

APPLICATION FOR MATERIAL LICENSE

JAN 23 1985

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

FEDERAL AGENCIES FILE APPLICATIONS WITH:

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

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

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

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

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

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

IF YOU ARE LOCATED IN:

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

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

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

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

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

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

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

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

- ☐ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER
☒ C. RENEWAL OF LICENSE NUMBER 34-01311-01

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

Good Samaritan Hospital and Health Center
2222 Philadelphia Drive
Dayton, Ohio 45406

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

same as 2.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

James W. Israel, Medical Physicist

TELEPHONE NUMBER

(513) 278-2612 ext. 2028

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

5. RADIOACTIVE MATERIAL

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

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

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

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AT

8507300038 850709
REG3 LIC30

10. RADIATION SAFETY PROGRAM.

11. WASTE MAN:

34-01311-01 PDR

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 7.C AMOUNT ENCLOSED \$ 580.00

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

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

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER

TYPED/PRINTED NAME

TITLE

DATE

Joseph W. Ferguson, Assistant Vice President/Operations Jan. 21, 1985

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

< \$250K
\$250K—500K
\$500K—750K
\$750K—1M

\$1M—3.5M
\$3.5M—7M
\$7M—10M
> \$10M

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

c. NUMBER OF BEDS

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

☐ YES

☐ NO

FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

COMMENTS

APPROVED BY

AMOUNT RECEIVED

CHECK NUMBER

CONTROL NO. 78165

DATE

PRIVACY ACT STATEMENT

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

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.
5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

Good Samaritan Hospital and Health Center, Dayton, Ohio

Items 5. and 6.

RADIOACTIVE MATERIAL AND USES

1. Radioactive Material for Medical Uses

a. Materials listed in 10 CFR - Radioactive materials listed in the following paragraphs of 10 CFR will be used as described in those paragraphs.

| <u>Listed in:</u> | <u>Maximum Possession Limit (mCi)</u> |
|-------------------------------------|---------------------------------------|
| 10 CFR 31.11 (for in vitro studies) | 6 |
| 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 | 5000 |
| 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 | 1500 |

b. Additional Materials for Medical Use - In addition, Xenon-133 as gas or gas in saline will be used for Blood Flow studies or Pulmonary Function studies, with a maximum possession limit of 1500 mCi.

2. Radioactive Material for Other Uses

| <u>Element and Mass Number</u> | <u>Form</u> | <u>Amount</u> | <u>Purpose</u> |
|--------------------------------|----------------------|---------------|---|
| Uranium (depleted in U-235) | Cadmium-plated metal | 182 kilograms | Shielding in a medical linear accelerator |

CONTROL NO. 78165

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

| | | | | |
|--|---|--|--|-------------|
| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER James W. Israel | | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE | | |
| 3. CERTIFICATION | | | | |
| SPECIALTY BOARD A | CATEGORY B | MONTH AND YEAR CERTIFIED C | | |
| American Board of Radiology | Diagnostic Radiological Physics | June 1983 | | |
| 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES | | | | |
| FIELD OF TRAINING A | LOCATION AND DATE(S) OF TRAINING B | TYPE AND LENGTH OF TRAINING | | |
| | | LECTURE/ LABORATORY COURSES (Hours) C | SUPERVISED LABORATORY EXPERIENCE (Hours) D | |
| a. RADIATION PHYSICS AND INSTRUMENTATION | West Virginia University Morgantown, W. Va. June 1974 - June 1976 | 40 | 500 | |
| b. RADIATION PROTECTION | " " | 30 | 500 | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | " " | 25 | 500 | |
| d. RADIATION BIOLOGY | " " | 5 | -- | |
| e. RADIOPHARMACEUTICAL CHEMISTRY | " " | 2 | -- | |
| 5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience) | | | | |
| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
| | | See attached sheet | | |

NRC-313M-Supplement A (continued)

| Isotope | Maximum Amount | Where Experience was Gained | Duration | Type of Use |
|---------|----------------|---|----------|--------------------------------------|
| Cs-137 | 650 mCi | Good Samaritan Hospital, Dayton, OH | 16 mos. | Implants |
| Ir-192 | 113 mCi | " " " | " | " |
| Au-198 | 200 mCi | " " " | " | " |
| I-125 | 31 mCi | " " " | " | " |
| Cs-137 | 250 mCi | Naval Hospital, Bethesda | 6 mos. | " |
| Ir-192 | 25 mCi | " " " | " | " |
| Ir-192 | 25 mCi | " " " | " | " |
| Co-60 | 4500 Ci | " " " | " | Teletherapy |
| Co-60 | 3000 Ci | Naval Regional Medical Center Philadelphia | 18 mos. | " |
| Tc-99m | 50 mCi | " " " " | 2 yrs. | Calibration of Dose Calibrator |
| Cs-137 | 50 mCi | Naval Damage Control Training Center, Philadelphia | 1 yr. | Training |

Curriculum Vitae

JAMES W. ISRAEL

Education:

Master of Science - Physics, West Virginia University, May 1976
Bachelor of Science - Physics, West Virginia University, May, 1974

Experience:

Good Samaritan Hospital, Dayton, Oh. - Medical Physicist May 1983-present
Naval Hospital, Bethesda, Md. - Radiation Specialist, July 1979-May 1983
Naval Regional Medical Center, Philadelphia, Pa. - Radiation
Specialist, July 1977-June 1979
Naval Damage Control Training Center, Philadelphia, Pa. - Radiation
Health Officer, July 1976-July 1977
West Virginia University Medical Center, Morgantown, W. Va. -
Radiology Research Assistant, July 1974-June 1976

NRC License Experience:

Radiation Safety Officer on the following licenses:
NRC License #34-01311-01 (Good Samaritan Hospital)
July 1983-present
NRC License #37-01848-01 (Nuclear Medicine, NRMC Phila.)
July 1977-June 1979
NRC License #37-01848-02 (Radiation Therapy, NRMC Phila.)
July 1977-June 1979
NRC License #37-05293-01 (Training, NDCTC Phila.)
July 1976-June 1979

Affiliations:

American Association of Physicists in Medicine
- Full member

Certification:

American Board of Radiology
- Diagnostic Radiological Physicist, June 1983

Additional Information

TABLE OF CONTENTS

All information required for Items 7. through 11., as described in Regulatory Guide 10.8, is provided in the attachments that follow. This renewal is submitted without reference to previous submittals, except for references to previous users (Attachment A), and to previously described procedures for Xenon use (Attachment M). The attachments are as follows:

| <u>Attachment</u> | <u>Subject</u> |
|-------------------|--|
| A | Individual Users |
| B | Radiation Safety Committee |
| C | Instrumentation |
| D | Calibration - Survey Instruments and Dose Calibrators |
| D-1 | Facilities and Equipment |
| D-2 | Personnel Training Program |
| E | Ordering and Receiving |
| F | Opening Packages |
| G | Rules for Safe Use of Radioactive Materials |
| H | Emergency Procedures |
| I | Area Survey Procedures |
| J | Waste Disposal |
| K | Therapeutic Use of Radiopharmaceuticals |
| L | Therapeutic Use of Sealed Sources |
| M | Use of Xenon-133 |
| N | Personnel Monitoring and ALARA |

Attachment A

INDIVIDUAL USERS

Licensed material will be used by, or under the supervision of, the following individuals for the materials and uses indicated:

| | |
|----------------------------|---|
| G. W. Bretz, M.D. | Groups I, II, and III Xenon-133 Iodine-131 for therapy Soluble phosphorus-32 for therapy <u>In vitro</u> studies |
| Dudley K. Campbell, M.D. | Groups I, II, III, IV, V, and VI, except gold-198 and colloidal phosphorus-32 for therapy Xenon-133 <u>In vitro</u> studies |
| Roger H. Cook, M.D. | All |
| Tomas S. Garnica, M.D. | Groups I, II, III, IV, and V, except gold-198 for therapy Xenon-133 <u>In vitro</u> studies |
| H. R. Hittner, M.D. | All |
| Donald Marger, M.D. | All |
| Thomas C. Mick, M.D. | All |
| L. H. van der Hoeven, M.D. | Groups I, II, and III Xenon-133 <u>In vitro</u> studies |
| Theodore K. Payne, M.D. | All |
| Stuart J. Sorkin, M.D. | Groups I, II, III, IV, and V Xenon-133 <u>In vitro</u> studies |
| W. P. Kirchner, M.D. | All, except Group VI |
| B. Must, Jr., M.D. | Groups II, III, and VI |

(continued)

Joel E. Janousek, M.D.

Groups I, II, and III
Xenon-133
In vitro studies
Iodine-131 for therapy

Michael R. Carroll, M.D.

