13-18845-01
030-14254

FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved GAO R0557

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 License 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

Goshen General Hospital
200 High Park Avenue
Goshen, Indiana 46526

TELEPHONE NO.: AREA CODE (219) 533 2141

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

David P. Mihalic, Consultant
Nuclear Medicine Associates, Inc.

TELEPHONE NO.: AREA CODE (216) 663 7000

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

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 13-18845-01
c. ☐ RENEWAL OF LICENSE NO. _____

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

Amend to add:

Jeanne Grossnickle, M.D.

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

Refer to NRC license #13-18845-01.

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		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
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		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
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		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.	X	1200

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
The purpose of this amendment is to: 1. Add Jeanne Grossnickle, M.D. as an authorized user. 2. Add Calicheck kit. 3. Change in procedure for doing area surveys and analyzing wipe tests. 4. Add the use of Xenon for pulmonary ventilation studies. 5. Change in film badge service. 6. Change in equipment. 7. Add ALARA program.			

License Fee Information
next page
on Reverse Side

8506040101 850515
REG3 LIC30
13-18845-01 PDR

OCT 25 1982

CONTROL NO. 07013

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. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE	**15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL** *(Check One)*
☐ Names and Specialties Attached; and	☐ Appendix G Rules Followed; or
☐ Duties as in Appendix B; or *(Check One)*	☐ Equivalent Rules Attached
☐ Equivalent Duties Attached	**16. EMERGENCY PROCEDURES** *(Check One)*
8. TRAINING AND EXPERIENCE	☐ Appendix H Procedures Followed; or
☒ Supplements A & B Attached for Each Individual User; and	☐ Equivalent Procedures Attached
☐ Supplement A Attached for RSO.	**17. AREA SURVEY PROCEDURES** *(Check One)*
9. INSTRUMENTATION *(Check One)*	☐ Appendix I Procedures Followed; or
☐ Appendix C Form Attached; or	☒ Equivalent Procedures Attached
☒ List by Name and Model Number	**18. WASTE DISPOSAL** *(Check One)*
10. CALIBRATION OF INSTRUMENTS	☐ Appendix J Form Attached; or
☐ Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	☐ Equivalent Information Attached
☐ Equivalent Procedures Attached; and	**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)*
☐ Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	☐ Appendix K Procedures Followed; or
☒ Equivalent Procedures Attached	☐ Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	**20. THERAPEUTIC USE OF SEALED SOURCES**
☐ Description and Diagram Attached	☐ Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	☐ Appendix L Procedures Followed; or *(Check One)*
☐ Description of Training Attached	☐ Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	**21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)**
☐ Detailed Information Attached	☒ Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	**22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS**
	☐ Detailed Information Attached
☐ Appendix F Procedures Followed; or	**23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b**
☐ Equivalent Procedures Attached	☐ Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Siemens Radiographics	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Siemens Radiographics	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

Applicant... 11837
Check No... 001284
Amount/Fee Category... $40 7B
Type of Fee... Amendment
Date Check Rec'd... 11/2/82
Received By... Brown

RECEIVED BY LFMB
Date... 11/2/82
Log... No PG 5 Reg III
By... Brown
Orig. To...
Action Compl... 11/3/82

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: $ 40.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
X Frank Yagel

(1) NAME *(Type or Print)*
X FRANK YAGEL

(2) TITLE
Administrator

c. DATE
X 10-21-82

FORM NRC-313M (8-78)

CONTROL NO. 07013

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 Form NRC-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 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 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.

CURRICULUM VITAE

Jeanne L. Sankey, M.D.

