COMMUNITY HOSPITAL OF ROANOKE VALLEY

December 5, 1988

U. S. Nuclear Regulatory Commission, Region II
Nuclear Materials Safety Section
101 Marietta Street, Suite 2900
Atlanta, Georgia 30323

RE: License Renewal
#45-12706-01

Gentlemen:

Community Hospital of Roanoke Valley, NRC license #45-12706-01, wishes to renew its license in its entirety.

We would also like to add to our license, Carbon-14, for urea breath test for the diagnosis of campylobacter pylori associated gastritis. This test will be performed by hospital laboratory under direction of Dr. Anthony Cuzzocrea. Enclosed in our application are policies and procedures for Carbon-14 incorporated into the laboratory policies and procedures. There is additional information at the end of our application concerning the C-14 breath test.

Enclosed you will find two (2) copies of our NRC license renewal application, and a check for the amount of $580.00.

Thank you for your attention to these requests.

Sincerely,

William R Reid

William R. Reid
President

WRR:wmg

Enclosure

License Fee Information on application.

'88 DEC 12 P3:55

RECEIVED

9002070077 890217
REG2 LIC30
45-12706-01 PDR

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

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

APPLICATION FOR MATERIAL LICENSE

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

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
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
NUCEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

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

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

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

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

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

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

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

- [ ] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [X] C. RENEWAL OF LICENSE NUMBER 45-12706-01

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

Community Hospital of Roanoke Valley
101 Elm Avenue, S.E.
Roanoke, Virginia 24029

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

101 Elm Avenue, S.E.
Roanoke, Virginia 24029

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Robert L. Murray, M.D. (Radiation Oncologist)

TELEPHONE NUMBER 8125
(703) 985-8150

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

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

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY 170.31 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
William R Reid	William R. Reid	President	12/3/88

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
Ren	Dec-3-II	7C		M. Fraser
AMOUNT RECEIVED	**CHECK NUMBER**			**DATE**
$580	800365			12/12/88

5. Radioactive Material

Byproduct Material	Amount	Purpose
5.a Material in 35.100	As needed	6.a Medical use
5.b Material in 35.200	As needed	6.b Medical use
5.c Material in 35.300	As needed	6.c Medical use
5.d Material in 35.400	1000 mCi	6.d Medical use

Item # 5,6
December 1, 1988

7. Individual(s) responsible for radiation safety program and their training and experience.

ATT 7.1.2 Authorized Users for Medical Use

The following are presently authorized users:

James G. Snead, M.D.	# 45-12706-01
Robert L. Murray, M.D.	Same
James Davies Rice, M.D.	Same
Marvin N. Lougheed, M.D.	Same
Hugh J. Scruggs, M.D.	Same
Marshall A. Wakat, M.D.	Same
R. Lewis Royster, M.D	Same
Anthony Cuzzocrea, M.D.	Same

ATT 7.3 Radiation Safety Officer

Robert L. Murray, M.D. Radiation Safety Officer at present on this NRC License # 45-12706-01.

8. Training for individuals working in or frequenting restricted areas.

"We have enclosed our procedure for review. Please see ATT 8.1

ATT 8.1

Nuclear Medicine Technologists, Brachytherapy source curators, ancillary personnel (nursing, housekeeping, and security - whose duties may require them to work in the vicinity of Radioactive Materials) will receive training by lectures, video-taped presentations, or demonstrations. These personnel will receive initial training, annual refresher training, and any necessary training preceding changes in duties, regulations, or the terms of the license.

Item # 8
ATT 8.1
December 1, 1988

LABORATORY

ATT. 8.1 TRAINING PROGRAM

All Chemistry department personnel are formally trained to perform RIA procedures using commercial kits.

Their training includes, besides radio-immunology, a thorough understanding of radiation, safety measures, precautions and waste disposal.

Yearly inservices enforced.

ATT. 8.1
Date: 12/01/88

9. Facilities and Equipment

9.1 Annotated Drawing - See ATT 9.1 (3 pages)

9.2 Survey Instrument Calibration

Survey instruments will be calibrated annually by the manufacturer or Industrial Electronics of Danville, Virginia or Physics Associates of Roanoke, Virginia. Industrial Electronics and/or Physics Associates will follow the procedure approved in the NRC License # 45-17344-01, or by use of a radium source in accordance with Virginia Radioactive Material License # Va-125-02. For Laboratory survey instrument calibration see ATT 9.2

9.3 Dose Calibrator Calibration

We have enclosed our procedure for review. Please see ATT 9.3

9.4 Personnel Monitor Program

Appropriate personnel monitors are provided for all hospital occupationally exposed personnel who are expected to receive as much as Alara Level I exposures. These are received on a monthly basis from R.S. Landauer Jr. & Co.

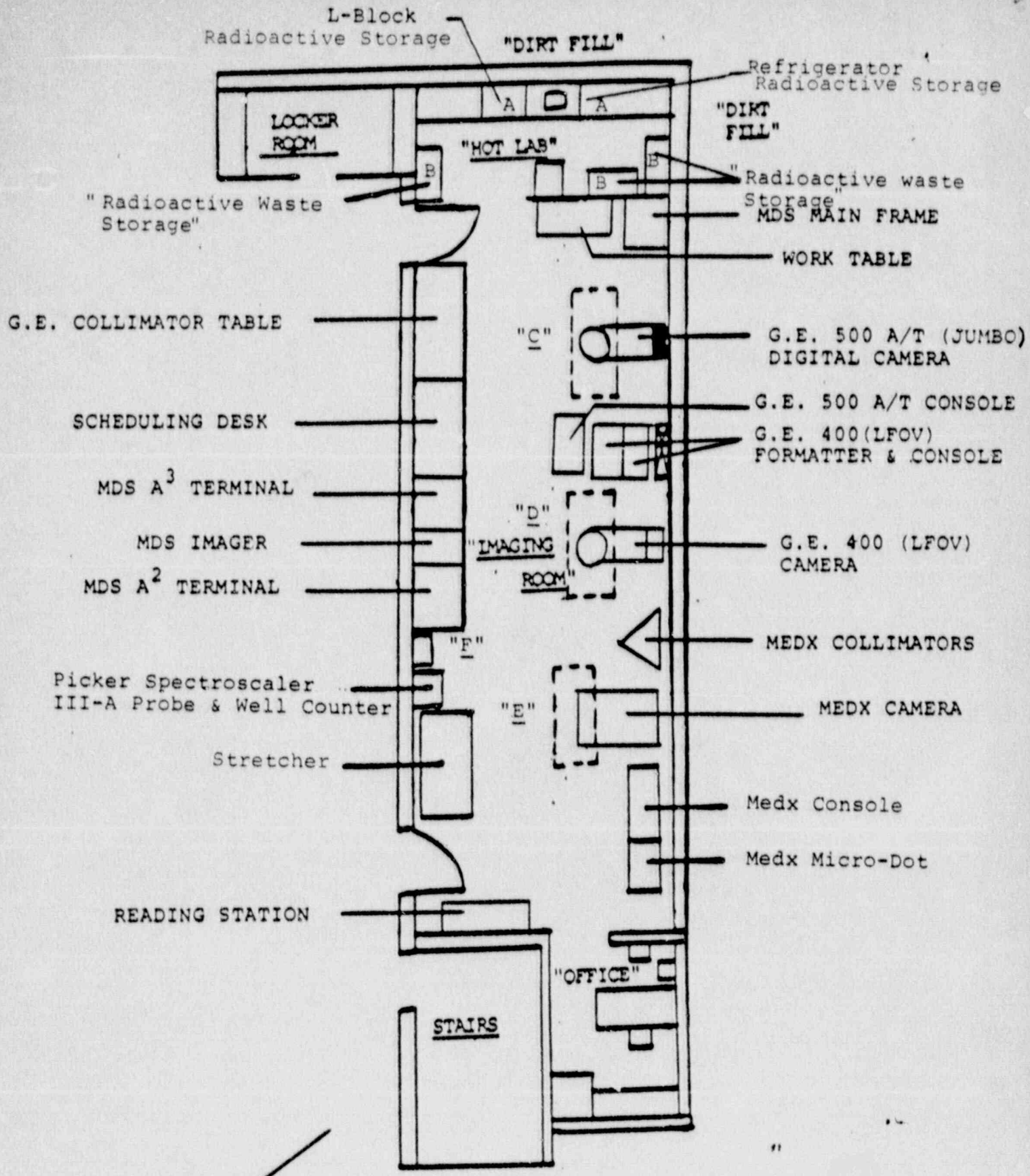
9.5 Imaging Equipment

N/A

9.6 Other Equipment and Facilities

-Three (3) gamma camera:
1. Medx Small Field of View
2. G.E. Large Field of View (400)
3. G.E. Jumbo Field of View (500)

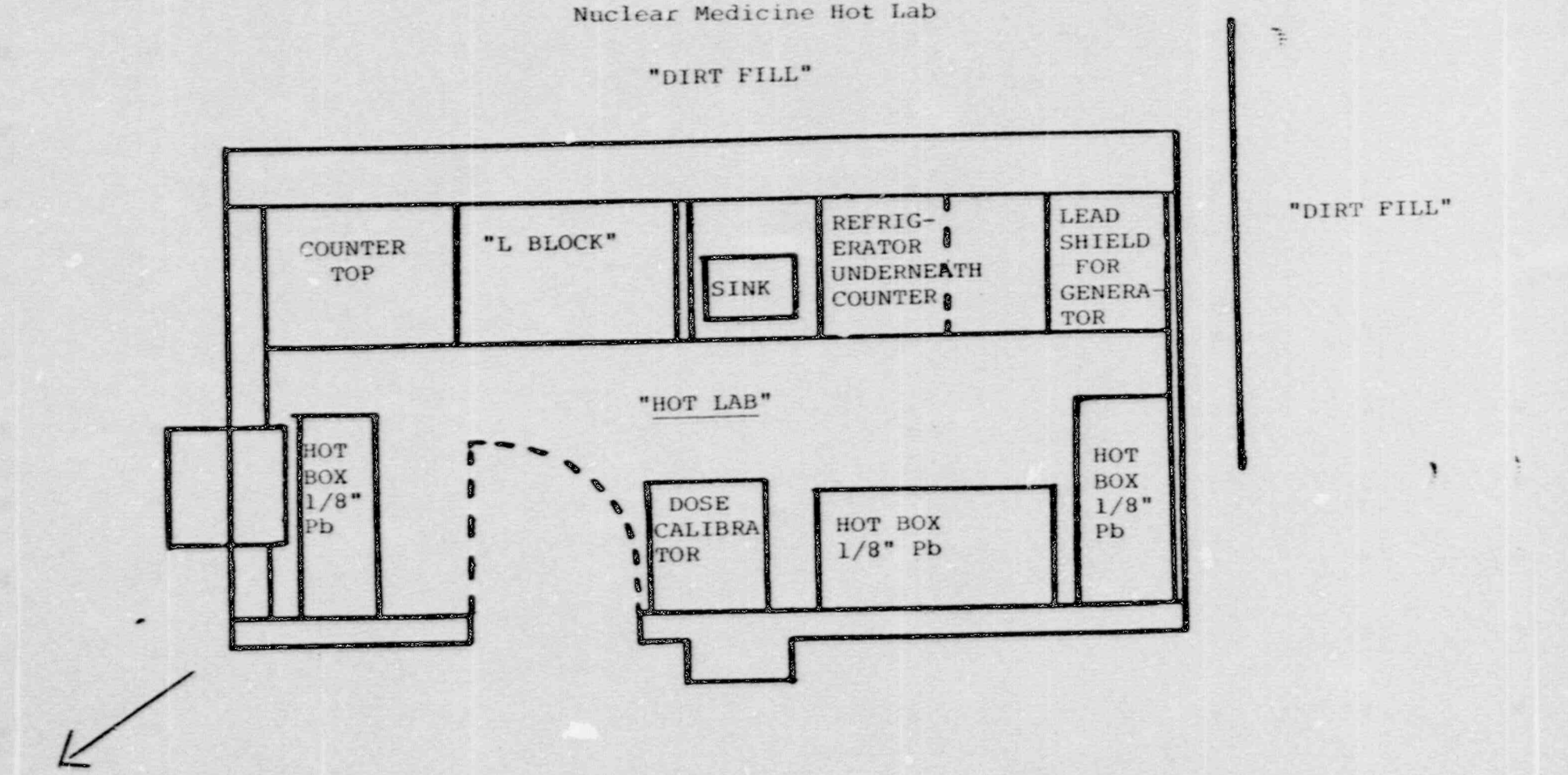
-Spectroscaler IIIA Thyroid uptake probe and well counter.
-Bicron Surveyor 2000 survey meter.
-Medical Data Systems A^2/A^3 computer.



Nuclear Medicine Department

ATT 9.1
DECEMBER 1, 1988
1/8" = 1'

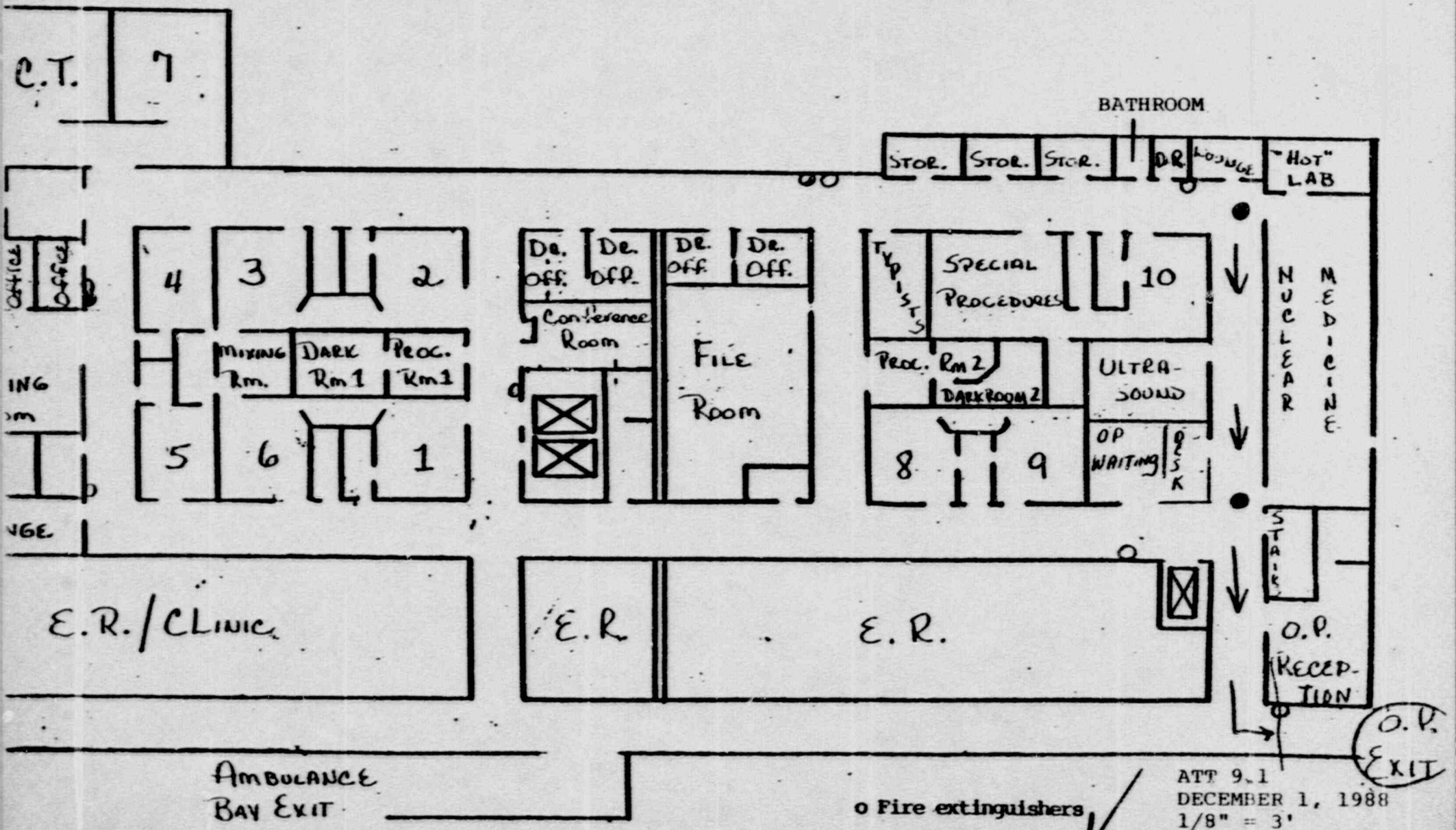
Nuclear Medicine Hot Lab



ATT 9.1
DECEMBER 1, 1988
1/4" = 1'

