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: 5-30-90

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

N

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

030
34301

IF YOU ARE LOCATED IN:

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

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

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

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

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
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)*

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER 21-26770-01
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

Caro Community Hospital
401 N. Hooper Street
Caro, MI 48732

Expd.

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

401 N. Hooper Street
Caro, MI 48732

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Pat Miller or (Tracy King, Medical Physics Consultants 313-662-3197

TELEPHONE NUMBER: 517-673-3141

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 7C
AMOUNT ENCLOSED $ 1400

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 P. Miller	William P. Miller	President and C.E.O.	12/05/96

mL30 4/1

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
AMOUNT RECEIVED	CHECK NUMBER			DATE
			Pm. 12-5-96	30217

55

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Section

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code:
Status Code: 3
Fee Category:
Exp. Date: 0
Fee Comments:
Decom Fin Assur Reqd:

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: CARO COMMUNITY HOSPITAL
   Received Date: 961209
   Docket No: 3034301
   Control No.: 302117
   License No.:
   Action Type: New Licensee

2. FEE ATTACHED
   Amount: 1400
   Check No.: 024439

3. COMMENTS

Signed D. Hersey
Date 12-6-96

1996 DEC 13 AM 8:47

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered (X/))

1. Fee Category and Amount: 7C $1400

2. Correct Fee Paid. Application may be processed for:
   Amendment
   Renewal ✓
   License

3. OTHER

Signed SC
Date 12/13/96

Log Dec 5 III
Remitter
Check No. 24439
Amount $1400
Fee Category 7C
Type of Fee App
Date Check Rec'd 12/13/96
Date Completed
By: SC

DEC 18 1996

050048

Caro
Community
Hospital

P.O. BOX 71 · 401 NORTH HOOPER · CARO, MICHIGAN 48723
(517) 673-3141

William P. Miller
PRESIDENT and CHIEF EXECUTIVE OFFICER

December 5, 1996

United States Nuclear Regulatory Commission
Region III, Medical Licensing Section
801 Warrenville Road
Lisle, IL 60532

Re: New License Application

Dear Sir/Madam,

Enclosed please find an application for a new license for Nuclear Medicine Services for Caro Community Hospital. Your consideration in reviewing the application as soon as possible is appreciated. Should you have any questions, you may contact myself or our consultant, Tracy King of Medical Physics Consultants, Inc. at 313-662-3197.

Sincerely,

William P. Miller

William P. Miller
President and C.E.O.

Enclosure

Caro Community Hospital
New Application
1996

APPLICABILITY TABLE

Item	Topic	
8.1	Training Program	Enclosed
8.2	Other Training Program	N/A
9.1	Facility Diagram & Equipment List	Enclosed
9.2	Survey Instrument Calibration	Per 10CFR35.51
9.3	Dose Calibrator Calibration	Enclosed
9.4	Personnel Monitoring Program	Enclosed
9.5	Mobile Imaging Equipment QA	N/A
9.6	Other Equipment and Facilities	N/A
10.1	Radiation Safety Committee	Enclosed
10.2	ALARA Program	Enclosed
10.3	Leak Test	Enclosed
10.4	Safe Use of Radiopharmaceuticals	Enclosed
10.5	Spill Procedures	Enclosed
10.6	Ordering and Receiving	Enclosed
10.7	Opening Packages	Enclosed
10.8	Unit Dose Records	Enclosed
10.9	Multidose Vial Records	Enclosed
10.10	Mo-99 Concentration Records	Enclosed
10.11	Implant Source Use Records	N/A
10.12	Area Survey Procedures	Enclosed
10.13	Air Concentration Control	Enclosed
10.14	Radiopharmaceutical Therapy	Enclosed
10.15	Implant Therapy	N/A
10.16	Other Safety Procedures	N/A
11.1	Waste Disposal	Enclosed
11.2	Other Waste Disposal	N/A
12.1	Quality Management Program	Enclosed

RADIOACTIVE MATERIAL AND USE

Byproduct Material	*Item 5* Amount	*Item 6* Purpose
Material in 35.100	As Needed	Uptake, dilution, and excretion studies
Material in 35.200	As Needed	Imaging and localization studies
Material in 35.300	As Needed	Radiopharmaceutical Therapy

Maximum possession limit of 1 Ci of I-131

RADIATION SAFETY PROGRAM RESPONSIBILITY

Item 7.1

Authorized User	Materials
Suryaroo Kurumety, M.D.	35.100, 35.200, and 35.300

Item 7.3

Radiation Safety Officer

Suryaroo Kurumety, M.D.

We have enclosed a copy of a license which previously listed Dr. Kurumety as an authorized user for Groups 35.100 and 35.200. He was also an approved authorized user at the Great Lakes Naval Hospital in 1990 and 1991. We have enclosed a copy of minutes from their radiation safety committee which approved him as an authorized user.

NRC Form 374A (8-82) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

PAGE 1 OF 1 PAGES

License number: 21-04078-01

Docket or Reference number: 030-02039

Amendment Number 35

Saginaw Osteopathic Hospital
515 North Michigan Avenue
Saginaw, Michigan 48602

In accordance with application dated October 13, 1982, License Number 21-04078-01 is amended as follows:

Condition 12. is amended to read:

12. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

M.S. Grillo, D.O.

Groups I, II and III
Xenon-133
In vitro studies
All Groups I, II and III Xenon-133 Iodine-131 hyperthyroidism dysfunction

Harvey Minkin, D.O.

Suryarao Kurumety, M.D.

Groups I, II and III
Xenon-133
Iodine-131 for treatment of hyperthyroidism and thyroid carcinoma

For the U.S. Nuclear Regulatory Commission

Date NOV 20 1992

By William F. Adam
Material Licensing Section
Region III

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association
and the American Society of Therapeutic Radiologists
Hereby certifies that

Suryarao Kurumety, M.D.

