VOID SHEET

TO: License Fee Management Branch

FROM: Reg III

SUBJECT: VOIDED APPLICATION

Control Number: 00013

Applicant: Univ of Minnesota

Date Voided: 8/26/91

Reason for Void: Combined w/ renewal CN 84669

P.J. Pedone 8/23/91
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

Final Review of VOID Completed:

- ☐ Refund Authorized and processed
- ☑ No Refund Due
- ☐ Fee Exempt or Fee Not Required

Comments:

Log completed ☑ SAC 9/30/93

Processed by:

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

PROGRAM CODE: 01100
STATUS CODE: 2
FEE CATEGORY: EX 3L 3E
EXP. DATE: 19880131
FEE COMMENTS: 170.11(A)(9)-STATE

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: MINNESOTA, UNIVERSITY OF
RECEIVED DATE: 900730
DOCKET NO: 3000842
CONTROL NO.: 300013
LICENSE NO.: 22-00187-46
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: ---0---
CHECK NO.: ---0---

3. COMMENTS

DECOMMISSIONING

SIGNED P Lutlaff
DATE 8-1-90

B. LICENSE FEE MANAGEMENT BRANCH (CHECK IF EXEMPTION CODE 03 IS ENTERED ✓)

FEE EXEMPT

1. FEE CATEGORY AND AMOUNT: _____

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

3. OTHER _____
_____

SIGNED _____
DATE 8/8/90

UNIVERSITY OF MINNESOTA

Office of the Vice President for Student Development
Boynton Health Service
Environmental Health & Safety
410 Church Street S.E.
Minneapolis, Minnesota 55455

(612) 626-6002

July 26, 1990

U. S. Nuclear Regulatory Commission
Region III Office, Bldg 4
799 Roosevelt Road
Glen Ellyn, Illinois 60137
Attn: Materials Licensing Section

RECEIVED
90 AUG 1 09:40

Gentlemen:

Enclosed is a "Statement of Intent" from the University of Minnesota, which will serve to satisfy the requirement for financial assurance for decommissioning under 10CFR Parts 30, 40, 70 and 72. The University of Minnesota Licenses covered by this financial assurance statement are as follows:

1. NRC Broadscope License # 22-00218-29 (covers radioactive materials storage and use of radioacitve materials in the University Hospital and Clinic, and in all Health Sciences use areas on the Minneapolis Campus)

2. NRC Broadscope License # 22-00187-46 (covers research and educational use of radioactive materials at the remainder of the University of Minnesota Campuses and Facilities)

3. University Radioactive Waste Management License # 22-00187-49 (for collection, packaging, storage and disposal of radioactice wastes generated under the two NRC Licenses listed above)

Please amend the NRC Licenses indicated above to incorporate the attached "Statement of Intent" from the University of Minnesota.

If you have questions concerning the "Statement of Intent" please contact me.

Sincerely,

Jerome W. Staiger

Jerome W. Staiger
Radiation Protection Officer

cc: Gus Donhowe
Robert Dickler
Cherie Perlmutter
Julie Sweitzer
Katherine Cram
Fay Thompson

ag 2D
FEE EXEMPT
10.11(a)(9) 8/8/90

RECEIVED
JUL 30 1990
REGION III

JUL 30 1990
CONTROL NO. 00013

STATEMENT OF INTENT

The Regents of the University of Minnesota offer this Statement of Intent under 10 C.F.R. Parts 30, 40, 70, and 72. The University of Minnesota is a state-chartered land-grant university.

The facilities covered by this "Statement of Intent" concerning financial assurance of decommissioning costs include the following:

1. Radioisotope storage and use facilities authorized under the University's two NRC Broadscope Services (#22-00187-46 and #22-00218-29). There are approximately 700 use areas including nuclear medical, therapeutic radiology and a large number of radiotracer research laboratories authorized as use areas under these two licenses. The University Radiation Protection Programs routinely survey all of these authorized use areas for contamination and radiation exposure levels to document compliance with license conditions. We routinely decommission several use areas a year as a result of staff turnover.

2. Radioactive waste storage and disposal facilities under University NRC License #22-00187-49. This license covers all radioactive waste processing, final packaging, decay storage, and temporary storage areas (about ten areas) for radioactive waste generated under the two NRC licenses listed above. Again, these areas are routinely surveyed by the Radiation Protection Program to assure compliance with license conditions, and each drum of waste is surveyed for exposure and contamination levels before transfer to the storage building.

Based on our experience with decommissioning use areas, we estimate an average staff time requirement of 1/2 day per use area (laboratory) for decommissioning. If all use areas were required to be decommissioned, this would correspond to 1.5 full time equivalents for one year or approximately $50,000.00 for staff time to accomplish decommissioning. Costs for shipment and disposal of radioactive wastes from these decommissioning activities would be less than what is currently required to ship and dispose of the radioactive waste now generated in a one-year period from all of these use areas. This cost is approximately $150,000.00 annually. Therefore, the total decommissioning costs projected for the licenses listed above would be less than $200,000.00.

The Regents will obtain funds for decommissioning any of these facilities when necessary.

The signatories below, the Senior Vice President for Finance and Operations, and the Director, University Hospital and Clinic, are authorized under the Regents' Policy on Delegation of Authority (attached) to represent the University in this Statement and transaction. There are two originally signed duplicates of this Statement, noted by the words "original" or "originally signed duplicate" in the lower right-hand corner.

Dated: 1/25/90

GORDON M. DONHOWE
Sr. Vice President for
Finance & Operations
University of Minnesota

Dated: 7/26/90

ROBERT M. DICKLER
Director
University Hospital & Clinic

ORIGINALLY SIGNED DUPLICATE

CONTROL NO. 0 0 0 1 3

[redacted]

DELEGATION OF AUTHORITY

RESOLVED, that the Regents of the University of Minnesota hereby delegate the following authority to the corporate officers and officers and employees of the University of Minnesota as hereinafter listed:

Corporate Officers

The President, or Chair or Vice Chair, and the Secretary, or the Treasurer of the Regents of the University of Minnesota are hereby authorized and empowered to execute all contracts, deeds, powers of attorney, releases, assignments, satisfaction of mortgages, and all other instruments relating to real property transactions and certificates of indebtedness, and all other transactions or duties customarily devolving upon said officers of the corporation.

President, Senior Vice President for Finance and Operations, Treasurer, Controller, or Assistant Controller

The President, the Senior Vice President for Finance and Operations, the Treasurer, the Controller, or the Assistant Controller are each hereby authorized and empowered, on behalf of the Regents of the University of Minnesota, to:

1. Execute all contracts, agreements, and all other instruments with the Government of the United States, or its agencies or subdivisions, and with nonfederal sponsors of research, training, and public service programs.

    a) This authority is also extended to the Assistant Vice President, the Director, Patents and Licensing, and the Assistant Directors, of the Office of the Office of Research and Technology Transfer Administration.

2. Submit proposals for research, development, service and training contracts, subcontracts, and grants and execute same.

    a) This authority is also extended to the Assistant Vice President, the Director of Patents and Licensing, and the Assistant Directors, of the Office of Research & Technology Transfer Administration, the Chancellor, Associate Chancellor, Business Director, Vice chancellor for Academic Administration and Associate Vice Chancellor for Academic Administration of the University of Minnesota, Duluth.

3. Accept gifts offered without unusual conditions or restrictions.

1) The authority to purchase equipment and supplies is also extended to the Director of Purchasing and Materials Management.

c) Trust, gifts, grants, bequests and donations and the correct assignments of such.

d) Intercollegiate athletic contests.

e) Lease and rental of equipment and facilities for University purposes.

f) Lease and rental of equipment and facilities for University purposes.