Groups I, II, and III
Xenon-133
In vitro studies
Iodine-131 for therapy

Robert L. Antonelli, M.D.

All, except Group VI

Michael J. Cohen

Groups I, II, and III
Xenon-133
In vitro studies

Gregory MacNealy

Groups I, II, and III
Xenon-133
In vitro studies

These individuals were listed previously as authorized users for the indicated materials and uses in Amendment #39 to NRC License #34-01311-01 with the following exceptions:

- 1) In the above-mentioned amendment, Dudley K. Campbell's materials and uses included the restriction, "except phosphorus-32 and gold-198 for therapy". A preceptor statement is attached, documenting that Dr. Campbell has the necessary experience so that the restriction on soluble phosphorus-32 can be dropped.
- 2) Michael J. Cohen and Gregory MacNealy are listed as authorized users for the indicated materials and uses in NRC License #34-02176-01.

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 | | | 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. |
|---|-------------------|-----------------------|---|
| FULL NAME Dudley K. Campbell, M.D. | | | |
| STREET ADDRESS 400 Limber Lost Trail | | | |
| CITY Dayton | STATE Ohio | ZIP CODE 45429 | |

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 | | |
| | 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 | | |
| 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 | | |
| | 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 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 MARROW STASES | 3 | |
| 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 | | | |

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

Stuart J. Sorkin, M.D.

b. NAME OF INSTITUTION

Good Samaritan Hospital

c. MAILING ADDRESS

2222 Philadelphia Drive

d. CITY

Dayton, Ohio 45406

5. MATERIALS LICENSE NUMBER(S)

34-01311-01

6. PRECEPTOR'S SIGNATURE

Stuart J. Sorkin, M.D.

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

Stuart J. Sorkin, M.D.

8. DATE

January 21, 1985

Attachment B

RADIATION SAFETY COMMITTEE

Chairman - The chairman shall be selected from among the staff radiologists.

Membership - The committee membership shall comprise the following, as a minimum:

Staff representative, Emergency Medicine
Staff representative, Family Practice Clinic
Staff representative, Dental Center
Staff representative, Internal Medicine
Staff representative, Laboratory Medicine
Staff representative, Radiation Therapy
Staff representative, Dermatology
Assistant Vice President, Operations
Director of Medical/Surgical Nursing
Managing Director, Radiological Sciences and Medical Imaging
Managing Director, Laboratory
Assistant Managing Director, Medical Imaging
Radiation Safety Officer

Frequency of Meeting - The committee shall meet as often as considered necessary by the chairman, but not less than once in each calendar quarter.

Purpose and Duties - The purpose of the Radiation Safety Committee is to oversee the Radiation Safety Program of Good Samaritan Hospital and Health Center, and to ensure that all uses of radioactive materials and radiation emitting devices are conducted in a safe manner and in accordance with the regulations of the Nuclear Regulatory Commission and the State of Ohio. The duties of the committee shall include the following:

- a. To review all proposals for diagnostic and therapeutic uses of radioactive materials and other sources of radiation, and to approve such procedures, or give reasons for disapproval.
- b. To develop rules regarding the receipt, handling, dispensing, storage, and disposal of radioactive materials.
- c. To develop and implement rules and procedures which ensure that diagnostic and therapeutic applications are carried out (1) in conformity with state and federal regulations, and (2) with the lowest practical radiation dose consonant with the desired clinical effect.

(continued)

- d. To recommend remedial action when there is a failure to observe protection recommendations, rules, or regulations.
- e. To ensure that the NRC byproduct material license is amended, when necessary, and that the application for renewal is submitted not less than thirty days prior to the license expiration date.
- f. To review the radiation safety program annually to determine that activities are being conducted safely and in accordance with NRC regulations and the conditions of the license. The review shall include an examination of all records, reports of the radiation safety officer, results of NRC inspections, and the adequacy of the management control system.
- g. To implement and maintain a program to keep radiation exposures as low as reasonable achievable.

Good Samaritan Hospital and Health Center, Dayton, Ohio

Attachment C

INSTRUMENTATION

Survey Instruments

| # of instruments | manufacturer | model # | minimum range | maximum range |
|---------------------|-----------------|---------|---------------------|------------------------|
| 2 | Victoreen | 490 | 0 - 0.2 mR/hr | 0 - 20 mR/hr |
| 1 | Victoreen | 470A | 0 - 3 mR/hr (or mR) | 0 - 1000 mR/hr (or mR) |
| 1 | Victoreen | 740F | 0 - 25 mR/hr | 0 - 25,000 mR/hr |
| 1 | Eberline | E120G | 0 - 10 mR/hr | 0 - 1000 mR/hr |
| 1 | Eberline | E140 | 0 - 500 cpm | 0 - 50,000 cpm |
| 1 | Nuclear Chicago | 2612 | 0 - 0.2 mR/hr | 0 - 20 mR/hr |

Pocket Dosimeters

| | | | |
|---|----------------------------------|------|------------|
| 1 | Dosimeter Corporation of America | 862 | 0 - 200 mR |
| 5 | Victoreen | 541L | 0 - 200 mR |

Dose Calibrators

| # of instruments | manufacturer | Model # |
|---------------------|--------------|---------|
| 1 | Capintec | CRC-6 |
| 1 | Capintec | CRC-17 |

(continued)

Diagnostic Instruments

| <u>type of instrument</u> | <u>manufacturer</u> | <u>model #</u> |
|--------------------------------|---------------------|-----------------|
| Gamma Camera | Picker | 4/15 |
| Gamma Camera | Picker | 4/12 |
| Gamma Camera | Picker | 5/15 |
| Nuclear Medicine Computer | ADAC | System I |
| Well Counter | Iso-Data | 20/20 Series |
| Well Counter | Packard | 5330 |
| Well Counter | ANSR | 7157 |
| Well Counter | Becton Dickinson | ARIA II |
| Uptake Probe & Scale | Picker | Spectroscaler 4 |
| Ibrinitor (Thrombosis Monitor) | Searle | 9273-1 |

Other Instruments

| <u>type of instrument</u> | <u>manufacturer</u> | <u>model #</u> |
|---------------------------|---------------------|----------------|
| Area Monitor | Nuclear Associates | 05-425 |
| Xenalert (Xenon Monitor) | Nuclear Associates | 36-751 |

Attachment D

SECTION 1. CALIBRATION OF SURVEY INSTRUMENTS

1. Survey instruments will be calibrated at least annually, and following repair.
2. Calibration will be performed at two points on each scale used for radiation protection purposes (i.e., up to 1 R/hr). The two points will be approximately 1/3 and 2/3 of full scale. The survey instrument will be considered properly calibrated when the instrument readings are within ± 10 percent. When scales are not checked, an appropriate precautionary note will be posted on the instrument.
3. Survey instruments will be calibrated by any one of the following:
 - a. by the manufacturer.
 - b. by the Radiation Safety Officer at this facility using one or more 3M Model 6D6C-CA Cs-137 sources of approximately 25, 37.5 or 50 millicuries. These sources have a calibrated accuracy of ± 5 percent, traceable to NBS. The calibration procedures described in Section 1 of Appendix D to Regulatory Guide 10.8 will be followed.
 - c. by Health Physics Associates Ltd., 3304 Commercial Avenue, Northbrook, IL 60062. HPA's procedures and sources have been approved by NRC and are on file in License #12-09160-01.

SECTION 2. CALIBRATION OF DOSE CALIBRATORS

1. Linearity - The Medical Physicist, or a technologist working under the physicist's supervision, will check linearity of the dose calibrators on a quarterly basis and after any maintenance, using the following procedure:
 - a. Obtain a vial of Tc-99m of approximately 150-200 mCi from the nuclear pharmacy.
 - b. Measure the activity of this vial the morning it arrives and also about 6, 24, 30, and 48 hours later. Record net activities (mCi) and times of measurement.
 - c. Using the 30-hour measurement as a standard, use the exponential decay law to find expected activities at the other times of measurement. (Note: $T_{1/2} = 6.02$ hrs.)

(continued)

- d. Calculate the percent difference between expected and measured values.
- e. If any of the differences are greater than ± 5 percent, then the physicist will either (1) arrange for the repair or recalibration of the dose calibrator so that all differences are less than 5 percent, or (2) prepare a graph on log-log paper relating measured activity to calculated activity, to be used during routine assays.

2. Accuracy - The Medical Physicist, or a technologist working under the physicist's supervision, will check accuracy of the dose calibrators twice yearly and after any maintenance.