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this fifteenth day of June, 1979
Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of

Diagnostic Radiology

THE AMERICAN BOARD OF RADIOLOGY
INCORPORATED IN THE DISTRICT OF COLUMBIA
1934

AMERICAN BOARD OF MEDICAL SPECIALTIES

E. Richard Eiser, President

C. Allen Good, Secretary

Conclusion/Recommendation/Action/Follow-up: This item is complete and removed from the Master Tracking Report.

3. NEW BUSINESS.

LEAK OF RIA EFFLUENT IN SECURITY VAULT, 38H. A long-term leak in the Security Vault of 38H has been traced to Hot Sink plumbing, RIA Lab, NDSL. Although effluent concentrations exceed NRC limits for an unrestricted area, personnel exposures are minimal. Licensing actions will be handled by NDSL. No further action from this Committee is required.

4. ADMINISTRATIVE.

a. Radioactive Material Authorized Users.

(1) The following tabulates the current list of Authorized Users.

Name	Approved Use	Date Approved
Dr. Shakir	35.100, 35.200, 35.300	12 Sep & 30 Dec 88
Dr. Chun	35.100, 35.200	29 Sep 89

(2) LT Mohaupt recommended that Dr. S. Kurumety be approved as an Authorized User under the auspices of 10 CFR 35.100 (Use of radiopharmaceuticals for uptake, dilution, and excretion studies) and 35.200 (Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies). The Committee unanimously approved that motion. Enclosure (4) verifies that he meets the training requirements.

b. Reference (c) contains the results of the Annual Inspection of the Nuc Med Permit. No discrepancies were noted.

c. Enclosure (5) presents the Quarterly Radiation Safety Survey results for NucMed. No discrepancies were noted.

d. The Inventory of Radioactive Materials [enclosure (6)] was reviewed. No discrepancies were noted and all swipes of sealed sources were negative for contamination.

e. Quarterly Exposure Review. Personal and posted dosimetry results 090CT90-19FEB91 and extremity results from 12SEP90-01FEB91 were reviewed.

The highest exposures were 62%, 7%, and 104% of the quarterly action levels for whole body, skin, and extremity exposures, respectively. The extremity exposure for one NucMed tech exceeded Action Level I, which requires RSO evaluation and Committee review. Enclosure (7) states that the exposure is resultant of a 40-day period where only one tech was working. Exposures since this period have reduced to acceptable levels. Since then, another NucMed tech has reported for duty.

f. Reference (d) alerts NRMP holders to a number of recent misadministrations caused by technician inattention. The letter was routed to all NucMed techs for their edification.

6470
NH-05
25 March 1991

From: Chairman, Radiation Safety Committee
To: Commanding Officer
Via: (1) Quality Assurance
(2) Executive Officer

Subj: RADIATION SAFETY COMMITTEE MINUTES FOR THE FIRST QUARTER OF 1991

Ref: (a) Code of Federal Regulations, Title 10, Part 35
(b) NAVHOSPGLAKESINST 6470.4D
(c) Annual Inspection of the Radiation Safety Program
(d) NEHC ltr 6470 Ser 311cm/12317 of 28 Nov 90

NRMP No 12-00211-11 NP

Encl: (1) Agenda
(2) Attendance Matrix
(3) Master Tracking Report for March 1991
(4) NRC Form Supplement A for Dr. S. Kurumety
(5) Radiation Safety Survey Results for March 1991
(6) Inventory of Radioactive Materials for March 1991
(7) RSO memo of 20 Dec 90
(8) CNO (op-45) ltr 5104 Ser 455C/1U599677 of 5 Feb 91

1. In accordance with references (a) and (b), the meeting was held on 21 Mar 91 at 1330 with LT Mohaupt presiding. Enclosure (1) lists the items for discussion and enclosure (2) shows the attendance.

2. Old Business.

a. The Dec 90 minutes were reviewed.

(1) The XO suggested to dispose of the Sr-90 eye applicator since we no longer use it. LT Mohaupt has contacted other major Naval Hospitals and they expressed no interest in obtaining the source. Other possible ways to get rid of the source is to give the source to a local hospital with an appropriate license or pay a source broker to take it. LT Mohaupt will make the contacts to evaluate these options. This item is entered on enclosure (3) as issue 91-1.

(2) The XO asked if we should dispose of any radionuclides down the drain. The amount of Co-57 disposed into the sewer was far less than that allowed by Part 20.106 of reference (a). Nuclear Medicine has stopped disposing Co-57 in the sewer. Now they send used/expired materials back to the manufacturer for disposal.

b. MTR # 89-8: Status of Ventilation Studies

Discussion: The aerosol system for nuclear medicine ventilation studies is operational.

SUPPLEMENT A

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
Suryani Nurumety	Michigan

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
American Board of Radiology	Diagnostic Radiology	15 June 1979

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION			
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

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

ISOTOPE	MCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE

Caro Community Hospital
New Application
1996

PERSONNEL TRAINING PROGRAM

Item 8.1

Personnel

All radiation workers and ancillary personnel whose duties will require them to work in the vicinity of radioactive materials will receive instruction. Ancillary personnel may include housekeeping, security, nursing, maintenance, and ECG technologists.

