030-14533

**HARVEY K. BUCHOLTZ, M.D.**
DIPLOMATE
AMERICAN BOARD OF INTERNAL MEDICINE
AMERICAN BOARD OF ENDOCRINOLOGY AND METABOLISM

2333 MORRIS AVENUE
SUITE #B-9
UNION, N.J. 07083
(201) 688-2244

1804 OAK TREE ROAD
EDISON, N.J. 08820
(201) 549-7470

License No. 29-18129-01

John E. Glenn, Ph.D, Chief
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, Pennsylvania 19406

Dear Dr. Glenn:

I would like to request the following amendments to my license No. 29-18129-01:

1) dose calibrator linearity will be determined by the use of the Calicheck method
2) add to the names of the licensees
   Gary W. Cushing, M.D.
   2333 Morris Avenue Suite B-9
   Union, New Jersey 07083
3) delete from the names of the licensees Kenneth W. Ordene, M.D., if this has not already been done.

Thank you for your time and attention to this.

Sincerely,

Harvey K Bucholtz MD

Harvey K. Bucholtz, M.D.

License Fee Information on Application

"OFFICIAL RECORD COPY"

09 NOV 1987

M-16

108052

| NRC FORM 313M (9-81) 10 CFR 35 | U.S. NUCLEAR REGULATORY COMMISSION<br>APPLICATION FOR MATERIALS LICENSE – MEDICAL | Approved by OMB 3150-0041 Expires 9-30-86 |
|---|---|---|

**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

Gary W. Cushing, M.D.
2333 Morris Ave.
Union, N.J., 07083

TELEPHONE NO.: AREA CODE( 201) 688 2244

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

Gary W. Cushing

TELEPHONE NO.: AREA CODE( 201 688 2244

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

a. ☐ NEW LICENSE
b. ☒ AMENDMENT TO LICENSE NO. 29-18129-01
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.)*

Gary W. Cushing

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.)*

Gary W. Cushing

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 | | 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 | XX | |
| 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 | XX | |
| XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | | |

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 |
|---|---|---|---|
| | | | |

108052

Log Dec. 21
Remitter M.E.N.D. P.A.
Check No. 134873
Amount $120
Fee Category 7C
Type of Fee AMD
Date Check Rec'd 12/2/87
Date Completed
By: A. Kennedy

## 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 | |
| ☐ | Names and Specialties Attached; and |
| ☐ | 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 |
| X | Supplement A Attached for RSO. |
| 9. INSTRUMENTATION *(Check One)* | |
| ☐ | 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)* |
| ☐ | Equivalent Procedures Attached; and |
| ☐ | Appendix D Procedures Followed for Dose Calibrator; or *(Check One)* |
| ☐ | Equivalent Procedures Attached |
| 11. FACILITIES AND EQUIPMENT | |
| ☐ | Description and Diagram Attached |
| 12. PERSONNEL TRAINING PROGRAM | |
| ☐ | Description of Training Attached |
| 13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL | |
| ☐ | Detailed Information Attached |
| 14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)* | |
| ☐ | Appendix F Procedures Followed; or |
| ☐ | Equivalent Procedures Attached |

| | |
|---|---|
| 15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)* | |
| ☐ | Appendix G Rules Followed; or |
| ☐ | Equivalent Rules Attached |
| 16. EMERGENCY PROCEDURES *(Check One)* | |
| ☐ | Appendix H Procedures Followed; or |
| ☐ | Equivalent Procedures Attached |
| 17. AREA SURVEY PROCEDURES *(Check One)* | |
| ☐ | Appendix I Procedures Followed; or |
| ☐ | Equivalent Procedures Attached |
| 18. WASTE DISPOSAL *(Check One)* | |
| ☐ | Appendix J Form Attached; or |
| ☐ | Equivalent Information Attached |
| 19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)* | |
| ☐ | Appendix K Procedures Followed; or |
| ☐ | Equivalent Procedures Attached |
| 20. THERAPEUTIC USE OF SEALED SOURCES | |
| ☐ | 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) | |
| ☐ | 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 | | FILM | | |
| | | TLD | | |
| | | OTHER (Specify) | | |
| b. FINGER | | FILM | | |
| | | TLD | | |
| | | OTHER (Specify) | | |
| c. WRIST | | FILM | | |
| | | TLD | | |
| | | OTHER (Specify) | | |

d. OTHER (Specify)

Same as for original license, no amendment

## 25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL
no change from original license

MAILING ADDRESS
Beth Israel Hospital, 22 Lyons Ave

CITY | STATE | ZIP CODE
Newark | NJ |

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

(2) LICENSE FEE ENCLOSED: $

b. APPLICANT OR CERTIFYING OFFICIAL (Signature)
Gary W. Cushing

(1) NAME (Type or Print)
Gary W. Cushing

(2) TITLE
M.D.

c. DATE
6/18/87

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 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.

NRC FORM 313M SUPPLEMENT A (9-81)

U.S. NUCLEAR REGULATORY COMMISSION

# TRAINING AND EXPERIENCE
# AUTHORIZED USER OR RADIATION SAFETY OFFICER

Approved by OMB 3150-0041 Expires 9-30-86

| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE |
|---|---|
| Gary W. Cushing | N.J. Ma. |

## 3. CERTIFICATION

| SPECIALTY BOARD A | CATEGORY B | MONTH AND YEAR CERTIFIED C |
|---|---|---|
| Internal Medicine | | 9/14/83 |
| Endocrinology and Metabolism | | 11/19/85 |

## 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 | See attached letters from Harvard University and Harvard Medical School | | |
| 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 |
|---|---|---|---|---|
| 125I | 5mCi | Boston, Beth Israel Hosp. | 7/83-6/86 | In vitro |
| 3H | 5mCi | | | |
| 14C | 250uCi | | | lab research |
| 32P | 200uCi | | | |

NRC FORM 313M SUPPLEMENT B
(9-81)

U. S. NUCLEAR REGULATORY COMMISSION

Approved by OMB
3150-0041
Expires 9-30-86

# 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
Gary Wayne Cushing

STREET ADDRESS
2333 Morris Ave.

CITY | STATE | ZIP CODE
Union | N.J. | 07083

**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<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| I-131 or I-125 or I-123 | DIAGNOSIS OF THYROID FUNCTION | 25 | RAIU/Scan for thyroid function and evaluation of goiter or nodules (imaging) |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | | |
| | IN VITRO STUDIES | | |
| OTHER | | | |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | see above | |
| P-32 | EYE TUMOR LOCALIZATION | | |
| Se-75 | PANCREAS IMAGING | | |
| Yb-169 | CISTERNOGRAPHY | | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | | |
| OTHER | | | |
| Tc-99m | BRAIN IMAGING | | |
| | CARDIAC IMAGING | | |
| | THYROID IMAGING | 20 | Thyroid nodular disease |
| | SALIVARY GLAND IMAGING | | |
| | BLOOD POOL IMAGING | | |
| | PLACENTA LOCALIZATION | | |
| | LIVER AND SPLEEN IMAGING | | |
| | LUNG IMAGING | | |
| | BONE IMAGING | | |
| OTHER | | | |

## PRECEPTOR STATEMENT *(Continued)*

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

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS *(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| P-32 *(Soluble)* | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 *(Colloidal)* | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | 4 | 29.9-100 mCi<br>majority w/ diffuse toxic goitre<br>remainder w/ toxic multi-nodular goitre or toxic nodule |
| | TREATMENT OF HYPERTHYROIDISM | 20 | |
| 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<br>I-131 | Rx of intractable angina by thyroid ablation | 1 | |

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

July, 1983 - June, 1986 Over the course of a 3 yr. endocrine fellowship well over 80 hours spent in ordering and evaluating radioisotope uptake scans, and therapies.

