MATERIALS LICENSE

Amendment No. 23

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.

398362

Licensee	
1. St. Francis Hospital & Health Centers 2. 1600 Albany Street Beech Grove, IN 46107	In accordance with application dated March 14, 1995 3. License Number 13-02128-03 is renewed in its entirety as follows: 4. Expiration Date January 31, 2002 5. Docket or Reference No. 030-09398

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 (I-131 not to exceed 1 curie)
D. Any byproduct material identified in 10 CFR 35.400	D. Any brachytherapy source identified in 10 CFR 35.400	D. .055 millicuries
E. Any byproduct material identified in 10 CFR 35.500	E. Sealed sources identified in 10 CFR 35.500	E. As needed
F. Iridium-192	F. Sealed sources (BYK Mallinckrodt Model CI L BV)	F. 2 sources, 1 source not to exceed 444 gigabecquerels (Gbq) (12 curies (Ci)), and 1 source not to exceed 370 Gbq (10 Ci).
G. Cesium-137	G. Sealed source (Tech Ops Model 77302)	G. 160 millicuries

050071

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
13-02128-03

Docket or Reference Number
030-09398

Amendment No. 23

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.

D. Medical use described in 10 CFR 35.400.

E. Medical use described in 10 CFR 35.500 in devices which have been evaluated and approved for licensing purposes by the U.S. Nuclear Regulatory Commission or an Agreement State.

F. One source to be used in a Nucletron-Oldelft Corporation MicroSelectron HDR remote afterloading brachytherapy advice for interstitial, intraoperative, and intracavitary radiotherapy in humans. The source activity may not exceed 370 Gbq (10 Ci) at the time of installation. One source in its shipping container for source replacement.

G. To be used in a Technical Operations Model 773 survey instrument calibrator for the calibration of survey instruments.

CONDITIONS

10. A. Licensed material listed in Items 6.A. through 6.F. may be used at St. Francis Hospital & Health Centers, 1600 Albany Street, Beech Grove, Indiana.

B. Licensed material listed in Items 6.A., 6.B., 6.C. (excluding thyroid carcinoma treatments exceeding 30 millicuries) may be used at St. Francis Hospital & Health Centers, South Campus, 8111 South Emerson Avenue, Indianapolis, Indiana.

11. A. Radiation Safety Officer: Berry L. Stewart, M.S.

B. HDR Physicist: Berry L. Stewart, M.S.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
13-02128-03

Docket or Reference Number
030-09398

Amendment No. 23

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized Users	Material and Use
A. Ira Blecker, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
B. Howard C. Kidman, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
C. Edgardo M. Sayoc, M.D.	10 CFR 35.100, 35.200, 35.300, 35.400 and 35.500 and iridium-192 in HDR remote afterloading device.
D. Orin W. Perkins, M.D.	10 CFR 35.100, 35.200 and 35.300.
E. Franklin W. Sequeira, M.D.	10 CFR 35.100, 35.200, 35.300, and 35.500.
F. Richard L. Scales, M.D.	10 CFR 35.100, 35.200, and 35.500.
G. Gregory A. Merchun, M.D.	10 CFR 35.100, 35.200 and 35.300.
H. Benny Sin-Ping Ko, M.D.	10 CFR 35.300.
I. Ramchandra Reddy, M.D.	10 CFR 35.100 and 35.200.
J. Thomas Guy Belt, M.D.	10 CFR 35.100, 35.200, 35.300 and 35.500.
K. Paul W. Sheets, M.D.	10 CFR 35.100 and 35.200.
L. John T. Mail, M.D.	10 CFR 35.100 and 35.200.

13. In lieu of 10 CFR 35.404(a), immediately after retracting the source from the patient into its shielded position in the remote afterlaoding device, a radiation survey shall be made of the patient and the remote afterloading device with a portable radiation detection survey instrument to conform that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.404(b).

14. In lieu of the source inventory required in 10 CFR 35.406, the licensee shall:

A. Promptly determine that all sources have returned to the safe, shielded position at the conclusion of each remote afterloading brachytherapy procedure.

B. Promptly make a survey of the area of use to confirm that no sources have been misplaced.

C. Make a record of the survey including the survey instrument used, dose rate expressed in mrem/hr (μSieverts/hr), time, date and name of the individual making the survey.

D. Retain the record of the survey in lieu of the record required in 10 CFR 35.406(d).

15. A. Access to the rooms housing the MicroSelectron-HDR afterloading brachytherapy device shall be controlled by a door at each entrance.

B. The entrance to the irradiation room shall be equipped with an electrical interlock system that will cause the source to return to the shielded position immediately upon opening of the entrance door. The interlock system shall be connected in such a manner that the source cannot be placed in the irradiation position until the entrance door is closed and the source "on-off" control is reset at the control panel.

C. Electrical interlocks on the entrance door to the irradiator room shall be tested for proper operation at least once each day of use.

D. In the event of malfunction of the door interlock, the irradiation device shall be locked in the "off" position and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

16. Prior to initiation of a treatment program, and subsequent to each source exchange using the MicroSelectron-HDR remote afterloading brachytherapy devices, 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 (10 CFR 20.1201).

(b) That radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.105(b) (10 CFR 20.1301).

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
13-02128-03

Docket or Reference Number
030-09398

Amendment No. 23

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

    A. Installation and replacement of the sealed sources contained in the Microselectron-HDR afterloading brachytherapy device(s).

    B. Any maintenance or repair operations on the remote afterloading brachytherapy unit(s) listed in Item 9., Subitem F. involving work on the source safe, the source drive unit, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

18. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

19. 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. Application dated March 14, 1995; and

    B. Letters with attachments dated February 27, 1990, September 18, 1995 and October 9, 1996 (with attachments).

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date January 14, 1997

By [signature]
Nuclear Materials Licensing Branch, Region III

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 02230
STATUS CODE: 2
FEE CATEGORY: 7C
EXP. DATE: 19950430
FEE COMMENTS:
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: ST. FRANCIS HOSPITAL CENTER
RECEIVED DATE: 950329
DOCKET NO: 3009398
CONTROL NO.: 398362
LICENSE NO.: 13-02128-03
ACTION TYPE: RENEWAL

2. FEE ATTACHED
AMOUNT: 1,440
CHECK NO.: 167338

3. COMMENTS

SIGNED [signature]
DATE 3-31-95

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED /✓/)

1. FEE CATEGORY AND AMOUNT: $1400 7C

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT
RENEWAL ✓
LICENSE

3. OTHER

SIGNED SC
DATE 4/4/95

RECEIVED
APR 07 1995
REGION III

95 APR -3 AM 8:55

NRC FORM 313 U. S. NUCLEAR REGULATORY COMMISSION

(10-94)
10 CFR 30, 32, 33
34, 35, 36, 39 and 40

APPLICATION FOR MATERIAL LICENSE

APPROVED BY OMB: NO. 3150-0120
EXPIRES 6-30-96

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 9 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-6 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

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

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 13-02128-03

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip code)*

ST. FRANCIS HOSPITAL & HEALTH CENTERS
1600 Albany Street
Beech Grove, IN 46107

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

SAME

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Berry Stewart, M.S. RSO

TELEPHONE NUMBER
(317) 783-8171

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 7C
AMOUNT ENCLOSED $ 1,440.00

13. CERTIFICATION *(Must be completed by applicant)* THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

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.

CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Michael D. Vollmer-V.P.Professional Serv,	Michael D. Vollmer	3-14-95

FOR NRC USE ONLY

RECEIVED
MAR 29 1995
REGION III

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
Renewal	APR 6 III	7C	$1440 (1400)	107338	Refunded #40
APPROVED BY			DATE		
SC			4/4/95		398362

NRC FORM 313 (10-94)

ITEMS 5 & 6: RADIOACTIVE MATERIAL AND PURPOSE

	Byproduct Material	Amount		Purpose
5.a	Material in 35.100	As needed	6.a	Medical use
5.b	Material in 35.200	As needed	6.b	Medical use
5.c	Material in 35.300	As needed	6.c	Medical use
5.d	Implant Material in 35.400	1000 mCi	6.d	Medical use
5.e	Eye applicator in 35.400	55 mCi	6.e	Medical use
5.f	Ir-192 High Dose Rate Remote Afterloader in 35.400	24000mCi*	6.f	Medical use
5.g	Material in 35.500	As needed	6.g	Medical use
5.h	Cs-137 Survey Meter Calibration Source	160 mCi	6.h	Calibration

* - Two Sources not to exceed 12000 mCi each. Not to be installed until $\leq$ 10000 mCi.

ITEM 7: RSO AND AUTHORIZED USERS

NAME	FUNCTION	LICENSE #
Berry L. Stewart, MS	RSO	13-02128-03
Ira Blecker, MD	Authorized User	13-02128-03
Howard C. Kidman, MD	Authorized User	13-02128-03
Edgardo M. Sayoc, MD	Authorized User	13-02128-03
Orin W. Perkins, MD	Authorized User	13-02128-03
Franklin W. Sequeira, MD	Authorized User	13-02128-03
Richard L. Scales, MD	Authorized User	13-02128-03
Gregory A. Merchun, MD	Authorized User	13-02128-03
Benny Sin-Ping Ko, MD	Authorized User	13-02128-03
Ramchandra Reddy, MD	Authorized User	13-02128-03
Thomas Guy Belt, MD	Authorized User	13-02128-03
Paul W. Sheets, MD	Authorized User	13-02128-03
John T. Mail, MD	Authorized User	13-02128-03

ITEM 8:

We have developed a training program for your review that is appended as ATT 8.1.

ITEM 9:

9.1 See attached drawings ATT 9.1.

9.2 We have developed a survey instrument calibration procedure for your review that is appended as ATT 9.2.

9.3 We will establish, and implement the model procedure for calibrating our dose calibrator that was published in Appendix C to Regulatory Guide 10.8, Revision 2, with the changes indicated in the appended ATT 9.3.

9.4 We will establish, and implement the model personnel external exposure monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2.

9.5 N/A

9.6 N/A

ITEM 10:

10.1 We will issue the Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that are appended as ATT 10.1.

10.2 We have developed an ALARA program for your review that is appended as ATT 10.2.

10.3 We have developed a leak testing procedure for your review that is appended as ATT 10.3

10.4 We have developed rules for the safe use of radiopharmaceuticals for your review that are appended as ATT 10.4.

10.5 We will establish and implement the model spill procedures published in Appendix J to Regulatory Guide 10.8, Revision 2.

10.6 We have developed a procedure for ordering and receiving radioactive material for your review that is appended as ATT 10.6.

10.7 We will establish and implement the model procedures for opening packages that was published in Appendix L Regulatory Guide 10.8, Revision 2.

10.8 We will establish and implement the model procedure for unit dosage record system that was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2, records may be maintained electronicaly via computer.

10.9 We will establish and implement the model procedure for a multidose vial record system that was published in Appendix M.2 to Regulatory Guide 10.8, Revision 2, records may be maintained electrcnicaly via computer.

10.10 N/A

10.11 We will establish and implement the model procedure for keeping an inventory of implant sources that was published in Appendix M.4 to Regulatory Guide 10.8, Revision 2.

10.12 We will establish and implement the model procedure that was published in Appendix N to Regulatory Guide 10.8, Revision 2.

10.13.1 We will collect spent nobel gases in a shielded trap and monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions.

10.13.2 We will collect spent aerosol in a shielded trap and, for reusable traps, monitor the trap effluent with an air contamination monitor that we will check regularly according to the manufacturer's instructions.

10.13.3 We will not vent directly vent spent aerosols and gases to the atmosphere and therefore no effluent estimation is necessary.

10.13.4 We will calculate spilled gas clearance time according to the procedure that was published in Appendix O.4 to Regulatory Guide 10.8, Revision 2.

10.14 We have developed a procedure for your review that is appended as ATT 10.14.

10.15 We have developed a procedure for radiation safety during implant therapy for your review that is appended as ATT 10.15.

11.1 We have developed a procedure for waste disposal for your review that is appended as ATT 11.1.

TRAINING:

Technical personnel should have completed an approved course of study in Nuclear Medicine Technology including the following subjects: principles and practices of radiation protection, and measurement of radioactivity, standardization and monitoring techniques and instrumentation, the mathematics and calculations basic to the use and measurement of radioactivity and the biological effects of radiation.

We will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, Revision 2, including review of the Quality Management Program.

All personnel working within a restricted area shall be briefed initially and at least annually in accordance with 10 CFR 19.12. The method of training will consist of either lectures, videotaped presentations or self study modules.

In addition employees of Nuclear Medicine are required to comply with the enclosed policy: EMPLOYEE ORIENTATION FOR NUCLEAR MEDICINE.

A. All technologists who daily use radioactive materials and frequent a restricted area:

1. Will receive a copy of the Contamination control procedures and General instructions to physicians and technologists to be employed as represented in the NRC license operation.

2. They will additionally be informed of the following:

a. The NRC byproduct license, its conditions and provisions for St. Francis Hospital may be found in the RSO's office. It is available for examination Monday - Friday from 7:00 - 3:30.

b. Parts 19 and 20 of the Title 10 Chapter 1 Code of Federal Regulations is also available for examination in the RSO's office Monday - Friday from 7: 00 - 3:30 P.M.

c. It is the obligation of the employee to report any unsafe or potentially unsafe conditions that may exist within the restricted area. Should such a situation be observed, immediately notify:

Berry L. Stewart, - 783-8171 Day; 784-0121 Night
Radiologist on Duty - 8291

d. Pursuant to Section 19.13 of 10 CFR 19, each occupationally exposed worker shall be apprised of his radiation exposure record including bioassay results. The notification shall be made in writing if so requested.

3. Technologists will also be provided with a copy of the emergency procedures as outlined in the renewal application.

B. Other individuals, i.e. housekeeping, security, clerical and transportation who frequent a restricted area, but do not routinely handle radioactive material will be provided the information in Addendum I.

C. NURSING STAFF EXPOSED TO PATIENTS CONTAINING THERAPEUTIC QUANTITIES OF RADIONUCLIDES

Nursing staff will be apprised orally and/or in writing of the procedures for handling a patient containing therapeutic quantities of radioactive material. The information will be that included in the application for license renewal, including fetal dose limits and pregnancy notification procedures.

They will additionally be provided orally and/or in writing, information contained in Addendum I.

D. FEMALE EMPLOYEES OCCUPATIONALLY EXPOSED TO IONIZING RADIATION

Employees in the above category in addition to being provided information as outlined above will be informed orally and/ or in writing of the possible health risks to children of women who are exposed to radiation during pregnancy, fetal dose limits pursuant to 10 CFR 20. The text for instruction will be the Appendix to Regulatory Guide 8.13

ADDENDUM I

INSTRUCTIONS TO INDIVIDUALS WHO FREQUENT A RESTRICTED AREA

As part of your routine job duties, you will he required to frequent restricted areas of the hospital containing radioactive material. The areas in which this material is stored are outlined on the enclosed drawing. The actual containers holding radioactive material will be labeled with the following symbol:

It is imperative that you do not remove any object bearing the above symbol from the area.