FIRE EXIT PLAN

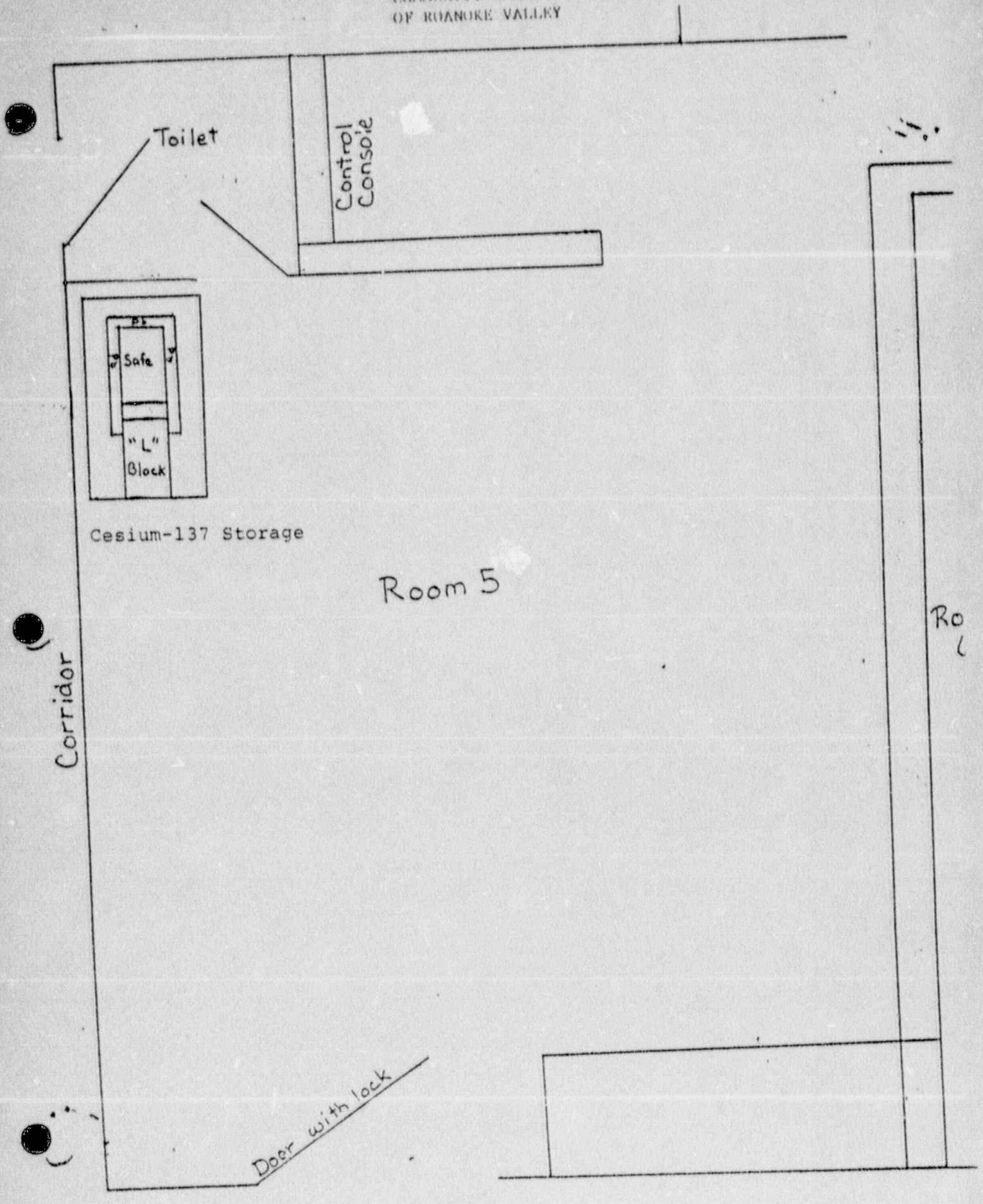
DEPARTMENT OF RADIOLOGY



- o Fire extinguishers
- • Fire Pull-station
- • Fire hose

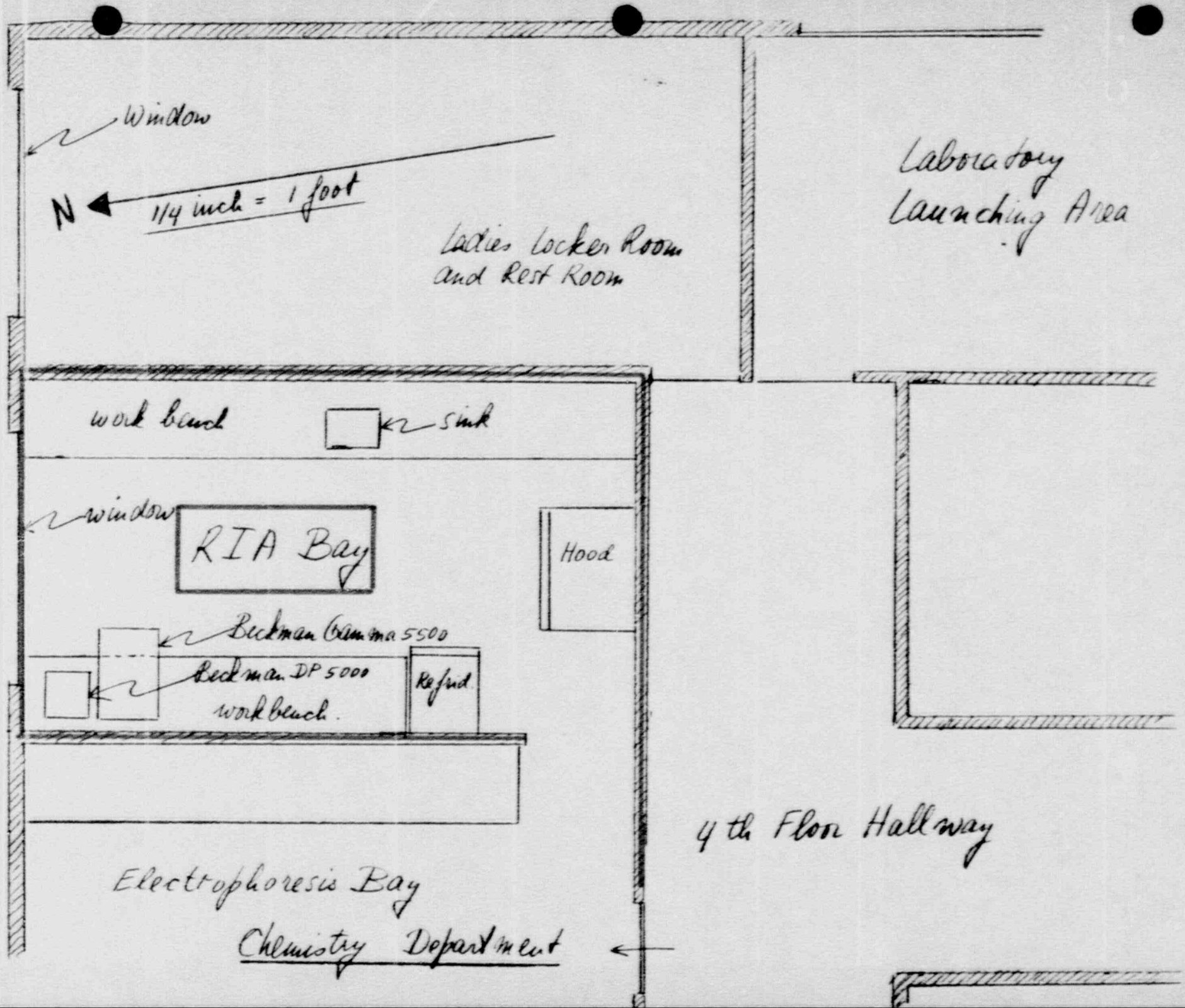
ATT 9.1
DECEMBER 1, 1988
1/8" = 3'

COMMUNITY HOSPITAL
OF ROANOKE VALLEY



5/8" - 1'

ATT. 9.1
DEC. 1, 1988



ATT. 9.1
Date 12/01/88

LABORATORY

ATT. 9.2 SURVEY INSTRUMENT CALIBRATION

SURVEY METER FOR I-125 AND COBALT-57

The survey meter in use is the "Mini Monitor 125" made by "Nuclear Associates, Inc.". Its lower detection limit is 0.002 microcurie.

METER CHECK

Check the battery first and verify that it reads between 275 and 300. Then using the Cs test source supplied, place the source on top of the meter over the marking "cpm" with the source label up. The meter should read betwen 50 and 150 cpm on the 10x range.
N.B. The plastic cap covering the detector must remain on the meter to prevent contamination.

GENERAL

As a reference or comparison one microcurie of I^{125} as a point source 5 mm. from the window produces 25,000 cpm, while the maximum amount of removable contamination allowed by the Nuclear Regulatory Commission is 0.005 microcurie or 125 cpm.

SURVEY METER FOR C-14

Bicron Analyst with B-50 probe.

This instrument is on order and delivery is contingent upon performing the C-14 Breath Test for the diagnosis of Campilobacter pylori associated gastritis.

ATT 9.3 Dose Calibrator Calibration

Dose Calibrator:

1. Capintec CRC-6A

Method:

Pre-measurment

1. The calibrator should be at room temperature and in a dry location. It should be located where the level of the background radiation is as low and as constant as possible.

2. Plug the power cord into a grounded, three-wire outlet (117± 10 volts, 50/60 Hz for the standard instrument; 220 V, 100V is optional).

3. Turn the "AC Power" switch to the "ON" position. Since a half-hour stabilization period is required after turning on the power, and since stability and accuracy of the instrument are improved by constant operation, the calibrator shall be powered at all times.

Amplifier Balance Adjustment

1. Set the "calibration control" dial to "000" by turning the knob fully counter-clockwise.

2. Set the "range" switch to 20 Ci.

3. When the 30 minute warm-up is completed, "D.C. balance" on the rear panel may be adjusted to obtain a meter reading of 0.00 or -0.00 Ci.

Background Elimination

1. On the 20 mCi or lower ranges, it may be necessary to adjust the meter reading due to background radiation or instrument leakage current. (Please note that if the calibrator is exposed to high humidity and the warm-up period has not been completed, high leakage may be present.) To nullify background radiation, first set the "range" selection switch to 200 uCi and the "calibration control" dial to 010.0 . The "background" knob now may be adjusted for a meter reading of zero or near zero. When adjusting for zero or making measurements, the "range" switch must be completely released inasmuch as any movement of the "range" switch will cause a temporary change in the reading.

Measurement of Activity

1. Set the "calibration Control" to the number corresponding to the isotope to be measured.

2. Select the "range" switch position. The switch should be set to the expected activity or to a higher range than the anticipated activity.

Dose Calibrator Calibration
Measurement of Activity Con't.

3. The isotope sample shall then be lowered into the well, using a sample holder for the measurement.

4. Re-select the "range" if required. (in the event the digital display shows a digit "1" in the extreme left column of the meter and the remaining digit positions blank out, turn the "range" switch clockwise to correct for overflow of the meter; if the meter reading does not display enough digits for the accuracy required, such as "-01$," then turn the "range" switch to the next sensitive position.)

Notes:

1. The meter reading must be multiplied by 3.5 for molybdenum 99 impurity measurement in technetium 99m.

2. Readings are normally stabilized within a few seconds.

3. Vertical positioning of samples in the well-from one inch below the top of the well to one inch above the bottom of the well-does not affect the measurement by more than 10% of the reading.

4. Positioning of the assay is automatically accomplished by using the sample holder which is supplied with the instrument.

5. After removing a sample from the well, it is good practice to note the presence of any background radiation, both as a check on possible contamination and as a check on the adjustments of the calibrator.

Calculation of Acitivity Concentration

1. Set the source volume in milliliters (ml) on the volume knob dial.

2. Depress the "function selection switch." The digital meter display will now show the concentration of the isotope per unit volume. The magnitude of the activity concentration is indicated by a light.

3. If the meter reading does not display enough digits, turn the "range" switch counter-clockwise; if the meter blanks out, turn the "range" switch clockwise.

Standard Sources

Isotope Calibrations

Isotopes other than those calibration numbers supplied by capintec may also be measured on the calibrator. New calibrations may be derived or transferred from another CRC-6A which has the particular calibration. In order to derive a calibration:

1. A 50 uCi or stronger standard of that isotope must be placed in the well.
2. The "range" switch is then set for the corresponding activity range.
3. The "calibration control" dial should be adjusted until the meter reading corresponds to the certified activity of the standard source.
4. The number appearing on the "calibration control" dial may then be used for all future measurements of that radioisotope.

Dose Calibrator Con't.

Constancy:

1. Daily with Cesium-137 sealed radioactive source.

2. Weekly with Cobalt-57 sealed radioactive source.

Standards:

1. Cesium-137 (NBS traceable standards)

2. Cobalt-57 (NBS traceable standards)

Linearity Calibration:

The linearity calibration will be performed quarterly with the Calicheck Kit from Calcorp, Inc. The manufacturer's instructions (dated March 2, 1982) will be followed. The source shall be equal to or greater than the patients maximum dose. The activities should be within ± 5% of the predicted if the instrument is linear and functioning properly. Errors greater than ± 5% indicate the need for repair or adjustments of the instrument.

Geometry dependence at installation (±5%)

Accuracy with two (2) sources (Cobalt-57 and Cesium-137) at installation and at least annually thereafter (±5%)

After repair, adjustment, or relocation of the dose calibrator, constancy, linearity, geometry and accuracy test will be performed as appropriate.

10. Radiation Safety Program

10.1 Radiation Safety Committee/Radiation Safety Officer

"We have enclosed our procedure for your review."See ATT 10.1

10.2 Alara Program

"We will follow the model procedure in Appendix G in Regulatory Guide 10.8, Revision 2, August 1987."

10.3 Leak Test

"We have enclosed our procedure for your review." See ATT 10.3

10.4 Safe Use of Radiopharmaceuticals

"We have enclosed our procedure for your review." See ATT 10.4

10.5 Spill Procedures

"We have enclosed our procedure for your review." See ATT 10.5

10.6 Ordering and Receiving

"We have enclosed our procedure for your review." See ATT 10.6

10.7 Opening Packages

"We have enclosed our procedure for your review." See ATT 10.7

10.8 Unit Dosage Records

"We have enclosed our procedure for your review." See ATT 10.8

10.9 Multidose Vial Records

"We have enclosed our procedure for your review." See ATT 10.9

10.10 Molybdenum Concentration Records

We obtain radiopharmaceuticals from a distrubutor. The distrubutor attaches a prescription to multidose vials of Tc-99m defining Mo-99 in microcuries per millicuries of Tc-99m. Radiopharmaceuticals containing more than 0.15 microcuries of Mo-99 per millicurie of Tc-99m will not be used.

10.11 Implant Source Use Records

"We have enclosed our procedure for your review." See ATT 10.11

10.12 Area Survey Procedures

"We have enclosed our procedure for your review." See ATT 10.12

10. Radiation Safety Program

ATT 10.1 Radiation Safety Committee/Radiation Safety Officer

Responsibility

The committee is responsibile for:

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

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

Duties

The committee shall:

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

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

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

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

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

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

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

ATT 10.1 Radiation Safety Committee/Radiation Safety Officer Con't.

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

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

Administrative Information

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

2. Membership must include one authorized user for each type of use authorized by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Management may appoint alternate members to participate in meetings in the case of absence of principal members.

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

10. Radiation Safety Program

ATT 10.1 Radiation Safety Committee/Radiation Safety Officer - November 1988

Radiation Safety Committee members and specialty:

Robert L. Murray, M.D. — Radiation Safety Officer & Chairman of the Radiation Safety Committee
Radiologist

Lee S. Anthony, Ph.D.
Physicist

Carl H. Bivens, M.D.
Internist

Billy L. Ferguson, R.T.
Technical Director, Radiology

Roger L. Haynes, R.T.-N.
Chief Technologist, Nuclear Medicine

Thomas S. McCallie
Executive Vice President

Anthony Cuzzocrea, M.D.
Pathologist

Hugh J. Scruggs, M.D.
Radiotherapist

Marshall A. Wakat, M.D.
Radiologist

James R. Castle, M.D.,ex officio
Pulmonary

Nadine Nelson, R.N.
Nursing Service

APPENDIX G

Model Program for Maintaining Occupational Radiation Exposure
at Medical Institutions ALARA
(See § 35.20.)

You may use the text as it appears here, saying on your application, "We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2."

If you prefer, you may develop your own ALARA program for NRC review. If you do so, you should consider for inclusion all the features in the model and carefully review the requirements of § 35.20. Say on your application, "We have developed an ALARA program for your review that is appended as ATT 10.2," and append your program.

