MATERIALS LICENSE

Amendment No. 55

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.

302083

Licensee	
1. St. Elizabeth Hospital	In accordance with letter dated December 5, 1996 3. License Number 48-10219-01 is amended in its entirety as follows:
2. 1506 South Oneida Street Appleton, WI 54915	4. Expiration Date June 30, 1994
	5. Docket or Reference No. 030-03466

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed
C. Any byproduct material identified in 10 CFR 35.300	C. Any radiopharmaceutical identified in 10 CFR 35.300	C. As needed (not to exceed 10 curies of I-131)
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy sources identified in 10 CFR 35.400	D. As needed
E. Iridium-192	E. Sealed sources (Byk Mallinckrodt Model CI L BV)	E. Two sources not to exceed 10 curies each

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200.

C. Medical use described in 10 CFR 35.300.

9/1

COPY

050037

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9. Authorized Use (Continued)

D. Medical use described in 10 CFR 35.400 and for instrument calibrations.

E. One source to be used in a Nucletron Corporation MicroSelectron-HDR remote afterloading brachytherapy unit for interstitial and intracavitary radiotherapy and for instrument calibration. One source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the irradiation device.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 1506 South Oneida Street, Appleton, Wisconsin and at 1611 Madison Street, Appleton, Wisconsin.

11. Radiation Safety Officer: Stanley Reed, M.S.

12. Authorized Users:

A. John I. Halloran, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.500.

B. Gregory J. Knudson, M.D., for material in 10 CFR 35.100, 35.200 and 35.300.

C. Patrick O'Brien, M.D., for material in 10 CFR 35.100 and 35.200, limited to cardiovascular clinical procedures.

D. Henry Chessin, M.D., for material in 10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit and 35.300 limited to strontium-89.

E. Stanley A. Reed, M.S., for sources in 10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit for survey meter calibration.

F. Robert G. Brucker, M.D., for material in 10 CFR 35.100 and 35.200.

G. T. O. Reinke, M.D., for material in 10 CFR 35.400 and iridium-192 in remote afterloading brachytherapy unit and 35.300 limited to strontium-89.

H. Robert R. Kinde, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.400 and iridium-192 in remote afterloading brachytherapy unit.

12. Authorized Users (Continued)

I. James E. Murphy, M.D., for material in 10 CFR 35.100 and 35.200.

J. Timothy H. Seline, M.D., for material in 10 CFR 35.100 and 35.200.

K. Michael W. Milde, for material in 10 CFR 35.100 and 35.200.

L. Stephanus J. Macrander, M.D., for material in 10 CFR 35.100 and 35.200.

M. Fred D. Panzer, M.D., for material in 10 CFR 35.100 and 35.200.

N. Peter Podlusky, M.D., for material in 10 CFR 35.100.

O. Kent W. Powley, M.D., for material in 10 CFR 35.100 and 35.200.

P. Sue A. Hausserman-Dugan, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.500.

Q. Uri Vaisman, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.500.

R. Rosita Sio Go, M.D., for material in 10 CFR 35.300, 34.400, 35.500 and iridium-192 in remote afterloading brachytherapy unit.

S. William O. Fletcher, M.D., for material in 35.100 and 35.200 limited to cardiovascular clinical procedures.

T. M. David Yoseloff, M.D., for material in 35.100, 35.200 and 35.500.

U. John R. Iglar, M.D., for material in 10 CFR 35.100 and 35.200.

V. Robert A. Belgam, M.D., for material in 10 CFR 35.300, 35.400 and iridium-192 in remote afterloading brachytherapy unit.

W. Kevin Dul, M.D., for material in 10 CFR 35.100 and 35.200.

X. Marion H. Scholz, M.D., for material in 35.400 and iridium-192 in remote afterloading brachytherapy unit.

Y. Brian Hebl, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.500.

Z. Stephen M. Brink, M.D., for material in 10 CFR 35.100, 35.200, 35.300 and 35.500.

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13. Pursuant to 10 CFR Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material.

14. The licensee shall maintain records of information related to decommissioning at the location listed in item 2 as specified in 10 CFR 30.35(g) until this license is terminated by the Commission.

15. A. Access to the rooms housing the Nucletron, Micro-Selectron HDR afterloading brachytherapy unit 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 a month. Records of test results shall be maintained for inspection by the Commission.

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.

16. Prior to initiation of a treatment program, and subsequent to each source exchange for the Nucletron, Micro-Selectron HDR afterloading brachytherapy units, radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

(1) The irradiator source housing, with the source in the shielded position. The maximum radiation levels at 10 centimeters from the surface of the main source safe shall not exceed 1 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 20.101.

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in 10 CFR 20.105(b).

B. Records of the survey results shall be maintained for inspection by the Commission for the duration of the license.

17. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services:

A. Installation and replacement of the sealed sources contained in the Nucletron, Micro-Selectron HDR afterloading brachytherapy unit(s).

B. Any maintenance or repair operations on the Nucletron, Micro-Selectron HDR afterloading brachytherapy unit(s) listed in Item 9., Subitem(s) 9.E. involving work on the source safe, the source driving 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. Notwithstanding the requirements of 10 CFR 35.404(a), the licensee may release from confinement for medical care patients with temporary eye plaque implants in place, provided that the survey requirements for permanent implant patients specified in 10 CFR 35.75(b) are met. Upon removal of the eye plaque, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall retain a record of the patient survey in accordance with 10 CFR 35.404(b).

