MATERIALS LICENSE

Amendment No. 22

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.

302016

Licensee	
1. Indiana University School of Medicine Radiation Safety Office	In accordance with letter dated October 22, 1996
2. 541 Clinical Drive Indianapolis, IN 46202-5111	3. License Number 13-02752-08 is amended in its entirety to read as follows:
	4. Expiration Date October 31, 2001
	5. Docket or Reference No. 030-09792

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. Cobalt-60	A. Sealed source model designation Picker Corp. P-3801A or P-3802A or Advanced Medical Systems, Inc. AMS-3802 or Neutron Products, Inc. NPI-20-7000W	A. 7,000 curies per source
B. Cobalt-60	B. Sealed source model designation Thomson CGR Medical Corporation COT-20	B. 6,670 curies per source
C. Uranium, depleted in uranium-235	C. Solid metal	C. 200 kilograms total possession limit

9. Authorized Use:

A. Medical use described in 10 CFR 35.600, in a Picker Corporation Model 6296 (C9M/80).

B. Medical use described in 10 CFR 35.600 in a Thomas CGR Medical Corporation Model Alcyon II teletherapy unit.

C. Shielding in teletherapy units.

190046

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
13-02752-08

Docket or Reference Number
030-09792

Amendment No. 22

CONDITIONS

10. Licensed material in Subitem 6.A. shall be used only in Room R016, 535 Barnhill Drive, Indianapolis, Indiana. Licensed material listed in Subitem 6.B. shall be used only in Room R017, 535 Barnhill Drive, Indianapolis, Indiana.

11. Radiation Safety Officer: Mack L. Richard, M.S.

12. A. The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.2.

Physicians designated to use licensed material in or on humans shall meet the training criteria established in 10 CFR 35, Subpart J and shall be designated by the licensee's Radiation Safety Committee, Charles Michael Hart, M.D., Chairman.

B. Licensed material for other than human use shall be used by, or under the supervision of, individuals designated by the radiation safety committee.

13. 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. Applications dated November 16, 1983 and August 11, 1986; and

B. Letters dated December 23, 1986, June 14, 1989, February 7, 1992, July 18, 1994, October 17, 1994 (with attachments) and October 22, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date December 9, 1996

By Evelyn R. Morton
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: 20011031
Fee Comments:
Decom Fin Assur Regd: Y

R9

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: INDIANA UNIVERSITY SCHOOL MEDICINE
   Received Date: 961104
   Docket No: 30[illegible]792
   Control No.: 302016
   License No.: 13-02752-08
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 470
   Check No.: 826515

3. COMMENTS

Signed D. Hersey
Date 11-5-96

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 SC
Date 11/14/96

NOV 1 8 1996

Log NOV 5 III
Remitter
Check No. 826515
Amount #470
Fee Category (7A) 2B
Type of Fee AmD
Date Check Rec'd 11/12/96
Date Completed 11/14/96
By: SC

RECEIVED NOV 12 AM 10:01
1996

INDIANA UNIVERSITY
PURDUE UNIVERSITY
INDIANAPOLIS

RADIATION
SAFETY OFFICE

October 22, 1996

Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III Office
801 Warrenville Road
Lisle, IL 60532-4351

Re: Teletherapy License #13-02752-08

Gentlemen:

Attached please find a request to amend our teletherapy license to include some modifications of the Picker C-9 teletherapy unit operation for total body irradiation (TBI). The reason for these modifications is to provide additional safety for the TBI patient.

A check for $470.00 is also attached in support of this amendment request. Should you have any questions, please do not hesitate to contact this office. Your prompt attention to this amendment request is appreciated.

Sincerely,

Mack L. Richard

Mack L. Richard, M.S.
Radiation Safety Officer

Attachments: 2

Clinical Building 159
541 Clinical Drive
Indianapolis, Indiana
46202-5111

317-274-4797
Fax: 317-274-2332

IU School of Medicine
IU Medical Center &
Associated Facilities

pm: 11-1-96

Request for Amendment
NRC License #13-02752-08

I. Background Information

A number of years ago, our Picker C-9 ^{60}Co teletherapy unit was designated to be exclusively used to perform total body irradiation (TBI) for bone marrow ablation for patients who are to receive bone marrow transplants. Initially, these patients were required to lie on their side at a specific distance from the teletherapy unit. The treatment head of the teletherapy unit was directed toward the patient and the treatment administered. The set up for this type of treatment was difficult and time consuming. Furthermore, the patient experienced a fair amount of discomfort due to the need for the patient to lie in the aforementioned treatment position for an extended period of time (20 to 30 minutes). Finally, the dose homogeneity and accuracy of lung shielding were not optimal for the maximal effectiveness of the treatment.