ALARA PROGRAM

Community Hospital of Roanoke Valley
(Licensee's Name)

December 1, 1988
(Date)

1. Management Commitment

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

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

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

   d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable

level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

2. 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 methods of use for which application has been made to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

(2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA.

(3) The RSC will ensure that the users justify their procedures and that individual and collective doses will be ALARA.

b. Delegation of Authority

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

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

(2) The RSC will support the RSO when it is necessary for the RSO to assert authority. If the RSC has overruled the RSO, it will record the basis for its action in the minutes of the quarterly meeting.

c. Review of ALARA Program

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

(2) The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances in which the investigational levels in Table 1 are exceeded. The principal purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when investigational levels are exceeded (see Section 6 below for a discussion of investigational levels).*

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

Table 1

Investigational Levels

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

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

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

3. Radiation Safety Officer

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 methods of use may be conducted on a more frequent basis.

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

(3) Quarterly review of records of radiation surveys. The RSO will review radiation surveys in unrestricted and restricted areas to determine that dose rates and amounts of contamination were at ALARA levels during the previous quarter and will prepare a summary report for the RSC.

b. Education Responsibilities for ALARA Program

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

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

c. Cooperative Efforts for Development of ALARA Procedures

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

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

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

d. Reviewing Instances of Deviation from Good ALARA Practices

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

4. Authorized Users

a. New Methods of Use Involving Potential Radiation Doses

(1) The authorized user will consult with the RSO and/or RSC during the planning stage before using radioactive materials for new uses.

(2) The authorized user will review each planned use of radioactive materials to ensure that doses will be kept ALARA. Trial runs may be helpful.

b. Authorized User's Responsibility to Supervised Individuals

(1) The authorized user will explain the ALARA concept and the need to maintain exposures ALARA to all supervised individuals.

(2) The authorized user will ensure that supervised individuals who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Individuals Who Receive Occupational Radiation Doses

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

b. Workers will be instructed in recourses available if they feel that ALARA is not being promoted on the job.

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

This institution hereby establishes investigational levels for occupational external radiation doses which, when exceeded, will initiate review or investigation by the RSC and/or the RSO. The investigational levels that we have adopted are listed in Table 1. These levels apply to the exposure of individual workers.

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

a. Personnel dose 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 dose is less than Table 1 values for the Investigational Level I.

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

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigational Level I and will report the results of the reviews at the first RSC meeting following the quarter when the dose was recorded. If the dose 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, review each such dose 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. Personnel dose equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigational Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at its first meeting following completion of the investigation. The details of these reports will be included in the RSC minutes.

d. Reestablishment of investigational levels to levels above those listed in Table 1.

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

The RSC will review the justification for and must approve or disapprove all revisions of investigational levels.

7. Signature of Certifying Official*

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

William R Reid
Signature

William R. Reid
Name (print or type)

President
Title

*The person who is authorized to make commitments for the administration of the institution (e.g., hospital administrator).

10. Radiation Safety Program

ATT 10.3 Leak Test

1. Make a list of all sources to be tested. This should include at least the isotope, the activity on a specified date, and the physical form.

2. Prepare a separate wipe sample for each source. A cotton swab, injection prep pad, filter paper, or tissue paper is suitable.

   a. For small sealed sources, it may be easier to wipe the entire accessible surface area. Pay particular attention to seams and joints.

3. The samples will be analyzed as follows:

   a. Select a thin-end-window GM survey meter that is sufficiently sensitive to detect 0.005 microcuries.

   b. Turn the GM survey meter on, perform the operational check, note background reading in millirem/hour. (should be $\leq$ 0.05 mR/hr)

   c. Survey the wipe sample.

   d. Record the wipe sample as follows:

      1. If the wipe sample reading is background then record the reading as background and continue the same analysis procedure for all sources to be tested.

      OR

      2. If the wipe sample is 0.005 microcurie or greater ($\geq$ 0.5 mR/hr), notify the Radiation Safety Officer. The source must be withdrawn from use to be repaired or discarded. If it is a source distributed under an NRC or Agreement State License, the NRC must be notified. (See paragraph 21.21(b) of 10 CFR Part 21 and paragraph 35.59(e) (2) of 10 CFR Part 35.)

   e. Sign and date the list of sources and data.

LEAK TEST PROCEDURE

A semi-annual leak test will be performed on all the Cesium sources by a certified health physicist.

A quarterly inventory of brachytherapy sources will be made.

Att. 10.3
Dec. 1, 1988

ATT 10.4 Safe Use of Radiopharmaceuticals

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 while preparing radioactive materials.

3. Monitor hands and clothing for contamination after preparation of therapeutic quantities of radioactive materials.

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

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

6. a. Assay each patient dose in the dose calibrator prior to administration.

   b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity.

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

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

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

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination daily. Decontaminate if necessary.

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

13. Always transport radioactive material in shielded containers.

LABORATORY

ATT. 10.4 SAFE USE OF RADIOPHARMACEUTICALS

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

4. Do not store food, drink, or personal effects in areas where radioactive material is stored or used.

5. Wear personnel monitoring devices at all times while in areas where radioactive materials are used or stored. These devices should be worn as prescribed by the Radiation Safety Officer. When not being worn to monitor occupational exposures, personnel monitoring devices should be stored in the work place in a designated low-background area.

6. Dispose of radioactive waste only in designated, labeled and properly shielded receptacles.

7. Never pipette by mouth.

8. Wipe-test byproduct material storage, preparation, and administration areas weekly for contamination. If necessary, decontaminate or secure the area for decay.

9. Use the time, distance and shielding concept as much as possible even when working with very low radiation materials.

10. Radiation Safety Program

ATT 10.5 Spill Procedure

Minor Spills

1. Notify: Notify persons in the area that a spill has occurred.

2. Prevent The Spread: Cover the spill with absorbent paper.

3. Clean Up: Use disposable gloves and remote handling devices. 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 GM survey meter, check the area around the spill, hands, and clothing such as shoes for contamination.

5. Report: Report incident to the Radiation Safety Officer.

Major Spills

1. Clear the Area: Notify all persons not involved in the spill to vacate the room.

2. Prevent the Spread: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. Shield The Source: If possible, the spill should be shielded,but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. Close The Room: Leave the room and lock the door(s) to prevent entry.

5. Call For Help: Notify the Radiation Safety Officer immediately.

6. Personnel Decontamination: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

LABORATORY

ATT. 10.5 SPILL PROCEDURES

When a radioactive spill occurs, immediately restrict the immediate area and contain the spill with absorbant materials such as paper towels. After the spill has been absorbed the area must be thoroughly washed with soap and water. With the survey meter flat on the affected area with the detector window down, it must read 50 cpm or less, which is considered to be the background. (As a comparison a 1 micro curie or I^{125} as a point source 5 mm. away from the window produces 25,000 cpm.) Repeat the washings until the survey meter reads 50 cpm. less. Discard the absorbing material used as well as the gloves in the specially marked solid radioactive waste container.

N.B. 1) Make sure that you are not wearing the gloves you used when monitoring. The instrument is very sensitive to contamination! Also measure the sink for contamination afterwards.

2) Always use absorbent plastic-backed paper on the work bench. It will completely contain a spill.

10. Radiation Safety Program

ATT 10.6 Ordering and Receiving

1. The Nuclear Medicine Technologist will order radioactive materials. The Radiation Safety Officer or designee will ensure that the requested materials and quantities are authorized by the license for use by the requesting authorized user and that possession limits are not exceeded.

2. For radioactive materials used, written records that identify the authorized user or department, isotope, chemical form, activity, and supplier will be made.

3. For deliveries during normal working hours, the carriers will deliver radioactive packages directly to the Nuclear Medicine Department.

4. For deliveries during off-duty hours the following procedure will be followed:

   Couriers delivering radioactive packages after hours will bring them to the Security Office on the second floor. The Security Officer will visually inspect the package for evidence of damage. The Security Officer will then sign for and deliver the package to the appropriate department. No other hospital personnel are to accept after hour deliveries of radioactive packages.

   If the radioactive package belongs to the Laboratory, the Security Officer will deliver the package to the Laboratory on the fourth floor. Laboratory personnel are to properly store the radioactive package.

   If the radioactive package belongs to the Nuclear Medicine Department, the Security Officer will place the package in the Nuclear Medicine Imaging Room and lock the door. Nuclear Medicine is located on the first floor beside Radiology.

   In the event the Security Officer suspects that a package is damaged, the Security Officer will:

   1. Ask the courier to remain with the package.
   2. The Security Officer will wear gloves and place the package on absorbent paper or place the package in a plastic bag to prevent spreading of possible contamination.
   3. Contact the Radiation Safety Officer:
      Robert L. Murray, M.D. Home:774-9113 Office: 985-8150
      Physics Associates: 563-0165
      Chief Nuclear Medicine Technologist: Roger L. Haynes - 977-3166

   * The Security Officers receive annual inservice concerning these matters.

LABORATORY

ATT. 10.6 ORDERING AND RECEIVING

1. The Chemistry Department will order RIA (I^{125}) kits, Schilling test kits, and breath test material as needed. Some RIA kits, because of their short shelf life, are on standing order and will be shipped immediately after iodination with I^{125}.

2. For deliveries during normal working hours, the carriers will deliver radioactive packages directly to the laboratory.

   For deliveries during off-duty hours the following procedure will be followed:

   Couriers delivering radioactive packages after hours will bring them to the Security Office on the second floor. The Security Officer will visually inspect the package for evidence of damage. The Security Officer will then sign for and deliver the package to the laboratory. No other hospital personnel are to accept after hour deliveries of radioactive packages. Laboratory personnel will then log in the shipment and store the package at the appropriate place; either room temperature locker, RIA refrigerator, or deep freeze. All storage areas are locked.

   In the event the Security Officer suspects that a package is damaged the Security Officer will:

   1. Ask the courier to remain with the package.
   2. Wear gloves and place the package on absorbent paper or place the package in a plastic bag to prevent spreading of possible contamination.
   3. Contact the Radiation Safety Officer:
      Robert L. Murray, M.D. Home: 774-9113 Office: 985-8150
      Physics Associates: 563-0165
      Chief Nuclear Medicine Technologist: Roger L. Haynes, 977-3166.

   *The Security Officers receive annual inservice concerning these matters.

10. Radiation Safety Program

ATT 10.7 Opening Packages

Procedures for Safely Opening Packages Containing Radioactive Materials

1. Radioactive Material packages delivered to the Nuclear Medicine Department will be monitored for external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours.

2. After the Nuclear Medicine Department has received radioactive packages, protective gloves and lab coats should be worn as necessary when opening the packages for the protection of the surveyor.

3. If the manufacturer's directions for opening or unpacking radioactive material are provided, follow the directions in addition to those below.

4. Survey packages at surface with a GM survey meter and record the reading. If a high reading is obtained to indicate content damage, contact the Radiation Safety Officer. If reading is within normal limits (either/or 1: does not exceed 200 mR/hr at the surface of the package 2: 10 mR/hr at 1 meter)proceed with opening.

5. Observe outer package for leakage stains.

   a. If stains are present, proceed to wipe 100 cm^2 area with a dry wipe and assay: record.
   b. If wipe has 0.01 μCi (22,000 DPM) proceed with caution.

6. Open the outer package and remove packing slip. Open inner package to verify contents (compare requisition packing slips, label on bottle) and integrity of final source container (inspect for breakage of seals or vials, loss of liquid, discoloration of packing material). Check also that shipment does not exceed possession limits.

7. Assay radioactive material with dose calibrator and record.

8. Store radioactive material in hot lab. A refrigerator is available if needed.

9. Packing material will be surveyed for contamination after radioactive materials are removed.

LABORATORY

ATT. 10.7 **OPENING PACKAGES**

1. The Chemistry Department will inspect the package for any visible damage, e.g. wet or crushed, before opening it. If there is any damage, they will notify the Radiation Safety Officer.

2. Chemistry then will proceed to open the package, verify the contents with the packing slip, log the contents in, and store it at its appropriate location.

10. Radiation Safety Program

ATT 10.8 Unit Dosage Records

For unit doses received from a supplier, the corresponding prescription will identify the following:

1. Radionuclide
2. Generic name or its abbreviation or trade name
3. Date of Dose
4. Supplier
5. Lot number or control number, if assigned
6. Activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time
7. If administered:
   a) Prescribed dosage is listed in the clinical procedure manual
   b) Measured activity in millicuries or microcuries and date and time of measurement are recorded
   c) Patient name
   d) Initials of the technologist who prepared the dose.
8. All unused doses are placed in the hot boxes in the Nuclear Medicine Departments Hot Lab for decay, and the corresponding prescriptions are attached to the appropriate logging forms.

   See ATT 10.8a for the logging forms of prescriptions used and unused.

COMMUNITY HOSPITAL OF ROANOKE VALLEY
DEPARTMENT OF NUCLEAR MEDICINE
NRC # 45-12706-01
RADIONUCLIDE STOCK SHEET

RADIONUCLIDE: _____

PT. NAME	DATE	TIME	ACTIVITY/ mCi	PRESCRIPTION #	KIT	TECHNOLOGIST

RADIONUCLIDE STOCK SHEET

UNUSED DOSES

ATT 10.8a
December 1, 1988

10. Radiation Safety Program

ATT 10.9 Multidose Vial Records

For multidose vials received from a supplier, the corresponding prescription will identify the following:

1. Radionuclide
2. Generic name or its abbreviation or trade name
3. Date of multidose vial
4. Date and time of assay and amount in both millicuries and cubic centimeters (cc) or milliliters (ml)
5. Supplier or kit manufacturer
6. If administered:
   a. Prescribed dosage is listed in the clinical procedure manual
   b. Date and time dosage was drawn and measured
   c. Calculated volume that is needed for the prescribed dosage
   d. Measured activity in millicuries or microcuries
   e. Patient name
   f. Initials of the technologist who prepared the dose.
7. The remaining unused radioactive material in the multidose vial is placed in the hot box in the Nuclear Medicine Departments Hot Lab for decay.

See ATT 10.9a for the logging form of multidose vials.

ROANOKE MEMORIAL HOSPITALS
NUCLEAR PHARMACY SERVICES

BELLEVIEW AT JEFFERSON STREETS
ROANOKE, VIRGINIA 24033 (703) 981-7081

^{99m}TECHNETIUM PERTECHNETATE FACTOR = 0.943/30 Min.

Date: ____________________

Generator # ____________________

^{99}Mo ____________________ uCi

________ total mCi at ________

________ mCi ________ ml at ______ Prepared RP Lot # ____________________

Total Elution ____________ ML. Rx ____________________ Hospital Volume ____________ ML.

TIME	mCi/ml	TIME	mCi/ml	TIME	mCi/ml
0800		1100		1400	
0830		1130		1430	
0900		1200		1500	
0930		1230		1530	
1000		1300		1600	
1030		1330		1630	

PATIENT	TIME	mCi/ml	mCi needed	ml disp.	ml remain	initial	prescription number

ATT 10.9a
December 1, 1988

INSTRUCTIONS FOR CESIUM HANDLERS

The Cesium 137 sources will be kept in a locked safe for storage.

Sources shall be accounted for at all times. An inventory of sources must exist and be checked quarterly.

LOADING APPLICATORS

When Cesium sources are removed from the safe for use, they must be logged out on the Cesium 137 inventory sheet documenting the correct information.

The patient log sheet shall also be completed with the appropriate information.

In carrying the loaded applicator through the hospital, use the Cesium cart marked "CAUTION-RADIOACTIVE MATERIALS". Perform a room survey after the sources have been implanted in the patient. Document on the patient's chart loading time, length and total amount of treatment. Make sure the nursing unit has placed the "RADIOACTIVE" sign on the patient's door, and the lead shields are in place.

UNLOADING CESIUM 137

Use the Cesium cart marked "CAUTION-RADIOACTIVE MATERIALS" to carry the loaded applicator through the hospital.

Remove the loaded applicator from the patient and do a visual check of the sources. Do a room survey after removal of sources to check that all sources have been removed before the patient is discharged. This is to be documented on the patient log sheet.

Document on patient's chart the time and date the sources were removed.

Unlock the Cesium safe and proceed to remove the Cesium from the applicator.

Upon returning the sources to the safe, the Cesium inventory sheet must be completed with the appropriate information.

SPECIAL INSTRUCTIONS

Use only forceps when handling the Cesium sources, using extreme care with the sources and applicator. Do not use force to remove tubes from the applicator. A slight tap on the applicator may cause the tube to fall out. Never use any type of sharp object to remove a Cesium tube from an applicator.

When a Cesium tube will not come out of an applicator by the above method, place the loaded applicator back in the Cesium cart marked "CAUTION-RADIOACTIVE MATERIALS" and lock the Cesium safe. Proceed to call one of the department supervisors, who will then take the necessary steps to have another authorized person attempt to remove the Cesium tube from the applicator, or to have the loaded applicator sent back to the company.