19. Notwithstanding the requirements of 10 CFR 35.406(a), after removal of each eye plaque, the patient may be released from the medical treatment facility after an inventory of the sources in each eye plaque is performed to confirm recovery of all sources. This must include disassembling the plaque to conduct a physical inventory of the seeds.

20. Notwithstanding the temporary nature of each eye plaque implant, the licensee must meet the requirements of 10 CFR 35.415(a)(5).

21. 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 U.S. 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. Application dated December 27, 1988 (except Item 9.3.2.G.5., and Attachment 10.12.4); and

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
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Docket or Reference Number
030-03466

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21. (Continued)

B. Letters dated August 10, 1988, December 5, 1988, December 30, 1988, March 29, 1989 (excluding Item 4.C. and Item 5.), July 11, 1989, February 25, 1992, April 2, 1992, September 14, 1992, November 5, 1992, December 11, 1992, September 24, 1996, November 19, 1996, and December 30, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date Jan 27 1997

By Evelyn B. Weaver
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: 02120
Status Code: 2
Fee Category: 7C 2B
Exp. Date: 19940630
Fee Comments: CODE 21
Decom Fin Assur Reqd: N

R9

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: ST. ELIZABETH HOSPITAL
   Received Date: 961125
   Docket No: 3003466
   Control No.: 302083
   License No.: 48-10219-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: ---X---
   Check No.: ---X---

X ADDL INFO
301914 - R9

3. COMMENTS

Signed D. Hersey
Date 12/4/96

1996 DEC 3 PM 1:45

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

1. Fee Category and Amount: 7C 2B FEE NOT REQUIRED

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed SC
Date 12/4/96

RECEIVED BY LFDCB
Date Dec 3 1996
Log Dec 2 III
By SC
Date Completed 12/4/96

DEC 0 9 1996

St. Elizabeth Hospital
A MEMBER OF AFFINITY HEALTH SYSTEM, INC.

November 19, 1996

United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

License No: 48-10219-01
Control No: 301914

Dear Medical License Reviewer:

This correspondence is in response to Control No. 301914 requesting additional information concerning episcleral treatments (eye plaques) using I-125 sealed sources.

1 - Reasons for exemption from 10 CFR 35.404:

a. Our physicians intending on performing this procedure are familiar with their training institution's (University of California, San Francisco) methods which routinely send eye plaques patients home with the temporary eye implant in place.

b. Since sending patients home with eye plaques sutured in place is common practice, insurance companies and reimbursement agencies are reluctant to pay the cost of being an inpatient. Keeping a healthy patient confined as an inpatient who poses no significant radiation hazard for four or more days makes little economic sense. A patient denied inpatient reimbursement may have the complete removal of the eye as the only option.

c. There is no significant radiation hazard (see #4) for the general public performing this procedure with I-125. The eye plaque is sutured in place and the sources are secured by the design of the plaque. The plaque also has a gold shield which provides appropriate attenuation of radiation levels for about half of the volume. A patch and shielding, if necessary, is secured over the eye to reduce radiation levels below 10 CFR 20.1301.

d. Sealed I-125 sources have a relatively low energy gamma emissions (under 35 keV) with a tissue half value layer of about 2 centimeters (lead HVL = .025 mm). This allows sources to be easily shielded over the eye and the patient's head and plaque's gold shield combine to provide radiation levels below legal limits. We perform many

1506 S. Oneida Street
Appleton, Wisconsin 54915
(414) 738-2000 • FAX: (414) 738-0949

permanent I-125 seed implants of the prostate using the same model seed and these patients are sent home the day of surgery with radiation levels below 2 mrem/hr near the abdomen surface. The total permanent activity for prostate implants is similar to a temporary eye plaque. The general public radiation risks for both of these procedures is minimal and should be consistently addressed in the regulations.

2 - Control of I-125 eye plaques when outside the hospital:

The eye plaque and procedures we intend on using will follow the guidelines of the Collaborative Ocular Melanoma Study (COMS). These commercial eye plaques have six suture lugs (see attachment #1) which secure the plaque directly to the eye. The sealed sources are secured in place using a silastic seed carrier insert glued to a gold shield. The I-125 sealed sources are handled in an appropriate shielded environment only by qualified medical physicists when preparing the eye plaque. During the surgical procedure a radiation oncologist (authorized user) and trained ophthalmologist will suture the eye plaque to the appropriate treatment position. Patients will be assessed to determine if they can follow instructions at home for appropriate eye plaque care. Any conceivable misuse condition that could occur at home could also occur in a hospital setting. The only advantage to being in the hospital is that the misuse/abuse condition would likely be detected quicker. In our opinion, an eye plaque will not lose its position unless significant abuse occurs, and the chances of losing sources is extremely unlikely. We are unaware of any situation where a COMS protocol patient personally removed the eye plaque or lost sources. A permanent prostate seed implant is far more likely to lose a source through the urethra.

When eye plaque patients return, the plaque will require surgical removal and all sources will be accounted for at this time. Our approach is to provide thorough patient training and assessment prior to performing this procedure.