Although the levels of radiation exposure expected to be encountered in these restricted areas is low, good radiation safety measures should be taken. No level of radiation exposure should be considered to be safe; there is always the possibility , however small, of harmful effects.

In order to minimize your exposure to radioactive materials, the safety principles of time, distance, and shielding should be applied, that is:

1. Keep the time of exposure to radiation as short as possible.

2. Maintain as great a distance as possible between the source of radiation and yourself.

3. Place shielding material between the source of radiation and yourself.

If you observe any condition in the restricted area that appears to be unsafe, (Wall monitor flashing RED in the Cobalt treatment room or continuous audible alarm in ' » Hot Lab) leave the area immediately and notify :

Berry L. Stewart - 783-8171 Day; 784-0121 ight
Nu lear Med tech 783-8484 Day; 783-8291 Night
Radiologist on Duty - 8291

SAINT FRANCIS HOSPITAL CENTER
DEPARTMENT OF RADIOLOGY
POLICY AND PROCEDURE

ORIGIN DATE: JAN-01-86
DIVISION: NUCLEAR MED.

EMPLOYEE ORIENTATION FOR NUCLEAR MEDICINE

PURPOSE:

To make all pertinent policies & procedures, equipment operation, and standardized methods known to new employees.

POLICY:

It is the policy of Nuclear Medicine to ensure that new employees are familiarized with the normal operation of the department, all facets of their job responsibilities, and all saftey items involving their position.

PROCEDURE:

All new employees are required to attend the hospital orientation program.

All new technical and clerical employees will attend a class concerning the use of the hospital computer system. This is given and documented by Educational Service Department.

All technical positions will be aclimated to the normal exam procedures by the current technical staff under the direction of the Senior Staff Technologist and the Chief Technologist.

Technical employees required to take call will have a minimum of 6 weeks in the normal operation of the department and will be instructed in the computer ordering, requisition recovery, and departmental charging procedures.

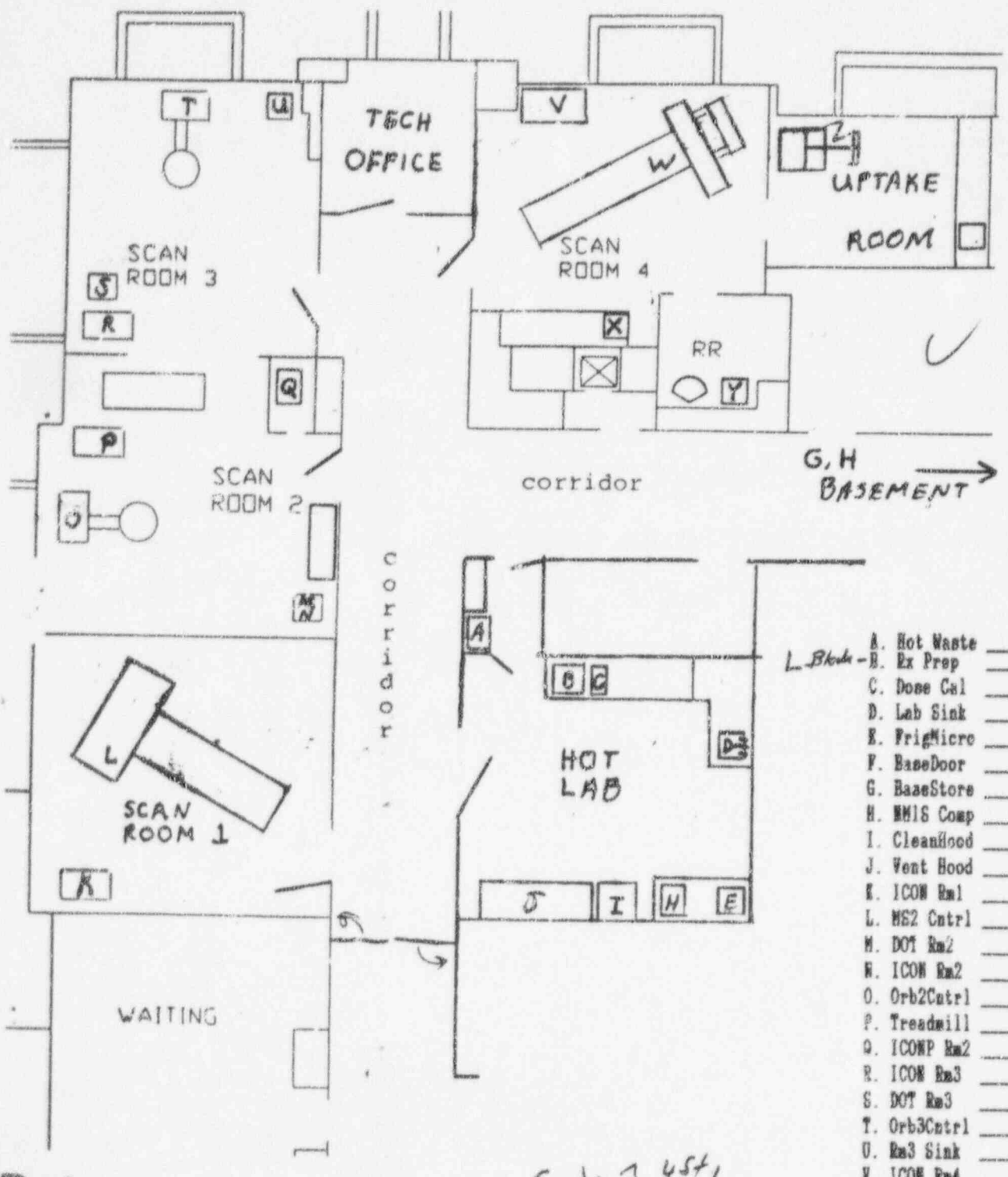
All technical positions within 6 months of hire will have available to them inservices on the following:

1. IV units, given by the IV team.
2. 02 equipment and safety, given by Respiratory Therapy.
3. Body mechanics, given by Educational Services.
4. Radiation safety, given by the Radiation Safety Office.

All positions will be made available for the normal hospital-wide inservicing for Fire, Mechanical, and Electrical Safety when shedulad.

Att 8.1
Mar. 14,1995

Weekly Wipetest



Scale ≈ 45 ft/1 cm

L Blade

A. Hot Waste ____
B. Rx Prep ____
C. Dose Cal ____
D. Lab Sink ____
E. FrigMicro ____
F. BaseDoor ____
G. BaseStore ____
H. MMIS Comp ____
I. CleanHood ____
J. Vent Hood ____
K. ICON Rm1 ____
L. MS2 Cntrl ____
M. DOT Rm2 ____
N. ICON Rm2 ____
O. Orb2Cntrl ____
P. Treadmill ____
Q. ICONP Rm2 ____
R. ICON Rm3 ____
S. DOT Rm3 ____
T. Orb3Cntrl ____
U. Rm3 Sink ____
V. ICON Rm4 ____
W. DIACAM ____
X. Sink Rm4 ____
Y. Sink Bath ____
Z Uptake ____
BKG ____

Date: _____

Tech: _____

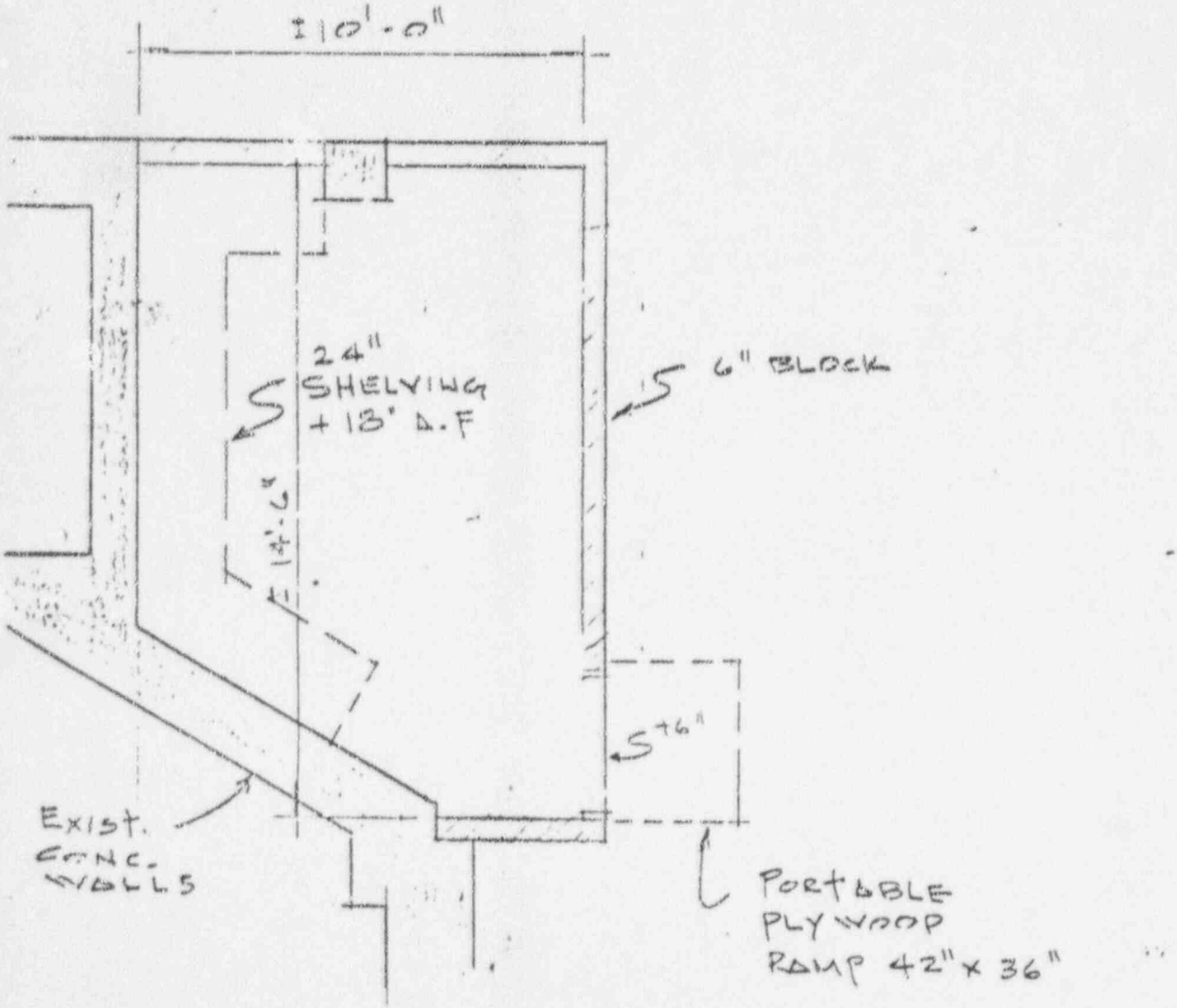
Device: _____

Att. 9.1
Mar. 14, 1995

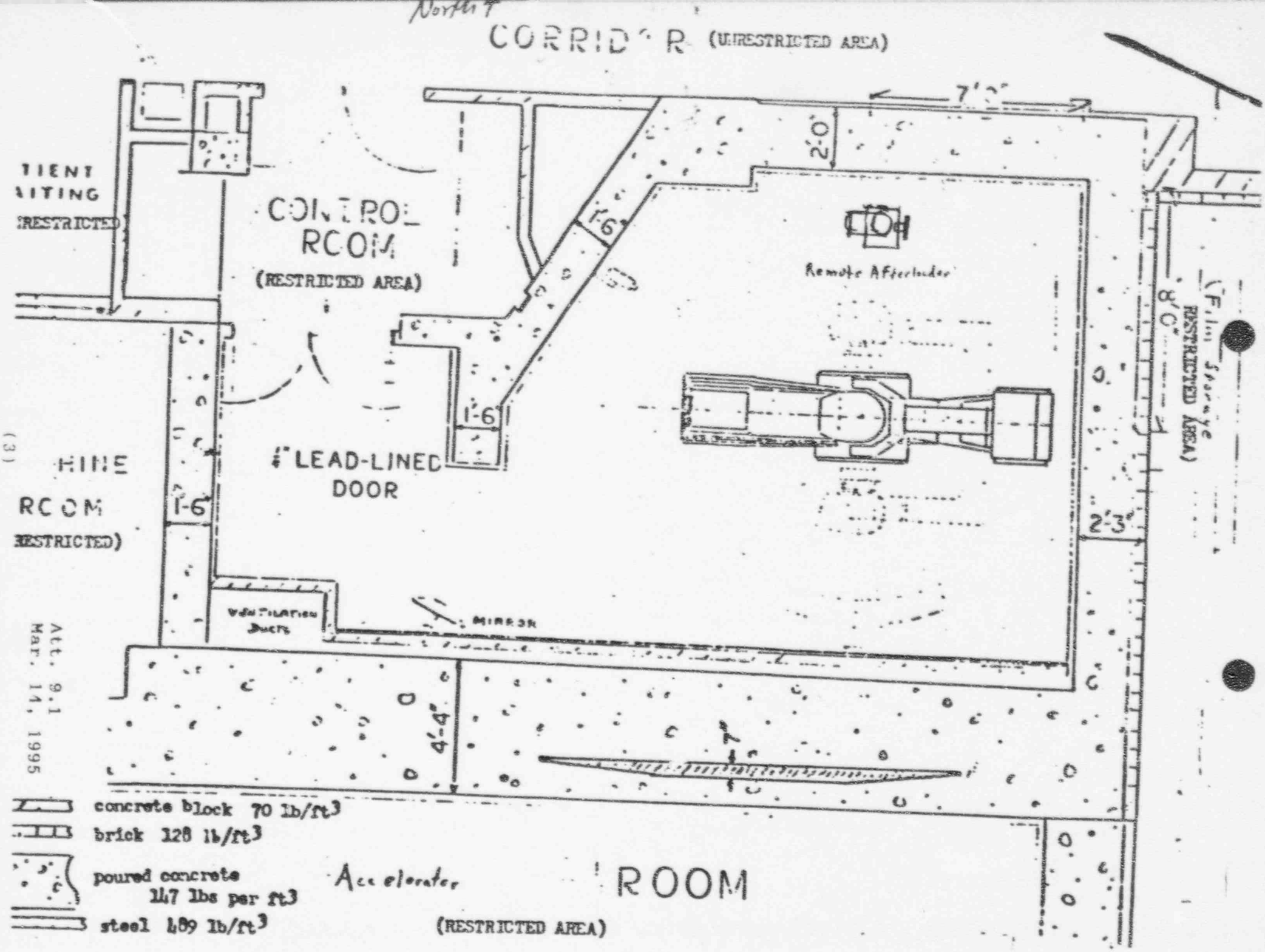
BY L E R DATE 7-8-78 SUBJECT STORAGE RM. SHEET NO. 1 OF 1