1) The authority to lease and rent equipment for University purposes is also extended to the Director of Purchasing and Materials Management.

g) Fringe benefit program for University employees. The authority to execute administrative documents required for the operation of the fringe benefit programs is extended to the Assistant Director for Employee Benefits, the Employee Benefits Operations Manager, and the Employee Benefits Program Manager.

h) Corporate liability and property insurance.

i) Patents, trademarks and other means of protection as provided for in the Regents' Patent and Technology Transfer Policy and applications therefore; licenses, assignments and transfer of patents and trademarks and other means of protection as provided for in the Regents' Patent and Technology Transfer Policy and payment of legal services relating thereto.

1) This authority is also extended to the Assistant Vice President and the Director, Patents and licensing, of the Office of Research & Technology Transfer Administration.

j) Student Teaching and School survey agreements.

k) Institutional memberships.

l) Health Sciences affiliation agreements.

m) The performance of experimental, developmental, or research work without formal advertising or solicitation of competitive

or Other Similar Organizations, adopted March 12, 1976; and the Delegation of Authority, adopted August 9, 1979.

APPROVED BY THE BOARD OF REGENTS - October 17, 1980
MODIFICATION OF TITLES APPROVED BY THE BOARD OF REGENTS - July 8, 1983
AMENDMENT - June 8, 1984
AMENDMENT - May 10, 1985
AMENDMENT - July 12, 1985
AMENDMENT - August 8, 1986
AMENDMENT - January 9, 1987
AMENDMENT - September 11, 1987
AMENDMENT - May 12, 1989

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1. Radioisotope storage and use facilities authorized under the University's two NRC Broadscope Services (#22-00187-46 and #22-00218-29). There are approximately 700 use areas including nuclear medical, therapeutic radiology and a large number of radiotracer research laboratories authorized as use areas under these two licenses. The University Radiation Protection Programs routinely survey all of these authorized use areas for contamination and radiation exposure levels to document compliance with license conditions. We routinely decommission several use areas a year as a result of staff turnover.

2. Radioactive waste storage and disposal facilities under University NRC License #22-00187-49. This license covers all radioactive waste processing, final packaging, decay storage, and temporary storage areas (about ten areas) for radioactive waste generated under the two NRC licenses listed above. Again, these areas are routinely surveyed by the Radiation Protection Program to assure compliance with license conditions, and each drum of waste is surveyed for exposure and contamination levels before transfer to the storage building.

Based on our experience with decommissioning use areas, we estimate an average staff time requirement of 1/2 day per use area (laboratory) for decommissioning. If all use areas were required to be decommissioned, this would correspond to 1.5 full time equivalents for one year or approximately $50,000.00 for staff time to accomplish decommissioning. Costs for shipment and disposal of radioactive wastes from these decommissioning activities would be less than what is currently required to ship and dispose of the radioactive waste now generated in a one-year period from all of these use areas. This cost is approximately $150,000.00 annually. Therefore, the total decommissioning costs projected for the licenses listed above would be less than $200,000.00.

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Dated: 1/25/90

GORDON M. DONHOWE
Sr. Vice President for
Finance & Operations
University of Minnesota

Dated: 1/26/90

ROBERT M. DICKLER
Director
University Hospital & Clinic

ORIGINAL

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2. Submit proposals for research, development, service and training contracts, subcontracts, and grants and execute same.

    a) This authority is also extended to the Assistant Vice President, the Director of Patents and Licensing, and the Assistant Directors, of the Office of Research & Technology Transfer Administration, the Chancellor, Associate Chancellor, Business Director, Vice chancellor for Academic Administration and Associate Vice Chancellor for Academic Administration of the University of Minnesota, Duluth.

3. Accept gifts offered without unusual conditions or restrictions.

CONTROL NO. 00013

[redacted]

1) The authority to purchase equipment and supplies is also extended to the Director of Purchasing and Materials Management.

c) Trust, gifts, grants, bequests and donations and the correct assignments of such.

d) Intercollegiate athletic contests.

e) Lease and rental of equipment and facilities for University purposes.

f) Lease and rental of equipment and facilities for University purposes.

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h) Corporate liability and property insurance.

i) Patents, trademarks and other means of protection as provided for in the Regents' Patent and Technology Transfer Policy and applications therefore; licenses, assignments and transfer of patents and trademarks and other means of protection as provided for in the Regents' Patent and Technology Transfer Policy and payment of legal services relating thereto.

1) This authority is also extended to the Assistant Vice President and the Director, Patents and licensing, of the Office of Research & Technology Transfer Administration.

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k) Institutional memberships.

l) Health Sciences affiliation agreements.

m) The performance of experimental, developmental, or research work without formal advertising or solicitation of competitive

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AMENDMENT - January 9, 1987
AMENDMENT - September 11, 1987
AMENDMENT - May 12, 1989

CONTROL NO. 00013

NOV 16 1990

University of Minnesota
Boynton Health Service
ATTN: Jerome W. Staiger
Radiation Protection Officer
410 Church Street S.E.
Minneapolis, MN 55455

Gentlemen:

This letter is to acknowledge our November 9, 1990 telephone conversation in which we confirmed an extension to November 30, 1990 for your response to Control No. 84669 and discussed the financial assurance requirements pursuant to 10 CFR Part 30, Section 30.35. During our conversation, we discussed the options available to your institution in order to comply with the regulation. Briefly, these options are as follows:

1. Amend your license(s) to decrease possession limits for radionuclides having half lives greater than 120 days to limits low enough not to require financial assurance.

2. Amend your license(s) to decrease possession limits for radionuclides having half-lives greater than 120 days to limits low enough to justify the financial assurance funds the institution will have available for decommissioning.

3. Maintain the possession limits currently listed on your license(s) and submit a decommissioning funding plan in accordance with Appendix F of the "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72", a copy of which you have received.

In addition, it will be in your best interest to refer to Appendix G of the above referenced guide when preparing your response to Control Nos. 00013, 00014, and 00015. Note that the limits for some unsealed radionuclides are quite low, in particular, americium-241, calcium-45, chlorine-36, and hydrogen-3.

If you have any further questions regarding this issue, please contact me at (708) 790-5625.

Sincerely,

Patricia J. Pelke
Materials Licensing Section

RIII
PJP
Pelke/ms
11/16/90

E

SEP 19 1990

University of Minnesota
Boynton Health Service
ATTN: Jerome W. Staiger
Radiation Protection Officer
410 Church Street S.E.
Minneapolis, MN 55455

Gentlemen:

We have reviewed the financial assurance documentation submitted by you for the University of Minnesota facilities covered under License Nos. 22-00218-29, 22-00187-46, and 22-00187-49 according to the Standard Review Plan for the Review of Financial Assurance Mechanisms for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72. We have determined that the financial assurance mechanism you submitted is not sufficient to ensure that adequate funds will be available to decommission the facilities covered under the above licenses.

The financial assurance amounts that licensees are required to obtain is based upon the possession limits authorized by each license. Based upon our review, the amount of $200,000 dollars will not be sufficient to decommission the facilities so that the sites will ultimately be available for unrestricted use for any public or private purpose. We have enclosed a copy of "Standard Format and Content of Financial Assurance Mechanisms required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72" which you should review, in particular, Appendix G, and submit additional financial assurance commitments.