Training Frequency

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

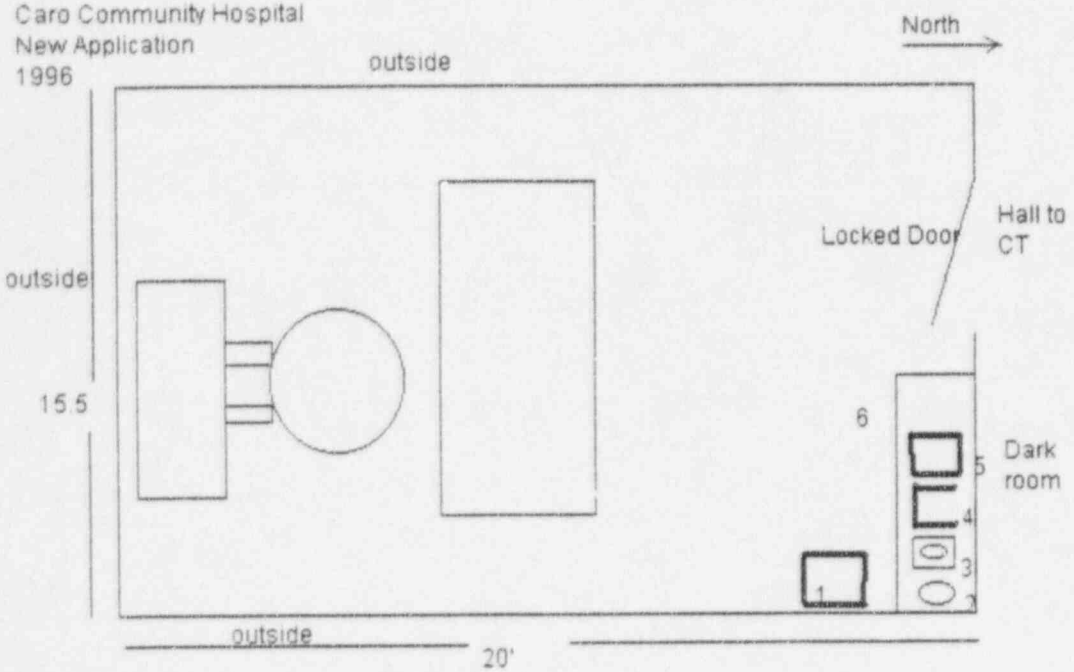
Instruction Topics

1. Applicable regulations and license conditions.
2. Areas where radioactive material is used or stored.
3. Potential hazards associated with radioactive material in each area where the employees will work.
4. Appropriate radiation safety procedures.
5. The licensee's in-house work rules.
6. Each individual's obligation to report unsafe conditions to the Radiation Safety Officer.
7. Appropriate response to emergencies or unsafe conditions.
8. The worker's right to be informed of occupational radiation exposure and bioassay results.
9. Locations where the license has been posted or made available, notices, copies of pertinent regulations, and copies of the license and license conditions, as required by 10CFR19.

Documentation will be kept on hand for review of the list of topics covered, the date of the instruction, and the names of those participating.

The method of instruction will be verbal and/or written.

Caro Community Hospital
New Application
1996



1. Leadlined waste container
2. Sink
3. Dose calibrator
4. Leadglass face shield
5. Leadbricks for storage
6. Package receipt area

This building is a permanent construction. It is not a residence.

Caro Community Hospital
New Application
1996

EQUIPMENT LIST

Item 9.1 *(cont.)*

Imaging Equipment
Scintillation Camera(s)

Dose Calibrator

Other
Lead Glass Face Shield
Leaded Syringe Shields
Remote Handling Tools
Lead Bricks
RadiacWash
Gloves
Lead Storage Containers
Xenon Trap System

Survey Meters

GM Survey Meter(s)
High Range (0-1000 mR/hr minimum)
Low Range (0-0.2 mR/hr)

Well Counter

Caro Community Hospital
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1996

CALIBRATION OF SURVEY INSTRUMENTS

Item 9.2

All survey Instruments will be calibrated and checked in accordance with 10 CFR 35.51. Survey instruments will be calibrated by :

1. The manufacturer,

2. Medical Physics Consultants: (NRC License # 21-20153-01), or

3. Any authorized user licensed to perform survey meter calibrations as a service.

CALIBRATION OF DOSE CALIBRATOR

Item 9.3

Test	Frequency	Tolerance
Constancy	Daily prior to patient dose assays	+/- 10%
Linearity	Installation, following repair, and quarterly	+/- 10%
Accuracy	Installation, following repair, and annually	+/- 10%
Geometry Dependence	Installation and following repair	+/- 10%

CONSTANCY testing will be performed using a long-lived reference source (e.g., Cesium-137) with activity greater than 50 microcuries. Zero or record the background reading on the appropriate setting. Assay the source for both the reference source setting and the most commonly used radiopharmaceutical settings. Record the readings and compare to the calculated values. The Radiation Safety Officer will be notified and the unit will be repaired or replaced if the constancy error exceeds 10 percent.

LINEARITY testing will be performed using a Technetium 99m source having activity at least as great as the maximum activity administered to patients. Testing will be conducted with the decay or the leaded-sleeve method over the entire range of administered activity and at least as low as 30 uCi.

Decay method: Assay the source at approximately 0, 6, 24, 30, 48, etc hours over the entire range of use(between the highest activity administered to patients and 30 uCi). Record the net activities, time, and date. Using a measured activity for reference which is closest to that which is commonly administered to patients,calculate the expected readings and compare to the measured readings. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the linearity error exceeds 10 percent over the range of activity.

Sleeve method: The sleeves will be calibrated for this type dose calibrator using the decay-method linearity test. Either the "Calicheck" or "Lineator" product will be used and the testing procedure will be performed according to the manufacturer's instructions. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the linearity error exceeds 10 percent over the range of use.

ACCURACY testing will be performed using Cesium-137 and Cobalt-57 or Barium-133 reference sources having NBS-traceable activities greater than 50 microcuries. The net measured activities will be compared to the calculated activities based on radioactive decay. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced if the accuracy error exceeds 10 percent.

GEOMETRY DEPENDENCE testing will be performed using a solution of technetium-99m having an activity concentration of 1-10 mCi/ml. The dose calibrator will be tested for syringe geometry dependence. Vial geometry dependence will also be tested in vials of radiopharmaceuticals are assayed.

