NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

APPLICATION FOR MATERIAL LICENSE

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 8-31-87

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.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

RECEIVED OCT 3 1988 NRC

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 JURISDICTION.

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

- [ ] A. NEW LICENSE
- [X] B. AMENDMENT TO LICENSE NUMBER 40-12378-01
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Sioux Valley Hospital
19th and Euclid Ave
Sioux Falls, South Dakota 57105

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

Same as 2

RECEIVED OCT -7 1988

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Corrine Kuhse, Supervisor, Nuclear Medicine

TELEPHONE NUMBER: (605)333-1000

SUBMIT ITEMS 5 THROUGH 11 ON 8½ 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 AND EXPERIENCE.

Refer to attached Item #7.1

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 $ 120.00

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, 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.

SIGNATURE—CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
x Richard L Bohy	x Richard L. Bohy	x Vice President Professional Services	x 9-1-88

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

- [ ] <$250K
- [ ] $250K–$500K
- [ ] $500K–$750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(Dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)*

- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
Amd	Oct-2-88	7C	8910240055 881116 REG4 LIC30 40-12378-01 PDR	
AMOUNT RECEIVED	CHECK NUMBER			DATE
$120	72752		46194	10/4/88

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.

5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

NAME OF AUTHORIZED USER	AUTHORIZATION
Kristen R. Erickson, M. D.	35.400

Please refer to attached Supplements A&B for Dr. Erickson's training & experience.

Item #7.1
1 of 1 page
Prepared: 8/25/88
Lic. #40-12378-01

EXHIBIT 2

SUPPLEMENT A

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
Kirsten R. Erickson, M.D.	South Dakota, New Mexico

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Therapeutic Radiology	Board Eligible Written Boards Oct.'88

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	University of New Mexico Cancer Center (7/85-6/88) Albuquerque, New Mexico	60	24
b. RADIATION PROTECTION	University of New Mexico Cancer Center (7/85-6/88) Albuquerque, New Mexico	60	30
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	University of New Mexico Cancer Center (7/85-6/88) Albuquerque, New Mexico	60	18
d. RADIATION BIOLOGY	University of New Mexico Cancer Center (7/85-6/88) Albuquerque, New Mexico	175	
e. RADIOPHARMACEUTICAL CHEMISTRY		N/A	N/A

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
Co-60	9000 Ci	UNM Cancer Ctr., Albq,NM	200 hrs.	Radiation Therapy (external beam)
Cs-137	57 mCi	UNM Cancer Ctr., Albq,NM	168 hrs.	Radiation Therapy
Ir-192	45 mCi	UNM Cancer Ctr., Albq,NM	234 hrs.	Radiation Therapy
Sr-90	37 mCi	UNM Cancer Ctr., Albq,NM	6 hrs.	Radiation Therapy
Au-198	30 mCi	UNM Cancer Ctr., Albq,NM	50 hrs.	Radiation Therapy

EXHIBIT 3

SUPPLEMENT B

SUPPLEMENT — **U. S. NUCLEAR REGULATORY COMMISSION**

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME
Kirsten R. Erickson, M.D.

STREET ADDRESS
Medical X-Ray Center
1417 S. Minnesota

CITY | STATE | ZIP CODE
Sioux Falls, South Dakota 57105

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
	Thyroid scan	N/A	N/A
	Thyroid uptake	N/A	
	Lung perfusion scan	N/A	
	Xenon ventilation study	N/A	
	Aerosol ventilation scan	N/A	
	Renal flow scan	N/A	
	Brain scan	N/A	
	Liver/spleen scan	N/A	
	Bone scan	N/A	
	Gastroesopnageal study	N/A	
	LeVeen shunt study	N/A	
	Cystogram	N/A	
	Dacryocystogram	N/A	
	Cardiac perfusion scan.	N/A	
	Cardiac stress ventriculogram	N/A	
	Cardiac rest ventriculogram	N/A	
	Gallium scan	N/A	

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER
Kirsten R. Erickson, M.D.

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheet.) D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	-	
P-32 (Colloidal)	INTRACAVITARY TREATMENT	-	
I-131	TREATMENT OF THYROID CARCINOMA	-	
	TREATMENT OF HYPERTHYROIDISM	-	
Au-198	INTRACAVITARY TREATMENT	-	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	-	
	INTRACAVITARY TREATMENT	28	
I-125 or Ir-192	INTERSTITIAL TREATMENT	39	
Co-60 or Cs-137	TELETHERAPY TREATMENT	120	
Sr-90	TREATMENT OF EYE DISEASE	3	
	RADIOPHARMACEUTICAL PREPARATION	-	
Mo-99/ Tc-99m	GENERATOR	-	
Sn-113/ In-113m	GENERATOR	-	
Tc-99m	REAGENT KITS	-	
Other Au-198	Interstitial Treatment	10	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE
University of New Mexico Cancer Center Radiation Oncology Dept. 900 Camino de Salud, N.E. Albuquerque, New Mexico 87131	7/85-6/86	658 hrs.

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Kutub Khan, M.D.

b. NAME OF INSTITUTION
Univ. of New Mexico Cancer Center

c. MAILING ADDRESS
900 Camino de Salud, N.E.

d. CITY
Albuquerque, NM 87131

5. MATERIALS LICENSE NUMBER(S)
NM UNM BM-33

6. PRECEPTOR'S SIGNATURE
X Khan

7. PRECEPTOR'S NAME (Please type or print)
Kutub Khan, M.D.

8. DATE
X 8-2-88

NRC FORM 312
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 5-31-87

APPLICATION FOR MATERIAL LICENSE

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.

RECEIVED JUL 8 1988

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

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 JURISDICTION.

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

- [ ] A. NEW LICENSE
- [X] B. AMENDMENT TO LICENSE NUMBER 40-12378-01
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Sioux Valley Hospital
19th & Euclid Ave
Sioux Falls, South Dakota 57105

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

Same as 2.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION | **TELEPHONE NUMBER**

Corrine Kuhse, Supervisor, Nuclear Medicine | (605) 333-1000

SUBMIT ITEMS 5 THROUGH 11 ON 8½ 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 AND EXPERIENCE.
Refer to attached Item #7.1

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 $ 120.00

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, 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.

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
x Richard L Bohy	x Richard L. Bohy	x Vice President/Prof. Services	6-29-88

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10M

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(Dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial–proprietary–information furnished to the agency in confidence)*
- [ ] YES
- [ ] NO

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
				462045
AMOUNT RECEIVED	CHECK NUMBER			DATE 462052

ITEM #5-6

Please amend license authorized possession limit for In vitro materials to reflect General license quantities & use as specified in 10 CFR 31.11 (Total In vitro possession limit not to exceed 200 uCi).

Item #5-6
1 of 1 page
Prepared: 6/27/88
Lic. #40-12378-01

NAME OF AUTHORIZED USER	AUTHORIZATION
Michael A. Burke, M. D.	35.400
David Patrick Dolan, M. D.	Cs-137 & Co-60, as a sealed source in needles and applicator cells for topical, interstitial, and intracavity treatment of cancer and; Ir-192 as seeds encased in nylon ribbon for interstitial treatment of cancer.
Kirsten R. Erickson, M. D.	35.400

For physicians training and experience, please refer to attached Supplements A & B for each individual.

Item 7.1
1 of 1 page
Prepared: 6/27/88
Lic. #40-12378-01

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
Michael A. Burke, M.D.	South Dakota / Kansas

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Radiation Oncology (Radiation Therapy)	Pending

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	University of Kansas Medical Center Kansas City Kansas July 1, 1985 → June 30 1988	160	50
b. RADIATION PROTECTION	Univ. Kansas Med Center Kansas City Kansas July 1 1985 → June 30 1988	60	50
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Univ. Kansas Med. Center Kansas City, Kansas July 1, 1985 → June 30 1988	40	40
d. RADIATION BIOLOGY	Univ. Kansas Med Center Kansas City Kansas July 1, 1985 → June 30 1988	130	50
e. RADIOPHARMACEUTICAL CHEMISTRY	N/A		

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
Cs-137	200 mCi	Univ. Kansas Med Center	180 hrs	Intracavitary
Ir-192	72 mCi	Univ. Kansas Med Center	360 hrs	Interstitial
I-125	30 mCi	University of Kansas "	50 hrs	Interstitial
P-32	15 mCi	University of Kansas "	30 hrs	Intracavitary
Sr-90	30 mCi	Univ. of Kansas "	10 hrs	Applicator
Co-60	11,000 Ci	Univ. of Kansas "	700 hrs	Teletherapy

EXHIBIT 3

SUPPLEMENT B

SUPPLEMENT — U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME: Michael Anthony Burke, MD

STREET ADDRESS: Med. X-Ray Center
1417 South Minnesota Ave

CITY: Sioux Falls | STATE: S. Dak | ZIP CODE: 57105

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
	Thyroid scan	N/A	
	Thyroid uptake	N/A	
	Lung perfusion scan	N/A	
	Xenon ventilation study	N/A	
	Aerosol ventilation scan	N/A	
	Renal flow scan	N/A	
	Brain scan	N/A	
	Liver/spleen scan	N/A	
	Bone scan	N/A	
	Gastruesophageal study	N/A	
	LeVeen shunt study	N/A	
	Cystogram	N/A	
	Dacryocystogram	N/A	
	Cardiac perfusion scan.	N/A	
	Cardiac stress ventriculogram	N/A	
	Cardiac rest ventriculogram	N/A	
	Gallium scan	N/A	

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER
MICHAEL A. BURKE M.D.

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	N/A	
P-32 (Colloidal)	INTRACAVITARY TREATMENT	3	
I-131	TREATMENT OF THYROID CARCINOMA	N/A	
	TREATMENT OF HYPERTHYROIDISM	N/A	
Au-198	INTRACAVITARY TREATMENT	N/A	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	N/A	
	INTRACAVITARY TREATMENT	20	
I-125 or Ir-192	INTERSTITIAL TREATMENT	48	
(Co-60) or Cs-137	TELETHERAPY TREATMENT	200	
Sr-90	TREATMENT OF EYE DISEASE	2	
	RADIOPHARMACEUTICAL PREPARATION	N/A	
Mo-99/ Tc-99m	GENERATOR	N/A	
Sn-113/ In-113m	GENERATOR	N/A	
Tc-99m	REAGENT KITS	N/A	
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE
UNIVERSITY OF KANSAS MED CENTER	July 85 → June 88	310

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Richard G. Evans, Ph.D., M.D.

b. NAME OF INSTITUTION
University of Kansas Medical Center

c. MAILING ADDRESS
39th & Rainbow

d. CITY
Kansas City, KS 66103

5. MATERIALS LICENSE NUMBER(S)

6. PRECEPTOR'S SIGNATURE
Richard G. Evans

7. PRECEPTOR'S NAME (Please type or print)
Richard G. Evans, Ph.D., M.D.

8. DATE
June 7 88

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
David Patrick Dolan, M.D.	South Dakota Kansas

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Therapeutic	Eligible 10/88

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	University of Kansas Medical Ctr.	180 hrs	40 hrs
b. RADIATION PROTECTION	Univ. of Kansas Med. Ctr.	20 hrs	10 hrs.
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Univ. of Kansas Med. Ctr.	10 hrs.	10 hrs.
d. RADIATION BIOLOGY	Univ of Kansas Med Ctr.	120 hrs	N.A.
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
Cs-137	212 mCi	Univ. of Kansas,	121 hr.	Intracavitary
Ir-192	90 mCi	Univ. of Kansas	387 hrs.	Brachytherapy
P-32	15 mCi	Univ of Kansas	3½ hr.	Intracavitary
Co^{60}	10,000 x 10^3 mCi	Univ of Kansas	700 hrs	Teletherapy

EXHIBIT 3

SUPPLEMENT B

SUPPLEMENT — U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME: David Patrick Dolan, M.D.

STREET ADDRESS: 2640 Regency Ct.

CITY: Sioux Falls | STATE: S.D. | ZIP CODE: 57106

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
	Thyroid scan	—	Not Applicable
	Thyroid uptake	—	
	Lung perfusion scan	—	
	Xenon ventilation study	—	
	Aerosol ventilation scan	—	
	Renal flow scan	—	
	Brain scan	—	
	Liver/spleen scan	—	
	Bone scan	—	
	Gastroesophageal study	—	
	LeVeen shunt study	—	
	Cystogram	—	
	Dacryocystogram	—	
	Cardiac perfusion scan.	—	
	Cardiac stress ventriculogram	—	
	Cardiac rest ventriculogram	—	
	Gallium scan	—	

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER
David P. Dolan, M.D.

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)* D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT	2	
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		
Co-60	INTERSTITIAL TREATMENT		
or Cs-137	INTRACAVITARY TREATMENT	10	
I-125 or I-192	INTERSTITIAL TREATMENT	35	
Co-60 or Cs-137	TELETHERAPY TREATMENT	150	
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE
University of Kansas Medical Center	7/1/85 thru 6/30/88	240 hrs.

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR: Richard G. Evans, PhD., M.D.

b. NAME OF INSTITUTION: Univ. of Kansas Med Ctr.

c. MAILING ADDRESS: 39th & Rainbow Blvd.

d. CITY: Kansas City, Ks 66103

5. MATERIALS LICENSE NUMBER(S):

6. PRECEPTOR'S SIGNATURE

7. PRECEPTOR'S NAME *(Please type or print)*

8. DATE: 26 May 88

EXHIBIT 2

SUPPLEMENT A

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
Kirsten R. Erickson, M.D.	South Dakota, New Mexico

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Therapeutic Radiology	Board Eligible Written Boards Oct.'88

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATES OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	University of New Mexico Cancer Center (7/85-6/88) Albuquerque, New Mexico	60	24
b. RADIATION PROTECTION	University of New Mexico Cancer Center (7/85-6/88) Albuquerque, New Mexico	60	30
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	University of New Mexico Cancer Center (7/85-6/88) Albuquerque, New Mexico	60	18
d. RADIATION BIOLOGY	University of New Mexico Cancer Center (7/85-6/88) Albuquerque, New Mexico	175	
e. RADIOPHARMACEUTICAL CHEMISTRY		N/A	N/A

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
Co-60	9000 Ci	UNM Cancer Ctr., Albq,NM	60 hrs.	Radiation Therapy (external beam)
Cs-137	57 mCi	UNM Cancer Ctr., Albq,NM	42 hrs.	Radiation Therapy
Ir-192	45 mCi	UNM Cancer Ctr., Albq,NM	60 hrs.	Radiation Therapy
Sr-90	37 mCi	UNM Cancer Ctr., Albq,NM	2 hrs.	Radiation Therapy
Au-198	30 mCi	UNM Cancer Ctr., Albq,NM	15 hrs.	Radiation Therapy

EXHIBIT 3

SUPPLEMENT B

SUPPLEMENT — U. S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS

FULL NAME
Kirsten R. Erickson, M.D.