3 - Patient radiation safety guidance:

All patients will receive pre-operating and post-operating instructions both written and verbal. Specific radiation safety instructions (see attachment #2) will also be reviewed and provided for these eye plaque patients.

4 - Compliance with dose limits of 10 CFR 20.1301:

The radioisotope I-125 has a half value layer of 0.025 millimeters of lead due to the relatively low energy gamma spectrum. We intend on providing shielding when necessary to keep radiation exposure rates below 1.0 mR/hr at 50 centimeters from the eye when performing temporary

implants for less than five days. This shield will be taped securely over the temporary implant and proper radiation safety instructions will be provided to the patient (see attachment #2). Attached is a copy of an article which measured dose rates around six separate patients. The maximum dose rate without any shielding at 50 centimeters was less than 5.0 mR/hr for this group. Based on this data and our prior experience with prostate I-125 implants we would conclude that it would be easy to have exposure rates below 1.0 mR/hr at 50 centimeters by adding pliable shields when necessary. The maximum exposure an individual would receive if they were at 50 centimeters for four days for twelve hours each day would be (1.0 mR/hr x 12 hr/day x 4 days) 48 mR. We will provide appropriate shielding such that no individual would be exposed to more than 100 mR for the procedure if they were at 50 centimeters for twelve hours each day of the implant. This criteria will provide sufficient radiation safety since it is extremely unlikely that an individual would be within 50 centimeters for this length of time and patients will also be instructed to maintain at least three feet from individuals while the treatment plaque is in position.

Please contact me if there are any questions concerning this response (414-738-2190).

Respectfully submitted,

Stanley A. Reed

Stanley A. Reed, MS, Medical Physicist

SARmmm
Attachments

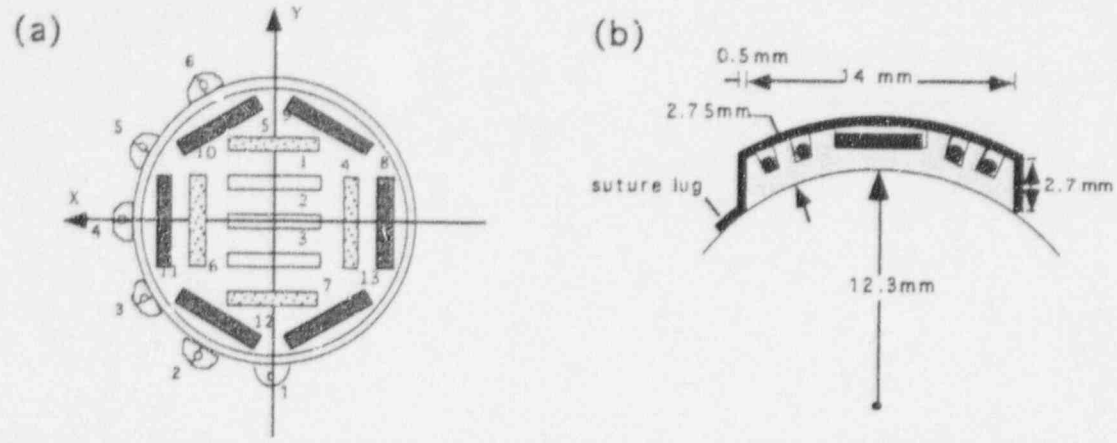

Figure 4. Seed arrangement in the silastic seed carrier insert and the gold plaque design. (a) Top view and (b) side view of a 14 mm COMS standard plaque.

