

## MATERIALS LICENSE

Amendment No. 13

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

301962

## Licensee

1. Southwestern Indiana Radiation Oncology Center
2. 700 North Burkhardt Road  
Evansville, IN 47715

In accordance with letters dated  
June 19, 1996 and October 15, 1996  
3. License Number 13-25945-01 is amended in  
its entirety to read as follows:

4. Expiration Date January 31, 2004

5. Docket or  
Reference No. 030-307126. Byproduct, Source, and/or  
Special Nuclear Material7. Chemical and/or Physical  
Form8. Maximum Amount that Licensee  
May Possess at Any One Time  
Under This License

A. Cobalt-60

A. Sealed source (model  
designation AECL  
C-146 or C-151 or  
Neutron Products,  
Inc. NPTT Series)

A. 14,000 curies  
total, not to  
exceed 7,000 curies  
per source

B. Strontium-90

B. Sealed source  
identified in 10 CFR  
Section 35.400(e)

B. No single source  
to exceed 50  
millicuries

C. Iridium-192

C. Sealed sources  
(RTS Technology,  
Inc. Model Nos.  
721, 722, 723, or  
724, Mallinckrodt  
Diagnostics B.V.,  
Dwg. No. GM  
212.03-000)

C. Two sources not to  
exceed 10 curies  
each

D. Uranium (Depleted in  
Uranium-235)

D. Solid metal

D. 300 kilograms total  
possession limit

## 9. Authorized Use:

- A. One source for medical use described in 10 CFR 35.600 in an AECL Theratron 780 teletherapy unit. One source in its shipping container as necessary for replacement of the source in the irradiation device.
- B. Medical use described in 10 CFR 35.400(e) in eye applicator devices which have been evaluated and approved by the Commission or an Agreement State.

270124

9611290041 961105  
PDR ADOCK 03030712  
C PDR

COPY

2<sup>ML</sup>  
30  
SD

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

13-25945-01

Docket or Reference Number

030-70712

Amendment No. 13

- C. One source to be used in Mick Radio-Nuclear Instruments, Inc. Gamma Med 12i HDR remote afterloading brachytherapy unit for interstitial and intracavitary radiotherapy. One source in its shipping container to be in possession of the licensee as necessary for replacement of source in the irradiation device.
- D. Shielding in teletherapy unit and HDR brachytherapy unit.

CONDITIONS

10. A. Licensed material in Items 9.A., 9.B. and 9.D. shall be used only at the licensee's facilities located at Southwestern Indiana Cancer Center, 700 North Burkhardt Road, Evansville, Indiana.
- B. Licensed material in Items 9.C. and 9.D. shall be used only at the licensee's facilities located at 6225 Columbia Street, Evansville, Indiana.
11. Radiation Safety Officer: Shannon Lamb, M.D.
12. Authorized Users
- |                             | <u>Material and Use</u> |
|-----------------------------|-------------------------|
| A. Alvin Korba, M.D.        | All                     |
| B. Shannon Lamb, M.D.       | All                     |
| C. Moises Domingo, M.D.     | Subitems 6.A. and 6.C.  |
| D. Devdas Sheth, M.D.       | All                     |
| E. Tristan Briones, M.D.    | Subitems 6.A. and 6.C.  |
| F. Kanta Desai, M.D.        | All                     |
| G. Aly Razeq, M.D.          | All                     |
| H. Pramod Prabhu, M.D.      | All                     |
| I. Crystal Reed, M.D.       | Subitems 6.A. and 6.C.  |
| J. Timothy R. O'Leary, M.D. | All                     |
13. Teletherapy Physicists: Saiyid Shah, Ph.D. or Arnold Sorensen