If you wish to provide a decommissioning funding plan instead of providing certification of financial assurance for decommissioning for the above referenced NRC licensed facilities, refer to Section 1.2 "Cost Estimating for Decommissioning Funding Plan" and Appendix F of the enclosed guide.

If you have any questions or require clarification on any of the information stated above, you may contact us at (708) 790-5625.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Numbers 00013, 00014, and 00015

Sincerely,

Original Signed By
Patricia J. Pelke
Material Licensing Section

Enclosure: Standard Format and
Content of Financial Assurance
Mechanisms Required for
Decommissioning Under 10 CFR
Parts 30, 40, 70 and 72

RIII
PJP
Pelke/ms
09/19/90

UNIVERSITY OF MINNESOTA
TWIN CITIES

Department of Environmental Health and Safety
Boynton Health Service, Room W-140
410 Church Street S.E.
Minneapolis, Minnesota 55455
(612) 626-6002

September 21, 1988

Materials Licensing Section
Region III, USNRC
799 Roosevelt Road
Glen Ellyn, IL 60137

Gentlemen:

Attached is a copy of our May 27, 1988 letter concerning renewal of University of Minnesota NRC License #22-00218-29 (Control # 85509). As requested under the alternative renewal procedure outlined in your notice, we have provided the following changes and information relative to license conditions and current program requirements.

1. Change Item 9.Q. to read, "To be used in a J.L. Shepherd...."

2. Incorporate in Item 10.A. of the license condition the further clarification of a comma after "Research East," and the substitution of "1633 Eustis Cardiovascular Research Center" in place of "Cardiovascular Research Center."

3. Change Item 12.A. to read, "Licensed materials shall be used by, or under the supervision of Individuals designated by the University of Minnesota Health Sciences Radiation Subcommittee and the designated chairperson of this subcommittee.

4. There are two Item 24 listings under license #22-00218-29 (Amendment 40 and Amendment 41). Please maintain Item 24 listed on Amendment 40 (for J.L. Shepherd Mark I Irradiators) as Item 24 under the license, and change Item 24 on Amendment 41 (dose calibrator linearity tests) to Item 26 under the license.

5. Listed below is the table of radiation detection instruments used by the Radiation Protection Program.

Type of Instrument	Number	Radiation Detected	Sensitivity (mR/hr or cpm)	Window (mg/cm^2)	Use
a. Ionization Survey Instruments	4	beta/gamma	1-2,500 mR/hr (1) 1-2,000 mR/hr (1) .05-100,000 mR/hr (1) 1-20,000 mR/hr (1)	all have beta window	Radiation Exposure Level Measurement
b. GM Survey Instruments	8	beta/gamma	0-200,000 cpm or .05-200 mR/hr	1.4 mg/cm^2	Contamination and Exposure Rate Measurement
c. Gamma Scintillators					
- high energy	2	gamma	0-200,000 cpm	> 50 keV	Contamination and relative intensity of gamma emission
- low energy	2	gamma	0-200,000 cpm	10-100 keV	
d. Alpha Scintillator	1	alpha	0-200,000 cpm	1 mg/cm^2	Contamination surveys

e. High purity germanium photon spectrometer and multichannel analyzer used for identification and quantification of photon emitting radionuclides in a variety of samples.

f. Liquid scintillation counter used for analysis of contamination smears and urine samples for beta emitting radionuclides.

g. Alpha spectrometer and scaler for analysis of samples and smears for alpha emitting radionuclides.

h. Two auto-gamma counting systems for analysis of air samples and smears for photon emitting radionuclides.

i. Shielded GM detector and scaler for analysis of contamination smears for intermediate and high energy beta emitters.

j. MDH 1015 Radiation Monitor and ion chambers, calibrated to NBC traceable standard, used for calibration of instrument calibration sources

In addition to the Radiation Protection Program instruments, the Division of Nuclear Medicine has several GM survey instruments and an ionization survey instrument which satisfy the Part 35 requirement . The Department of Therapeutic Radiology has two GM survey instruments, two ionization survey instruments, and several area radiation monitors which meet the requirements Part 35. All of the portable radiation survey instruments are currently calibrated by the Radiation Protection Program on a schedule of once every six months. However, we request that the renewed license be changed to specify a calibration frequency of once per year and following repair as specified in Part 35.

6. Attached are two copies of the Nuclear Medicine Radiation Protection Procedures Manual which incorporates the training and protection requirements, ALARA program, and the responsibilities of the University Radiation Protection Program. As part of the ALARA program, syringe shields will be used in the withdrawal and preparation of individual patient doses unless it is shown that the use of the syringe shield will increase hand dose during such procedures. Also, we request a variance from Part 35, Subpart F, Section 35.315 (a) (8) to remove the requirement for monitoring of individuals associated with the preparation and administration of I-131 therapy doses. This variance is requested because the University of Minnesota Nuclear Medicine Division receives and administers radioiodine therapy doses in capsular form only. Over the past several months we have monitored Nuclear Medicine staff and nursing staff associated with I-131 therapy patients who receive I-131 in capsular form, and have detected no I-131 thyroid uptake above the background detection level of the thyroid counting system (see attached report).

7. Attached are two copies of the Brachytherapy Procedure Book for the Department of Therapeutic Radiology, which has been updated to incorporate the requirements of Part 35, Subpart G.

If you have any questions concerning the information provided with this request for renewal of NRC License #22-00218-29, please call me.

Sincerely,

Jerome W. Staiger

Jerome W. Staiger
Radiation Protection Officer

JS/dr
enclosures

UNIVERSITY OF MINNESOTA
TWIN CITIES

Department of Environmental Health and Safety
Boynton Health Service, Room W-140
410 Church Street S.E.
Minneapolis, Minnesota 55455
(612) 626-6002

May 27, 1988

Mike McCann
Materials Licensing Section
799 Roosevelt Road
Region III USNRC
Glen Ellyn, IL 60137

Dear Mr. McCann:

This is to confirm my telephone call on May 27, 1988 to notify you of our request for renewal of NRC license #22-00218-29, which will expire on June 30, 1988. The updated information on the current program, listing changes in license conditions and support documents for the renewal application, will be sent in about one week. We are currently meeting with the Division of Nuclear Medicine and the Department of Therapeutic Radiology staffs to assure that Part 35 regulatory changes are addressed in the updated information we will submit.

Thank you for your consideration and assistance in this request for renewal of University of Minnesota NRC license #22-00218-29.

Sincerely,

Jerome W. Staiger

Jerome W. Staiger
Radiation Protection Officer

JWS:mw

PERSONNEL THYROID COUNT RESULTS
CARE OF I-131 THERAPY PATIENTS

I-131 DOSE	DATE/SHIFT	DR./RN ID#	COUNTS ABOVE BACKGROUND*
150 mCi	2-17-88/day	RN1	Not above background (NAB)
	2-17-88/eve	RN2	NAB
	2-18-88/pm	RN3	NAB
	2-18-88/day	RN4	NAB
100 mCi	2-18-88/day	RN5	NAB
	2-18-88/eve	RN2	NAB
	2-19-88/pm	RN6	NAB
	2-19-88/day	RN4	NAB
104 mCi	3-9-88/day	DR1	NAB
	3-9-88/day	RN7	NAB
	3-9-88/pm	RN8	NAB
	3-10-88/eve	RN9	NAB
153 mCi	5-23-88/day	DR2	NAB
	5 23-88/day	RN10	NAB
	5-23-88/eve	RN*	NAB
	5-24-88/pm	RN11	NAB
	5-24-88/day	RN12	NAB
131 mCi	7-11-88/day	DR1	NAB
	7-11-88/day	RN1	NAB
	7-11-88/eve	RN11	NAB
	7-12-88/pm	RN13	NAB
103 mCi	8-23-88/day	RN14	NAB
	8-23-88/day	DR2	NAB
	8-23-88/day	DR3	NAB
	8-23-88/eve	RN15	NAB
	8-24-88/day	RN16	NAB
88 mCi	8-25-88/day	DR2	NAB
	8-25-88/day	DR4	NAB
	8-25-88/day	RN12	NAB
	8-25-88/eve	RN13	NAB
	8-26-88/pm	RN13	NAB
67 mCi	8-26-88/day	RN17	NAB
	8-26-88/eve	RN15	NAB