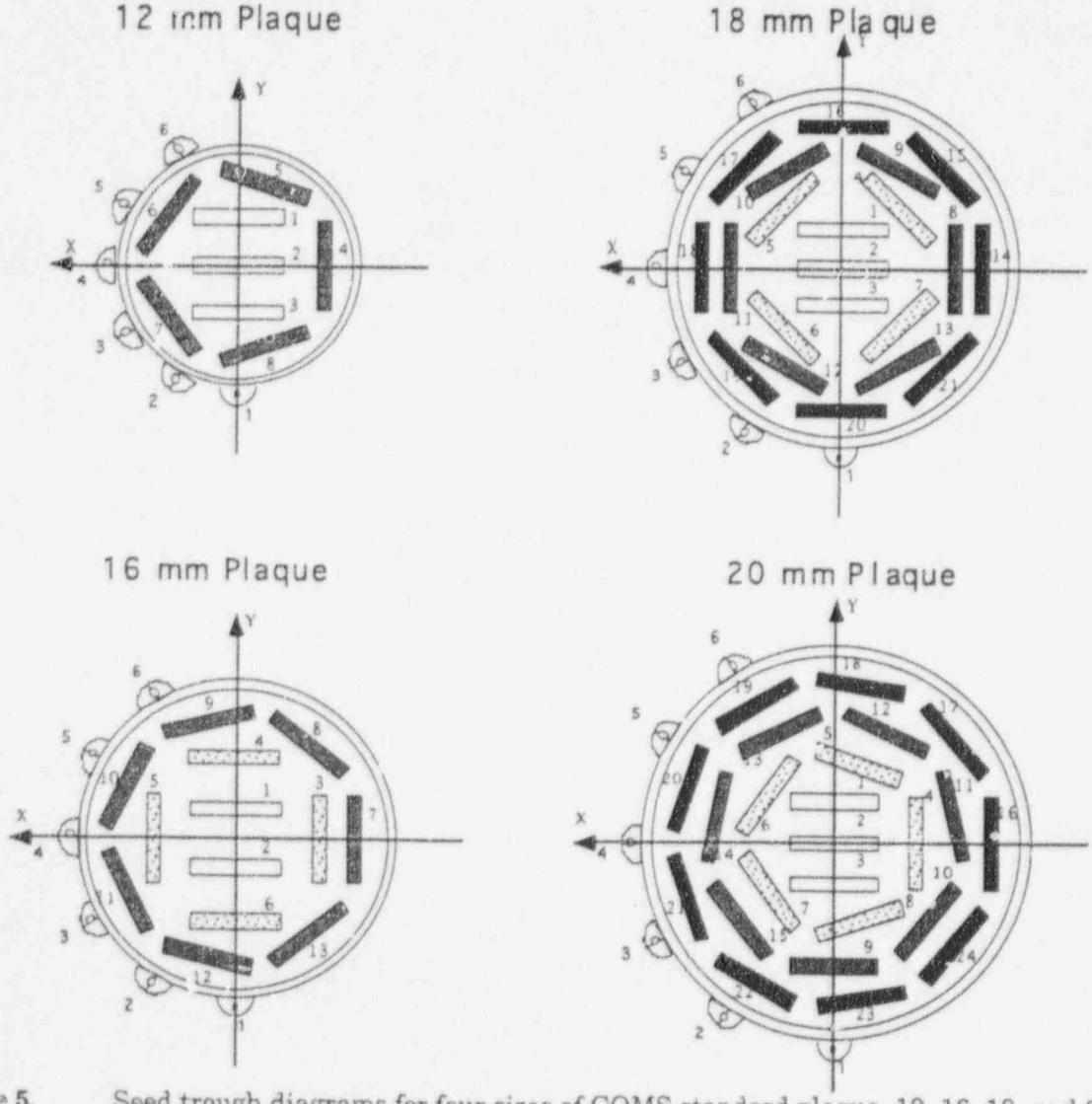

Figure 5. Seed trough diagrams for four sizes of COMS standard plaque, 12, 16, 18, and 20 mm in diameter.

RADIATION SAFETY RECOMMENDATIONS FOR DISCHARGED PATIENTS WITH A TEMPORARY I-125 EYE PLAQUE

1) NAME: _____ has received a sealed source implant containing _____ seeds for a total activity of _____ mCi of _____ on (date) _____. The maximum measured radiation exposure rate at this date was _____ mR/hr at the skin surface and _____ mR/hr at three feet from the implant.

2) Radiation Safety Precautions:

   a) Do not get within three feet for times exceeding five minutes for persons who may be pregnant or under the age of 18 while the eye plaque is in place. Children and pregnant or possibly pregnant women have no time limitations if they stay at least six feet from the patient.

   b) The treated eye generally has an additional layer (shield) taped in place to reduce radiation levels outside the treatment area. This shall be kept in place for the entire treatment. If this shield loses its position either retape/secure the shield or call one of the individuals listed below, or the Radiation Therapy Department (738-2184).

   c) The treatment plaque on the eye is unlikely to move. If for any reason it is felt this plaque is not secure immediately call the physician listed below or the Radiation Therapy Department.

3) There are no radioactive contamination problems associated with this treatment. Dishes, tableware, clothing, linens, toilet apparatus, etc. used or touched by the patient may be used by anyone else without any special precautions. Touching the patient will not contaminate anyone.

4) Should the patient (or family member) have any questions about this procedure, please call the undersigned physician.

_____ _____
Physician

_____ _____
Physicist

_____ _____
Date of Interview

_____
Persons at Interview

Attachment #2

Radiation Protection

Choroidal Melanoma and Iodine-125 Plaques

Camille A. Myers, RN, BSN
David H. Abramson, MD, FACS

Choroidal melanoma is the most common primary intraocular tumor found in adults. The frequency of occurrence in the United States is approximately 1400 to 1500 new cases diagnosed annually. These tumors have equal incidence in males and females and usually affect only one eye.[1] Although any age group can be affected, the mean age is 50 years.[2] There is a higher incidence of choroidal melanoma in fair-skinned people such as Scandinavians, and a low incidence in individuals with darker skin such as Africans.[1] Because choroidal melanomas have the potential to grow, metastasize, and eventually kill their host, it is important to study their clinical features as well as their treatment (Figure 1).

ABOUT THE AUTHORS: Ms. Myers is the clinic coordinator and research nurse for the Collaborative Ocular Melanoma Study (COMS) of the NIH for New York Hospital/Cornell Medical Center; Dr. Abramson is from the Cornell University Medical Center, New York, New York.

Characteristics

Four characteristics are significant when considering the potential survival of a patient with a choroidal melanoma: tumor size, tumor location, patient age, and tumor cell type.[3] The most important characteristic affecting survival is the size of the melanoma at the time of diagnosis. Tumors less than 10 mm in height or with a volume (maximal tumor height × maximal tumor diameter × minimal tumor diameter) less than 1,000 mm^3 have demonstrated a low incidence of metastasis.[1] With regard to location, tumors of the ciliary body appear to be more deadly than those of the posterior pole. Shammas and Blodi showed that patient mortality was greater when the anterior border of the melanoma was anterior to the equator.[3] Regarding patient age, as age at the time of diagnosis increases, the prognosis for the patient's survival decreases. Patients under 60 years of age were shown to have a better prognosis than patients older than 60 years.[3] Finally, the type of cells contained within the melanoma is related to patient survival. Patients with choroidal melanomas containing epithelioid cells have a significantly higher mortality rate than those containing Spindle A or Spindle B cells.[4] Although cell type has been demonstrated as superior in judging prognosis, it can only be determined by enucleation.