COPY

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

13-25945-01

Docket or Reference Number

030-30712

Amendment No. 13

14. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterloading device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to conform that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).
15. In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:
- A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each remote afterloading brachytherapy procedure.
  - B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.
  - C. Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr ( $\mu$ Sieverts/hr), time, date and name of the individual making the survey.
  - D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).
16. Prior to initiation of a treatment program, and subsequent to each source exchange using the remote afterloading brachytherapy devices, radiation surveys and tests shall be performed in accordance with the following:
- A radiation survey shall be made of:
- (1) The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 100 centimeters from the surface of the main source safe shall not exceed 0.60 milliroentgen per hour.
  - (2) All areas adjacent to the treatment room with the source in the "irradiation" position. The survey shall clearly establish:
    - (a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.1201.
    - (b) That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.1301.
17. The following shall be performed only by manufacturer's representatives or persons specifically authorized by the Commission or an Agreement State to perform such services:

COPY

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

13-25945-01

Docket or Reference Number

030-30712

Amendment No. 13

- A. Installation and replacement of the sealed sources contained in the Gamma Med afterloading brachytherapy device.
- B. Any maintenance or repair operations on the remote afterloading brachytherapy units listed in Item 9., Subitem C. involving work on the source safe, the source drive unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.
18. A. Access to the room housing the Mick Nuclear Gamma Med 12i remote afterloading brachytherapy device shall be controlled by a door at each entrance.
- B. The entrance to the irradiation room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.
- C. Electrical interlocks on the entrance door to the irradiator room shall be tested for proper operation at least once each day of use.
- D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.
19. The licensee is exempted from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35(d) for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change.
20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Letters dated August 26, 1993, December 17, 1993, July 17, 1995 and November 7, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date

November 5, 1996

By

Lillian C. Casey

Nuclear Materials Licensing Branch, Region III

**COPY**



BETWEEN:

License Fee Management Branch, ARM  
and  
Regional Licensing Sections

(FOR LFMS USE)  
INFORMATION FROM LTS

Program Code: 02300  
Status Code: 0  
Fee Category: 7A 2B  
Exp. Date: 20040131  
Fee Comments:  
Decom Fin Assur Req'd: N

56  
21

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: SOUTHWESTERN IN RADIA. ONCOL. CNTR.  
Received Date: 961021  
Docket No: 3030712  
Control No.: 301962  
License No.: 13-25945-01  
Action Type: Amendment

2. FEE ATTACHED

Amount: 470  
Check No.: 50067

3. COMMENTS

Signed  
Date

D. Hersey  
10-22-96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered / \_\_ /)

1. Fee Category and Amount:

7A 2B

\$470

2. Correct Fee Paid. Application may be processed for:

Amendment  
Renewal  
License

3. OTHER

Signed  
Date

SC  
10/25/96

1996 OCT 25 AM 11:11

OCT 31 1996

Log	OCT 11 III
Remitter	Oncology Assoc. Disbursements
Check No.	50067
Amount	\$470
Fee Category	7A 2B
Type of Fee	Amendment
Date Check Rec'd	10/25/96
Date Completed	10/25/96
By:	SC



## Southwestern Indiana Radiation Oncology Center

700 N. Burkhardt Road • Evansville, Indiana 47715 • (812) 474-1110 • FAX (812) 474-1303

Aly Razeq, M.D.  
Shannon Lamb, M.D.  
Crystal Reed, M.D.

Al Korba, M.D.  
Radiation Oncologist  
Medical Director

Radiological Physicists:  
Arnold Sorensen, B.S.  
Saiyid Massroor Shah, Ph.D.

October 15, 1996

CHIEF, MATERIALS LICENSING SECTION  
US NRC REGION III  
801 WARRENVILLE ROAD  
LISLE IL 60532 4351

Ref: #13-25945-01  
Subject: Amendment to License

Dear Sir:

Please amend License #13-25945-01 for the following:

- 1) Substitute Shannon Lamb, M.D. as Radiation Safety Officer instead of Alvin Korba, M.D.
- 2) Authorize the use of Iodine-131 and Strontium-89.