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

a. NAME OF SUPERVISOR
Johanna Pallotta, M.D.

b. NAME OF INSTITUTION
Beth Israel Hospital

c. MAILING ADDRESS
330 Brookline Ave

d. CITY
Boston, Ma. 02215

5. MATERIALS LICENSE NUMBER(S) Beth Israel Hospital
NRC License # 20-00-742-18, Exp. date December, 1991.

6. PRECEPTOR'S SIGNATURE
Johanna A. Pallotta M.D.

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

8. DATE
2-3-87

NRC FORM 313M SUPPLEMENT B (9-81) Permit Number 23, expires November 30, 1988



GPO 890-913

HARVARD UNIVERSITY
UNIVERSITY HEALTH SERVICES
ENVIRONMENTAL HEALTH AND SAFETY

*46 Oxford Street*
*Cambridge, Massachusetts 02138*
*(617) 495-2061*

December 2, 1985

TO WHOM IT MAY CONCERN:

This is to certify that GARY CUSHING participated in the STUDY PROGRAM IN THE SAFE USE OF RADIOISOTOPES IN RESEARCH conducted by Environmental Health & Safety, University Health Services, and satisfactorily completed a final examination given at the end of the program.

The program was designed to impart the principles and practice of radiation safety as it concerns the use of radioactive materials. Additionally, it presented elementary information on radioactivity measurement standardization and monitoring techniques, mathematics and calculations basic to the use and measurements of radioactivity, and on biological effects of radiation.

Jacob Shapiro, Ph.D.
Radiation Protection Officer

JS:dp

102052

H-323

HARVEY K. BUCHOLTZ, M.D.
34 Center St.
Springfield, NJ 07081

5/25/83

Nuclear Regulatory Commision
Region 1 Materials Program
Section 2
631 Park Ave.
King of Prussia, PA 19406

Gentlemen:

29

Enclosed are two copies of the license renewal application for the licensee Harvey K. Bucholtz, M.D., license # 20-18129-01. Please note that a request for the addition of Kenneth W. Ordene, M.D.as a licensed user for invitro studies,in Group I, Iodine 131 for treatment of hyperthyroidism, and treatment of thyroid carcinoma. A copy of preceptor statements A & B are enclosed. Also enclosed is a check payable to the NRC for the sum of $150.00 as required as per 10 CFR 170. If you have any questions regarding this license renewal application, please contact me.

Sincerely,

Harvey K. Bucholtz, M.D.

M.E.N.D. Inc.,

Applicant 5985
Check No
Amount/Fee Category $150-7C
Type of Fee Renewal
Date Check Rec'd 6/8/83
Received By Brown

RECEIVED BY LFMB
Date 6/8/83
Log June 51
By Brown
Orig. To
Action Compl. 6/8/83

ML10

"OFFICIAL RECORD COPY"

01427

MAY 3 1 1983

| NRC FORM 313M (9-81) 10 CFR 35 | U.S. NUCLEAR REGULATORY COMMISSION<br>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

Harvey K. Bucholtz, M.D.
34 Center Street
Springfield, N.J. 07081

TELEPHONE NO.: AREA CODE ( 201 ) 467 9595

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

Harvey K. Bucholtz, M.D.

TELEPHONE NO.: AREA CODE (201) 467-9595

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

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 29-18129-01

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

Harvey K. Bucholtz, M.D.
Kenneth W. Ordene, 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.)*

Harvey K. Bucholtz, M.D.

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 | x | 1.0 |
| 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 | 2000 |
| 10 CFR 35.100, SCHEDULE A, GROUP IV | n/a | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP V | n/a | AS NEEDED |
| 10 CFR 35.100, SCHEDULE A, GROUP VI | n/a | |

| ADDITIONAL ITEMS: | MARK ITEMS DESIRED "X" | MAXIMUM POSSESSION LIMITS *(In millicuries)* |
|---|---|---|
| IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM | x | 50 |
| PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES | N/A | |
| PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS. | n/a | |
| GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS. | n/a | |
| IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA | x | 50 |
| XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | n/a | |

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 |
|---|---|---|---|
| None | | | License Fee Information on ~~Next Page~~ 5/25/83 Cover Ltr, 01127 |

NRC FORM 313M (9-81)

MAY 31 1983

## 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 |
| | Duties as in Appendix B; or *(Check One)* |
| X | ~~Equivalent Duties Attached~~ See note |
| **8. TRAINING AND EXPERIENCE** | |
| X | Supplements A & B Attached for Each Individual User; and Refer to letters dated 5/27 & 6-12-79 |
| | 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)* |
| X | 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)* | |
| | Appendix G Rules Followed; or |
| X | Equivalent Rules Attached |
| **16. EMERGENCY PROCEDURES** *(Check One)* | |
| | Appendix H Procedures Followed; or |
| X | 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)* | |
| | Appendix K Procedures Followed; or |
| X | Equivalent Procedures Attached |
| **20. THERAPEUTIC USE OF SEALED SOURCES** | |
| N/A | 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)** | |
| N/A | Detailed Information Attached |
| **22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS** | |
| N/A | Detailed Information Attached |
| **23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b** | |
| N/A | Detailed Information Attached |



"OFFICIAL RECORD COPY"

## 24. PERSONNEL MONITORING DEVICES

| | TYPE (Check appropriate box) | | SUPPLIER | EXCHANGE FREQUENCY |
|---|---|---|---|---|
| a. WHOLE BODY | X | FILM | Seimens Gammasonics | Monthly |
| | | TLD | | |
| | | OTHER (Specify) | | |
| b. FINGER | | FILM | | |
| | X | TLD | Seimens Gammasonics | Monthly |
| | | OTHER (Specify) | | |
| c. WRIST | | FILM | Not Used | |
| | | TLD | | |
| | | OTHER (Specify) | | |

d. OTHER (Specify)

None

## 25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL
Newar Beth Israel Medical Center

MAILING ADDRESS
201 Lyons Ave

CITY | STATE | ZIP CODE
Newark, N.J. 07112 | NJ | 07112

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) | b. APPLICANT OR CERTIFYING OFFICIAL (Signature) |
| | (1) NAME (Type or Print) |
| (1) LICENSE FEE CATEGORY 7B | (2) TITLE |
| (2) LICENSE FEE ENCLOSED $150.00 | c. DATE |

NRC FORM 313M (9-81)

Notice

At this time, only Iodine 131 is being used for diagnostic and therapeutic purposes. If in the future, a need exists for using Group III radioactive materials for diagnostic purposes, a "L" shield and additional lead shielding shall be purchased and utilized for the preparation of the radiopharmaceutical kits. The Geometrical Variation Test shall be performed only if Group III radioactive materials are used for diagnostic purposes.

ML10

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Please note that since the application is a physician in private practice, this section is not required with this not required with this application.

"OFFICIAL RECORD COPY"

Dr. Ordene

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: Kenneth W. Ordene

STREET ADDRESS: 34 Center St

CITY: Springfield | STATE: NJ | ZIP CODE: 07081

**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<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| I-131 or I-125 | DIAGNOSIS OF THYROID FUNCTION | | |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | | |
| | IN VITRO STUDIES | ~1000 | |
| OTHER | | | |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | | |
| P-32 | EYE TUMOR LOCALIZATION | | |
| Se-75 | PANCREAS IMAGING | | |
| Yb-169 | CISTERNOGRAPHY | | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | | |
| OTHER | $^{123}$I UPTAKE + SCAN | 450 | |
| Tc-99m | BRAIN IMAGING | | |
| | CARDIAC IMAGING | | |
| | THYROID IMAGING | | |
| | SALIVARY GLAND IMAGING | | |
| | BLOOD POOL IMAGING | | |
| | PLACENTA LOCALIZATION | | |
| | LIVER AND SPLEEN IMAGING | | |
| | LUNG IMAGING | | |
| | BONE IMAGING | | |
| OTHER | | | |

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 |
|---|---|
| KENNETH ORDENE, MD | N.J |