Treatment

There are several currently available treatments for choroidal melanomas. Smaller tumors,

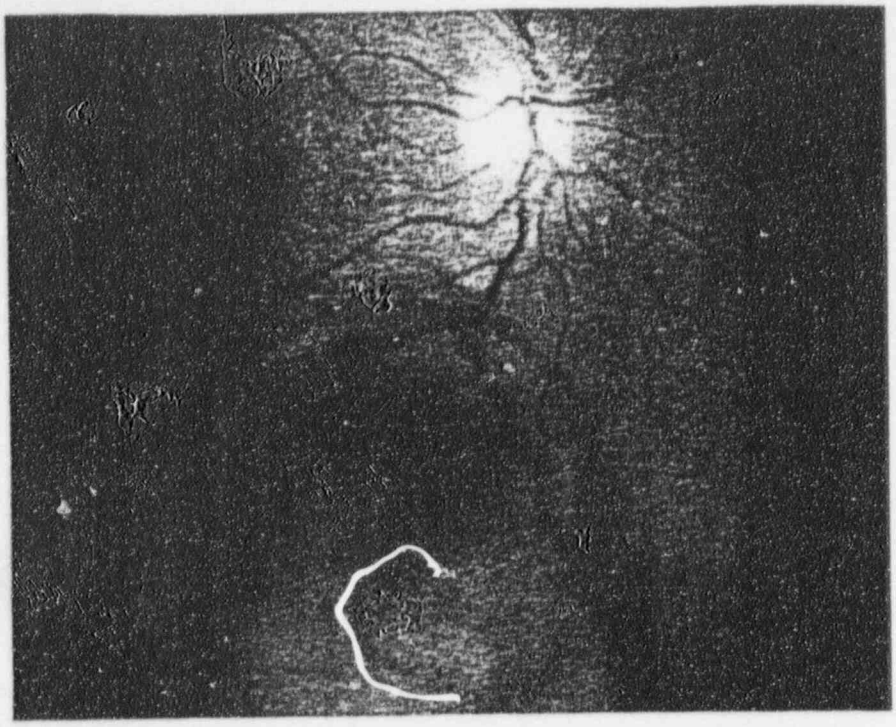

FIGURE 1: Choroidal melanoma.

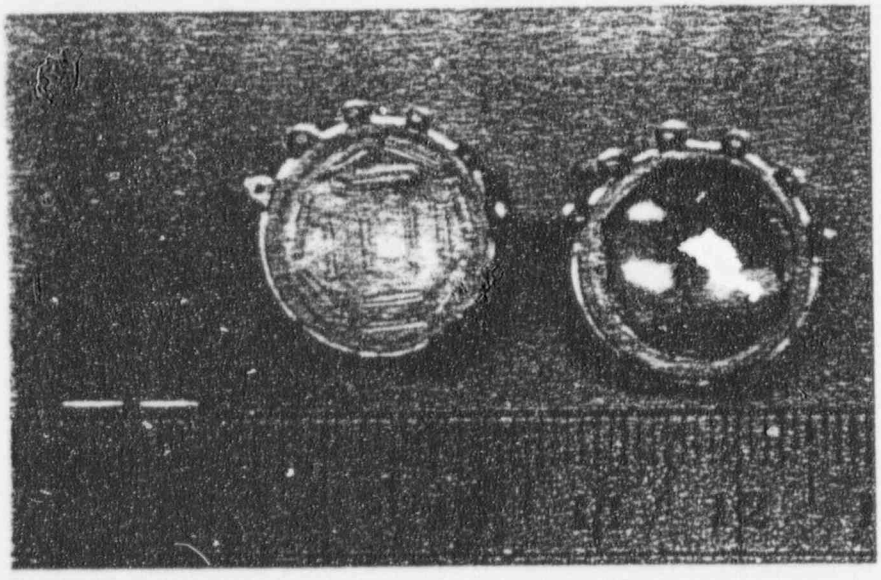

FIGURE 2: Iodine-125 plaque.

those less than 3 mm in height, may be treated by photocoagulation, or even observed until growth has been documented. Tumors greater than 3 mm in height may be treated by enucleation or radiotherapy. Prompt enucleation had been the preferred method of treatment[5] until the 1930s, when Stallard developed a technique whereby platinum dics containing various rings of radioactive Cobalt-60 were sutured to the sclera overlying the tumor. This conservative technique not only permitted the patient to retain the eye, but also preserved vision in certain cases.[6]

Although all the fundamentals of radiation absorption at the cellular level are not understood in great detail, inhibition of metabolic activity is the basic and critical feature of the radiation process.[7] The goal of radiotherapy is to destroy or inhibit tumor cell growth without damaging normal tissue such as the lens, which is the most radiosensitive portion of the eye. The most obvious effect of radiation to the lens is cataract formation. The unit used to measure the dose of radiation absorbed by body tissues is called the rad, or radiation absorbed dose. The amount of radiation emitted as well as the exposure level depend on the type and strength of the radioactive isotope. Another factor to consider is its half-life, or the time required for one half of the material's mass to decay.[8]

