NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 21

MATERIALS LICENSE

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.

397734

Licensee	
1. Indiana University School of Medicine Radiation Safety Office	In accordance with letter dated October 17, 1994 3. License Number 13-02752-08 is renewed in its entirety to read as follows:
2. 541 Clinical Drive Indianapolis, IN 46202-5111	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.

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COPY 4

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
13-02752-08

Docket or Reference Number
030-09792

Amendment No. 21

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 and October 17, 1994 (with attachments).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date Oct. 17, 1996

By [signature]
Nuclear Materials Licensing Branch, Region III

COPY

NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 21

MATERIALS LICENSE

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371734

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C. Shielding in teletherapy units.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
13-02752-08

Docket or Reference Number
030-09792

Amendment No. 21

CONDITIONS

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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 and October 17, 1994 (with attachments).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date Oct. 17, 1996

By _____
Nuclear Materials Licensing Branch, Region III

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INDIANA UNIVERSITY
PURDUE UNIVERSITY
INDIANAPOLIS

RADIATION
SAFETY OFFICE

October 17, 1994

Materials Licensing Section
U.S.N.R.C. - Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Gentlemen:

This correspondence is to request renewal of NRC license No. 13-02752-08 issued to Indiana University School of Medicine for use of ^{60}Co teletherapy. As suggested in your recent correspondence, we have attached to this letter supporting information from section 2 of Appendix L of the Teletherapy Guide (FC 414-4). Also attached please find a check made out to the NRC in the amount of $1200.00 in support of this renewal application.

Should you have any questions, please do not hesitate to contact this office. Thank you for your timely consideration in this matter.

Sincerely,

Mack L. Richard

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

Attachments: 1

cc: G. Bepko, Chancellor

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

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

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IU School of Medicine
IU Medical Center &
Associated Facilities

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SUPPORTING INFORMATION FOR RENEWAL
OF NRC LICENSE #13-02752-08

The following information is submitted in accordance with Appendix L of Draft Regulatory Guide FC 414-4. Each response is keyed to the corresponding information requested in Appendix L.

a. License #: 13-02752-08

b. Indiana University School of Medicine
Attn: Radiation Safety Office
541 Clinical Drive
Indianapolis, IN 46202-5111

c. Mailing address same as item b.

d. Department of Radiation Oncology
Room Numbers R016 & R017
535 Barnhill Drive
Indianapolis, IN 46202

e. The teletherapy unit locations have not changed since the last license renewal application dated June 14, 1989. No changes have been made which affect the patient viewing systems.

f. All electrical and mechanical stops that limit the use of the primary beam of radiation are still installed and continue to operate as described in the amendment request dated August 11, 1986.

g. All items currently authorized under items 6 through 9 under amendment No. 19 are correct as stated.

h. License amendment No. 20 dated October 4, 1994 authorizes the Radionuclide Radiation Safety Committee (RRSC) to review and approve authorized users under this license.

i. The Radiation Safety Officer, Mr. Mack L. Richard, M.S. is correct as stated in condition 11 of amendment No. 20. Furthermore, we hereby request that the RRSC be allowed to review and approve individuals to serve as teletherapy physicists. The RRSC shall use the criteria specified in 10 CFR 35.961 and shall maintain documentation of all committee actions associated with such reviews and approvals. If this request is approved, it is not necessary to list the names of the teletherapy physicists on the license.

j. Responses to Items 8, 10.5, and 10.6 of Draft Regulatory Guide FC 414-4:

1. Item 8 - Training for Individuals Working In or Frequenting Restricted Areas

a. Radiation Oncology Personnel - All Radiation Oncology personnel involved in utilizing the teletherapy units receive a minimum of 5 days of on-the-job training prior to actually setting up patients for treatment. This training is provided by an individual who is fully qualified to operate the teletherapy unit. Such training includes both routine operations as well as emergency procedures which are posted at each teletherapy machine console. Personnel are informed of new or changed regulations, procedures, restrictions, etc. via departmental meetings (held at least every 6 months) and/or written instructions from the Radiation Safety Office or the Radiation Oncology department. This combination of training modalities includes all requirements specified in 10 CFR 19 and 10 CFR 35.610.

b. Ancillary Personnel (e.g. housekeeping, maintenance, etc.) - All employees of the university are required to attend an orientation session provided by the Personnel Department. During this session, a document entitled "INSTRUCTIONS TO INDIVIDUALS ENTERING AREAS CONTAINING RADIOACTIVE MATERIALS" (see Attachment 1) is distributed to each employee. Changes in current procedures and/or retraining shall be

accomplished by providing verbal and/or written information through the appropriate supervisory personnel.

c. General - NRC Form 3 "Notice to Employees" is posted throughout the university in areas where radioactive materials are used or stored. Included on the posted NRC Form 3 is information regarding the availability of the institution's NRC licenses, amendments, regulations, etc. as required in 10 CFR 19.

