NRC Form 313T
(8-82)
10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

Approved by OMB
3150-0093
Expires 1-31-85

APPLICATION FOR MATERIALS LICENSE – TELETHERAPY

INSTRUCTIONS – Complete Items 1 through 22 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 22 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20, 21, and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 22 and the appropriate fee enclosed.

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

St. John Hospital
Department of Radiology
7911 Detroit Avenue
Cleveland, Ohio 44102

TELEPHONE AREA CODE 216 NUMBER 651-7000

1.b. STREET ADDRESS(ES), ACTUAL LOCATION OF TELETHERAPY SOURCE, INCLUDING BUILDING NAME, ROOM NUMBER, ETC.

Cobalt Room
Radiation Therapy Department
St. John Hospital
7911 Detroit Avenue
Cleveland, Ohio 44102

030 00346

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Shirley Z. Jucius, M.S.

TELEPHONE AREA CODE 216 NUMBER 651-7000 X1009

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

- [ ] a. NEW LICENSE
- [ ] b. AMENDMENT TO LICENSE NO. _____
- [X] c. RENEWAL OF LICENSE NO 34-00869-04

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Paul S. Lavik, M.D.
Hae K. Hong, M.D.

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

The Radiation Safety Officer will be Paul S. Lavik, M.D. with consultation from Shirley Z. Jucius, M.S.

6. SEALED SOURCES TO BE USED IN TELETHERAPY UNITS *(Attach supplemental pages if necessary)*

	BYPRODUCT MATERIAL (Element and Mass No.)	NAME OF SOURCE MANUFACTURER	SOURCE MODEL NUMBER	MAXIMUM ACTIVITY PER SOURCE	NUMBER OF SOURCES
A.	Cobalt-60	AECL	C-146	6000	2
B.					
C.					

7. TELETHERAPY UNITS *(Attach supplemental pages, if necessary)*

	NAME OF MANUFACTURER (Include description, if unit is custom made)	MODEL NUMBER
A.	AECL	Theratron 780
B.		
C.		

8. USE *(Attach supplementary pages, if necessary)*

A	B	C	
X			HUMAN USE ONLY
			HUMAN AND OTHER USE *(Specify on separate sheet)*

RECEIVED BY LFMB
Applicant
Check No. 23260
Amount Fee Category $370.00
Type of Fee R10
Date Check Rec'd 6/22/84
Received By
Date 6/22/84
Ck
Date June 19
By
Orig To
Action Compl

9. PERSONNEL MONITORING DEVICES

	TYPE (Check and/or complete as appropriate)	SUPPLIER (Service Company)	EXCHANGE FREQUENCY
	(1) FILM BADGE – WHOLE BODY	R. S. Landauer Jr. and Co.	monthly
	(2) THERMOLUMINESCENT DOSIMETER (TLD)–WHOLE BODY		
	(3) OTHER *(Specify)*		

8507190498 850626
REG3 LIC30
34-00869-01 PDR

Control No. 76961

JUN 18 1984

INFORMATION REQUIRED FOR ITEMS 10 THROUGH 21

For Items 10 through 21, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the teletherapy licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10. Rev. _____ Date March 1982

10. MEDICAL ISOTOPE COMMITTEE		15. BEAM STOPS	
X	Names and specialties attached; and *(check one)*	X	Description of stops used to restrict beam orientation attached.
X	a. Duties as in Appendix A, or	16. SHIELDING EVALUATION	
	b. Equivalent duties attached.		Evaluation of proposed shielding attached.
11. TRAINING AND EXPERIENCE		17. OPERATING AND EMERGENCY PROCEDURES	
	a. Supplements A & B attached for each individual user; and	X	a. Description of operating procedures attached; and
	b. Supplement A attached for RSO.	X	b. Copy of emergency procedures attached.
12. INSTRUMENTATION *(check one)*		18. INSTRUCTION OF PERSONNEL *(check one)*	
X	a. Appendix C form attached, or	X	a. Training program and schedule in Appendix H followed, or
	b. List manufacturer's name and model number.		b. Description of instruction program for employees attached.
13. CALIBRATION OF INSTRUMENTS *(check one)*		19. LEAK TESTS OF SEALED SOURCES	
	a. Appendix D, Part 2 procedures followed for instrumentation calibration, or	X	Description of leak test procedures attached.
X	b. Description of sources, calibration frequency and equivalent procedures attached.	20. QUALIFIED EXPERT *(Use only if the individual fails to meet 10 CFR 35.24 requirements.)*	
14. FACILITIES AND EQUIPMENT			Statement of qualifications of the expert who will perform teletherapy calibrations attached.
	a. Description and drawing of facilities attached; and	21. ALARA PROGRAM *(check one)*	
X	b. Description of patient viewing and communicating systems attached; and	X	ALARA Program as in Appendix I, or
	c. Description of area safeguards attached.		Equivalent ALARA Program attached.