Today, Iodine-125, a low gamma emitting radioisotope, is used in the treatment of choroidal melanomas because of its ability to inhibit tumor cell mitosis while preserving surrounding normal tissues. Prior to surgery, radiation physicists prepare and arrange Iodine-125 seeds in gold "plaques" according to ultrasonic measurements of tumor height and basal diameter (Figure 2). A standard dose of radiation to the apex of the tumor is 10,000 rads for approximately seven days. Radiation physicists confirm their calculations and the duration of Iodine implants by computer programs.

Radiation Safety

Nurses working with Iodine-125 plaque patients should be concerned with radiation safety. The purpose of this study is to analyze one available method for minimizing radiation exposure to nurses. Guidelines for safe exposure levels have been established by the National Council on Radiation

TABLE 1
Three Principles of Radiation Protection

Time: As little time as necessary should be spent near the radioactive source.

Distance: As much distance as possible should be placed between the nurse and the patient (preferably a minimum of three arm lengths). Film badges that monitor the amount of radiation received should be worn by all nursing staff, medical personnel, and visitors who come in contact with the melanoma patient.

Shielding: Protective shielding should be used when possible and when warranted.

Protection and Measurements. For nurses who do not work around radiation sources (and for the general public), the maximum permissible dose is 0.5 rad, or 500 millirads per year. Natural environmental radiation may account for 80 millirads per person per year, while a routine chest x-ray can account for 10 millirads per x-ray. For nurses and health care workers routinely exposed to ionizing radiation, the maximum permissible dose is 5 rads per year[8] (Table 1).

Concentrating on the principle of shielding, this study focused on whether protective lead-lined glasses could block a significant amount of radiation emitted by the Iodine-125 plaque and hence enhance protection of the nursing staff. This is an important concept, as Iodine-125 plaques are becoming more popular as an alternative to enucleation. The glasses used in this study were made by the Voix Corporation, and used 0.75 mm lead equivalent protection with frontal and temporal (or side) lenses. The weight of the glasses was 2.8 oz. A total of six patients, all hospitalized for Iodine-125 plaque treatment of choroidal melanomas in their right eye, were measured on their third postoperative day. The same Victoreen Model 440 was used (without its cap to measure the small amounts) on all patients because of its sensitivity in measuring low level gamma radiation and its stability.

Methods

Each patient was asked to sit in a chair, as measurements were first taken without the glasses and then with the Voix lead-lined glasses. Measurements were taken at the surface of the right eye at 35 cm, at 0.5 m, and at 1 m, respectively. All measurements were expressed in milli-roentgens (mR) per hour (roentgens correspond to a rad on approximately a 1:1 ratio). To calculate the percentage of radiation measured, surface measurements without the glasses were used as a baseline of 100%. Measurements at respective distances without the glasses were compared with this baseline, as were four measurements taken with the Voix glasses (Table 2).

Results

When an average was taken of all six cases at the surface level, the percentage of radiation measured with the Voix glasses was reduced by over 90% when compared with the average radiation measured without the glasses (Figure 3). At 35 cm, average measured radiation with the glasses was less than 0.07%, or approx-

TABLE 2
Radiation Measurements With and Without the Use of Voix Glasses

Patient	Distance	Without Glasses	% Radiation Measured	With Voix Glasses	% Radiation Measured
1	Surface	100 mR/h	100%	2.5 mR/h	2.5%
	35 cm	80 mR/h	0.8%	<0.1 mR/h	<0.1%
	0.5 M	0.2 mR/h	0.2%	<0.1 mR/h	<0.1%
	1.0 M	0.1 mR/h	0.1%	<0.1 mR/h	<0.1%
2	Surface	120 mR/h	100%	9.0 mR/h	7.5%
	35 cm	1.7 mR/h	1.4%	<0.1 mR/h	<0.08%
	0.5 M	0.6 mR/h	0.5%	<0.1 mR/h	<0.08%
	1.0 M	<0.1 mR/h	<0.08%	<0.1 mR/h	<0.08%
3	Surface	>300 mR/h	100%	26 mR/h	8.6%
	35 cm	7.0 mR/h	2.3%	0.2 mR/h	0.06%
	0.5 M	4.0 mR/h	1.3%	<0.1 mR/h	<0.03%
	1.0 M	0.4 mR/h	0.1%	<0.1 mR/h	<0.03%
4	Surface	100 mR/h	100%	12 mR/h	12%
	35 cm	1.0 mR/h	1.0%	<0.1 mR/h	<0.1%
	0.5 M	0.2 mR/h	0.2%	<0.1 mR/h	<0.1%
	1.0 M	<0.1 mR/h	<0.1%	<0.1 mR/h	<0.1%
5	Surface	300 mR/h	100%	20 mR/h	6.6%
	35 cm	8.2 mR/h	2.7%	1.0 mR/h	0.03%
	0.5 M	1.0 mR/h	0.3%	<0.1 mR/h	<0.03%
	1.0 M	<0.1 mR/h	<0.03%	<0.1 mR/h	<0.03%
6	Surface	300 mR/h	100%	40 mR/h	13.3%
	35 cm	9.0 mR/h	3.0%	0.1 mR/h	0.03%
	0.5 M	4.8 mR/h	1.6%	<0.1 mR/h	<0.03%
	1.0 M	0.7 mR/h	0.2%	<0.1 mR/h	<0.03%