The sources used for the instrument accuracy tests are described in the following table.

| <u>Radionuclide</u> | <u>Calibrated Activity (mCi)</u> | <u>Calibration Date</u> | <u>Accuracy</u> |
|---------------------|----------------------------------|-------------------------|-----------------|
| Co-57 | 7.05 | 7-1-84 | $\pm 5\%$ |
| Ba-133 | 0.27 | 11-2-79 | $\pm 5\%$ |
| Cs-137 | 0.10 | 10-2-75 | $\pm 3.8\%$ |

Any of these sources may be replaced by a source of the same radionuclide, with approximately the same activity and an accuracy of ± 5 percent or better, traceable to NBS.

The accuracy will be tested using procedures described in Section 2 of Appendix D to Regulatory Guide 10.8.

3. Constancy - A technologist will check the constancy of the dose calibrators each morning before they are used, using the following procedure:

- a. Set and record background reading. Investigate higher than normal background levels to determine their origin and to eliminate them, if possible, by decontamination, relocation, etc.
- b. Use the three sources described in paragraph 2 above.
- c. Measure (1) the net activity of the Cs-137 source at the setting for Mo-99, (2) the net activity of the Co-57 source at the setting for Tc-99m, and (3) the net activity of the Ba-133 source at the setting for Ba-133.

(continued)

d. Plot the measured net activities on the graph provided by the physicist. This graph shows upper and lower bounds for ± 5 percent accuracy, taking into account natural decay and the difference in measured value when one radionuclide is measured at the setting for another radionuclide.

e. If any of the measured activities are outside the ± 5 percent limits, arrange for repair or adjustment of the instrument.

4. Geometrical Variation - At installation and after any major repair, the Medical Physicist will test the geometrical variation of the dose calibrator. Procedures described in Section 2 of Appendix D to Regulatory Guide 10.8 will be followed, except that a chart relating correction factors to volumes may be used in place of the graph described in paragraph 4.

5. Linearity - Alternate Method - As an alternative to the method of testing linearity described in paragraph 1 above, a linearity device such as the Lineator (Atomic Products Corporation #086-507) may be used. Such a linearity device consists of a number of lead lined tubes that can be arranged concentrically to provide varying degrees of attenuation for an enclosed source. It would be used as follows:

a. To obtain baseline data initially,

- 1) perform a conventional linearity test as described in paragraph 1 to assure that the calibrator is linear to within 5%.
- 2) Using a 150-200 mCi Tc-99m source, measure apparent activity of the source unshielded, and then with each combination of shields in the linearity device.
- 3) Determine the ratios of shielded activity to unshielded activity for each of the shielding combinations in the linearity device. Record these ratios.

b. On a quarterly basis, and after any maintenance:

- 1) Repeat steps 2) and 3) from subparagraph a.
- 2) Compare measured activity ratios to baseline activity ratios. Calculate percent differences.
- 3) If any of the percent differences are greater than $\pm 5\%$, the physicist will arrange for repair or recalibration of the dose calibrator.

Attachment D-1

FACILITIES AND EQUIPMENT

In the Nuclear Medicine Section, radioactive materials are used in seven rooms. Materials are received, stored, and used for diagnostic or therapeutic purposes in six rooms on the first floor of the South Building. Another room, in the basement of the North Building, is used for storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. Facilities and equipment available in these rooms are as follows:

a. Hot Lab (Room #CC15.5N) - All radioactive materials, except low level invitro kits and I-131 doses, are received and stored prior to use in this room, and doses are assayed prior to delivery to patients. The room contains:

- 1) a Fisher laboratory fume hood,
- 2) a Nuclear Associates Area Monitor #05-425,
- 3) a Nuclear Associates Lead-Lined Refrigerator,
- 4) a Nuclear Associates Storage Container for Small Vials (lead),
- 5) a Nuclear Associates Lead Tabletop Shield additionally shielded with 1" x 7" x 7" blocks,
- 6) two Squibb Tc-99m Generator Shields and one NEN Tc-99m Generator Shield surrounded by walls of 2" x 4" x 8" blocks, used to store hot trash such as needles and syringes,
- 7) three lead-lined boxes used as secondary storage for hot trash when shields described in (6) above are full,
- 8) various leaded glass syringe shields,
- 9) the dose calibrators.

b. Uptake Room (Room #DD15.5E) - Diagnostic and outpatient therapeutic doses of I-131 are stored and administered in this room. The room contains

- 1) a shielded box constructed of 2" x 4" x 8" lead blocks with a 7" x 7" x 1" lead cover, used to store diagnostic doses of I-131 prior to administration,
- 2) a Squibb Tc-99m Generator Shield used to store therapeutic doses of I-131 prior to administration,

(continued)

- 3) a table where many of the survey instruments are stored, and
- 4) the Picker uptake probe.

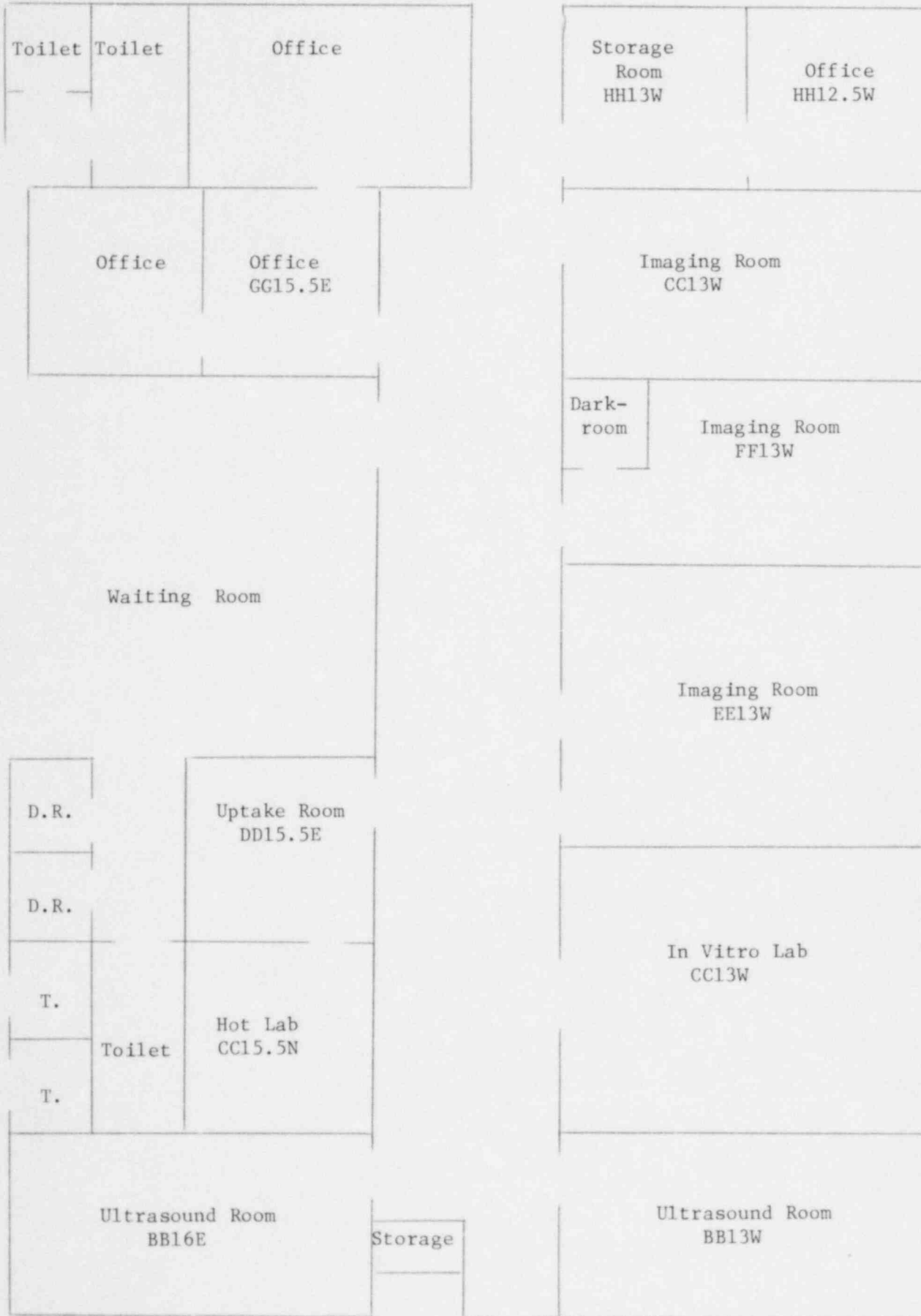
c. Invitro Room (Room #CC13W) - Invitro tests are performed in this room, and the radioactive material used in thosetests are stored here. Equipment in the room includes

- 1) a lead-lined box for storing radioactive waste prior to transfer to the Storage Room,
- 2) two refrigerators for storing radioactive materials before they are used, and
- 3) three well counters.

d. Imaging Rooms (Rooms #EE13W, FF13W, and GG13W) - Diagnostic imaging studies are performed in these rooms. Each room contains a Picker Dyna Camera. The system in Room EE13W is connected to an ADAC computer which is used for cardiac studies. A Xenon-study setup, consisting of a Xenon Lung Function Unit, Xenon Gas Trap, and Xenalert monitor (all from Nuclear Associates), can be moved to any of the three imaging rooms.

e. Waste Storage - The Waste Storage Room is located in the basement of the North Building. It is always locked, and keys are maintained by the Medical Physicist and the Assistant Director of Medical Imaging. The room contains steel storage drums (supplied by ADCO Services, Inc., Tinley Park, IL) for disposal of long-lived waste, and considerable space for holding short-lived waste during decay. The room is surveyed weekly with a low-level radiation monitor.