## 3. CERTIFICATION

| SPECIALTY BOARD<br>A | CATEGORY<br>B | MONTH AND YEAR CERTIFIED<br>C |
|---|---|---|
| | | |

## 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

| FIELD OF TRAINING<br>A | LOCATION AND DATE(S) OF TRAINING<br>B | TYPE AND LENGTH OF TRAINING | |
|---|---|---|---|
| | | LECTURE/ LABORATORY COURSES (Hours)<br>C | SUPERVISED LABORATORY EXPERIENCE (Hours)<br>D |
| a. RADIATION PHYSICS AND INSTRUMENTATION | Montefiore Medical Center 7/81 - 6/82 | 20 | 5 |
| b. RADIATION PROTECTION | " | 5 | - |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | " | 5 | - |
| d. RADIATION BIOLOGY | " | 3 | - |
| e. RADIOPHARMACEUTICAL CHEMISTRY | " | 3 | - |

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

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| $^{131}I$ | 250 mCi | Montefiore Hosp. Bronx N.Y. | 7/1/81 - 6/30/82 | Thyroid Ca |
| $^{131}I$ | 20 mCi | " | " | Hyperthyroidism |
| $^{125}I$ | 2 mCi | " | " | Protein labelling in vitro tests |

## PRECEPTOR STATEMENT *(Continued)*

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

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| P-32 *(Soluble)* | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 *(Colloidal)* | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | 19 | |
| | TREATMENT OF HYPERTHYROIDISM | 184 | |
| 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 $^{123}I$ | THYROID UPTAKES + SCANS | 460 | |
| $^{125}I$ | PROTEIN LABELLING | 12 | |
| $^{125}I$ | IN VITRO TESTS | ABOUT 1000 | |

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

7/1/81 - 6/30/82 - about 8 hrs/wk

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

a. NAME OF SUPERVISOR: [illegible], PhD.

b. NAME OF INSTITUTION: Montefiore Medical Center

c. MAILING ADDRESS: 111 E 210 ST / Bronx NY / [illegible]

d. CITY

5. MATERIALS LICENSE NUMBER(S): 188-7

6. PRECEPTOR'S SIGNATURE: Leroy A. Sugarman, MD

7. PRECEPTOR'S NAME *(Please type or print)*: LEROY A. SUGARMAN, M.D

8. DATE: May 3, 1983

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

Dr. Ordene

## EXPERIENCE WITH RADIATION

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| Co 57 | | | | |
| Ga 67 | | | | |
| Se 75 | | | | |
| Kr 81 | | | | |
| Tc99/Mo99 | | | | |
| In 111 | | | | |
| I 131 | 20mCi | MONTEFIORE MEDICAL CENTER BRONX N.Y. | 7/1/81 - 6/30/82 | Therapy of Hyperthyroidism |
| I 131 | 250mCi | MONTEFIORE MED. CENTER | 7/1/81 - 6/30/82 | Therapy of Thyroid Ca |
| Xe 133 | | | | |
| Yb 169 | | | | |
| Tl 201 | | | | |

APPENDIX C

## INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: Atomic Products

      Manufacturer's model number: CDV 700

      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: None

      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

   Manufacturer's name: Mallinckrodt

   Manufacturer's model number: N/A

   Number of instruments available: 1

3. Instruments used for diagnostic procedures

| Type of Instrument | Manufacturer's Name | Model No. |
|---|---|---|
| Rectilinear Scanner | Picker | Magnascanner III |

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

   None

## CALIBRATION OF SURVEY INSTRUMENTS

CHECK APPROPRIATE ITEMS

__X__ 1. Survey instruments will be calibrated at least annually and following repair.

__X__ 2. Calibration will be performed at two points on each scale. The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within + 10% of the calculated or known values for each point checked. Readings within ± 20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

__X__ 3. Survey instruments will be calibrated.

_____ a. By manufacturer

_____ b. At the licensee's facility

(i) Calibration source
Manufacturer's name _____
Model No. _____
Activity in millicuries _____
Accuracy _____
Traceability to primary standard _____

(ii) The calibration procedures in Appendix D, Section I will be used.

or

(iii) The step-by-step procedures, including radiation safety procedures are attached.

__X__ c. By a consultant or outside firm

(i) Name Bio-Med Associates Inc.

(ii) Location 753 Boulevard, Kenilworth, N.J. 07060

(iii) Procedures and sources

__X__ have been approved by NRC and are on file in License No. 29-14367-01

_____ are attached.

## CALIBRATION OF INSTRUMENTS

### Consistency Checks of Survey Meters

1. Prior to use, each survey meter is tested employing a long-lived check source in a reproducible geometry. The meter reading is noted for comparison in future tests to assure consistency of response.

2. The consultant physicist maintains a log of spot-checks on each survey meter. The variation of greater than ±20% from the initial check after calibration will warrant repair and/or re-calibration.

## Methods for Calibration of a Dose Calibrator

All radiopharmaceuticals are assayed for activity to an accuracy of ±10%. The instrument is tested as follows:

I. Daily checks are performed using a long lived reference standard (e.g., 200uCi of Cs-137 or 1mCi of Co-57). The two standards will be alternated for the daily test. The standard reading is corrected for background and compared to the decay corrected calibrated activity. An observed deviation of greater than ±5% will warrant recalibration and/or repair. This check is performed by the nuclear medicine technician. The date, decay corrected activity, background, net standard assay, and percent deviation are logged. Deviations greater than ±5 are reported to the consultant radiation physicist for futher evaluation.

II. Monthly checks are performed using each of the following long lived reference standards:

| Radionuclide | Activity | Accuracy |
|---|---|---|
| Cobalt 57 | 1.12 mCi | ± 5% |
| Barium 133 | 250 uCi | ± 5% |

The standard readings are compared to their decay corrected calibrated activities as shown in the attached sample log sheet "Dose Calibrator Standard Sensitivity". A deviation of greater than ±5 on any standard will warrant recalibration or repair. This check is performed by the consultant radiation physicist. For dose calibrators employing activity concentration mode (Activity per ml.), this mode will be tested monthly employing one of the above reference standards according to the attached sample log sheet "Dose Calibrator Concentration Calculation Test". A deviation of greater than ±5 will warrant recalibration or repair. These monthly tests are performed by the consultant radiation physicist.

III. Quarterly tests are performed using a long lived reference standard (e.g., Cs-137) and recording the apparent activity indicated at all of the commonly used radionuclide settings. The source readout is compared to previous tests (correcting for decay) and a percent difference is computed. A deviation of greater than ±5 will warrant recalibration or repair. Tests of background energy linearity and condition of the chamber liner and source holder are also performed. A sample log sheet is attached specifying the "Quarterly Dose Calibrator Analysis".

Tests of the instrument activity are also performed quarterly employing a Iodine 131 source. The maximum activity used will be no more than 10mCi based on therapeuticdoses presently administered.

(1) Entire elution of a generator is assayed, the volume of the eluate is approximated, and the concentration is calculated. For example, the eluate may be 200mCi in 10ml or 20mCi/ml.
(2) At the time the study is to be performed the concentration is decay corrected.
(3) To prepare a given dose, the desired activity is divided by the decay corrected concentration yielding the volume to be administered.
(4) Prior to injection the individual dose is assayed (correcting for geometrical variation if necessary) to verify the proper activity.

A similar procedure is employed in administration of radiopharmaceutical kits. The activity to be used in the kit is assayed and volume approximated. After the kit is properly prepared, the concentration in mCi/ml is assayed using the total volume employed in the kit (correcting for the volume of saline or other diluting agent added). At the time of administration, the procedures listed above in steps (2) through (4) are followed.

The activity linearity test is performed by assaying the Tc-99m source at various times and comparing the readings to the expected decay corrected values. This is achieved by constructing a semi-log graph of the readings vs. time. (See attached sample log sheet "Activity-Range Sensitivity Check"). The graph permits data points to be plotted up to 56 hours of decay time. If more than 56 hours of decay time is required to encompass the entire range of activities administered, the data points will be compared to the calculated decay values and percentage errors computed. If the deviation between the instrument reading and decay corrected value is greater than ±5% at any point in the range of administered activities, the instrument will be repaired.

