Point Pleasant Hospital

"Pointing the way to better health care."

OSBORN AVE. & RIVERFRONT 201-892-1100 POINT PLEASANT, N.J. 08742

RICHARD J. LEONE
PRESIDENT

July 28, 1983

REGARDING: LIS # 29-05013-01

'83 AUG -2 A9:34

Dear Sir:

Inadvertently the second part of the most recent NRC renewal application was not included in our first mailing. Enclosed is the remainder of the renewal application. Please include this part of the application with the previously submitted first part.

If you have any questions or need any assistance please contact the undersigned.

Lynn Brocious RT

LYNN BROCIOUS RT.

RADIATION SAFETY COMMITTEE

Meeting Frequency

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

Responsibilities

The committee is responsible for

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

Duties

The committee shall

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments.
2. Review the training and experience of any individual who uses radioactive material (including physicians, technologists, physicists, and pharmacists) and determine that the 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 19.2 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.

RADIATION SAFETY COMMITTEE

Duties (continued)

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, to include the ALARA Program. The review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspections, written safety procedures, and management control system.
7. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
8. Maintain written records of all committee meetings, actions, recommendations, and decisions.
9. Ensure that the byproduct material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel.

Members

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

1. The radiation safety officer,
2. The hospital administrator, or other administrative official directly responsible to the hospital administrator in the hospital's internal chain of command,
3. A physician specialist from each department where radioactive materials are used, and
4. A representative of the hospital's nursing staff.

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

ITEM 7.

Authorized Users (as previously listed on Amendment 20)

1. James F. Dougherty, M.D.
2. Michael Zito, M.D.
3. Theresa L. Siebert, M.D.
4. Robert Monaco, M.D.
5. Donald Shields, M.D.
6. Lino M. Alcasid, M.D.

INSTRUMENTATION

1. Survey Meters

Picker 642081	0 - 50,000 cpm
Victoreen 740F	0 - 25,000 mR
Victoreen 491	0 - 100 mR
Atomic Products	0 - 50 mR

2. Dose Calibrator

Capintec CRC-17
Capintec CRC-6A

3. Diagnostic Instrumentation

Siemens large field camera
Siemens HP/Phogamma 4 camera
Picker Spectroscaler 4R Thyroid uptake probe

CALIBRATION OF SURVEY METER INSTRUMENTATION

Survey meter calibrations will be conducted on a ~~quarterly~~ yearly basis by Health Physics Services, Inc., Potomac, Maryland, using sealed Cesium-137 sources of approximately 500 mCi, authorized by the State of Maryland under license Number MD-31-035-01. The calibration procedures are on file with the NRC, under License No. 19-19791-01.

DOSE CALIBRATOR CALIBRATION AND LINEARITY PROCEDURES

1. On a daily basis, the constancy of the dose calibrator will be determined with two sources: 200 uCi of Cesium-137, and greater than one millicurie of Cobalt-57. These sources are NBS traceable with an accuracy of 100±5%. Should the error of the constancy measurement be greater than ±5%, appropriate adjustment or instrument repair will be affected.

2. On a quarterly basis, Health Physics Services, Inc., Potomac, Maryland, will conduct the dose calibrator calibrations under Maryland License Number MD-31-035-01.

   A Cobalt-57 source of approximately 10 millicuries will be used to insure the dose calibrator accuracy. Should the calibration deviate by greater than ±5%, appropriate adjustment or instrument repair will be conducted. This quarterly procedure will be repeated using a Cesium-137 and a Barium-133 source of approximately 0.2 millicuries each. The three calibration sources are NBS traceable with an accuracy of 100±5%

3. The linearity of the dose calibrator will be determined quarterly, by Health Physics Services, Inc., in accordance with the NRC Medical Licensing Guide, Appendix D, Section 2.E., over the full range of activities of Technetium used. Should the linearity (measured versus calculated) vary by greater than ±5%, appropriate corrective action will be conducted.

4. Test for geometrical variation will be conducted in accordance with Appendix D, Section 2, Item F., of the NRC Medical Licensing Guide, unless certified data is supplied by the dose calibrator manufacturer.