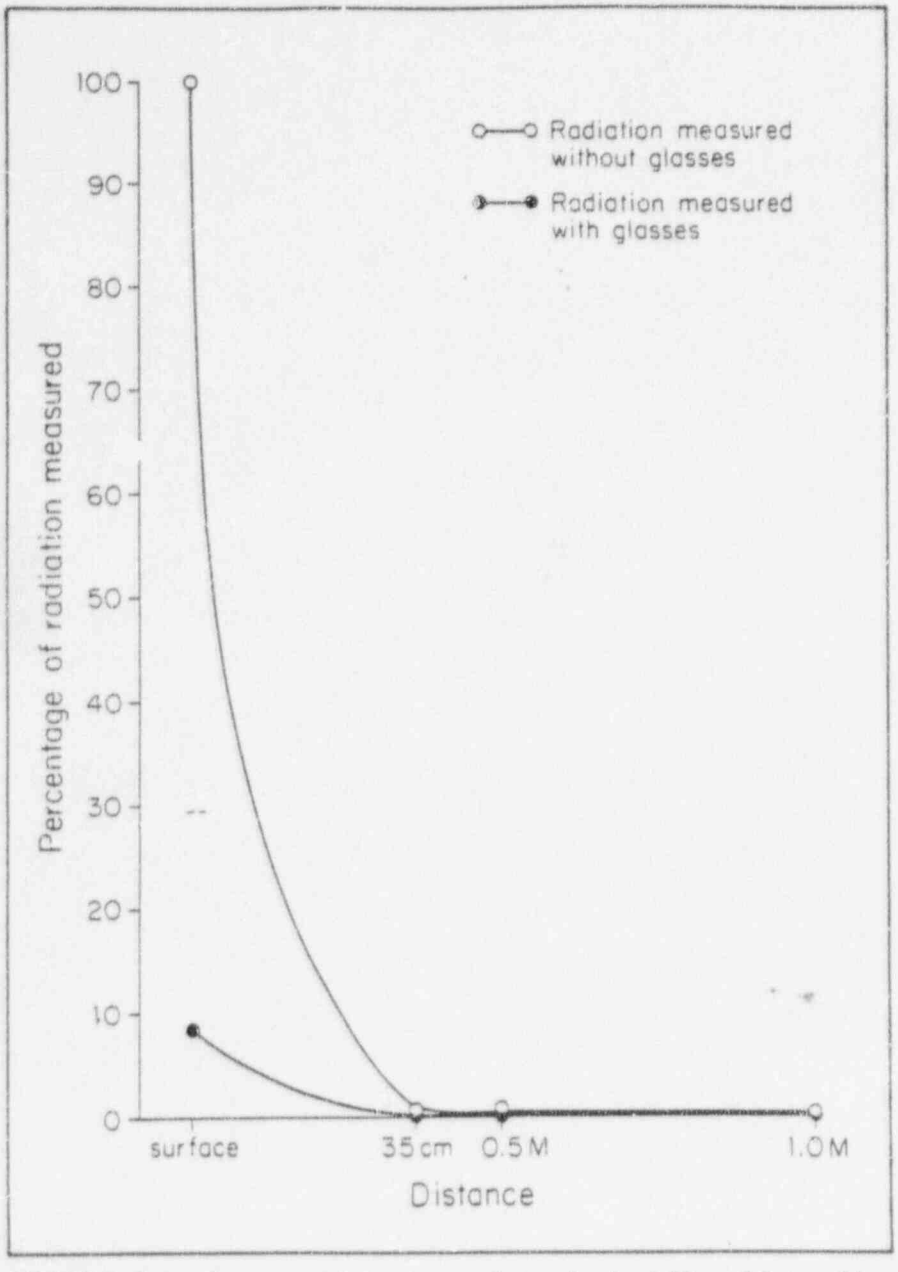

FIGURE 3: Curve of average radiation measured at surface level, 35 cm, 0.5 m, and 1 m.

imately one twenty-fifth; the average measured radiation without the glasses was 1.87%. At 0.5 m, the average measured radiation with the glasses was less than 0.07%, or approximately one tenth the 0.68% average measured without the glasses. Finally, at 1 m, average measured radiation was less than 0.07% with the glasses, compared with 0.10% without the glasses. Overall as distance from the eye increased (with the glasses), actual radiation reduction decreased but was measurable. Although the glasses were able to block the majority of surface radiation, it appears that at distances of 35 cm, 0.5 m and 1 m, very little difference was noted with or without the glasses.

The following limitations to this study should be noted. Not all tumors were the same apical height or basal diameter, and therefore their volumes varied. Volume ranged from 44 mm^3 to 1325 mm^3. Also, not all tumors were in the same location within the eye. Four tumors were located on the nasal side and two were located on the temporal side. Because measurements were taken straight on, these various sizes and locations affected the comparability of the measurements. In addition, only six patients were studied. Finally, although the Victoreen 440 Detector was used, it could not measure radiation exposures of less than 0.1 mR/h.