V. A one-time test is performed (usually at installation) to access the instrument accuracy with regard to geometrical variation of source containers. This test is performed with each radionuclide used. The following specifies procedures performed in the geometrical variation test:

(1) For each different vial and syringe used to contain a given radioactive material for assay, a 0.1ml aliquot (1-5mCi) of equal activity will be prepared.
(2) A 30cc vial will always be employed since each of the previously described reference standards are 20cc in a 30cc vial.
(3) Each 0.1ml aliquot will be transferred to each vial or syringe.
(4) Each vial and syringe will be diluted with water and reassayed as indicated in the attached sample log sheet "Geometrical Variation Test".
(5) All instrument readings for each volume of liquid in the vial or syringe will be divided by the reading obtained for 20cc of liquid in the 30cc vial to obtain the correction factor.
(6) The correction factor is a number to divide into the indicated instrument reading to obtain the true activity.

This test is performed by the consultant radiation physicist, who will make a determination as to whether a geometrical correction factor need be employed to assure overall ±10% accuracy. This determination will be made with regard to the magnitude of the inaccuracies encountered in the other tests. Generally, a geometrical correction factor of less than 2% may be ignored.

# CALIBRATION OF DIAGNOSTIC EQUIPMENT

All the diagnostic equipment shall be calibrated in accordance to the manufacturer's recommendations. As needed any modifications requiring special attention, shall be noted and accomadations shall be made implement any additional tests needed.

Date _____

## Geometrical Variation Test

Hospital: _____

Instrument: _____

Radionuclide: _____

### 30cc Vial

| Time of Assay | Volume | Reading | Decay Corrected Reading | Correcti Factor |
|---|---|---|---|---|
| | 0.1 ml | | ---------- | |
| | 2 ml | | | |
| | 4 ml | | | |
| | 6 ml | | | |
| | 8 ml | | | |
| | 10 ml | | | |
| | 12 ml | | | |
| | 14 ml | | | |
| | 16 ml | | | |
| | 18 ml | | | |
| | 20 ml | | | 1.000 |
| | 22 ml | | | |
| | 24 ml | | | |
| | 26 ml | | | |
| | 28 ml | | | |
| | 30 ml | | | |

Correction factor = $\frac{\text{Decay Corrected Reading @ Volume (x)}}{\text{Decay Corrected Reading @ Volume (20 ml for 30 m}}$

Page 2 Geometrical Variation Test Continued

1cc Syringe

| Time of Assay | Volume | Reading | Decay Corrected Reading | Correction Factor |
|---|---|---|---|---|
| | 0.1 ml | | | |
| | 0.2 ml | | | |
| | 0.3 ml | | | |
| | 0.4 ml | | | |
| | 0.5 ml | | | |
| | 0.6 ml | | | |
| | 0.7 ml | | | |
| | 0.8 ml | | | |
| | 0.9 ml | | | |
| | 1.0 ml | | | |

3cc Syringe

| Time of Assay | Volume | Reading | Decay Corrected Reading | Correction Factor |
|---|---|---|---|---|
| | 0.1 ml | | | |
| | 0.5 ml | | | |
| | 1.0 ml | | | |
| | 1.5 ml | | | |
| | 2.0 ml | | | |
| | 2.5 ml | | | |
| | 3.0 ml | | | |

Page 3 Geometrical Variation Test Continued

5cc Vial

| Time of Assay | Volume | Reading | Decay Corrected Reading | Correctio Factor |
|---|---|---|---|---|
| | 0.1 ml | | | |
| | 0.5 ml | | | |
| | 1.0 ml | | | |
| | 1.5 ml | | | |
| | 2.0 ml | | | |
| | 2.5 ml | | | |
| | 3.0 ml | | | |
| | 3.5 ml | | | |
| | 4.0 ml | | | |
| | 4.5 ml | | | |
| | 5.0 ml | | | |

Other Container

| Time of Assay | Volume | Reading | Decay Corrected Reading | Correctio Factor |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

# QUARTERLY DOSE CALIBRATOR ANALYSIS

HOSPITAL: _____

MODEL DOSE CALIBRATOR: _____

DATE: _____

1. Check liner
   a. Contaminated?
   b. In place?

2. Check support
   a. In tact?

3. Instrument Zero
   a. Was zeroed?
   b. Adjustment necessary?

4. Lead shielded? Yes _____ No _____

5. _____ reference standard is _____ uCi today. When placed in the dose calibrator it read on the following settings:

| | | Cap. | Eon | Pick. | % different from original |
|---|---|---|---|---|---|
| _____ | uCi @ Mo-99 setting | 30x3.5 | 342 | 2133 | _____ |
| _____ | uCi @ Tc-99 setting | 80 | 501 | 1117 | _____ |
| _____ | uCi @ Ga-67 setting | 94 | 478 | 1139 | _____ |
| _____ | uCi @ Cr-51 setting | 100x10 | 459 x10 | 6586 | _____ |
| _____ | uCi @ Co-57 setting | 112 | 453 | 1138 | _____ |
| _____ | uCi @ I-131 setting | 151 | 327 | 1194 | _____ |
| _____ | uCi @Xe-133 setting | 188 | 497 | 1205 | _____ |
| _____ | uCi @Tl-201 setting | 205 | 458 | -- | _____ |
| _____ | uCi @Cs-137 setting | 220 | 260 | 1253 | _____ |
| _____ | uCi @ Se-75 setting | 258 | 210 | 1236 | _____ |
| _____ | uCi @ I-123 setting | 277 | 260 | -- | _____ |
| _____ | uCi @ I-125 setting | 319 | 421 | 0151 | _____ |

 Quarterly Dose Calibrator Analysis

| | | Cap. | Eon | Pick. | % difference from original |
|---|---|---|---|---|---|
| _____ uCi @ | P-32 setting | 550x100 - | | 6347 | _____ |
| _____ uCi @ | Ra-226 setting | 778 | 058 | 0139 | _____ |
| _____ uCi @ | Yb-169 setting | 044 | -- | -- | _____ |
| _____ uCi @ | Co-60 setting | 990 | 035 | 0218 | _____ |
| _____ uCi @ | Xe-127 setting | ___ | ___ | ___ | _____ |