I-131 and Sr-89 will be used at:  
6225 Columbia St., Evansville IN 47715

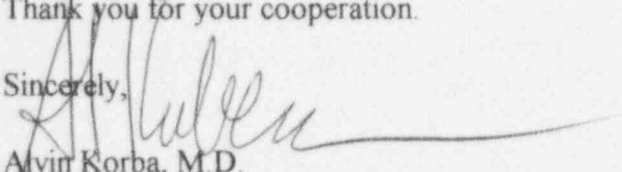
Please note that the mailing address for the license does not change.

I-131 and Sr-89 will be administered to the patients for therapeutic reasons on outpatient basis and as such individual doses will not exceed 30mci.

Necessary information is enclosed with this letter. If you <sup>have</sup> any further questions, please call Saiyid M. Shah, Ph.D.

Thank you for your cooperation.

Sincerely,

  
Alvin Korba, M.D.  
Radiation Safety Officer  
AK:rw

pm: 10-17-96

RECEIVED

OCT 21 1996

REGION III

• Business Office •

906 S. Hebron; P.O. Box 15040 • Evansville, Indiana 47716-0040 • (812) 476-1367  
In Indiana, 1-800-843-7117; Outside Indiana, 1-800-331-9294 • FAX 812-477-4153

301962

## REQUEST TO AMEND LICENSE #13-25945-01

A. Substitute the name of Shannon Lamb, M.D. as Radiation Safety Officer instead of Alvin Korba, M.D. She is a diplomate of American Board of Radiology in Therapeutic Radiology and is listed as authorized user on this license.

B. Addition of Radioactive materials

By Product Material	Amount	Purpose
I-131	As needed	Medical use
Sr-89	As needed	Medical use

Authorized Users

Alvin Korba, M.D.

Aly Razek, M.D.

Shannon Lamb, M.D.

Timothy O'Leary, M.D.

All of them are diplomates of the American Board of Radiology in Therapeutic Radiology/Radiation Oncology.

## TRAINING PROGRAM

1. Training will be provided by a qualified medical physicist to all personnel involved in the use to these radioactive

materials. As per requirements of 10CFR19.12, the instructions will include:

- a) All terms of license pertinent to radiation safety.
- b) Identification of area where radioactive material is used or stored.
- c) Potential hazards associated with radioactive materials used or stored.
- d) Radiation safety procedures appropriate to their respective duties.

- e) Pertinent NRC or other applicable rules and regulations.
  - f) Obligation to report unsafe conditions to Radiation Safety Officer.
  - g) Appropriate response to emergencies and unsafe conditions.
  - h) Right to be informed of their radiation exposure bioassay results, if applicable.
  - i) Location where the license has been posted or made available including notices,
  - j) Copies of the pertinent regulations and copies of the pertinent licenses and
  - k) License conditions (including applications and applicable correspondence).
  - l) Institution's policy and procedures pertinent of safe use of radioactive materials.
2. All new radiation workers will receive radiation safety instructions before assuming duties.
- All radiation workers will, at least annually, receive refresher training. They will also receive additional training whenever there is a significant change in duties, regulations, or the term of the license.
3. Ancillary staff (e.g. clerical, housekeeping) whose duties may require to work in the vicinity of radioactive materials will receive radiation safety instructions, appropriate to their position. Thereafter they will, at least annually, receive refresher training. They will also receive training whenever there is a significant change in duties, regulations, or the term of the license.
4. All training programs provided to the radiation workers and ancillary staff will be site specific and pertinent to their respective responsibilities.
5. All the records of this training shall be maintained at least for a period required by NRC and will include:
- (i) Date(s) when training was held
  - (ii) Name(s) of individual(s) who attended the training



(iii) Name(s) of the instructor(s)

(iv) Brief outline of the topics discussed.

Every session will have questions and answers period allocated and the attendees will be encouraged to participate actively.

## **FACILITIES AND EQUIPMENT**

### **1. Radioactive Materials Storage.**

Radioactive materials will be stored in designated hot lab area.