CHKD BY DATE

SUB. BSMT. X-RAY



North



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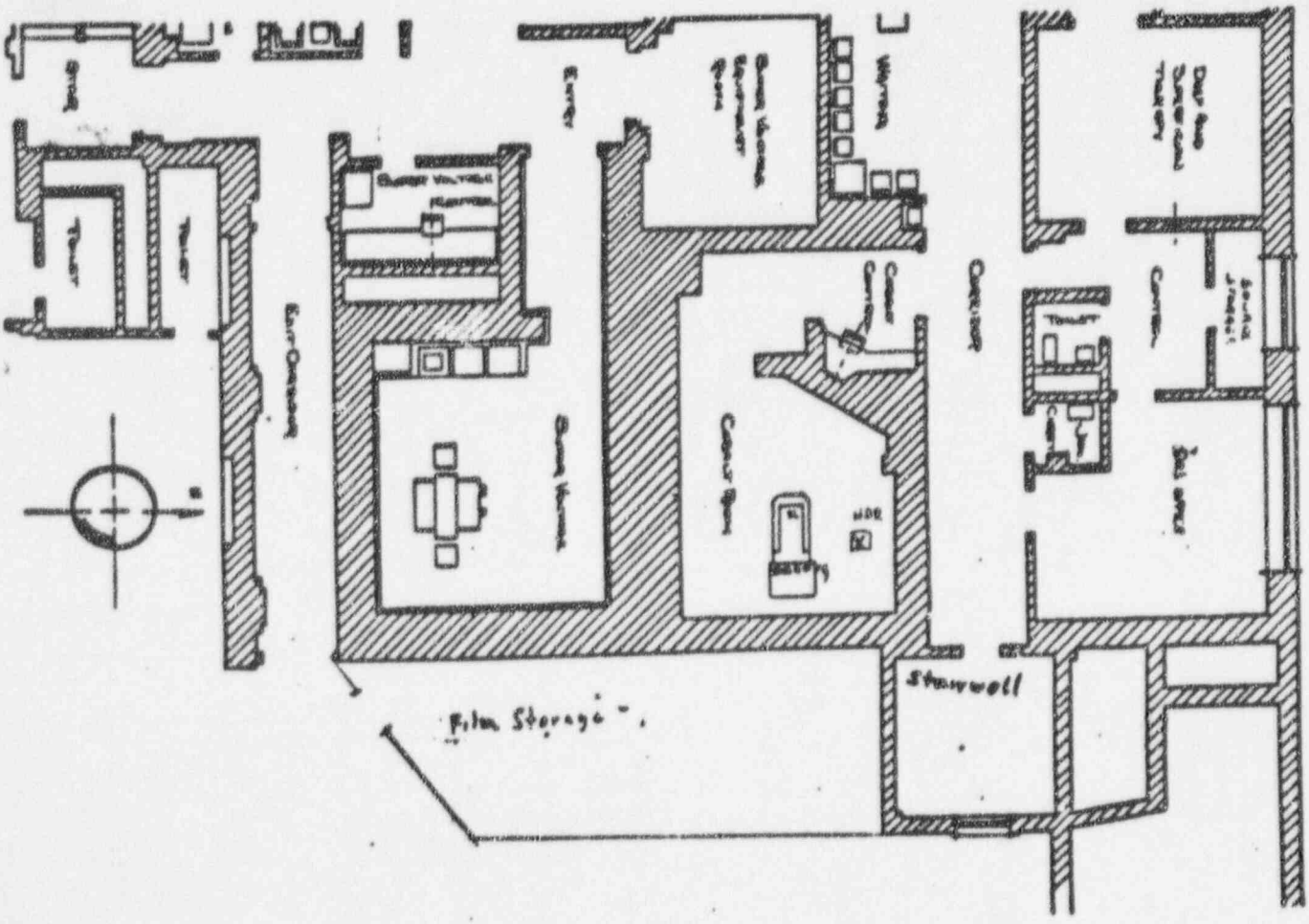
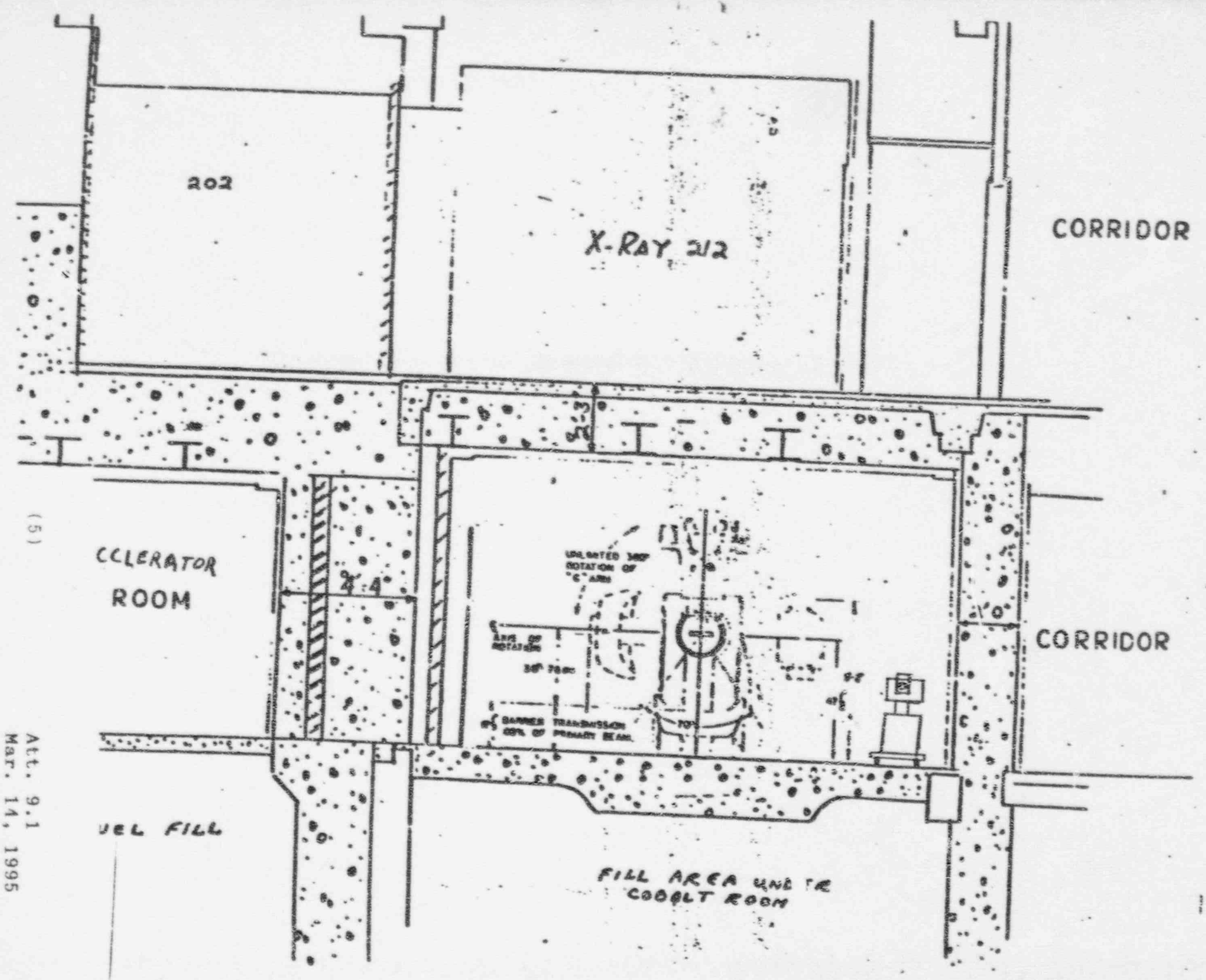
Att. 9.1
Mar. 14, 1995



Att. 9.1
Mar. 14, 1995



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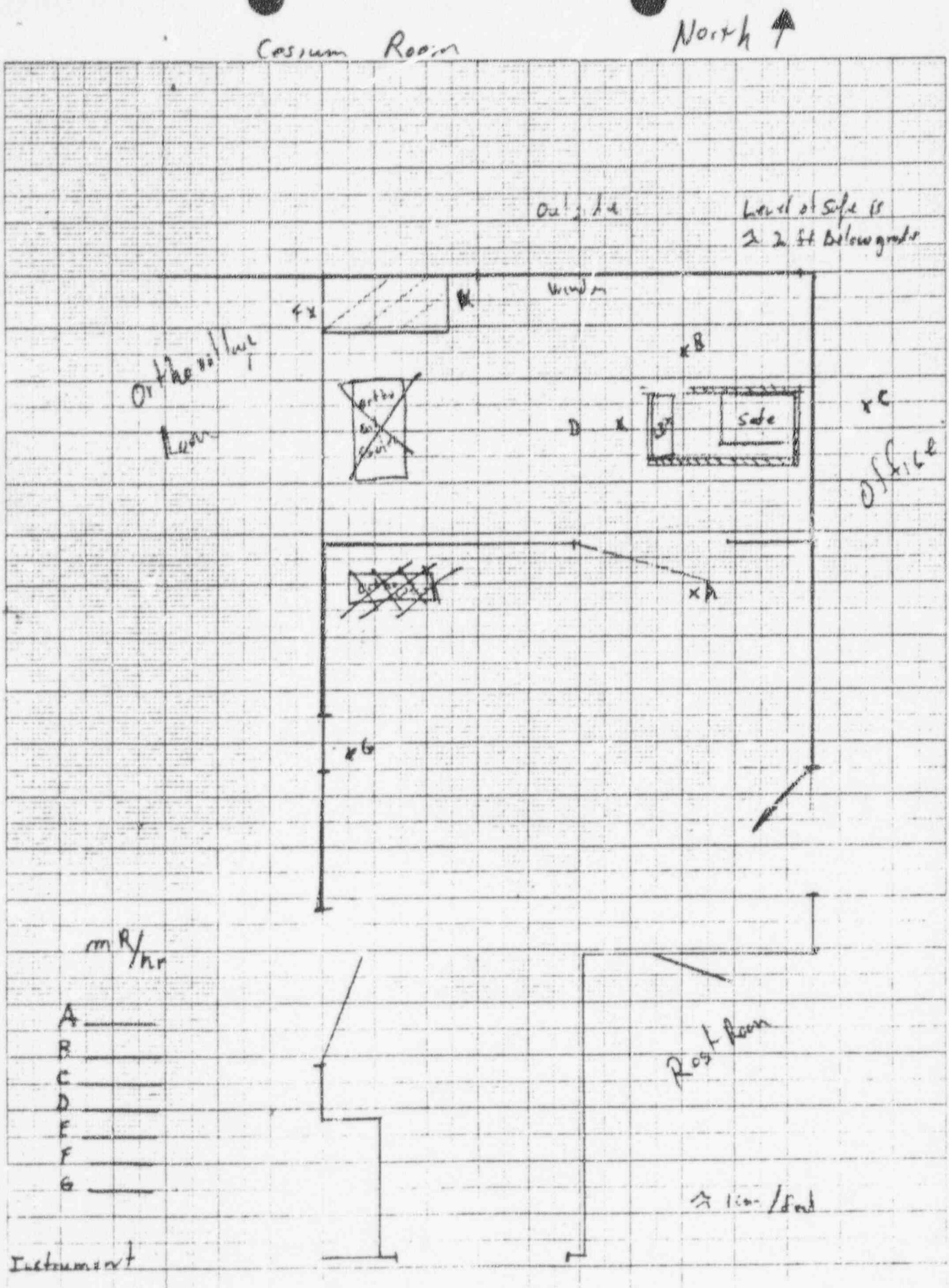
Att. 9.1
Mar. 14, 1995


Cesium Room
North
Level of Safe is
2 2 ft Below grade
Window
Safe
mR/hr
A
B
C
D
E
F
G
Instrument
Roof Plan
☆ Iron Bolt

PROCEDURE FOR CALIBRATING SURVEY INSTRUMENTS

1. The source used for calibration is a Cs-137 survey meter calibrator with an activity of approximately 150 mCI, traceable to NBS.

2. The inverse square law and radioactive decay law will be used to correct for change in exposure rate due to changes in distance and source decay.

3. A record will be made of each survey meter calibration.

4. A single point on a survey meter scale will be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than 20 percent.

5. Three kinds of scales are frequently found on survey meters.

   a. Meters on which the user selects a linear scale must be calibrated at no less than two points on each scale. The points should be at approximately 1/3 and 2/3 of full scale.

   b. Meters that have a multidecade logarithmic scale must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

   c. Meters that have an automatically ranging digital display device for indicating rates must be calibrated at no less than one point on each decade and no less than two points on one of the decades. Those points should be at approximately 1/3 and 2/3 of the decade.

6. Readings above 1000 mR/hr will not be calibrated but may be checked for operation and approximately correct response.

7. At the time of calibration, the apparent exposure rate from a check source will be determined and recorded.

8. The procedure used to calibrate the survey meter will be that recommended by the manufacturer of the Survey Meter Calibrator unless noted otherwise on the report. The calibration will include the following:

   a. A description of the instrument that includes manufacturer, model number , serial number and type of detector;

   b. The calibration source will be the Survey Meter Calibrator, if a different source is used a description of the source including exposure rate at a specified distance will be included;

   c. For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected for the instrument:

d. The reading indicated with the instrument in the "battery check" mode (if available);

e. The angle between the radiation flux field and the detector will be perpendicular unless noted otherwise;

f. For detectors with removable shielding, an indication of whether the shielding was in place or removed during the calibration procedure;

g. The apparent exposure rate from the check source;

h. The name of person performing the calibration and the date of the calibration will be recorded.

9. The following information will be attached to the instrument as a calibration sticker or tag:

a. The source that was used to calibrate the instrument if other than the Survey Meter Calibrator'

b. The proper deflection in the battery check mode (unless this is clearly indicated on the instrument) and check mode is present;

c. For each scale or decade, one of the following as appropriate:

(1) The average correction factor (if > than 15 %)

(2) A graph or graphs from which the correction factor for each scale or decade may be deduced (if > than 15 %), or

(3) An indication that the scale was checked for function but not calibrated or an indication that the scale was inoperative;

d. The angle between the radiation flux and the detector during the calibration if other than perpendicular;

e. The apparent exposure rate from the check source.

Note: One word reminders or symbols that are explained on the Survey Meter Calibration Report may be used on the calibration sticker.

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test :

Linearity Check Source (Tc-O4-99m), 100 mCi (+/- 10%)

B. Sources used for Instrument Accuracy and Constancy :

Radionuclide	Activity (mCi)	Date	Accuracy
Co-57	5.550	01/01/93	+/- 5.0%
Cs-137	0.196	02/05/90	+/- 4.0%
Co-60	0.102	01/11/90	+/- 4.0%

C. The procedure described in the instruction manual for CALICHECK Dose Calibrator Linearity Test Kit will be used for Linearity determination. The procedures described in Appendix C, Regulatory Guide 10.8, Revision 2 will used be for the remainder of the calibration of the dose calibrator.