CALIBRATION OF DIAGNOSTIC INSTRUMENTATION

Calibrations of diagnostic instrumentation, to include gamma cameras and associated instrumentation will be conducted in accordance with the manufacturers' instructions.

Daily floods will be conducted to insure integrity of the camera.

FACILITIES AND EQUIPMENT

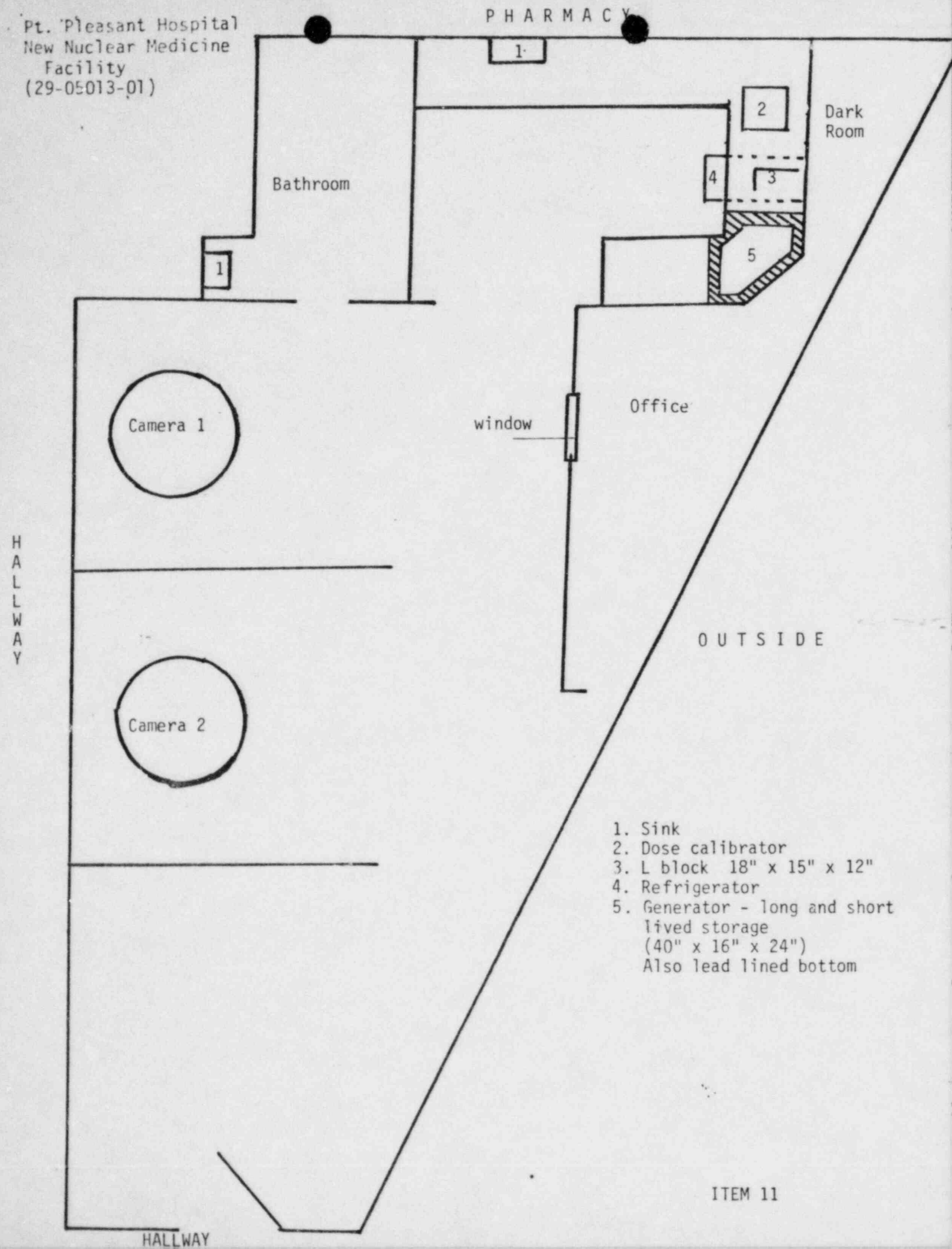
Radiation Handling Equipment

To enable personnel to work safely with unsealed radioactive materials, the Nuclear Medicine laboratory will have the proper radiation handling equipment. The following is a list of basic radiation handling equipment which is available in the Nuclear Medicine department.