North Corridor



South Corridor

Attachment D-2

PERSONNEL TRAINING PROGRAM

All personnel who work with, or in the vicinity of, radioactive materials will receive training. The extent of that training will depend on the individual's involvement with radioactive materials.

1. General Instruction - All involved ancillary personnel will receive initial orientation and approximately annual refresher training in radiation safety, either in lecture or videotape form. This training will include, but will not be limited to, personnel from the following departments:

- a. Surgery
- b. Security
- c. Housekeeping
- d. Facilities Engineering
- e. Oncology Nursing Unit

2. Specific Instruction - The personnel specified in this section will receive training before assuming duties with, or in the vicinity of, radioactive materials; during annual refresher training; and whenever there is a significant change in duties, regulations, or terms of the license.

a. Nuclear Medicine technologists will receive annual training in a series of no fewer than six training sessions per year. The sessions will consist of lectures, videotapes, or demonstrations, and will be given, or coordinated by, the Radiation Safety Officer.

b. Radiation Therapy technicians work with radioactive materials only very infrequently, since the Radiation Safety Officer and the Radiation Therapist do most of the source handling for brachytherapy implants. Therefore, their annual training will consist of a single one-hour sessions per year.

3. Content of Instruction - The above training sessions will be derived from the outlines presented in the Nuclear Regulatory Commission Draft Regulatory Guide and Value/Impact Statement (Division 8, Task OP 212-4), "RADIATION PROTECTION TRAINING FOR PERSONNEL EMPLOYED IN MEDICAL FACILITIES", issued in January 1984.

ATTACHMENT E

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. For routine diagnostic studies, the Assistant Director of Medical Imaging has placed a standing order for commonly used isotopes (e.g., Tc-99m, Xe-133, etc.) with a local nuclear pharmacy. These doses are delivered by a carrier from the pharmacy.
2. The Assistant Director/Medical Imaging or his designee must place all special orders for radioactive material and must ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
3. During normal working hours, carriers must be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.
4. During off-duty hours, the procedures outlined in the attached memo will be observed.

(continued)

MEMO



DATE January 17, 1985

TO Jerome P. Schaaf, Director, Security

FROM Joseph F. Kelly, Managing Director, Radiological Sciences and Medical Imaging

SUBJECT Receipt of Packages Containing Radioactive Material

In the event that radioactive materials are delivered to the hospital during hours that the Nuclear Medicine Department is closed, the following procedures will be observed:

1. Security personnel will escort the carrier of the radioactive material to the Radiology Department.
2. Radiology Department personnel will sign for the package(s).
3. Radiology Department personnel will transport the radioactive material to Nuclear Medicine Department where it will be secured in the Nuclear Medicine Cold Room (Room DD15.5E).
4. If the package is wet or appears to be damaged, immediately contact the Assistant Director/Medical Imaging or his designee. Ask the carrier to remain at the hospital until it can be determined that neither he nor the delivery vehicle is contaminated. The Assistant Director/Medical Imaging will determine if the Radiation Safety Officer should be notified.

Assistant Director/Medical Imaging: Jack Spivey, R.T.
Office Phone: 278-2612 ext. 2331
Home Phone: 236-5407

ATTACHMENT F

PROCEDURES FOR SAFELY OPENING PACKAGES
CONTAINING RADIOACTIVE MATERIAL

1. Visually inspect package for any sign of damage (e.g., package wet or crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.
2. Always measure surface exposure rate. If greater than 200 mR/hr, stop procedure and notify Radiation Safety Officer or his designee. The Radiation Safety Officer will immediately notify the Region III office of the NRC at phone (312) 932-2500, and the final delivering carrier.
3. Put on gloves.
4. Open the outer package (following manufacturer's directions, if supplied) and remove packing slip. Open inner package to verify contents (compare packing slip and label on bottle), and check integrity of final source container (inspecting for breakage of seals or vials, loss of liquid, discoloration of packing material). Check also that shipment does not exceed possession limits.
5. Monitor the packing material for contamination before discarding.
 - a) If contaminated, treat as radioactive waste.
 - b) If not contaminated, obliterate radiation labels before discarding in regular trash.
6. Record results of measurements on a form such as the attached "Radioactive Shipments Receipt Report".

(continued)

Radioactive Shipments Receipt Record

[illegible]

Attachment G

GENERAL RULES FOR SAFE 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 and clothing for contamination after each procedure or before leaving the area.
- 4) Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being.
- 5) Do not eat, drink, smoke or apply cosmetics in any area where radioactive material is stored or used.
- 6) Do not store food, drink, or personal effects with radioactive material.
- 7) Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10 percent. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.
- 8) Wear film badges at all times while in areas where radioactive materials are used or stored. Film badges should be stored in a low background area when not being worn to monitor occupational exposure.
- 9) Wear TLD finger badges during assay and injection of radio-pharmaceuticals.
- 10) Dispose of radioactive waste only in specially designated and properly shielded receptacles.
- 11) Never pipette by mouth.

(continued)

- 12) Confine radioactive solutions in covered containers plainly identified and labelled with the name of the compound, radio-nuclide, date, activity, and radiation level if applicable.
- 13) Always transport radioactive material in shielded containers.

Attachment H

EMERGENCY PROCEDURES

Emergency Procedures

a. Minor Spills

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

b. 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 and 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 or his alternate immediately.
- 6) PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

(continued)

RADIATION SAFETY
POINTS OF CONTACT

Radiation Safety Officer:

James W. Israel
Office: 278-2612, extension 2028
Home: 298-7057

Chairman, Radiation Safety Committee*:

T. K. Payne, M.D.
Office: 278-2612, extension 2085
Home: 293-9614

Assistant Managing Director*:

Medical Imaging:

Jack Spivey
Office: 278-2612, extension 2331
Home: 236-5407

*Both the Assistant Managing Director of Medical Imaging and the Chairman of the Radiation Safety Committee shall act as alternates to the Radiation Safety Officer in the event that he cannot be contacted.

Note: Names and phone numbers listed above
will be corrected if and when there are changes
in the personnel occupying the listed positions.

Attachment I

AREA SURVEY PROCEDURES

The surveys described below are necessary to assure that personnel are not exposed to high levels of external radiation, and that personnel do not receive internal contamination. These surveys will be performed by the Nuclear Medicine technician on call, or by the Medical Physicist, and results of the surveys shall be reported to the Radiation Safety Officer.

- a. Daily - All elution and preparation areas shall be surveyed daily with a low-range thin-window G.M. survey meter and decontaminated if necessary. Any area showing over 0.1 mR/hr will be considered contaminated. Corrective action and followup surveys will be recorded.
- b. Weekly - Other laboratory areas where radioactive materials are used will be surveyed weekly with a low-range thin-window G.M. survey meter and decontaminated if necessary. Any area showing over 0.1 mR/hr will be considered contaminated. Corrective action and followup surveys will be recorded.
- c. Bi-weekly - Areas where unsealed radioactive materials are used or stored shall be wipe tested at least bi-weekly. Filter paper or cotton swabs shall be used to wipe areas of approximately 100-150 square centimeters at random locations throughout the Nuclear Medicine department, and these wipe samples will then be counted to determine whether or not any removable contamination is present. If a removable contamination level of 200 dpm or greater is recorded, clean-up shall be initiated. If the level is 1000 dpm or greater, a contamination zone shall be established until the contamination has been removed, or has decayed to acceptable limits.

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

- a. Location, date, and identification of equipment used, including pertinent counting efficiencies.
- b. Name of person conducting the surveys.

(continued)

- c. Drawing of area surveyed, identifying relevant features such as active storage areas, waste areas, etc.
- d. Measured exposure rates, keyed to location on the drawing, pointing out rates that require corrective action.
- e. Detected contamination levels, keyed to location on drawing.
- f. 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.

For daily surveys where no abnormal exposure rates are found, only the date, the identification of the person performing the survey, and the measured exposure rates will be recorded.

Attachment J.