* Detection Level = 0.006 μCi

Univ. of Minnesota, Radiation Protection Program

NUCLEAR MEDICINE DEPARTMENT

RADIATION PROTECTION PROCEDURE MANUAL:

ALARA GUIDE

AND COMPLIANCE WITH PART 35 OF THE FEDERAL REGULATIONS

Revised
6/01/88

CONTENTS

RADIATION PROTECTION PROGRAM RESPONSIBILITIES

- Review Monthly Dosimetry Reports
- Survey Instrument Calibration
- Inventory and Leak-Testing of Sealed Sources
- Contamination Surveys
- Monitoring of I-131 Therapy Patients
- Ventilation Measurements
- Records and Reports of Misadministrations
- Annual Meetings

INTRODUCTION

This manual has been designed to act as a training guide, training record, and procedure manual for the Division of Nuclear Medicine at the University of Minnesota. The procedures outlined in this manual are designed to assure that dose equivalents are ALARA, (As Low As Reasonably Achievable). All workers are required to know and follow the ALARA procedures. References are made throughout this manual to Part 35 of the Code of Federal Regulations, Volume 51, Number 200. The procedures outlined are designed for compliance with the Federal Regulations.

All personnel are required to read this manual in its entirety before they will be allowed to work in the Nuclear Medicine Department. The Nuclear Medicine Department must document that new personnel are trained in each area of nuclear medicine work, (see "Training Record"). The Radiation Protection Representative will sign and date the training record when satisfied that the employee is qualified to perform the work safely, according to radiation protection procedures and Nuclear Medicine Department procedures.

A copy of this manual will be available in the Nuclear Medicine Radiopharmaceutical Preparation Lab (2-452) at all times for quick reference. If you have any questions regarding radiation protection principles please contact the Radiation Protection Program at 626-6002.

TRAINING RECORDS

Name: _____

Date of employment: _____

ITEM:	Date completed:	*Tech initials:	Supervisor initials:
Radiation Protection Tapes			
Orientation			
Read Radiation Protection Manual			
Radiopharmaceutical Preparation			
Generator Elution			
Quality Control Procedures			
Radioactive Material Shipments			
Radiation Surveys			
Waste Procedures			

* (By initialing each area as completed, the technologist is verifying his/her understanding of the principles and procedures involved.)

Signature: _____ Date: _____
(Radiation Protection Program Representative)

Comments:

Training Records

Nuclear Medicine Technologist Certification Date: _____

Continuing Education

Date	Description

SUMMARY OF
CFR 10, PART 35
RECORD KEEPING REQUIREMENTS

The following records must be retained to be in compliance with CFR 10, Part 35

Length of time records must be retained:

3 Years	5 Years	10 Years	Indefinitely
GM meter	Leak test -sealed source	Misadministrations	Geometric variation
Dose calibrator			
-linearity			
-daily constancy			
-annual calibration			
Daily & weekly survey records			
I-131 therapy (over 30mCi)			

Signature requirements of the RPP representative:

- Training records
- Weekly survey records
- Dose calibrator
  - -linearity
  - -annual calibration
  - -geometric variation
- Sealed source leak test and inventory
- I-131 therapy (over 30mCi)
- Survey instrument calibration
- Review of monthly dosimetry reports
- Ventilation checks
- Sealed source leak test

Signature or initials of Nuclear Medicine Technologists:

- Training records
- Dose calibrator constancy checks
- Daily GM survey records
- Radiopharmaceutical doses injected
- Radioactive material shipment inspections
- Molybdenum breakthrough check

RADIATION PROTECTION

Radiation protection precautions and procedures are necessary to minimize personnel radiation exposure to ionizing radiation during the storage, preparation, and use of radioactive materials. Radiation exposure control can be divided into two areas of concern: 1) External radiation exposure control and 2) Contamination control. The methods used to protect ourselves from the potentially harmful effects of radiation are different in each of these two areas of concern and will be dealt with separately.

I. RADIATION EXPOSURE

External radiation exposure results from exposure to the ionizing radiation emitted by radioactive materials. One need not contact the radioactive material itself to be exposed to ionizing radiations emitted by a radioactive material.

Three factors affect the amount of radiation exposure one receives from external sources: 1) Time, 2) Distance , and 3) Shielding. These methods can be used separately, but a combination of all three is most effective.

A. Time - Exposure can be minimized by reducing time spent near radioactive materials. The time of exposure to ionizing radiation can be reduced by the following:

1. Practice a procedure to work out problems and increase proficiency before radioactive material is actually used ("dry-runs" of the procedure).
2. Plan ahead.
3. Do not spend unnecessary time in close proximity to the sources of ionizing radiation.

B. Distance - Radiation exposure decreases very rapidly with the distance from a point source (inverse square relationship). For this reason, even small increases in distance at close proximity to a radiation source can have a large effect on reducing exposure.

1. In a room containing radioactive materials, arrange storage and use areas to maximize distance from areas normally occupied by personnel.
2. Use remote handling equipment whenever handling high activity radiation sources (ask Radiation Protection Officer which activities require this).
3. Set up radioactive work areas away from non-radioactive work areas, so that persons not working with radioactive materials are not exposed.

C. Shielding - In conjunction with time and distance, the use of appropriate radiation shields can greatly reduce radiation exposure. The amount and type of shielding required depends upon the type of radioactive material to be shielded. Consult with the Radiation Protection Program for assistance in obtaining or designing appropriate radiation shields.

II. CONTAMINATION CONTROL

Contamination control deals with uncontained radioactive material which can be spread from one surface to another. When uncontained radioactive material contaminates surfaces, the potential personnel exposure arises from actually transferring the radioactive material to hands, clothing, food, room air, etc. Once radioactive material adheres to skin or clothing, neither time, distance nor shielding are available to protect you from the ionizing radiation being emitted by the radioactive material. Uncontained radioactive materials may result in internal uptake in an individuals body via ingestion through the mouth, absorption through the skin, or by inhalation of airborne radioactive materials.

A. To Minimize Hazards From Loose Surface Contamination

1. Wear gloves when handling potentially contaminated objects.
2. Cover the work area with plastic backed absorbent paper, (examples: tray in dose prep area, floor under injection site of Tl-201 heart study patients).
3. If there is any chance of spilling radioactive material, work in a radioisotope tray lined with plastic backed absorbent paper. (This will confine a spill and help prevent the spread of contamination).
4. Any work with radioisotopes which might produce airborne gases, vapors or particles should be confined to a hood that has been checked for adequate air flow.
5. When you have touched a potentially contaminated object, do not touch anything you do not want contaminated until gloves have been removed and hands surveyed for possible contamination.
6. Do not hold contaminated materials over unprotected areas.
7. Clearly mark those objects which are contaminated with radiation caution tape.
8. Do not leave potentially contaminated areas unattended and unmarked. (They present a hazard to people who do not know the area might be contaminated).
9. Monitor all equipment used with or near radioisotopes after each use and before moving them to uncontaminated areas, (example: lead pigs used to carry individual patient doses).
10. Monitor the work area and surroundings with a GM survey meter after each use to check for contamination and prevent contamination buildup.
11. Use and store radioisotopes only in authorized radioisotope laboratories.
12. No eating, drinking, smoking or storage of food in a radioisotope laboratory.
13. Constantly think about how to prevent cross contamination.
14. Monitor hands and shoes after each use of radioactive materials and before leaving the radiation use area to assure they are not contaminated.