Lead bricks
Lead vial and container shields
Laboratory coats or equivalent
Absorbent pads
Disposable gloves
Decontaminating agents
Signs and labels indicating the presence of radioactive material
Syringe shields

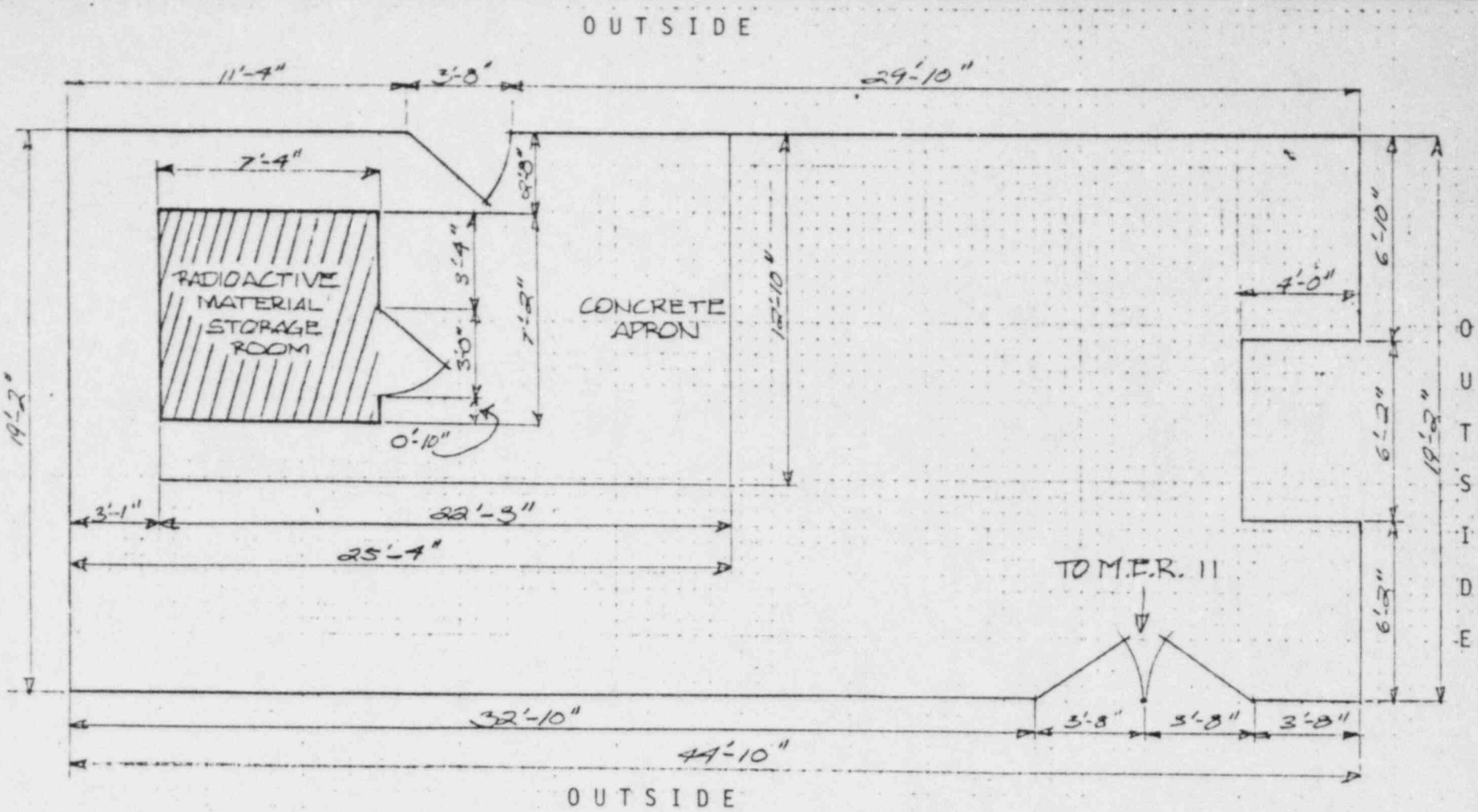
A diagram of the facilities is also enclosed herewith.