22. CERTIFICATE

(This item must be completed by the applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certifies that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED *(See section 170.31, 10 CFR 170)*	b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)* Sister Judith Ann Karam, C.S.A.
	(1) NAME *(Type or print)* Sister Judith Ann Karam, C.S.A.
(1) LICENSE FEE CATEGORY Teletherapy	(2) TITLE President
(2) LICENSE FEE ENCLOSED $ 270.00	c. DATE June 14, 1984

WARNING: 18 U.S.C. Section 1001; Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

10. Radiation Safety Committee

Paul S. Lavik, M.D.	Radiotherapist
William J. Fayen, M.D.	Nuclear Medicine
Shirley Z. Jucius, M.S.	Radiation Physicist
John Wysocki	Administrative Rep.
Mary Lou Vogelberger, R.N.	Nursing Rep.

Duties as in Appendix A and Sect. 35.11 dated August 25, 1982

Item #10

June 14, 1984

Control No. 76961

11. Training and Experience

Paul S. Lavik, M.D.
Hae-Kyung Hong, M.D.

See Application dated Dec. 15, 1981
April 8, 1982
June 14, 1982

Paul S. Lavik, M.D. is the Radiation Safety Officer with consultation from Shirley Z. Jucius, M.S. (Credentials submitted December 15, 1981).

Item # 11
June , 1984

Control No. 76961

APPENDIX C

INSTRUMENTATION

1. Survey meters

a. Manufacturer's name: Victoreen Panoramic S/N 1967

Manufacturer's model number: 470A

Number of instruments available: 1

Minimum range: 0 mr/hr to 3 mr/hr

Maximum range: 0 mr/hr to 1000 mr/hr

b. Manufacturer's name: _____

Manufacturer's model number: _____

Number of instruments available: _____

Ranges: _____

Minimum range: _____ mr/hr to _____ mr/hr

Maximum range: _____ mr/hr to _____ mr/hr

2. Beam-on Monitor

Manufacturer's name: Nuclear Associates Primalert 35

Manufacturer's model number: Model 05-437 S/N 21092

Number of instruments available: 1

Backup Battery Power Supply: Yes _____ No X

3. Dosimetry System

a. Electrometer

Manufacturer's name:	Victoreen	~~Capintec~~
Manufacturer's model number:	570	192

b. Probes

Manufacturer's name:	Victoreen	~~Victoreen~~
Manufacturer's model number:	131	70-5
Number of probes:	1	1
Ranges:	100R	25R

4. Other (use additional pages)

Control No. 76961

Item #12
June 14, 1984

b. Probes

Capintec	Capintec	Capintec	Capintec
PR-06C	PS-033	PR-16C	PM-30
1	1	1	1
2000R	2000R	2000R	20R

Item #12
June 14, 1984

Control No. 76961

13. Calibration of Instruments

Survey Meter calibrated annually by:

Nuclear Medicine Associates, Inc.
9700 Garfield Blvd.
Cleveland, Ohio 44125

Last Calibration May 1984

Electrometers and Probes calibrated bi-annually by:

University of Wisconsin
Radiation Calibration Services
Department of Medical Physics
1530 Medical Sciences Center
1300 University Avenue
Madison, Wisconsin 53706

Last Calibration November 1983

14. Facilities and Equipment

b. Patient Viewing
Closed Circuit TV system
Window in door and mirror

Communicating System
Talk-A-Phone intercom

Item #14
June 14, 1984

Control No. 76961

15. Beam Stops

Refer to survey submitted January 11, 1984 and supplementary information submitted April 4, 1984