Approximately 1 year ago, a moving treatment table was designed to allow the patient to lie in a supine position, directly under the treatment head. For each individual treatment, the treatment table (and the patient) make one pass through the primary beam. The treatment table is connected to a control panel (separate from the teletherapy unit console) which allows the user to program in a start and stop position for treatment (in mm) and the speed of the table movement (in mm/minute). A shielding tray can be attached to the table between the patient and the source to provide shielding of various organs (e.g., lungs) during the treatment. An "attenuator tray" is also placed between the source and patient to obtain the desired radiation dose rate.

A number of safety features are included with the moving treatment table and the attenuator tray. An interlock switch is incorporated into the attenuator tray which prevents movement of the treatment table unless the attenuator tray is properly positioned. This prevents the movement of the patient into the primary beam unless the attenuator tray properly positioned.

The treatment table speed is constantly monitored and displayed during the treatment at the table control panel. If the actual table speed varies from the preprogrammed table speed by more than 0.2 cm/min for at least 15 seconds, an audible alarm sounds and the treatment is then terminated by the operator (e.g., radiation therapist) by returning the source to the shielded position. This feature assures that irregularities in the table motion do not cause the delivered radiation dose to differ by more than 2% from the prescribed dose.

The radiation dose to the patient is continuously monitored by properly calibrated "entrance" and "exit" diodes connected to an electrometer located at the control console. Thus, the operator can monitor the radiation dose as it is being delivered and suspend treatment if necessary.

Once the table has reached the preprogrammed stop position, an audible signal is produced and the operator switches the source to the shielded position.

II. Proposed Interface of Treatment Table to Source Movement

As illustrated above, any problems associated with the attenuator tray or the moving treatment table results in some type of audible signal which, in turn, requires that the operator make an appropriate response (e.g., return the source to the shielded position). Likewise, the actual termination of the

treatment once the table has reached the preprogrammed position requires the operator to return the source to the shielded position. Even though the aforementioned procedures have been very effective, it is the opinion of both Radiation Oncology and Radiation Safety Staff that some relatively minor hardware modifications will enhance the safety of this type of treatment.

The proposed modifications are as follows:

1. The signal from the interlock switch for the attenuator tray will be incorporated into the interlock circuit for the source movement. Thus, if the attenuator tray is not in the proper position, the source will not move to the unshielded position.

2. The signal that provides an audible alarm should the treatment table speed vary from the preprogrammed table speed will be incorporated into the interlock circuit for the source movement. This will result in the source returning to the shielded position if the treatment table speed varies by more than 5% from the preprogrammed table speed for at least 15 seconds. This would also cause the source to return to the shielded position if the treatment table movement stops prior to reaching its preprogrammed stop position.

3. The electronic signal that indicates that the treatment table has reached its preprogrammed stop position will be incorporated into the interlock circuit for the source movement. This will result in the source automatically returning to the shielded position at the conclusion of the treatment.

III. Personnel Responsible for Modifications

The aforementioned modifications shall be made and tested by individuals who are specifically licensed to maintain and/or repair a Picker C-9 teletherapy unit.

IV. Verification of Moving Table Functions and Interlocks

To assure that all of the interlocks associated with TBI treatments are functioning properly, the following monthly checks of the equipment will be performed in addition to the currently required checks:

1. Proper operation of attenuator tray interlock,
2. Source retraction when table is stopped by operator,
3. Source retraction when table reaches preprogrammed position,
4. Table stop function operational,
5. Verify accuracy of table speed, and
6. Verify accuracy of table position indicator.

All checks will be documented and corrective action implemented as necessary.

DEC 1 0 1996

Mack L. Richard, M.S.
Indiana University School
of Medicine
Radiation Safety Office
541 Clinical Drive
Indianapolis, IN 46202-5111

Dear Mr. Richard:

Enclosed is Amendment No. 22 to your NRC Material License No. 13-02752-08 in accordance with your request.

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 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:

   a. When you decide to terminate all activities involving materials authorized under the license; or

3020/6

b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material.

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, 10 CFR Part 2, Appendix C. 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
Materials Licensing Branch

License No.: 13-02752-08
Docket No.: 03009792

Enclosure: Amendment No. 22

DOCUMENT NAME: M:\03009792.CL6

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

OFFICE	DNMS/RIII								
NAME	EMATSON:jaw								
DATE	12/ /96								

OFFICIAL RECORD COPY

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

November 5, 1996

Mack L. Richard, M.S.
Radiation Safety Officer
Indiana University School of Medicine
Radiation Safety Office
541 Clinical Drive
Indianapolis, IN 46202-5111

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 10/22/96)

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 nonroutine and has been assigned to Evelyn (Dixie) Matson for an expedited review. If you should have any question please contact Ms. Matson at (630) 829-9887.

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. 302016
License No. 13-02752-08