Whenever a Cesium tube is found to be damaged in any way, including being bent, assume that it may be leaking. Wipe the source on a piece of filter paper. If the filter paper indicates above background, place it in an air-tight container, appropriately shielded; survey your hands, applicators and the immediate vicinity. Notify your supervisor, the Radiation Safety Officer, and the physicist regarding the situation. Tell them of the possibility of source leakage, and request an immediate wipe test of the source.

Personnel in the immediate vicinity of sources which appear to be leaking shall be notified of the fact. They should stand far enough from the source so that they are not receiving any significant external gamma radiation (at least a couple of meters), but should not leave the general area until they can be checked for the presence of contaminating material on their persons and clothing.

Containment of contamination from a leaking source within a defined area is accomplished by keeping the contamination within the area, and by keeping people out. If a Cesium tube is leaking, have a perimeter established through which no one may pass in either direction without permission of the physicist in charge.

Misplaced source: Sources must be accounted for at all times. An inventory of sources must exist, and must be checked quarterly. When Cesium is removed from the safe for a patient, it must be logged out, and logged back in. If a source is unaccounted for, notify your supervisor, the Radiation Safety Officer, and the physicist. If a check of the safe and Cesium inventory log fail to account for the source, notify the Director of Radiology, Radiation Physicist, Hospital Administrator, and hospital Director of Security. A search should be started with a survey meter. If not quickly found, a "hold" should be placed on solid waste (trash) going from the suspected area, and from the hospital itself.

In case of the need for assistance from outside the hospital, and/or the necessity to report an incident in accordance with current regulations, the appropriate emergency numbers are listed on the Sources for Assistance sheet. They may be called at any time, day or night, without hesitation.

PROCEDURE TO FOLLOW IN THE EVENT OF A LOST CESIUM TUBE

QUICK REFERENCE

1. Report the incident to the Director of Radiology.

2. Notify: Chairman of Radiology Department
   Radiation Physicist
   Hospital Administration
   Hospital Director of Security

3. If the source is believed to be lost in the patient's room:

   a. Assure that no material is removed from the room eg. linen, clothing, dressings, trash, bed pans, etc.

   b. Survey the room, patient, and contents of the room.

4. If the source is believed to be lost in a particular area other than the patient's room:

   a. Survey that area.

PROCEED AS FOLLOWS IN EITHER SITUATION #3 or #4

5. If survey is negative, notify Mr. Arch (Housekeeping Ext. 8255) to institute a "hold" on all solid waste from the hospital.

6. Survey such solid waste.

7. If results are negative, survey the incinerator.

8. If results are negative, continue search and notify the Virginia State Department of Health (1-804-323-2300) of the loss of the source, and the NRC as appropriate (1-404-331-4503).

20. THERAPEUTIC USE OF SEALED SOURCES CON'T.

SOURCES OF ASSISTANCE

Dr. Robert L. Murray Radiation Safety Officer, CHRV	774-9113	
Billy L. Ferguson, R.T.N. Technical Director	389-1255	
Sylvia Dickerson, R.T.R. Chief Technologist	992-4819	
Rita Gibson, R.T.R. Brachytherapy Curator	334-2614	
Dr. Lee S. Anthony Consulting Physicist	563-0165 985-8150	Office, Home CHRV
Lee S. Anthony, Jr., B.S. Consulting Physicist	384-6984 563-0165	Home Office

CITY OF ROANOKE OFFICE OF EMERGENCY SERVICES:

Mr. Warren E. Trent	981-2425 366-5656	Office Home
Mr. Glen L. Lyle	389-7271 362-1194	Office Home

SALEM

Lt. William Mayo	375-3095 362-5092	Office Home
Virginia State Department of Health (BRH)	1-804-786-5932	
Office of Emergency & Energy Services	1-804-323-2300	
Nuclear Regulatory Commission	1-404-331-4503	

Att. 10.11
Date: 9/26/83
Revised: 3/31/86
Dec. 1, 1988

CESIUM-137 STOCK 10-19-78

No. of Sources	Mg. Ra., Eqiv/ Source (nominal)	Average Mg. Ra. Equi/ (Assayed)	Color Code	Location In Safe	Eqiv/ Filt. mm. Pt.Ir	Active Length	Physical length
4	5 mg.	5.44	Blue	Left Drawer	.5 mm.	14 mm.	20 mm.
15	10 mg.	10.8	Green	Left Drawer	.5 mm.	14 mm.	20 mm.
10	15 mg.	16.2	Yellow	Right Drawer	.5 mm.	14 mm.	20 mm.
4	20 mg.	21.7	Orange	Right Drawer	.5 mm.	14 mm.	20 mm.
2	25 mg.	26.4	Red	Right Drawer	.5 mm.	14 mm.	20 mm.

ATT 10.11
December 1, 1988

QUARTERLY

CESIUM 137 INVENTORY

STOCK

	DATE											
4 Tubes	5 mg. Ra. Equi/ source (nominal) color code Blue											
15 Tubes	10 mg. Ra. Equi/ source (nominal) color code Green											
10 Tubes	15 mg. Ra. Equi/ source (nominal) color code Yellow											
4 Tubes	20 mg. Ra. Equi/ source (nominal) color code Orange											
2 Tubes	25 mg. Ra. Equi/ source (nominal) color code Red											
	Total milligrams Ra. Equi/ in safe											
	Total milligrams Ra. Equi/ in patient											
	Sources in repair											
	Total tubes Accounted for											
	Initials											

Att. 10.11
Dec. 1, 1988

PATIENT'S NAME _____ DATE _____

ROOM # _____

CESIUM 137 INVENTORY

SOURCES	5 mg. Ra. Equi. Source Color Code BLUE	10 mg. Ra. Equi. Source Color Code GREEN	15 mg. Ra. Equi. Source Color Code YELLOW	20 mg. Ra. Equi. Source Color Code ORANGE	25 mg. Ra. Equi. Source Color Code RED
Number of sources in safe before insertion.					
Number of sources removed from safe for insertion at _____ AM/PM					
Number of sources remaining in safe during treatment					
Number of sources returned to safe after treatment at _____ AM/PM					
Total sources in safe after completion of treatment					

Person removing sources from safe _____ Date _____

Person returning sources to safe _____ Date _____

PATIENT LOG SHEET

UNIT NUMBER: _____ DATE: _____

NAME: _____ AGE: _____ ROOM NUMBER: _____

ADDRESS: _____

REFERRED BY: _____ RADIOLOGIST: _____

TOTAL MILLIGRAMS Ra. Equi. USED: _____ DIAGRAM:

APPLICATOR: _____

LOADED BY: _____

LENGTH OF TREATMENT: _____ DATE: _____

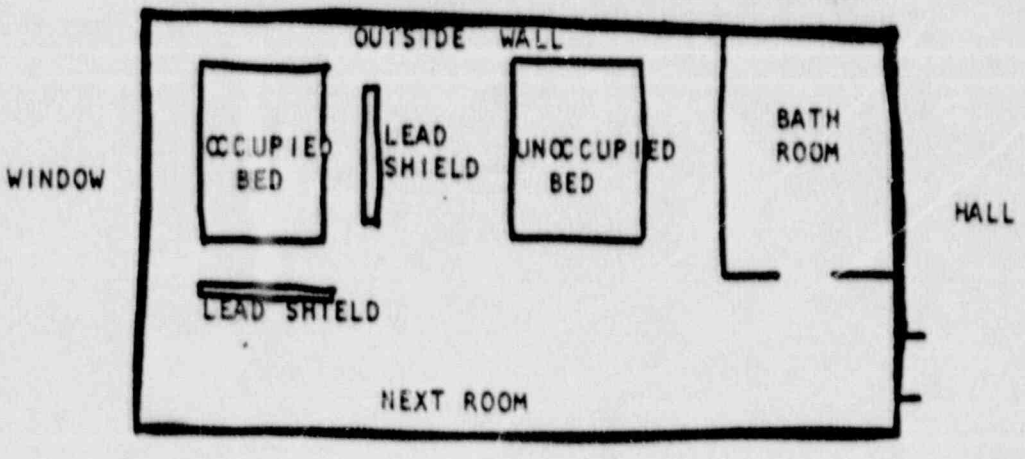
APPLICATION TIME: _____ DATE: _____

REMOVAL TIME: _____

UNLOADED BY: _____

_____ INSERTION

ROOM SURVEY AFTER SOURCES IMPLANTED IN PATIENT



ROOM SURVEY AFTER REMOVAL OF CESIUM SOURCES: _____

The following individuals are allowed to handle the Cesium 137 sources:

Rita Gibson, R.T.R.

Susan Haynes, R.T.R.

Sharon Tribbett, R.T.R.

Lee S. Anthony, Ph.D., C.H.P., C.R.P.

Att. 10.11
Dec. 1, 1988

The following individuals are allowed to handle the I-125 seed implant sources:

Rita Gibson, R.T.R.

Roger Haynes, R.T.N.

Lee S. Anthony, Ph.D., C.H.P., C.R.P.

Andrea Flora, R.T.N.

Debbie Hayslett, R.T.N.

Delores Stakes, R.T.N.

Brenda Ferguson, R.T.N.

Lee S. Anthony, Jr. B.S., M.A.

Att.10.11
Dec. 1, 1988

PROCEDURE FOR I-125 IMPLANTATION OF THE PROSTATE

1. The patient is to be scheduled by the attending physician.

2. Treatment plan is to be prepared at Roanoke Memorial Hospitals by the radiation therapist, the therapy physicist, and the dosimetrist.

3. The RMH therapy physicist will contact Dr. Anthony requesting the number and activity of seeds required, and indicating the patient's name and date of implant.

4. Dr. Anthony will contact the Chief Nuclear Medicine technologist, who will obtain the P.O. Number, and place the order.

5. When the order arrives, the physicist and a Nuclear Medicine technologist will open and survey the package. They will then assay the seeds as a group, using the Nuclear Medicine dose calibrator. The assay value will be placed with records of receipt of the materials.

6. The cartridges of the applicator shall be loaded by the physicist and/or the brachytherapy curator within 24 hours before the procedure. Ideally, the loading should precede the sterilization of the apparatus. If not, the seeds will be loaded under sterile conditions.

7. The loaded applicator and I-125 seeds shall be stored in the Nuclear Medicine Hot Lab until they are needed in the O.R.

8. The physicist or brachytherapy curator shall accompany the I-125 to the O.R. for sterilization. They shall be identified as radioactive material.

9. After sterilization, the seeds will either be used right away in the O.R., or they will be returned to the Nuclear Medicine department by the department's therapy source curator.

10. At the time of implantation, the therapy curator and the physicist will carry the seeds and a survey meter to the O.R. They will assist the radiation therapist in the loading of the implant applicator, monitor the area, survey the O.R. after removal of the patient for lost seeds, and account for all seeds.

11. They will return any unused seeds to Nuclear Medicine Hot Lab for storage.

12. The documentation of the seeds when they arrive to the hospital, activity, amount of seeds used for the procedure, the amount of unused seeds that are returned to Nuclear Medicine for storage, along with the patient's name, are kept in the Nuclear Medicine department.

13. The patient shall be placed in a private room. The patient's door and chart shall be marked with a radioactive sign.

14. After the patient returns to the room, the surrounding area shall be monitored with a radiation measurement survey instrument. This shall be documented on the patient room survey sheet and shall include time, date, instrument used and person conducting the survey. These records shall be kept for two years.

15. A note shall be placed either on the patient's door or in the patient's chart to indicate how long visitors may stay in the room. No one under age 18 shall be permitted to visit with the patient, unless authorization has been given by the physicist and radiation safety officer. This shall be done on a patient-by-patient basis.

16. The radiation therapist will order films of the pelvis to be taken a day or two after the surgery. The therapy curator will follow the procedure for taking the films needed. These films will identify the seeds and to determine if they are located within the prostate gland area properly.

17. The patient's urine and bed linen shall be kept in the patient's room until it is checked by a Nuclear Medicine technologist or the therapy curator with a survey meter. Any seeds that have been passed or found shall be returned to the Nuclear Medicine Hot Lab for storage. If a nurse should find a seed in the patient's urine, she shall put it in the lead container with forceps that will be provided by the Radiology Department, and call the therapy curator or radiation safety officer so it can be picked up.

18. Instructions shall be given to the patient before discharge by the radiation oncologist or the physicist.

19. The Radiation Safety Officer shall be notified if the patient dies or has a medical emergency.

I-125 IMPLANTS

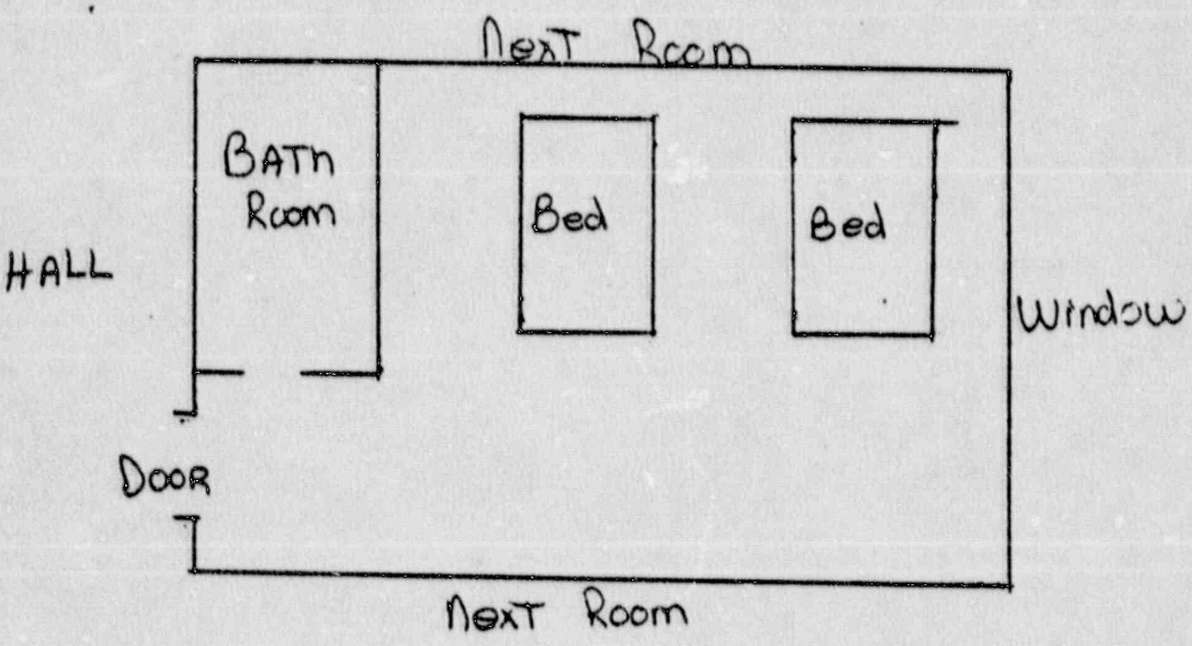
PATIENT ROOM SURVEY

PATIENT _____ ROOM # _____

DATE _____ TIME _____

PERSON CONDUCTING SURVEY _____

INSTRUMENTS USED _____



NUMBER OF SEEDS IMPLANTED _____

NUMBER OF SEEDS UNUSED _____

NUMBER OF SEEDS PASSED OR FOUND IN THE PATIENT'S ROOM _____

TOTAL NUMBER OF SEEDS IMPLANTED IN THE PATIENT UPON DISCHARGE OF THE PATIENT _____

10. Radiation Safety Program

ATT 10.12 Area Survey Procedures

Ambient Dose Rate Surveys

1. Survey Areas

a. In radiopharmaceutical elution, preparation, and administration areas, survey at the end of each day of use with a radiation detection survey meter. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

b. In radiopharmaceutical storage and radiopharmaceutical waste storage areas of the Hot Lab, survey weekly with a radiation detection survey meter.

2. Immediately notify the RSO if you find unexpectedly high or low levels.

Removable Contamination Surveys

1. Survey Areas

a. In radiopharmaceutical elution, preparation, and administration areas, survey weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms need not be surveyed.

b. The wipe sample assay procedure should be sufficiently sensitive to detect the presence of 200 dpm/100 cm^2 of removable contamination. "See ATT 10.12a."

2. Immediately notify the RSO if you find unexpectedly high levels.

Records

1. Keep a record of survey results. It must include the following information:

a. The date, area surveyed, and equipment used.

b. The name or initials of the person who made the survey.

c. A drawing of the areas with trigger levels as established by the RSO.

d. Record the survey readings in mR/hr unless the reading is background and then just place a check mark (✓) in the appropriate space to indicate background levels.

e. Actions taken in case of excessive dose rates or contamination and followup survey information.