ADDRESS: 3482 St. Albans
Cleveland Heights, Ohio 44121

TELEPHONE: (216) 382-2382 (Home)
(216) 444-6621 (Business)

PERSONAL: Birthdate: September 8, 1951
Sidney, Ohio
Married
Spouse's Occupation: Ophthalmologist
One child

EDUCATION:

DePauw University, Greencastle, Indiana
B.A. - 1973

Case Western Reserve University, Cleveland, Ohio
M.D. - 1978

POST DOCTORAL TRAINING:

Cleveland Clinic Foundation, Cleveland, Ohio
Internship - July, 1978 to June, 1979
6 months Internal Medicine, 6 months Radiology

Cleveland Clinic Foundation, Cleveland, Ohio
Radiology Residency - July, 1979 to Present

Diagnostic Radiology Training:
Nuclear Medicine (3 months), Angiography (5 months), Neuroradiology (4 months), Computed Tomography (2 months), Ultrasound (3 months), Pediatrics (2 months)

HONORS:

National Merit Scholar
Phi Beta Kappa
Alpha Omega Alpha

BOARD CERTIFICATIONS:

Diplomate of National Board of Medical Examiners - June 1979
Candidate for Diagnostic Radiology Certification,
Written Examination - September, 1981 - Passed

12/81

GOSHEN GENERAL HOSPITAL

Goshen, Indiana

APPLICATION FOR APPOINTMENT TO THE MEDICAL STAFF

IDENTIFYING INFORMATION

LAST NAME: GROSSNICKLE	FIRST NAME: JEANNE	INITIAL: L.	BIRTHPLACE: SIDNEY, OHIO		DATE OF BIRTH: 9-8-51
OFFICE ADDRESS	CITY	STATE	ZIP CODE	AREA CODE	TELEPHONE
HOME ADDRESS: 3482 ST. ALBANS	CITY: CLEVELAND HTS.	STATE: OHIO	ZIP CODE: 44121	AREA CODE: 216	TELEPHONE: 382-2382
CITIZENSHIP: U.S.A.	MARITAL STATUS: ☒ M ☐ S ☐ W ☐ D		NAME OF SPOUSE: BRUCE		

PRACTICE LIMITED TO: DIAGNOSTIC RADIOLOGY

OTHER MEDICAL INTERESTS IN PRACTICE, RESEARCH, ETC.:

PRACTICING WITH WHOM AND NATURE OF AFFILIATION: S. D. GUNDERSON, M.D. PART TIME

MEDICAL EDUCATION

COLLEGE OR UNIVERSITY: DEPAUW UNIVERSITY	DEGREE: B.A.	
ADDRESS: GREENCASTLE, INDIANA		DATE OF GRADUATION: 5-73

MEDICAL EDUCATION

MEDICAL SCHOOL: CASE WESTERN RESERVE UNIVERSITY	DEGREE: M.D.	
ADDRESS: ADELBERT RD. CLEVELAND OHIO		DATE OF GRADUATION: 5-31-78

INTERNSHIP

HOSPITAL: CLEVELAND CLINIC FOUNDATION	ADDRESS: EUCLID AVENUE, CLEVELAND OHIO 44106	DATES: 7-1-78 TO 6-30
TYPE OF INTERNSHIP: SIX MONTHS MEDICINE, 6 MOS. RADIOLOGY	SPECIAL	DATES

RESIDENCIES

FELLOWSHIPS, PRECEPTORSHIPS, TEACHING APPOINTMENTS, POSTGRADUATE EDUCATION (CHRONOLOGICAL ORDER: DATES, LOCATIONS, CHIEFS OF STAFF)

LOCATION	DATES
RADIOLOGY RESIDENT, CLEVELAND CLINIC FOUNDATION	7-1-79 TO 8-31-

AFFILIATIONS

PRESENT CAPACITY WITH THIS HOSPITAL	DATES

LIST ALL PRESENT AND PREVIOUS HOSPITAL AFFILIATIONS, IN CHRONOLOGICAL ORDER (INCLUDE ASSISTANTSHIPS AND APPOINTMENTS)

NAME AND LOCATION OF HOSPITAL	CAPACITY	DATES

BIOGRAPHY

ON SEPARATE SHEET, FURNISH A LIST OF SCIENTIFIC PAPERS OR ESSAYS YOU HAVE WRITTEN, AND A LIST OF SCIENTIFIC MEETINGS YOU HAVE ATTENDED DURING PREVIOUS THREE YEARS (INCLUDE REPRINTS).