2. Item 10.5 - Operating Procedures

a. Receipt and Disposal of Radioactive Materials - All radioactive material receipts and disposals are coordinated through the Radiation Safety Office. This office has the responsibility to assure that all regulations and license conditions regarding receipts and disposals are met.

b. Use of the Teletherapy Unit - Any individual who has received training as specified above in Item 8 is permitted to utilize either teletherapy unit in accordance with the operating manual which is available at the operating console of each machine. This manual may be supplemented with additional procedures as necessary and appropriate.

c. Safety Device Checks - The following safety devices are checked at least weekly or prior to machine use (whichever is less frequent): television monitors, intercoms, all indicator lamps, deadman switches, collimator rotation, gantry rotation, beam interceptor, optical distance indicators, lasers, field size, congruency film check, wedges, blocking trays, bolus, table movements, turntable rotation, emergency off buttons, door interlocks, timer function, and radiation area monitors (with check source). It should be noted that some of these safety checks are not applicable for the Picker C9 Unit when it is used for partial or total body irradiation (TBI).

d. Personnel Dosimetry - Based upon a review of past personnel monitoring records, it does not appear that personnel monitoring is required under 10 CFR 20.1502 for personnel who utilize either ^{60}Co teletherapy unit. While not required by regulation, personnel monitoring is still utilized to demonstrate compliance with 10 CFR 20.1502 and to assess radiation exposures to personnel during emergency situations. Personnel monitoring results are reviewed by a member of the Radiation Safety Staff and compared with regulatory limits as well as the action levels which have been established within the university's ALARA program. Copies of the personnel monitoring reports are provided to the Radiation Oncology Department. The vendor which provides personnel monitoring services is NVLAP accredited.

e. Procedures for Securing the Teletherapy Units - The Radiation Oncology Department is considered a restricted access area and is posted as such. During non-working hours (i.e. other than Monday through Friday, 8:00 a.m. to 5:00 p.m.), both teletherapy rooms are locked and the keys to the teletherapy unit consoles are removed and placed in an office area. These keys are available to Radiation Oncology personnel only.

f. Instrument Calibration and Checks - Survey instruments are calibrated by the Radiation Safety Staff in accordance with procedures which have been submitted and approved by the NRC under the university's broad scope medical license (#13-02752-03). These procedures comply with 10 CFR 35.51. The radiation monitors in each of the teletherapy rooms are checked in accordance with 10 CFR 35.615(d)(3) by a member of the Radiation Oncology staff (e.g. radiation therapist, physicist, dosimetrist, et. al.).

g. Full Calibration - Full calibration measurements are conducted and recorded in accordance with 10 CFR 35.632 utilizing a dosimetry system which is calibrated as specified in 10 CFR 35.630(a).

h. Monthly Spot Check Measurements - Spot check measurements are performed and recorded in accordance with 10 CFR 35.634 utilizing a dosimetry system which has been calibrated in accordance with 10 CFR 35.630(b). These spot checks are performed utilizing procedures specified in the TG-21 protocol for calibration of ^{60}Co teletherapy units as published by the AAPM.

i. Leak Tests - Leak tests are performed by the Radiation Safety Staff. These leak tests consist of swiping the area near the collimator blades with a "Q-Tip" or other sampling media and counting the sample in a gamma counter which has been calibrated for ^{60}Co. All leak test results are maintained in the Radiation Safety Office.

k. Inspection and Servicing of the Teletherapy Units - Five year inspections shall be performed and documented in accordance with 10 CFR 35.647 by persons(s) specifically licensed to do so by the NRC or an Agreement State.

l. Limitation on Work Done on Teletherapy Units - Any maintenance or report of either teletherapy unit shall be performed in accordance with 10 CFR 35.605.

m. Survey Reports - Radiation surveys for teletherapy facilities shall be performed and documented in accordance with 10 CFR 35.641. Reports shall be provided to the NRC as required in 10 CFR 35.645.

n. Relocation of Teletherapy Unit - It is understood that a license amendment is required prior to the relocation of any teletherapy unit.

o. Recordkeeping - All records which are required to be maintained shall be kept in either the Radiation Safety Office or the Radiation Oncology Department.

3. Item 10.6 - Emergency Procedures

a. The emergency procedures specified in Appendix I of Draft Regulatory Guide FC 414-4 are posted at each teletherapy unit console.

b. Procedures for Notifying Proper Persons in the Event of an Accident or Unusual Occurrence - Names and telephone numbers are included on the posted emergency instructions.

k. Responses to Items 10.1, 10.2, and 10.3 of Draft Regulatory Guide FC 414-4:

1. Item 10.1 - Personnel Monitoring Program - The written procedures for personnel monitoring specified in Item 10.1.2 of Draft Regulatory Guide FC 414-4 have been implemented. Appropriate section changes with respect to the revised version of 10 CFR 20 are noted.

2. Item 10.2 - Instrumentation - The instrumentation specified in Item 10.2.2 of Draft Regulation Guide FC 414-4 is available.