RADIATION SAFETY COMMITTEE

Responsibility:

The Committee is resp ~ 'ble for:

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

2. Ensuring that all ·se of radioactive material is conducted in a safe manner in accordance with NRC regulations; the conditions of the license; and is consistent with the ALARA philosophy and program.

Duties:

The Committee shall:

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for license and its amendments.

2. Review the training and experience of any individual who uses radioactive material (including physicians, technologists, physicists and pharmacists) and determine that the qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license.

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of the radioactive material (e.g, nursing, security, and housekeeping personnel) are properly instructed as required by Section 19.12, of 10 CFR Part 19.

4. Review and approve all requests for use of radioactive material within the institution.

5. Prescribe special conditions that will be required during a proposed use of radioactive material such as requirements for bioassays, physical examinations of users and special monitoring procedures.

6. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspection, written safety procedures and management control system.

7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.

8. Maintain written records of all committee meetings, actions, recommendations, and decisions.

9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures and personnel.

Administrative:

1. The radiation safety committee shall meet as often as necessary to conduct business, but not less than once in each calendar quarter.

2. The membership will include at least the following, an authorized user for each type of use authorized by the license, the RSO, a representative of nursing service, and a representative of management who is neither RSO nor authorized user. Alternates may be appointed by management to participate in meetings, as well as adjunct members deemed necessary.

3. To establish a quorum, one-half of the Committee's membership, including the RSO or assistant RSO and the management representative, must be present.

ST. FRANCIS
HOSPITAL
CENTER
75th Anniversary

November 22, 1989

TO: All Employees

FROM: Paul J. Stitzel
President and CEO

SUBJ: Delegation of Authority

Berry L. Stewart, M.S., has been appointed Radiation Safety Officer and is responsible for ensuring the safe use of radiation. The Radiation Safety Officer is responsible for managing the radiation safety program; identifying radiation safety problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; and ensuring compliance with regulations. The Radiation Safety Officer is hereby delegated the authority necessary to meet those responsibilities.

The Radiation Safety Officer is also responsible for assisting the Radiation Safety Committee in performance of its duties.

1600 Albany Street • Beech Grove, IN 46107 • (317) 787-3311

Saint Francis Hospital Center

SISTER MARY HENRITA, O.S.F.
EXECUTIVE DIRECTOR

DON D. HANACHER
ADMINISTRATOR

August 14, 1980

ADDENDUM TO ST. FRANCIS HOSPITAL'S ALARA PROGRAM

The Model Program for Maintaining Occupational Radiation Exposures at Medical Institutions, ALARA has been adopted for use in our institution with the exceptions listed below:

(1). Under Management Commitment, delete item 1, b.

We feel this independent audit is not necessary as a member of management is on the RSC and all this information is available in the minutes of RSC meetings.

(2). Under Radiation Safety Officer, delete item 3, a, (3) as is, and replace with the following:

The Radiation Safety Officer will review all radiation level surveys performed by Nuclear Medicine personnel quarterly, to determine that all levels are consistent with ALARA.

Surveys about therapeutic facilities will be performed at the frequencies indicated by NUREG-0339, "Draft Licensing Guide for Teletherapy Programs." These surveys will be reviewed by the RSO upon completion.

Item 10.2
Mar. 14, 1995

1600 ALBANY STREET • BEECH GROVE, INDIANA 46107 • (317) 787-3311 • MEMBER GREATER INDIANAPOLIS HOSPITAL DISTRICT

APPENDIX O

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

ST. FRANCIS HOSPITAL, RADIATION THERAPY DEPT.

(Licensee's Name)

AUG. 14, 1980

(Date)

1. Management Commitment

a. We, the management of this (medical facility, hospital, etc.), are committed to the program described in this paper for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures, and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)[1] and a Radiation Safety Officer (RSO).

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgment, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

[1] Private practice physician licenses do not include an RSC.

2. Radiation Safety Committee (RSC)[2]

a. Review of Proposed Users and Uses

(1) The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

(3) The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

(1) The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

(2) The RSC will support the RSO in those instances where it is necessary for the RSO to assert his/her authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

[2] The RSO on private practice physician licenses will assume the responsibilities of the RSC under Section 2.

c. Review of ALARA Program

(1) The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table 0-1 below are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see Section 6).[3]

(3) The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

3. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

(1) Annual review of the radiation safety program. The RSO will perform an annual review of the radiation safety program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

(2) Quarterly review of occupational exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of Section 6 of this program

b. Education Responsibilities for ALARA Program

(1) The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

(2) The RSO will ensure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC, and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

(1) The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

(2) The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and will encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices and, if possible, will determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

4. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

(1) The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

(2) The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of Authorized User to Persons Under His/Her Supervision

(1) The authorized user will explain the ALARA concept and his/her commitment to maintain exposures ALARA to all persons under his/her supervision.

(2) The authorized user will ensure that persons under his/her supervision who are

[3] The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection," serve as check points above which the results are considered sufficiently important to justify further investigations.

subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. **Persons Who Receive Occupational Radiation Exposure**

   a. The worker will be instructed in the ALARA concept and its relationship to working procedures and work conditions.

   b. The worker will know what recourses are available if he/she feels that ALARA is not being promoted on the job.

6. **Establishment of Investigational Levels in Order to Monitor Individual Occupational External Radiation Exposures**

   This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The Investigational Levels that we have adopted are listed in Table 0-1 below. These levels apply to the exposure of individual workers.

Table 0-1

	Investigational Levels (mrems per calendar quarter)	
	Level I	*Level II*
1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2. Hands and forearms; feet and ankles	1875	5625
3. Skin of whole body*	750	2250

*Not normally applicable to nuclear medicine operations except those using significant quantities of beta-emitting isotopes.

The Radiation Safety Officer will review and record on Form NRC-5, "Current Occupational External Radiation Exposures," or an equivalent form (e.g., dosimeter processor's report), results of personnel monitoring not less than once in any calendar quarter as required by § 20.401 of 10 CFR Part 20. The following actions will be taken at the Investigational Levels as stated in Table 0-1:

a. Quarterly exposure of individuals to less than Investigational Level I.

   Except when deemed appropriate by the RSO no further action will be taken in those cases where an individual's exposure is less than Table 0-1 values for the Investigational Level I.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

   The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Exposure equal to or greater than Investigational Level II.

   The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the RSC minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

d. Reestablishment of an individual occupational worker's Investigational Level II to a level above that listed in Table 0-1.

   In cases where a worker's or a group of workers' exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

   The RSC will review the justification for, and will approve, all revisions of Investigational Level II. In such cases, when the exposure equals or exceeds

- the newly established Investigational Level II, those actions listed in paragraph 6.c above will be followed.

7. Signature of Certifying Official[4]

I hereby certify that this institution (or private practice) has implemented the ALARA Program set forth above.

Signature

RALPH K. YACKO

Name (print or type)

Associate Administrator

Title

Institution (or Private Practice) Name and Address

[4]The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator) or, in the case of a private practice, the licensed physician.

LEAK TESTING SEALED SOURCES

1. All sources tested will be listed.

2. All Cs-137 brachytherapy sources will be wipe tested simultaneously. (They are listed individually on the Activity sheet.

3. This will be done using a cotton swap to wipe the sources while they are in their storage drawers.

4. If the results of this test exceed the permissible limits, then the sources will be wipe tested on an individual basis to identify the problem source.

5. The source carrier and surface of the L-Block shield will be wipe tested.

6. The shielded storage container of the beta applicator will be wiped.

7. For larger sealed sources the wipe will be taken near the radiation port and on the activating mechanism.

8. For the teletherapy machine, the wipe will be taken with the source in the off position. The following areas will be wiped: the area near the shutter mechanism ; the primary and secondary collimators and trimmers.

9. All sources will be tested with an individual cotton swab and identified, with the exception noted in #2 above.

10. The samples will be analyzed as follows:

   a. An instrument that is sufficiently sensitive to detect 0.005 microcuries will be used.

   b. To estimate the efficiency of the analyzing system, a check source with a certified activity will be used. If the appropriate isotope is not available the a certified source with a similar spectrum will be used.

   c. The sample will be counted in the same geometry as the certified check sources.

   d. The wipe sample counts per minute will be recorded for each source tested, then the estimated activity in microcuries will be calculated based on the activity measured with the certified sources.

e. If the wipe sample activity is 0.005 microcuries or greater, notify the RSO. The source will be withdrawn from service to be repaired or discarded. The NRC will be notified if it is a regulated source.

g. The results will be signed and dated.

CONTAMINATION CONTROL PROCEDURES AND

GENERAL INSTRUCTIONS TO PHYSICIANS AND TECHNOLOGISTS

Only those persons who satisfy the criteria found in 10 CFR 35 and who are named in Item 7 of this application shall be authorized to use radionuclides.

Careful techniques and extreme personal cleanliness are the primary means of preventing contamination and entrance of radioactivity into the body. Therefore, the following rules should be observed in radionuclide laboratories where unsealed sources are used or stored.

1. Order shall be maintained according to the dictates of good housekeeping procedures. Waste or contaminated materials shall not be permitted to accumulate.

2. Eating, drinking, smoking or applying make-up as well as storage of food, drinks, or personal effects will not be permitted in a restricted area.

3. Pipetting by mouth will not be permitted in a restricted area. A bulb should be used to pipette radioactive material.

4. Personnel monitoring devices shall be worn while frequenting the restricted area. Finger exposure monitors will be used during elution of generators, during preparations, assay, injection of radiopharamaceuticals, and when holding patients during procedures.

5. Technetium-99m shall be assayed for Mo-99m content. If the Tc-99m is found to contain greater than 1 uCi of Mo-99 per mCi of Tc-99m it will not be considered acceptable for human use. Similarly, if-greater than 5 uCi of Mo-99 would be present for administration to the patient, the Tc-99m will not be considered acceptable for human use.

6. All radionuclides and radiopharmaceuticals will be assayed for activity prior to administration to a patient. The dosage will not be administered if the dosage is more than 10 percent off from the prescribed dose. A log will be kept of the date, radionuclide or radiopharmaceutical and activity administered to each patient.

7. Laboratory coats or other protective outer garments and disposable gloves should be worn while handling radioactive material. To avoid spread of contamination, remove gloves at work area and remove lab coat before leaving the Nuclear Medicine facility.

8. Personnel who handle radioactive materials should monitor their hands, and clothing prior to leaving a restricted area.

9. Areas in which radioactive materials are handled shall be monitored. This includes a wipe test of storage, preparation, and administration areas (at least once per week). The survey shall be recorded.

10. Contaminated equipment or equipment suspected of contamination shall be isolated in a designated lab or storage area and should be monitored before being removed from the laboratory.

11. Removable contamination shall not be allowed to remain. Radioactive waste disposal will be in designated, labeled, and properly shielded receptacles.

12. Work surfaces should be covered with disposable absorbent paper and trays should be used for carrying out manipulations of radioactive materials where spillage may occur. The trays should be covered with absorbent plastic-backed material. The absorbent material should be changed when measurable radioactivity has built up or when they are unsuitable for further work. These materials should be treated as radioactive waste.

13. Procedures involving gaseous, volatile or dust-forming radioactive materials shall be confined to hoods or glove boxes when appropriate.

14. Radioactive solutions shall be confined in covered containers which are plainly identified and labeled with name of compound, radionuclide, date activity and radiation level if applicable.

15. Syringes and unit dosages will be labeled with the radiopharmaceutical name or abbreviation, type of study, or the patients name. A log book or computer log will be used to record at a minimum the following information: Isotope, name of compound, the date and time of receipt or preparation, total prepared activity, specific activity, at a specified time, total volume prepared, total volume remaining, the measured activity of each patient dosage.

16. Disposable supplies should be used whenever possible.

17. All radiopharmaceuticals shall be manipulated behind suitable shielding. Remote handling devices should be used whenever practical. All vials and syringes should be shielded during preparation and administration of patient doses.

18. Open wounds on exposed body surfaces shall be properly dressed and protected before working with radioactive materials.

19. All radioactive materials including flood sources, syringes, and waste will be transported in shielded containers.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The Chief Nuclear Medicine Technologist or his designate will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded. See attached description.

2. During normal working hours carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.

3. During off-duty hours the carrier will deliver the radioactive packages to the Nuclear Medicine Department and deposit the material in the locked storage area. The carrier has a key.

4. If for some reason the carrier can not access the locked storage area during off-duty hours, security personnel will accept delivery of radioactive packages in accordance with the procedures outline in Department of Radiology's memorandum (attached).

PROCEDURE FOR ORDERING RADIOPHARMACEUTICALS

1. The Nuclear Medicine Personnel will list the patients name and scheduled exam on the Schedule Board in the Nuclear Medicine Department after receiving a request.

2. The evening before the scheduled exams, the designated Nuclear Medicine Technologist will call the Radiopharmacy and request the number of particular doses for each scheduled exam. The radiopharamaceuticals are ordered in exam batches, not for individual patients.

3. The Radiopharmacy have the acceptable dose ranges for each exam performed.

4. When the radiopharmaceuticals arrive they ar placed in the hot lab, grouped by exam type, in their individual shielded container.

5. When the technologist prepares to administer the radiopharmaceutical to the patient, the technologist assays the activity in the dose calibrator and writes it on the label on the syringe container.

6. After injecting the patient, the patients name is written on the label.

7. After injecting the patient, a copy of the label is removed from the container and secured in a log book.

8. The used syringe is returned to the shielded container, placed in the transport case and returned to the radiopharmacy.

MEMORANDUM FOR: Secu ity Personnel

FROM: Radiological Services

SUBJECT: RECEIPT OF PACKAGES CONTAINING RADIOACTIVE MATERIAL

Any packages containing radioactive material that arrive between 4:30 PM and 7:00 AM, or on Saturdays and Sundays shall be delivered to the Emergency Department and signed for by the Security Guard on duty and taken immediately to the Nuclear Medicine Department. Unlock the door and place the package on top of the counter next to the sink, and relock the door.

If the package is wet or appears to be damaged, immediately contact the hospital Radiation Safety Officer, or Nuclear Medicine technologist. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated.

RADIATION SAFETY OFFICER:	Berry L. Stewart, M.S.
OFFICE PHONE:	783-8171
HOME PHONE:	784-0121
NUCLEAR MEDICINE TECHNOLOGIST	
OFFICE PHONE:	783-8484
ON CALL:	783-8291

DEPARTMENT OF RADIOLOGY

DIVISION OF NUCLEAR MEDICINE
ST. FRANCIS HOSPITAL CENTER
1600 ALBANY STREET
BEECH GROVE, INDIANA

NURSING PROCEDURE FOR IODINE-131 THERAPY PATIENTS EXCEEDING 30 mCi

1. The patient is to have **NO** personal articles that he/she wishes to keep. (EXCEPTION: GLASSES & HEARING AID)

2. **PREGNANT** OR **LACTATING** nurses are **NOT** to attend patient.