Conclusion

It can be concluded that although the glasses blocked a high percentage of radiation at surface level, the difference at 35 cm, 0.5 m, and 1 m were negligible. The Voix glasses can offer some protection for the nursing staff and visitors. Although the glasses are expensive (approximately $240.00 per pair) and three patients described them as "heavy," they were able to block some radiation, as previously discussed. Finally, because Iodine is a low gamma emittor, very little radiation is measurable as distance increases, especially at distances of greater than or equal to 1 m.

References

1. Abramson DH: Intraocular tumors. *Hosp Pract* 1984; October:101.
2. Garner A, Klintworth GK. *Pathobiology of Ocular Disease*. New York, Marcel Dekker, Inc, 1982, pp 652-688.
3. Shammas HF, Blodi FC: Prognostic factors in choroidal and ciliary body melanomas. *Arch Ophthalmol* 1977; 95:63-69.
4. Gass JD: Problems in the differential diagnosis of choroidal nevi and malignant melanomas. *Trans Am Acad Ophthalmol Otolaryngol* 1977; 83:19-60.

JAN 2 2 1997

Stanley A. Reed
St. Elizabeth Hospital
1506 South Oneida Street
Appleton, WI 54915

Dear Mr. Reed:

Enclosed is Amendment No. 55 to your NRC Material License No. 48-10219-01 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.

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.

302083

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 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
Evelyn R. Matson
Nuclear Materials Licensing Branch

License No. 48-10219-01
Docket No. 030-03466

Enclosure: Amendment No. 55

DOCUMENT NAME: M:\03003466.CL7
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OFFICE	DNMS/RIII	N							
NAME	ERMatson:brt								
DATE	01/27/97								

OFFICIAL RECORD COPY

St. Elizabeth Hospital
A MEMBER OF AFFINITY HEALTH SYSTEM, INC.

December 30, 1996

United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Attn: Evelyn R. Matson
License No: 48-10219-01
Control No: 302083

Dear Ms. Matson:

On December 30, 1996, we had a telephone conversation concerning a request for additional information for our amendment which would allow episcleral eye plaque patients to be sent home while treatment was occurring. It is our understanding that the Nuclear Regulatory Commission desires some form of radioactive material identification on the patient who is being treated. In order to comply with this request we will provide either a wrist band for the patient or clearly label the implant. The label/wrist band will identify radioactive materials, the isotope and activity.

Please contact me if you have any additional questions (414-738-2190).

Sincerely,

Stanley A. Reed

Stanley A. Reed, MS, Medical Physicist

SARmmm

pm: 12-31-96

1506 S. Oneida Street
Appleton, Wisconsin 54915
(414) 738-2002 • FAX: (414) 738-0949

UNITED STATES NUCLEAR REGULATORY COMMISSION
REGION III
CONVERSATION RECORD

(X) TELEPHONE (X) OUTGOING ( ) INCOMING ( ) CONVERSATION TIME: 9am DATE 12/30/96

NAME OF PERSON(S) CONTACTED: ORGANIZATION: TELEPHONE NO.:
Stan Reed
St. Elizabeth
414-738-2190

SUBJECT:
Amendment to License No. 48-10219-01
Letter dated Nov. 19, 1996
Control No. 302083

SUMMARY:

The NRC needs that following additional information:

1. ~~Provide considerations for prescreening patients for their ability to comply with the instructions and the requirements of the release protocol.~~ Statement included already in Letter dated Nov. 19, 1996, Item 2.

2. Consider the use of an identification device such as a wrist badge to identify the use of radioactive material and in place of Part 20 radiation safety signs.

ACTION REQUIRED:
Please respond in writing within 15 days, provide two copies of your response and refer to Control No. 302083.

ACTION TAKEN:

NAME OF PERSON DOCUMENTING CONVERSATION: SIGNATURE: DATE:
Evelyn R. Matson 12\30\96
630-829-9822

St. Elizabeth Hospital
A MEMBER OF AFFINITY HEALTH SYSTEM, INC.

December 5, 1996

United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

NRC License No: 48-10219-01

Dear Medical License Reviewer:

Upon review of our latest amendment No. 54 an error was noted for one of our authorized users. Stephen M. Brink, MD was listed for only material in 10 CFR 35.500, however, this was in addition to a prior request for 10 CFR 35.100, 35.200, and 35.300 for Stephen M. Brink. A letter dated December 7, 1995, furnished proof of his accreditation from the American Board of Radiology. In addition, he is also listed on NRC License Number 48-26288-01 for all these areas. A copy of license 48-26288-01 was sent in August 1996. Please correct Stephen M. Brink, MD as an authorized user of 35.100, 35.200, 35.300, and 35.500.

Sincerely,

Stanley A. Reed

Stanley A. Reed, MS, Medical Physicist

SARmmm

Pm: 12-6-96

1506 S. Oneida Street
Appleton, Wisconsin 54915
(414) 738-2000 • FAX: (414) 738-0949

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

December 3, 1996

Stanley A. Reed, M.S.
Radiation Safety Officer
St. Elizabeth Hospital
Department of Radiology
1506 South Oneida Street
Appleton, WI 54915

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 11/19/96)

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 _X_ 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. 302083
License No. 48-10219-01