### **2. Survey Instrument Calibration.**

Radiation survey meters will be calibrated not to exceed twelve months or after a major repair.

The calibration will be performed by a commercial facility authorized by NRC or an agreement state to perform this service. At this time we plan to use **Stan Huber Associates** for the calibration of survey meters.

### **3. Dose Calibrator Calibration Procedure**

We will establish and implement the model procedure for calibrating our dose calibrator that was published in appendix C to Regulatory Guide 10.8, Revision 2.

## **SAFE USE OF RADIOPHARMACEUTICALS**

The following rules will be followed for the safe use of radiopharmaceuticals:

- 1) Wear laboratory coats, or other protective clothing's at all times in areas where radioactive materials are used.
- 2) Wear disposable gloves at all times while handling radioactive materials.
- 3) Do not eat, drink, smoke, apply cosmetics or place personal items in any area where radioactive materials are used or stored.

- 4) Assay each patient dose in dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10%.
- 5) Wear personnel monitoring devices (film badge or TLD) at all times while in area where radioactive materials are used or stored. The radiation monitoring badges should be worn at chest or waist level.
- 6) Wear TLD finger badges during assay, and injection of radiopharmaceuticals.
- 7) Dispose of radioactive waste only in specially designated receptacles.

## **SPILL PROCEDURES**

The following spill procedures will be used.

### **a) Minor Spills Emergency Procedures.**

- 1) Notify persons in the area that a spill has occurred.
- 2) Cover the spill with absorbent paper.
- 3) Use disposable gloves and handling tongs. Carefully fold the absorbent paper and put it into a plastic bag and dispose of the Radioactive Waste Container. Make sure all the contaminated materials are placed in a plastic bag.
- 4) Survey around the spill, hands, and clothing with a radiation survey meter for contamination.
- 5) Report the incident to Radiation Safety Officer.

### **b) Major Spill Emergency Procedures**

- 1) All people not involved in the spill are to vacate the area.
- 2) Cover the spill with absorbent pads, do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

- 3) If possible, the spill should be shielded. But only if it can be done without further contamination or without significantly increasing radiation exposure.
- 4) Leave the room and lock the door(s) to prevent entry.
- 5) Notify Radiation Safety Officer immediately.
- 6) Contaminated clothes, if any, should be removed and stored for further evaluation by RSO. If spill is on the skin, flush thoroughly and then wash with mild soap with luke warm water.

### **Ordering and Receiving**

1. Only the Radiation Safety Officer or a designee will authorize each order for radioactive materials and ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that the possession limits are not exceeded.
2. a) The authorized user who will perform the procedure will make a written request that indicates:
  - i) Isotope
  - ii) Activity
- b) The person who receives the material will check the authorized user's written request to confirm that the material received is in conformity with the order.
3. Iodine-131 for therapeutic use will be ordered in precalibrated capsule form. Strontium-89 will be ordered in precalibrated unit doses.

### **OPENING PACKAGES**

The following procedure will be followed for opening packages:

1. Packages will be inspected for any sign of damage. If damage is noted, the procedure will be stopped and the Radiation Safety Officer will be notified immediately.
2. Exposure rate will be measured at the surface and at 1 meter from the package. If the exposure is determined to be higher than expected, the procedure to open the package will be stopped and the Radiation Safety Officer will be notified immediately. The dose rate at 1 meter should be equal or less than that indicated as the Transport Index for "Yellow II" or Yellow III" labeled packages. The surface dose for such packages should not exceed 200 mrem/hr. The dose rate from packages with "white" labels should be less than 0.1 mrem/hr at the package surface.
3. The package will be opened with the following precautionary steps:
  - i) Remove the packing slip.
  - ii) Open the outer package following supplier's instructions, if provided.
  - iii) Open the inner package, if any, and verify that the contents agree with the packing slip.
  - iv) If anything is other than expected, stop and notify RSO.
4. If there is any reason to suspect contamination, wipe the external surface of the final container and remove the sample to a low background area. Assay the wipe sample to determine if there is any removable radioactivity. Wear gloves to avoid personal contamination.
5. Check the authorized user request to ensure that the material received is the same as ordered.
6. Make a record of the receipt.