6. Yes _____ No _____ Instrument was adjusted or repaired, to read ±

   Yes _____ No _____ Instrument was within ±5% of previous values

   Yes _____ No _____ A correction factor was posted. It is _____

7. Volume and Concentration Check

   a. _____ in 20 cc vial reads _____ uCi/cc _____ N/A

   b. _____ in 20 cc vial calculated is _____ uCi/cc

   c. % of difference is _____

8. Accuracy of Standards
   Decay corrected expected uCi/assay uCi x 100 = % accuracy

   Co-57

   Cs-137

   Ba-133

   Co-60

   Ra-226

9. Comparison of Pushbutton to Manual setting _____, _____ N/A

10. Any modules missing? _____, _____ N/A

11. Cs-137/Co-57 decay-corrected ratio =

    This is _____ % different from last quarter's; therefore,

12. Comments

Checked by: _____

# Linearity Test-- Iodine 131

| Day/Time of Day | Time After $T_o$ | Inst. Reading | Bkgd. Reading | Correc. Reading | % Remain. Activity | % Expected Activ. | % Error |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
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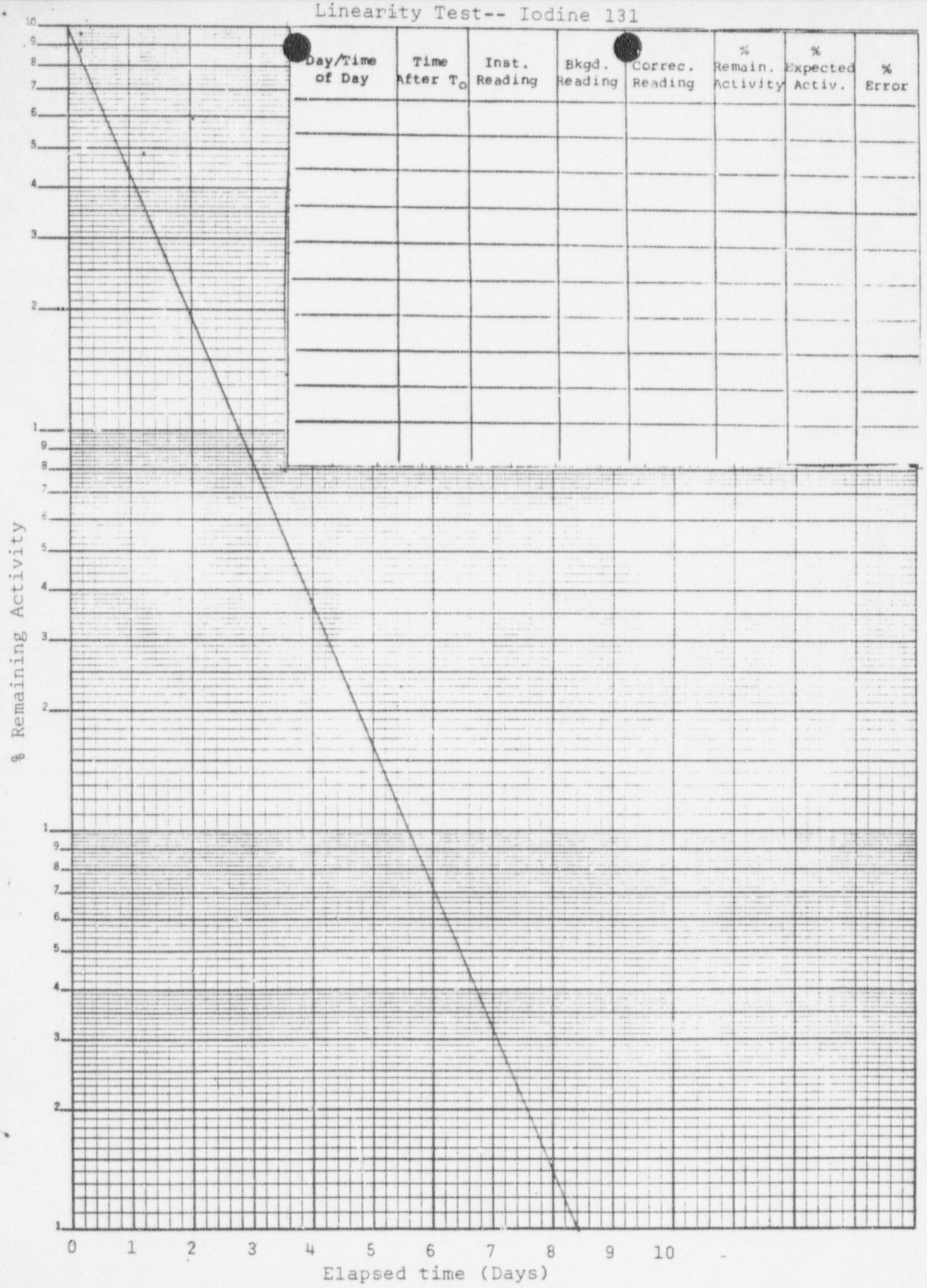


# FACILITIES AND EQUIPMENT

See the diagram and survey sheet attached. The following radiation safety equipment are present:

1. Handling tools
2. 1" Lead shielded radioactive waste container
3. 1/2" thick lead shielded fort, 12"x12"x4"
4. Disposable rubber gloves
5. Lab coats are worn by technologists
6. Absorbant pad
7. Vials & pill containers are stored in their lead pigs

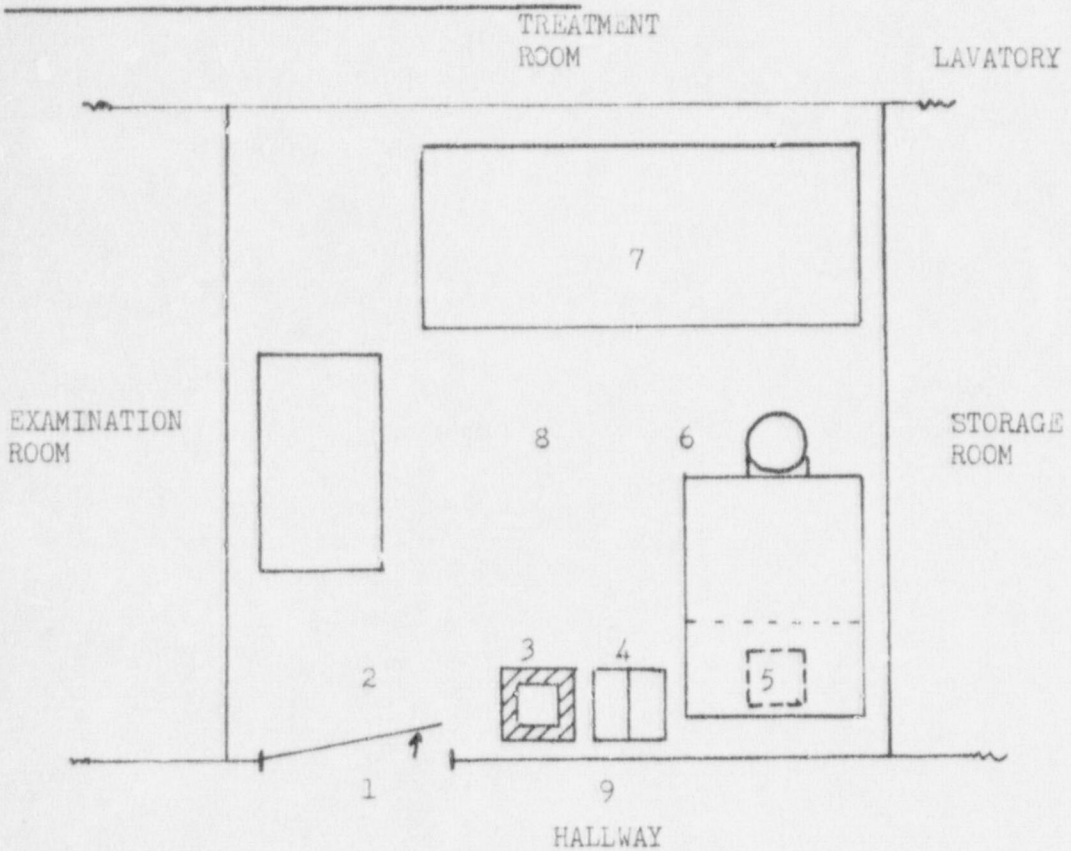
DR. BUCHOLTZ'S OFFICE, NUCLEAR MEDICINE SECTION

DATE: _____

SURVEYED BY: _____

INSTRUMENTATION: _____

_____




| # | LOCATION | mR/hr | cpm/100cm² |
|---|---|---|---|
| 1 | Door/Floor | | |
| 2 | Floor | | |
| 3 | Lead Fort | | |
| 4 | R/A Waste Cans | | |
| 5 | Dose Calib. | | |
| 6 | Scanner | | |
| 7 | Table | | |
| 8 | Floor | | |
| 9 | Wall/ Floor | | |
| 10 | Background | | |

NOTES:

# PERSONNEL TRAINING PROGRAM

I. Individuals who work in or frequent restricted areas will be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

This instruction will include:

a. All terms of the license pertinent to radiation safety.

b. Areas where radioactive material is used or stored.

c. Potential hazards associated with radioactive material.

d. Radiological safety procedures appropriate to their respective duties.

e. Pertinent NRC regulations.

f. Rules and regulations of the license.

g. Obligation to report unsafe conditions to the radiation safety officer.

h. Appropriate response to emergencies or unsafe conditions.

i. Right to be informed of their radiation exposure and bioassay results.

j. Locations 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.

II. Individuals whose duties may require them to work in the vicinity of licensed material will be informed about radiation hazards and appropriate precautions at the time of initial employment and at least annually thereafter. This information will be provided initially at hospital employee orientation sessions and annually thereafter at in-service meetings.