STREET ADDRESS
Medical X-Ray Center
1417 S. Minnesota

CITY | STATE | ZIP CODE
Sioux Falls, South Dakota 57105

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
	Thyroid scan	N/A	N/A
	Thyroid uptake	N/A	
	Lung perfusion scan	N/A	
	Xenon ventilation study	N/A	
	Aerosol ventilation scan	N/A	
	Renal flow scan	N/A	
	Brain scan	N/A	
	Liver/spleen scan	N/A	
	Bone scan	N/A	
	Gastroesophageal study	N/A	
	LeVeen shunt study	N/A	
	Cystogram	N/A	
	Dacryocystogram	N/A	
	Cardiac perfusion scan.	N/A	
	Cardiac stress ventriculogram	N/A	
	Cardiac rest ventriculogram	N/A	
	Gallium scan	N/A	

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER
Kirsten R. Erickson, M.D.

PRECEPTOR STATEMENT *(Continued)*

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN *(Continued)*

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES	-	
P-32 (Colloidal)	INTRACAVITARY TREATMENT	-	
I-131	TREATMENT OF THYROID CARCINOMA	-	
	TREATMENT OF HYPERTHYROIDISM	-	
Au-198	INTRACAVITARY TREATMENT	-	
Co-60 or Cs-137	INTERSTITIAL TREATMENT	-	
	INTRACAVITARY TREATMENT	28	
I-125 or Ir-192	INTERSTITIAL TREATMENT	39	
Co-60 or Cs-137	TELETHERAPY TREATMENT	120	
Sr-90	TREATMENT OF EYE DISEASE	3	
	RADIOPHARMACEUTICAL PREPARATION	-	
Mo-99/ Tc-99m	GENERATOR	-	
Sn-113/ In-113m	GENERATOR	-	
Tc-99m	REAGENT KITS	-	
Other Au-198	Interstitial Treatment	10	

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

LOCATION	DATES	CLOCK HOURS OF EXPERIENCE
University of New Mexico Cancer Center Radiation Oncology Dept. 900 Camino de Salud, N.E. Albuquerque, New Mexico 87131	7/85-6/88	179 hrs.

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR
Kutub Khan, M.D.

b. NAME OF INSTITUTION
Univ. of New Mexico Cancer Center

c. MAILING ADDRESS
900 Camino de Salud, N.E.

d. CITY
Albuquerque, NM 87131

e. MATERIALS LICENSE NUMBER(S)
NM UNM BM-33

5. PRECEPTOR'S SIGNATURE

7. PRECEPTOR'S NAME (Please type or print)
Kutub Khan, M.D.

8. DATE
6/2/88

462049
462052

SIOUX VALLEY HOSPITAL

P.O. Box 5039
1100 South Euclid Avenue
Sioux Falls, South Dakota 57117-5039
(605) 333-1000

June 24, 1988

Jack Whitten, Health Physicist
U. S. Nuclear Regulatory Commission
Regional Licensing Section
Region IV
611 Ryan Plaza Dr., Suite 1000
Arlington, Texas 76012

Re: Control Number 461918

Dear Mr. Whitten:

This letter is in response to your correspondence dated April 26, 1988 pertaining to issuance of Amendment #34 for Sioux Valley Hospital and a request for information pertaining to a decontamination survey report for a cardiac imaging room.

Enclosed please find a facility diagram which includes the decommissioned cardiac imaging room. A wipe test was conducted of all areas surveyed with a G-M meter. This wipe test was evaluated in a well detector. Results obtained were essentially background.

I trust that the enclosed information satisfies all of the constraints in order to amend the Byproduct Materials License eliminating the cardiac imaging room as an authorized location of use.

If you should have further questions or comments regarding this response, please do not hesitate to contact me.

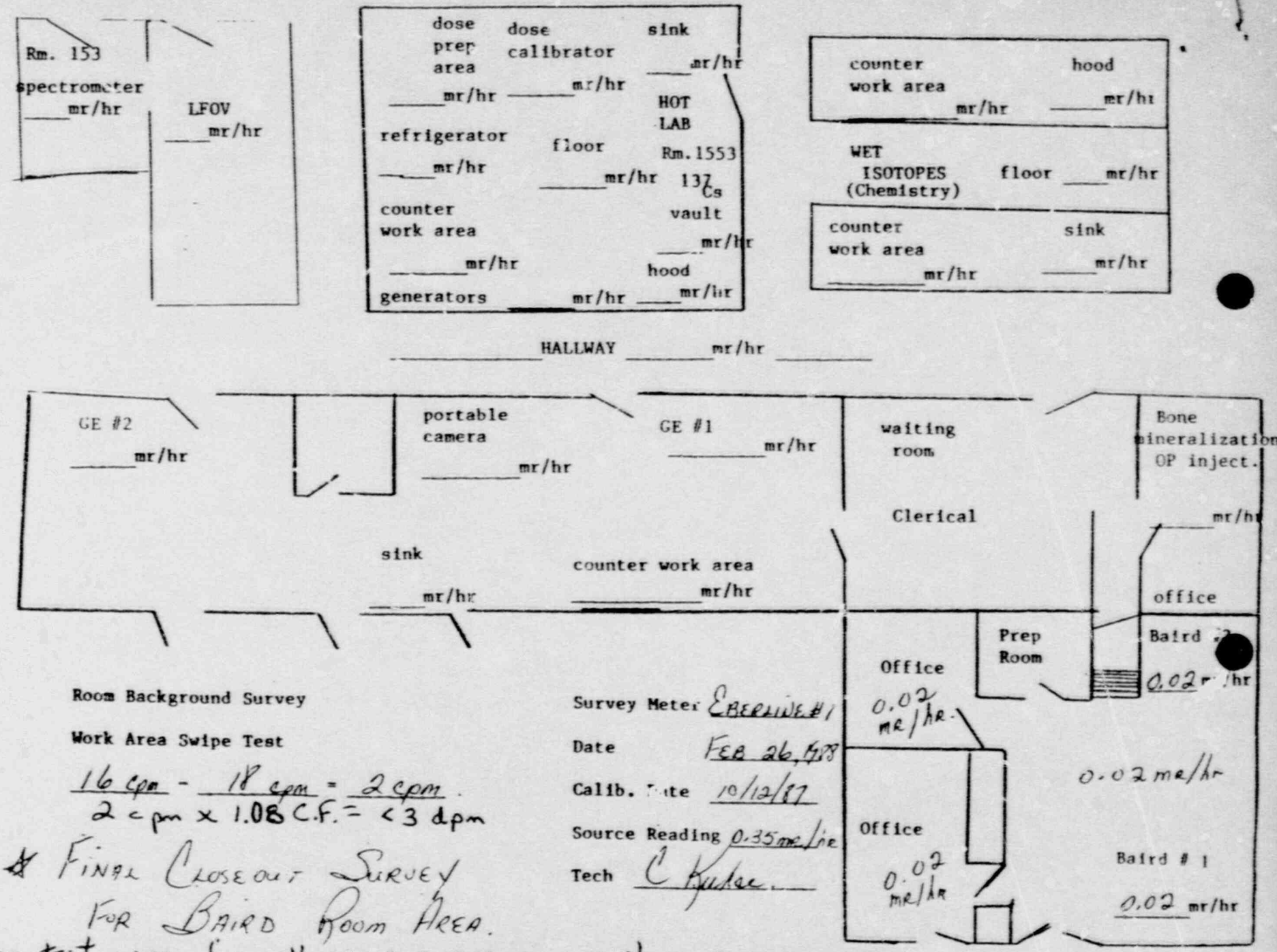
Sincerely,

Richard L Bohy

Dick Bohy, Vice President Professional Services
Sioux Valley Hospital

DB/mg

462049



Room Background Survey

Work Area Swipe Test

16 cpm - 18 cpm = 2 cpm.
2 cpm x 1.08 C.F. = < 3 dpm

Survey Meter EBERLINE #1

Date FEB 26, 1988

Calib. Date 10/12/87

Source Reading 0.35 mr/hr

Tech C Kuster

* FINAL CLOSEOUT SURVEY FOR BAIRD ROOM AREA.

1 WIPE TEST USED FOR ALL AREAS SURVEYED WITH A G-M METER

6202A

NRC FORM 313
(7-87)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 6-30-90

APPLICATION FOR MATERIAL LICENSE

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.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCLEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

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 JURISDICTION.

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

- [ ] A. NEW LICENSE
- [X] B. AMENDMENT TO LICENSE NUMBER 40-12378-01
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Sioux Valley Hospital
Department of Pathology
19th & Euclid Ave.
Sioux Falls, S.D. 57105

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

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Chris Wagner, Consultant, NMA Medical Physics Services

TELEPHONE NUMBER: (415) 626-8536

SUBMIT ITEMS 5 THROUGH 11 ON 8½ 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 AND 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: $ 120.00

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, 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.

SIGNATURE—CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
X Richard L Bohy	X Richard L. Bohy	X Vice Pres. Prof Services	X 3/28/88

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER			DATE

46 1918

NRC FORM 313M SUPPLEMENT A (9-81) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Bert Warner Larson, M.D.	South Dakota

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Nuclear Medicine	Nuclear Medicine	12/87

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

NAME OF AUTHORIZED USER	AUTHORIZATION
Amend to Add:	
Bert Warner Larson, M.D.	35.100, 35.200, 35.300, and 35.500; and for in vitro studies

For Dr. Larson's training and experience, please refer to attached Supplement A and letter from American Board of Nuclear Medicine.

Amend to Delete:

Shanteri Nayak, M.D.

Item #8
1 of 1 page
Prepared: 3/14/88
Lic. # 40-12378-01

The American Board of Nuclear Medicine

900 Veteran Avenue · Los Angeles, California 90024-1786 Telephone (213) 825-6787

December 10, 1987

BERT WARNER LARSON, M.D.
MINNEAPOLIS VA MEDICAL CENTER
NUCLEAR MEDICINE 115
54TH STREET & 48TH AVE. SOUTH
MINNEAPOLIS, MN 55417

Dear Doctor:

With great pleasure, the American Board of Nuclear Medicine informs you that you have passed its September 12, 1987 Certifying Examination in the broad field of nuclear medicine and are now recognized as a certified specialist in nuclear medicine. A certificate indicating this recognition will be sent to you in the near future. The American Board of Nuclear Medicine congratulates you upon your achievement and this recognition!

The scores below indicate your performance in the several content areas of the examination. Please consult the enclosed interpretive note for further explanation. The Board hopes this information will be helpful.

Content Area	Percent You Answered Correctly	Comparison Group Mean % Correct
Bas. Sci.- Rad. Hlth-NMR	69	62
Cardiovascular	68	66
Endocrine	79	63
Gastrointestinal	78	69
Hematology/Oncology	87	69
Neurology	73	73
Pulmonary	74	70
Renal	78	67
Musculo-skeletal	50	67

Sincerely yours,

I. Ross McDougall

I. Ross McDougall, M.B., Ch.B., Ph.D.
Chairman

02601

FACILITIES DIAGRAM & INFORMATION

The cardiac imaging room noted on previous application dated 3/28/85 is being terminated from the license as a restricted area of use. A close-out survey has been performed. Results of this close-out survey are available on file for reference in the event of inspection. The close-out survey information contained the following:

a. Date of survey
b. Instrument used
c. Background reading
d. Keyed diagram showing locations
e. Readings in mR/hr at different locations
f. Results of wipe tests of same locations
g. Person performing the survey

Additionally, it is requested three new imaging rooms be added to the license as authorized areas of use. Xenon-133 studies will not be performed in these new rooms. Please refer to attached Item #11 for specifics.

Facilities and Equipment

Diagram

Air Supply

Air Exhaust

Sink

Lead Castle

Lead Shielding

___ Scanner

1 Uptake/Well

2 Camera

3 Lockable Door

___ Receipt Area

___ Generator

___ Kit Preparation

___ Isotope Storage

___ Dose Preparation

___ Waste Storage

___ Dose Calibrator

___ Refrigerator

4 Bone Mineral Analyzer

Adjacent Areas

5 Sliding door

6 CVS Stress Labs

7 Hall

8 Office

9 Reception

10 Cath. Lab

11 Adjacent Imaging Room

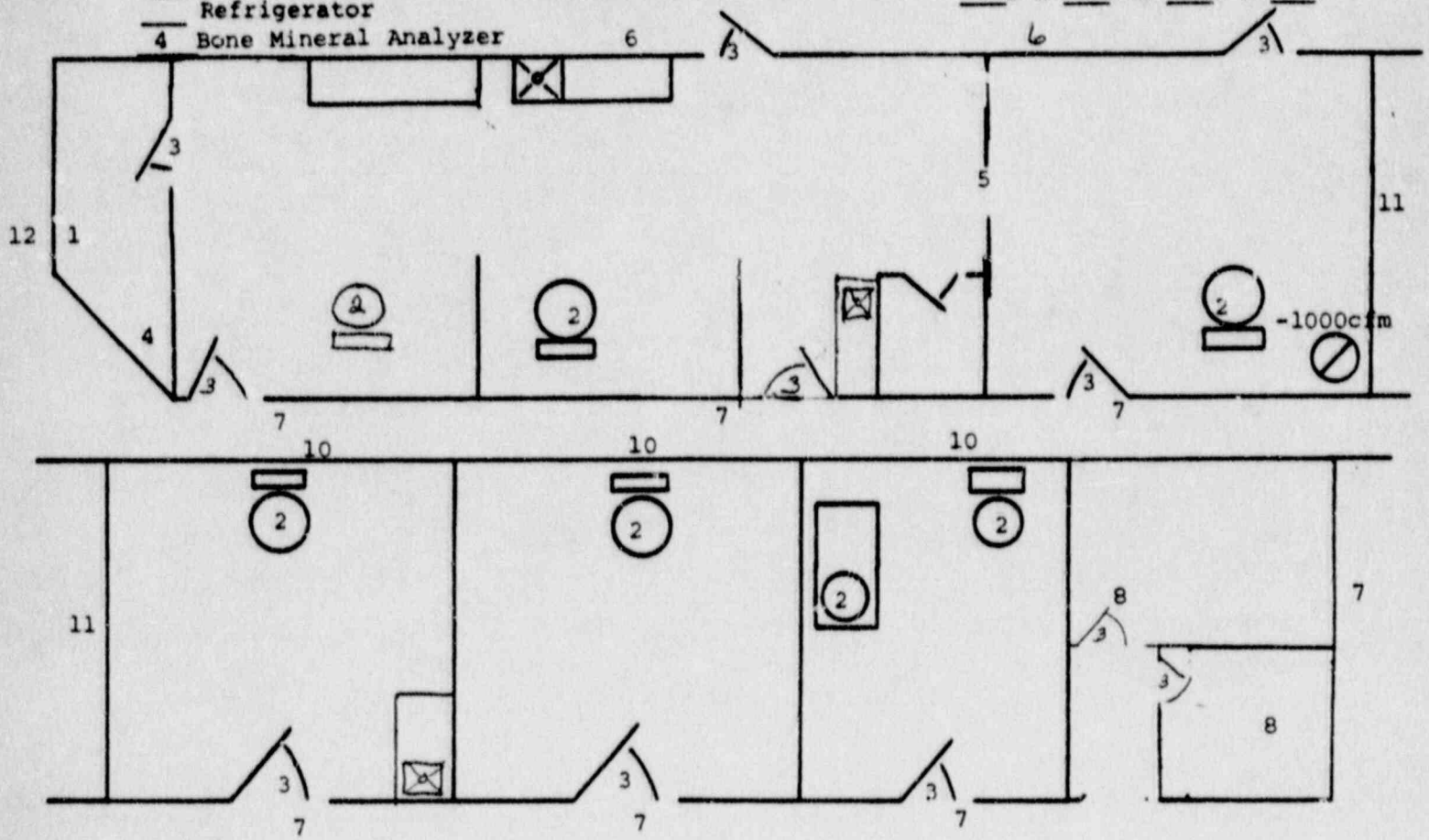
12 Outside

___ L x ___ W x ___ H x ___ T

___ L x ___ W x ___ H x ___ T

___ L x ___ W x ___ H x ___ T

___ L x ___ W x ___ H x ___ T



The department configuration is in a linear fashion. approximate area 170' x 18'.