Syringe geometry dependence: assay 0.5 cc of the solution in a 3 cc plastic syringe. The solution in the syringe will then be diluted with water and assayed at incremental volumes of 1.0, 1.5, and 2.0 cc. Record all readings. Select a standard volume closest to that normally used for patient doses and divide the activity by the other measured activities. If any error exceeds 10 percent, correction factors will be applied to the appropriate volumes and a correction factor chart will be applied to the dose calibrator. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the geometry error exceeds 10 percent.

Vial geometry dependence: assay 1.0 cc of the solution in a vial of the type most commonly used. The solution in the vial will then be diluted with water and assayed at incremental volumes of 1-3 ml up to the maximum volume assayed in the vial. The assays should take place within 10 minutes. Record all readings. Select a standard volume closest to that normally used for mixing kits and divide the activity by the other measured activities. If any error exceeds 10 percent, correction factors will be applied to the appropriate volumes and a correction factor chart will be applied to the dose calibrator. The Radiation Safety Officer must review and sign the test document. The Radiation Safety Officer will be notified and the unit will be repaired or replaced or patient dosage readings will be mathematically corrected if the geometry error exceeds 10 percent.

Caro Community Hospital
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1996

PERSONNEL MONITORING PROGRAM

Item 9.4

1. The RSO or delegate will promptly review all film or TLD exposure reports to look for workers or groups of workers whose reported exposures are unexpectedly high or low.

2. All individuals who are occupationally exposed to ionizing photon radiation on a regular basis will be issued a film or TLD whole body monitor.

3. All individuals who handle radioactive material on a regular basis will be issued a film or TLD finger monitor.

4. The exposure results of ancillary personnel who are badged may be reviewed at six month intervals. If the results show that they do not receive greater than 10% of the quarterly permissible limits, their badges may be discontinued. If their duties change and increased exposure to radiation is possible, they will be issued badges at that time.

5. Other individuals who are exposed to radiation on an occasional basis such as security personnel who deliver packages, secretarial personnel, and nurses who occasionally care for patients who have received diagnostic dosages will not normally be issued exposure monitors.

6. Film and TLD badges for nuclear medicine technologists will be changed on a monthly basis. Badges supplied for personnel who do not normally receive 10% of the maximum permissible yearly dose may be changed on a quarterly basis. In all cases the manufacturer/supplier's recommendations will be followed with regard to length of use and frequency of processing.

7. All film and TLD badges will be processed by a NVLAP contract service.

RADIATION SAFETY COMMITTEE CHARTER
AND
RADIATION SAFETY OFFICER DELEGATION OF AUTHORITY

Item 10.1

RESPONSIBILITIES

The Radiation Safety Committee (RSC) shall:

1. Ensure that ionizing radiation will be used safely, to include the review as necessary of training programs, equipment, facility design, supplies and procedures.

2. Ensure that ionizing radiation is used in compliance with all state and federal regulations and all licenses and registrations granted for usage.

3. Ensure that the usage of ionizing radiation is consistent with the As Low As Reasonably Achievable (ALARA) philosophy and program.

4. Establish investigation levels for individual occupational radiation exposures, consistent with the ALARA philosophy and program.

5. Entrust to the Radiation Safety Officer (RSO), the day to day responsibility of management of the radiation safety program, reportable to the committee as noted below.

MEMBERSHIP REQUIREMENTS

The RSC membership must consist of:

1. The Radiation Safety Officer

2. An authorized user of each type of use of ionizing radiation.

3. A representative of Nursing Service.

4. A representative of management, who does not serve in one of the capacities noted above.

5. Other members as deemed appropriate.

DUTIES

The RSC shall:

1. Be familiar with all pertinent regulations, all license applications, all licenses their conditions and amendments.

2. Review the training and experience of the proposed authorized users, the RSO and the teletherapy physicist to determine that their qualifications are sufficient to enable the individuals to perform their duties safely and are in accordance with the regulations and all licenses issued to the facility.

3. Review on the basis of safety and approve or deny, consistent with the limitations of the regulations, the license, and the ALARA philosophy, all requests for authorization to use radioactive material within the facility.

4. Review recommendations on ways to maintain individual and collective doses ALARA.

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

6. Review on the basis of safety, and approve with the advice and consent of the RSO and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted within the regulations.

7. Review quarterly with the assistance of the RSO a summary of the occupational radiation dose records, consistent with the ALARA program.

8. Review quarterly with the assistance of the RSO, all incidents or unusual occurrences, such as misadministrations of ionizing radiation, spills, etc. which involved ionizing radiation.

9. Identify radiation safety problems, as well as initiate, recommend, provide and verify corrective actions.

10. Establish a program to ensure that all persons whose duties may require them to work in or frequent areas where radioactive materials are used are appropriately instructed as required in 10CFR19.12.

11. Review at least annually the radiation safety program to insure compliance with all regulations, conditions of licensure and the ALARA program to include records, reports from the RSO, inspection results and adequacy of the management control system.

12. Maintain written minutes of all RSC meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions and results of all ballots.

13. Ensure that the byproduct material license is amended if required prior to any changes in facilities, equipment, policies, procedures, and personnel.

MEETING POLICIES

1. The RSC shall meet as often as necessary to conduct its' business, but not less than quarterly.

2. To conduct business, at least one-half of the membership must be present including the RSO and management's representative.

RADIATION SAFETY OFFICER

The Radiation Safety Officer (RSO) shall:

1. Investigate overexposures, accidents spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, Misadministrations, and other deviations from the radiation safety practices approved by facility management and/or the Radiation Safety Committee, if applicable.

2. Establish, implement, and collect in a centralized location policies and procedures as follows:

    a. Authorization for the purchase of radioactive material.
    b. Receipt and opening of packages containing radioactive material.
    c. Storage of radioactive material.
    d. Inventory control of radioactive material.
    e. Safe use of radioactive material.
    f. Emergency procedures in the event of loss, theft, etc.
    g. Periodic radiation surveys
    h. Checks of radiation survey and other radiation safety instruments.
    i. Disposal of radioactive material.
    j. Personnel training of those who work in or frequent areas of radiation

3. Maintain a record systems to include at least the following:

   a. All records, reports, written policies and procedures required by regulatory agencies concerning radioactive material.

   b. A copy of the regulations governing the possession, use and disposal of licensed material, such as Title 10 Code of Federal Regulations.