WASTE DISPOSAL

Materials Supplied by a Nuclear Pharmacy - A large portion of the radioactive materials used in Nuclear Medicine are obtained from a local nuclear pharmacy in individual doses. Unused doses, and used containers containing radioactive residue are returned to the nuclear pharmacy for disposal.

Liquid Waste will be disposed of:

- a. in the sanitary sewer system in accordance with paragraph 20.303 of 10 CFR Part 20, or
- b. by the commercial waste disposal service listed below.

Solid Waste will be:

- a. held for decay in the Waste Storage Room described in Attachment D-1 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; or
- b. disposed of by the commercial waste disposal service listed below.

The Commercial Waste Disposal Service will be:

ADCO Services, Inc., Tinley Park, Illinois
NRC License #12-11286-1

Attachment K

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

1. Radiation Safety Procedures

a. Radiopharmaceuticals will be used therapeutically only by physicians listed as authorized users on the NRC License. The physician supervising any radioisotope therapy must be authorized for that particular isotope.

b. All persons treated with Iodine-131 in excess of 30 millicuries or Gold-198 will be placed in a private room with a toilet. The room and toilet areas more likely to be contaminated will be covered with protective material as appropriate to the amounts of contamination expected. Particular attention should be paid to objects likely to be touched by the patient; e.g., telephones, doorknobs, and other items that would be difficult to contaminate.

c. The patient's room will be properly posted in accordance with paragraph 20.203 of Title 10 of the Code of Federal Regulations.

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

e. The form, "Nursing Instruction for Patients Treated with Phosphorus-32, Gold-198, or Iodine-131", which appears at the end of this attachment (or a similar form, containing all the requested information), will be completed immediately after administration of the treatment dose. A copy will be posted on the patient's chart.

f. All linens will be surveyed for contamination, and, if necessary, will be held for decay.

g. 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 by the Radiation Safety Officer or his designee, checked for

(continued)

contamination, and disposed of as normal or radioactive waste, as appropriate.

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

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

j. 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.

k. Iodine-131 Therapy on an Outpatient Basis - Patients being treated with less than 30 millicuries may be treated on an outpatient basis provided the following precautions are observed:

1) The patient will be asked to remain in the clinic for one hour after ingesting the radioactive iodine to insure that the dose is not regurgitated.

2) The patient will receive oral instructions from the physician concerning hazards of contamination and of external radiation.

3) At the discretion of the physician performing the therapy, the patient may be given a copy of the form, "Instruction for Outpatient Treated with Iodine-131". The patient will be asked to read the form while waiting in the clinic, and to ask any questions that may occur.

1. Nursing Instructions

1) Nurses should spend only that amount of time near the patient required for ordinary nursing care. Special restrictions may be noted on the precaution sheet on the patient's chart. Nurses should read these restrictions before administering to the patient. Call the Nuclear Medicine Department with any questions about the care of these patients.

(continued)

- 2) Visitors will be limited to those 18 years of age or over unless other instructions are noted on the precaution sheet on the patient's chart.
- 3) Patients must remain in bed while visitors are in the room and visitors should remain at least six (6) feet from the patient.
- 4) Patients containing radioactive materials are to be confined to their rooms except for special medical or nursing purposes approved by the Nuclear Medicine Department.
- 5) 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.
- 6) Attending personnel should wear rubber or disposable plastic gloves when handling urinals, bedpans, emesis basins, or other containers having any material obtained from the body of the patient. Wash gloves before removing and then wash hands. The gloves should be left in the patient's room in the designated waste container. These gloves need not be sterile or surgical in type.
- 7) Disposable items should be used in the care of these patients, whenever possible. These items should be placed in the designated waste container. Contact the Radiation Safety Officer or designee for proper disposal of the contents of the designated waste container.
- 8) All clothes and bed linens used by the patient should be placed in the laundry bag provided and should be left in the patient's room to be checked by the Radiation Safety Officer or designee.
- 9) All nondisposable items should be placed in a plastic bag and should be left in the patient's room to be checked by the Radiation Safety Officer or designee.
- 10) Surgical dressings should be changed only as directed by the physician. Gold-198 leaking from a puncture wound will stain the dressing dark red or purple. Such dressing should not be discarded but should be collected in plastic bags and turned over to the Radiation Safety Officer or designee. Handle these dressings only with tongs or tweezers. Wear disposable gloves.

(continued)

11) For Iodine-131 patients:

a. Urine from Iodine-131 patients will not be collected unless so requested, in which case it will be collected in special containers provided by the Radiation Safety Officer or designee. The patient should be encouraged to collect his own urine in the container. If the patient is bedridden, a separate urinal or bed pan should be provided. The urinal or bed pan should be flushed several times with hot soapy water after use.

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

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

d. Vomiting within 24 hours after oral administration, urinary incontinence, or excessive sweating within the first 48 hours may result in contamination of linen and floor. In any such situations or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or designee. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

e. All vomitus and any contaminated linens will be stored in plastic bags and must be kept in the patient's room for disposal by the Radiation Safety Officer or designee. Feces need not be routinely saved, unless ordered on the chart. The same toilet should be used by the patient at all times and it should be well flushed (3 times).

12) Utmost precautions must be taken to see that no urine or vomitus is spilled on the floor or the bed. If any part of the patient's room is suspected to be contaminated, notify the Radiation Safety Officer or designee.

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

(continued)

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

15) When the patient is discharged, call the Radiation Safety Officer or the Nuclear Medicine Department, and request that the room be surveyed for contamination before turning over to housekeeping for cleaning.

2. Handling Procedures to Prevent Personnel Contamination

The following procedures will be followed to assure that personnel handling I-131 are not exposed to significant levels of contamination:

- a. I-131 in therapeutic quantities will be ordered only as needed.
- b. The therapeutic dose shall be kept in its lead shipping container (except during assay) until it is administered to the patient.
- c. The cap of the I-131 dose vial will not be opened until the isotope is to be administered to the patient.
- d. The I-131 dose will be dispensed as soon as practical after receipt.
- e. If the dose is to be administered in the patient's room, it will be transported to the patient's room on a cart or some similar means to provide distance between the isotope and the technologist transporting it. Absorbent pads will be used on the transport cart to absorb any spillage of the isotope.
- f. Disposable plastic or rubber gloves will be worn during handling.
- g. Protective clothing (e.g., lab coat) will be worn during handling.
- h. Whenever handling of the dose vial is required, such as during assay, forceps will be used.
- i. To avoid contamination problems, only I-131 capsules or liquid in closed form* will be used.
- j. Personnel involved in any significant contamination incident, such as breakage of a capsule or closed vial, will be bioassayed to determine the thyroid uptake of the I-131.

*liquid in closed form consists of a closed vial of I-131 into which a straw is inserted. The patient ingests the I-131 through the straw, and release of I-131 into the room is minimized.

Date: _____

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

Patient's Name: _____

Room No.: _____ Physician's Name: _____

Radioisotope administered: _____

Date and Time of administration: _____, 19____ a.m.
p.m.

Dose received: _____ Method of administration: _____

Exposure rates in mR/hr

Date _____ 3 feet from bed _____ 10 feet from bed

(Comply with all checked items)

- ____ 1. Visiting time permitted: _____
- ____ 2. Visitors must remain _____ from patient, except for brief periods to shake hands, deliver mail, etc.
- ____ 3. Patient may not leave room.
- ____ 4. Visitors under 18 are not permitted.
- ____ 5. Pregnant visitors are not permitted.
- ____ 6. Film badges must be worn.
- ____ 7. Pocket chambers will be worn for supplementary personnel monitoring of individual tasks.
- ____ 8. Tag the following objects and fill out the tag:
- ____ door _____ chart
- ____ bed _____ wrist
- ____ 9. Disposable gloves must be worn while attending patient.
- ____ 10. Patient must use disposable utensils.
- ____ 11. All items must remain in room until approved for removal by the Radiation Safety Officer or his designee.
- ____ 12. Smoking is not permitted.
- ____ 13. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.
- ____ 14. Other instructions: _____

In case of emergency, contact: _____ name _____ on/off duty phone #'s _____

1) Radiation Safety Officer - _____
or 2) RSO Designee - _____

Nuclear Medicine Section
Good Samaritan Hospital and Health Center
Dayton, Ohio

INSTRUCTIONS FOR OUTPATIENT TREATED WITH IODINE-131

Patient's Name: _____

SS# _____

At _____ am
_____ pm on _____, 19 _____, you were
treated with an oral dose of radioactive iodine (I-131)
in the Nuclear Medicine Section at Good Samaritan Hospital.

In the next 24 hours a part of this radioactive medication
will be taken up by the thyroid. The rest will be excreted
mostly through the bowel movement, urine, and saliva. If you
should happen to vomit, or lose control of your bowel or urine
during this time period, please contact the Nuclear Medicine
Section at 278-2612, extension 2334, immediately.