Item #11

1 of 1 pages

Prepared 3/14/88

ADDENDUM TO ITEM #13

Presently, Sioux Valley Hospital is authorized, in part, to receive from and transfer radioactive materials to Laboratory of Clinical Medical (LCM) on an occasional basis. The mobile services have been divested by LCM. The same mobile service operations are now conducted under the name of W.A. Boade, M.D., LTD., NRC License #40-26908-01. It is requested this authorization be amended to reflect W. A. Boade, M.D., LTD, not LCM.

Additionally, Sioux Valley Hospital and W.A. Boade, M.D., LTD, have entered into an agreement that, if authorized, will provide common hot lab operations. The hot lab activities will be conducted under the license requirements of W.A. Boade, M.D., LTD. Therefore, it is requested authorization be granted to reflect a routine transfer between the two licensees, as opposed to occasional.

Radioactive material shipments will be received by Sioux Valley Hospital in accordance with procedures outlined in Item #13 of our license.

Nuclear Medicine Associates, Inc.

December 7, 1983

W. A. Boade, M.D.
Pathology Department
Sioux Valley Hospital
19th and Euclid Streets
Sioux Falls, South Dakota 57105

Re: License Renewal

Dear Dr. Boade:

Attached please find an application for your NRC license. In order for the application to be complete, it must be supported with the information checked below:

__X__ 1. Read the application carefully for completeness and accuracy. If any changes are made, please be sure we have a copy of the changes as submitted.

__X__ 2. Have the Certifying Official of the organization named on the license application sign and date Item #26 on page three of form NRC 313M.

__X__ 3. Have the Certifying Official of the organization named on the license sign and date page three of the NMA cover letter and page seven of the ALARA commitment. These documents are also to be forwarded to the NRC with the renewal application.

__X__ 4. Attach a check for $150.00 payable to: U.S. Nuclear Regulatory Commission.

__X__ 5. Retain a copy for your files and send two complete copies of all material to the address below:

send Registered Mail - Return Requested

Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive Suite 1000
Arlington, Texas 76012

If you have any questions concerning the enclosed renewal application, please do not hesitate to contact me.

Sincerely,

FBloe

Frank T. Bloe
Consultant

FTB:jed
Enc.

1/4/84 Dec I III Brown

35608 #150.-TB Renewal 1/4/84 Brown

1/5/84

9700 GARFIELD BLVD. • CLEVELAND, OHIO 44125 • (216) 641-5799

60152

Nuclear
Medicine
Associates, Inc.

December 7, 1983

U.S. Nuclear Regulatory Commission
Regional Licensing Section
Region IV
611 Ryan Plaza Drive Suite 1000
Arlington, Texas 76012

Re: License Application

Gentlemen:

Attached is an application for renewal of U.S. NRC License Number 40-12378-01 issued to Sioux Valley Hospital. In accordance with the instructions found on page two of Form NRC 313M, we are submitting the following supplementary information.

( ) The appropriate documentation to add authorized user(s) is attached (See NRC 313M, Supplements A and B).

(X) Item #10. The methods and frequency for dose calibrator calibration and survey meter calibration are attached.

(X) Item #12. A detailed description of our personnel training program is attached.

(X) Item #13. A detailed description of our procedures for ordering and receiving radioactive material is attached.

(X) Item #14. The procedures for safely opening packages containing radioactive materials as outlined in Appendix F, Licensing Guide 10.8 will be followed with the following exceptions. The procedures shall not be applicable to prepackaged in vitro kits except that radiation labels will be obliterated. In addition, evaluation of final source container wipe smears will be performed with a survey meter listed in Item #9 of this application.

(X) Item #15. General rules for the safe use of radioactive materials, as outlined in Appendix G of the Licensing Guide will be subscribed to at this institution. Additionally, in accordance with 10 CFR 20.501, authorization is requested to dispose of the following records subsequent to NRC inspection of these records.

9700 GARFIELD BLVD. • CLEVELAND, OHIO 44125 • (216) 641-5799

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1. Dose calibrator accuracy, constancy and linearity checks.
2. Survey meter calibration records.
3. Instrument calibration and quality assurance records (e.g., camera, well, uptake probe, etc.).
4. Records of training for occupational and non-occupational personnel.
5. Radiation Safety Committee minutes.

Provided that:

1. The record was examined during a routine NRC inspection.
2. The record is in excess of two years from the date of generation.
3. Disposal of the record does not conflict with the requirements of other state and federal agencies.

(X) Item #16. Emergency procedures outlined in Appendix H will be posted and implemented when necessary. The individuals to be notified and their telephone numbers will also be posted and revised as necessary.

(X) Item #17. A detailed description of the procedures for performing area surveys and analyzing wipe test smears is attached.

(X) Item #19. The procedures and precautions for radiopharmaceutical therapy as described in Appendix K of Regulatory Guide 10.8 will be followed with the exception that for I-131 patients, the urine will not normally be collected and only patients containing > 30 mCi must be hospitalized. In addition, for I-131 therapy:

1. Liquid sources will be opened in a vented hood if available. Gloves, tongs, and lead shielding will be utilized by personnel handling I-131 sources.

2. Liquid I-131 sources received in closed remote displacement containers designed for direct oral administration to a patient will be treated with the same radiation safety precautions as are employed in the use of capsules containing this radionuclide.

3. The criteria and procedures for a personnel bioassay program will be as described in Regulatory Guide 8.20, September, 1979.

4. Nursing instructions as defined in Appendix K shall not apply to P-32 except in the colloidal form in which case the nurse will be advised to observe the wound and report any drainage to the Radiation Safety Officer who will be responsible for changing the dressings.

5. If a patient is hospitalized with < 30 mCi, radiation safty procedures shall be applied until such time as the residual activity in t[illegible] mCi (Reference: NCRP #37).

(X) Item #20. A detailed description of the program and procedures for the therapeutic use of sealed sources is attached.

(X) Item #21. A detailed description of the facilities, equipment and procedures involved in the use of radioactive gases (i.e., Xenon-133) is included.

(X) ALARA Program is attached.

If you have any questions regarding this application, please do not hesitate to call Frank T. Bloe, from Nuclear Medicine Associates, Inc., Cleveland, Ohio at (216) 641-5799.

Application Prepared by:

FBloe

Frank T. Bloe, Consultant
Nuclear Medicine Associates, Inc.

Date: _____

Application Reviewed and Approved by:

[signature]

Title:

NRC FORM 313M (9-81) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION **APPLICATION FOR MATERIALS LICENSE – MEDICAL**	Approved by OMB 3150-0041 Expires 9-30-83

INSTRUCTIONS – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

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

Sioux Valley Hospital
Department of Pathology
19th and Euclid Ave.
Sioux Falls, South Dakota 57105

TELEPHONE NO.: AREA CODE (605) 336-3440

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

Same

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Frank T. Bloe, Consultant
Nuclear Medicine Associates, Inc.

TELEPHONE NO.: AREA CODE (216) 641-5799

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO.
c. ☒ RENEWAL OF LICENSE NO. 40-12378-01

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

Refer to Item #8

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

W.A. Boade, M.D. with consultation from Nuclear Medicine Assoc., Inc. Cleveland, Ohio 44125

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	5,000
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI	X	200

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM	X	As needed
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES	X	As needed
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA	X	As needed
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	X	300

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE

Applicant
Check No. 35608
Amount/Fee Category 150-7B
Type of Fee Renewal
Date Check Rec'd 1.4.84
Received By Brown

RECEIVED BY LFMB
Date 1/4/84
Log No. 10-1 III
By Brown
Orig. To
Action Compl. 1/5/84

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NRC FORM 313M (9-81)

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. 1 Date: Oct., 1980

7. MEDICAL ISOTOPES COMMITTEE	
	Names and Specialties Attached; and
X	Duties as in Appendix B; or *(Check One)*
	Equivalent Duties Attached
8. TRAINING AND EXPERIENCE	
X	Supplements A & B Attached for Each Individual User; and appropriate references
	Supplement A Attached for RSO.
9. INSTRUMENTATION *(Check One)*	
X	Appendix C Form Attached; or
	List by Name and Model Number
10. CALIBRATION OF INSTRUMENTS	
	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*
X	Equivalent Procedures Attached; and
	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*
	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	
X	Description and Diagram Attached
12. PERSONNEL TRAINING PROGRAM	
X	Description of Training Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	
X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	
X	Appendix F Procedures Followed; or
	Equivalent Procedures Attached

15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Appendix G Rules Followed; or
	Equivalent Rules Attached
16. EMERGENCY PROCEDURES *(Check One)*	
X	Appendix H Procedures Followed; or
	Equivalent Procedures Attached
17. AREA SURVEY PROCEDURES *(Check One)*	
	Appendix I Procedures Followed; or
X	Equivalent Procedures Attached
18. WASTE DISPOSAL *(Check One)*	
X	Appendix J Form Attached; or
	Equivalent Information Attached
19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X	Appendix K Procedures Followed; or
	Equivalent Procedures Attached
20. THERAPEUTIC USE OF SEALED SOURCES	
X	Detailed Information Attached; and
	Appendix L Procedures Followed; or *(Check One)*
	Equivalent Procedures Attached
21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached
22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
	Detailed Information Attached
23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer, Jr. & Sons	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R.S. Landauer, Jr. & Sons	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

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

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)*

(1) LICENSE FEE CATEGORY: 7B

(2) LICENSE FEE ENCLOSED: $ 150.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

X

(1) NAME *(Type or Print)*

X

(2) TITLE

X

c. DATE

X

NRC FORM 313M (9-81)

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the applicant meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use, and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

RADIATION SAFETY COMMITTEE

The membership of this committee will consist of at least three members and will include:

1. the radiation safety officer;
2. the hospital administrator or other administrative official directly responsible to the hospital administrator in the hospital's internal chain of command;
3. an authorized user for each type of use permitted by the license; and
4. a representative of the hospital's nursing staff.

The names and qualifications of the committee members will be documented in the committee's records, will be updated as necessary, and will be available for inspection by the NRC.

Item #7
1 of 3 pages
Prepared: 12/7/83
Lic. #40-12378-01

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APPENDIX B

RADIATION SAFETY COMMITTEE

Responsibility

The committee is responsible 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 use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

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 the license and its amendments.

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

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security and housekeeping personnel) are properly instructed as required by § 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 inspections, written safety procedures, and the adequacy of the institution's 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, as specified in the license.

Meeting Frequency

The Radiation Safety Committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

NAME OF AUTHORIZED USER	AUTHORIZATION
W. Allan Boade, M.D.	All
John F. Barlow, M.D.	All
Richard A. Jaqua, M.D.	All
Richard D. Schultz, M.D.	All
Karl H. Wegner, M.D.	All
Andrew I. Soye, M.D.	Groups I, II, III, I-131 and P-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metasteses
Robert F. DeClark, M.D.	Iodine 131, Phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metasteses
Donald G. Nordstrom, M.D.	Phosphorus 32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases; Group VI
Gayla S. Lowery, M.D.	Group VI
B. T. Pitt-Hart, M.D.	In Vitro Studies Licensed material of the types, quantities and forms specified in Section 35.31 of 10 CFR 35 for use in accordance with the provisions of paragraphs (a) and (c) contained therein

Item #8
1 of 1 page
Prepared: 12/7/83
Lic. #40-12378-01

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APPENDIX C

INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name Dosimeter Corporation
   Manufacturer's model number 3007
   Number of instruments available 1
   Minimum range: 0 mR/hr to 0.5 mR/hr
   Maximum range: 0 mR/hr to 50 mR/hr

   b. Manufacturer's name Victoreen
   Manufacturer's model number 470A
   Number of instruments available 4
   Minimum range: 0 mR/hr to 3.0 mR/hr
   Maximum range: 0 mR/hr to 1000 mR/hr

2. Dose calibrator(s)
   Manufacturer's name Capintec
   Manufacturer's model number CRC-10
   Number of instruments available 1

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.
Camera	Siemens	LFOV
Camera	Siemens	ZLC
Camera	Baird Atomic	System 77
Camera	Picker	Dynamo
Well/uptake	Atomic Products	261

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

   Xe-133 charcoal trap - Pulmonex 130 - 500

APPENDIX C

INSTRUMENTATION

1. Survey meters

a. Manufacturer's name Eberline

Manufacturer's model number 3332

Number of instruments available 1

Minimum range: 0 mR/hr to 0.2 mR/hr

Maximum range: 0 mR/hr to 2000 mR/hr

b. Manufacturer's name _____

Manufacturer's model number _____

Number of instruments available _____

Minimum range: _____ mR/hr to _____ mR/hr

Maximum range: _____ mR/hr to _____ mR/hr

2. Dose calibrator(s)

Manufacturer's name _____

Manufacturer's model number _____

Number of instruments available _____

3. Instruments used for diagnostic procedures

Type of Instrument	Manufacturer's Name	Model No.