4. Review and sign the following radiation safety program records, if applicable:

   a. Sealed Source Inventories
   b. Sealed Source Leak Tests
   c. Dose Calibrator Linearity Tests
   d. Dose Calibrator Accuracy Tests
   e. Dose Calibrator Geometrical Variation Tests
   f. Misadministration documentation
   g. Changes in the radiation safety program
   h. Radiation surveys of sealed source storage.

5. Inform facility management at least annually of the status of the licensed material program.

6. Establish in concert with the Radiation Safety Committee (RSC), if applicable, personnel exposure investigational levels as a part of the ALARA program and philosophy.

7. Approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety with the advice and consent of management and the RSC, if applicable.

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MAINTAINING OCCUPATIONAL RADIATION EXPOSURE ALARA

Item 10.2

1. Management Commitment

   a. We, the management of this medical facility, 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 facility. 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 exposures 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

(1) The RSC will delegate authority to the RSO for the 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 actions 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 investigation levels in Table I 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 investigation levels are exceeded.

Table I: Investigation Levels

Body Part Exposed (mrems per calendar quarter)	Level I	Level II
1. Whole body; head and trunk; active blood forming organs; or gonads	125	375
2. Hands and forearms; feet and ankles	1250	3750
3. Skin of the whole body	1250	3750
4. Eye (lens)	375	1125

(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 RSC, 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. Review 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 the 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.

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 Investigation levels in Order to Monitor Individual Occupational External Radiation Doses

This facility hereby establishes investigation levels for occupational external radiation doses which, when exceeded will initiate review or investigation by the RSC and/or RSO. The investigation 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. The following actions will be taken at the investigation levels as stated in Table 1:

a. Personnel dose less than Investigation 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 Investigation Level I.

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

The RSO will review the dose of each individual whose quarterly dose equals or exceeds Investigation 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 Investigation 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 Investigation Level II.,

The RSO will investigate in a timely manner the causes of all personnel doses equaling or exceeding Investigation Level II and, if warranted, will take action. A report of the investigation, any actions taken, and a copy of the individual's NRC Form-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. Re-establishment of investigation Levels to levels above those listed in Table 1.

In cases where a worker or group of workers' doses need to exceed an investigation level, a new, higher investigation level maybe established for that individual or group on the basis that it is consistent with good ALARA practices. Justification for new investigation levels will be documented. The RSC will review the justification for and must approve or disapprove all revisions of investigation levels

7. Signature of Certifying Official

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

William P Miller

Signature

William P. Miller

Name (Print or Type)

President & CEO

Title

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PROCEDURE FOR LEAK-TESTING SEALED SOURCES

Item 10.3

Leak tests will be analyzed by Medical Physics Consultants, Inc. (NRC License No. 21-20153-01), or anyone licensed by the NRC to perform leak testing as a service.

Item 10.4

RULES FOR THE 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. Either after each procedure or before leaving the area, monitor your hands and clothing for contamination in a low background area.

4. Use syringe shields for routine preparation of patient dosages and administration to patients, except in those circumstances in which their use is contraindicated. In these exceptional cases, consider the use of other protective methods such as remote delivery of the dose.

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

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

7. Wear personnel monitoring devices (as prescribed by the RSO) at all times while in areas where radioactive materials are used or stored. Store personnel monitoring devices at the facility in a designated low-background area.

8. Wear a finger exposure monitor during the elution of generators; during the preparation, assay, and injection of radiopharmaceuticals, and when holding patients during procedures.

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

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

11. With a radiation detection survey meter, survey the generator storage, kit preparation, and injection areas daily for contamination. If necessary, decontaminate or secure the area for decay as appropriate.

12. Confine radioactive solutions in shielded containers that are clearly labeled with the isotope, compound name, and the date and time of receipt or preparation. Syringes and/or syringe shields shall be labeled with the radiopharmaceutical name or abbreviation contained within, type of study, or patient's name.

13. Assay each patient dose in the dose calibrator before administration. Do not use a dose if it differs from the prescribed dose by more than ten percent, except prescriptions of less than 10 uCi. Check the patient's name and I.D. number and the prescribed radionuclide, chemical form, and dosage before administering.

14. Always keep radioactive materials in shielded locations or containers.

15. When practical, use a cart or wheelchair to move flood sources, syringes, waste, and other radioactive material.

16. Do not pipette by mouth.

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EMERGENCY PROCEDURES

Minor Spills

1. NOTIFY: Notify persons nearby that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use isposable gloves and remote handling tools. Carefully fold the absorbent paper with the clean side out and insert in a plastic bag for transfer to a radioactive waste container. Also place the contaminated gloves and any other contaminated disposable material in the bag.

4. SURVEY: Survey the area with a low-range, GM survey meter. Check the area around the spill, hands, clothing, and shoes for contamination.

5. REPORT: Report the incident to the RSO who will supervise the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to ensure that the Report and Survey are completed properly.

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 paper, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: This should be done only if it can be done without further contamination or a significant increase in radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. NOTIFY: Notify the RSO immediately.

6. PERSONNEL DECONTAMINATION: Decontaminate personnel by removing contaminated clothing and flushing the contaminated skin with lukewarm water and then washing with mild soap. If contamination remains, induce perspiration by covering the area with plastic. Then wash the affected area again to remove any contamination released by the perspiration.

7. REPORT: The RSO will supervise the cleanup of the spill and complete the Radioactive Spill Report and the Radioactive Spill Contamination Survey. The RSO may delegate the actual clean-up and survey performance to a trained technologist. However, the RSO will retain the ultimate responsibility to see that the report and the survey are completed properly.