MEMBERSHIP

ARE YOU A MEMBER OF THE _____ COUNTY MEDICAL ASSOCIATION? ☐ YES ☒ NO

PROFESSIONAL SOCIETIES

DO YOU HAVE AN APPLICATION PENDING? ☐ YES ☒ NO

DO YOU INTEND TO APPLY? ☒ YES ☐ NO

IF MEMBER PAST OR PRESENT OR APPLICANT TO OTHER COUNTY, STATE OR NATIONAL SOCIETY, GIVE NAME

FELLOWSHIP

AMERICAN COLLEGE OF	DATE
AMERICAN COLLEGE OF	DATE
MEMBER OF AMERICAN ACADEMY OF FAMILY PRACTICE? ☐ YES ☐ NO	DATE

FELLOWSHIP IN OTHER SPECIALTY COLLEGES

CERTIFICATION

CERTIFIED BY AMERICAN BOARD OF (NAME OF BOARD)		DATE
BOARD QUALIFIED (NAME OF BOARD)		DATE
SPECIALTY BOARD STATUS (NAME OF BOARD)	ARE YOU CERTIFIED? ☐ YES ☐ NO	DATE

DICAL UCATION

ON SEPARATE SHEET, LIST ALL POSTGRADUATE ACTIVITIES WHICH YOU HAVE ATTENDED, OR FOR WHICH YOU HAVE RECEIVED CREDIT IN THE PAST TWO YEARS.

ENSING

MEDICAL LICENSE (NAME OF STATE AND COUNTY)	DATE	LICENSE NO.	REGISTRATION NO.
TEMPORARY OHIO LICENSE			
OTHER MEDICAL LICENSE (NAME OF STATE AND COUNTY) INDIANA STATE MEDICAL LICENSE HAS BEEN APPROVED — LICENSE # PENDING	DATE	LICENSE NO.	
OTHER MEDICAL LICENSE (NAME OF STATE AND COUNTY)	DATE	LICENSE NO.	

DICAL FERENCES

IF POSSIBLE, INCLUDE TWO MEMBERS OF CLEVELAND CLINIC FOUNDATION HOSPITAL MEDICAL STAFF, OTHER THAN THOSE WHO MIGHT BE LISTED UNDER "AFFILIATIONS." NOTE: REFERENCES WILL BE EVALUATED PRIMARILY BY THE EXTENT OF DIRECT CLINICAL OBSERVATION AND OTHER WORK WITH THE APPLICANT.

DOCTOR	ADDRESS	
MEREDITH WEINSTEIN, MD	CLEVELAND CLINIC FOUNDATION,	EUCLID AVENUE
DOCTOR: MARGARET ZELCH, MD	ADDRESS: CLEVELAND CLINIC FOUNDATION	CLEVELAND, OHIO
DOCTOR: A. LALLI, MD	ADDRESS: CLEVELAND CLINIC FOUNDATION	44106

EVIOUS ACTICE

INCLUDE MILITARY EXPERIENCE. LIST IN CHRONOLOGICAL ORDER.

LOCATION	DATES
LOCATION	DATES
LOCATION	DATES

NSWER TO ANY OF THE FOLLOWING THREE QUESTIONS IS "YES", PLEASE GIVE FULL DETAILS ON SEPARATE SHEET OF PAPER.

A. Has your license to practice medicine in any jurisdiction ever been limited, suspended or revoked? ... ☐ Yes ☒ No

B. Have your privileges at any hospital ever been suspended, diminished, revoked or not renewed? ..... ☐ Yes ☒ No

C. Have you ever been denied membership or renewal thereof, or been subject to disciplinary action in any medical organization? ..... ☐ Yes ☒ No

EREBY LY TO THE PITAL FOR POINTMENT

- ☒ TO THE ATTENDING STAFF IN THE DEPARTMENT OF RADIOLOGY
- ☐ TO THE CONSULTING STAFF ASSIGNED IN THE DEPARTMENT OF
- ☐ OTHER (SPECIFY)

VILEGES SIRED

- ☐ MEDICAL ☐ SURGICAL ☐ OBSTETRICAL ☐ GYNECOLOGICAL ☐ PEDIATRIC ☐ ORTHOPEDIC ☐ DENTAL
- ☒ OTHER (SPECIFY) DIAGNOSTIC RADIOLOGY, NUCLEAR MEDICINE, ULTRASOUND
- ☐ SPECIAL PROCEDURES (SPECIFY)
- ☐ SPECIALTY OR SUB-SPECIALTY CONSULTATION (SPECIFY)

IN MAKING APPLICATION FOR APPOINTMENT TO THE MEDICAL STAFF OF THIS HOSPITAL I AGREE TO ABIDE BY ITS BYLAWS AND BY SUCH RULES AND REGULATIONS AS IT MAY FROM TIME TO TIME ENACT.