The University limit for loose surface contamination is anything above background. When loose surface contamination on an object or an area is above background, it must be decontaminated and resurveyed.

B. Procedures In the Event of a Contamination Incident

1. Restrict personnel access to contaminated area.
2. Notify your supervisor and the Radiation Protection Program (626-6002).
3. While wearing disposable gloves, shoe covers, and a laboratory coat, carefully wipe down the contaminated area with a slightly dampened disposable cloth or towel. (Water with a little liquid soap is usually sufficient - do not use a soaking wet towel as this may lead to more contamination from excess radioactive liquid running and getting into cracks).
4. After each wipe, fold the towel inward, and dispose of the towel in a radioactive waste receptacle. Do not reuse towels, as this may transfer contamination to noncontaminated areas.
5. Always work inward from the least contaminated to most contaminated areas (this helps prevent spreading the contamination).
6. After the area has been wiped several times, monitor the area.
7. Repeat the decontamination procedure until the loose surface contamination is background.
8. After disposing of gloves and shoe covers, monitor hands, clothing and shoes for contamination prior to leaving the area.

INSPECTION OF RADIOACTIVE MATERIALS SHIPMENTS
(INCOMING AND OUTGOING)

A. When receiving a shipment of radioactive materials, wear disposable gloves and TLD ring dosimeter.

B. Before opening any radioactive shipment, survey the package with a GM survey meter both at 1 meter, and at the surface. Also, take a smear survey of the exterior of the package to check for removable contamination. If contamination of 500 cpm or greater is found contact the RPP. Record these readings, (see example form).

C. Shipments that are volatile or gaseous, (such as Xe-133 or I-131) should be opened in the radioisotope hood.

D. The shipping container must be disposed of properly. If a smear survey indicates contamination, dispose of the shipping box in the radioactive waste container, and call the Radiation Protection Program (626-6002). If a smear survey indicates no contamination, the box may discarded as non-radioactive waste after removal of all radiation labels and markings (dispose of labels in the radioactive waste container).

E. All outgoing radioactive material packages must be monitored for contamination by smear surveys and external radiation levels by GM survey before leaving the Radiopharmaceutical Prep Lab.

If the radiactive material package is for shipment to a radioactive material user outside of the University of Minnesota follow this procedure:

a) Obtain a copy of the current NRC license for the individual and institution to be receiving the package. Provide a copy of this license to the RPP for NRC records. If the RPP already has a copy of the current license, an additional copy from the receiving institution is not necessary.

b) A DOT approved package and label must be used for shipment of the radioactive material.

c) Appropriate shipping papers and package content forms must be completed.

d) Prior to final sealing of the package, deliver it to the RPP for inspection, survey and completion of restricted articles transport forms.

e) Deliver sealed, labelled package with transport forms to Health Sciences Shipping Dock for shipment via a common carrier.

F. A copy of all monthly Nuclear Medicine radioactive shipments will be delivered to Radiation Protection by the fifth day of the next month.

TRANSFER OF RADIOISOTOPES WITHIN THE UNIVERSITY

If the radioactive materials package is for another radioactive materials user at the University of Minnesota, it must be delivered to the Radiation Protection Program (W-180 Boynton Health Service). The Radiation Protection Program will document proper compliance with NRC regulations by the user of the radioactive material and will deliver the package to the user.

Exception: Stations may receive Co-57 Schillings Capsules if they are doing a Schillings uptake test.

RADIATION PROTECTION PROCEDURES FOR NUCLEAR MEDICINE PERSONNEL DURING RADIOPHARMACEUTICAL PREPARATION

All Nuclear Medicine personnel must abide by the following procedures. New personnel will not be allowed to work in the Radiopharmaceutical Preparation Lab until the Radiation Protection Program Representative is satisfied that they have received adequate radiation protection training.

1. No one will work at a speed which may cause them to compromise established radiological protection practices.

2. Film badges and TLD rings must be worn at all times. The TLD ring must be worn on the finger which will be closest to the source of radiation (on the hand which holds syringes) and positioned on the finger such that the TLD chip will be as close to the source of radiation as possible, (toward the palm).

3. Never assume anything in the Prep Lab (Rm 2-452) to be uncontaminated (this includes syringe shields, vials in the refrigerator, etc.).

4. At least one pair of gloves will be worn at all times in the Prep Lab.

5. After working in a dose preparation station, survey hands with the portable GM instrument to ensure they are not contaminated before handling materials outside of the station.

6. Keep fingers as far away as possible from eluate vials and doses in syringes. Never allow fingers to come in contact with the unshielded dose vials or unshielded syringes.

7. Always use a syringe shield when preparing a radiopharmaceutical and whenever feasible during administration to the patient. (This is part of the University's licensing agreement with the NRC.)

8. Minimize handling of radioiodine capsule containers. Do not pick up ^{131}I or ^{123}I capsules with your fingers. Use designated tongs.

9. All transfers and handling of ^{131}I capsules must be done in the hood in the Prep Lab.

10. All shipping containers and lead pigs must be returned to the Prep Lab after use and surveyed before they are used again.

11. If skin contamination occurs, decontaminate immediately and notify the Chief Nuclear Medicine Technologist. If decontamination is not successful, the Radiation Protection Program must be notified.

12. There will be NO eating, drinking, smoking or storage of food or beverages in radioisotope laboratories or imaging rooms.

PROCEDURE FOR WHOLE BODY GM SURVEY IN THE EVENT OF POTENTIAL OR SUSPECTED CONTAMINATION

In addition to the requirement for survey of hands after each dose preparation, a whole body survey should be done prior to leaving the Prep. Lab if personnel contamination due to spillage of radioactive material is suspected. The limit for personnel contamination is 100 cpm above background using a GM survey instrument with the probe within 1/2 inch of the individual, but not touching the body. Perform this survey in a low background area of the lab.

A. Before picking up the GM survey probe, monitor your hands to prevent contamination of the probe.

   1. Cover probe with a plastic cover (e.g. disposable glove) to prevent its contamination.

   2. If hands are found to be contaminated, have someone with uncontaminated hands do the survey. Decontaminate hands by washing in the sink in 2-452. Do not touch anything enroute to the sink. If both hands are contaminated have someone else operate the faucets. Wash with soap and water until your hands are less than 100 cpm above background.

B. Survey entire body. Pay particular attention to face, arms, front of lab coat and shoes.

   NOTE: If clothing is found to be contaminated, carefully remove clothing and place in a plastic bag. Do not touch contaminated areas of clothing and do not shake clothing while removing. Resurvey area of body that was covered by contaminated clothing. The contaminated clothing bag may be labelled and held in the radioisotope storage area to allow for decay of the contamination to background.

C. Anytime personnel contamination is found, decontaminate immediately and notify the Chief Nuclear Medicine Technologist. If decontamination is not successful, the Radiation Protection Program must be notified (626-6002).