3. Nurses are to follow the attendance times on the worksheet.

4. Nurses are to wear their individual film badge while caring for patient.

5. **USE** rubber glove when working in the patient's room and dispose of them in the trash receptacles provided by Nuclear Medicine.

6. All linen is to be placed in the receptacle provided for linen.

7. Instruct **ALL PATIENTS** (male & female) to urinate in a sitting position, wear latex gloves, and to flush the toilet **TWO (2)** times after each use.

8. **NO** visitors for the first 24 hours. Visitors are permitted after the first day with the exception of persons younger than 25 years of age and pregnant or lactating women. They are to follow the nursing attendance times and are not allowed any closer to the patient than 6 feet. **Visitors must report to the nursing station before entering patients room.**

VISITING SHOULD BE DISCOURAGED.

9. **EMERGENCY INSTRUCTIONS** ---- If vomiting or incontinence occurs within the first 48 hours after dosing:

Contact Nuclear Medicine at ext. 8484 Mon-Fri 7am - 5pm.

Nuclear Med tech on call ext. 8291 or
Berry Stewart RSO 784-0121
Radiologist on call ext. 8291

ATT 10.14
Mar. 14, 1995

I-131 METASTATIC THYROID THERAPY PROTOCOL

IODINE-131 EXCEEDING 30 mCi

1. Put patient in private isolation room . Prefer room 915 or 914 on nine tower.

2. Have patient wear hospital gown. No personal clothing.

3. Floor is to collect all clothing, sheets, etc., in plastic bag. This is to be stored in radionuclide waste room. Save these in separate bags in waste room.

4. Instruct **ALL PATIENTS** (male & female) to urinate in a sitting position, wear latex gloves, and to flush the toilet **TWO** (2) times after each use.

5. After administering the I-131 to the patient, measure the exposure rate at one meter from the patient's abdomen. Should be approximately 25 mR/hr.

6. Record exposure rate on patient's chart.

7. Post signs on patient's: chart; bed; room door; and Cardex.

8. Check patient every day and measure exposure rate from patient's neck at a distance of 1 meter. Record on chart. When exposure rate is **6.6 mR/hr or less**, patient may be released.

9. Check patient every day and measure exposure rate (R) at (2) feet and (6) feet to figure nursing attendance times. R (mR/hr) Enter time in chart.

   Z = Nursing attendance time in minutes.
   D = 10 mr per day (Max. allowable exposure for nursing)
   Y = Attendance time in hours.
   R = Exposure rate at distance from patient

$$(Y) = \frac{(D)}{(R)} \; ; \; (Z) = (Y) \times (60)$$

10. Any individual nurse is permitted to attend the patient **ONLY** one (1) time during the stay, and then **ONLY** according to the recommended nursing attendance times.

11. A final survey of the patient's room must be done before the room can be released for use by another patient.

St. Francis Hospital & Health Centers
Beech Grove, Indiana

Nursing Services Administration

Protocol: Care of the Patient Receiving Iodine 131 Therapy

Purpose: To outline the nursing management of the patient receiving Iodine 131 therapy.

Level: Interdependent

Scope: 9 Tower

Expected Outcome of Care:

To provide patient, staff, and visitor protection and immediate identification of complications of therapy.

Patient Teaching:

Admitting will notify 9 Tower when a patient is scheduled for admission. Prior to the patient's admission, a 9 Tower RN will contact the patient at home to initiate patient teaching and to establish a rapport. The following to be discussed with the patient:

Personal Belongings

- No personal belongings other than glasses, dentures and hearing aids. If a patient desires additional belongings, they must know that belongings will be stored after dismissal and not returned for 3 months. Encourage patients to bring magazines, puzzles, etc. (that may be thrown away) to help occupy time. Bring hard candy (ie lemon drops) to suck on to decrease the radioactive dose to the salivary glands.

Visitors

- No children under 18 years of age or lactating or pregnant visitors allowed.
- No visitors are allowed during the first 24 hours (except in unusual situations where approved by the attending physician). During the remainder of the patient's hospital stay, exposure time for visitors will be the same as for personnel at 6 foot distance for that day. Refer to worksheet on front of chart.
- Visitors must wear isolation apparel (gown, disposable gloves/foot covers) while visiting patient.
- Isolation apparel will be removed and disposed of in proper containers within the patient room.

Urine/Stool/Emesis

- Patients will use the toilet in the room for both urine and

stool. Instruct patient to don disposable gloves before use of toilet. Flush twice after each use. Men will sit to urinate to eliminate splashing. If unable, use urinal and pour carefully into toilet. Discard gloves and wash hands thoroughly.
- If vomiting occurs within 48 hours, someone from Nuclear Medicine will assist in the cleaning. Notify your nurse immediately. A disposable wash basin will be available for vomiting.

Isolation
- Will be placed in a special isolation room (T915). Patient cannot leave the room until radioactive contamination precautions are lifted.
- There will be little personal contact.
- May communicate through door, via intercom or phone.
- Bring magazine, etc., that can be thrown away.
- TV will be working.
- Notify dietary of isolation - paper-products only.

Preparation of Room: Prior to dosing, Nuclear Medicine personnel will assist with the preparation of the room. (T915)
- Floors, chairs, tables to be covered with paper or chuxs. (Nuclear Medicine)
- Towels, gowns, linen, and all bedside supplies will be placed in room. (Nursing)
- Patient should have no personal belongings except glasses, dentures and hearing aids. (Nursing)
- Two receptacles are to be in room, one for trash/one for linen. (Nuclear Medicine)
- Obtain a disposable BP cuff/stethoscope (Nursing)
- Radiation Isolation Cart to be outside of room (Nursing)
- Disposable Ambu Bag outside of room (Nursing)

General: Complete admission assessment sheet prior to dosing (usually patients are admitted and dosed same day).
- Assure that all lab work/x-rays have been completed, especially TSH level. (TSH levels are only run on Monday-Wednesday-Friday and take 3 hours.)

- All women of child bearing age must have a pregnancy test completed prior to dosing. (Use Administrative Policy and Procedure #660.01 as a guide).
- Remove all patient belongings from room.
- A technician from Nuclear Medicine and the Radiologist will come to the floor to administer Iodine 131.

Nursing Care
- Staff will have minimal contact with the patient.
- Staff will take medications, meal tray and other needed supplies inside the patient's room and place them on the bedside table just inside the door, for the patient to obtain.
- Staff will communicate with the patient from hallway/intercom every shift/prn. Must have visual contact at least every shift from doorway.

- Lactating or pregnant staff should not be assigned to care for patient.
- Staff will not enter room unless an emergency situation arises. Before entering: gown, glove, cover hair and shoes, and mask. Discard coverings in proper containers within the patient's room.
- Patient's well-being will not be placed in jeopardy.
- Notify charge nurse in ICU and CCU of a potential Code Blue. Leave the cart outside of room and bring in only necessary equipment. Record all employees present.
- In the event of a code, proceed in a normal fashion. Nuclear Medicine will provide evaluation immediately following the code situation.
- Rotate staff so that they are not assigned for Patient Care more than 8 hours per hospitalization. Nurses will follow the attendance times on the worksheet located on the patient's chart. A counter will be worn when entering patient room.
- Bedside chart forms will be kept outside the room.
- If vomiting or incontinence occurs within the first 48 hours after dosing, notify the Nuclear Medicine Department at 8484 or Nuclear Medicine Tech on call for clean up (call 8291 to find out who is on call).

Medication:

1. May administer Tigan 200 mg Suppository, one every 4 - 6 hours prn for nausea/vomiting.

If allergic to Tigan, call Radiologist.

- Notify the radiologist on call of any problems that occur.

- Diet prior to dosing should be clear liquids. NPO for 2 hours immediately before dose. Remain on clear liquid 2-4 hours after dosing then diet as at home. Force fluids after clear liquids, diet as tolerated by patient.
* No red food dye and no seafood for one week after receiving dose. Flush any left over food down toilet to prevent odor from waste.

Vital Signs
Will be taken on a prn basis. A disposable BP cuff and stethoscope will be on the isolation cart. Once used, they will remain in the patient's room.

Post Admission Patient Teaching: Assess patient knowledge regarding teaching completed prior to admission. Answer any questions the patient/significant other may have.
The following will be discussed in addition to the Pre-Admission Teaching.

Elimination
- Patients will use the toilet in the room for both urine and stool. Instruct patient to don disposable gloves before use of toilet. Flush twice after each use. Men will sit to urinate to eliminate splashing. If unable, use urinal and pour carefully into toilet. Discard gloves and wash hands thoroughly.

Linen
- All linen is to be placed in large containers (provided by Nuclear Medicine) lined with red plastic bags and placed at foot of patient's bed. Containers to be picked up by Nuclear Medicine.
- Patient will have 2 full size sheets, 2 draw sheets, 3 towels, 3 washclothes and 3 gowns in room prior to dosing.

Vomiting/Nausea
If vomiting occurs within the first 48 hours, contact the nurse immediately so that the Nuclear Medicine Department can be contacted. If at all possible, vomit in a disposable wash basin to prevent contamination. Do not use emesis basin.

Bath
Patient may take sponge bath. No showers, tub baths, or shampooing. The dirty water from a sponge bath should be collected in a basin and dumped into the toilet and flushed x 2.

Medications
Patient will be given routine home meds as ordered by physician. Instruct patient on administration of suppository.

Documentation: Complete pertinent parameters on flow sheet. Update care plan and complete 24 hour progress notes. Document patient teaching on appropriate forms.

Discharge Planning/Patient Teaching:
All patients who have had Radioactive Iodine-131 will have the following patient teaching documented upon discharge:
Upon dismissal patients and/or their significant other will verbalize home care. Patients will receive a copy of the Nursing Discharge Summary and Instruction Sheet.

Medications
Take as directed by physician.
Specifically ask about thyroid medications.

Activity
As tolerated around home, unless otherwise specified.

Diet
Previous home diet, unless otherwise instructed by physician.
No red food dye or sea food for one week following dose.

Elimination
Continue to flush toilet twice after each use for 2 weeks. No other precautions need to be taken. Males should sit to urinate or continue to use a urinal.

Special Precautions
Do not hold any small children for 2 weeks after dismissal.
Not to go in crowded places, shopping, church, etc. for 2 weeks.
Sleep alone and no sexual relations for 2 weeks.
Limit contact with family, friends, children under 18 years of age or pregnant/lactating women for 2 weeks.

Call physician for any problems or concerns.

Follow Up Visit
Call for follow up visit with physician as instructed by the physician.

Developed By: 9 Tower (Medical-Surgical)

Date: 1986

Committee Approvals and Date:

Radiation Safety Committee: 6/28/90; 6/15/94
Pharmacy & Therapeutics Committee: 9/4/90
Nursing Council Standards: 04/28/94
Education Standards Committee: 3/16/94

References

St. Francis Hospital Nursing Protocol, Nursing Care for Iodine 131 Therapy Patients, 10/3/91.

St. Francis Hospital Center, Department of Radiology Division of Nuclear Medicine, Nursing Procedures for Iodine 131 Therapy Patients Exceeding 30 MCI, Revision June 1990.

St. Francis Hospital Center, Department of Radiology, Division of Nuclear Medicine, Iodine 131 Cancer Therapy Worksheet, June 1990.

Russell, Rebecca, RN, MSN, Clinical Nurse Specialist - February 1994.

Hentz, Debby, Nursing Manager, Surgical Unit - February 1994.

Stinson, Jim, CNMT, Assistant Chief, Nuclear Medicine - 2/94.

Perkins, Orrin, MD, Nuclear Medicine - 2/94.

Approved by: Nursing Council

_____ _____
Vice-President of Patient Services Date

A61.Proto/I-131/therapy
05/02/94

SAINT FRANCIS HOSPITAL CENTER
DEPARTMENT OF RADIOLOGICAL SERVICES

NUCLEAR MEDICINE DIVISION

POST IODINE-131 PATIENT INSTRUCTIONS

1. Should sleep alone for the next three (3) days.

2. If possible use a separate toilet from other family members for the next three (3) days. Flush toilet twice after use.

3. Clean any urine spills with toilet paper and flush down toilet.

4. Avoid close, extended contact with small children for the next three (3) days. Example - do not sit next to someone in a car for an hour or more, do not have a child sit on your lap for an hour or more, etc.

   Casual contact is acceptable which would be at a distance of three (3) feet or more.

   DO NOT kiss or hold infants for the next three (3) days.

5. **DO NOT BREAST FEED** for the next two (2) weeks.

6. Check with your referring physician for information on restarting your medication.

7. Make an appointment at 6 months from dosing with I-131 to see your referring physician for check-up.

SAINT FRANCIS HOSPITAL CENTER
DEPARTMENT OF RADIOLOGY
POLICY AND PROCEDURE

NO. 722.33

EFFECTIVE DATE: MAR-01-89
DIVISION: NUCLEAR MED

TECHNOLOGIST THYROID BIOASSAY FOR THERAPEUTIC I-131 USE

PURPOSE:

To provide radiation safety monitoring of I-131 thyroid uptake in occupational workers (CFR Part 35.315,a,8)

POLICY:

The Nuclear Medicine Department will provide a method of monitoring the thyroid burden of occupational workers involved with the therapeutic use of I-131 requiring the patient to be Hospitalized (more than 30.0 mCi).

PROCEDURE:

All personnel which prepared or administered or assisted in preparing or administering the dose of I-131 will, within 3 days after the usage, perform a bioassay.

Bioassay is as follows:

Utilize the ADC Thyroid probe.

On the "THYROID BIOASSAY FOR RADIOIODINE - WORKSHEET"

1. Do a two (2) minute count over the neck, record.
2. Do a two (2) minute count for background, record.
3. Record the Detector Efficiency (EFF)
4. Record the Minimum Detectable Activity (MDA)
5. Radiation Safety Officer to get worksheet.
6. Calculations will be done and if Thyroid Burden is considered significant, additional blood work will be required.
7. Negative results of the Bioassay testing will be reported at the quaterly Radiation Safety Committe meetings.

SAINT FRANCIS HOSPITAL CENTER
DEPARTMENT OF RADIOLOGY
NUCLEAR MEDICINE DIVISION

THYROID BIOASSAY FOR RADIOIODINE - WORKSHEET

Personnel Data

Name: _____ SS#: _____ - _____ - _____

Date of Exposure: ___ / ___ / ___ Dose Used: _____ MCI

****

1. Gross Thyroid: _____ cts. / _____ min count time = _____ cpm

Equipment Data

Counting Instrument: _____ SN# _____

Standard Used: _____ Standard Activity: _____ UCI

****

2. Room Background: _____ cts. / _____ min count time = _____ cpm

3. Gross Standard: _____ cts. / _____ min count time = _____ cpm

Detector Efficiency (EFF)

Efficiency = _____ cpm/uCi (Net Std. cpm / uCi in Std.)