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PACKAGE ORDER AND RECEIPT PROCEDURES

Item 10.6

1. The Radiation Safety Officer (RSO) or a designee must authorize each order for radioactive materials and 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. The RSO will establish and maintain a system for ordering and receiving radioactive material. The system must contain the following information:

   a. For routinely used materials

   (1) Written records that identify the authorized user or department, isotope, chemical form, activity, supplier will be made.

   (2) The above records will be checked to confirm that material received was ordered through proper channels.

   b. For occasionally used materials

   (1) The authorized user who will perform the procedure will make a written request that indicates the isotope, radiopharmaceutical, activity, and supplier.

   (2) The person who receives the material will check the physician's written request to confirm that the material received is what was ordered.

   For deliveries during normal working hours, the RSO will tell carriers to deliver radioactive packages directly to a specified area.

   If off duty deliveries are necessary, the delivery personnel will be provided a key to the Nuclear Medicine Department . They will then proceed to the Nuclear Medicine Department and place the package inside at the location designated by a "Deliveries Here" sign. They will then re-lock the door.

SAMPLE MEMORANDUM

To: Delivery Personnel

From: Radiation Safety Officer

Subject: Delivery of Packages Containing Radioactive Materials

Please deliver all radioactive material packages directly to the Nuclear Medicine Department. Place the package at the location indicated as "Deliveries Here." Please re-lock the door when you leave the area. If you have any questions, please call the individuals below for assistance.

If the package appears to be damaged, immediately contact one of the individuals identified below. Do not leave until it can be determined that neither you nor your delivery vehicle is contaminated.

If you have any questions concerning this memorandum, please call me.

Dr. Kurumety, RSO _____ Phone _____

Technologist _____ Phone _____

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PROCEDURE FOR OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

Item 10.7

In accordance with 10CFR20 effective 1-1-94, packages will be opened as soon as practicable after receipt but no later than 3 hours post receipt or if received during non-working hours within 3 hours of the opening of the receiving department.

1. Put on gloves to prevent hand contamination.

2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop and notify the RSO.

3. Measure the exposure rate from the package at 1 meter and at the package surface. If the rate is higher than expected, stop and notify the RSO. The surface dose rate should not exceed 200 millirem per hour. Packages with the "White I" labels should be less than 0.5 millirem per hour at the package surface.

4. Wipe the external surface of the package. Assay the wipe with a instrument sufficiently sensitive to detect 2000 dpm. If removable contamination exceeds 2200 dpm/100 cm^2, notify the RSO. Packages containing only special form or gas radioactive material will not be tested for removable contamination.

5. Follow the steps listed below when opening the package.

   a) Remove the packing slip.
   b) Open the outer package following the supplier's instructions, if available.
   c) Open the inner package and verify that the contents agree with the packing slip.
   d) Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material. If there is any reason to suspect contamination, wipe test the final source container. If removable contamination exceeds 2200 dpm/100 cm^2, notify the RSC.
   e) If anything unusual is noticed, stop and notify the RSO.

6. Verify that the material received is the material ordered.

7. Monitor the packing material and the empty packages for contamination with a GM survey meter before discarding. If contaminated, treat as radioactive waste. If not contaminated, deface all radiation labels before discarding.

8. Record the receipt and all readings taken.

9. For packages received under a general license in 31.11, follow the steps listed below for each package.

   a) Visually inspect the package for damage. If damage is noted, stop and notify the RSO.
   b) Verify that material received is the material ordered.

BYPRODUCT MATERIAL USE

Item 10.8 **Unit Dose Records shall contain:**

1. Technical Data
   a. Radionuclide
   b. Generic name, its abbreviation, or trade name
   c. Date of receipt
   d. Supplier
   e. Lot or control number
   f. Activity in millicuries or microcuries as recorded on unit dosage or packing slip and its associated time

2. Administrative Data
   a. Prescribed dosage unless listed in procedure manual
   b. Time and date of administration
   c. Measured activity
   d. Patient name and ID number
   e. If discarded, method and date of disposal
   f. Initials of person recording the information

Item 10.9 **Multidose Vial Records shall contain:**

1. Technical Data
   a. Radionuclide
   b. Generic name, its abbreviation, or trade name
   c. Date of receipt or preparation
   d. Date, time, volume, and activity of initial assay
   e. Supplier or kit manufacturer

2. Administrative Data
   a. Prescribed dosage unless listed in procedure manual
   b. Date and time dosage was drawn and measured
   c. Calculated volume needed for prescribed dose
   d. Measured activity
   e. Patient name and ID number
   f. Method of disposal and date
   g. Initials of person recording information

Item 10.10 **Molybdenum Concentration Records shall contain:**

a. Date the generator was received
b. Date and time of elution
c. Measured Mo-99 activity in microcuries
d. Product of the measured Mo-99 activity and the correction factor noted by the molybdenum breakthrough pig manufacturer
e. Measured Tc-99m activity in millicuries
f. Ratio of the total Mo-99 microcuries per millicurie of Tc-99m which must be less than 0.15 at the time of administration. At the time of elution, the ratio should be less than 0.07 uCi of Mo-99 per mCi of Tc-99m. If it is not, stop and notify the RSO.
g. Initials of the person who made the record.
h. Method and date of disposal.

AREA SURVEY PROCEDURES

Item 10.12

Surveys for contamination and ambient exposure rates will be performed in accordance with 10 CFR 35.70.

1. All areas where radiopharmaceuticals are eluted, prepared, and administered will be surveyed at the end of each day of use for ambient radiation exposure rates and weekly for removable contamination. If diagnostic administrations are occasionally made in patients' rooms and special care is taken to remove all paraphernalia, those rooms will not be surveyed.
2. All areas where radioactive materials are stored will be surveyed weekly for ambient radiation exposure rates and for removable contamination.