NUCLEAR PHARMACY
UNIVERSITY OF MINNESOTA

NUCLEAR PHARMACY PRESCRIPTION DELIVERY RECORD

HOSPITAL _____ PHYSICIAN _____ DATE _____

NUCLEAR PHARMACY RECORD					HOSPITAL RECORD			
Procedure	Agent	Assay	Assay Time	Rx No.	Patient	Dose	Time	Tech
BRAIN Tc 99m								

P-347

LOG OF RECEIPT OF RADIOACTIVE MATERIALS

Control No.	Radiopharmaceutical	Volume, Assay, Assay Date	Manufacturer/ Lot No.	Date Recei	Tech Initials

NUCLEAR PHARMACY SHIPMENT SURVEYS

Date: ____________________

Destination	Radioisotope	Rx Number	Package Survey Results
			SURFACE: mR/hr
			1 METER: mR/hr
			WIPE: cpm/100 sq. cm
			TECH INITIALS:
			SURFACE: mR/hr
			1 METER: mR/hr
			WIPE: cpm/100 sq. cm
			TECH INITIALS:
			SURFACE: mR/hr
			1 METER: mR/hr
			WIPE: cpm/100 sq. cm
			TECH INITIALS:
			SURFACE: mR/hr
			1 METER: mR/hr
			WIPE: cpm/100 sq. cm
			TECH INITIALS:
			SURFACE: mR/hr
			1 METER: mR/hr
			WIPE: cpm/100 sq. cm
			TECH INITIALS:
			SURFACE: mR/hr
			1 METER: mR/hr
			WIPE: cpm/100 sq. cm
			TECH INITIALS:
			SURFACE: mR/hr
			1 METER: mR/hr
			WIPE: cpm/100 sq. cm
			TECH INITIALS:
			SURFACE: mR/hr
			1 METER: mR/hr
			WIPE: cpm/100 sq. cm
			TECH INITIALS:
			SURFACE: mR/hr
			1 METER: mR/hr
			WIPE: cpm/100 sq. cm
			TECH INITIALS:

NON-TECHNETIUM DISPENSING RECORD

Place Any Labels Here

Product ______________

Control No. ______________

No. Of Vials ______________

Investigational ______________

Lot No. ______________

Date Received ______________

Vial Letter	Date	Isotope	Dispensed Activity	Rx #	Number or Volume	Initials

SURVEYS FOR AMBIENT RADIATION EXPOSURE AND CONTAMINATION

(Part 35.220 and 35.70)

According to the Title 10, Part 35 regulations of the Code of Federal Regulations, the Nuclear Medicine Department must have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 mrem/hr to 100 mrem/hr (i.e., G.M.), and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 mrem/hr to 1000 mrem/hr (i.e., cutie pie).

Daily Survey Areas:

1. At the end of each day, it is the responsibility of the Nuclear Medicine staff to conduct a survey with a GM radiation detection survey instrument in areas where radiopharmaceuticals are prepared and administered.

   - Dose rates should be able to be detected as low as 0.1 mR/hr.

2. Radiation dose rate trigger levels shall be established.

   a. Within radiopharmaceutical storage, preparation, and waste storage areas: $\geq$ 2 mR/hr at 1 foot.

   b. Administration and scanning areas : $\geq$ 0.5 mR/hr.

   c. Unrestricted areas: $\geq$ 0.25 mR/hr (walls outside of prep. lab, hallways, etc.).

   d. If dose exceeds trigger level, the Radiation Protection Division shall be notified.

   e. Records will be kept for 2 years.

   *See the following example.

Weekly Survey Areas:

The Radiation Protection Program will survey once per week all areas where radiopharmaceuticals are routinely prepared for use, administered & stored.

APPROVED USER: Dr. Boud[redacted]au

DEPT: [redacted]Nuclear Medicine

SURVEYED BY

SURVEY TYPE:

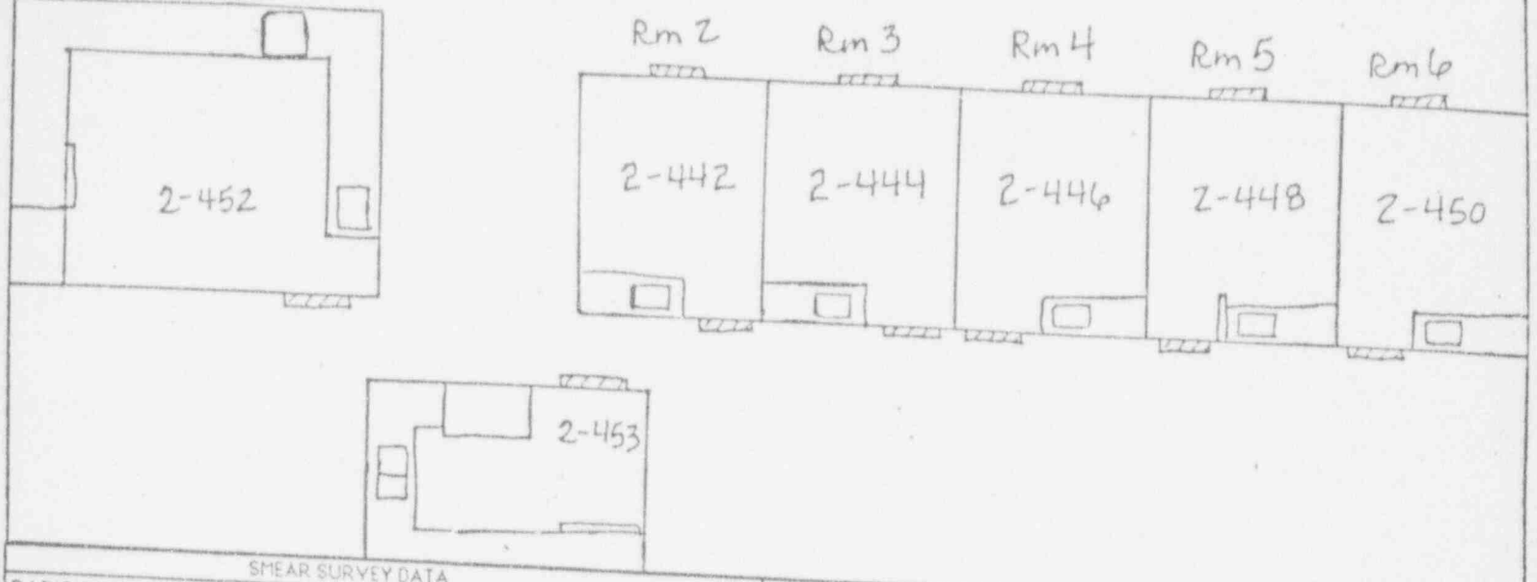
DATE

BUILDING: Health Science - Unit J

ROOM NUMBER: see below

MAP OF ROOM(S) - CLEARLY INDICATE ALL ROOM NUMBERS

Hot Lab



SMEAR SURVEY DATA

RADIOISOTOPE(S) ANALYZED:

% EFFICIENCY FOR RADIOISOTOPE(S):

INSTRUMENT USED:

BACKGROUND (CPM):

MDA (minimum detectable counts):

NO.	LOCATION	CPM/100cm²

PORTABLE G-M SURVEY DATA

INSTRUMENT USED:

BACKGROUND (CPM) or (mr/hr):

NO.	LOCATION	CPM/100cm² or (mr/hr)