2. The RSO will review and initial those cases in which the trigger levels are exceeded.

See ATT 10.12b for the survey form.

COMMUNITY HOSPITAL OF ROANOKE VALLEY

DECEMBER 9, 1987

SURVEY METER SENSITIVITY

A CESIUM-137 SOURCE WITH ACTIVITY OF .0059 μCi OR 1.3 X 10^4 DPM CAUSES A RESPONSE OF 0.55 mR/hr. ON TIMES ONE (1) SCALE (2π GEOMETRY) WITH THE BICRON SURVEYOR 2000 GM SURVEY METER SERIAL # A289L WITH THIN END WINDOW GM TUBE WITH PLASTIC CAP ON. ALSO, A RESPONSE OF 1.2 mR/hr. ON TIMES ONE (1) SCALE FOR THE OPERATIONAL CHECK SOURCE.

Lee S. Anthony

LEE S. ANTHONY, Ph. D.
CONSULTING PHYSCIST

ATT 10.12a
December 1, 1988

P. O. BOX 12946 • ROANOKE, VIRGINIA 24029 • (703) 985-8100

Community Hospital of Roanoke Valley- NRC # 45-12706-01
Department of Nuclear Medicine
Radiation Surveys and Wipe Test

Monday: ___/___/___ Mo. Da. Yr.

A._____ D._____
B._____ E._____
C._____ F._____

_____
Surveyor

Tuesday: ___/___/___ Mo. Da. Yr.

A._____ D._____
B._____ E._____
C._____ F._____

_____
Surveyor

Wednesday: ___/___/___ Mo. Da. Yr.

A._____ D._____
B._____ E._____
C._____ F._____

_____
Surveyor

Thursday: ___/___/___ Mo. Da. Yr.

A._____ D._____
B._____ E._____
C._____ F._____

_____
Surveyor

Friday: ___/___/___ Mo. Da. Yr.

A._____ D._____
B._____ E._____
C._____ F._____

_____
Surveyor

Wipe Test: ___/___/___ Mo. Da. Yr.

A._____ D._____
B._____ E._____
C._____ F._____

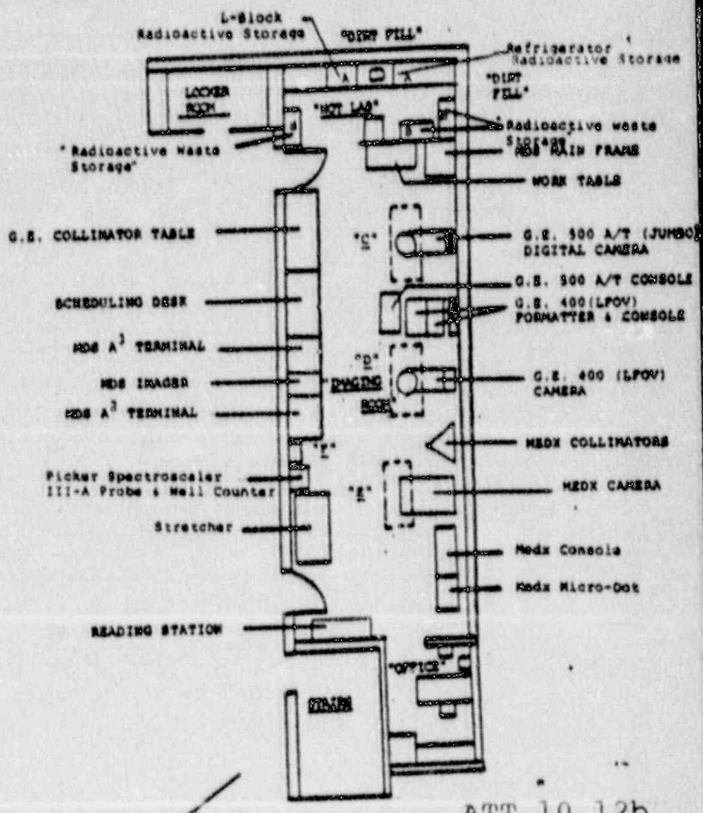
_____
Surveyor

Trigger Levels = Daily Survey- 5 mR/hr Wipe Test- 46 mR/hr.

If the radiation detection survey meter reads at normal background for the daily surveys and wipe test, place a (✓) in the appropriate box to signify no contamination. If the reading is above background, record the reading in mR/hr, decontaminate and re-survey. After decontamination, record reading again in mR/hr. However, if contamination exceeds trigger levels, immediately notify the Radiation Safety Officer.

The daily surveys and wipe test will be performed with the following instrument:

1. Bicron Surveyor 2000 ,serial # A289L range of .01 to 2000 mR/hr(With internal detector) with a normal background of .01 to .03 mR/hr.



ATT 10.12b
December 1, 1988

AREA SURVEY

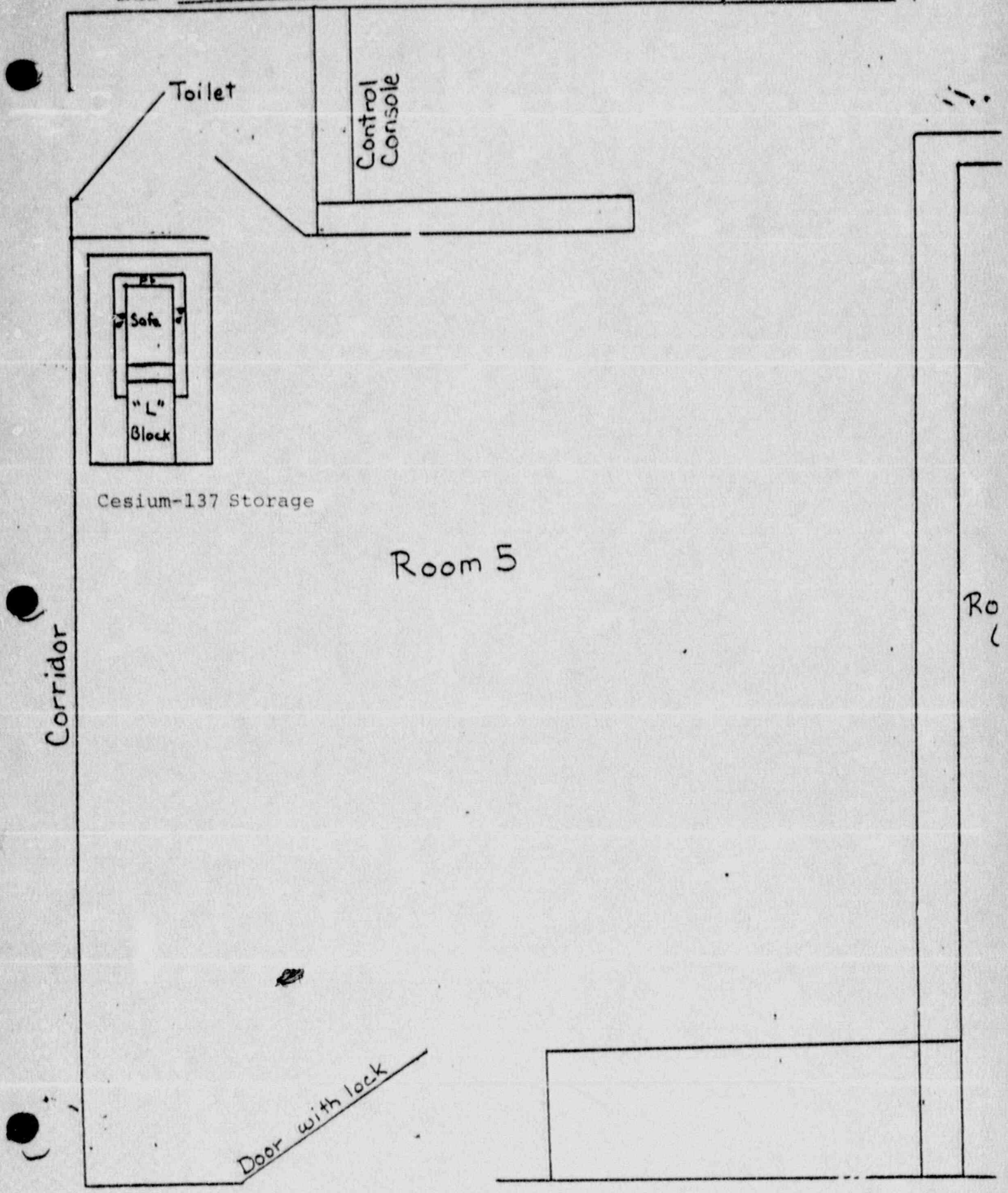
A quarterly room survey of the Cesium safe storage area will be performed by a certified health physicist.

QUARTERLY SURVEY

DATE _____

COMMUNITY HOSPITAL
OF ROANOKE VALLEY

SURVEY METER USED: _____



CERTIFIED HEALTH PHYSICIST

Rev. 10.12

Dec. 1, 1988

LABORATORY

ATT. 10.12 AREA SURVEY PROCEDURES

1. SURVEY METER

The survey meter in use is the "Mini Monitor 125" made by "Nuclear Associates, Inc.". Its lower detection limit is 0.002 microcurie.

METER CHECK

Check the battery first and verify that it reads between 275 and 300. Then using the Cs test source supplied, place the source on top of the meter over the marking "cpm" with the source label up. The meter should read between 50 and 150 cpm on the 10x range.

N.B. The plastic cap covering the detector must remain on the meter to prevent contamination.

GENERAL

As a reference or comparison one microcurie of I^{125} as a point source 5 mm. from the window produces 25,000 cpm, while the maximum amount of removable contamination allowed by the Nuclear Regulatory Commission is 0.005 microcurie or 125 cpm.

2. WORK AREA

The work area includes the sink. Both need to be monitored and records kept. The maximum allowable removable contamination is 125 cpm. Record.

3. COUNTING AREA

The counting area also allows a maximum of 125 cpm. Record.

4. STORAGE AREA

Remove all radioactive materials and measure the shelves. Also here the maximum allowable background cannot exceed 125 cpm. Record.

5. Carbon-14 is monitored by the Bicron Analyst with B-50 probe survey meter similarly as described in 2., 3.,and 4.

6. Surveys are done at the end of each day that tests involving radioactive isotopes are run, and subsequently recorded.

ATT 10.13-4 Calculating spilled gas clearance times.

In the event we should use Xenon-133, the following procedure will be followed

Procedure For Routine Use and Storage of Xenon 133 Gas

1. Xe-133 gas is dispensed from the NRP-186 calidose gas dispensing system to the Radx model number 101 Ventil-Con controlled gas delivery system. The Ventil-Con is capable of administration of 133 Xenon either as a direct bolus injection or as a homogenous air/xenon/oxygen mixture, and may be used for all three phases of lung ventilation function: single breath, steady state and washout.

If a bolus injection is used, the Xe-133 will be calibrated before injection with Capintec CRC-6A Dose Calibrator. However, if a homogeneous air/xenon/oxygen mixture method is utilized, the Ventil-Con system continuously monitors the concentration by an in-line Geiger-Muller tube accompanied by a display in mCi/liter on a large scale analog meter on the control panel.

All personnel handling Xe-133 doses will wear finger badges in addition to their whole body badges in order to monitor radiation exposure to the extremities.

Xe-133 will be administered to patients via a Radx Model 101 Ventil-Con in accordance with Radx instructions for use. Face masks or mouth pieces with nose clamps will be used to prevent loss of Xe-133 during the patient sutdy. Exhaled Xe-133 will be collected by a Radx Model 120 Xe trap. This model has a built in saturation detector which gives audio/visual signal when the Xe-133 in the trap exhaust port reaches 2×10^{-2} uCi/ml. For further information about the trap see Item # 10 of this application "CALIBRATION OF INSTRUMENTS:RADX VENTIL-CON AND TRAP FOR XENON-133 GAS DELIVERY SYSTEM".

2. "STORAGE AREA": The hot lab is adjacent to the imaging room. The Xe-133 is shipped in lead containers and stored behind the " L " block in the hot lab. See attachment # 1.

3."Imaging Room": The Nuclear Medicine Department is located on the ground floor of the hospital with dirt beneath us and laboratories above us, and is surrounded by (1) dirt fill, (2) dirt fill, (3) locker room, and (4) the Imaging room. The Xe-133 is now dispensed by the Radx Model 101 Ventil-Con controlled gas delivery system in the imaging room. Ventilation of the rooms in the nuclear medicine department is as follows:

> Total supply air rate is 2150 cfm; total exhaust rate is 2340 cfm, giving rise to the room's negative pressure. (See print for locations of individual supply and exhaust ducts, attachment #2.) The air is exhausted to the roof, with no recirculation.

EMERGENCY PROCEDURES:

In case of accidental release of Xe-133, the following procedures will be followed:

The department will be evacuated. The Xenon trap will be turned on, and the room closed. The room will not be re-opened until a minimum of ten (10) complete air changes have taken place. The current exhaust system provides one complete air change in 3.3 minutes or 17.9 complete air changes in one hour.

All rooms will remain closed and will not be used until the radiation level in the room or rooms as determined by a low level survey meter shows less than 0.1 mR/hr.

AIR CONCENTRATION OF Xe-133 IN RESTRICTED AREAS:

1. Hot lab = Xe-133 will be stored in the hot lab behind the " L " block.

2. Imaging room: Assumptions

a. Five (5) patients per week.
b. One (1) out of twenty (20) patients will disconnect from the machine and exhale entire lung contents of Xe-133 into the room.
c. 10 mCi of Xe-133 used per patient average.
d. The Ventil-Con is reported by Radx to lose approximately 1% per day by diffusion through membranes and the Ventil-Con is normally loaded with 50 mCi of Xenon; thus 2.5 mCi are lost per week.
e. The Xenon trap activates a warning system when the concentration in the exhaust port exceeds 2×10^{-2} uCi/ml. This system will be checked once a month with a Cs-137 source held at a predetermined distance from the center of the Geiger-Muller tube which will produce one beep every two seconds average. Distance to hold the Cs-137 source depends upon the activity of the source which is calculated by the following formula:

$$S = 1.7 \times \sqrt{A}$$

S = Distance (Centimeter)

$\sqrt{A}$ = Square root of the source activity.

It is assumed for this calculation that the activity in the trap is at the above level for the washout period of each patient.

The trap pumps at 5 liters/minute. The average washout time = 10 minutes. Xenon loss per patient through the trap = 5×10^3 ml/min. x 10 minutes x 2×10^{-2} uCi/ml = 1×10^{-3} uCi/patient.

It should be emphasized that this is a maximum figure and that the dynamics of Xe-133 adsorption on a charcoal would dictate that once Xe-133 begins to pass through the system, its concentration grows geometrically which would activate the alarm and the charcoal cartridge would be replaced.

Xe-133 per week lost into the room contribution from:

Ventil-Con	2.5 mCi
Patients	2.5 mCi
Xenon trap(1 mCi/patient x 5 per week)	5.0 mCi
Total	10.0 mCi
	1×10^4 uCi/week

Room exhaust rate = 2340 = 5.6×10^6 ft.^{3}/40 hr. week.
= 1.6×10^{11} ml/40 hr. week.

$$\text{Xe-133 concentration/40 hr. -wk.} = \frac{1 \times 10^4 \text{ uCi/week}}{1.6 \times 10^{11} \text{ ml/week}} = 6 \times 10^{-8} \frac{\text{uCi}}{\text{ml}}$$

This figure is well below the MPC of a restricted area as set forth in 10 CFR PART 20 as 1×10^{-5} uCi/ml.

CONCENTRATION IN UNRESTRICTED AREAS:

The Xe-133 lost into the Imaging room as described in section 2 of air concentration of Xe-133 in restricted areas will be exhausted into the atmosphere above the roof of the hospital wing, at least 44 feet, and one 90° turn form the nearest air inlet. This constitutes and unrestricted area and 20.106 of 10 CFR 20 requires that the concentration average over a periood of one year not exceed 3×10^{-7} uCi/ml.

1. Xe-133/year exhausted to the atomosphere contribution from:
   Imaging room = 10 mCi/wk x 52 = 5.2×10^{2} mCi
   Total = 5.2×10^{5} uCi/yr.

2. Air flow per year
   Exhaust rate of imaging room = 2340 cfm
   Exhaust per year = 3.34×10^{3} ft^3/minute x 60 $\frac{min.}{hr.}$ x 24 $\frac{hrs}{day}$ x 365 $\frac{days}{yr.}$

   $= 1.2 \times 10^{9}$ ft^3/yr.

   $= 3.4 \times 10^{13}$ ml/yr.

3. Average concentration per year $\frac{5.2 \times 10^{5} \text{ uCi/yr}}{3.4 \times 10^{13} \text{ ml/yr}} = 1.5 \times 10^{-8}$ uCi/ml.