3. Laboratory areas where each process involves less than 200 uCi of byproduct materials will be surveyed monthly for ambient radiation exposure rates and removable contamination.

4. Surveys for ambient exposure rates will be performed with a radiation detection survey instrument able to detect as low as 0.1 mR/h. The results will be recorded in millirem per hour.

5. Surveys for removable contamination will consist of a series of wipes which will be assayed using a procedure sufficiently sensitive to detect 2000 dpm. The results will be recorded as net dpm per 100 square centimeters.

6. The trigger level for exposure rate surveys will be established based upon typical readings for specific areas and will be in accordance with 10CFR20.

7. The trigger level for removable contamination surveys will be the detection of values equal to or less than the recommended levels in Table N-1 of the Regulatory Guide 10.8. For example, the action level for Tc-99m contamination will be 2000 dpm or lower.

8. Survey results greater than the trigger levels will result in decontamination or shielding procedures necessary to reduce the exposure or contamination levels to the trigger levels or lower on repeat surveys.

9. A record shall be kept of all survey results. The record will include:

   a. Location, date, and type of equipment used.
   b. Initials of the person conducting the survey.
   c. Drawing of the area surveyed.
   d. Trigger levels keyed to the location on the drawing.
   e. Results keyed to the location on the drawing.
   f. Corrective actions taken in case of contamination or excessive exposure rates and reduced contamination levels after corrective action.

10. The RSO or their designee will review the survey results on a quarterly basis for conformance to established trigger levels. The designee will be the consulting radiological/medical physicist. The physicist will report significant deviations to the RSO in writing.

11. The method for determining the efficiency factor of each counting instrument used to detect contamination for wipe testing is as follows:

    A= Calculated source activity of sample isotope in dpm

    B= Measured source counts of sample isotope in cpm

    C= Measured background counts in cpm

    D= B-C (Net Counts in cpm)

    $$\text{Efficiency Factor} = \frac{\text{Calculated activity in dpm (A)}}{\text{Net counts in cpm (D)}}$$

    Wipe sample in dpm = Net counts of wipe sample x Efficiency factor

12. The RSO will be notified of all positive wipe test and ambient survey results.

Item 10.13

PROCEDURES FOR AIR CONCENTRATION CONTROL OF XENON-133

Spent gas will be collected in a shielded trap. We will follow the procedures listed below for monitoring the trap effluent.

1. The trap effluent will be collected from the exhaust of the trapping system upon initial use of each trap and once each month in which the system is used.

2. The trap effluent from one patient study will be collected in a plastic bag.

3. The activity in the bag will be monitored by holding the bag against a camera which has been adjusted to detect Xe-133 and comparing its counts per minute (cpm) to background cpm.

4. A record will be kept of the date, background cpm, and bag cpm.

5. An action level will be established based on a multiple of background or the activity released during a single study. Significant increases in the bag cpm above normal, indicate that the trap is breaking down and will be replaced.

6. If a xenalert system is available, the manufacturer's instructions will be followed for monitoring the trap effluent.

7. Manufacturer's directions will be followed for replacing the trap.

8. All rooms in which radioactive Xenon-133 gas studies are performed will be maintained at negative pressure.

Item 10.13.2

WORKER DOSE FROM AEROSOLS

1. "We will collect spent aerosol in a single use shielded trap and therefore no effluent monitoring is needed".

PUBLIC DOSE FROM AIRBORNE EFFLUENT

Item 10.13.3

1. "We will not directly vent spent aerosols and gases to the atmosphere and, therefore, no effluent estimation is necessary."

EMERGENCY PROCEDURES FOR ACCIDENTAL RELEASE OF XENON-133

1. Notify persons in the room that a spill (release) has occured.

2. All persons should vacate the room at once.

3. Notify the RSO (or his designee, if RSO is not present) immediately.

4. Prevent entry into the room until the calculated evacuation time has occurred. The evacuation time is calculated as follows:

Evacuation time (t) = (-V/Q) ln(CV/A) where:

A = the highest activity of gas in a single container, (uCi).
Q = the total room air exhaust determined by measuring in (ml/min) the airflow to each exhaust vent in the room.
C = the maximum permissible air concentration in restricted and unrestricted areas. For Xe-133, DAC = $1x10^{-4}$ uCi/ml (restricted)
V = the volume of the room (ml).

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RADIATION SAFETY PROCEDURES FOR IODINE THERAPIES

Item 10.14

We will adopt Appendix P "Model Procedure for Radiation Safety During Iodine Therapy over 30 milliCuries" that was published in Regulatory Guide 10.8, Revision 2 with the exception that due to personnel scheduling, the bioassays of individuals preparing or administering the therapy I-131 dosage will preferably be performed at 24 hours but may be performed any time between 6 and 72 hours post exposure.

Item 11.1

WASTE DISPOSAL

Liquids and Gases

Liquids may be disposed of by release to the sanitary sewer or evaporative release to the atmosphere.

1. Disposal to the sanitary sewer system will be made in accordance with 10 CFR 20(effective 1-1-94). A record will be kept of the following: date, radionuclide, estimated activity released, and place where material was released.

2. Permissible concentrations in effluents will be kept within the limits numerated in 10 CFR 20 (effective 1-1-94). A record will be kept of the date, radionuclide, estimated activity released, estimated concentration, and vent site at which the material was released.

Decay in Storage

1. Only material with a physical half-life of less than 65 days may be decayed in storage at the facility.

2. Each container will be tagged to include:
   a. the date sealed or set into storage
   b. the longest-lived isotope in the container
   c. the initials of the person setting the waste for decay.

3. Material will be decayed for at least 10 half-lives.

4. Prior to disposal as in-house waste, each container will be monitored as follows:

   a. Low-range GM survey meter will be checked for proper operation.
   b. Waste will be monitored in a low level area.
   c. Any shielding around the container will be removed.
   d. All surfaces of each individual container will be monitored.
   e. Only those containers which cannot be distinguished from background radiation levels will be disposed of after all radioactive labels have been defaced.
   f. The date on which the container was placed in storage will be recorded.
   g. The date of disposal will be recorded.
   h. The type of material will be recorded.