Pt. Pleasant Hospital
New Nuclear Medicine
Facility
(29-05013-01)



1. Sink
2. Dose calibrator
3. L block 18" x 15" x 12"
4. Refrigerator
5. Generator - long and short lived storage (40" x 16" x 24") Also lead lined bottom

ITEM 11



TOTAL SQUARE FEET - 520.8
STORAGE AREA (INSIDE) - 36.0
STORAGE AREA (OUTSIDE) - 52.6

NOTE: INSIDE AREA DETERMINED USING 7½" NOMINAL WIDTH FOR BLOCK WALL.

Point Pleasant Hospital
Point Pleasant NJ

Entry door is always locked with appropriate "Caution Radioactive Material" sign posted.

NORTHERN OCEAN HOSPITAL SYSTEM, Inc. ENGINEERING AND MAINTENANCE DEPARTMENT		
TITLE: RADIOACTIVE MAT'L STORAGE ROOM		DRAWING NO.: A-6
DESIGN / DRAWING BY: D. MAXWELL	SCALE: 3/16" = 1'-0"	DATE: 5 JULY, '85

PERSONNEL TRAINING PROGRAM

The personnel training program will be given to all personnel who work with or in the vicinity of radioactive materials. The training will be in the form of lectures and the duration of each session will depend on the extent of applicability to the employees involved. The training program will be of sufficient scope to ensure that all personnel, including technical, clerical, nursing, housekeeping, and security personnel receive proper instruction in the items specified in 19.12 of 10 CFR Part 19, to include:

A. Areas where radioactive material are used or stored.
B. Potential hazards associated with radioactive material
C. Radiological safety procedures appropriate to their respective duties.
D. Pertinent NRC regulations.
E. Rules and regulations of the licensee.
F. Pertinent terms of the license.
G. Their obligation to report unsafe conditions.
H. Appropriate response to emergencies or unsafe conditions.
I. Their right to be informed of their radiation exposure and bioassay results.
J. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence), as required by 10 CFR Part 19.

Personnel will be properly instructed as follows:

A. Before assuming duties with or in the vicinity of radioactive materials.
B. During annual refresher training.
C. Whenever there is a significant change in duties, regulations, or the terms of the license.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. The Chief Nuclear Medicine technologist or his desjgnee will place all orders for radioactive material, and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.
2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the Nuclear Medicine Department.
3. During off-duty hours, security personnel will accept delivery of radioactive packages in accordance with the procedures outlined in the enclosed memorandum.
4. A system for ordering and receiving radioactive materials will be established and maintained. The system will consist minimally of the following:
   a. Ordering of routinely used materials
      (1) Written records that identify the isotope, compound, activity levels, and supplier, etc., will be used.
      (2) The written records will be referenced when opening or storing radioactive shipment.
   b. Ordering of specially used materials (e.g., therapeutic uses)
      (1) A written request* will be obtained from the physician who will perform the procedure.
      (2) Persons ordering the materials will reference the physician's written request when placing the order. The physician's request will indicate isotope, compound, activity level, etc.
      (3) The physician's written request will be referenced when receiving, opening, or storing the radioactive material.
   c. It is essential that written records* be maintained for all ordering and receipt procedures.

* In the case of cial orders, the physician's written request and appropriate shipping/rece l records will be referenced and the dose assayed prior to its administrati n.

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RICHARD J. LEONE
PRESIDENT

FOREWORD

Ionizing radiation is among the most versatile and useful tools of modern medicine and biomedical research. Like many other instrumentalities of medicine, ionizing radiation is potentially hazardous unless used with strict adherence to safety rules and procedures. Thus, the safety rules which govern the uses of radiation are concerned with preventing genetic damage as well as with protecting the health of the exposed individual.

The rules and procedures set forth here have one single, straightforward purpose: to protect the patients, employees, and visitors from unnecessary and potentially harmful radiation.