You will be emitting low levels of radiation for the next few
weeks. These radiation levels are low enough that there are
no restrictions on your contact with other people, except
that for the next 48 hours it is advised not to hold children.

I have read the above instructions
and I understand them.

patient's signature

date

ATTACHMENT L

THERAPEUTIC USE OF SEALED SOURCES

Contents

| | page #'s |
|--|----------|
| 1. Area of Storage of Sealed Sources | L2-L3 |
| 2. Special Handling Precautions, | L4-L5 |
| 3. Determination of Radiation Dose to the Extremities. | L6 |
| 4. Transporting Sealed Sources | L7 |
| 5. Positive Inventory Control and Radiation Surveys. | L8-L9 |
| 6. Radiation Safety Procedures | L10-L13 |
| 7. Leak Test Procedures. | L14 |

1. Area of Storage of Sealed Sources

The area of storage of the sealed sources is the superficial x-ray treatment room of the Radiation Therapy Department which is in the basement of the hospital building. (See floor plan on next page.) The walls of this room contain a minimum of 1/8" lead shielding which extends to the ceiling. The ceiling is 1/16" lead equivalent.

The cesium 137 sealed sources are stored in a lead safe that was purchased from the Radium Chemical Company. The right and left sides of the safe are 2.5" thick. The top and bottom sides of the safe are 4" thick. The front of the safe, which contains two small access panels, is 2" thick. The rear of the safe is 2" thick and borders an underground, outside wall of the room. A 2" thick "L-Block" with a leaded glass viewing panel, which was also purchased from the Radium Chemical Company, is in position in front of the lead safe. The safe is kept locked at all times except when loading or unloading the sealed sources.

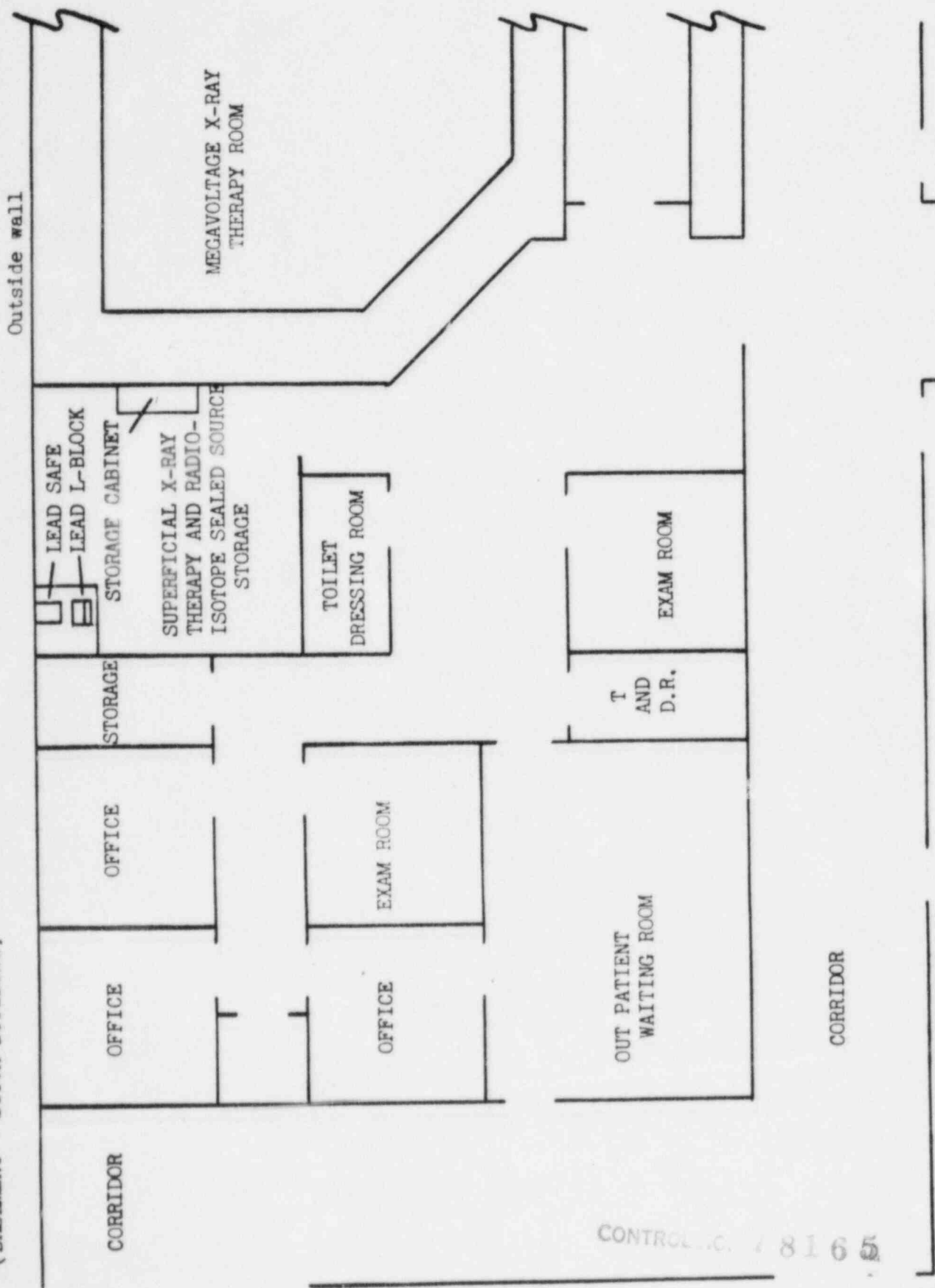
The shorter half-lived sealed sources (gold-198, iodine-125, and iridium-192) will be ordered as needed, kept in their protective lead shipping containers, and stored in the lockable steel storage cabinets which are located in the superficial x-ray treatment room. The storage cabinets will be locked at all times except when loading or unloading the protective lead shipping containers which hold the sealed sources. These lead containers will then be transported either to surgery for the loading of the applicator tools or to the patient's room for afterloading as in the case of Ir-192 seeds in nylon ribbon.

The closest unrestricted area of full occupancy is the physicist's office, which is approximately 7 feet from the storage area. A 10 mg.Ra.eq. Cs-137 source outside the lead enclosure results in an exposure rate of less than 0.5 mR/hr in this office. The same source, when behind the lead L-block, results in exposure rates of less than 0.2 mR/hr at all points outside the room.

(continued)

GOOD SAMARITAN HOSPITAL
RADIATION THERAPY DEPARTMENT
DAYTON, OHIO

(BASEMENT - SOUTH BUILDING)



CONTROL NO. 18165

2. Special Handling Precautions

In handling sealed sources, long forceps are always used to remove cesium-137 from the safe and to load it into the applicators. Long forceps are also always used in handling the shorter half-lived sealed sources. (Au-198, I-125, Ir-192) In the case of radioactive seeds, long forceps are used to load them into the implantation gun or syringe. In the case of temporary interstitial implants, (i.e., Ir-192 seeds in nylon ribbon), long forceps are used in the afterloading technique of loading the nylon ribbon into and through the nylon tube which has previously been implanted into the patient.

Persons handling the sealed sources always stand directly behind the lead and lead-glass L-Block except when using the shorter half-lived sealed sources (Au-198, I-125) in surgery, in which case the loading is done behind a portable lead barrier constructed with 2" X 4" X 8" lead blocks. Pregnant employees are not allowed to handle sealed sources or to assist in surgical procedures involving radioactive implants. The loaded Cs-137 applicators are transported in heavy lead containers for use on the hospital units. The shorter lived sealed sources are transported to surgery in their lead shipping containers. Cesium sources will be wipe tested at a maximum interval of three years* by the hospital medical physicist. A Victoreen 470A survey meter is available for radiation protection purposes. The maximum exposure rate at a distance of one meter from each patient in whom brachytherapy sources have been inserted will be measured immediately after administration of the material and recorded in the patient's chart.

* See attached information sheet from 3M indicating Nuclear Regulatory Commission approval of three year leak test for Model 6D6C tube sources.