NO EATING, DRINKING, SMOKING, MOUTH PIPETTING OK?	Y	N	na
WASTE STORAGE OK?	Y	N	na
NEW H2O SOLUBLE SCINT. FLUID ?	Y	N	na
INVENTORY RECORDS OK?	Y	N	na
QUARTERLIES OK?	Y	N	na
NEW MANUAL IN LAB?	Y	N	na

COMMENTS

APPROVED USER: Dr. Boudreau

SURVEYED BY:

DEPT: Nuclear Medicine

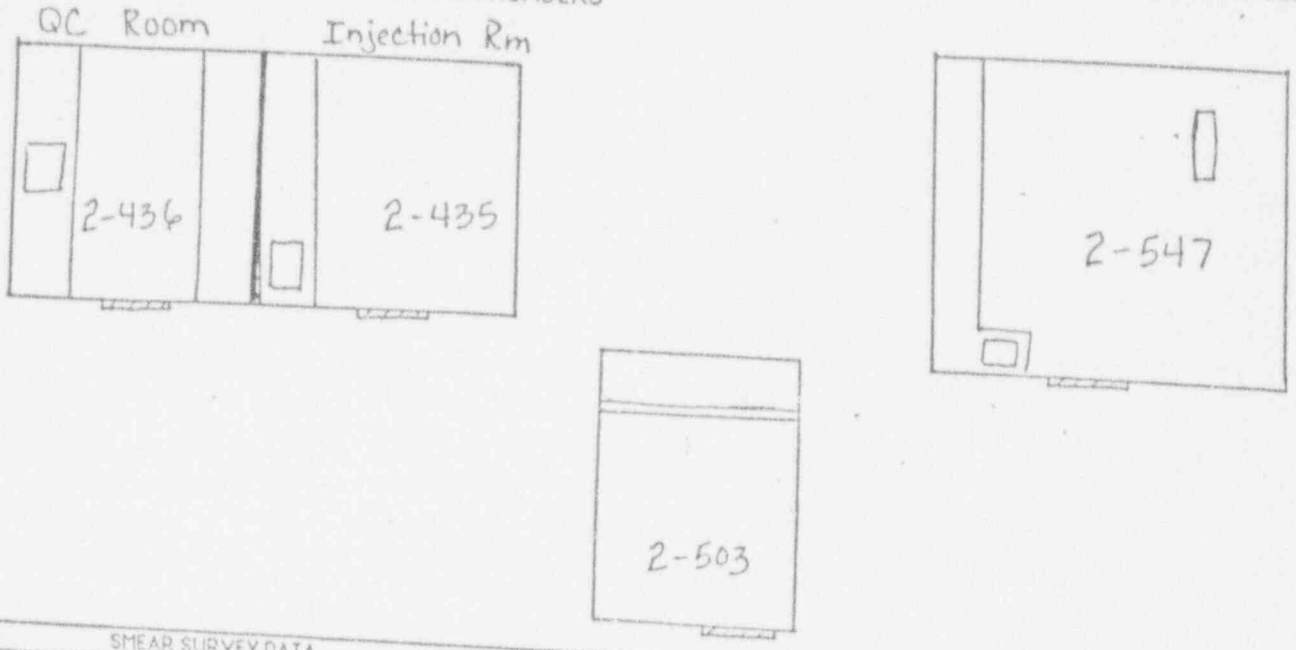
BUILDING: Health Science - Unit J

SURVEY TYPE:

DATE

ROOM NUMBER: See below

MAP OF ROOM(S) - CLEARLY INDICATE ALL ROOM NUMBERS



SMEAR SURVEY DATA

RADIOISOTOPE(S) ANALYZED:

% EFFICIENCY FOR RADIOISOTOPE(S):

INSTRUMENT USED:

BACKGROUND (CPM):

MDA (minimum detectable counts):

NO.	LOCATION	CPM/100cm²

PORTABLE G-M SURVEY DATA

INSTRUMENT USED:

BACKGROUND (CPM) or (mr/hr):

NO.	LOCATION	CPM/100cm² or (mr/hr)

NO EATING, DRINKING, SMOKING, MOUTH PIPETTING OK?	Y	N	na
WASTE STORAGE OK?	Y	N	na
NEW H2O SOLUBLE SCINT. FLUID ?	Y	N	na
INVENTORY RECORDS OK?	Y	N	na
QUARTERLIES OK?	Y	N	
NEW MANUAL IN LAB?	Y	N	

COMMENTS

PROCEDURE FOR ELUTION OF A GENERATOR

1) The elution of a generator is done behind lead bricks. Wear TLD ring dosimeter and gloves.

2) Place an elution vial in a lead shield and swab the septum of the vial with an alcohol swab.

3) Place the shielded eluate vial into the collection area of the generator and proceed with elution of Tc-99m according to manufacturer's directions.

4) To minimize exposure, leave the generator room during the elution time.

5) When the elution is finished, immediately reshield the generator and place the lead cover on the collection vial.

6) Assay the eluate vial and perform a Molybdenum breakthrough test. The amount of Mo-99 breakthrough must be less than 0.15 uCi/mCi of Tc-99m (see next page).

   NOTE: Always handle vials containing radioactive materials with tongs to reduce exposure.

7) Label the elution vial lead shield with assay results, volume, date, time and generator number. (See label #1.)

PERMISSIBLE MOLYBDENUM-99 CONCENTRATION

(Part 35.204)

A. Each time the generator is eluted, the quantities of Technetium-99m and the Molybdenum-99 contamination must be determined. The Molybdenum present in the eluent is know as the amount of Molybdenuin breakthrough. The maximum allowable level is 0.15 μCi of ^{99}Mo for each mCi of ^{99m}Tc, with no more than 5μCi of ^{99}Mo allowed per patient dose.

B. Procedure for determining ^{99}Mo breakthrough:

1.) Zero the dose calibrator on the ^{99}Mo assay setting prior to obtaining readings.

2.) Place the eluent vial in the Molybdenum shield and then into the dose calibrator; measure the activity of ^{99}Mo in μCi.

NOTE: Always handle vials containing radioactive materials with tongs to reduce exposure.

3.) Place the vial in the well, change the settings to ^{99m}Tc and measure the activity of ^{99m}Tc in mCi.

4.) Record the ratio of these measures expressed as μCi of ^{99}Mo per mCi of ^{99m}Tc.

C. Molybdenum breakthrough records must be kept for three years, and must include the measurements listed above (B.2, B.3 and B.4), the time and date of measurement, and the initials of the technologist performing the measurements. (See example form.)

D. Technetium eluents containing ^{99}Mo above the limits stated above must not be used.

RADIOPHARMACEUTICAL MANUFACTURE AND DISPENSING OF TECHNETIUM - 99m

Date: _____

Elutions of ^{99}Mo - ^{99m}Tc Generators

Generator #	Volume	Total Activity	Activity (mCi/ml)	^{99}Mo(uCi)	*uCi ^{99}Mo/mCi ^{99}Tc	Time	Activity Dispensed	Volume Dispensed	Disp T

*(Maximum limt 0.15 uCi ^{99}Mo/mCi ^{99m}Tc)

RADIOPHARMACEUTICAL PREPARATIONS

Target Organ	Product	Product Lot #	Manufacturer	Generator #	Activity	^{99m}Tc Volume	Saline Volume	Total Volume	Activity Dispensed	Time

RADIOPHARMACEUTICAL MANUFACTURE AND DISPENSING OF TECHNETIUM - 99m

ators

Activity	Activity (mCi/ml)	^{99}Mo(uCi)	*uCi ^{99}Mo/mCi ^{99}Tc	Time	Activity Dispensed	Volume Dispensed	Dispensed To	Prescription #	Tech. Initials

*(Maximum limt 0.15 uCi ^{99}Mo/mCi ^{99m}Tc)

RADIOPHARMACEUTICAL PREPARATIONS

ct Lot #	Manufacturer	Generator #	Activity	^{99m}Tc Volume	Saline Volume	Total Volume	Activity Dispensed	Time	Prescription #	Tech. Initials

DOSE WITHDRAWAL PROCEDURES AND PRECAUTIONS

A. General Precautions

A syringe shield should be used whenever possible to reduce exposure. Use a syringe shield: 1) when mixing radiopharmaceutical kits, 2) when drawing individual patient doses, and 3) when injecting patients. The mandatory use of syringe shields unless contraindicated is part of the University's licensing agreement with the NRC. With practice, the removal of the syringe shield for dose calibrator measurement can become very efficient. The radiation exposure to the hands can be reduced from 10,000 mR/hr to less than 100 mR/hr with the use of a shielded syringe!