This is well below the MPC of 3×10^{-7} uCi/ml and since the calculations represent worst conditions, the safety margin appears adequate.

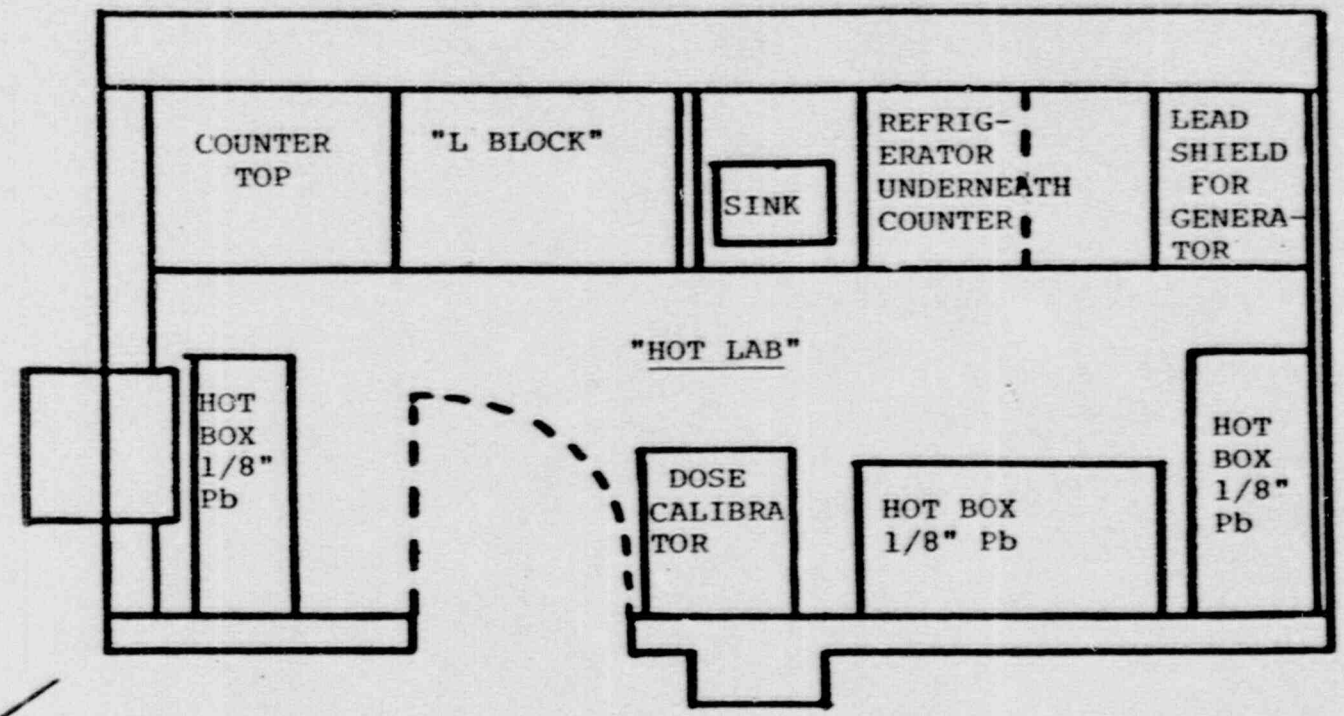
ADSORPTION ONTO CHARCOAL TRAPS:

The Xenon trap from Radx has a Geiger-Muller detector system monitoring the exhaust port of the trap. It is designed in such a fashion that when the unit is first turned on the alarm activates for a few seconds to indicate that the system is functional. The alarm is set to activate when the concentration in the exhaust port exceeds 2×10^{-2} uCi/ml. The exhaust will empty into the imaging room and has been considered in previous calculations.

Saturated filters will be plugged and placed in storage benind a minimum of 1/8" lead shielding in the hot lab for a period of not less than 15 half-lives.

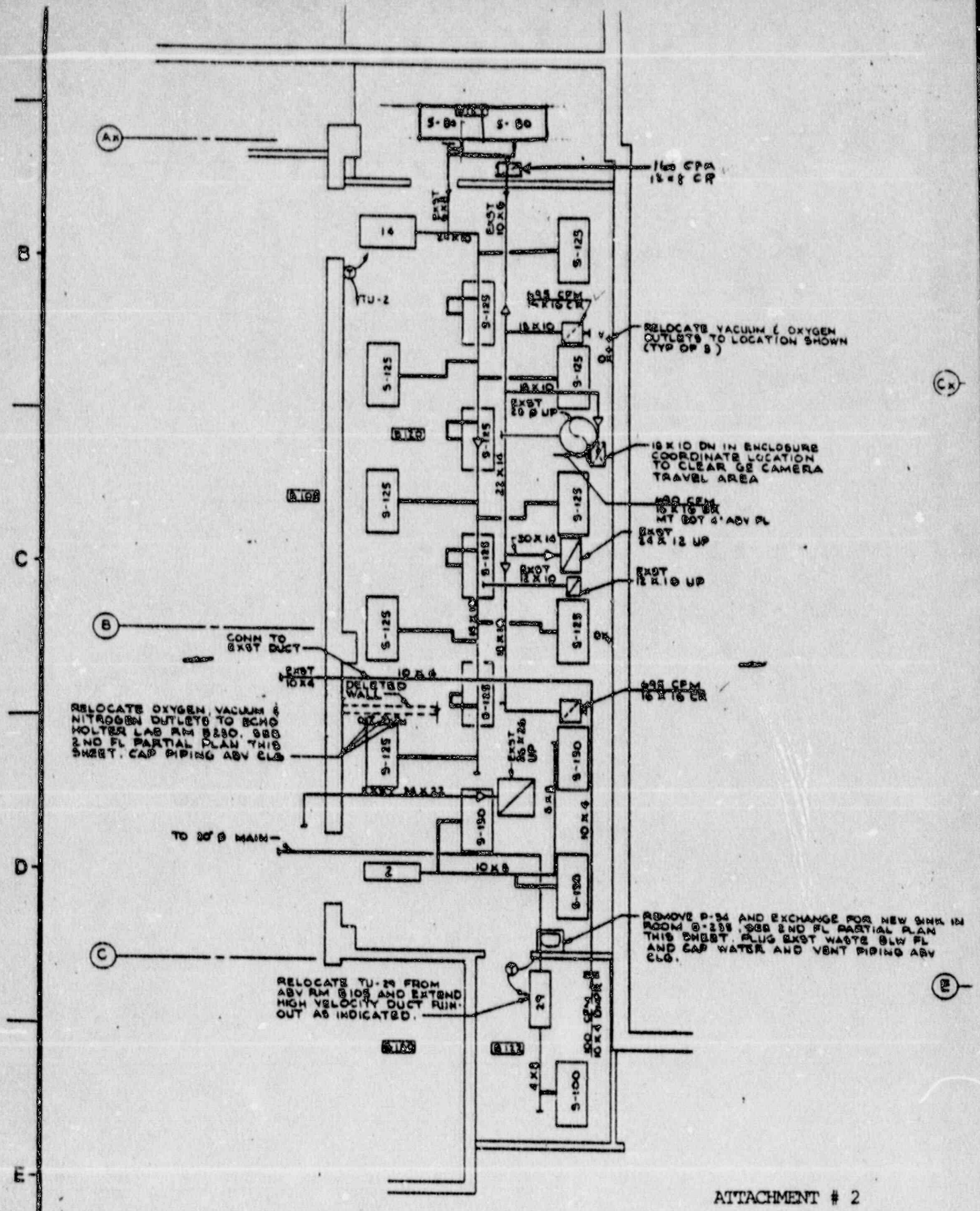
Since the filters are plugged and completely sealed, it is not anticipated that it will contribute to the Xe-133 air concentration.

Nuclear Medicine Hot Lab
"DIRT FILL"



"DIRT FILL"

ATT 10.13-4
DECEMBER 1, 1988
1/4" = 1'



ATTACHMENT # 2

ATT 10.13-4
December 1, 1988

THERAPEUTIC USE OF RADIOPHARMACEUTICALS

I. Iodine-131 as sodium iodide for treatment of hyperthyroidism and cardiac dysfunction.

1. Radioactive material tags shall be placed on the patient's chart, bed and door. The radioactive material sign on the door shall state to the effect "NO EXPECTANT MOTHERS ALLOWED."

2. The nursing staff will be informed to notify Nuclear Medicine personnel of any vomitus material emitted by the patient during the first 24 hours of treatment.

3. All radioactive labels shall be removed upon discharge.

II. Iodine-131 as sodium iodide for treatment of thyroid carcinoma.
Gold-198 as colloid for intracavitary treatment of malignant effusions.
Phosphorus-32 as soluble phosphate for the treatment of polycythemia vera, leukemia and bone metastasis.
Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions.

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

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

3. Surveys of the patient's room and surrounding areas will be conducted as soon as practicable after administration of the treatment dose. Exposure rates will be measured after administration at the patient's bedside, 3 feet (or 1 m) from the patient, and at the room entrance. 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 chart and on his door. The results of daily surveys will be used to recalculate permitted times, which will be posted on the patient's chart and on his door.

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

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

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

THERAPEUTIC USE OF RADIOPHARMACEUTICALS CON'T.

7. Disposable plates, cups, eating utensils, tissue, surgical dressings, and other similar waste items will be placed in a specially designated container. The material will be collected daily by the Radiation Safety Officer or his designee, checked for contamination, and disposed of as normal or radioactive waste, as appropriate.

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

9. 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.

Nursing Instructions

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

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

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

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

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

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

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

THERAPEUTIC USE OF RADIOPHARMACEUTICALS CON'T.

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

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

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

k. For I-131 patients:

(1) To the degree possible with cooperative patients, urine will be voided in toilet 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 soapy water after use.

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

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

(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 floor. In any situation where the patient's room may be contaminated or if radioactive urine and/or feces is spilled during collection, call the Radiation Safety Officer or his designee, Ext. 8150. Meanwhile, handle all contaminated material with disposable gloves and avoid spreading contamination.

(5) Keep all contaminated wastes in plastic bags in the patient's room for disposal by the Radiation Safety Officer or his designee. Feces, urine, and vomitus need not be routinely saved unless ordered. The same toilet should be used by the patient at all times and it should be well flushed (3 times). The Radiation Safety Officer will establish procedures for disposal of wastes (see Item 11 below).

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

THERAPEUTIC USE OF RADIOPHARMACEUTICALS CON'T.

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

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

11. Waste Disposal

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

The use of liquid Iodine-131 will be avoided if at all possible. However, in the event it is to be used the following procedure shall be followed:

1. The patient, doctor administering the radioactive Iodine-131, and technologists shall go to the hospital laboratory to the exhaust hood for administering Iodine-131 to the patient.

2. The liquid Iodine-131 shall be placed on absorbent paper within the exhaust hood.

3. All personnel handling the radioactive Iodine-131 (liquid) shall wear gloves.

4. The exhaust hood shall be turned on, then the liquid Iodine-131 shall be opened and administered to the patient.

5. A survey shall be made of the exhaust hood and surrounding areas for possible contamination.

6. The doctor administering the radioactive Iodine-131 and all involved personnel are required to have a thyroid uptake within 72 hours.

* In the event that a patient should expire while the radioactive material label is present on the patient's chart, the Nursing supervisor shall contact the Radiation Safety Officer, ROBERT L. MURRAY, M.D. # 8150 and the Nuclear Medicine Department #8125 so proper radiation surveys may be performed to comply with NRC regulations.

In the event this should occur, the body is not leave the hospital under any circumstances until proper surveys are performed.

ATT 10.14 Radiopharmaceutical Therapy Con't.

Date _____

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

Patient's Name: _____

Room No.: _____ Physician's Name: _____

Radioisotope Administered: _____

Date and Time of Administration: _____

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.

_____ 3. Patient may not leave room.

_____ 4. Visitors under 18 are not permitted.

_____ 5. Pregnant visitors are not permitted.

_____ 6. Film or TLD badges must be worn.

_____ 7. Pocket chambers will be worn for supplementary personnel monitoring of individual tasks.

_____ 8. Tag the following objects and fill out the tag:

_____ door _____ chart

_____ bed _____ wrist

_____ 9. Disposable gloves must be worn while attending patient.

_____ 10. Patient must use disposable utensils.

_____ 11. All items must remain in room until approved for removal by the Radiation Safety Officer or his designee.

_____ 12. Smoking is not permitted.

_____ 13. Room is not to be released to Admitting Office until approved by the Radiation Safety Officer or his designee.

_____ 14. Other instructions.

In case of an emergency contact:

RSO _____

Name On-duty/Off-duty Telephone Numbers

NURSING CARE FOR PATIENTS RECEIVING CESIUM TREATMENTS

1. Every patient receiving cesium treatment is to be restricted to bed and placed in a hospital room alone or a private room with bathroom facilities and should not be allowed to roam, therefore, during the administration of the treatment.

2. The patient's door shall be posted with a sign. "Caution-Radioactive Material".

3. Nurses should spend only the adequate amount of time near the patient required for ordinary nursing care. Private duty nurses remaining in the room should be instructed by the doctor as to the distance to maintain except during actual nursing operations.

4. Brachytherapy patients are allowed visitors in accordance with the following restrictions:

    1. All visitors should remain behind the cesium shield at a distance of more than three (3) feet from the shield. At no time should a visitor be at the foot of the bed or on the opposite side of the shield.
    2. Visiting periods should be no longer than 15 minutes.
    3. Females of child bearing age should be discouraged.
    4. Pregnant women and children under 18 are not permitted.

5. Instruments and containers used to handle cesium sources do not become radioactive. Special instruments are used only to simplify handling and to maintain appropriate distances from the hands to the source.

6. No special precautions are needed for sputum, urine, vomitus, feces, dishes, instruments, and utensils.

7. Bed linen is to be held in the patient's room until the sources are removed from the patient and all accounted for.

8. Perineal care is not given during treatment, but the perineal pad may be changed whenever necessary. If the pad is changed, be sure the radioactive sources or containers are not disturbed or loosened. Should one become dislodged from the containers, notify the Radiology Department immediately. Never try to re-position or replace cesium source, capsules or containers. Do not directly handle with your hands. Leave source alone in patient's room and call the Radiology Department immediately.

9. Surgical dressings and bandages should be changed only as directed by the attending physician or other designated personnel.

10. Nurses working with a cesium patient will wear body film badges.

which will be changed on a monthly basis. Badges will be worn only by the individual they are assigned to.

11. The patient's room will be surveyed by the Radiology Department after the removal of the applicator, to assure all cesium sources have been removed.

12. When there is only one cesium patient being treated at a time, both bedside shields should be used; one at the side of the bed and one placed at the foot of the bed.

13. If the patient expires or has any other medical emergency, notify the Radiology Department (8150) or the Radiation Safety Officer, Robert L. Murray, M.D., 774-9113.

NURSING CARE OF THE PATIENT WITH AN IODINE-125 IMPLANT FOR CARCINOMA OF THE PROSTATE

1. Patients selected for I-125 implant of the prostate usually have early-stage cancer of the prostate (Stage B or C) with no evidence of widespread metastases. In conjunction with the implantation of the prostate with radioactive material, the patient usually undergoes a bilateral pelvic lymphadenectomy. Both procedures are done through a supra-pubic incision.

2. Iodine-125 "seeds" are implanted in the O.R. in what is called a permanent implant; i.e., the seeds are left in the gland or tissues and not removed at a later time. The seeds of I-125 give off a low-energy gamma radiation which is very easily shielded (27 Kev energy) and is mostly absorbed by the patient's pelvic tissues. An intense dose of radiation is given to the area of the implant (prostate), but there is rapid "fall-off" of radiation levels a few centimeters away (i.e., in the bowel and/or bladder). The isotope of I-125 has a half life of 60 days, so precautions are usually taken for the first 3 - 4 months when there is still significant radioactivity.

3. The patient gets x-rays of the pelvis taken post-op to identify the seeds and to determine if they are located within the prostate gland area properly. Usually 30 - 60 seeds are implanted and the x-ray films allow the radiation therapist to re-check on the number implanted and account for all of the seeds. Occasionally, a patient will pass one of the seeds through his catheter (if implanted too near the urethra or bladder neck). The urine, catheter and catheter bag shall be saved until a technologist comes to the room and checks it with a radiation survey meter. Should a seed be found, place it in the covered metal container using long-handled forceps, which will be provided by the Radiology Department, and then call the brachytherapy curator or radiation safety officer at 985-8150 in the Radiology Department.