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

CALIBRATION OF INSTRUMENTS

A. Survey meters will be checked for operability prior to each use. This will be accomplished by holding the detector against an instrument check source or the dose calibrator sealed constancy source depending on the instrument or range to be tested. If any reading with the same geometry is not within ± 20% of the reading displayed after calibration, the instrument will be recalibrated. The reading obtained will be included on all recorded surveys.

The units will be calibrated after servicing and at least annually by the manufacturer or by Nuclear Medicine Associates, Cleveland, Ohio, in accordance with the procedure outlined in application for NRC license #34-16272-01. Records of these calibrations will be maintained and recommendations for repair will be followed. A survey meter will not be used beyond the anniversary of its last successful calibration.

Arrangements will be made for the availability of at least one survey meter while a unit is away for calibration or repair.

B. The dose calibrator will be calibrated as follows:

1. Sealed sources will be used to establish accuracy. They will consist of:

Nuclide	Suggested Activity	Activity (mCi)	Accuracy
Co-57	3-5 mCi	1 mCi or more	Within ± 5%
Ba-133	0.1-0.3 mCi	100 uCi or more	Within ± 5%
Cs-137	0.1-0.3 mCi	100 uCi or more	Within ± 5%

2. The accuracy of the assay of the above standards will be at least ± 5% and traceable to National Bureau of Standard sources.

3. The calibration procedure will be as follows:

a. The dose calibrator will be checked for accuracy at annual intervals and following repair using sealed sources having energies which encompass that portion of the spectrum of energies for which the dose calibrator is used. Nuclides that will be used are listed in Item 1 above.

The activity displayed by the dose calibrator must agree with the stated assay within ± 5% of the limits of the standard's calibration accuracy. If the unit displays readings with an error greater than ± 5%, arrangements will be made for immediate repair or adjustment.

b. The dose calibrator will be checked for constancy each day of use. This will be accomplished using a Cs-137 standard. The sealed source will be placed in the chamber and the unit set to measure that nuclide. The activity displayed with background and decay considered, must fall within ± 5% of the predicted activity based on the value obtained at the time of the original accuracy test.

The daily constancy check will be extended to include verification of displayed activities using the same standard but with the dose calibrator set to measure each of the different nuclides to be assayed on that day. With background and decay considered, variation in displayed activities must fall within ± 5% of the activity shown at the time of the most recent accuracy check. If variations greater than ± 5% are noted, arrangements will be made for immediate repair or adjustment.

c. The dose calibrator will be checked for activity linearity at quarterly intervals and following repair. This test will be performed using the maximum dose received from a Radiopharmacy or the first elution from a new Mo/Tc generator. In the latter case, after assaying the entire elution vial, an aliquot will be drawn calculated to contain 200 mCi. The aliquot will be assayed for agreement with the calculated activity to within ± 5%. If 200 mCi cannot be spared for performance of linearity testing, an aliquot less than 200 mCi will be drawn and used. The reduced amount will then be established as the maximum activity to be employed for patient doses or kit preparation for the remainder of the quarter or until linearity testing can be repeated utilizing a greater activity. In this way, the accuracy of the unit will be assured in the measurement of activity from the maximum or hand to a quantity approximately the maximum amount drawn and assayed for kit preparation.

To reduce personnel exposure from a whole vial measurement of activity, an alternate method of obtaining a source for the activity linearity check may be used. An aliquot such as 0.5 to 1.0 ml will be withdrawn from the elution vial and assayed in a syringe. The concentration of the eluent can be determined by dividing the displayed activity by the volume in the syringe. A 200 mCi aliquot contained in the

proper volume can then be withdrawn from the elution vial and used for the linearity test. If 200 mCi cannot be used, the amount used may be less but the same restrictions as cited in the paragraph immediately preceding will apply. In this way, the accuracy of the dose calibrator will also be assured in the measurement of activities approximating the maximum quantities used for kit preparation.

The linearity test will be continued by repeating the assay of the test aliquot several times a day over a two to three day period until a measurement is made in which the activity displayed is approximately the minimum dose likely to be used in a patient study and also less than the activity displayed during the annual accuracy check utilizing the standard with the energy similar to that of Tc-99m. In this way, the accuracy of the dose calibrator will be assured in the measurement of individual doses throughout the entire ranges of doses drawn for kit preparation and patient studies.

The above linearity test data will be plotted as a function of activity vs. time and compared to predicted activities vs. the same time. The acceptable range of error will be ± 5%. If test result error exceeds ± 5%, arrangements will be made for immediate repair or adjustment. The unit may be used in the interim using predetermined correction factors.

As an alternative procedure, the linearity test can be performed with the use of the Calicheck kit from Calcorp, Inc. The manufacturer's instructions for use will be followed. The source used shall be the first elution of a new generator or the activity of the largest dose obtained from a Radiopharmacy if a Radiopharmacy is used. Limits of acceptability and corrective actions will be as described above.

d. The dose calibrator will be tested for geometrical variation at the time of installation and following chamber or liner repair or replacement. This test will be performed using approximately 2 mCi of Tc-99m in a geometrical configuration approximating that of a point source. The source geometry will then be changed by dilution with assays performed at each step. A comparison will also be made to quantify the reduction in displayed activity caused by assaying sources in plastic versus glass containers.

The data will be analyzed relating the various readings to the reading acquired while the test source was in the geometry of the Co-57 accuracy standard. Correction factors will be used in clinical assays when geometry induced errors exceed ± 2%.

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In the event the dose calibrator should fail or if it is away for repairs, the nuclear medicine program will be continued through the implementation of the following procedure:

1. A substitute dose calibrator will be acquired.

2. Eluents and/or doses will be assayed in a dose calibrator located at the nearest cooperating institutions having a functional and properly calibrated unit. If activities must be transported for this purpose, they will be shielded with sufficient lead to reduce levels to 2.0 mR/hr or less on contact with the shield, wrapped in sufficient absorbant toweling to absorb ten times the liquid volume contained in the vial or syringe, marked with labels indicating the presence of radioactivity, and carried by one occupational person assigned to this task throughout the entire trip. This same person will perform the assay, record the data, and return the activity to the location of authorized use.

Method #2 will be depended upon only in cases of medical emergency and until a functional dose calibrator can again be acquired. If only the activity of the eluent is known, mathematical calculations will be used to determine activity needed for patient doses.

The above assay techniques will enable the measurement of Technetium-99m and its Molybdenum-99 contaminant to within ± 10% of the true assay. Every effort will be made to expedite repair and return of the dose calibrator.

Diagnostic instrumentation will be calibrated as follows:

1. The camera pulse height analyzer will be calibrated using Tc-99m and a uniform flood check will be performed each day of use.

FACILITIES AND EQUIPMENT DESCRIPTION

All radioactive sources are stored in such a manner (lead, concrete, refrigerator) so as to not exceed 2mR/hr at the surface of the barrier.

Mo-99/Tc-99m generator when used will be stored and eluted in the designated area. It will be shielded with lead bricks such that levels from all avenues of approach do not exceed 2.0mR/hr. Spent generators will be stored in the location identified in the attached diagram.

During elution, the eluate will be collected, assayed, and stored in a vial held in a quarter inch lead pig except during brief periods of transfer. Transfer of the eluate or portions of the eluate will be made by the use of syringes retained in lead shields designed for this purpose.

Eluates and compounds made from eluates will be drawn, synthesized, assayed and stored in lead vials or syringes such that levels as measured at contact with a low level survey meter do not exceed 2.0mR/hr except for brief periods during the actual transfer.

Radioactive materials obtained from radiopharmacy suppliers will be stored in their original shipping containers. If necessary, the doses will be placed behind additional shielding to reduce activity levels emitted from the container to 2mR/hr or less.

Syringe shields will be used on all accessories requiring the transfer of radiopharmaceuticals from vial to vial and in drawing up patient doses. Syringe shields will also be used in the administration of doses to patients except when the patients well being may be compromised. Under these circumstances, the dose containing syringes will be kept shielded up to the moment of injection.

Steps in the preparation of compounds requiring periods of heating, shaking, agitation or mixing will be performed utilizing lead shielding and/or mechanical or ultrasonic agitation equipment and/or remote handling devices (tongs, forceps, etc.) such that levels during the above period as measured by a low level survey meter do not exceed 2.0mR/hr.

Protective outer garments, such as laboratory coats and rubber gloves will be worn while handling radioactivity in uncontained form.

All possible set-ups will be made on easily cleanable trays. All trays and all other work surfaces will be covered with disposable absorbent paper.

A decontamination kit will be maintained in the department. It will include the following items:

DECONTAMINATION KIT

ITEM	PURPOSE
1. Warning tape, chalk, & signs	posting of area
2. Plastic bags, small	shoe covers, wet containers
3. Disposable gloves	hand protection
4. Masking tape	fasten shoe covers, etc.
5. Forceps, tongs	safe handling
6. Large plastic bags	for contaminated material
7. Sponges, 4 x 4	sopping up
8. Paper towels	blotting & drying
9. Radiac wash or detergent	detergent
10. Scouring powder	friction
11. Tags	identification
12. Scissors	cut absorbent paper, etc.
13. Whatman #1 filter paper	taking swipes following decontamination
14. Chux	cover area following decontamination
15. G-M survey meter	monitoring

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Facilities and Equipment

Diagram

Air Supply
Air Exhaust
___ Scanner
___ Uptake/Well
___ Camera
1 Lockable Door
2 Receipt Area
3 Generator
4 Kit Preparation
5 Isotope Storage
6 Dose Preparation
7 Waste Storage
8 Dose Calibrator
9 Refrigerator

Sink
Lead Castle

Adjacent Areas

10 Hall
11 Patient Waiting
12 Secretary office
___
___
___
___
___

Lead Shielding

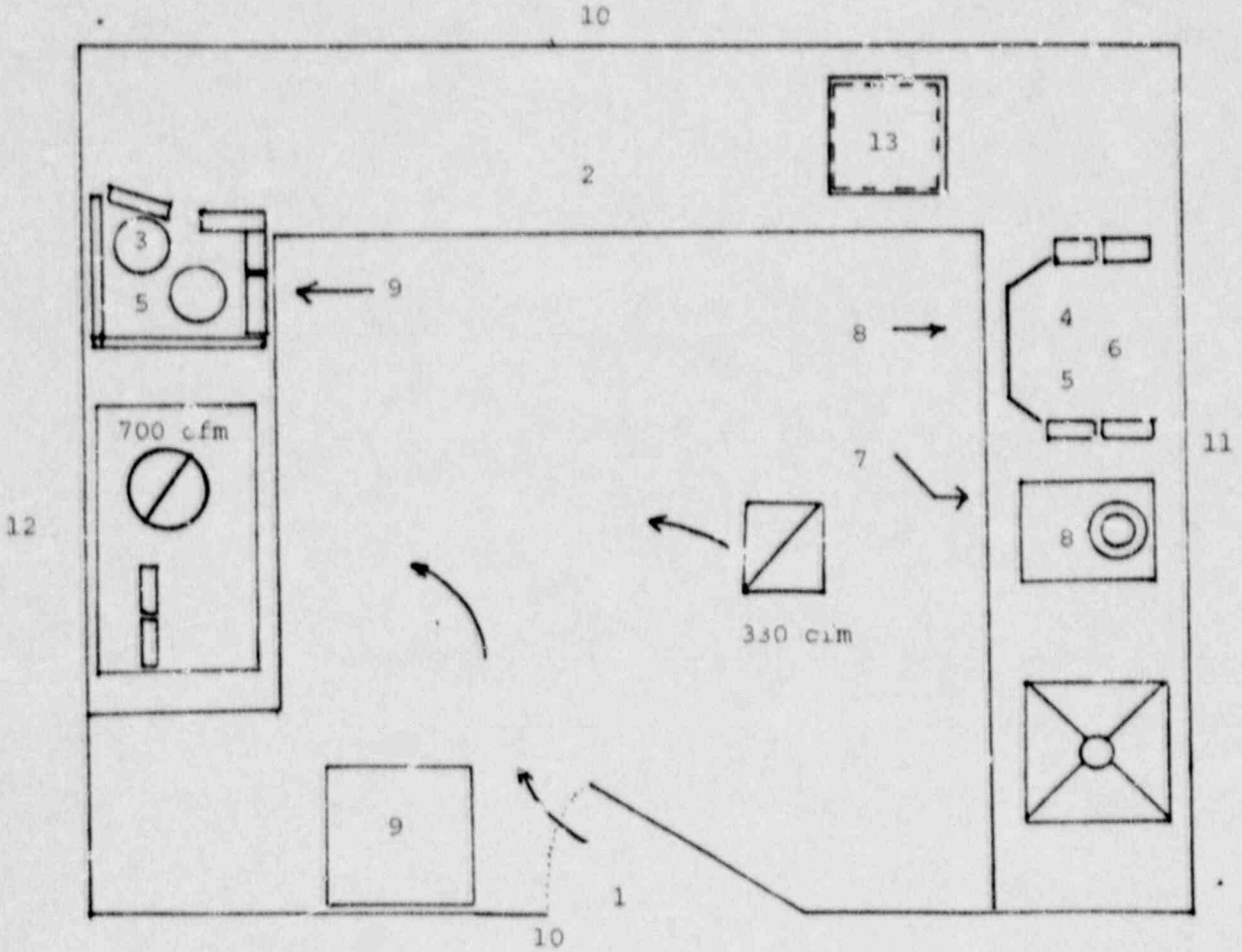
7 Pb Storage box under counter
2' L x 2' W x 1' H x ½" T

8 Pb Shield + Pb Bricks
18"L x10" W x12" H x ½" T

9 Pb Shield + Pb Bricks
2'L x 2' W x 1' H x ½" T

13 Pb Safe for Group VI
12"L x12" W x 14"H x 4"T

Hot Lab



Approximate area = 10' x 12'

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Facilities and Equipment Diagram

- Air Supply
- Air Exhaust
- ___ Scanner
- 1 Uptake/Well
- 2 Camera
- 3 Lockable Door
- ___ Receipt Area
- ___ Generator
- ___ Kit Preparation
- ___ Isotope Storage
- ___ Dose Preparation
- ___ Waste Storage
- ___ Dose Calibrator
- ___ Refrigerator