Item #15
June 14, 1984

17. Operating Procedures

1. Safety Device Checks

Safety devices should be checked periodically to ensure that they are operating properly. The checks will be made monthly by the Radiation Physicist as part of the monthly spot check measurements. The results of the measurements will be recorded in the notebook entitled "Cobalt Data Book". Any malfunctions or defects will be promptly corrected. Malfunctions of the timer, collimating system or source transport system will result in cessation of patient treatments until the malfunction is repaired. The Primalert, beam-on monitor and all control panel lights will be checked daily for proper functioning and recorded on a check list. Any malfunction will be promptly corrected. If the Primalert should malfunction, personnel will be required to enter the room with the Victoreen Panoramic Survey Meter.

2. Personnel Dosimetry

All teletherapy personnel will wear film badges, to be placed between the shoulders and the hips. In the event that a person receives or suspects that he or she has received a high exposure, the Radiation Physicist should be notified immediately. The film badge of the affected person will be processed immediately. When not being worn, the film badges will be stored in an area which does not receive any radiation.

3. Procedures for Securing Teletherapy Unit

When the teletherapy unit is unattended, the control panel will be locked. Doors to the treatment area will be locked outside of normal working hours.

4. Instrument Calibration

The Victoreen Panoramic Survey Meter will be calibrated annually by Nuclear Medicine Associates, 9700 Garfield Blvd., Cleveland, Ohio 44125. The meter will be hand delivered and picked up after calibration. The Victoreen 570 and Capintec 192 dosimetry systems will be calibrated bi-annually by an approved calibration laboratory. The instruments will be secured in their storage cases using the specially designed packing material. The instruments will be shipped via UPS in their specially designed shipping containers. The instruments will be picked up after calibration and hand carried back to avoid the possibility of damage to the instruments.

5. Full Calibration of Teletherapy Units

The annual teletherapy source calibration will be performed by the Radiation Physicist. The procedures for full calibration of teletherapy units specified in Section 35.21 of 10 CFR Part 35 will be followed.

6. Monthly Spot-Check Measurements of Teletherapy Units

The monthly spot check of the teletherapy unit will be performed by the Radiation Physicist. The procedures for monthly spot check measurements of teletherapy units specified in Section 35.22 of 10CFR Part 35 will be followed.

7. Leak Testing

The leak test of the Cobalt source will be performed by the Radiation Physicist utilizing a Mark V leak test kit supplied by Applied Health Physics, Inc., 2986 Industrial Blvd, Box 197, Bethel Park, Pa. 15102. Instructions for use of the Mark V leak test kit supplied by Applied Health Physics, Inc. will be followed.

8. Record keeping

The daily treatment records will be maintained by personnel during the course of their work. Film badge records will be maintained by the Chief Technologist in the Radiology Department. Records of the annual source calibrations, monthly spot check measurements and leak test results will be maintained by the Radiation Physicist.

9. Emergency Procedures

The emergency procedures to be followed in the event of an emergency or other unusual occurrence are posted at the control console of the teletherapy unit. They are as follows:

IN THE EVENT OF EQUIPMENT FAILURE RESULTING IN THE SOURCE REMAINING "ON"

IMMEDIATELY ENTER THE TREATMENT ROOM AND:

1. CLOSE ADJUSTABLE FIELD DEFINER
2. REMOVE PATIENT FROM TREATMENT ROOM
3. MANUALLY RETURN SOURCE TO "OFF" POSITION FOLLOWING POSTED PROCEDURE

4. TELEPHONE: PAUL S. LAVIK, M.D.
473-4161
651-7000 Ext. 1007

AND

AECL MEDICAL
ELK GROVE, ILLINOIS
(312) 593-3242

CAUTION: STAY OUT OF THE DIRECT BEAM AT ALL TIMES

IN THE EVENT OF A POWER FAILURE, THE ROOM SHOULD BE ENTERED USING THE VICTOREEN PANORAMIC SURVEY METER TO ENSURE THAT THE SOURCE HAS RETURNED TO THE "OFF" POSITION

IF THE DRAWER FAILS TO CLOSE, PROCEED AS FOLLOWS:

1. Remove the patient from the treatment room.

2. The drawer return emergency T-bar, which is supplied with the unit and located at the control station, inside the door, should be placed over the beam condition indicating rod. Forward pressure on the source drawer with the T-bar will push the drawer backwards and into the safe position.