Radiation Safety Officer Robert L. Murray, M.D.	Home - 774-9113
Brachytherapy Curator Rita Gibson, R.T.R.	Home - 1-334-2614

4. <u>NURSING OF THE PATIENT WITH AN I-125 IMPLANT</u>

   a. In the operating room there is very limited exposure of the nurses and other personnel to radiation. The Iodine-125 seeds are shielded in containers for the most part and then implanted rather quickly into the prostate tissue. The nurses are usually several feet away from the prostatic area, and if monitored, they would receive little or no radiation at this time.

NURSING CARE OF THE PATIENT WITH AN I-125 IMPLANT (Continued)

b. In the recovery area, the patient should be placed in a private area or well away from other patients. Special note should be made to ensure that any pregnant patients or children in the recovery area are well away from the patient with a radioactive implant.

c. In general, no pregnant nurses or personnel should attend the patient with a radioactive implant. There is probably no real danger to the fetus for the pregnant mother to be exposed briefly to a patient with an Iodine-125 implant. There is very little radiation emitted from the pelvic area. However, no chances are taken as there is very little knowledge of how little radiation might cause harmful effects.

d. Patients receiving I-125 implants shall be placed in a private room. The patient's door and chart shall be marked with a radioactive sign.

e. As in all radioactive implants, personnel attending the Iodine-125 implant case should move quickly in performing their duties and keep as much distance from the region of the body containing the implant as possible. The patients should by no means be neglected, but it is advised that no unnecessary time be spent close to the patient in the area of the implant. Speed and distance are the best radiation protectors available.

f. In transporting the patient with an Iodine-125 implant, the nurses and other personnel should try to remain at the head or foot of a stretcher rather than at the side or near the pelvis. When on the elevators, try to select the less crowded elevators and advise other people on the elevator that the patient does contain a radioactive material. Certainly, it would be reasonable to ask a pregnant visitor or person on the elevator to wait until the radioactive patient had gotten out of the elevator.

g. During the recovery period following the implant, the patients can be ambulated within a few days. During this time, the nurses attending the patient can transport the patient in a wheelchair or support the patient for ambulation while walking in the halls. Very brief exposures of 15 to 20 minutes at a distance of 2 to 3 feet from the pelvis should not be harmful to personnel.

h. There is really no need for any type of shielding around the patient with the Iodine-125 implant.

i. All of the patient's bed linen is to be held in the patient's room until it is checked by the Radiology Department with a survey meter. This is to assure that no seeds have become dislodged in the linen.

j. The brachytherapy curator or radiation safety officer should post the door of the patient's room with a sign which reads "Caution - Radioactive Materials". A label should be placed on the front of the patient's chart to indicate that this patient does contain a radioactive isotope.

k. It may be of some interest to know what levels of radiation are considered safe for persons working with radioactive materials. The critical organs of the body to be considered when exposed to radiation are the eyes, the gonads, and the bone marrow. These areas are usually allowed 5 Rem per year for persons working around radioactive materials or with radioactive patients. The general public is allowed 1/10th of that dose or 0.5 Rem per year. Areas such as the skin, arms, and hands are allowed more. A radioactive dose of 0.5 Rem is also thought to be safe for a fetus. For the patient with the radioactive Iodine-125 implant of the prostate, the exposure rate at the surface of the patient is usually somewhere around 5 mR per hour, and at this rate it would take 1000 hours to receive the acceptable 5 Rem per year dose. At one meter from the surface of the patient it would take 10 times that long or 10,000 hours to receive the acceptable dose limit.

5. VISITOR POLICY

Generally it is desirable to restrict visitors with any type of radioactive implant. With the Iodine-125 implant, it is reasonable to allow immediate family to visit in the room with the patient so long as there are no pregnant members of the family and no one under 18 years of age. Only with authorization of the physicist and radiation safety officer shall a person under 18 years of age be permitted to visit. This shall be done on a patient-to-patient basis. Limiting the visitors helps to minimize confusion and makes the situation more controllable. Again, the measures taken are really over protective, but it is best to ask all of the visitors to remain approximately 5 to 6 feet from the bedside while visiting. Certainly if a visitor steps up to the bedside for a few minutes there is no significant harm. There will be a note on the chart or patient's door indicating how long visitors may stay.

6. INSTRUCTIONS TO THE PATIENTS

Patients who get the radioactive implant with Iodine-125 seeds are given an instruction sheet by the attending radiation oncologist before they are discharged.

7. The radiation safety officer shall be notified if the patient dies or has a medical emergency.

Radiation Safety Officer	985-8150	
Robert L. Murray, M.D.	774-9113	(Home)

11. Waste Management

11.1 Waste Disposal

"We have enclosed our procedure for your review." See ATT 11.1

11.2 Other Waste Disposal

N/A

11. Waste Management

ATT 11.1 Procedure For Disposal By Decay-In-Storage

1. Needles, syringes, kits,etc., will be placed in lead lined hot boxes (1/8"), in one of two containers. One container will be labeled for Tc-99m only, the other container will be for longer lived radionuclides (Ga-67, Tl-201,In-111). Iodine-131 diagnostic capsules will be placed in lead pigs which in turn are placed in the hot boxes.

2. When either container or lead pig is full, the tops will be closed and the last date of entry (Mo/Da/Yr) will be written on the containers. These containers will remain in the hot box for decay-in-storage. Alcohol swabs, gauze and other injection paraphernalia are kept inside lead lined trash cans that are double bagged. When these trash cans become full, the trash bag tops are sealed with tape and the Mo/Da/Yr are written on the bags and the bags are placed in the hot boxes for decay-in-storage.

3. The materials will be decayed for a minium of 10 half-lives. (The container with Ga-67,Tl-201, In-111 will remain in storage for decay for a minimum of 10 half-lives for the longest lived radionulcide for this group which is Ga-67.)

4. Prior to disposal as in-house waste, monitor each container as follows:

   a. Check your radiation detection survey meter for proper operation;

   b. Plan to monitor in a low-level (less than 0.05 millirem per hour) area;

   c. Remove any shielding from around the container;

   d. Monitor all surfaces of each individual container.

   e. Discard as in-house waste only those containers that cannot be distinguished from background. Record the date on which the container was sealed, the disposal date, and type of material. Check to be sure no radiation labels are visible.

   f. Containers that can be distinguished from background radiation levels must be returned to the storage area for further decay.

11. Waste Management

ATT 11.1 Procedure for Returning Generators to the Manufacturer

Used Mo-99/Tc-99m generators may be returned to the manufacturer. This permission still requires the licensees to comply with 10 CFR Part 71 and Department of Transportation (DOT) regulations.

1. Retain the records needed to demonstrate that the package qualifies as a DOT Specification 7A container (see DOT regulations, paragraph 173.415(a) of 49 CFR Part 173).

2. Assemble the package in accordance with the manufacturer's instructions.

3. Perform the dose rate and removable contamination measurements required by paragraph 173.475(i) of 49 CFR Part 173.

4. Label the package and complete the shipping papers in accordance with the manufacturer's instructions.

LABORATORY

ATT. 11.1 **WASTE DISPOSAL**

According to the Nuclear Regulatory Commission (NRC) "Codes of Federal Regulations" (CFR), Appendix B-10-CFR-20, the following maximum amounts of radioactive material per month can be disposed of in the sink (sewage) or as solid garbage (dump):

I^{125} - solid:	4×10^{-5} microCi/cubic cm. garbage/month
I^{125} - liquid:	6×10^{-3} microCi/ml. hospital sewage/month
Co^{57} - solid:	2×10^{-2} microCi/cubic cm. garbage/month
Co^{57} - liquid:	1×10^{-2} microCi/ml. hospital sewage/mo.
C^{14} - solid:	N.A. (acid washings of used cup into drain)
C^{14} - liquid:	2×10^{-2} microCi/ml.

The average monthly water consumption of this hospital, which should about be equal to the sewage generated, is 4,965,000 gallons or 1.87×10^{10} ml.

The maximum amount of radioactivity used in the laboratory per month is 200 microCi.

Thus $\frac{200 \text{ microCi}}{1.87 \times 10^{10} \text{ ml.}}$ - about 1×10^{-8} microCI/ml. which is three orders of magnitude below the maximum permissible load. Therefore, it is permissible to dispose of radioactive waste in the sink or trash can.

10. Radiation Safety Program Con't.

10.13 Air Concentration Control

We will check airflow and negative pressure semi-annually when Xenon 133 is in use.

1. "We will collect spent noble gas in a shielded container and will establish and implement the model procedure for checking trap effluent that was published in Appendix 0.3 to Regulatory Guide 10.8, Revision 2."

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

3. For aerosol studies, we use a system that employs a built in single-use trap. For Xenon studies, we use a delivery system which has a built in trap, which we monitor in accordance with manufacturer's recommendation. Therefore, no calculations need be performed for worker's immersion in noble gases or aerosol.

4. "We have enclosed our procedure for your review." See ATT 10.13-4.

10.14 Radiopharmaceutical Therapy

"We have enclosed our procedure for your review ." See ATT 10.14

10.15 Implant Therapy

"We have enclosed our procedure for your review." See ATT 10.15

10.16 Other Safety Procedures

N/A

The C-14 Urea Breath Test is regularly performed at the University of Virginia Medical Center.

For more information on this test contact:

Barry G. Marshall, M. D.
Dept. of Internal Medicine
Box 145
University of Virginia Medical Center
Charlottesville, Virginia 22908

(804) 924-8997

804-924-5916 - CPSI
IND placed ?
FDA approved

BREATH TEST PROCEDURE

Supplies Needed:

Toothbrush (1)
Straw or Pipette (6)
Stopwatch
Carbon 14-urea (1) 5 uCi
Collection Vials (6)

1. Make sure patient is fasting at least 6 hours and has not had Pepto-Bismol or antibiotics in last month.

2. Have patient remove any removable partials or dentures.

3. Obtain baseline sample
   Instructions to patient:
   "Blow bubbles until it turns absolutely clear. When it turns clear, you can stop. Be careful not to drink it."

4. Patient to brush teeth with toothpaste.
   Instructions to patient:
   "Please brush your teeth, gums, and tongue well so your entire mouth is clean. Do not swallow any water. Keep toothbrush."

5. Patient to drink C-14 (I dilute this with a small amount of water first.). (Start stopwatch as patient drinks C-14.)

6. Patient to brush teeth again using toothbrush and water. (No toothpaste)
   Again remind patient not to swallow any water.

7. Obtain breath samples at 2, 15, 20, 25, and 30 minutes.

   (Patient may replace partial/dentures after 2 minute sample.)

Addendum:

If patient accidentally gets collection fluid in mouth, have them immediately rinse their mouth thoroughly with water. This should be sufficient. If they swallow collection fluid

1. Rinse mouth
2. Give Maalox
3. Give Carafate
4. Notify MD

Carbon-14 Urea Breath Test for the Diagnosis of Campylobacter Pylori Associated Gastritis

Barry J. Marshall and Ivor Surveyor

Australian National Health and Medical Research Council, Royal Perth Hospital, Perth, Western Australia

a) At present only 5 μCi of C-14 labeled are given.

Urease in the human gastric mucosa is a marker for infection with *Campylobacter pylori* (CP), an organism suspected of causing chronic gastritis and peptic ulceration. To detect gastric urease, we examined 32 patients who were being evaluated for possible peptic ulcer disease. Fasting patients were given 10 μCi (370 kBq) of ^{14}C-labeled urea. Breath samples were collected in hyamine at intervals between 1 and 30 min. The amount of ^{14}C collected at these times was expressed as: body weight × (% of administered dose of ^{14}C in sample)/(mmol of CO_2 collected). The presence of *C. pylori* colonization was also determined by examination of multiple endoscopic gastric biopsy specimens. On average, patients who were proven to have *C. pylori* infection exhaled 20 times more labeled CO_2 than patients who were not infected. The difference between infected patients and *C. pylori* negative "control" patients was highly significant at all time points between 2 and 30 min after ingestion of the radionuclide ($p < 0.0001$). The noninvasive urea breath is less expensive than endoscopic biopsy of the stomach and more accurate than serology as a means of detecting *Campylobacter pylori* infection. Because the test detects actual viable CP organisms, it can be used to confirm eradication of the bacterium after antibacterial therapy.

J Nucl Med 29:11–16, 1988

Campylobacter pylori (CP) produces large amounts of urease (urea-amidohydrolase), an enzyme not present in mammalian cells and absent from the normal human gastric mucosa (*1,2*). The new bacterium may be the cause of type B gastritis (*3–5*), an inflammatory condition of the stomach thought by some to cause peptic ulceration (*6*). Other urease-producing bacteria rarely colonize the stomach, so tests for gastric urease are specific and sensitive detectors of CP infection, and thus of gastritis. This paper describes a simple breath test to detect gastric urease.

PATIENTS AND METHODS

Evaluation of the test was performed on 32 consecutive patients (23 men, 9 women) referred to our institution's ulcer research clinic. At upper gastrointestinal endoscopy, every patient had four biopsy specimens taken from the prepyloric antral mucosa, two for histopathology, one for gram-stain and culture, and one for a rapid urease test (see following). Biopsy specimens were processed in a manner previously described (*7*). For the purposes of this study, *C. pylori*-positive patients were defined as those with characteristic bacteria detected on gram-stained smear, culture, or histology (*5*).

For the rapid urease test (*2*), a biopsy specimen was inserted into a yellow gel ("CLOtest") containing urea and a pH indicator. Urease was present if a red color change occurred as a result of the production of ammonia from the hydrolysis of urea. When the CLOtest was positive, the time taken for the color change to occur was recorded by the endoscopist. These data were collected to see whether the rapid urease biopsy test and the breath test were equivalent means of quantitating gastric mucosal urease.

Nonessential medications were omitted during the 12 hr before the breath test, and patients were excluded from the study if they had taken antibiotics or bismuth-containing drugs during the previous 28 days [medications that could suppress CP infection (*5*)]. The breath test was always performed within 7 days of an elective endoscopy (either before or after). Clinical data and microbiologic, histologic, and breath-test results for individual patients were collected independently and were not collated until evaluation of data from each patient was complete. The protocol was approved by the Royal Perth Hospital Human Rights Committee and all patients gave written informed consent for the test.

The principle of measuring carbon-14 (^{14}C) as carbon dioxide excretion in the breath was adopted from previous reports (*8–10*). Carbon-14-labeled urea was supplied as a freeze-dried

Received Dec. 1, 1987; revision accepted July 30, 1987.

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ampoule. The contents of the ampoule 250 μCi (9.25 MBq) were dissolved in sterile water and made up to 100 ml. This resulted in a stock solution of 2.5 μCi (92.5 kBq/ml), that was stored at 2° to 4°C before use. The patient dose was gravimetrically dispensed from the stock solution so that 370 kBq (10 μCi) of radioactivity could be administered to the patient in 25 ml of water. At the same time a 1:125 dilution of the stock solution was prepared as a standard for liquid scintillation counting.

Patients fasted for at least 6 hr, usually overnight, before the test. To diminish contamination from urease-producing commensal flora in the mouth, patients brushed their teeth with water only, that was not swallowed. The patient then gave a control breath sample before drinking the isotope. After administration of the isotope the patient again cleaned his teeth and rinsed his mouth over a washbasin with the water running. For each sample, the patient exhaled through a short corrugated tube connected to a chamber of calcium chloride granules as a drying agent (Fig. 1). The breath then bubbled into a 20-ml scintillation counter vial containing 0.5 mmol of hyamine dissolved in 2 ml of ethanol. The breath sample was complete when a pH indicator (thymolphthalein) in the hyamine solution changed from blue (alkaline) to colorless (acid). Most patients were able to change the color of the hyamine solution with a single long breath, thus decreasing contamination of the breath from urea hydrolyzed in the oropharynx. In retrospect, the drying step could have been omitted, but the drying chamber ensured that patients could not accidentally inhale the hyamine solution.

Samples were obtained at baseline, and at 1, 2, 5, 10, 15, 20, 25, and 30 min after the patient had drunk the isotope. During the test, patients were allowed to move around, but they usually sat upright reading magazines. Whenever possible, a 24-hr urine sample was collected after the test.

After addition of 10 ml of scintillation fluid, standards were counted in duplicate in a liquid scintillation counter. Counts were corrected to disintegrations per minute (DPM) using an external standard, quench program. Samples were counted to a 1% coefficient of variation and results were expressed as

$$(\text{DPM/mmol } CO_2 \text{ collected}) \times 100 \times \text{body-weight (kg)}/(\text{DPM administered}), \text{ and}$$

$$(\text{DPM/ml urine}) \times \text{urine volume} \times (100/\text{DPM administered})$$

The breath radioactivity was multiplied by body weight to correct for the influence of endogenous CO_2 production on the breath-specific activity of ^{14}C (7). The calculation gave a result that was independent of the ^{14}C dose administered, the amount of CO_2 collected, and the weight of the patient.

An example of a calculation from a positive patient is given below.