Minimum Detectable Activity (MDA)

MDA = _____ uCi MDA = $\frac{3 \sqrt{R/t}}{EFF}$ R = Bkg cpm
t = Bkg count time (min)

Thyroid Burden Caculations

Thyroid Burden = _____ uCi (Net Thyroid cpm / EFF)

PROCEDURE FOR RADIATION SAFETY DURING IMPLANT THERAPY

1. All patients treated with brachytherapy sources will be placed in a private room with toilet. Preferably 915 or 914.

2. The patient's room will be properly posted in accordance with 20.105(b) of 10 CFR Part 20.

3. Surveys of the patient's room and adjacent areas on the same floor will be conducted as soon as practicable after sources are implanted. The rooms above and below will not be surveyed unless the implant is loaded with sources that exceed 80 mgRaeq's of Cs-137.*

   * Based on the facts: (1) to prevent patient anxiety in the rooms above and below the implants; (2) the floor decks are 12 feet apart and are 6 inches of concrete; (3) the average implant is less than 50 hours in duration; (4) 80% of the implants are less than 25 mgRaeq's; (5) measurements made in the rooms above and below the room used for implants with 87.41 mgRaeq of Cs-137 in free space were less than 1.5 mR/hr.

   Exposure rate measurements will be taken at the patients bedside, three feet away and at the entrance to the room.

   The Radiation Safety Officer or his designate will then determine how long a person may remain at these positions and will post these times in the patients chart.

4. The form, Nursing Instructions for Patients Treated with Brachytherapy Sources, will be completed immediately after sources are implanted and placed in the patient's chart.

5. Radiation levels in unrestricted areas will conform to the requirements of Section 20.105(b), 10 CFR Part 20.

6. Nurses will use personnel dosimeters when caring for the patient.

7. At the conclusion of treatment, a survey will be performed to ensure that all sources have been removed from the patient and accounted for. All warning signs will be removed and pocket dosimeters will be returned to the department.

8. Instructions to Nurses

   a. Special restrictions may be noted on the precaution sheet in the patient's chart. Nursing should read these instructions before administering to the patient. Call the Radiation Therapy Dept. if you have any questions about the care of these patients.

   b. Nurses should spend the minimum necessary time near a patient for routine care.

   c. A film badge, or pocket dosimeter will be available outside the room along with a log sheet to record the dosimeter readings.

d. If possible pregnant nurses should not be assigned to the personal care of these patients.

e. Never touch needles , capsules or containers holding brachytherapy sources. If sources become dislodged use long forceps and put them in the shielded container provided; contact the Radiation Therapy Dept. immediately.

f. Bed bath by the nurse should be omitted while the sources are in place.

PROCEDURE FOR SEALED SOURCES

a. STORAGE

All sealed sources used for brachytherapy are stored within a 4 inch lead safe.

b. SAFE HANDLING OF BRACHYTHERAPY SOURCES

1. Never handle radioactive therapy sources directly with the hands. Always use forceps or other special tools to manipulate these sources.

2. To keep your whole body radiation dose to a minimum when working with radioactive sources, always stand behind the special shield provided for this purpose. You should observe the sources through the leaded glass appended to the shield top and work as quickly as practical.

3. Unusual manipulations should be tested in advance with non-radioactive dummy sources to find the most rapid and efficacious manner of performing them.

4. Any removal or return of sources to the permanent storage vault must be recorded in the log book to insure that the location of all sources is known at all times.

5. Unless a source transfer is being conducted, the storage vault will be locked and the room will not be accessible to unauthorized personnel.

6. Perform and record leak tests on the sources every six (6) months.

7. Perform and record an inventory of the sources on a quarterly basis.

DETERMINING EXTREMITY DOSE

TLD rings Are provided for personnel who must handle brachytherapy sources.

c. TRANSPORTATION

All brachytherapy sources are transported in a shielded carrier. A radioactive materials caution label is affixed to the cylinder.

d. ACCOUNTABILITY

A record of issue and return of all sealed sources shall be kept. To confirm the removal of the implant at the end of the treatment, a source count shall be done as well as a radiation survey of the patient. A Physical inventory shall be made at least every six months and a written record kept.

e. SURVEYS

Exposure rate measurements will be taken at the patient's bedside, three feet away and at the entrance to the patient's room.

A survey will be performed at the conclusion of the treatment to ensure that all sources have been removed from the patient and the room.

HIGH DOSE RATE REMOTE AFTERLOADER

A. Intended Use:

The MicroSelectron-HDR system is intended to be used for intraluminal, intracavitary, interstitial and intraoperative treatment of cancer.

B. Proposed Users:

The device will be used by the individuals on our current license listed to use Group 35.400 materials.

C. Training of Individuals:

On-site training will be provided by the Manufacturer, including training in programming, and operating the device as well as Emergency Procedures. (See training enclosure.)

The procedure for unloading or loading sources from transport container are part of the on-site training.

The source will be installed by a qualified representative of Nucletron.

The training and instructions will be provided by a qualified representative of Nucletron Corporation, and refresher training will be provided on an annual basis.

The unit will not be used unless there is an individual who has been trained in the use of the unit and the Emergency Procedures, on-site.

Individuals who use the unit will be inserviced annually on the use of the unit. Topics will include: programming, operation, and Emergency Procedures. Also "dry-runs" of emergency procedures will take place at time intervals not to exceed twelve (12) months.

D. Facilities:

a. The unit will be placed in the Cobalt-60 Therapy Room. The room currently houses a Picker C9 Cobalt unit NRC License N 13-02128-02. Drawings enclosed attachment ATT 9.1.

b. There is a TV System for continuous viewing of the patient. If this system fails there is also a mirror system that enables constant viewing of the patient.

c. There is an interlock on the treatment room door which when opened will initiate a "Stop" sequence on the Selectron Computer. There is an Emergency Stop button mounted in the room as well as on the MicroSelectron-HDR itself.

As the room is also a Cobalt-60 Therapy Room, it is currently a restricted area and so indicated by signs and warning lights.

When the MicroSelectron-HDR is in use the Cobalt unit will be turned off and the key secured.

There is a Monitor in the room to serve as an independent indicator of the presence of radiation indicating that the source is or is not in the "safe" condition.

Once the entry interlock is tripped it must be reset to activate the unit.

d. The maximum on time in any 8 hour period should not exceed 2 hours.

The maximum exposure rates in adjacent areas are:

Area	Exposure (mR/hr)
Corridor	0.238
Control Room	1.603
Film Storage	0.047
Accelerator Room	<0.001
Floor	Dirt Fill

E. Operating procedures:

a. Prior to use, appropriate staff will be provided with written operating procedures. These procedures will include: policies for securing unit, daily checks as required by NRC (*), assurance that only patient is in room when unit is in the on mode, and confirmation of treatment time calculation.

(*) NOTE: Daily checks will be done, only on the days the unit will be used to treat patients.

b. The dose or activity accuracy will be determined, in air with a calibrated dosimetry system, to within ± 10% on an annual basis or after each source change.

c. The calibrated dosimetry system will meet the requirements of 10CFR 35.630, and the primary chamber will be a re-entrant type chamber.

d. The timer accuracy and source travel time will be determined at the time dose accuracy is measured if a re-entrant chamber is not used for calibration.

e. Constancy checks will be performed on at least a quarterly basis

f. The calibrations will be performed by a qualified physicist, our physicist is Berry L. Stewart, M.S., who is on our current license.

F. Emergency Procedures:

A Copy of the Emergency Procedures will be posted near the control console. They will be similar to the copy of the emergency procedures enclosed.

G. Leak Test:

Leak testing is done by the manufacturer and the source will be on site less than five months , therefore additional leak testing is not required.

H. Waste Disposal:

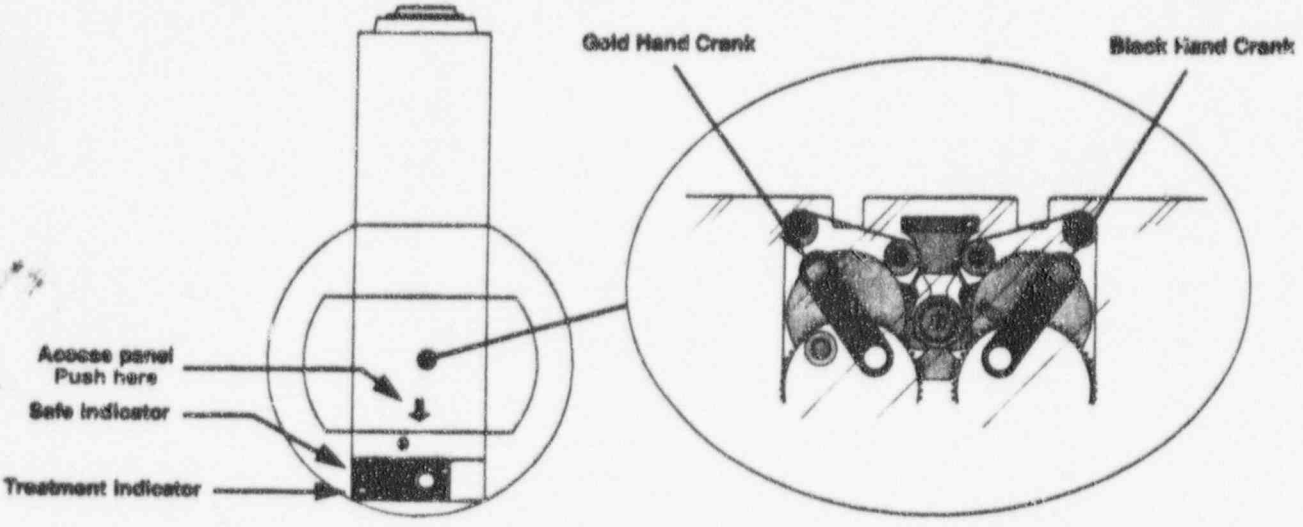
Sources will be returned to the vendor or someone who is licensed by the NRC to receive byproduct material.

EMERGENCY PROCEDURES
FOR
microSelectron-HDR ^{192}Ir
IF THE SOURCE FAILS TO RETURN TO THE SAFE

1. Depress RED EMERGENCY STOP BUTTON on master emergency stop switch. If the source retracts, go to step 7, otherwise step 2.

2. Enter the treatment room.

   - PUSH down on the access panel on top of the treatment unit to access the GOLD hand crank. Turn it in the direction of the arrows until it blocks.
   - If the source retracts, go to step 7, otherwise step 3.



Access Panel Location **Gold Hand Crank Location**

3. Disconnect the applicator from the machine. Move the machine well away from the patient.

4. Check the patient for radiation. If detected, remove the applicator from the patient, ensuring that radiation is confined to the applicator.

5. IMMEDIATELY assist the patient from the room. A suitably qualified person must now ensure that the applicator is shielded.

6. Leave the room. Close the door. Mark it NO ENTRY.

7. Retain the treatment data printout and contact the following:

Physicist: B. Stewart ..... Tel. 8171 Home 784-0121

Doctor: E. Sajac, MD ..... Tel. 8171

Nucletron Representative: ..... Tel. 1-500-538-2249

The unintended radiation dose to which those present have been subjected should be estimated and recorded by a suitably qualified person.

ATT 10.15
Mar., 14, 1995

WASTE DISPOSAL PROCEDURES

We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2. *

* The residual activity of the radiopharmaceutical left in the syringe is returned to the Radiopharmacy.

JAN 14 1997

Michael D. Vollmer
Vice President Professional Services
St. Francis Hospital and Health Centers
1600 Albany Street
Beech Grove, IN 46107

Dear Mr. Vollmer:

Enclosed is Amendment No. 23 renewing your NRC Material License No. 13-02128-03 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.

398262

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
Gidget Watson
Nuclear Materials Licensing Branch

License No. 13-02128-03
Docket No. 030-09398

Enclosure: Amendment No. 23

DOCUMENT NAME: M:\03009398.CL7
To receive a copy of this document, indicate in the box: "**C**" = Copy without attachment/enclosure "**E**" = Copy with attachment/enclosure "**N**" = No copy

OFFICE	DNMS/RIII								
NAME	GWatson:brt								
DATE	01/14/97 GW								

OFFICIAL RECORD COPY

ST. FRANCIS HOSPITAL & HEALTH CENTERS
Our Specialty is Life.

10/09/96

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

Reference: Control # 398362

Dear Ms. Watson

The enclosed information is in response to your request for additional information regarding the renewal of St. Francis Hospital's Materials License #13-02128-03.

Training Program:

1. The initial training (for new users), and refresher training on an annual basis will be provided by the manufacturer. Trainee's competency will be determined by the manufacturer's instructor, most probably by demonstration to the instructor. Training records provided by the manufacturer will be maintained for a period of at least three years. Retraining will include dry runs of emergency procedures. Ref. Item ATT 10.15 section C. of application dated 3/14/95.

Facilities:

2.a The patient is under constant observation during treatments via closed circuit TV system, and intercom. The patient is also visible via a mirror system that can be seen thru the window in the door if the TV system should fail, also audio communication is possible thru the door. If visual or audio communication is not possible, patient treatment will be suspended until such time communication is possible.

2.b If during the interlock check there is a malfunction and it is determined repairs are needed, service will be called and the unit will be locked in the OFF position and used only to affect repairs until such time that proper interlock function is restored.

2.c The console keys are located in the desk drawer in the locked control room, when not in use.

2.d A copy of the emergency procedures is enclosed. Briefly to enter the treatment room in an emergency situation, the following would occur;

2.e The radiation monitor is checked with a dedicated check source, each day the treatment unit will be used, for proper operation. The results will be documented and any identified problems with the monitor will be addressed by repair or replacement. The monitor provides a visible indication of radiation and can be seen upon entering the treatment room. The monitor has a back-up power supply independent of the treatment unit.

Compliance with Restricted/Unrestricted Area Radiation Levels:

3. Following source replacement, a survey will be performed to determine the maximum radiation levels at 10 cm from the surface of the Treatment unit with the source in the shielded position. This survey will be performed by either the Vendor Service Rep, immediately after the source replacement, or the Radiation Safety officer prior to use. The survey will be reviewed by the RSO, initialed and dated.

To assure compliance with the limits set forth in 10 CFR 20.1201 and 10 CFR 20.1301 for restricted and unrestricted areas, a survey will be performed with the maximum strength source (10.0 Curies) of all surrounding areas with the source in the exposed position. Unless the source activity is greater than that used for the initial survey, or structural changes are made in the facility, the initial survey will be sufficient to demonstrate the above compliance. (See ATT 10.15 dated 3/14/95, Section D.d. for calculations of the maximum exposure levels in adjacent areas.)

If source strength is greater than the maximum activity used or there are structural changes then a new area survey will be performed.

The results of all surveys will be maintained for the duration of the license.

Pursuant to 10 CFR 20.1904, at least one "Caution Radioactive Materials" label will be affixed to the treatment unit.

Operating Procedures

4.a The treatment room will be secured when unattended.

4.b Treatment planning removable media will be labelled with patients name and ID number.

4.c See enclosure RO-32 (III) V.

4.d See enclosure RO-32 (III) V.

4.e See Enclosure RO-32 (III) CC.