Jeanne L Hrazanickle M.D.

CONTROL NO. 07013

FORM NRC-313M-SUPPLEMENT A (8-78)

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
Jeanne Grossnickle, M.D.	OHIO

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
Radiology		

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	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Cleveland Clinic Foundation 9500 Euclid Avenue Cleveland, Ohio 44106	50	50
b. RADIATION PROTECTION	Training was between	15	15
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	July 1, 1978 and	10	10
d. RADIATION BIOLOGY	June 30, 1982	10	10
e. RADIOPHARMACEUTICAL CHEMISTRY		15	15

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Tc-99m Tl-201 I-131 Xe-133 Yb-169 Ga-67	100 mCi 20 mCi 5 mCi 100 mCi 10 mCi 5 mCi	Cleveland Clinic Foundation 9500 Euclid Avenue Cleveland, Ohio 44102	3½ months full time during above dates	Routine diagnostic clinical exams

William Pavlicek

William Pavlicek, M.S., CHP
Radiation Safety Officer

FORM NRC-313M Supplement A

CONTROL NO. 07013

FORM NRC-313M-SUPPLEMENT B
(8-78)

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. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Jeanne Grossnickle, M.D.

STREET ADDRESS

3482 St. Albans

CITY	STATE	ZIP CODE
Cleveland Heights	Ohio	44121

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
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION	17	
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES	3	
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING	68	
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY	4	
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES	121	
OTHER		713	
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING	443	
	LUNG IMAGING	121	
	BONE IMAGING	710	
OTHER	Tl-201 Heart Imaging	525	

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		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR		
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS		
Other GA-67	Tumor Imaging	63	

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

Between 7/1978 and 6/1982 a total of 500 hours of clinical radioisotope training.

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

a. NAME OF SUPERVISOR
S.A. Cook, M.D.

b. NAME OF INSTITUTION
The Cleveland Clinic Foundation

c. MAILING ADDRESS
9500 Euclid Avenue

d. CITY
Cleveland, Ohio 44106

5. MATERIALS LICENSE NUMBER(S)
34-00466-01

6. PRECEPTOR'S SIGNATURE
x Sebastian A Cook

7. PRECEPTOR'S NAME *(Please type or print)*
Sebastian A. Cook, M.D.

8. DATE
x Sebastian A Cook 5/6/82

FORM NRC-313M-SUPPLEMENT B
(8-78)

CONTROL NO. 07013

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		
I-125 or Ir-192	INTERSTITIAL TREATMENT		
Co-60 or Cs-137	TELETHERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99/ Tc-99m	GENERATOR	5	
Sn-113/ In-113m	GENERATOR		
Tc-99m	REAGENT KITS	5	
Other			

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

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

a. NAME OF SUPERVISOR
Shaun D. Gunderson, M.D.

b. NAME OF INSTITUTION
Goshen General Hopsital

c. MAILING ADDRESS
200 High Park Avenue

d. CITY
Goshen, Indiana

5. MATERIALS LICENSE NUMBER(S)
13-18845-01

6. PRECEPTOR'S SIGNATURE
Shaun D. Gunderson, M.D.

7. PRECEPTOR'S NAME *(Please type or print)*
Shaun D. Gunderson, M.D.

8. DATE
10/4/82

FORM NRC-313M-SUPPLEMENT 8
(8-78)