- Sink
- Lead Castle

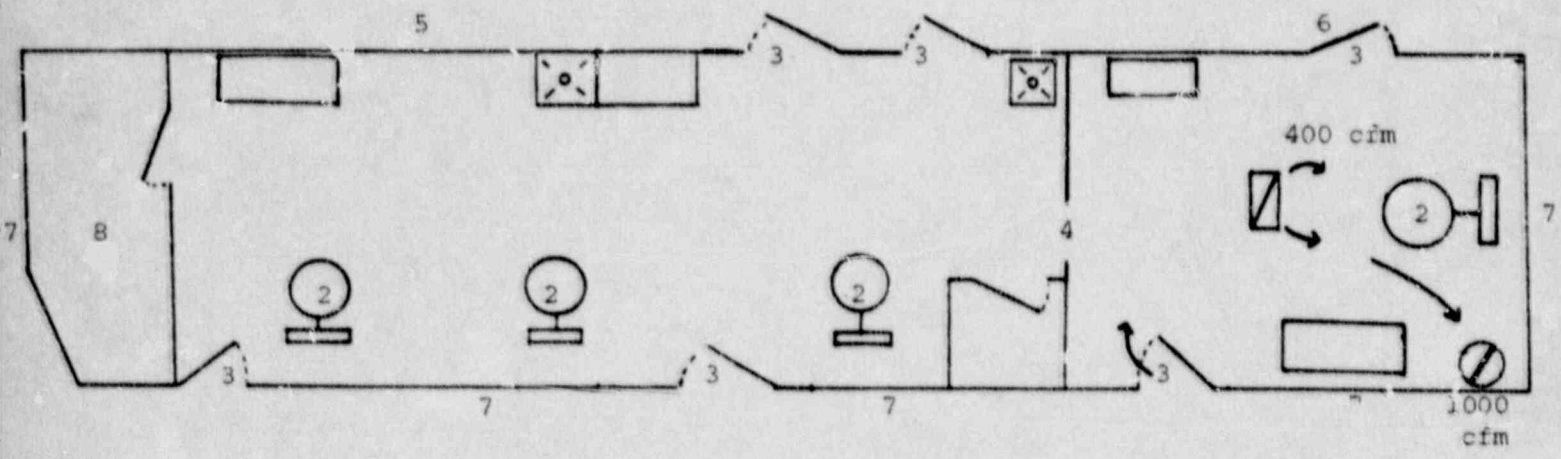
Adjacent Areas

4 Sliding door
5 X-ray
6 Cath. lab
7 Hall
8 Office
9 Files-histology
10 Secretary area
___ _____

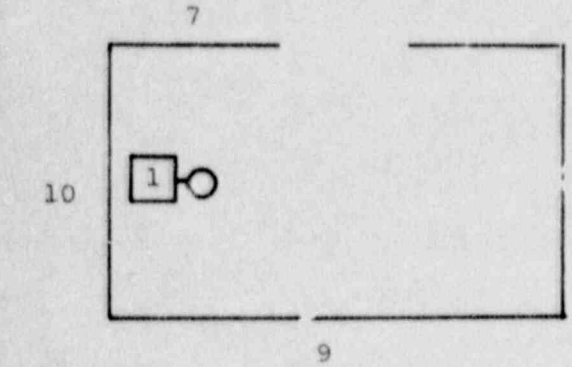
Lead Shielding

___ L x ___ W x ___ H x ___ T
___ L x ___ W x ___ H x ___ T
___ L x ___ W x ___ H x ___ T
___ L x ___ W x ___ H x ___ T

Nuclear Medicine
Imaging Area



(Across from hot lab)



Approximate area = 88' x 18'

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PERSONNEL TRAINING PROGRAM

In accordance with Section 19.12 of 10 CFR, Part 19, the following is a description of the training required for all personnel who work with or in the vicinity of radioactive materials:

1. The nuclear medicine department will be staffed by individuals who will be classified as occupational employees. These individuals will perform their duties from the radiation safety viewpoint under the direction of the physician(s) named on the license application.

2. Every effort will be made to hire nuclear medicine technology registered or registry eligible personnel to work with radioactive material. Orientation of such personnel for a day or two by the physician(s) named on the license and/or by the supervising technologist will include the following:

   a. Indicate areas where radioactive materials are used or stored.
   b. Potential hazards associated with radioactive materials.
   c. Radiological safety procedures appropriate to their respective duties.
   d. Pertinent NRC regulations.
   e. The rules and regulations of the license.
   f. The pertinent terms of the license.
   g. Their obligation to report unsafe conditions.
   h. Appropriate response to emergencies or unsafe conditions.
   i. Their right to be informed of their radiation exposure and bioassay results.
   j. Location where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR, Part 19.

If evaluation of the radiation handling techniques of a new technologist is found to be inadequate, arrangements will be made to send the employee for a 40 hour formal course from our consulting physicists, Nuclear Medicine Associates, Inc., Cleveland, Ohio. This course combines didactic and clinical training which will include points "b" through "i" listed above as well as quality control and patient procedures.

3. Our consulting physicists, mentioned in this addendum, will visit our facility quarterly to review all procedures, equipment and records. Personnel will receive refresher training relative to duties, regulations, or terms of the

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license during these visits or by the physician(s) named on this license application, or by supplementary training at least annually or more frequently, as needed.

4. Access into areas where radioactive material is stored or used will be restricted for nonoccupational personnel. When it is necessary for nonoccupational personnel to enter these areas, as in the case of certain patients who need special care, personnel so involved will be present under the direction of the nuclear medicine technologist, who will ensure that the exposure of these persons is held to the minimum required for the performance of the nuclear medicine procedure. Further, all nonoccupational personnel will receive instruction as to the location and potential hazards associated with radioactive material during their hospital orientation process and annually thereafter in the form of verbal instructions and/or hospital interdepartment memos.

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PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The chief nuclear medicine technologist or his/her designee 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. The receipt area identified in the Item #11 diagram is designed such that radiation levels in unrestricted areas do not exceed the limits specified in 10 CFR 20.105.

2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Pathology Dept, Dose Prep Rm #1551. If this is not practical, responsible personnel (indicated in the memorandum below) will sign for packages containing radioactive materials and immediately take them to this location. Alternatively, trained nuclear medicine personnel will sign for and transport packages to the appropriate department.

3. During off-duty hours, supervisory personnel will arrange to have delivery of radioactive packages in accordance with the procedures outlined in the following directive:

TO: Managerial Personnel of:

Nursing Dept.
Emergency Room
Receiving
Security

FROM:

SUBJECT: Delivery of packages containing radioactive materials

If couriers or common carriers attempt delivery of packages containing radioactive materials, the supervisor on duty will be contacted. He/she will make arrangements to have the package delivered to the designated receipt area by specially trained personnel who have been assigned this duty. The packages will be secured against unauthorized removal. If packages are wet or appear to be damaged, the RSO is to be immediately contacted.* The carrier should be requested to remain until it can be determined that neither he nor the delivery vehicle is contaminated.

Personnel not trained in the proper handling of radioactive materials are not to personally accept packages containing radioactive materials.

*Radiation Safety Officer: As currently listed.

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The purpose of this part of the application is to allow byproduct material to be recieved from and transferred to the Laboratory of Clinical Medicine (license #40-15027-01) or McKennan Hospital (800 E. 21st St., Sioux Falls) on an occasional basis, e.g., if a shipment is delayed or cancelled by the manufacturer. Deliveries to this part of the country are infrequent and sometimes unpredictable. Unless we are able to acquire substitute doses, the quality of patient care might suffer unnecessarily. We therefore request exemption from 10 CFR 35.14(b)(1).

PROCEDURES FOR THE TRANSPORT OF RADIOACTIVE MATERIAL

1. Byproduct material will be transported as prepared, designated doses, and vials of Tc-99m in eluant and prepared kit form between the above mentioned facilities for administration to patients prior to undergoing diagnostic testing. Activity will be drawn, assayed in the dose calibrator, placed in a syringe shield, wrapped in absorbant toweling and packed into a latched, lead-lined, syringe carrier. Alternately, each source may be shielded individually and carried in a secured, unshielded carrier.

2. The carrier will be marked with a radioactive materials notice. Prior to dispatch, the activity in the carrier will be surveyed with the low level G-M survey meter to insure that levels on contact do not exceed 2.0 mR/hr.

3. The activity will be transported between facilities, using a hospital/laboratory owned vehicle. The activity will not be left unattended or in the charge of anyone else by the hospital/laboratory courier service. Prepared doses will be administered following remeasurement of dose via a dose calibrator.

4. All residues, unused doses, contaminated syringes, alcohol swabs, etc., may be re-wrapped in the absorbant toweling on site, stored in the syringe carrier and transported back to shipping facility for disposal or may be decayed in storage and disposed at either location.

Appendix F

Procedures For Safely Opening Packages
Containing Radioactive Material

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205 (a) (1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 uCi/100 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).

2. For all packages, the following additional procedures for opening packages will be carried out:

   a. Put on gloves to prevent hand contamination.

   b. Visually inspect package for sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

   c. Measure exposure rate at 3 feet (or 1m) from package surface and record. If > 10 mr/hr, stop procedure and notify Radiation Safety Officer.

   d. Measure surface exposure rate and record. If > 200mR/hr, stop procedure and notify Radiation Safety Officer.

   e. Open the package with the following precautionary steps:

      (1) Open the outer package (following manufacturer's directions if supplied) and remove packing slip.

      (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition, † packing slip, and label on bottle.

      (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).

      (4) Check also that shipment does not exceed possession limits.

†In the case of special order (e.g., therapy doses) also compare with physician's written request.

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f. Wipe external surface of final source container shield and remove wipe to low background area. Check wipes with a thin-end window G-M survey meter, and take precaution against the spread of contamination as necessary.

g. Monitor the packing material and packages for contamination before discarding.

(1) If contaminated, treat as radioactive waste.

(2) If not contaminated, obliterate radiation labels before discarding in regular trash.

3. Maintain records of the results of checking each package.

Appendix G

General Rules For the Safe Use of Radioactive Material in the Nuclear Medicine Department

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

5. a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

   b. Do not store food, drink, or personal effects with radioactive material.

6. a. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10 percent.

   b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. The devices should be worn at chest or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.

8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

9. Dispose of radioactive waste only in specially designated and properly shielded receptacles.

10. Never pipette by mouth.

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11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Always transport radioactive material in shielded containers.

APPENDIX H

Emergency Procedures

Minor Spills

1. NOTIFY: Notify persons in the area that a spill has occurred.
2. PREVENT THE SPREAD: Cover the spill with absorbent paper.
3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.
4. SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands and clothing for contamination.
5. REPORT: Report incident to the Radiation Safety Officer.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.
2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.
3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.
4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.
5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.
6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: To be filled in on original
OFFICE PHONE:
HOME PHONE:

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

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SURVEY PROCEDURES

A. All elution, preparation and designated injection areas will be surveyed daily with G-M survey meter and decontaminated, if necessary.

B. Laboratory areas where only small quantities of radioactive material are used (less than 200uCi) will be surveyed monthly.

C. All other laboratory areas will be surveyed weekly.

D. The weekly and monthly survey will consist of:

1. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1mR/hr.

2. A series of wipe tests to measure contamination levels. Analysis of wipe tests will be performed using a low level G-M survey meter.

The procedure will be as follows:

a. Perform wipe tests.
b. Place smear(s) in a "baggy" or disposable glove.
c. Adjust response time to the longest time constant, if applicable.
d. Select most sensitive range.
e. Turn beta shield on probe to open position.
f. Wait until reading stabilizes.
g. Read and record background.
h. Place smear in contact with open position of probe.
i. Wait until the reading stabilizes.
j. Read and record wipe results.

Action levels for smear analysis using the G-M survey meter will be set at any response above background. If action levels of removable contamination are found, decontamination efforts will be initiated to provide for clean-up or to prevent spread. In order to avoid unnecessary personnel exposure, contamination strongly suspected as being caused by Tc-99m may be shielded and/or covered to prevent spread and be allowed to decay.

E. A permanent record will be kept of the weekly or monthly survey results, including negative results. The record will include:

1. Location, date and type of equipment used.

2. Name of person conducting the survey.

3. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

4. Measured exposure rates, keyed to location on drawing (point out rates that require corrective action).

5. Detected contamination levels, keyed to locations on drawing.

6. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

APPENDIX J

WASTE DISPOSAL

1. Liquid waste will be disposed of (check as appropriate).

__X__ In the sanitary sewer system in accordance with 20.303 of 10 CFR, Part 20.

__X__ Held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.

_____ By commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

2. Mo-99/Tc-99m generators will be (check as appropriate).

__X__ Returned to the manufacturer for disposal.

__X__ Held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the generators will be disposed of as normal trash.

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

3. Other solid waste will be (check as appropriate).

__X__ Held for decay until radiation levels, as measured in a low background area with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated, and the waste will be disposed of in normal trash.

__X__ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

4. The commercial waste disposal service used will be:

_____
(Name) (City, State)

NRC/Agreement State License No. _____

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APPENDIX K

RADIATION SAFETY PROCEDURES FOR
THERAPEUTIC USE OF RADIOPHARMACEUTICALS

1. All patients treated with I-131 or Au-198 will be placed in a private room that has a toilet. The large surfaces in the room and toilet areas that are more likely to be contaminated will be covered with absorbent pads or protective material as appropriate to the amounts of contamination to be expected. Attention should be given to objects likely to be touched by the patient, e.g., telephones, doorknobs, and other items that would be difficult to decontaminate. Plastic bags or wrappings that are waterproof and easily disposable should be used on the smaller items.

2. The patient's room will be properly posted or attended in accordance with §§ 20.203 or 20.204 of 10 CFR Part 20.

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured at the patient's bedside and 3 feet (or 1 m) from the patient after administration and at the entrance to the room. The Radiation Safety Officer or his designee will then determine how long a person may remain at these positions and will post these times of the patient's chart and on his door. The results of daily surveys will be used to recalculate permitted times, which will be posted on the patient's chart and on his door.

4. The form, Nursing Instructions for Patients Treated with Phosphorus-32, Gold-198, or Iodine-131 (or a similar form containing all the requested information), will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

5. Radiation levels in unrestricted areas will be maintained less than the limits specified in paragraph 20.105(b) of 10 CFR Part 20.

6. All linens will be surveyed for contamination before being removed from the patient's room and, if necessary, will be held for decay.