(continued)

Consignee: Good Samaritan Hospital and Health Center RECALIBRATION70-4.12
23 Apr 1981Address: 2222 Philadelphia, Dayton, OH 45406Invoice No. KM49582**Measurement**

The following radioactive sources are certified by Minnesota Mining and Manufacturing Company (3M) to have been subjected to the tests described below and to have given the results listed.

| Model Number | Serial Number | Nominal Milligram Radium Equivalent Cesium-137 | Milligram Radium Equivalent* Cesium-137 | Millicuries** Cesium-137 |
|----------------|---------------|---|---|-----------------------------|
| 6501 (6D6C-CA) | 3095 | 10 | 9.4 | 23.8 |
| | 3071 | | 9.4 | 23.8 |
| | 3060 | | 9.4 | 23.8 |
| | 3063 | | 9.5 | 23.9 |
| | 3069 | | 9.6 | 24.1 |
| | 3064 | | 9.5 | 23.9 |
| | 3094 | | 9.5 | 24.0 |
| | 3109 | | 9.5 | 24.0 |
| | 3099 | | 9.5 | 23.9 |
| | 3108 | | 9.5 | 23.9 |
| | 3087 | | 9.6 | 24.2 |
| | 3098 | | 9.4 | 23.6 |
| 6502 (6D6C-CA) | 1774 | 15 | 14.2 | 35.7 |
| | 1773 | | 14.3 | 36.1 |
| | 1776 | | 14.3 | 36.0 |
| | 1778 | | 14.3 | 36.1 |
| 6503 (6D6C-CA) | 1260 | 20 | 18.4 | 46.3 |
| | 1272 | | 18.7 | 47.2 |
| | 1280 | | 17.5 | 44.0 |
| | 1270 | | 18.5 | 46.5 |

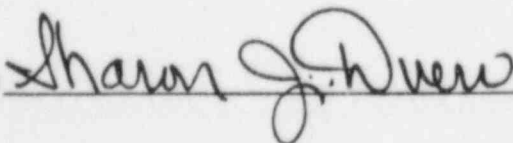
*mg Radium equivalent calculated as described.

**Cesium-137 activity measured as described.

In compliance with our NRC distribution license, Model 6500-6507 and Model 6520-6524 sources require leak testing at a maximum interval of three (3) years.

No other certification is to be implied.

Quality Control



15 Dec 1983

Date

Form 20818-B-PWO

Medical Products Division/3M
St. Paul, MN 55144



3. Determination of Radiation Dose to the Extremities

All personnel who have been designated as handlers of sealed sources are required to wear both a film body badge and a TLD finger badge during any sealed source handling procedure. These film and TLD badges are presently being supplied by R.S. Landauer and Company and are read and reported on a monthly basis. Pocket Dosimeters, manufactured by Nuclear Associates, Inc. are also available for high radiation and/or prolonged exposure control. These dosimeters are model #862.

(continued)

4. Transporting Sealed Sources

a. Cs-137 will be transported to the patient's room in an Ernst Carrier or a Heyman Carrier, both of which were obtained from Radium Chemical Co. These carriers will be transported on a cart with a long handle.

b. Other sealed sources will be transported to the patient's room or to surgery in their lead shipping containers. Any excess Au-198 or I-125 seeds will be returned to the storage area in their original shipping containers. Excess Ir-192 ribbons will be returned to the storage area in their original shipping containers. Ir-192 ribbons which have been removed after an implant will be returned to the storage area in the above-mentioned Ernst carrier and then placed in their original shipping containers.

(continued)

5. Positive Inventory Control and Post-Implant Surveys

The Radiation Therapy Department maintains a log book which was made specifically for the purpose of accounting for the sealed sources. This log book is kept in the storage area. Each time sources are removed from the storage area, the following information is entered into the log book:

- 1) date and time of removal
- 2) patient's name and Radiation Therapy number
- 3) responsible physician (name and phone extension)
- 4) type of source removed
- 5) quantity and strength of each source removed
- 6) type of applicator
- 7) signature of individual who removed the sources

The maximum exposure rate at one meter from the patient is measured immediately after administration of the sealed sources and entered both on the radiation precaution notice on the patient's chart and in the log book with the signature of the individual performing the measurement.

When the sources are returned to the storage area, the following information is entered into the log book:

- 1) date and time of return
- 2) type of source returned
- 3) quantity and strength of each source returned
- 4) signature of individual certifying complete return

The patient in whom the sealed sources were used is not permitted to be dismissed from the hospital until the following conditions have been carried out in the order in which they are listed:

- 1) The sealed sources used for his treatment have been returned to their storage area and "logged in" as per the above procedure.
- 2) The patient has been resurveyed to confirm that no radioactive sources have been inadvertently left within him. (In the case of permanent implants, the recommendation of NCRP #37 will be followed)
- 3) The patient's room has been resurveyed to confirm that no radioactive sources have been inadvertently left within it.
- 4) The individual who conducts these surveys (Medical Physicist or his designee) indicates in the log book that he has surveyed the patient and his room and has found no evidence of inadvertently remaining sealed sources.

(continued)

An inventory of all the sealed sources is performed on a quarterly basis by the Medical Physicist or his designee. The results of the inventory are maintained by the medical physicist.

(continued)

6. Radiation Safety Procedures

a. All sealed source brachytherapy will be performed under the supervision of a radiotherapist or general radiologist practicing therapy.

b. All sealed sources designed for therapeutic use will be kept in the Superficial X-ray treatment room of Radiation Therapy except when in use. The Cesium-137 sources are stored in the lead safe, which is locked at all times except when sources are being loaded or unloaded. Sealed sources with shorter half lives, such as Iridium-192, Iodine-125, and Gold-198, will be ordered as needed and kept in their lead shipping containers in the lockable steel storage cabinets in the same room.

c. Because of the significant radiation levels around these sources, the following special precautions are to be used while handling sealed sources:

1) Always use long forceps to handle the sources. Wear a TLD finger badge when handling sealed sources.

2) When loading the afterloading devices for Cesium-137 therapy or preparing other isotopes for transfer to the loading site, always stand behind the lead and lead-glass L-Block in front of the Cesium safe.

3) Transport Cesium-137 to the hospital unit in a heavy lead container. Transport other sealed sources either in their lead shipping containers or in specially designed, shielded holders.

d. Nursing Instructions

1) Patient's Room

a) It is essential that all patients, in whom it is expected that the exposure rate at one meter will be greater than 10 mR/hr, be placed in room 6340. Other patients who may be placed in this room must be informed that they will be transferred to another room if this room is needed for an intracavitary/interstitial radioisotope therapy patient.

b) If a second radioisotope therapy patient is to be treated concurrently, that patient will be placed in room 6338.

(continued)

c) A Radiation Protection Notice is placed by the Radiation Safety Officer or designee on the outside of the door indicating that the patient is receiving radioisotope therapy. This notice defines visitor restrictions, if any, and refers hospital personnel to the Nursing Procedures and/or to the special instructions found in the patient's chart. A similar notice that radioactive materials are in use is placed by the RSO (or designee) on the outside cover of the patient's chart. This notice indicates the exposure rate in mR/hr at one meter from the patient, the phone number to call in case of an emergency, and the date on which it is expected that the radiation precautions will no longer be in effect. A radioactive precaution tag will also be placed in a wristband and attached to the patient. When the radiation precautions are no longer in effect, the RSO (or designee) will remove all precaution signs.

2) Visitors

a) No persons under 18 years of age or pregnant women may visit. Exceptions may be made in the case of urgency but the visits must be brief and a distance of six feet or more should be maintained. Exceptions will be made only by the attending physician.

b) Adult visitors should be instructed to observe the visitation limitations indicated on the form which has been attached to the patient's door.

c) Even though the restrictions require that visitors remain six feet from the patient, it is permissible for them to approach within six feet to shake hands and deliver mail, etc., as long as the time at close proximity to the patient is kept brief.

3) Hospital Personnel

a) Pregnant employees should not enter the patient's room.

b) Hospital personnel should spend no more time with the patient than is required for efficient patient care. The following visitation limitations are considered safe, and should not be exceeded by personnel not wearing film badges unless longer time limits have been designated by the RSO (or designee):

(continued)

i) Ten (10) minutes per day at bedside.

ii) Forty (40) minutes per day if at least three feet from patient.

iii) One hundred sixty (160) minutes per day if at least six feet from patient.

c) Nurses on the Oncology Ward will wear film badges when working with patients containing sealed sources. Personnel who have been assigned radiation monitoring film badges should not exceed the time limitations set forth below unless longer limits for an individual patient have been designated by the RSO (or designee):

i) Twenty (20) minutes per day at bedside.

ii) Eighty (80) minutes per day if at least three feet from patient.

iii) Five (5) hours per day if at least six feet from patient.

The above time limits are based on 50 intracavitary/interstitial patients per year.

d) Requisitions to other departments which will require their personnel to perform some task at the bedside, should be stamped "Radiation Precautions": (Laboratory, X-ray, EKG, etc.)

4) Patient Care

a) Never touch needles, capsules, or containers holding brachytherapy sources. If a source becomes dislodged, use long forceps and put it in the shielded container provided; contact the Radiation Safety Officer, the Radiation Therapy Department, or the Nuclear Medicine Department at once.

b) Maintain complete bed rest where indicated. A patient with removable sources in or upon his body should not be permitted to leave the room. A patient with permanent implants should not be permitted to leave the room until it has been determined that the patient poses no radiation hazard.