RADIATION DETECTION INSTRUMENTS

TYPE OF INSTRUMENT	MANUFACTURER	MODEL #	No.	MAXIMUM RANGE MINIMUM RANGE
G-M Survey Meter	Dosimeter Corp. of America	3700	1	0-0.5 mR/hr 0-5.0 mR/hr 0-50 mR/hr
G-M Survey Meter/ Ionization Meter	Eberline	E-520	1	0-0.2 mR/hr 0-20 mR/hr 0-200 mR/hr 0-2000 mR/hr
Dose Calibrator	Capintec	CRC-30	1	
Scintillation Probe and Counter	Picker	Spectroscaler IV with 2" Probe	1	
Gamma Camera	Picker	Dynacamera V	1	

Item #9
Prepared 10/13/82
Lic. #13-18845-01

Addendum to Item #10 for NRC License #13-18845-01

As an alternative to our present procedure, the dose calibrator can be checked for activity linearity with the use of a device called Calicheck from Calcorp, Inc. The manufacturer's instructions for use, as revised March 2, 1982, will be followed. Test results will be recorded and retained for inspection. Corrective action as stated in our license application will be followed if unacceptable linearity is demonstrated.

Prepared October 13, 1982

SURVEY PROCEDURES

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

B. Laboratory areas where only small quantities of radioactive material are used (less than 200 uCi) 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 0.1 mR/hr.

2. A series of wipe tests to measure contamination levels. Analysis of wipe tests will be performed using a 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. Move to an area exhibiting natural background.
   d. Determine the operational status of the survey meter.
   e. Adjust response time to the longest time constant (if applicable).
   f. Select most sensitive range.
   g. Turn beta shield on probe to open position, if applicable.
   h. Wait 40 seconds, or four times the time constant, if applicable.
   i. Read and record background.
   j. Place smear on contact with open portion of probe.
   k. Wait 40 seconds, or four times the time constant, if applicable.
   l. 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.

Item #21

Procedures and Precautions for the Use of Radioactive Gasses

I. Quantities:

A. An average of 10 exams per week may be done.

B. Average activity per exam is 20 mCi.

C. Possession limit of 1200 mCi is authorized.

II. Use and Storage:

A. Xenon-133 will be stored in the fume hood located in the hot lab. It will be stored in its original shipping container 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 hood are 2.0 mR/hr or more.

B. The hot lab fume hood where Xenon is stored is under negative pressure. It is continuously exhausted at 165 cfm. Air is supplied to the hot lab at a rate of 150 cfm, therefore the fume hood and entire hot lab are under negative pressure at all times.

C. The exhaust system for Goshen General Hospital is handled by a two-speed fan mounted at rooftop and greater than 10 meters away from any potential re-entry port to the hospital.

The two fan speeds are such that on low speed (normally on continuously), the ventilation rate is 865 cfm from both the camera room and the hot lab; on high speed, 1300 cfm from both rooms. The air supply to the camera room (B119) is 585 cfm while the hot lab (B120) is supplied with 150 cfm. The exhaust evacuates the camera room with a rate of 700 cfm on low speed (via two grills rated 350 cfm each) while the hot lab is vented at 165 cfm on low speed. On high speed, these values bec me 1050 cfm in the camera room and 250 cfm in the hot lab. The total exhaust is 1300 cfm. Under low speed operation then, both rooms are exhausted at 865 cfm with an air supply of 735 cfm, thus guaranteeing negative pressure at all times.

There are also two transfer grills (12" x 12") from the camera room through the wall common to the hot lab to supply make-up air from the camera room into the hot lab during the times when the high volume of air is being removed from the room. These two transfer grills are located six inches above the floor and eight feet above the floor.

Under normal conditions, the low speed fan is continuously operating and an automatic damper is open to the camera room allowing for the removal of air from both the camera room and the hot lab. There are two emergency switches;

one located in the camera room and one located in the hot lab next to the fume hood. The emergency switch in the camera room will cause the system to operate at high speed with the damper open causing the high volumes of air listed above, to be removed from both the camera room and the hot lab. The emergency switch in the hot lab will cause the fan to operate at high speed but with the damper closed to prevent air from being removed from the camera room and having the entire exhaust be through the fume hood. This emergency switch in the fume hood overrides the emergency switch in the camera room in the event that both are turned on at the same time. In this way, all air goes through the fume hood with its needs being supplied by air from the camera room through the transfer grills and through the open doorway to the hot lab.