7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The material will be collected daily by the Radiation Safety Officer or his

designee, checked for contamination, and disposed of as normal or radioactive waste, as appropriate

8. Nondisposable items used for these patients will be held in plastic bags in the patient's room and will be checked for contamination by the Radiation Safety Officer or his designee. Items may be returned for normal use, held for decay, or decontaminated, as appropriate.

9. If urine and vomitus from I-131 therapy patients are collected, they will be stored for decay in the radioactive waste storage area. Such stored wastes will be retained until they have reached background levels, as measured with a low-level survey meter. They will then be released to the sanitary sewer system.

10. Before a therapy patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated if necessary, and all radioactive waste and waste containers will be removed.

11. Nursing Instructions

    a. Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these restrictions before administering to the patients. Call the Nuclear Medicine Department or the Radiation Safety Officer with any questions about the care of these patients. Nursing personnel who attend the patient will wear personnel monitoring devices as advised by the Radiation Safety Office.

    b. Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart.

    c. Patients must remain in bed while visitors are in the room and visitors should remain at least 3 feet (or 1 m) from the patient.

    d. Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.

    e. No nurse, visitor, or attendant who is pregnant should be permitted in the room of a patient who has received a therapeutic amount of radioactivity until the patient no longer presents a radiation hazard. Female visitors should be asked whether they are pregnant.

f. Attending personnel should wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins, or other containers having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves should be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.

g. Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Radiation Safety Officer or his designee for proper disposal of the contents of the designated waste container.

h. All clothes and bed linens used by the patient should be placed in the laundry bag provided and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

i. All nondisposable items should be placed in a plastic bag and should be left in the patient's room to be checked by the Radiation Safety Officer or his designee.

j. Surgical dressings should be changed only as directed by the physician. Au-198 leaking from a puncture wound may stain the dressings dark red or purple. Such dressings should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or his designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

k. For I-131 patients:

(1) To the degree possible with cooperative patients, urine will be collected in special containers provided by the Radiation Safety Officer or his designee. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal or bed pan should be provided. The urinal or bed pan should be flushed several times with hot soapy water after use.

(2) If the nurse helps to collect the excreta, disposable gloves should be worn. Afterward, hands should be washed with the gloves on and again after the gloves are removed. The gloves should be placed in the designated waste container for disposal by the Radiation Safety Officer or his designee.

(3) Disposable plates, cups, and eating utensils will be used by patients who are treated with I-131.

(4) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may results in contamination of linen and floor. In any situation where the patient's room may be contaminated or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or his designee, Ext. _____. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(5) Keep all contaminated wastes and vomitus in plastic bags in the patient's room for disposal by the Radiation Safety Officer or his designee. Feces need not be routinely saved unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed (3 times). The Radiation Safety Officer will establish procedures for disposal of wastes (see Item 12 below).

l. If a nurse, attendant, or anyone else knows or suspects that his or her skin or clothing, including shoes, is contaminated, notify the Radiation Safety Officer or his designee immediately. This person should remain in an area adjacent to the patient's room and should not walk about the hospital. If the hands become contaminated, wash them immediately with soap and water.

m. If a therapy patient should need emergency surgery or should die, notify the Radiation Safety Officer or the Nuclear Medicine Department immediately.

n. When the patient is discharged, call the Radiation Safety Officer or his designee or the Nuclear Medicine Department and request that the room be surveyed for contamination before remaking the room.

12. Waste Disposal

When contaminated wastes are transported to the Waste Storage/Disposal area, precautions will be taken to minimize external irradiation of personnel. Stored wastes will be shielded to maintain exposure to personnel in restricted and unrestricted areas ALARA.

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH
PHOSPHORUS-32, GOLD-198, OR IODINE-131

Patient's Name: _____

Room No: _____ Physician's Name: _____

Radioisotope Administered: _____

Date and Time of Administration: _____

Dose Received: _____ Method of Administration: _____

Date	Exposure Rates in mR/hr 3 feet from bed	10 feet from bed

(Comply with all checked items)

_____1. Visiting time permitted: _____
_____2. Visitors must remain _____ from patient.
_____3. Patient may not leave room.
_____4. Visitors under 18 are not permitted.
_____5. Pregnant visitors are not permitted.
_____6. Film or TLD badges must be worn.
_____7. Pocket chambers will be worn for supplementary personnel monitoring of individual tasks.
_____8. Tag the following objects and fill out the tag:

_____ door _____ chart
_____ bed _____ wrist

_____9. Disposable gloves must be worn while attending patient.
_____10. Patient must use disposable utensils.
_____11. All items must remain in room until approved for removal by the Radiation Safety Officer or his designee.
_____12. Smoking is not permitted.
_____13. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.
_____14. Other instructions.

In case of an emergency contact:

RSO

_____

Name On-duty/Off-duty Telephone Numbers

ITEM #20

THERAPEUTIC USE OF SEALED SOURCES

Special procedures for patients treated with byproduct material listed in Group VI, Schedule A, Section 35.100 of 10 CFR, Part 35, are as follows:

a. Areas where sealed sources will be stored will be found in map accompanying this item.

b. See "Safety Precautions in Clinical Applications". (Item #20, Form E).

c. The form, Nursing instructions for Patients Treated with Radioactive Sources, (Item #20, Form A), will be completed immediately after sources are implanted and placed in the patient's chart. Nurses will be instructed via Item #20, Form F.

d. Nurses caring for brachytherapy patients will be assigned personnel monitoring devices. TLD finger badges will also be assigned to nurses who must provide extended personal care to the patient and to personnel handling sealed sources.

e. Sources will be transported from the storage site to place of use via the original shipping container or an equivalent lead container which is at least 1" thick.

f. At the initiation of treatment, an inventory will be performed on all therapy sources to insure total accountability. At the conclusion of treatment, another inventory will be performed to insure that all sources have been returned. (Refer to Item #20, Form B). In addition, a survey will be performed to ensure that all sources have been removed from the patient and that no sources remain in the patient's room or any other area occupied by the patient. At the same time, all radiation signs will be removed and all personnel monitoring devices assigned to nurses will be collected. Item #20, Form C will be used as a check-off procedure.

g. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after sources are implanted. Exposure rate measurements will be taken at the patient's 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 patient's chart. Refer to Item #20, Form D. Radiation levels in unrestricted areas will be maintained less than the limits specified in Section 20.105(b), 10 CFR, Part 20. (i.e., 2 mrems in any one hour or 100 mrems in any seven consecutive days).

h. Patients treated with sealed sources will be assigned to a private room.

i. For I-125 seeds, the Radiation Safety Program to be implemented will be that as outlined in the attached Guidelines listed as page 9 of this item.

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ITEM 20, FORM A

NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH RADIOACTIVE SOURCES

Patient's Name: _____

Room Number: _____ Physician's Name: _____

Isotope Activity: _____

Date and Time of Administration: _____

Date and Time Sources are to be removed: _____ Isotope: _____

_____

Exposure Rates in mR/hr

Bedside	3 feet from bed	10 feet from bed

(Complete checked items)

_____1. Wear personnel monitoring device
_____2. Wear rubber gloves
_____3. Place laundry in linen bag and save.
_____4. Housekeeping may not enter the room.
_____5. Patient may not have visitors
_____6. No pregnant visitors.
_____7. No visitors under 18 years of age.
_____8. A dismissal survey must be performed before patient is discharged.
_____9. Patient must have a private room.
_____10. Other instructions.

RSO _____, _____/_____
on duty/off duty telephone number

Prepared: 12/7/83
Lic. #40-12378-01

ITEM 20, FORM B

RECEIPT/SHIPMENT RECORD
RADIATION SOURCE THERAPY APPLICATIONS

Patient _____ _____ ID# _____ RM _____

PRE-TREATMENT INVENTORY

			Subtotal
_____	sources of	_____ mg	_____
_____	sources of	_____ mg	_____
_____	sources of	_____ mg	_____
_____	sources of	_____ mg	_____

Applicator(s) _____ Total _____ mg.

POST TREATMENT INVENTORY

_____	sources of	_____ mg	_____
_____	sources of	_____ mg	_____
_____	sources of	_____ mg	_____
_____	sources of	_____ mg	_____

Applicator(s) _____ Total _____ mg.

COMMENTS:

Certified by: _____ Date: _____

IMPORTANT: THIS RECORD MUST BE PERMANENTLY MAINTAINED

Prepared: 12/7/83
Lic. #40-12378-01

ITEM 20, FORM C

RAD. TION THERAPY SOURCE USAGE RECORD

Patient _____ ID# _____ RM _____

Ordering Physician _____

Applicator(s) used _____ Sources _____
mR/hr at 1 meter from applicator (not after loading) _____ mR/hr
Date and time of insertion _____ a.m./p.m. _____

	Yes	See Comments
Lead aprons not worn during insertion?	( )	( )
X-ray techs informed prior to obtaining localizing films?	( )	( )
Recovery room nurses instructed to use time/distance?	( )	( )
Patient assigned private room?	( )	( )
Exposure monitors issued to nursing personnel?	( )	( )
Safety instruction given to nurses?	( )	( )
Safety procedures placed in patients chart?	( )	( )
Caution sign placed on patient's chart?	( )	( )
Caution signs placed on patient's room door?	( )	( )
Nursing care rotated?	( )	( )
Known pregnant nurses not attending patient?	( )	( )
Pregnant visitors prohibited?	( )	( )
Visitors under 18 prohibited?	( )	( )
Safety survey performed and recorded?	( )	( )
Limits of nursing care time posted?	( )	( )
Removal notice posted in patient's chart prior to removal of all posted signs?	( )	( )
All signs removed?	( )	( )
Room surveyed and background rad. levels present?	( )	( )

Date/Time of Removal _____ a.m./p.m. _____
Applicator _____ Sources _____

COMMENTS:

CERTIFIED BY _____ Date _____

IMPORTANT: THIS RECORD MUST BE PERMANENTLY MAINTAINED

ITEM 20, FORM D

Radiation Hazard Evaluation Form

(to be filled out by Radiation Safety Officer for his use)

Name _____ Date and _____

Time of Death _____

Radioisotope _____

Amount administered _____

Route of Administration _____

Amount present _____

Distribution within body _____

_____

_____

_____

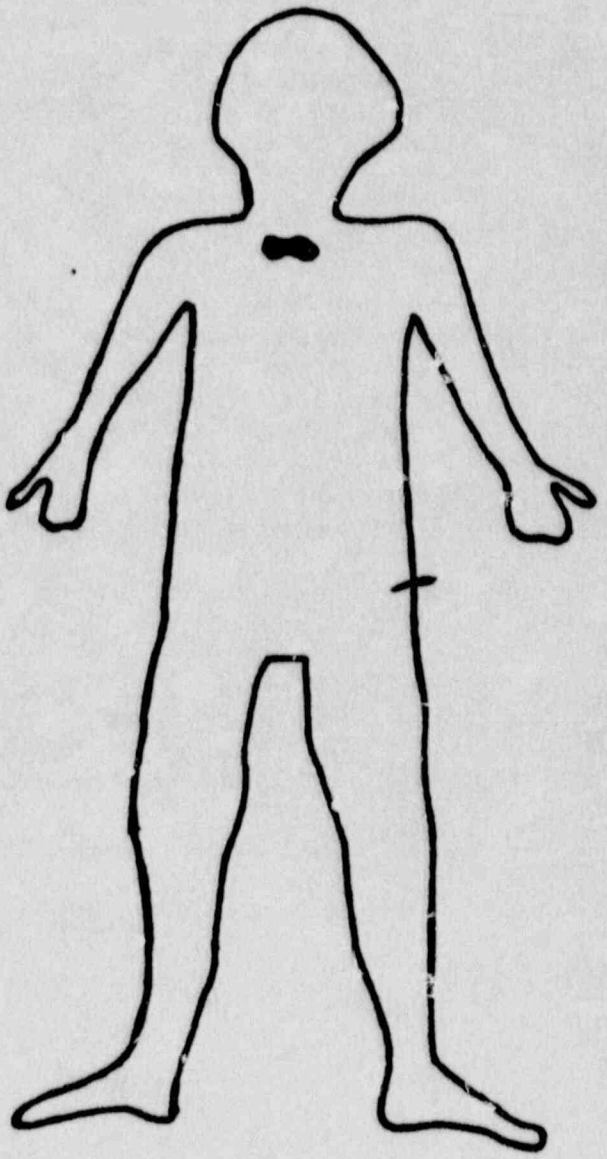
Indicate Distances _____

Suggest ring badges if exposure

0.25 R/hr @ 25 cm

See NCRP #37 p. 27.

Limit hand exposure to 1.5 Rems



Date of Survey _____

Instrument Used _____

Signed _____
Radiation Safety Officer

Date _____

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ITEM #20, FORM E

SAFETY PRECAUTIONS IN CLINICAL APPLICATIONS

I. Transfer and Preparation of Sources

a. Forms will be used to record pre and post-use inventory. (Item #20, Form B)
b. Sources will be dispensed with suitable protective devices and techniques, to include long forceps and TLD finger badges.

II. Application of Sources to the Patient

a. Distance, time, and when possible shielding, will be used to reduce radiation exposure to personnel attending the patient.
b. Appropriate signs will be used to indicate levels of radiation exposure.
c. Consideration will be given to the proximity of patients in adjoining rooms.
d. A patient being treated with brachytherapy sources will wear suitable identification.
e. Patient will not be allowed to leave his room unless accompanied by a hospital attendant.
f. Persons who have short-lived sources which are not removable from their bodies will be allowed to leave the hospital provided precautions necessary to prevent other persons from receiving more than the permissible dose of radiation are observed.

III. Removal of Sources from Patient

a. Sources will be removed with same safety precautions as those used in their application.
b. No linens, dressings, clothing or equipment will be removed from room until all sources are accounted for.
c. Assurance of complete removal of all sources will be obtained using a G-M survey meter held in the treatment area of the patient.
d. Should the patient die before brachytherapy is complete, the sources will be removed at once.

IV. Return of Sources to Storage

a. Following cleaning, sources will be returned immediately to their storage place.
b. Post-use inventory form will be completed to insure complete return of all sources to storage.
c. Inventory of all sealed sources will be performed on a quarterly basis and recorded.

ITEM #20, FORM F

1. Special restricts may be noted on the precaution sheet i the patients chart. Nurses should read these instructions before administering to the patient. Call the Nuclear Medicine Department if you have any questions about the care of these patients.

2. Nurses should spend only the minimum necessary time near a patient for routine nursing care, but must obtain and wear a personnel monitoring device.

3. When a nurse receives an assignment to a therapy patient, a film or TLD badge should be obtained immediately from the Nuclear Medicine Department. The badge shall be worn only by the nurse to whom it is issued and shall not be exchanged between nurses.