(continued)

c) Perineal care and enemas are not given during gynecological treatment, but the sanitary napkin may be changed when necessary. In this case, care shall be taken to ensure that radioactive sources or source containers are not disturbed or loosened. The sanitary napkin will be saved in the same manner as items designated in paragraph (e) below.

d) Surgical bandages and dressings should be changed only by the physician in charge or by another individual designated by him and trained in radiation techniques.

e) All linen, dressings, clothing, and equipment in the room at the time of source removal shall be kept within the patient's room until released by the Radiation Safety Officer (or designee).

Release of the above named materials shall not occur until the sources have been returned to their storage area and the patient and his (or her) room have been resurveyed to confirm that no radioactive sources have been inadvertently left behind.

f) No special precautions are needed for sputum, urine, vomitus, stools, dishes, or utensils except to be sure that no source is lost via these routes by accidental premature removal.

g) It shall be the responsibility of Nursing Service to advise the Radiation Safety Officer when the room has been vacated and is ready for survey.

5) Emergency Situations

a) If a radioactive source should work itself out or otherwise get free, it shall immediately be picked up with forceps and placed in the protective lead container which has been left in the patient's room. Both the physician in charge and the Radiation Safety Officer must be notified at once.

b) If a radioactive patient dies in the hospital, the physician who pronounces him dead should be responsible for making sure that a radioactive precaution tag is attached to the body. The physician in charge of the case and the Radiation Safety Officer shall be notified at once.

(continued)

7. Leak Test Procedure

Leak testing is performed on all Group VI and calibration sealed sources as specified in 10CFR 35.14 (b) (5) and 10 CFR 13.14 (3) (1) respectively, at intervals not exceeding six months, except for the 3M Cs-137 Model 6D6C tube sources which are leak tested at intervals not exceeding three years as approved by the NRC.

Each applicable sealed source is swabbed with a sterile, alcohol premoistened prep pad. If the surface dose rate from radiation with significant ranges in air is excessive, e.g. greater than 1 rem/min, the wiping of the source will be done with long handled tools and the lead and leaded-glass "L-Block" will be between the sealed source and the individual conducting the test.

The prep pad is placed into a labeled test tube.

The test tube is counted for radioactivity in a well counter with the following control settings:

MeV range: 2.0
Toggle switch: window
Lower level: 010
Upper level: 1000
Calibration: checked with 0.28 uCi source Cs-137 with
MeV range = 1, LL = 637, W = 050

The count rate divided by the calibration factor equals the activity collected from the sealed source during the wipe procedure.

The Minimum Detectable Activity (MDA) of this system is approximately 1.3×10^{-5} uCi, depending on the background counting rate at the time of the measurement. This MDA is low enough to insure that the presence of 0.005 uCi of removable contamination can be detected.

If it is determined that a source is leaking, that source shall be immediately removed from service, sealed in a separate container, and returned to the supplier for repair or disposal. A report shall be filed within five days of the test with the U.S. Nuclear Regulatory Commission, Region III, Office of Inspection and Enforcement, Glenn Ellyn, Illinois 60137, describing the equipment involved, the test results, and the corrective action taken.

ATTACHMENT M

PROCEDURES AND PRECAUTIONS FOR USE OF Xe-133

Xenon-133 will be used as described in our letters of February 3, 1983 and June 19, 1984, with the following modifications:

- a. The supplier of Xenon-133, listed as Pharmatopes, Inc., in the letter of February 3, 1983, has changed its name to Syncor Corp.
- b. Our letter of February 3, 1983, requested a possession limit of 6000 mCi. Instead, we require a possession limit of 1500 mCi.

Attachment N

PERSONNEL MONITORING AND ALARA

a. Personnel Monitoring will be accomplished using devices supplied by R. S. Landauer, Jr., and Company. Such devices will be exchanged on a monthly basis, and will consist of:

1. Whole Body - Film Badges
2. Wrist - Film Badges
3. Finger - TLD Rings

b. The ALARA Program is outlined in the following pages.

PROGRAM FOR MAINTAINING OCCUPATIONAL
RADIATION EXPOSURE ALARA

Good Samaritan Hospital and Health Center

January 21, 1985

I. Management Commitment

- a. We, the management of this hospital, are committed to the program described in this paper for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). In accord with this commitment, we hereby recognize the Radiation Safety Committee, which has representation from the hospital administration, as the official hospital organization which will foster the ALARA concept, promote its use, and review the results.
- b. The Radiation Safety Officer, who is a voting member of the Radiation Safety Committee, will perform an annual review to determine the adherence to the ALARA concept. It will be his responsibility to review the past exposure records and operating procedures and if he deems necessary to make recommendations to the RSC as to how exposures might be lowered. The review will be evaluated by the chief administrative officer of the hospital or his designee. The review will then be evaluated by the RSC at the first regularly scheduled meeting following the audit.
- c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will significantly reduce exposures at reasonable costs. We will be able to demonstrate that the review has been evaluated, that modifications have been considered where appropriate, and that they have been implemented where reasonable. Where modifications have been considered but not implemented, we will be prepared to describe the reasons for not implementing them.
- d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

II. Radiation Safety Committee

- a. Review of Proposed Users and Uses
 1. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to assure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

2. When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and should have considered the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.
 3. The RSC will ensure that the user justifies his procedures and that they are consistent with ALARA concepts.
- b. Delegation of Authority
1. The RSC will delegate sufficient authority to the RSO for enforcement of the ALARA concept.
 2. The RSC will support the RSO in those instances where it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the committee's quarterly meeting.
- c. Review of the ALARA Program
1. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.
 2. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table I below are exceeded. The principle purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see paragraph VI).
 3. The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers.
- d. Educational Responsibilities for an ALARA Program

The RSC will ensure that continuing education has been provided for the appropriate employees to keep them abreast of the ALARA Program and of the RSC's, RSO's, and administration's commitment to the ALARA philosophy.

III. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

1. Annual review of the Radiation Safety Program. The RSO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

2. Quarterly review of Occupational Exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph VI of this program.
 3. Quarterly review of records of Radiation Level Surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.
- b. Cooperative Efforts for Development of ALARA Procedures
1. The RSO will maintain close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.
 2. The RSO will encourage and evaluate suggestions from individual workers for improving health physics practices.
- c. Reviewing Instances of Deviation from ALARA Practices
- The RSO will ensure that all instances of known deviation from ALARA practices will be investigated; and if possible, the causes will be determined. When the cause is known, the RSO will recommend changes in the program to maintain exposures ALARA.

IV. Authorized Users

- a. New Procedures Involving Potential Radiation Exposure
1. The authorized user will consult with and obtain the approval of the RSO and RSC before using radioactive materials for a new procedure.
 2. The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.
- b. Responsibility of Authorized Users to Those He Supervises.
1. The authorized user will convey the importance of and his commitment to the ALARA Program to those he supervises.
 2. The authorized user will ensure that those under his supervision who are subject to occupational radiation exposure have been trained and educated in good health physics practices and in maintaining exposures ALARA.

V. Persons Who Receive Occupational Radiation Exposure

- a. The worker will be instructed in the ALARA concept and its relationship to his working procedures and work conditions.
- b. The worker will be informed as to what recourses are available if he feels that ALARA is not being promoted on the job.

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

This institution hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Committee and/or the Radiation Safety Officer. The Investigational Levels that we have adopted are listed in Table 1 below. These levels apply to the exposure of individual workers arising in whole or in part from NRC licensed byproduct material.

Table 1

| | Investigational Levels- (mrems per calendar quarter) | |
|--|---|-----------------|
| | <u>Level I</u> | <u>Level II</u> |
| 1. Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads. | 175 | 425 |
| 2. Hands and forearms; feet and ankles. | 1875 | 5625 |

The Radiation Safety Officer will review the results of personnel monitoring, not less than once in any calendar quarter, as is required by 10 CFR 20, 20.401. The following actions will be taken at the Investigational Levels as stated in Table 1:

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

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

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

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

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

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

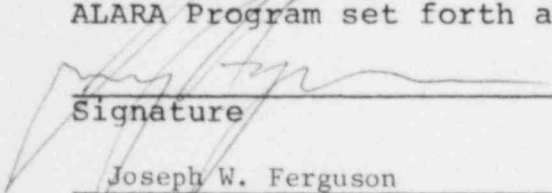
d. Re-establishment of an individual occupational worker's Investigational Level II Above That Listed in Table I.

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

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

VII. Signature of Certifying Official

I hereby certify that this institution has implemented the ALARA Program set forth above.



Signature

Joseph W. Ferguson
Name (print or type)

Assistant Vice President/Operations
Title

Institution Name and Address:

Good Samaritan Hospital
Dayton, Ohio