3. Item 10.3 - Calibration of Portable Survey Instruments - Calibration procedures for survey instruments have been reviewed and approved in the university's broad medical license (#13-02752-03). These procedures comply with the requirements specified in 10 CFR 35.51.

l. Condition 13.B. or the university's existing license contains documents dated June 5, 1989 and August 27, 1990 which reference a Quality Assurance/Quality Control (QA/QC) Program that was established before the Quality Management Program (QMP) rule (10 CFR 35.32) was in effect. When the QMP was established in accorance with 10 CFR 35.32, the essential parts of the existing QA/QC Program were incorporated into the QMP. Please delete all references to the QA/QC Program from the conditions of the renewed license to eliminate redundancy and confusion.

m. A Radiation Safety Committee (called the Radionuclide Radiation Safety Committee (RRSC)) has been established and fulfills the requirements specified in 10 CFR 35.22.

n. An ALARA Program has been reviewed and approved by the NRC for the university's broad medical license (#13-02752-03). This ALARA Program also includes ^{60}Co teletherapy.

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ATTACHMENT 1

INSTRUCTIONS TO INDIVIDUALS ENTERING AREAS CONTAINING RADIOACTIVE MATERIALS

(Revised April, 1987)

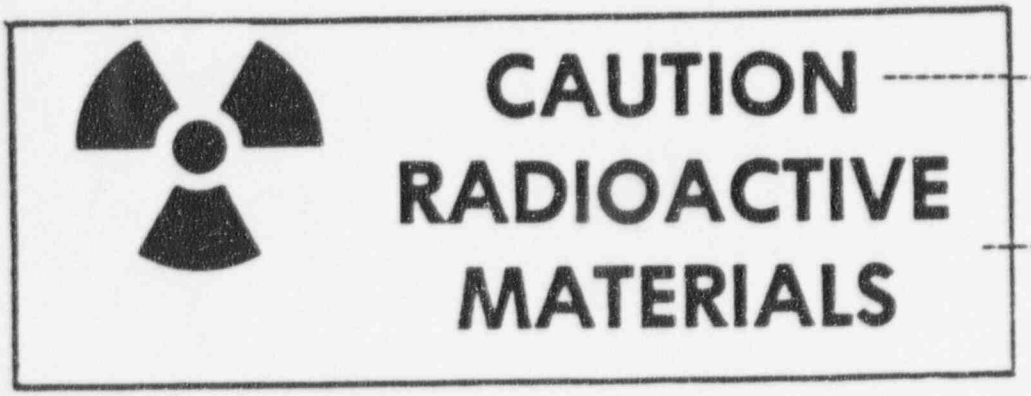
As part of your routine job duties, you may be required to enter an area of the university/hospital complex containing radioactive material. The areas in which this material is used and/or stored are located throughout the Indiana University - Indianapolis campus. All of these areas are required to be posted with the radiation warning symbol. The actual containers holding radioactive material will also be labelled with this symbol. An illustration of the radiation symbol is found below. It is important that you do not touch any object labelled with a radiation warning symbol nor should such an object be removed from the area in which it is stored. Although levels of radiation exposure expected in these restricted areas are low, any exposure to radiation should be maintained as low as reasonably acheivable (ALARA). In keeping with the ALARA philosophy, to minimize your exposure to radioactive materials, the safety principles of time and distance should be applied - that is:

1. Keep the time of exposure to radiation to a minimum while performing your assigned duty, and

2. Maintain a reasonable distance between the source of radiation and yourself.

If you observe any condition in a restricted area that appears to be unsafe, leave the area immediately and notify the Radiation Safety Office at 274-4797 (if on campus dial extension 4-4797) during the normal working hours of 8:00 a.m. to 5:00 p.m., Monday through Friday. For times other than normal working hours, contact the University Operator (0) and request that the Radiation Safety Officer be paged and a member of the Radiation Safety Staff will return the page.

If you have any questions regarding any federal, state, and/or university regulations regarding radiation safety or wish to review said regulations or related information (e.g. the Nuclear Regulatory Commission license, license application, or results of inspections) please do not hesitate to contact the Radiation Safety Office at the telephone number listed above.



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OCT 18 1996

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

Dear Mr. Richard:

Enclosed is Amendment No. 21 renewing your NRC Material License No. 13-02752-08 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.

In response to your request for your Radionuclide Radiation Safety Committee (RRSC) to review and approve individuals and to serve as teletherapy physicists, we have added License Condition No. 12.B. to your license.

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, Radiation Safety Officer, or Teletherapy Physicist 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).

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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 or Teletherapy Physicists;

   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
Gidget Watson
Nuclear Materials Licensing Branch

License No. 13-02752-08
Docket No. 030-09792

Enclosure: Amendment No. 21

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OFFICE	DNMS/RIII	N							
NAME	GWatson:brt								
DATE	08/15/96								

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OFFICIAL RECORD COPY

OCT 2 8 1994

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

Dear Mr. Richard:

SUBJECT: LICENSE RENEWAL APPLICATION

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference the control number specified and your license number.

Sincerely,

Original Signed By
Marianne Meenan, Chief
Nuclear Materials Support Section

License No.: 13-02752-08
Control No.: 97734

DOCUMENT NAME: M:\03009792.DT4
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OFFICE	DRSS/RIII									
NAME	MMEENAN:ga									
DATE	10/28/94									