4. Pregnant nurses should not be assigned to the personal care of these patients.

5. Never touch needles, capsules or containers holding brachytherapy sources. If a source becomes dislodged, use long forceps and put it in the corner of the room or in the shielded container provided; contact the Nuclear Medicine Department at once.

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

7. Perineal care is not given during gynecologic treatment; the perineal pad may be changed when necessary, unless orders to the contrary have been written.

8. Surgical dressings and bandages used to cover the area of needle insertion may be changed only by the attending physician or radiologist, and MAY NOT BE DISCARDED until directed by the radiologist. Dressings should be kept in a basin until checked by the radiologist or member of the Nuclear Medicine Department.

Special orders will be written for oral hygiene for patients with oral implants.

9. No special precautions are needed for sputum, urine, vomitus, stools, dishes, instruments, utensils or bedding unless specifically ordered.

10. These patients must stay in bed unless orders to the contrary are written.

11. Visitors will be limited to those 18 years of age or over, unless other instructions are noted on the precaution sheet in the patient's chart.

12. Visitors should sit at least three feet from the patient and should remain no longer than the times specified on the form posted on the patient's door and in his chart.

13. No nurse, visitor or attendent who is pregnant should be permitted in the room of a patient while brachytherapy sources are implanted in the patient. Female visitors should be asked whether they are pregnant.

14. Emergency Procedures:

a. If an implanted source becomes loose or separated from the patient, or

b. If the patient dies, or

c. If the patient requires emergency surgery, immediately call

_____. Phone No. (days)_____

(nights)_____.

15. At the conclusion of treatment, call the Radiation Safety Officer and request that the patient and room be surveyed to be sure all radioactive sources have been removed.

ITEM #20

GUIDELINES

RADIATION SAFETY PRECAUTIONS FOR THERAPEUTIC USE OF I-125 SEEDS

GENERAL

1. Personnel who prepare, insert or retrieve I-125 seeds must wear a finger or wrist type monitoring device to monitor radiation exposure to the extremities.

2. To maintain accountability of the seeds, a source inventory should be performed at the following times: a) when the seeds are removed from storage; b) before and after the seeds are loaded in the applicator; c) before and after surgery.

3. In transporting seeds from storage - preparation areas to the place of use, adequate shielding must be employed to insure compliance with 10 CFR 20.105(b).

INSTRUCTIONS TO NURSES (for hospitalized patients)

1. Nurses will be given a description of the size and appearance of the seeds.

2. Handle dislodged seeds with a spoon or forceps, never by hand. Place the dislodged seeds in a shielded container provided by the Radiation Safety Officer.

3. Surgical dressings and bandages used to cover the area of the insertion may be changed only by the attending physician. Dressings should be kept in a basin until checked by the Radiation Safety Officer.

4. All bed linen must be checked with a radiation survey meter before being removed from the patient's room to insure that no dislodged sources are inadvertently removed.

5. No special precautions are needed for sputum, urine, vomitus, stools, dishes. instruments, or utensils unless specifically ordered.

6. Emergency Procedures

   a) If a seed becomes loose or dislodged from the patient, or

   b) If the patient dies, or

   c) If the patient requires emergency surgery, immediately call

   _____

   Telephone No. (Days) _____ (Nights) _____

7. When the patient is discharged, call the Radiation Safety Officer and request a radiation survey of the room.

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PROCEDURES AND PRECAUTIONS FOR USE OF XENON-133

I. Quantities to be Used:

A. Patient information

1. 10 studies per week
2. 10 mCi per patient

B. Possession limit: 300 mCi

II. Use and Storage Areas:

A. The hot lab shown in the attached diagram will be used to store and dispose of all the Xenon received by decay. The hot lab will be used to prepare individual doses and assay them prior to use. The camera room will be used for all patient administrations and for the imaging procedures.

Xenon will be stored in its original shipping safe until used. Accessory lead shielding will be used (i.e., 1/8" - 1/4" lead vials or sheet) whenever survey measurements at the face of the hot lab hood are 0 mR/hr or more. The closest unrestricted area is a secretarial office, approximately 1.0 feet away. The wall board construction, cabinet steel wall, distance and accessory lead shielding will reduce levels in this room to well below 0.6 mR/hr during the manipulation and disposal of the gas.

B. The exhaust through the hood in the hot lab has a flow rate of 600 cfm. The air supply to the hot lab has a flow rate of 330 cfm. This ensures a constant negative pressure in the hot lab at all times.

The exhaust system in the camera room has a flow rate of 900 cfm. The air supply to the camera room has a flow rate of 400 cfm.

C. With the roof fans operating under aforementioned conditions, the designated rooms are at negative pressure. The air flow will be toward these exhaust systems and directly towards the roof.

III. Procedures for Routine Use: (Camera Room)

A. In the camera room the sliding door will be drawn closed. One of the doors will be adjusted so a sensible draft is felt at the opening to allow for make-up air.

The patient will be fitted with the rebreathing and collection apparatus, and then instructed as to the procedure. Trial runs without Xenon will be conducted whenever patient condition permits.

The Xenon will be administered and three to four views obtained. During the washout phase, the Xenon will be collected in the gas trap until practically no Xenon remains in the patient as evidenced by the camera persistence scope.

Whole body film badges and TLD finger badges will be worn by occupational personnel handling Xenon. Visitors will be excluded from the camera room during Xenon use unless their presence is required for patient care or desired for educational or observational purposes.

B. An activated charcoal gas trap will be used for patient studies. A Pulmonex 130-500 delivery system with gas trap or equivalent is used. This system will be used in accordance with manufacturer's instructions.

Face masks that cover both mouth and nose or nose clamps for use with the mouthpiece delivery systems will be employed to reduce leakage of the Xenon into the camera room.

C. On a semi-annual basis, the exhaust flow rates from the camera rooms and the hot lab will be checked to assure that a change in exhaust rate has not occurred and a check of the air supply will be made to assure negative pressure in the rooms.

IV. Emergency Procedures:

In the event there is an accidental patient associated loss of Xenon into the camera room, the exhaust system will clear the room to levels less than 1×10^{-5} uCi/ml in less than 10 minutes.

For Camera Room:

Activity per loss (A) = 10 mCi = 10^4 uCi

Room Volume (V) = 18' x 10' x 9'

= 1620 $ft.^3$

= 4.6×10^7 ml

Clearance rate (λ) = $\frac{900 \text{ cfm}}{1620 \text{ ft.}^3}$

= 55% $min.^{-1}$

Initial Concentration (C_o) = $\frac{10^4 \text{uCi}}{4.6 \times 10^7 \text{ ml}}$

= 2.17×10^{-4} uCi/ml

Evacuation time (t) = ten minutes

Final Concentration C = $C_o e^{-\lambda t}$

= $(2.17 \times 10^{-4}) e^{-.55 \times 10}$

= 8.9×10^{-7} uCi/ml

This value is less than 1×10^{-5} uCi/ml permitted for a restricted area.

For Hot Lab:

Activity per loss (A) = 10 mCi = 10^4 uCi

Room Volume (V) = 10' x 12' x 9.5'

= 1140 $ft.^3$

= 3.2×10^7 ml

Clearance rate ( ) = $\frac{600 \text{ cfm}}{1140 \text{ ft.}^3}$

= .53 min.$^{-1}$

Initial Concentration (C_o) = $\frac{10^4 \text{ uCi}}{3.2 \times 10^7 \text{ ml}}$

= 3.1×10^{-4} uCi/ml

Evacuation time (t) = ten minutes

Final concentration (C) = $C_o e^{-t}$

= $(3.1 \times 10^{-4}) e^{-.53 \times 10}$

= 1.5×10^{-6} uCi/ml

This value is less than 1×10^{-5} uCi/ml.

All unnecessary personnel will evacuate the room if patient care is not compromised. The camera room/hot lab door will be guarded against inadvertant entry during this time period.

A survey meter will be placed on the floor of either room so it can be observed from the door When exposure levels reach background, the room may be re-entered. Alternatively, the camera may be turned on periodically to collect counts for a present time. When background levels are reached, the room may be re-entered.

V. Air Concentration of Xe-133 in Restricted Areas:

A. Camera Room

1. It is estimated that 100 mCi will be used per week (A).
2. 15% of the Xenon will be lost into the camera room due to patient associated losses and the inability of the gas trap to trap 100% of the Xenon (f).
3. A room exhaust of 900 cfm will be used in this calculation for volume (V).

V = 900 cfm x 6.797×10^7 ml/40 hr wk.

V = 6.1×10^{10} ml/wk.

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4. The average concentration (C) will be:

$$C = \frac{A}{V} \times f$$

$$= \frac{100 \text{ mCi wk}^{-1} \times 1 \times 10^{3} \text{ uCi/mCi} \times .15}{6.1 \times 10^{10} \text{ ml/wk}}$$

$$= 2.5 \times 10^{-7} \text{ uCi/ml}$$

This value is less than that required for restricted areas, 1×10^{-5} uCi/ml.

B. Hot lab:

1. It is estimated that 100 mCi will be used per week (A).
2. 5% of the Xenon will be lost into the hot lab due to leakage of the sources in storage (f).
3. The hot lab air exhaust is 600 cfm.

$$V = 600 \text{ cfm} \times 6.797 \times 10^{7} \text{ ml/40 hr wk/cfm}$$

$$V = 4.1 \times 10^{10} \text{ ml/wk}$$

4. The average concentration (C) will be:

$$C = \frac{A}{V} \times f$$

$$= \frac{100 \text{ mCi} \times 1 \times 10^{3} \text{ uCi/mCi} \times .05}{4.1 \times 10^{10} \text{ ml}}$$

$$= 1.2 \times 10^{-7} \text{ uCi/ml}$$

This value is also less than that required for restricted areas.

VI. Methods of Xenon-133 Disposal:

A. All Xenon unused will be disposed of by decay in storage in the hood. Containers and apparatus will be surveyed unshielded with the low level survey meter held on contact with source containing device. If levels are the same as background, the containers will be disposed after defacing the labels.

All escaped Xenon will be vented through the exhaust system.

1. It is anticipated that 1.04 Curies (20% of 5.2 Ci/yr) will be vented to the atmosphere per year. This includes activity liberated as accidental losses and leakage.

2. An air flow rate of 600 cfm in the hot lab and 900 cfm in the camera room may be used in the calculation:

3. Air volume per year is: (V)

$$V_1 = 600 \text{ cfm} \times 1.484 \times 10^{10} \text{ ml/yr/cfm}$$

$$\underline{+V_2} = 900 \text{ cfm} \times 1.484 \times 10^{10} \text{ ml/yr/cfm}$$

$$V = 2.2 \times 10^{13} \text{ ml/yr}$$

4. The average concentration of air to the environment is: (C)

$$C = \frac{A}{V}$$

$$= \frac{1.04 \text{ Ci/yr} \times 10^{6} \text{ uCi/Ci}}{2.2 \times 10^{13} \text{ ml/yr}}$$

$$= 4.7 \times 10^{-8} \text{ uCi/ml}$$

This value does not exceed the quantity 3×10^{-7} uCi/ml permitted in 10 CFR 20.106 for unrestricted areas.

B. At intervals not to exceed 20 patients, the gas trap will be evaluated for trapping efficiency. A reading

with a low level G-M meter will be taken at the patient's ventilation tubing during equilibrium. This will be the reading (A) for a pre-trap measurement for this study. A second reading (B) will be taken at the trap exhaust port during the washout phase. This will be the post trap measurement. If reading "B" is more than 10% of reading "A", the trap will be considered less than 90% efficient and the cartridge will be replaced.

Saturated filters will be stored for decay in the cabinet such that levels do not exceed 2.0 mR/hr at the exterior. A survey will be conducted without the benefit of shielding and if levels are those of background, the filter may be discarded.

Model Program for Maintaining Occupational Radiation Exposures at Medical Institutions ALARA

Sioux Valley Hospital
(Licensee's Name)

12/7/83
(Date)

I. 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 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).

b. We will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

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 judgement, 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.

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1 Private practice physician licenses do not include a RSC.

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II. 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 assure 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 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.

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.