Room sizes are as follows: Camera Room = 19'8" x 18' x 9'. Ante room = 7'8" x 8'4" x 9'. Hot lab = 12' x 8' x 9'.

III. Procedure for Routine Use:

A. The camera room door will be opened to a six inch gap at the door jamb if patient's condition permits.

While doing a Xenon study, the exhaust system will be turned on high speed.

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 RadX Ventil-Con 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 ten minutes.

For Rooms B119, B120 and Ante Room:

Activity per loss (A) = 20 mCi = 2×10^{4} uCi

Room volume (V) = 19'8" x 18' x 9' + 12' x 8' x 9' + 7'8" x 8'4" x 9'

= 4625 ft.^{3}

= 1.3×10^{8} ml

Clearance rate (λ) = $\frac{1300 \text{ cfm}}{4625 \text{ ft.}^3}$

= .28 min.$^{-1}$

Initial concentration (C_o) = $\frac{2 \times 10^{4} \text{ uCi}}{1.3 \times 10^{8} \text{ ml}}$

= 1.5×10^{-4} uCi/ml

Evacuation time (t) = 10 minutes

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

= $(1.5 \times 10^{-4}) \, e^{-.28 \times 10}$

= 9.1×10^{-6} uCi/ml

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

All unnecessary personnel will evacuate the room. The camera room door will be guarded against inadvertant entry during this time period.

A survey meter will be placed on the floor so it can be observed from the door. When background levels are reached, the room may be re-entered. Alternatively, the camera may be turned on periodically to collect counts for a present time. When no significant reduction in count rate is noted, the room may be re-entered.

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

A. It is estimated that 200 mCi will be used per week (A).

B. 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).

C. A minimum room exhaust rate of 1300 cfm will be used in this calculation.

$V = 1300 \text{ cfm} \times 6.797 \times 10^{7} \text{ ml/40 hr wk/cfm}$

$V = 1300 \times 6.797 \times 10^{7}$

$V = 8.84 \times 10^{10} \text{ ml/wk}$

D. The average concentration (C) will be:

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

$$= \frac{200 \text{ mCi} \times 1 \times 10^{3} \text{ uCi/mCi} \times .15}{8.84 \times 10^{10} \text{ ml}}$$

$$= 3.4 \times 10^{-7} \text{ uCi/ml}$$

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

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 1.6 Curies of Xenon will be vented to the atmosphere per year. This includes activity liberated as accidental losses and leakage.

2. An air flow rate of 1300 cfm will be used in the calculation:

3. Air flow per year is (V):

$V = 1300 \text{ cfm} \times 1.484 \times 10^{10} \text{ ml/yr/cfm}$

$V = 1.9 \times 10^{13} \text{ ml/yr}$

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

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

$$= \frac{1.6 \text{ Ci} \times 10^{6} \text{ uCi/Ci}}{1.9 \times 10^{13} \text{ ml}}$$