PACKAGE MONITORING LOG SHEET

| NUCLIDE | MANUFACTURER | DATE | SURVEYOR | TIME | CONDITION O.K. ✓ | RAD. UNITS OF LABEL mR/hr (DOT) | RADIATION LEVELS mR/hr SURFACE | RADIATION LEVELS mR/hr 3' FROM SURFACE* | CONTENTS & S-I-P AGREE-YES ✓ | WIPE RESULTS OUTSIDE | WIPE RESULTS SURFACE CONTAINERS | WIPE RESULTS MATERIAL | SURVEY RESULTS CARTON | DISPOSITION OF PACKAGE O.K. ✓ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
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be omitted where surface readings are less than 10mR/hr. If package is contaminated and/or over 200mR/hr at surface

mR/hr @ 3 feet), notify carrier and local Nuclear Regulatory Commission Office (215) 337-5000.

# LABORATORY RULES FOR THE USE OF RADIOACTIVE MATERIAL

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, feet, and clothing for contamination after each generator elution and radiopharmaceutical kit preparation, and after each dose preparation/administration or before leaving the area with the GM Survey Meter. Log the meter readings.

4. Use syringe shields for preparation of patient doses and administration to patients except in circumstances, such as pediatric cases, where their use would compromise the patient's well-being.

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

6. 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%.

7. Wear personnel monitoring devices (Film badge or TLD) at all times while in areas where radioactive materials are used or stored. These should be worn at chest or waist level.

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 receptacles. Survey receptacles daily to assure exposure levels are less than 2.0 mR/hr. in restricted areas and less than 0.2 mR/hr. in non-restricted areas.

10. Never pipette by mouth.

11. Survey generator, kit preparation, and dose preparation areas after each procedure or at the end of the day with GM Survey Meter, and log readings. If necessary, reposition sources and/or shielding to maintain exposure levels less than 2.0 mR/hr. Also perform a wipe test for each area listed above and log results. Decontamination procedures are warrented if removable contamination found on any wipeyields a larger than background reading on the GM survey meter with the window open.

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

13. Always transport radioactive material in shielded containers.

14. Always use disposable coverings (with plastic backing) where radioactive materials in solution are prepared.

15. Always use remote handling tongs when handling or assaying unshielded sources, especially if in quantities greater or equal to patient doses. This is extremely important for the elution of a generator.

# 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. REPORT: Report incident to the Radiation Safety Officer.

4. 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. Include all other contaminated materials such as disposable gloves.

5. SURVEY: With a G.M. Survey Meter, check the area around the spill, your hands and clothing for contamination. Perform a wipe test to assure the absence of removable contamination before continuing normal operations. Log survey and wipe test results and other related information on the incident for laboratory records.

## 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:

   a. Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer.

   b. Rinse the affected area promptly with water.

   c. If contamination covers a large area and a shower is warrented, bring the G.M. Survey Meter and have someone survey the contaminated individual to assure that decontamination is effective.

d. Wash thoroughly with a non-abrasive detergent. Lanoclean is recommended. It contains corn meal that has a mild scrubbing action but doesn't scratch the skin.

e. Scrub the area thoroughly using detergent and a suitable brush but being careful not to abrade the skin.

f. Continue these procedures until there is no further reduction in the level of contamination, or until the possibility of damage to the skin makes further scrubbing inadvisable.

g. If the level of fixed contamination is more than 5 mR/hr. on a G.M. monitor or there are special circumstances contact the Radiation Safety Officer.

RADIATION SAFETY OFFICER: Harvey K. Bucholtz, MD

OFFICE PHONE: 467-9595

## SURVEY PROCEDURES

A. All elution, kit preparation, and dose preparation areas will be surveyed daily with a G.M. survey meter and decontaminated if necessary as specified in Item 15 "Laboratory Rules For the Use of Radioactive Material", Section II.

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 by the nuclear medicine staff, and monthly by consultant radiation physicist.

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. The method for performing wipe tests will be sufficiently sensitive to detect the contamination limits listed in Section F. (Page 2)

E. A permanent record will be kept of all survey results, including negative results. The record will include:

1. Location, date, and identification of equipment used.

2. Name of person conducting the survey.

3. Drawing of area surveyed, identifying relevant features such as activ 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.

F. Ideally, any contamination more than a few dpm above background should be cleaned up; however the following table specifies limits of acceptable levels of contamination for common medical radionuclides:

| Type of Surface | I-131, Mo-99, Se-75, P-32 | Tc-99m, I-125, Cr-51, Co-57, Ga-67, Tl-201, I-123 |
|---|---|---|
| | dpm/100 $cm^2$ | dpm/100 $cm^2$ |
| 1. Unrestricted Areas | 220 | 2200 |
| 2. Restricted Areas | 2200 | 22000 |
| 3. Personal Clothing worn outside restricted areas | 220 | 2200 |
| 4. Protective clothing worn only in restricted areas | 2200 | 22000 |
| 5. Skin | 220 | 2200 |

Contamination levels exceeding those listed above warrant establishment of a contamination zone until contamination is removed. For fixed contamination: that which after repeated attempts fails to reduce levels significantly, 5 tires the levels listed above in lines 1 and 2 are acceptable without isolation of the area.

Exact contamination on a wipe can be quantized if a NaI well crystal is possessed. Where no NaI well crystal exists the following instrumentation will be employed to assess contamination:

In performing monthly department surveys the consultant radiation physicist estimates the dpm content of a wipe employing a ~1000 dpm Co-57 reference source and the NaI crystal detector contained in the Rectilinear Scanner, Thyroid Uptake Probe, or Gamma Camera.

In daily and weekly surveys the nuclear medicine staff assesses the removable contamination extent contained in a wipe by employing a G.M. Survey Meter (with the beta shield removed). Wipes are counted in a low background area, bringing the detector window as close as possible to the wipe. Each wipe will be counted for a minimum of 15 seconds allowing 15 seconds between counts for the meter to equilibrate. A wipe that registers a reading that is larger than background levels will warrant decontamination procedures.

## APPENDIX J

## WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with § 20.303 of 10 CFR Part 20.

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.

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

___X___ Other (specify) DECAY TO BACKGROUND

_____

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

___X___ Returned to the manufacturer for disposal.

_____ 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.

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

_____ Other (specify) _____

_____

4. The commercial waste disposal service used will be

NONE

(Name) (City, State)

NRC/Agreement State License No. _____

*Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

**These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.



Item 18
5/83

PROCEDURES FOR USE OF GROUP IV RADIOPHARMACEUTICALS
FOR TREATMENT OF PATIENTS

1. All in-patients undergoing internal nuclear medicine therapy will be placed in a private room with a toilet.

2. The patient's room will be properly posted in accordance with Section 20.203, 10 CFR Part 20.

3. The form, Nursing Instructions for Patients Treated with Phosphorous-32 or Iodine-131, will be completed immediately after administration of the treatment dose. A copy will be posted in the patient's chart.

4. Radiation levels in unrestricted areas will be maintained less than the limits specified in Section 20.105(b), 10 CFR Part 20.

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

6. 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 designate) checked for contamination, and disposed of as normal or radioactive waste, as appropriate.

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

8. Urine and vomitus, from Iodine-131 therapy patients will be disposed in compliance with Section 20.303, 10 CFR Part 20.

9. 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.

10. 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 in the patient's chart. Nurses should read these instructions before administering to the patients. Call the Nuclear Medicine Department if you have any questions about the care of these patients.

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

c. Patients must remain in bed while visitors are in the room and visitors should remain at least three feet from the patient.

d. Radioactive patients 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 must 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 must 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 Nuclear Medicine Department 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 left in thepatient's room to be checked by a member of the Nuclear Medicine Department.

i. All non-disporable items should be placed in a plastic bag and left in the patient's room to be checked by a member of the Nuclear Medicine Department.

j. For Iodine-131 patients:

(1) The urinal or bedpan should be flushed several times with hot soapy water after use. A separate bedpan or urinal should be kept for the patient until he/she is discharged.

(2) If the nurse helps to collect the excreta, she should wear disposable gloves. Afterwards she should wash her hands 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 Nuclear Medicine Department.