## **RECORD KEEPING**

The following records will be maintained for the use of I-131 and Sr-89.

- i) Radionuclide with generic name or its abbreviation or trade name.
- ii) Date of receipt
- iii) Supplier
- iv) Activity in millicurie as recorded on the unit dosage or packing slip and its associated time.
- v) Date of administration or disposal
- vi) If administered, as prescribed dosage, by measured activity in mci, date and time of measurement.
- vii) If discarded, the date and method of disposal.
- viii) Initials of the individual who made the record.

## **AREA SURVEY PROCEDURES**

- i) A quarterly survey will be performed of the storage area with a radiation measurement survey meter to confirm that the radiation levels are below permissible levels.
- ii) RSO will be notified immediately if unexpectedly high or low levels of radiation are measured.
- iii) A record of the quarterly survey will be maintained with the following information:
  - a) Date and equipment used.
  - b) Name or initial of the person who made the survey.
  - c) Action taken in case of excessive dose rates.



## WASTE MANAGEMENT

### 1. General Guidance

- i) All radioactive labels to be defaced or removed from empty containers and packages prior to disposal in in-house waste.
- ii) The staff will be reminded not to mix the non-radioactive waste, such as leftover reagents, boxes, and packing material with radioactive waste.

### 2. Disposal of Liquids

- i) Wherever possible, unused radioactive material will be returned to the vendor(s).
- ii) Short lived materials with physical half life less than 65 days, unless returned to the vendor, will be disposed of by Decay-in-Storage (DIS) with the following procedure:
  - a) Radioactive waste will be placed in a separate container.
  - b) Once the container is full, it will be sealed with string and tape. An identification tag will be attached that will include the date sealed, the longest lived radio isotope in the container, and the initials of the person sealing the container. After this, the container will be transferred to the DIS area.
  - c) The material will be decayed for at least 10 half-lives.
  - d) Prior to disposal as in-house waste, each container will be monitored as following:
    - 1) Radiation survey meter will be checked for proper operation.
    - 2) Any shielding will be removed from around the container and surface of the container will be measured in a low back (less than 0.05 mr/hr) area.

- 3) The contents of the container will be discarded as in-house waste if the exposure around the container cannot be distinguished from the background.
- A record of the date on which the container was sealed, the disposal date and the type of material will be maintained. If the exposure around the container is determined to be above the background level, it will be returned to storage area for further decay.

license.app

NOV 06 1996

Alvin Korba, M.D.  
Southwestern Indiana Radiation  
Oncology Center  
700 North Burkhardt Road  
Evansville, IN 47715

Dear Dr. Korba:

Enclosed is Amendment No. 13 to your NRC Material License No. 13-25945-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

- A. Please note that we were unable to authorize the use of therapeutic radioactive drugs at this time because the information submitted in your letter dated October 15, 1996, was insufficient for us to complete our review. If you wish to pursue this authorization, please address the information requested below and submit it to us as additional information to Control No. 301962. We will then continue our review, without an additional fee, limited to this authorization. Be advised that, if you request anything other than this authorization, an amendment fee will be required.

Please provide the following:

1. On a revised, detailed version of your facility diagram, please indicate the position of each of the areas described below (a-d) and describe the type, dimensions, and thicknesses of shielding that you will use. Exhibit 6 and section 9.1 of the enclosed Regulatory Guide 10.8, Rev. 2, may be helpful in preparing your response and provides an example of a facility diagram that is acceptable to the NRC.
  - a. Receipt and storage of the radioactive therapy drugs.
  - b. Locations of lockable doors, the direction of north and the scale of the diagram (or the actual dimensions.)

301962

- c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. If this area is not located within your main department, describe where and how you will secure the material from unauthorized access/removal.
- d. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, etc.).