5. Mo-99/Tc-99m generators will be held for at least 60 days before being dismantled. When dismantling generators, a low range GM survey meter will be kept at the work area. The oldest generator will be dismantled first, working forward chronologically. Each individual column will be held in contact with a low-level survey instrument in a low background (less than 0.05 mR/hr) area. The generator date and disposal date will be logged in the disposal records. Radiation labels will be removed or defaced on the generator shield. Generators may also be returned to the manufacturer for disposal. Manufacturer's instructions will be followed.

Unit Dose Waste

If a unit dose pharmacy is used, the materials supplied by them (e.g., syringes, needles, etc.) may be returned to the unit dose pharmacy in the original shipping container. Pertinent DOT regulations will be followed as specified by the unit dose pharmacy.

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QUALITY MANAGEMENT PROGRAM

Item 12.1

1. Objective

". . .to provide high confidence that byproduct material will be administered as directed by the authorized user."

2. Responsibility, Authority, and Audit

The responsibility and authority to establish and implement the Quality Management (QM) Program shall be given to the Chief Nuclear Medicine Technologist.

3. Instruction

All individuals responsible for prescribing, preparing, or administering dosages which require written directives as outlined in this program will be instructed in the requirements of the Quality Management Program on an annual basis.

4. Elements for Medical Use - Radiopharmaceutical Therapies and NaI I-125 or I-131 >30 uCi

A. Prior to administration, a written directive will be prepared for:

i. any therapeutic administration of a radiopharmaceutical and
ii. any administration of NaI I-125 or I-131 greater than 30 uCi.

With regard to diagnostic and therapeutic radiopharmaceuticals "A written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, containing the following information:

patient name
patient identification number, if available
radiopharmaceutical
dosage
route of administration

Revisions to written directives may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage.

Oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user within 48 hours of the oral revision.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

B. Prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive by the person administering the radiopharmaceutical.

1. The patient shall be called by name.
2. The patient shall be asked to spell their name.
3. The patient shall be asked to state their birth date.
4. The patient shall be asked to state their Social Security Number.
5. The patient shall be asked for some identification such as driver's license.
6. The in-patient's wrist band shall be checked.

If the information obtained from both of any two of these methods do not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive verification that this procedure is intended for this patient is obtained.

C. Each administration is in accordance with the written directive.

The technologist shall read the written directive before preparing or administering the radiopharmaceutical. If any portion of the written directive is unclear to the technologist, they shall contact an authorized user for clarification. The radiopharmaceutical shall not be administered until the intent of the written directive is thoroughly understood by the technologist. If the technologist preparing the dose is different from the technologist administering the dose, both technologists shall read and understand the written directive.

The technologist shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration) are in accordance with the written directive. The actual dose calibrator assay shall be verified with the dosage listed on the written directive.

After administration of a radiopharmaceutical, the individual administering the dosage shall make a written record that documents the adminstered dosage in auditable form, date the written record, and sign or initial the written record.

D. Retention of written directives

Each written directive and a record of each administered radiopharmaceutical dosage shall be retained for three years after the date of administration.

E. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

Upon identification of an unintended deviation, an investigation of the incident shall be made. The cause of the incident shall be determined and, if appropriate, corrective procedures will be implemented. Documenting and reporting of the unintended deviation shall be in accordance with the reporting rules of Part 35.

F. Recordable Events

All recordable events shall be evaluated within thirty(30) days after discovery. A recorable event shall be responded to by: (1) assembling the relevant facts including the cause; (2) identifying what, if any, corrective action is required to prevent recurrence; and (3) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

5. Annual Review

The annual review shall be conducted by a member of management and the consulting medical physicist. The review shall be conducted at intervals not to exceed 12 months. The review shall determine the effectiveness of the QM program. Areas identified as inadequate shall be modified to meet the objectives of 35.32(a).

Records of each review, including the evaluations and findings in an auditable form for three years.

Audit:

Frequency: An audit of the quality management program shall be conducted at twelve (12) month intervals.

Responsibility: The audit shall be conducted by the consulting medical physicist. Management shall be briefed in writing of the findings.

Sampling: If patient administrations exceed 100, 20% of these will be used for the audit.
If patient administrations exceed 20 but are less than 100, 20 of these will be used for the audit.
If patient administrations are less than 20, all of these will be used for the audit.

All misadministrations and recordable events previously identified will be included in the annual review.

If misadministrations are identified during the course of the annual review, the sample size will be increased to include all procedures of the type involved in the misadministration.

If recordable events are identified during the course of the annual review, the sample size will be increased to include all procedures of the type involved in the misadministration.

Scope: The audit shall evaluate the following items.

1. The compliance rate of having written directives prior to administration of a radiopharmaceutical or radiation in those cases where written directives are required.

2. The content of the written directive is as required.

3. The instruction of the supervised individual(s) in the licensee's written quality management program and requirement of following the authorized user's instructions.

4. The methods of verifying the patient's identity by more than one method is performed as stated in the QM program.

5. The compliance rate of verifying the patient's identity by more than one method.

6. Radiopharmaceutical or radiation administrations are in accordance with the written directives.

7. The compliance of the staff in identifying, evaluating, and taking appropriate corrective actions for unintended deviations from the written directive.

8. The compliance with the requirement to respond to each recordable event.

9. The compliance with the requirements to notify and report a misadministration.

10. The compliance with the requirements to keep the appropriate records, including:
    - the annual reviews
    - the written directives
    - the radiopharmaceutical dosages
    - the recordable events
    - the misadministrations

6. Revisions to the program

If the program is revised, the revisions will be submitted to the NRC within 30 days after the revision has been made.