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

(4) Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and/or floor. In any such situation or if radioactive urine and/or feces is spilled during collection, call the Nuclear Medicine Department, Ext. 467-3545. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(5) The same toilet should be used by the patient at all times and it should be well flushed (3 times).

k. If a nurse, attendant or anyone else knows or suspects that his skin, or clothing, including shoes, is contaminated, notify the Nuclear Medicine Department immediately. This person should remain in the patient's room and not walk about the hospital. If the hands become contaminated, wash immediately with soap and water.

l. If a therapy patient should need emergency surgery or should die, notify the Nuclear Medicine Department immediately.

m. When the patient is discharged call the Nuclear Medicine Department and request that the room be surveyed for contamination before remaking the room.

n. No patient shall be released from the hospital until his/her radioactivity content has reduced such that a dose to other persons in excess of 0.5 rem will not be absorbed.

# NURSING INSTRUCTIONS FOR PATIENTS TREATED WITH PHOSPHOROUS-32 OR IODINE-131

Patient's Name: _____

Room No.: _____ Physician's Name: _____

Radioisotope Administered: _____

Date and Time of Administration : _____

Dose Received: _____ Method of Administration: _____

(Comply with all Check Items)

_____ 1. Visiting time permitted: _____

_____ 2. Visitors must remain _____ from patient.

_____ 3. Patient may not leave room.

_____ 4. Visitors under 18 not permitted.

_____ 5. Pregnant visitors not permitted.

_____ 6. Film badges must be worn. (If required, only personnel who have been issued a film badge may enter the room.)

_____ 7. Use and complete the following tags:

_____ door _____ bed _____ chart _____ wrist

_____ 8. Gloves must be worn while attending patient.

_____ 9. Patient must use disposable utensils.

_____10. All items must remain in room until OK'd by Radiation Safety.

_____11. Smoking is not permitted.

_____12. Do not release room to admitting until OK'd by Radiation Safety.

_____13. Other instructions

In case of emergency contact :

RSO Harvey K. Bucholtz, M.D. 467-9595 / 549-7470

Name on/off duty telephone number

# IODINE 131 Information

As a limited nuclear medicine department operation, only Iodine 131 available in solid capsule form will be used for human administration. Unless a capsule should be inadvertantly crushed, or the total adminstered dosage meets or exceeds the monitering levels as described in NRC Regulatory Guide 8.20, bioassays of the nuclear medicine departmental personnel will not be done. All Iodine 131 orders will be received no earlier than 24 hours prior to administration to the patients, thereby reducing the elasped storage period to as little as possible.

ALARA PROGRAM

We, the management of this medical facility are committed to the ALARA program as specified in Appendix O, of Regulatory Guide 10.8, Rev. October 1980.

Newark Beth Israel Medical Center
201 Lyons Avenue, Newark, New Jersey 07112 / at Osborne Terrace
Telephone (201) 926-

April 12, 1983

Harvey Bucholtz, M. D.
34 Center Street
Springfield, New Jersey 07081

Dear Doctor Bucholtz:

This letter will serve as verification of your privileges to admit patients to the Newark Beth Israel Medical Center after the introduction of radioactive isotopes should the need arise.

Sincerely,

Lester M. Bornstein
Executive Director

jmw

Newark Beth Israel Medical Center
201 Lyons Avenue, Newark, New Jersey 07112 / at Osborne Terrace
Telephone (201) 926-

April 12, 1983

Kenneth Ordene, M. D.
34 Center Street
Springfield, New Jersey 07081

Dear Doctor Ordene:

This letter will serve as verification of your privileges to admit patients to the Newark Beth Israel Medical Center after the introduction of radioactive isotopes should the need arise.

Sincerely,

Lester M. Bornstein
Executive Director

jmw

ML10

"OFFICIAL RECORD COPY"

The Ra diation safety procedures for the use of therapeutic use of Iodine 131 are as described in NRC Regulatory Guide 10.8 Revision 1, Oct. 1980, Appendix K.

Instrumentation Available

| QTY | Type |
|---|---|
| 2 | Victoreen 493 GM |
| 1 | Baird Atomic 446 Survey meter ( C.P.) |

MS-12
P5

Harvey K. Bucholtz, M.D.
DIPLOMATE
AMERICAN BOARD OF INTERNAL MEDICINE
AMERICAN BOARD OF ENDOCRINOLOGY AND METABOLISM

34 CENTER STREET
SPRINGFIELD, N.J. 07081
(201) 467-9595

1804 OAK TREE ROAD
EDISON, N.J. 08820
(201) 549-7470

August 31, 1983

John E. Glenn, Ph.D., Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs
Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, Pennsylvania 19406

License No. 29-18129-01
Docket No. 030-14533
Control No. 01427

Dear Sir,

In response to your letter of June 28, 1983, to renew License No. 29-18129-01 additional information is provided.

1. Enclosed are credentials for Kenneth W. Ordene, M.D. Included is a letter from Sherman L. Heller, P.h.D. outlining the course of instruction given to Dr. Ordene as well as his clinical experience.

2. The request for 50 millicuries of Iodine-131 for treatment of thyroid carcinoma is an error; the correct request should be 30 millicuries of Iodine-131.

If you require any additional information feel free to contact me.

Sincerely,

Harvey K. Bucholtz M.D.
MF

HKB:kr
Enc.

Harvey K. Bucholtz, M.D.

01427

SEP 0 6 1983

111 EAST 210TH STREET, BRONX NEW YORK 10467

Telephone
Area Code 212

August 11, 1983

To Whom It May Concern:

During his fellowship at Montefiore Medical Center, Dr. Kenneth Ordene, M.D. attended a series of Nuclear Medicine Physics Lectures. Attached is a list of the lecture topics. Each of the 12 topic areas consisted of 2 one hour lectures for a total of 24 lecture hours.

In addition, hands-on laboratory experience included the use of survey meters, quality control procedures for gama cameras and uptake probes and radiation monitoring and protection procedures.

If I can be of any further assistance, feel free to contact me.

Sincerely,

Sherman L. Heller, Ph.D.

# NUCLEAR MEDICINE PHYSICS LECTURES

Structure of matter, nuclides and radioactive processes, ionization, excitation, x-rays, Auger electrons, decay and decay schemes.

Laws of decay, half-life, production of radionuclides.

Interaction of radiation with matter. Mechanism of interaction for charged particles, lighter vs. heavier particles, x- and gamma rays, attenuation and transmission, half-value layer.

Detection of high energy radiation. Gas filler detectors, scintillation detectors(counters), associated electronics, energy resolution.

Dosimetry and Radiation safety. Radiation units, exposure units, protection and precautions, radiation monitoring instruments.

Instrumentation I. Non-imaging devices and scanners. Thyroid probes, well counters, liquid scintillation detectors, focussed collimators, pulse height analyzers, tomographic scanners.

Instrumentation II. Gamma camera. Single crystal, multicrystal, collimators, resolution, sensitivity.

Other imaging devices. Positron cameras, solid state,emission tomography.

Statistics. Standard deviation, background, counting rate, dead time.

Detectibility in a scan. Object contrast, information density, sensitivity, resolution, scatter, attenuation, motion of the object, contrast enhancement.

Quality control. Resolution, uniformity, value of floods and flood correction, linearity, peaking photomultiplier tubes.

Computers in Nuclear Medicine. Available types, data acquisition, background subtraction, contrast enhancement, flood correction, effect of data manipulation on statistics, temporal and spatial smoothing.