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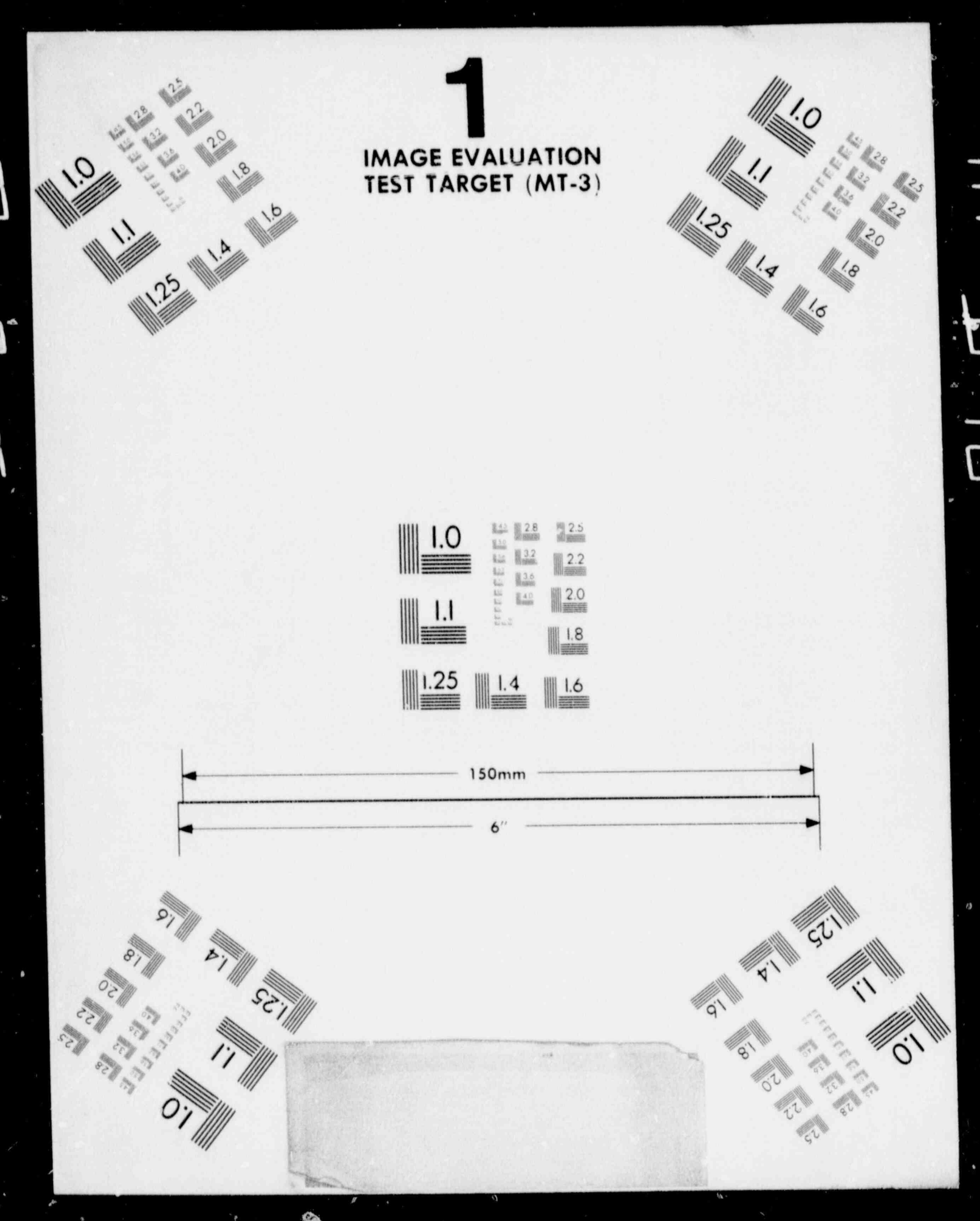
[2] The RSO on private practive physician licenses will assume the responsibilities of the RSC under Section II.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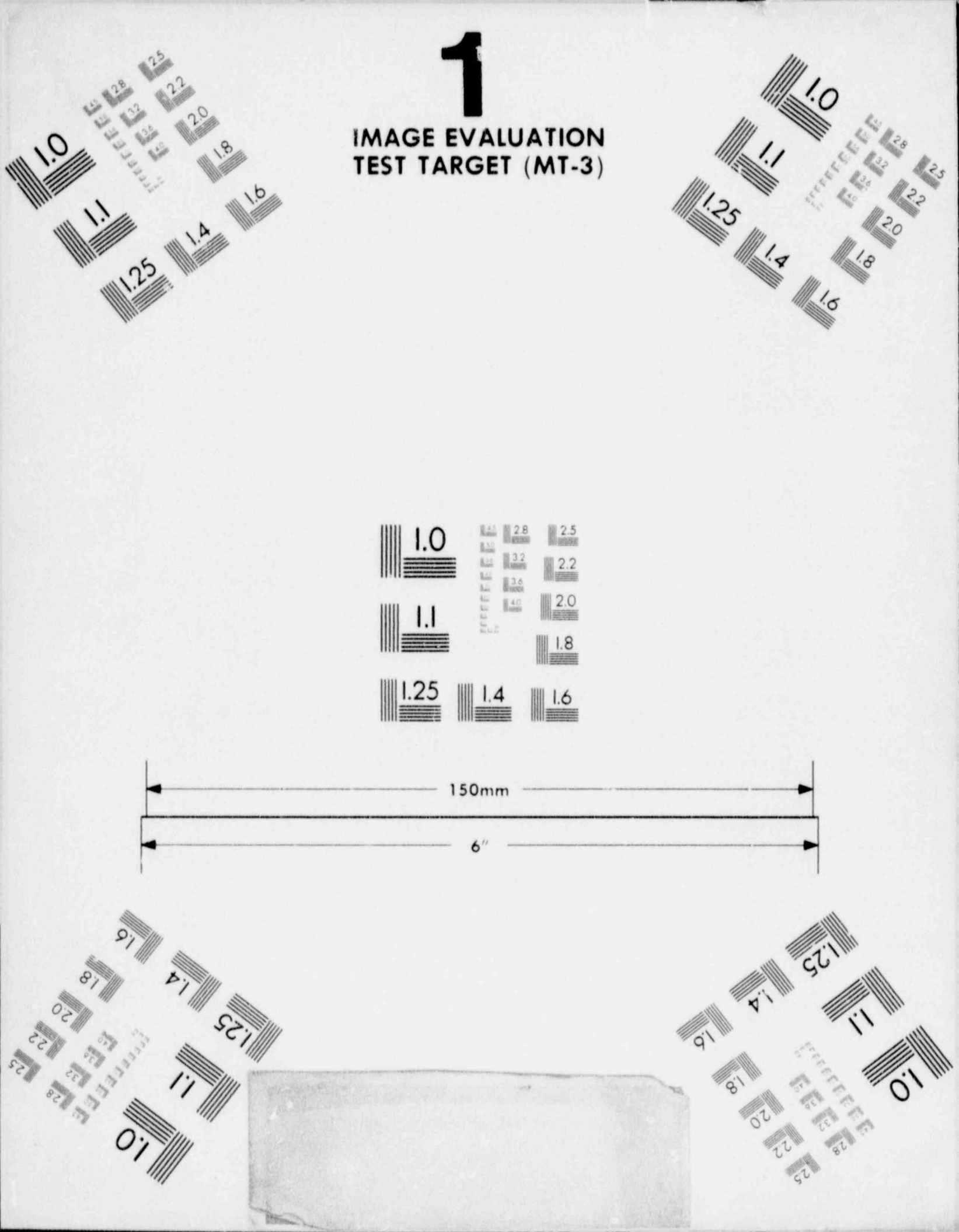
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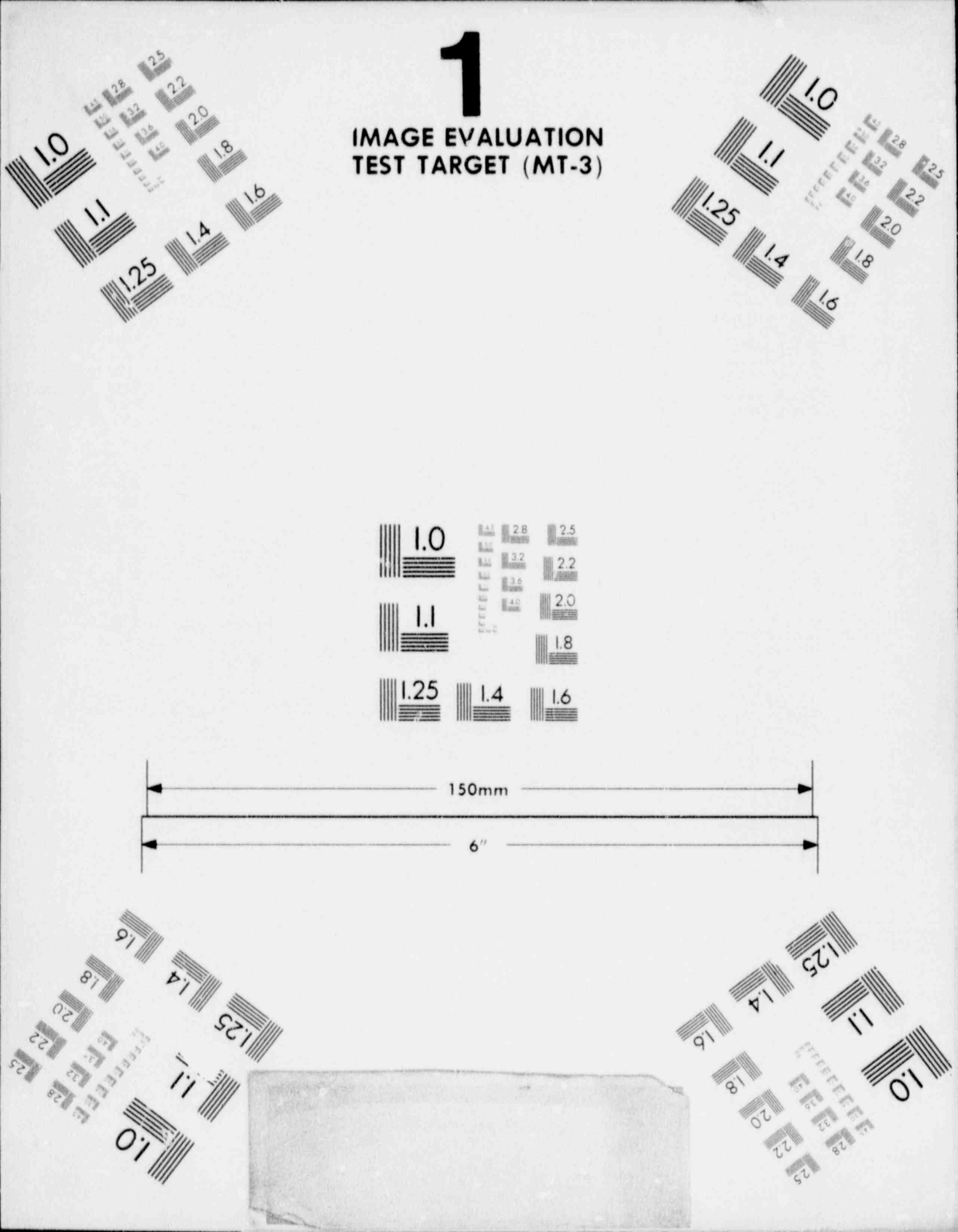
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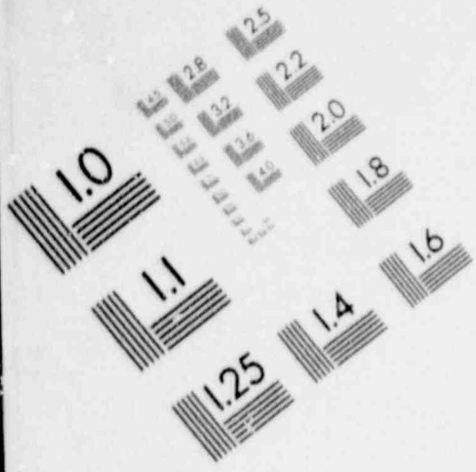

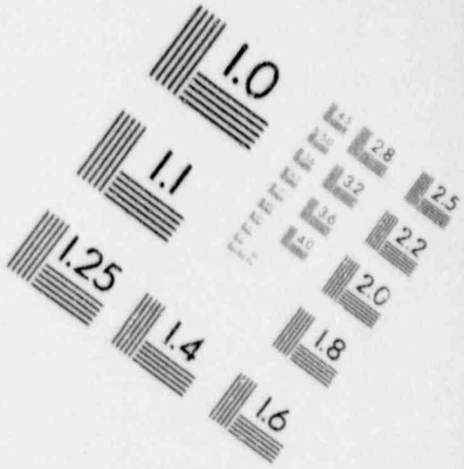

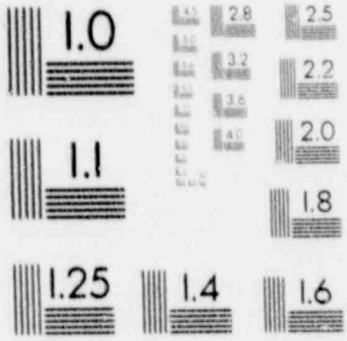

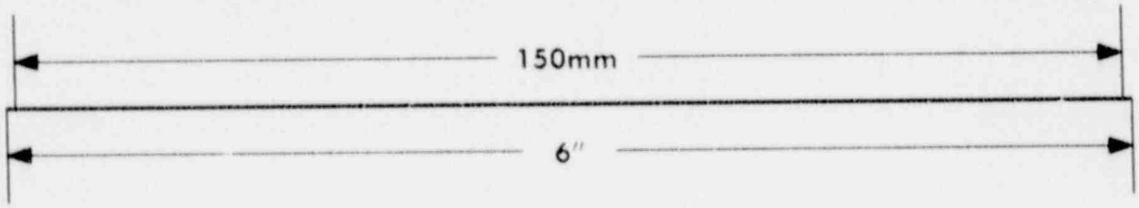

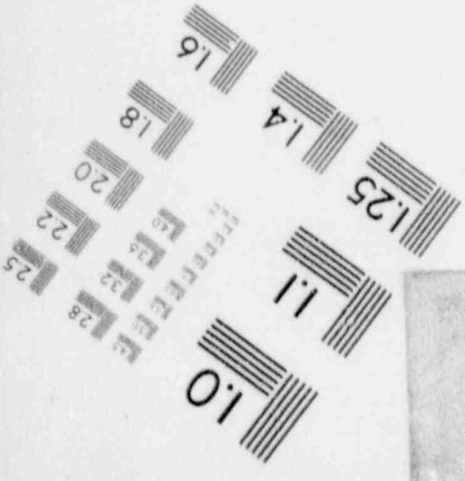

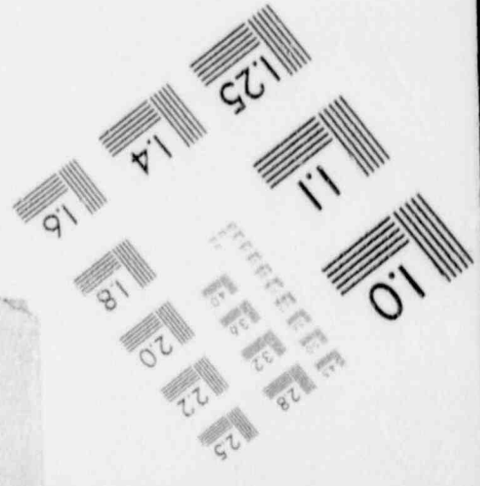

2. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table I below are exceeded. The principle purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and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

III. 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 paragraph VI of this program.

3. Quarterly review of records of Radiation Level Surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for an ALARA Program

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

2. The RSO will assure 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.

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[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 investigation.

c. Cooperative Efforts for Development of ALARA Procedures

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 encourage the 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, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

IV. 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 the Authorized User to Those He Supervises

1. The authorized user will explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he surpervises.

2. The authorized user will ensure that those under his supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

V. Persons Who Receive Occupational Radiation Exposure

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

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

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

This institution (or private practive) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Committee and/or the Radiation Safety Officer. The Investigational Levels that we have adopted are listed in Table I below. These levels apply to the exposure of individual workers.

TABLE 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 is required by 10 CFR 20, §20.401. The following actions will be taken at the Investigational Levels as stated in Table 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 I 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. He will report the results of his 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, take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form MRC-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 Committee 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. Re-establishment of an individual occupational worker's Investigational Level II Above That Listed in Table I.

In cases where a worker's or a group of worker's 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 Radiation Safety Committee will review the justification for, and will approve, all revisions of Investigational Levels II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph c above will be followed.

VII. Signature of Certifying Official[4]

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

_____
Signature

_____
Name (print of type)

_____
Title

Institution (or Private Practice) Name and Address:

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

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