4.f See Enclosure RO-32 (III) DD.

4.g Written, as well as verbal instructions will be provided to individuals assigned to complete the daily and monthly safety checks, if other than the physicist of record.

Daily Checks

5.a See enclosure RO-33 1.

5.b See enclosure RO-33 1.

5.c See enclosure RO-33 5.

5.d See enclosure RO-33 12 & 13.

5.e See enclosure RO-33 12 & 13.

5.g The results of the daily checks including the results and initials of individual performing checks will be maintained for at least three years.

Monthly Checks:

6.a Source position accuracy will be determined to within ± 1 mm of the programed position.

6.b Timer accuracy will be determined.\

6.c Source guide tubes will be measured prior to use to assure agreement ±1 mm.

6.d Per manufacturer recommendation, the battery test will be performed on a quarterly basis at the time of source replacement by the manufacturer's representative.

6e. The records of the monthly checks will be maintained for a minimum of three years and will include:
date of check; results of check; position of accuracy check programed and actual; the initials of individual performing the checks.

Calibration of Afterloading Device

7a. See enclosure ATT 10.15 dated Sep 30, 1996 (E.f).

7.b See enclosure ATT 10.15 dated Sep 30, 1996 (E.b; E.c).

7.c The calibration records will be maintained for at least three years and will contain the following:

the manufacturer's name, model number, and serial number for both the HDR and source;

the manufacturer's name and model numbers of the dosimetry system used for calibration;

the name of individual who performed the calibration;

the apparent activity of the HDR , the manufacturer's expected activity (corrected for decay), agreement should be within ± 5%.

7.d As the medical physicist will be doing the calibration, any measurement discrepancies will be known.

7.e The HDR unit will be calibrated on a quarterly basis after source replacement, prior to the first use of the new source for patient treatments.

7.f Source homogeneity will be confirmed via autoradiography.

7.g The dosimetry system that will be used to perform calibrations is made up of a Keithley electrometer or equivalent and a Standard Imaging Inc. HDR-1000 re-entrant chamber. The system will be calibrated by an accredited calibration at intervals not exceeding two years. The calibration records will be maintained.

7.h The source inventory will be performed on at least a quarterly basis, via autoradiography. The records will be maintained in accordance with 10 CFR 35.59(g).

Emergency Procedures

8.a See enclosure ATT 10.15 dated Sep. 30, 1996 F.

8.b After the patient is removed to a safe area in an emergent situation and the source has been placed in a shielded container, the room will be locked and posted NO ENTRY, and secured until source recovery is started by the manufacturer.

8.c Emergency source recovery equipment, including a shielded container, and remote handling tools, will be stored in the treatment room. At this time there are no procedures performed that would require the surgical removal of an applicator or the cutting of the source cable. If in the future the nature of our practice

changes, then the contents of the emergency recovery kit will be addressed.

8.d See enclosure RO-33a.

Maintenance

9. Maintenance and repair will be performed by the manufacturer at the manufacturer's recommended frequency and to the manufacturer's specifications. All records of service and inspections provided by the manufacturer will be maintained for the duration of the device's use.

If you have any further questions, please feel free to contact Berry L. Stewart, MS, RSO at 317-783-8171.

Sincerely,

Lois Slemp

Lois Slemp Vice
President
Prof. Services

Enclosures:

nucletron®
service corporation

NUCLETRON TRAINING SEMINAR

Institution: ST. Francis

City, State, Zip: Beach Grove, IN.

1. **Teaching Aids Used**

User's Manual	X
Applicators & Accessories	
Source Container & Dummy Sources	X
Other	

2. **Topics Covered**

Explanation of Remote Afterloading	X
Explanation of Radiation Protection	X

Applications		**Applicators & Accessories**		**Equipment Operation**	
Bronchus		Bronchus		Treatment Unit	X
Interstitial		GYN		Handling	X
Intracavitary		Esophagus		Power Requirements	X
Intraoperative		Interstitial		Console	X
		Other		Treatment	X
				Start	X
				Interrupt	X
				Emergency Stop	X
				Alarm & Error Codes	X

Radioactive Source: Ir 192
isotope

Receiving		**Shipping**		
Unpacking	X	Release	X	
Acceptance	X	Packing	X	
Calibration	X	Documents	X	
Installation	X	Measurements	X	Emergency Procedures X

All areas marked were covered during training

Instructor

Title

2-23-96
Date

Title

Date

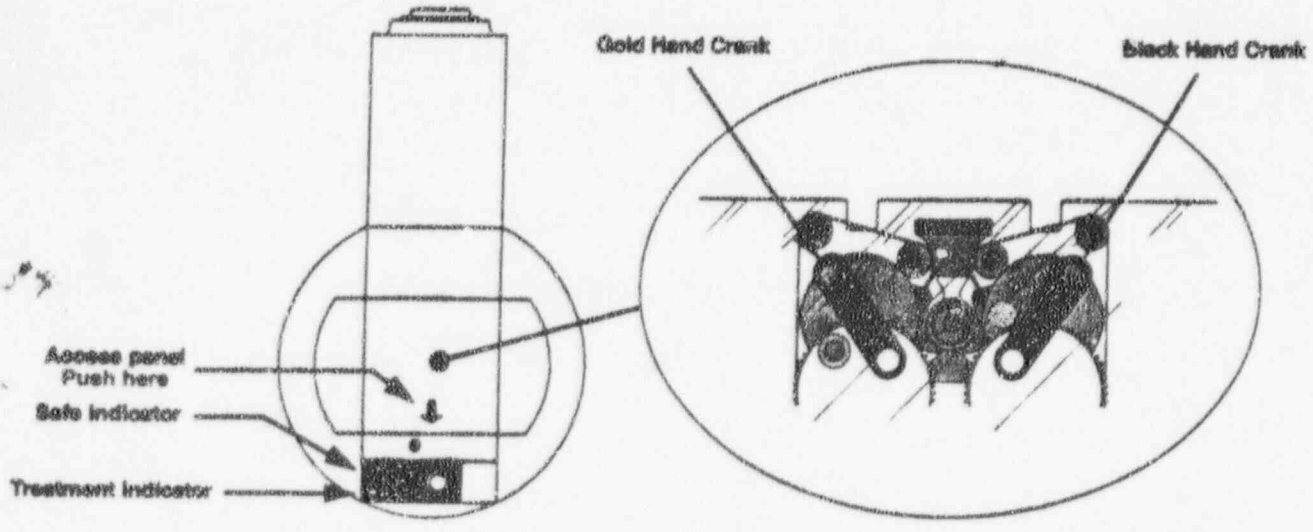
*List of all attendees accompanies this form

EMERGENCY PROCEDURES
FOR
microSelectron-HDR ^{192}Ir
IF THE SOURCE FAILS TO RETURN TO THE SAFE

1. Depress RED EMERGENCY STOP BUTTON on master emergency stop switch. If the source retracts, go to step 7, otherwise step 2.

2. Enter the treatment room.

   - PUSH down on the access panel on top of the treatment unit to access the GOLD hand crank. Turn it in the direction of the arrows until it blocks.
   - If the source retracts, go to step 7, otherwise step 3.



Access Panel Location **Gold Hand Crank Location**

3. Disconnect the applicator from the machine. Move the machine well away from the patient.

4. Check the patient for radiation. If detected, remove the applicator from the patient, ensuring that radiation is confined to the applicator.

5. IMMEDIATELY assist the patient from the room. A suitably qualified person must now ensure that the applicator is shielded.

6. Leave the room. Close the door. Mark it NO ENTRY.

7. Retain the treatment data printout and contact the following:

Physicist: B. Stewart Tel. 8171 Home 784-0121

Doctor: E. Sajac, MD Tel. 8171

Nucletron Representative: ..... Tel. 1-500-536-2249

The unintended radiation dose to which those present have been subjected should be estimated and recorded by a suitably qualified person.

ATT 10.15
Mar., 14, 1995

HIGH DOSE RATE REMOTE AFTERLOADER

A. Intended Use:

The MicroSelectron-HDR system is intended to be used for intraluminal, intracavitary, interstitial and intraoperative treatment of cancer.

B. Proposed Users:

The device will be used by the individuals on our current license listed to use Group 35.400 materials.

C. Training of Individuals:

On-site training will be provided by the Manufacturer, including training in programming, and operating the device as well as Emergency Procedures. (See training enclosure.)

The procedure for unloading or loading sources from transport container are part of the on-site training.

The source will be installed by a qualified representative of Nucletron.

The training and instructions will be provided by a qualified representative of Nucletron Corporation, and refresher training will be provided on an annual basis.

The unit will not be used unless there is an individual who has been trained in the use of the unit and the Emergency Procedures, on-site.

Individuals who use the unit will be inserviced annually on the use of the unit. Topics will include: programming, operation, and Emergency Procedures. Also "dry-runs" of emergency procedures will take place at time intervals not to exceed twelve (12) months.

D. Facilities:

a. The unit will be placed in the Cobalt-60 Therapy Room. The room formerly housed a Picker C9 Cobalt unit NRC License N 13-02128-02. Drawings enclosed attachment ATT 9.1.

b. There is a TV System for continuous viewing of the patient. If this system fails there is also a mirror system that enables constant viewing of the patient.

c. There is an interlock on the treatment room door which when opened will initiate a "Stop" sequence on the Selectron Computer. There is an Emergency Stop button mounted in the room as well as on the MicroSelectron-HDR itself.

The room is currently a restricted area and so indicated by signs.

There is a Monitor in the room to serve as an independent indicator of the presence of radiation indicating that the source is or is not in the "safe" condition.

Once the entry interlock is tripped it must be reset by key to activate the unit.

d. The maximum on time in any 8 hour period should not exceed 2 hours.

The maximum exposure rates in adjacent areas are:

Area	Exposure (mR/hr)
Corridor	0.238
Control Room	1.603
Film Storage	0.047
Accelerator Room	<0.001
Floor	Dirt Fill

E. Operating procedures:

a. Prior to use, appropriate staff will be provided with written operating procedures. These procedures will include: policies for securing unit, daily checks as required by NRC (*), assurance that only patient is in room when unit is in the on mode, and confirmation of treatment time calculation.

(*) NOTE: Daily checks will be done, only on the days the unit will be used to treat patients.

b. The dose or activity accuracy will be determined, in air with a calibrated dosimetry system, to within ± 5% after each source change.

c. The calibrated dosimetry system will meet the requirements of 10 CFR 35.630, and the primary chamber will be a re-entrant type chamber.

d. The timer accuracy and source travel time will be determined at the time dose accuracy is measured, if a re-entrant chamber is <u>not</u> used for calibration.

e. Constancy checks will be performed on at least a quarterly basis

f. The calibrations will be performed by a qualified physicist, our physicist is Berry L. Stewart, M.S., who is on our current license.

F. Emergency Procedures:

A Copy of the Emergency Procedures will be posted near the control console. They will be similar to the copy of the emergency procedures enclosed.

SAINT FRANCIS HOSPITAL CENTER
DEPARTMENT OF RADIOLOGY
POLICY AND PROCEDURE

NO. 721.

EFFECTIVE DATE: JUL-01-88
DIVISION: RAD. ONC.
REVISION DATE: SEP-01-96

IR-192 HDR APPLICATION

PURPOSE:

This document establishes the process by which the Radiation Oncology Department administers a high dose rate brachytherapy treatment

POLICY:

It is the policy of Radiation Oncology to ensure that all radiation treatments using the HDR Remote afterloader are given to the appropriate site, and normal tissues are not subjected to unnecessary radiation.

PROCEDURE:

A. Patients are referred to the Radiation Oncology Department for radiation therapy.

B. Prior to the initiation of this treatment the patient will have a consultation with the Radiation Oncologist. The procedure will be explained to the patient prior to treatment, and a consent form will be signed.

C. Using information provided by the referring physician, and the information obtained during the consultation with the patient, the Radiation Oncologist will determine the therapy desired based on established criteria.

D. The treatment procedure is a multiple stage process. The first stage involves the placement of the treatment catheter. This will be accomplished by the referring physician, who is credentialed to perform Bronchoscopies at SFHC, and Endoscopy personnel using a portable Bronchoscopy unit in the Simulator room, by a Radiologist in the Special Procedures room in X-Ray, or GYN Applicators will be placed by the Radiation Oncologist in the simulator rm or Surgery.

(I)

E. The patient will either report to Radiation Oncology, X-Ray or to Endoscopy prior to the scheduled treatment time to be premedicated. This is at the discretion of the Physician doing the Bronchoscopy Procedure or catheter placement.

F. If the patient reports to Endo first, the patient will be premedicated and brought to the Radiation Oncology Dept. by Endo for the Bronchoscopy Procedure.

G. The patient will be transferred and secured (strapped) to the simulator couch and the Bronchoscopy performed for Endobronchial Procedures.

H. During the Bronchoscopy Procedure the Physician will place the endbronchial applicator with the assistance of the Radiation Oncologist.

I. When the applicator (s) has been placed the physician removes the Bronchoscope over the applicator catheter.

J. At this time the Physician performing the Bronchoscopy is finished. If the patient is deemed by the endo personnel to be stable, the patient will be released to Radiation Oncology. If the patient is not deemed stable the Endo personnel will remain and monitor the patient for the duration and if need be, return the patient to the endoscopy department to be recovered after the completion of the treatment.

K. When the patient is released to Rad. Onc. the patient will be monitored by the Rad. Onc. Nurse.

(II)

L. After placement of the catheter, the catheter will be loaded with dummy seeds. The patient will be located on the planning jig and Anterior and Lateral films will be taken.

M. The Radiation Oncologist will identify the treatment volume on the films and prescribe a dose.

N. The Dosimetrist will then take the films and run a computerized treatment plan to determine the dwell times. Dose calculations will be checked by a second party, when possible, prior to the initiating treatment.

O. After films have been approved the patient can be removed from the simulator table and placed on a cart with the siderails up.

P. When the treatment plan is complete it will be reviewed by the physician and initialed to indicate his approval and it's agreement with the written directive .

(III)

Q. When the plan is approved the patient will be taken to the treatment room.

R. The connector will be placed on the applicator and the applicator connected to the HDR Unit.

S. The proper dwell positions and times will be then programed into the control unit.

T. BEFORE TREATMENT the programed positions and times will be checked and initialed by a second party.

U. The treatment will then be given. During the entire treatment, the patient will be monitored via TV and Intercom, and the Physician and medical physicist will be present.

V. Upon completion of the treatment, the patient, applicators and unit will be surveyed with a survey meter to assure the source has returned to the storage safe. The results of the survey will be recorded asnd maintained

W. After the survey, the applicator will be disconnected from the unit and the connector removed. The Nurse will then remove the catheter, clean it and send it to be sterilized or dispose as indicated.

X. The hardcopy of the treatment will be placed in the patients chart along with the computer plan.

Z. Then, depending upon the patients condition, the patient will either be released to go home or returned to Special Procedures recovery where he/she will continue to be monitored until released.

