If you have any questions or require clarification of any of the above stated information, contact us at (312) 790-5625.

Sincerely,

Original Signed By
J. R. Madera
Materials Licensing Section

Enclosure(s):

1. Amendment No. 05
2. Regulatory Guide 8.20
3. Regulatory Guide 10.8

RTH
JRM
Madera/ld
05/09/85

CONVERSATION RECORD

TIME

DATE

5/8/85

TYPE

☐ VISIT

☐ CONFERENCE

☒ TELEPHONE

☐ INCOMING

☒ OUTGOING

ROUTING

NAME/SYMBOL

INT

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

ORGANIZATION (Office, dept., bureau, etc.)

TELEPHONE NO.

219/287-4146

John D. Schew, PhD, Consultant Holy Cross Parkview Hosp. 936-3181

SUBJECT

Renewal Application Classification & addition conditions discussion

SUMMARY

Q. Is material still being procured from Memorial Hospital in South Bend, IN.?

A. According to Dr. Schew, PhD (Consultant) no material is being procured from Memorial Hosp.

License Cond. 15 was added - Reg. Guide 8.20 (Biossray Program).

License Condition 16 was added - App. K, Reg. Guide 10.8 (Radiation Safety Procedures for Therapeutic Radiopharmaceuticals).

L/c 17 was added - Calicheck procedures.

ACTION REQUIRED

N/A

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

J.R. Made

5/8/85

ACTION TAKEN

SIGNATURE

TITLE

DATE