Age = 60 Sex = M

DPM of standard = 176,000;
Proportion of dose in standard = 1/125;
Weight of patient = 180 lb = 180/2.2 kg;
Concentration of hyamine = 0.25 mM;
Volume of collecting solution = 2 ml;
DPM of sample taken 10 min after dose = 6433.

$$\text{result} = \frac{6433 \times 100 \times 180/2.2}{(176{,}000 \times 125) \times (2 \times .25)} = 4.78$$

In CP-negative patients DPM values of 300 are expected after 10 min (result of 0.37 for the demonstration patient given above). Baseline samples in most patients were around 100 DPM with a background of ~70 DPM.

When the 32 patients described above had been examined by both breath test and biopsy, the breath test was used as an accessory means of diagnosis in 40 additional patients who were undergoing evaluation for dyspepsia. These patients could not be included in the formal study because they either did not have a gastric biopsy taken, or they had recently received antibacterial therapy.

RESULTS

Of the 32 patients who took part in the formal evaluation study, 16 were CP+ and 16 were CP−. Clinical data on these patients are given in Table 1.

Table 2 gives detailed breath-test results for these patients. It demonstrates a significant difference between the CP+ and CP− groups at time points after 1 min ($p < 0.0001$, t-test). Graphic comparison of the two groups is shown in Figure 2.

In CP+ patients the maximal urease activity was in the stomach so the $^{14}CO_2$ increased and remained high after the urea was swallowed. In the CP− persons, however, the maximal urease activity was in the mouth and the esophagus. In this group the peak $^{14}CO_2$ excretion was immediately after ingestion with a subsequent decline as the urea entered the sterile acid environment of the stomach.

As shown in the figure, the standard deviation was wide for both curves, but at 10 min any value >1.5 was CP+ and any value <0.5 was CP−. In the CP− group the highest values were from a patient with deformity of the pylorc-duodenal segment who had previously undergone pyloroplasty and vagotomy. In this patient there may have been some other urease-producing bacterial flora in the stomach as a result of diminished acid secretion and gastric stasis. Bacteria (not *C. pylori*) were seen adhering to the mucosa in the histologic sections on this patient. His breath-test results at 5, 10, and 15 min were 1.26, 1.11, and 0.99.

In the CP+ patients breath-test values at 5, 10, and 15 min were all above 1.5. Although there was no overlap with the CP− group in this study, the relatively small number of patients examined causes the confidence intervals for each group to be wide so that both CP− and CP+ patients may be found in the region between 0.75 and 0.92. Therefore, there may be some patients who give an indeterminate result, i.e., values between 0.70 and 1.5 at times 10 and 15 min. In the majority of patients, however, a single sample at 15 min will provide adequate data.

Twenty-four-hour urine collections were obtained from 11 CP− and 13 CP+ patients (Table 3). The amount of ^{14}C (presumed to be in urea) excreted in the CP− patients was 62% of the administered dose (s.d.

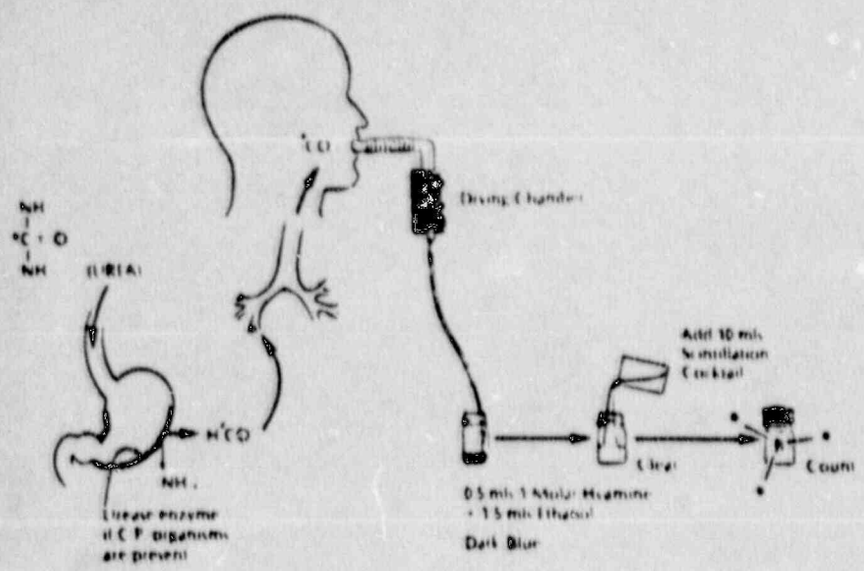

FIGURE 1
Diagram showing apparatus used to perform the test. In subsequent studies the drying chamber has been omitted and patients have blown through a disposable 1-ml plastic pipette

13, range 47–93%); and in the CP+ patients was 42% of the administered dose (s.d. 12, range 14–65%). These differences were again highly significant ($p < 0.0001$ t-test).

In all 32 patients, the presence of *C. pylori* organisms was also determined by the rapid urease biopsy test performed at the time of endoscopy. For the 16 CP+ patients, the average time taken for the biopsy urease test to change color was 4 min, (range 1–10 min) but there was no correlation between the reaction time of the biopsy urease test and $^{14}C\ CO_2$ excretion detected with the breath test.

Figure 3 shows individual breath-test results for the 40 patients who could not be included in the evaluation study (64 tests, four patients were tested on two occasions). To improve the resolution of the curves, a logarithmic scale has been used on the Y axis. Twenty-one patients had large amounts of gastric urease (A) and 14 patients had no gastric urease (B). Separate from these groups was a small subgroup of patients in the low-positive and high-negative range (C). Most of these were patients who had forgotten their instructions and had taken antibiotic medication or bismuth in the week of the test, or had taken cimetidine in the 24 hr before the test. For example, one patient was taking 250 mg of amoxycillin daily until the day before his test which gave a result in the high negative range (°1). After ceasing his antibiotic we repeated the test 2 wk later by which time gastric urease activity had increased three-fold (°2) indicating probable recrudescent CP infection.

There were 57 patients in whom a 24-hr urine collection was performed after taking the isotope. There was a strong correlation ($r = -0.71$) between ^{14}C excretion in the urine and the log of the maximum $^{14}CO_2$ breath value. The urinary ^{14}C excretion assisted in radiation dosimetry calculations.

TABLE 1
Characteristics of 32 Patients in the Formal Evaluation Study

	Number	Mean age (yr)	Men	Women	Duodenal ulcer	Gastric ulcer	Other
CP−[1]	16	45	14	2	9	1	6
CP+[1]	16	46	9	7	14	0	2

[1] CP− = *C. pylori* not detected by culture, histologic examination or Gram stain of gastric antral biopsy specimens
[1] CP+ = *C. pylori* detected by any one of these tests

Dosimetry

Ingested urea may pass unaltered into the urine or may be hydrolyzed by bacteria through the following

TABLE 2
Breath Test Results on 32 Patients

Time (min)	No of pts	Mean	s.d.	Minimum	Maximum
Negative findings for *C. pylori* (16 patients)					
1	11	0.84	0.50	0.15	1.69
2	11	0.55	0.39	0.04	1.39
5	13	0.30	0.30	0.02	1.26
10	13	0.22	0.30	0.02	1.10
15	16	0.20	0.32	0.01	1.03
20	12	0.29	0.39	0.01	1.26
25	12	0.33	0.43	0.01	1.40
30	16	0.27	0.40	0.01	1.50
Positive findings for *C. pylori* (16 patients)					
1	13	1.81	1.10	0.24	3.50
2	13	3.73	1.34	1.53	5.82
5	15	4.30	1.67	1.66	7.80
10	15	4.38	1.80	1.83	7.90
15	16	3.97	1.59	1.65	6.21
20	14	3.11	1.34	1.32	4.96
25	14	2.58	1.13	1.16	4.22
30	16	2.36	1.07	0.96	4.13

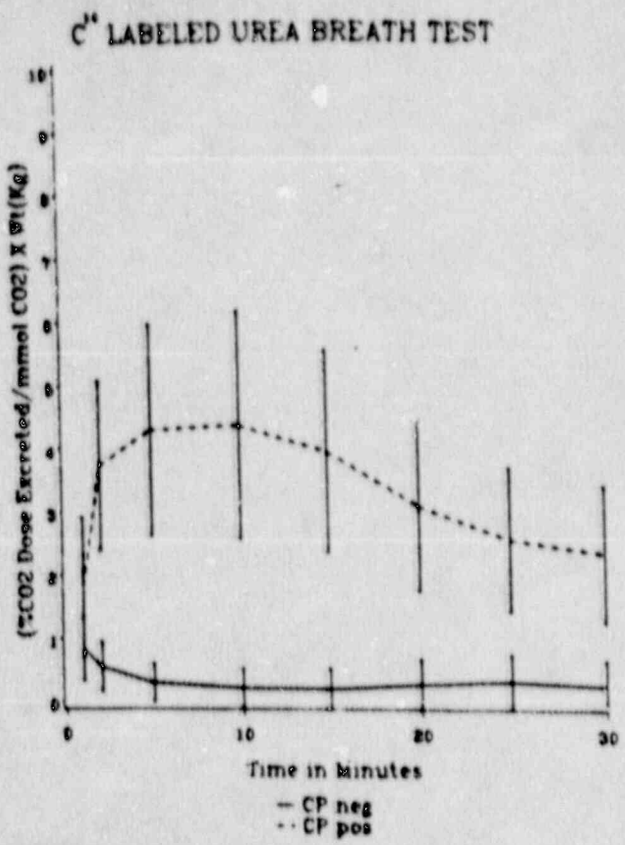

FIGURE 2
Graphed results from the 32 evaluable patients (16 CP+ 16 CP−).

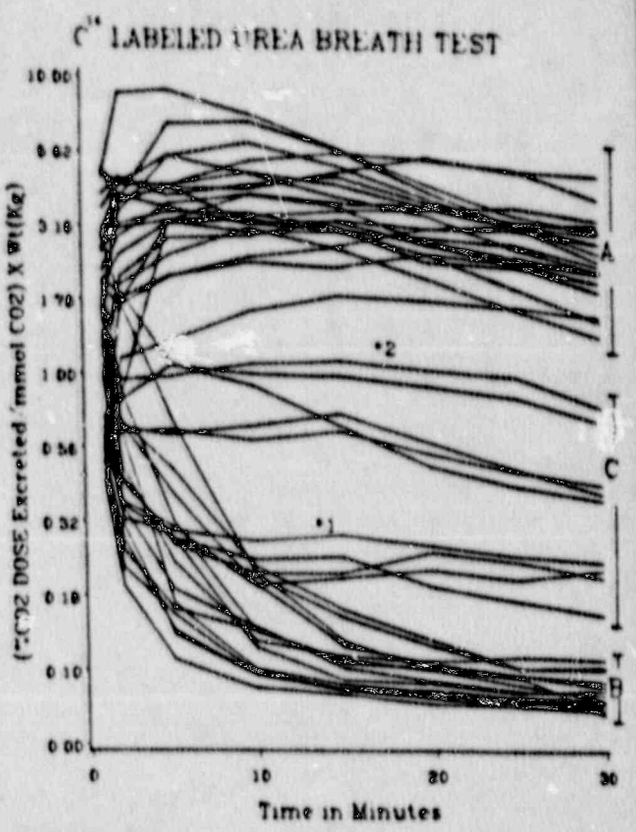

FIGURE 3
Graphed results from 40 "nonevaluable" patients (biopsy not performed or patient on recent antibacterial therapy). There is a high, clearly positive group (A), a low clearly negative group (B), and an equivocal group (C). Patients in group C may have had partial suppression of urease production after antibacterial therapy. *1 is the initial study of a patient who had taken amoxycillin the day before the test. *2 is the same patient 2 wk later when a threefold increase in gastric urease activity had occurred. Note that in this illustration, a logarithmic scale has been used on the "y" axis.

reaction:

urea

$$\begin{array}{l} NH_2 \\ | \\ C{=}O + 2H_2O + H^+ \xrightarrow[urease]{} \underset{2NH_4^+}{\text{ammonium}} + \underset{HCO_3^-}{\text{bicarbonate}} \\ | \\ NH_2 \end{array}$$

In the CP+ patients, an average of 40% of the ^{14}C dose was excreted in the urine. The metabolism of the remaining 6 μCi (222 kBq) of ^{14}C can be determined from the paper of Yap et al. (*11*) who studied CO_2 excretion in volunteers who received labeled bicarbonate intravenously. From his data it may be inferred that the radiation dose to body fat for CP+ patients having our test is 40 μGy, bone 180 μGy, lung 6 μGy and gonads 3.6 μGy. In CP− patients 70% of the administered isotope is excreted in the urine so the bladder-wall receives the highest radiation dose. Assuming half the equilibrium dose rate irradiates the bladder wall, the dose to this organ is ~70 μGy (10 μGy = 1 mren).

TABLE 3
24-hr Urinary Excretion of ^{14}C as % of Dose Ingested

	No pts	Mean	s d	Min	Max
CP−	11	67	13	47	93
CP+	13	42	12	14	65

DISCUSSION

Serologic studies indicate that ~20% of adults in western countries have colonization of the gastric mucosa with *C. pylori* (*12–15*). In biopsy studies of healthy subjects in Holland (*2*) and the USA (*16*), persons colonized with *C. pylori* all had gastritis, whereas subjects who did not have *C. pylori* had histologically normal gastric mucosa. These studies suggest that evidence of *C. pylori* infection alone is sufficient to make the diagnosis of gastritis.

Gastric urease tests depend on the fact that mammalian cells cannot produce urease (*1*), so the presence of the enzyme always indicates bacterial metabolism. Our test was devised after we observed diminished urea in the gastric juice of *C. pylori* infected patients (*17*) and noted the high specificity of a biopsy urease test for

diagnosing both *C. pylori* infection and active gastritis (*2*). A similar breath test using ^{13}C has been described by Graham et al. (*18*). Graham's test has the advantage of using a nonradioactive isotope. On the other hand, the ^{13}C method is time-consuming and requires a mass spectrometer. Our test is a quick one to perform, so we recall patients with equivocal results for a second test rather than have all patients carry out a prolonged collection. Unlike the results from serologic studies, equivocal breath tests tend to be due to transient aberrations, rather than persistently borderline values of gastric urease activity.

Examination of the 40 patients classified as "non-evaluable" (44 tests) shows that equivocal results occur if the patient has been exposed to antibiotics or bismuth compounds in the weeks preceding the test (Fig. 3). It was our practice to perform endoscopy and biopsy 14 days after antibacterial therapy to test for continuing *C. pylori* infection. The breath test is less sensitive than multiple gastric biopsy specimens, so we recommend a longer period (e.g., 28 days) between cessation of therapy and the test.

Most of the CP+ patients evaluated had duodenal ulcer disease so normal or high acid secretion can be assumed to have been present. We did not test any patients with achlorhydria, or who were actually taking H2-receptor antagonist drugs. When gastric pH rises above 3.0, urease-producing commensal flora from the mouth may grow and give rise to false-positive test results. To avoid this event, drugs such as cimetidine should be stopped 24 hr before the test, and the patient's clinical details and recent medications should be known by the person reporting the test.

This breath test has been a useful additional means of diagnosing *C. pylori* infection at our institution. In other studies (*19*) we have found that serologic tests which detect IgG antibodies to *C. pylori* are sensitive indicators of infection (90% sensitivity for an ELISA test) but cannot be used to confirm eradication of the organism because antibodies decline so slowly after cure. Thus, until now, confirmation of bacteriologic cure required biopsy. It seems wasteful to perform endoscopy merely to obtain a sample of tissue for bacteriologic examination. In most patients, a breath test 28 days after therapy can confirm eradication of the organism. If an equivocal result is obtained, the test may be repeated after a further 14 days.

We hope that the ^{14}C breath test will allow nonendoscopists to study gastritis and *C. pylori* infection. In dyspeptic patients with negative radiologic examinations this test provides useful additional information as to the state of the gastro-duodenal mucosa. If a sufficiently high result is taken as positive for CP (e.g., 1.5 on our scale), false-positive results can be eliminated. The test would then be useful for epidemiologic studies in normals.

When gastric urease activity is high, viable *C. pylori* organisms are almost always present, whereas serologic tests remain positive for many months after eradication of the organism. For this reason, the ^{14}C-urea breath test is the most sensitive and specific noninvasive method presently available for the diagnosis of *C. pylori* infection.

ACKNOWLEDGMENTS

The authors acknowledge the assistance of the staff of the Department of Nuclear Medicine and Radionuclide laboratory RPH, Professor Goodwin's lab (microbiology), Dr J.R. Warren (histopathology), Michael Plankey (CNMT), and Alice Cullu for editing the manuscript.

This work was supported by the Australian National Health and Medical Research Council and The Royal Perth Hospital Research Fund.

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