AA. Patients from X-Ray will be returned to the Specials Room for removal of catheter as determined by the Radiologist and handled as a regular special procedure patient.

BB. Administrative Policy 735.01 Anesthesia Monitoring of Patient Receiving local anesthesia and/or sedative type medication will be followed.

CC. No treatment procedure will be conducted for which a decoupled or jammed source cannot be removed expeditiously from the patient and securred. The ultimate decision on treatment remains with the authorized user.

DD. Nursing personnel will be provided specific (written) instructions as needed.

APPROVED BY : Radiation Oncology P&P/QA Committee -- 7/93

Edgardo Sayoc, M.D. Chairman Radiation Oncology	Joan Andrews, Director Oncolocy

Berry L. Stewart, M.S.
Medical Physicist

MICRO-SELECTRON HDR OPERATING PROCEDURES

On the day of an HDR application the following checks must be performed prior to any patient treatments.

1. Check; radiation monitor with dedicated check source, TV and intercom are operational. Record rad monitor check.

2. With the key, turn the unit on and program the unit for a 10 second time at dwell position #10.

3. Without connecting an applicator attempt to initiate treatment. An error (#42) should occur.

IF ERROR DOES NOT OCCUR, STOP!

Notify Physics Immediately.

4. Attach the Source Ruler to the indexer. Initiate treatment via the START button.

5. Observe that the source indication lights on the control console are illuminated and the in room monitor is illuminated when the source is in the treatment mode and the Safe light is illuminated when in the non-treatment mode.

6. Depress the INTERRUPT button observe that the source returns to the safe as indicated by the console lights and the in room monitor.

7. Enter the room and note the reading on the check ruler. It should indicate **980.5 ± 1.0.**

IF NOT NOTIFY PHYSICS IMMEDIATELY!

8. Return to the console, close the door and hit the START button, the treatment should resume.

9. Immediately open the door. The source should retract to the safe as will be indicated by the console lights and room monitor. The door interlock must be key reset.

IF NOT NOTIFY PHYSICS IMMEDIATELY!

10. When the unit has satisfactorily passed the above checks patients can then be treated according to the procedures in the operation manual supplied by Nucletron.

11. Take autoradiograph to assure source positioning.

12. Immediately prior to initiating patient treatment the tube shall be checked for kinks and imperfections.

13. All applicators will be checked for apparent kinks and imperfections **BEFORE** being sent for sterilization.

PROCEDURES TO FOLLOW FOR A STUCK OR DECOUPLED HDR SOURCE

If a source fails to return to the safe position upon completion of the treatment or after the interrupt button has been depressed then the following procedure should be performed.

EVERYONE NOTE THE TIME!

The RSO, Physicist or his designee will perform the following:

1. Depress the interrupt button to return source to housing. If source doesn't retract;

2. Depress Red Emergency Stop button located on master emergency stop switch. If source doesn't retract;

3. Depress Red Emergency Stop button on wall in treatment room. If source doesn't retract:

4. Depress Red Emergency Stop Button on the treatment unit. If source doesn't retract:

5. Gain access to the GOLD hand crank located in the top of the unit, by depressing top panel, and turn the GOLD crank in the direction indicated by the arrows. If the source doesn't retract:

6. The RSO/Physicist will secure the applicator at the face of the treatment unit. The Dosimetrist, RN, and Physician will remove the applicator from the patient by effectively pulling the patient off of the applicator. (All patients are treated on a gurney).

EVERYONE NOTE THE TIME!

7. The patient will be wheeled to an area around the corner from the treatment unit, (in the treatment room) to minimize exposure. The staff assisting the patient will stay in the shielded area and perform a radiation survey of the patient prior to removing to the hallway.

8. The RSO/Physicist will place the applicator containing the source in the shielded container using the forceps as necessary. The room will be secured, surveyed, posted and the manufacturer notified.

UNDER NO CIRCUMSTANCES SHOULD THE INTEGRITY OF THE APPLICATOR SYSTEM BE COMPROMISED!

(ie: **DO NOT CUT THE APPLICATOR**)

NO ONE WILL BE ALLOWED INTO THE TREATMENT ROOM UNTIL A MANUFACTURER'S REPRESENTATIVE ARRIVES!

9. The Physician will assess the patient's condition and either send the patient to special procedures recovery or dismiss.

10. The RSO will immediately collect all personnel monitors and send them to be read out on an emergency basis. The RSO will also get a total time estimate to perform a patient dose calculation as necessary.

11. Notify the appropriate agencies as necessary.

SEP 1 1 1996

Lois Slemp
V. P. Professional Services
St. Francis Hospital
and Health Centers
1600 Albany Street
Beech Grove, IN 46107

Dear Ms. Slemp:

We have reviewed your application dated March 14, 1995, requesting a renewal of NRC Material License No. 13-02128-03 and find that we will need additional information pertaining to the HDR unit as follows:

1. Training Program

   a. Please specify the method you will use to determine each trainee's competency to use the device for each type of proposed use.

   b. Confirm that your authorized user retraining will include "hands-on" training (using dummy sources) for your emergency procedures (i.e. "dry runs").

   c. Confirm that records of initial and refresher training provided for both device operators and ancillary personnel will be maintained for a period of three years. These records must include the instructor(s) name, the attenders names, the training date(s), and an outline of the topics discussed.

2. Facilities

   a. Describe the viewing and intercom backup system to be used if the primary systems fails. In lieu of a backup system, you may choose to commit to suspend further treatments until the primary system is repaired.

   b. Describe the required actions in the event of an interlock malfunction. This must include a confirmation that the device will be locked in the "off" position and not used, except as may be necessary for interlock system repair or replacement, until proper interlock system function is restored;

   c. Describe the method to ensure that the console keys are inaccessible to unauthorized persons.

   d. Describe your emergency entry provisions.

e. Confirm that the radiation monitor is checked with a dedicated check source for proper operation each day before the device is used;

f. Confirm that the operability check is documented and that these documents are maintained for a period of three years;

g. Confirm that the radiation monitor will be promptly repaired or replaced if found to be either inoperable or evidencing intermittent problems.

h. Confirm that the radiation monitor provides visible notice of the presence of radiation that is observable by an individual entering the room;

i. Confirm that the radiation monitor is equipped with a back-up power supply that is separate from the power supply to the afterloading device;

3. Compliance With Restricted/Unrestricted Area Radiation Level Limits

a. Describe the survey program that will be implemented to demonstrate compliance with 10 CFR 20.1501; including a requirement to conduct surveys following source replacement. These surveys must demonstrate:

(1) The maximum radiation levels at 10 centimeters from the nearest accessible surface of the source safe with the source in the shielded position;

(2) That radiation levels in restricted areas accessible to radiation workers are not likely to cause personnel exposure in excess of the limits specified in 10 CFR 20.1201; and

(3) That radiation levels in unrestricted area will not result in a dose to any member of the public in excess of the limits specified in 10 CFR 20.1301.

Please confirm that records of these surveys will be maintained for the duration of the license.

b. Confirm that a conspicuous, durable label stating "Caution Radioactive Materials," will be affixed to at least one outer surface of the remote afterloading device as specified in 10 CFR 20.1904.

4. Operating Procedures

Provide a copy of your operating procedures. These procedures must require the following:

a. The treatment room to be secured when unattended;

b. Treatment planning computer removable media will be labelled with the corresponding patient's name and identification number;

c. A survey of the device will be performed immediately after each use of the device; including the connectors and applicator apparatus, the full catheter guide tube length, and the device external surface;

d. A record of the device and patient survey maintained;

e. No treatment procedure will be conducted for which a decoupled or jammed source cannot be removed expeditiously from the patient and placed in shielded container; and

f. Nursing personnel provided specific (written) instructions for patient care.

g. Confirm that written, as well as verbal instructions will be provided to individuals assigned to complete the daily and monthly safety checks.

5. Daily Checks

Confirm that the following **daily** safety checks of your remote afterloader device will be performed and describe the method used to perform these checks:

a. The permanent radiation monitor check with a dedicated check source for proper operation;

b. TV monitor and intercom system check to verify proper operation;

c. Console operational function check, indicator lamp test, other status and operational displays;

d. Applicator and connector mechanical integrity check;

e. Applicators, source guide tubes, and connectors visually inspected for mechanical integrity;

f. Commitment to provide verbal as well as written instruction to individuals providing daily safety checks; and

g. Confirm that records of your daily safety checks of your remote afterloader device will be maintained for three years and will include the following information:

(1) The date of the check;

(2) The results; and

(3) The initials of the individual who performed the check.

6. Monthly Checks

Confirm that the following **monthly** safety checks of your remote afterloader device will be performed in accordance with the manufacturer's instructions at intervals not to exceed 30 days:

a. Source position accuracy within the catheter guide tube to within ± 1 millimeter of the programmed position;

b. Timer accuracy and linearity;

c. Measurement of source guide tubes to confirm length to 1 mm accuracy;

d. Backup battery test to verify emergency source retraction capability upon power failure (i.e., a function test with the AC power disconnected); and

e. Confirm that records monthly safety checks of your remote afterloader device will be maintained for three years and will include the following information:

(1) The date of the checks;

(2) The results of the checks;

(3) For the source position accuracy check, the programmed position and actual position of the source following activation of the device; and

(4) The initials of the individual who performed the check.

7. Calibration of Afterloading Device

a. Submit the name(s) and qualifications of the individual(s) who will perform the device calibrations. Specify the individuals experience with the dosimetry system which will be used to perform calibration measurements.

b. Provide a description of the method used to determine the exposure rate under specific criteria (i.e., distances used for the measurement, whether the measurement is an "in-air" measurement or done using a phantom, configuration of the chamber with respect to the source guide tube and device, scatter factors used to compute the exposure rate, etc.).

c. Specify your calibration recordkeeping requirements, including a commitment to maintain a record of calibration measurements and associated calculations for a period of three years. The records must include:

(1) The calibration date;

(2) The manufacturer's name, model number and serial number for both the HDR and the source;

(3) The manufacturer's name, model number and serial number of the instrument used to measure the HDR device output;

(4) The name of the individual who performed the measurement; and

(5) The HDR output expressed in R/hr; and the manufacturer's "expected" output value (decay corrected); These values should be within ±5%.

d. Confirm that the radiation safety officer or medical physicist will be consulted prior to performing further patient treatments if the measured output differs by greater than ±5% from the manufacturer's "expected" decay corrected output.

e. Specify the calibration frequency. Calibration is required following a new source(s) installation prior to patient treatment, and recommended monthly thereafter.

f. Describe your method for confirming source homogeneity. This may be done by autoradiography, following source replacement but prior to patient treatment.

g. Provide a description of the dosimetry system which will be used to perform calibration measurements. Confirm that the dosimetry system will be calibrated by a laboratory accredited by NIST or AAPM within the previous two years and after any servicing that may have affected the dosimetry system. Confirm that dosimetry system calibration records will be maintained for inspection.

h. Describe your method for conducting source inventories. Specify that physical source inventories will be performed quarterly (10 CFR 35.59) and records maintained in accordance with 10 CFR 35.59(g).

8. Emergency Procedures

a. Confirm that emergency procedures are provided to device operators, authorized user(s), and other personnel as necessary.

b. Specify requirements for restricting and posting the treatment area to minimize the risk of inadvertent exposure to personnel not directly involved in the emergency source recovery.

c. Identify where you will store emergency source recovery equipment and specify what equipment may be necessary for the various equipment failures described in the procedures. At a minimum, emergency equipment should include shielded storage containers, remote handling tools, and if appropriate, supplies necessary to surgically remove applicators or sources from the patient, including scissors and cable cutters.

d. Specify step-by-step instructions/actions for single and/or multiple equipment failures and the individual(s) responsible for implementing the actions. Clearly specify which steps are to be taken under different scenarios (i.e., source decoupling versus a jammed source). The actions specified for emergency source removal should give primary consideration to minimizing exposure to the patient and healthcare personnel while maximizing patient safety.

9. Maintenance

a. Confirm that all maintenance and repair of the device will be performed by the manufacturer or by individuals specifically authorized by the NRC or an Agreement State. If maintenance and repair will be performed by someone other than the manufacturer, specify the individual and provide a copy of the NRC or Agreement State license authorizing this individual for maintenance and repair activities.

Note: Maintenance and repair means installation, replacement, relocation or removal of the sealed source or an afterloading device that contains a sealed source; or any adjustment involving any mechanism on the afterloading device, treatment console, or interlocks that could expose the source, reduce the shielding around the source or affect the source drive controls.

b. Confirm that HDR inspection and service records will be maintained for the duration of device use. These records must include: the inspection/service date; the name of the individual who performed the inspection/service; the NRC or Agreement State license number authorizing the individual to perform

the inspection/service; a description of the inspection/service performed, including a list of the components inspected and a list of components serviced or replaced; and the signature of the inspector.

c. Confirm the following inspection and service criteria for the HDR device:

(1) The HDR device will be fully inspected and serviced at intervals not to exceed 12 months, to ensure proper functioning of the source exposure mechanism;

(2) All scheduled service recommended by the manufacturer will be performed in accordance with the manufacturer's instructions;

(3) Inspection and service will only be performed by the manufacturer or other persons specifically licensed to do so by the NRC or an Agreement State; and

(4) Records of these inspections will be maintained.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 398362.

If you have any questions or require clarification on any of the information stated herein, you may contact us at (630) 829-9887.

Sincerely,

Original Signed By
Gidget Watson
Nuclear Materials Licensing Branch

License No. 13-02128-03
Docket No. 030-09398

Enclosure:
P&G Dir. FC 86-4, Rev.1

DOCUMENT NAME: M:\03009398.DF6
To receive a copy of this document, indicate in the box: "**C**" = Copy without attachment/enclosure "**E**" = Copy with attachment/enclosure "**N**" = No copy

OFFICE	DNMS/RIII									
NAME	GWatson:brt									
DATE	09/ 11 /96 GW									

OFFICIAL RECORD COPY

CONVERSATION RECORD

TIME | DATE 9/10/96

O VISIT O CONFERENCE X TELEPHONE

X INCOMING
O OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT: Berry Stewart, RSO
317/865-5171

ORGANIZATION (OFFICE, DEPT.ETC.): St. Francis Hospital & Health Centers

TELEPHONE NO.:

SUBJECT
License No. 13-02128-03

SUMMARY
I requested the following information in regards to renewal application dated March 14, 1995:

1. To specify a possession limit for I-131 as used in 10 CFR 35.300 material.

Mr. Stewart stated that **1 curie** would be sufficient.

2. I also informed Mr. Stewart that I would be sending a deficiency ltr. regarding the HDR unit.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION: Victor L Wilson | SIGNATURE | DATE: 9/10/96

ACTION TAKEN

SIGNATURE | TITLE | DATE

April 4, 1995

St. Francis Hospital Center
ATTN: Berry L. Stewart, M.S.
Radiation Safety Officer
1600 Albany Street
Beech Grove, IN 46107

SUBJECT: LICENSE RENEWAL APPLICATION

Dear Mr. Stewart:

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
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