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 |
|---|---|
| KENNETH ORDIENE, MD | N.J |

### 3. CERTIFICATION

| SPECIALTY BOARD<br>A | CATEGORY<br>B | MONTH AND YEAR CERTIFIED<br>C |
|---|---|---|
| | | |

### 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

| FIELD OF TRAINING<br>A | LOCATION AND DATE(S) OF TRAINING<br>B | TYPE AND LENGTH OF TRAINING | |
|---|---|---|---|
| | | LECTURE/ LABORATORY COURSES (Hours)<br>C | SUPERVISED LABORATORY EXPERIENCE (Hours)<br>D |
| a. RADIATION PHYSICS AND INSTRUMENTATION | Montefiore Medical Center 7/81 - 6/82 | 20 | 5 |
| b. RADIATION PROTECTION | " | 5 | - |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | " | 5 | - |
| d. RADIATION BIOLOGY | " | 3 | - |
| e. RADIOPHARMACEUTICAL CHEMISTRY | " | 3 | - |

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

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| $^{131}I$ | 250 mCi | Montefiore Hosp. Bronx N.Y. | 7/1/81 - 6/30/82 | Thyroid Ca |
| $^{131}I$ | 20 mCi | " | " | Hyperthyroidism |
| $^{125}I$ | 2 mCi | " | " | Protein labelling In vitro tests |

FORM NRC-313M-SUPPLEMENT
(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

Kenneth W. Ordene

STREET ADDRESS

34 Center St

CITY | STATE | ZIP CODE

Springfield NJ 07081

**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<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>*(Additional information or comments may be submitted in duplicate on separate sheets.)*<br>D |
|---|---|---|---|
| I-131 or I-125 | DIAGNOSIS OF THYROID FUNCTION | [redacted] | |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | [redacted] | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | | |
| | IN VITRO STUDIES | ~1000 | |
| OTHER | | | |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | [redacted] | |
| P-32 | EYE TUMOR LOCALIZATION | [redacted] | |
| Se-75 | PANCREAS IMAGING | [redacted] | |
| Yb-169 | CISTERNOGRAPHY | [redacted] | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | [redacted] | |
| OTHER | $^{123}$I UPTAKE + SCAN | [redacted] | |
| Tc-99m | BRAIN IMAGING | [redacted] | |
| | CARDIAC IMAGING | [redacted] | |
| | THYROID IMAGING | [redacted] | |
| | SALIVARY GLAND IMAGING | [redacted] | |
| | BLOOD POOL IMAGING | [redacted] | |
| | PLACENTA LOCALIZATION | [redacted] | |
| | LIVER AND SPLEEN IMAGING | [redacted] | |
| | LUNG IMAGING | [redacted] | |
| | BONE IMAGING | [redacted] | |
| OTHER | | | |

EXPERIENCE WITH RADIATION

| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
|---|---|---|---|---|
| Co 57 | | | | |
| Ga 67 | | | | |
| Se 75 | | | | |
| Kr 81 | | | | |
| Tc99/Mo99 | | | | |
| In 111 | | | | |
| I 131 | 20mCi | MONTEFIORE MEDICAL CENTER BRONX N.Y. | 7/1/81 - 6/30/82 | Therapy of Thyroid Cancer |
| I 131 | 250mCi | MONTEFIORE MED. CENTER | 7/1/81 - 6/30/82 | Therapy of Thyroid Ca. |
| Xe 133 | | | | |
| Yb 169 | | | | |
| Tl 201 | | | | |

## PRECEPTOR STATEMENT (Continued)

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

| ISOTOPE<br>A | CONDITIONS DIAGNOSED OR TREATED<br>B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION<br>C | COMMENTS<br>(Additional information or comments may be submitted in duplicate on separate sheets.)<br>D |
|---|---|---|---|
| P-32 (Soluble) | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | | |
| P-32 (Colloidal) | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | 49 | |
| | TREATMENT OF HYPERTHYROIDISM | 184 | |
| Au-198 | INTRACAVITARY TREATMENT | 3 | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | 3 | |
| | INTRACAVITARY TREATMENT | 4 | |
| I-125 or Ir-192 | INTERSTITIAL TREATMENT | | |
| Co-60 or Cs-137 | TELETHERAPY TREATMENT | 1 | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | 2 | |
| Mo-99/ Tc-99m | GENERATOR | 2 | |
| Sn-113/ In-113m | GENERATOR | 2 | |
| Tc-99m | REAGENT KITS | 2 | |
| Other<br>$^{125}I$ | THYROID UPTAKE + SCANS | 450 | |
| $^{125}I$ | PROTEIN LABELLING | 12 | |
| $^{125}I$ | IN VITRO TESTS | ABOUT 1000 | |

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

7/1/81 - 6/30/82 - about 8hrs/wk

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

a. NAME OF SUPERVISOR: [illegible], Ph.D

b. NAME OF INSTITUTION: Montefiore Medical Center

c. MAILING ADDRESS: 111 E 210 St / Bronx NY / 10467

d. CITY

5. MATERIALS LICENSE NUMBER(S): 188-7

6. PRECEPTOR'S SIGNATURE: Leroy A. Sugarman, MD

7. PRECEPTOR'S NAME (Please type or print): LEROY A. SUGARMAN, M.D

8. DATE: May 3, 1983

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(8-78)

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(3) Followup of patients when required.

(4) Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc.

Note A:

The requirements specified in Sections 2a, b, and c may be satisfied concurrently in a 3-month training program IF all three areas are integrated into the program.

Note B:

For each physician named in Item 4 of Form NRC-313M, complete Supplements A (Training and Experience) and B (Preceptor Statement) of Form NRC-313M. For each subject covered in basic training, state where the training was obtained, the dates, total number of hours, and type of training. Hours of training should be broken down into lecture or laboratory hours or on-the-job training (OJT). OJT must have been obtained in a formalized training program. Be sure that individual hours of training can be traced to the institution where the training was received. Each hour of training should be listed under only *one* subject category (i.e., the most applicable subject category).

**Alternatives**

Certification by (a) the American Board of Nuclear Medicine, or (b) the American Board of Radiology in Diagnostic Radiology with Special Competence in Nuclear Radiology will be accepted as evidence that a physician has had adequate training and experience to use Groups I, II, and III.

3. **Training for Specific Diagnostic Procedures**

A physician who wishes to be authorized for only one or two specific diagnostic procedures should have training in basic radioisotope handling techniques and clinical procedures commensurate with the procedures and quantities of byproduct material being requested. Such requests will be examined on a case-by-case basis by the Commission with the assistance of the ACMUI.

4. **Training for Therapy Procedures Involving Radiopharmaceuticals**

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Groups IV and/or V in §35.100 of 10 CFR Part 35, a physician should have:

a. Training in basic radioisotope handling techniques applicable to the use of unsealed sources for therapy procedures, including (80 hours)

(1) Radiation physics and instrumentation (25 hours)

(2) Radiation protection (25 hours)

(3) Mathematics pertaining to the use and measurement of radioactivity (10 hours)

(4) Radiation biology (20 hours)

(These requirements are in lieu of, not in addition to, those specified in Section 2a above.)

b. Clinical training in specific therapy procedures:

*For Group IV*

(1) I-131 for treatment of hyperthyroidism and/or cardiac conditions:

Clinical experience in the diagnosis of thyroid function and active participation in the treatment of *ten patients*.

(2) Soluble P-32 for treatment of polycythemia vera, leukemia, and/or bone metastases:

Active participation in the treatment of *three patients* with any combination of these three conditions.

(3) Colloidal P-32 for intracavitary treatment:

Active participation in the treatment of *three patients*.

*For Group V*

(1) I-131 for treatment of thyroid carcinoma:

Clinical experience in diagnosis of thyroid function, personal participation in the treatment of *ten patients* with hyperthyroidism and/or cardiac dysfunction, and active participation in the treatment of *three patients* with thyroid carcinoma.

(2) Colloidal Au-198 for intracavitary treatment:

Active participation in the treatment of *three patients*.

5. **Training for Therapy Procedures Involving Sealed Sources**

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Group VI in §35.100 of 10 CFR Part 35, a physician should have:

a. Training in basic radioisotope handling techniques applicable (200 hours)

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LMS

PROGRAM CODE: 02200
STATUS CODE: 0
FEE CATEGORY: 7C
EXP. DATE: 19880930
FEE COMMENTS: _____

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: BUCHOLTZ MD., HARVEY K.
RECEIVED DATE: 871109
DOCKET NO: 3014533
CONTROL NO.: 108052
LICENSE NO.: 29-18129-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: 120
CHECK NO.: 134813

3. COMMENTS

SIGNED Forta
DATE 11/23/87

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

1. FEE CATEGORY AND AMOUNT: 7C $120

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

3. OTHER _____
_____

SIGNED S. Kimberley
DATE 12/2/87