NOTE:

1. The amber colored portion of the emergency T-bar must be entirely inside the front head cover before the source is in the fully safe position. This will reduce external radiation fields to normal levels and allow repairs to be made to the drawer.
The front portion of the T-bar is painted red and the source can be considered relatively safe if no red marking appears outside the front cover.

FOR EMERGENCY SERVICE
TELEPHONE:

(312) 593-3242
AECL MEDICAL
ELK GROVE, ILL.

Item #17
June 14, 1984

10. Procedures for Notifying Proper Persons in the Event of an Accident or Unusual Occurrence

The emergency prodecures shown above specify the appropriate persons to be notified in the event of an accident or unusual occurrence. In the case of a misadministration of dose, that is the treatment dose differing from the final prescribed total treatment dose by more than 10 percent, the procedures in Section 35.42 of 10 CFR Part 35 should be followed.

Item #17
June 14, 1984

Control No. 76961

19. Leak Tests of Sealed Sources

The Cobalt source is leak tested utilizing a Mark V leak test kit supplied by Applied Health Physics Inc. The attached instructions are followed.

Item #19
June 14, 1984

Applied HEALTH PHYSICS inc.
2986 Industrial Blvd. • Box 197 • Bethel Park, Pa. 15102 • Phone 412 • 563-2242

INSTRUCTIONS FOR USE OF MARK V LEAK TEST KIT ON SEALED SOURCES

These procedures are to be followed by the individual trained and authorized by the licensee's RSO to employ the Mark V Leak Test Kit for leak testing sealed sources of radioisotopes. Should any question arise concerning proper use of the Kit, contact Applied Health Physics, Inc.

1. Pre-Test Procedures

In preparing the Mark V Leak Test Kit, follow these simple procedures:

a. Remove the plastic cap with its cotton swab insert from the plastic test tube. Add a few drops of water to dissolve the powdered wetting agent in the tube. Slightly dampen the swab's cotton tip with the wetting agent solution, and discard any unused solution that may remain in the tube.

Return the prepared swab to the test tube.

b. Complete the information required on the self-sticking, circular leak test label which is included in the Kit, and securely attach to the midsection of the test tube.

c. Obtain a remote handling device, such as an AHP Protecta-Holder, which will be used in manipulating the swab stick during the actual testing procedure.

d. Carry out final preparation for all radiation protection measures that must be employed.

2. General Testing Procedures

The following general testing procedures should be used on sealed sources:

a. Grasp the cap or the bare end of its swab stick with the AHP Protecta-Holder or other suitable remote handling device.

b. Carefully, but firmly, wipe the dampened tip of the cotton swab over surface areas of the sealed source. With certain sealed sources that are located or permanently used in special equipment, it is only necessary to wipe surfaces of the mounting or storage device on which radioisotope contamination might be expected to accumulate.

c. Immediately following the wiping procedure, dispense with the remote handling device and securely replace the cap and its swab insert in the labeled plastic test tube. Avoid touching the cotton tip to the body or other objects.

Control No. 76961

Item #19
June 14, 1984

3. Post-Test Procedures

Pursuant to completion of the leak test, these steps must be taken:

a. Complete the Mark V Leak Test Data Form in a legible fashion. This form must be signed by the individual who performed the sealed source leak test.

b. Enclose the Data Form and the sealed plastic test tube in the mailing box, and seal the box. Fill in the proper return address on the Applied Health Physics, Inc.'s shipping label and securely attach to the box.

c. Monitor all external surfaces of the mailing box with a calibrated survey meter, such as a Geiger-Mullet meter with an end-window probe detector. Post Office Department regulations require that radiation levels at any surface of the box must be less than 10 milliroentgens for 24 hours; i.e., an average of approximately 0.4 milliroentgens per hour.

If results of the survey meet these requirements, proceed with mailing the Mark V Leak Test Kit to Applied Health Physics, Inc. Should the survey indicate that any surface of the box has a dose-rate greater than 0.4 milliroentgens per hour, immediately notify Applied Health Physics, Inc. by telephone.

Item #19
June 14, 1984