The existing radiation safety program has many facets designed to keep the levels of exposure to personnel at a minimum. This program has three main phases:

PHASE I

Achieve the objective of maintaining radiation exposures to "As Low As Reasonably Achievable" (ALARA) to employees, visitors, students, and patients who are not under medical supervision for the administration of radiation or radioactive materials for diagnostic or therapeutic purposes.

PHASE II

Control operational procedures by the user of radiation sources.

PHASE III

Evaluate the radiation safety program performed by the Radiation Safety Officer, health physics consultant, and the Radiation Safety Committee.

We, the management of this hospital, are committed to the program described herein for keeping exposures, individual and collective, to as low as reasonably achievable (ALARA).

All primary users of radiation sources are encouraged to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

Richard J. Leone
Administrator

DATE 7-21-83

RADIATION SAFETY PROGRAM (ALARA)

I. INTRODUCTION

A. Purpose

This program sets forth the philosophy and general management policies that are established by this hospital to achieve the objective of maintaining radiation exposures to "as low as reasonably achievable" (ALARA), for employees, visitors, students, and patients not under medical supervision for the administration of radiation or radioactive materials for diagnostic or therapeutic purposes.

B. Policy

In addition to complying with the limits set forth in pertinent regulations, guides, and standards, users and supervisors of radiation sources shall make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas to as low as reasonably achievable.

II. MANAGEMENT COMMITMENT

A. The management and the entire staff of this hospital are committed to the program described herein for keeping radiation exposures, individual and collective, to as low as reasonably achievable.

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

C. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our 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 where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

D. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

E. The services of Health Physics Services, Inc., has been contracted to assist in the program management to insure that all pertinent hospital staff and employees receive appropriate briefings and training in radiation safety including ALARA concepts.

III. RADIATION SAFETY COMMITTEE

In addition to other responsibilities delineated in pertinent radiation control standards, the Radiation Safety Committee (RSC) shall:

A. Determine whether current procedures are, in fact, maintaining radiation exposures to ALARA. The efforts of the radiation safety officer (RSO), health physics consultant, users and supervisors of radiation sources will be reviewed during the committee meeting.

B. When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

C. Perform an annual audit of all aspects of the radiation safety program to insure that the overall philosophy and policies of the ALARA program are being accomplished.

D. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and the uses for which he has applied, to assure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

E. Delegation of Authority

1. The RSC will delegate authority to the RSO and his consultant staff for enforcement of the ALARA concept.

2. The RSC will support the RSO in those instances where it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

F. 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 where Investigational Levels in Table 1 below are exceeded. The principle purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded.

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

IV. RADIATION SAFETY OFFICER, AND HIS CONSULTANT STAFF ARE RESPONSIBLE FOR THE FOLLOWING:

A. Annual and Quarterly Review

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

2. Quarterly review of Occupational Exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph VII of this program.

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

B. Education Responsibilities for an ALARA Program

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

2. The RSO will assure that authorized users, workers, and ancillary personnel who may be exposed to radiation will be instructed in 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 opportunites to participate in the formulation of 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 suggestion of individual workers for improving health physics practices and encourage the use of thos procedures.

D. Reviewing Instances of Deviation from Good ALARA Practices

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

V. AUTHORIZED USERS

A. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radiation sources for a new procedure.

2. The authorized user will evaluate all procedures before using radiation sources to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

B. Responsibility of the Authorized User to Those He Supervises

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

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

VI. PERSONS WHO RECEIVE OCCUPATIONAL RADIATION EXPOSURE

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

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

VII. ESTABLISHMENT OF INVESTIGATIONAL LEVELS IN ORDER TO MONITOR INDIVIDUAL OCCUPATIONAL EXTERNAL RADIATION EXPOSURES

This institution hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Officer or consultant staff. The Investigational Levels that we have adopted are listed in Table 1 below. These levels apply to the exposure of individual workers.

TABLE 1

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

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

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

A. Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table 1 values for the Investigational Level I.

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

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

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

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

D. Re-establishment of an individual occupational worker's Investigational Level II above that listed in Table 1.

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

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

VIII. SIGNATURE OF CERTIFYING OFFICIAL

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

Richard J. Leon

Signature of Administrator (or his designee)

Richard J. Leon

Name (print or type)

President

Title