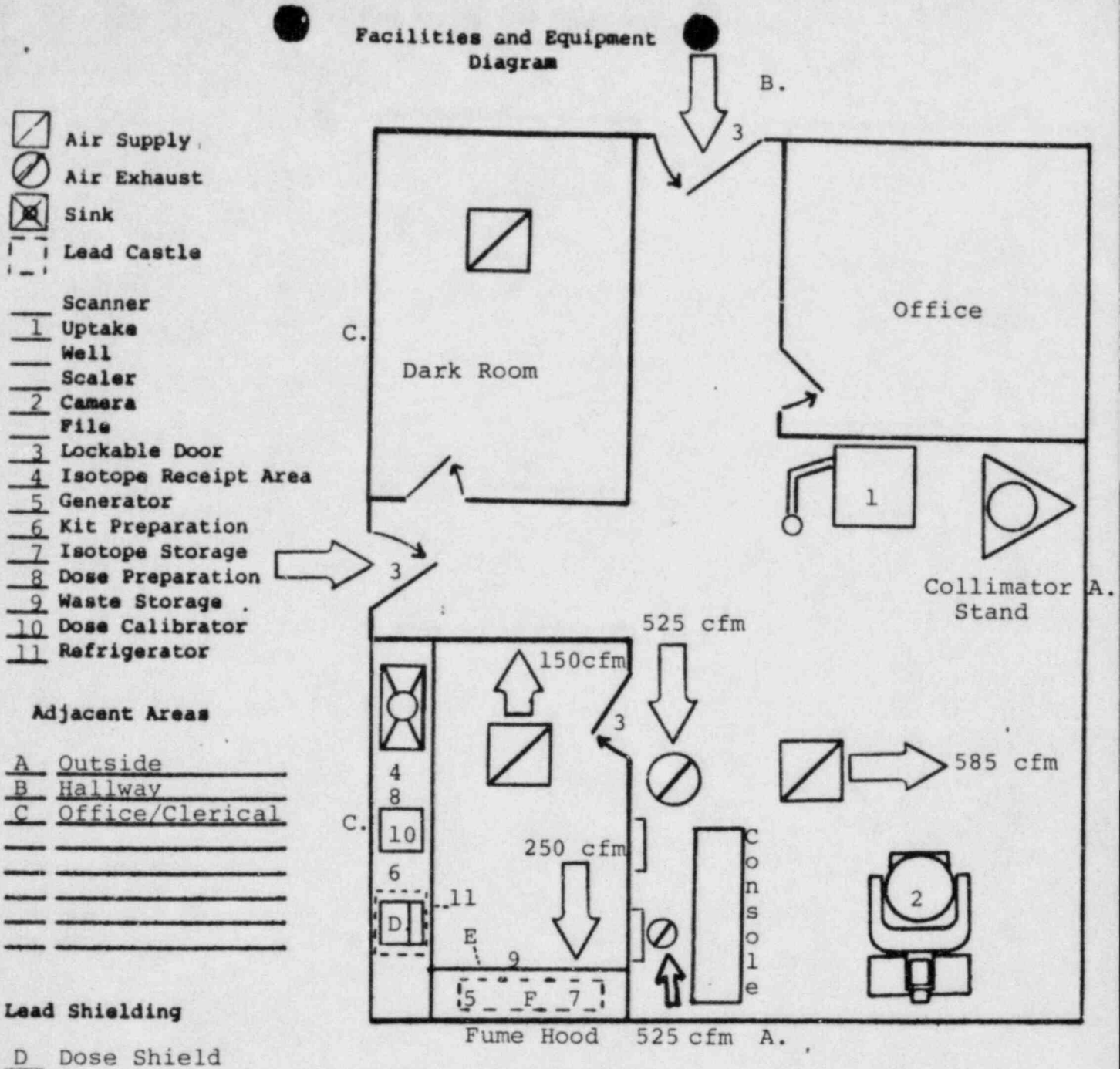
$$= 8.4 \times 10^{-8} \text{ uCi/ml}$$

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

B. After approximately every twenty patients, the discharge air from the gas trap will be monitored with the G-M survey meter held against the tubing to detect Xenon "pass through". When discharge air readings reach 1/10 of air intake maximum readings during the equilibrium phase of the study, it will be assumed the charcoal trap efficiency has fallen to less than 90%. At that time, the cartridge will be exchanged.

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.

Facilities and Equipment Diagram



Air Supply
Air Exhaust
Sink
Lead Castle

___ Scanner
1 Uptake
___ Well
___ Scaler
2 Camera
___ File
3 Lockable Door
4 Isotope Receipt Area
5 Generator
6 Kit Preparation
7 Isotope Storage
8 Dose Preparation
9 Waste Storage
10 Dose Calibrator
11 Refrigerator

Adjacent Areas

A Outside
B Hallway
C Office/Clerical
___ _____
___ _____
___ _____
___ _____
___ _____
___ _____

Lead Shielding

D Dose Shield

12" L x 15" W x 16" H x ½" T

E Storage

30" L x 10" W x 6" H x ½" T

F Generator

16" L x 12" W x 12" H x 2" T

___

___ L x ___ W x ___ H x ___ T

Item #21
6 of 6 pages
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