In addition, identify adjacent areas across the walls from use and storage locations and show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301 (enclosed).

- 2. Please resubmit and describe your routine area survey program to meet the requirements of 10 CFR 35.70, enclosed, including the type and frequency of surveys, the areas you will survey, the levels of contamination that you consider to be acceptable, and provisions for maintaining records of surveys. Appendix N of enclosed Regulatory Guide 10.8, Rev. 2, may be helpful in preparing your response and provides a program that is acceptable to the NRC.

Please note that the "Area Survey Procedures" provided in your letter dated October 15, 1996, appear to be based upon requirements in 10 CFR 35.59, which apply only to sealed sources.

- 3. It appears that a more appropriate request for the authorization you seek would be "for materials in 10 CFR 35.300, excluding iodine-131 for thyroid carcinoma treatments." The advantage of the revised authorization is that it does not restrict your use of only certain radionuclides, it just excludes the one type of use for which hospitalization is required, per 10 CFR 35.75.

If this authorization is satisfactory please confirm that you would prefer us to substitute this wording for the request for individual isotopes made in your October 15, 1996 letter.

- 4. Your Quality Management (QMP) program does not address all of the types of use for which you are requesting authorization on your NRC license. Specifically, 10 CFR 35.300 materials, excluding iodine-131 for thyroid carcinoma treatments, were not addressed.

10 CFR 35.32(a) states, in part, that a licensee must establish and maintain a written Quality Management (QMP) program for all 10 CFR Part 35 uses applicable to their program. Please submit a revised copy of your QMP program addressing the use of materials in 10 CFR 35.300, excluding iodine-131 for thyroid carcinoma treatments.

5. Please note that, at this time, we must limit your authorization for iodine-131, as listed in 10 CFR 35.300, in order to preclude your having to file an emergency plan, per 10 CFR 30.32(ii) and 30.72, enclosed. Your total possession limit for iodine-131 must be less than 10 curies and will include waste activity also. Please advise us of the possession limit you wish to have for iodine-131.
- B. Please note that, at this time, we changed the expiration date in item no. 4 of your license to reflect the one-time extension of your license, in accordance with 10 CFR 30.36(a)(2), copy enclosed. You should have received additional correspondence from us concerning this regulation and its effects on your license.
- C. In accordance with your letter dated June 19, 1996, we approved Timothy O'Leary, M.D., as an authorized user.
- D. If you have any questions concerning this amendment or the information requested above, please contact Colleen C. Casey at (630) 829-9841.
- E. Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct 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. Notify NRC, in writing, within 30 days:
    - a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
    - b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).



3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.
4. Request and obtain a license amendment before you:
  - a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
  - b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;
  - c. Change Radiation Safety Officers;
  - d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
  - e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
  - f. Change ownership of your organization.
5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions. Since serious consequences

A. Korba

-5-

to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By  
Colleen C. Casey  
Nuclear Materials Licensing Branch

License No.: 13-25945-01

Docket No.: 030-30712

Enclosures: 1. Amendment No. 13  
2. 10 CFR Part 20  
3. 10 CFR Part 30  
4. 10 CFR Part 35  
5. NRC Form 313  
6. Reg. Guide 10.8, Rev. 2

DOCUMENT NAME: M:\03030712.CL6

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII <i>CCCEC</i>							
NAME	CCASEY:jaw							
DATE	10/05/96							

OFFICIAL RECORD COPY



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

October 22, 1996

Shannon Lamb, M.D.  
Radiation Safety Officer  
Southwestern Indiana Radiation  
Oncology Center  
700 North Burkhardt Road  
Evansville, IN 47715

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE  
(Letter Dated 10/15/96)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

☐ New License                      ☒ Amendment                      ☐ Renewal  
☐ Termination                      ☐ Auth User (Amendment not required)  
☐ Other \_\_\_\_\_

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 301962  
License No. 13-25945-01