There are three ways to cause contamination while drawing doses from the radiopharmaceutical vial: 1) back-pressure in the vial forcing liquid between the needle and the rubber septum, 2) a vacuum in the vial which sucks material out of the needle as it is pulled from the septum, and 3) coring of the septum from repeated punctures at the same spot.

To prevent coring, do not stick needles repeatedly through the same spot on a septum. Puncture locations should be varied within the confines of the target area on the septum.

It is preferable to have a partial vacuum in a vial rather than back-pressure. Never inject air into a vial containing radioactive materials. Injecting air creates back-pressure which can force liquid through needle holes in septa. After injecting liquid into a vial always withdraw an equal volume of air from the vial to minimize back-pressure problems.

Maintain firm control of the syringe barrel and plunger. Plungers of new plastic syringes are usually stuck to the barrel of the syringe. It is proper technique to "break" them apart before attempting to draw a dose. This is done by pulling the plunger out several millimeters and then pushing it back in. The plunger will then glide smoothly throughout the length of the syringe barrel. Needles are properly placed on syringes by using a twisting action. Needle guards (caps) are removed by pulling (not twisting) them straight off.

Monitor hands frequently and change gloves when contaminated.

Wear your TLD ring on the first or second finger of the hand which holds the syringe during dose withdrawal, turn the TLD chip towards the palm of your hand. This will give the most accurate evaluation of hand exposure.

Vials containing doses of radioactive material should never be touched with the hands. Vials should be handled with tongs at all times. This reduces exposure and helps prevent contamination.

Keep fingers as far from the dose in a syringe as is practical. This helps reduce hand exposure.

All dose withdrawals should be done behind the leaded glass dose preparation shield.

B. General Dose Withdrawal Procedure

1. Using a shielded syringe, insert the needle into the septum while the vial is upright. This prevents any potential back-pressure from forcing liquid through the hole made by the needle.

2. Invert the vial and hold it at an angle to the syringe to minimize hand exposure.

3. Draw a small amount of eluate into the syringe. For example, with a 3 cc syringe, approximately 0.5 cc of material should be drawn up.

4. Insert the needle all the way into the vial.

5. Tap the syringe firmly once or twice with a finger to force the air bubbles to the base of the needle hub.

6. Expel the air bubbles into the vial.

7. Reposition the needle and draw the dose to the appropriate volume.

NOTE: To save time and reduce exposure, calculate the approximate volume needed for a dose before drawing it.

NOTE: When drawing several doses at approximately the same activity, check the first dose in a calibrator before drawing the others.

8. Holding the plunger firmly in place in the syringe barrel, turn the vial right-side up.

9. Draw the plunger out until an air bubble is seen near the hub of the needle. This clears radioactive material from the needle itself, preventing contamination of the vial septum as liquid is sucked from the needle by the partial vacuum in the vial.

10. Extract the needle from the septum while maintaining firm control of the syringe.

NOTE: Never pull a needle from a vial that is upside down. The back-pressure will force liquid through the needle hole, or liquid will seep through a hole caused by coring of the septum.

PROCEDURE FOR ASEPTIC TECHNIQUE

1.) A fresh alcohol swab should be used for each vial.

2. An alcohol swab is folded and held with a hemostat.

3.) Immediately discard swabs into the radioactive waste after wiping septa of vials containing radioactive materials.

4.) In some cases after drawing a dose a drop of radioactive material may appear on the septum. This drop should be blotted using a swab.

5.) Never touch used alcohol swabs, the jaws of the hemostat, or vial septa.

6.) All used swabs should be discarded in an appropriate lead-shielded radioactive waste container.

7.) Hemostats with swabs should never be laid on the absorbent towels lining the dose-prep station since this will contaminate the towels and the swab. (They should be discarded into the appropriate radioactive waste container immediately following use.)

PROCEDURE FOR RADIOPHARMACEUTICAL KIT PREPARATION

1.) Use a syringe shield on the dose to be injected.

2.) Insert the needle of the syringe containing the dose through the septum of an upright vial.

3.) Pump the syringe plunger several times to force most of the liquid out of the syringe and into the vial.

NOTE: The syringe can be held at an angle to the vial so that the lead container protects most of the hand from exposure.

4.) Withdraw a volume of air equal to the volume of liquid inserted and extract the needle. (Leave this air in the syringe for disposal. Ejecting this air will cause aerosolization of contaminated droplets.)

5.) Discard the contaminated syringe into the lead-shielded radioactive waste container.

ASSAYING AND LABELLING RADIOPHARMACEUTICAL KITS AND DOSES

(Parts: 35.60, 35.61)

A. Syringe shields must be used when: 1) preparing radiopharmaceutical kits, 2) drawing-up individual patient doses, and 3) when injecting patients.

B. All vials containing radiopharmaceutical kits must be kept in a lead vial radiation shield. Each vial must be labelled showing the radiopharmaceutical name. (See example label #2.)

C. All work involving radiopharmaceutical kits and individual doses must be done behind lead shielding with leaded glass.

D. When assaying radiopharmaceutical kits, tongs should be used to transfer the vial in and out of the dose calibrator.

E. All syringes containing radiopharmaceutical doses to be administered must be labelled showing the radiopharmaceutical name, the clinical procedure to be performed, or the patient name. (See example label #3.)

RADIOPHARMACEUTICAL DOSE MEASUREMENTS AND RECORDS

(Part: 35.53)

1. Each radiopharmaceutical dosage must be measured before medical use.

2. Records of these measurements must be retained for three years and must include: radiopharmaceutical name, lot number, expiration date, isotope, patient's name, patient's identification number, prescribed dosage, activity at the time of measurement (if less than 10 microcuries - this is simply verified), date and time of measurement, and the initials of the technologist making the record. The prescribed dosages for each study are listed in the Nuclear Medicine Procedure Manual. The date, time, radiopharmaceutical, isotope, patient name, patient ID number, activity measured and technologist initials are listed on the Daily Report Sheet or the Patient Request Form (charge slip). The lot numbers are listed on the Radiopharmaceutical Dispensing Record and the Log of Radioactive Materials.

3. Doses administered must be within 10% of the prescribed dose.

GENERATOR ELUTION VIAL LABEL (Example #1):

RADIOPHARMACEUTICAL KIT LABEL (Example #2):

INDIVIDUAL RADIOPHARMACEUTICAL DOSE LABEL (Example #3):

RADIATION EXPOSURE TO PERSONNEL DURING RADIOPHARMACEUTICAL PREPARATION

A. Preparation of Radiopharmaceuticals

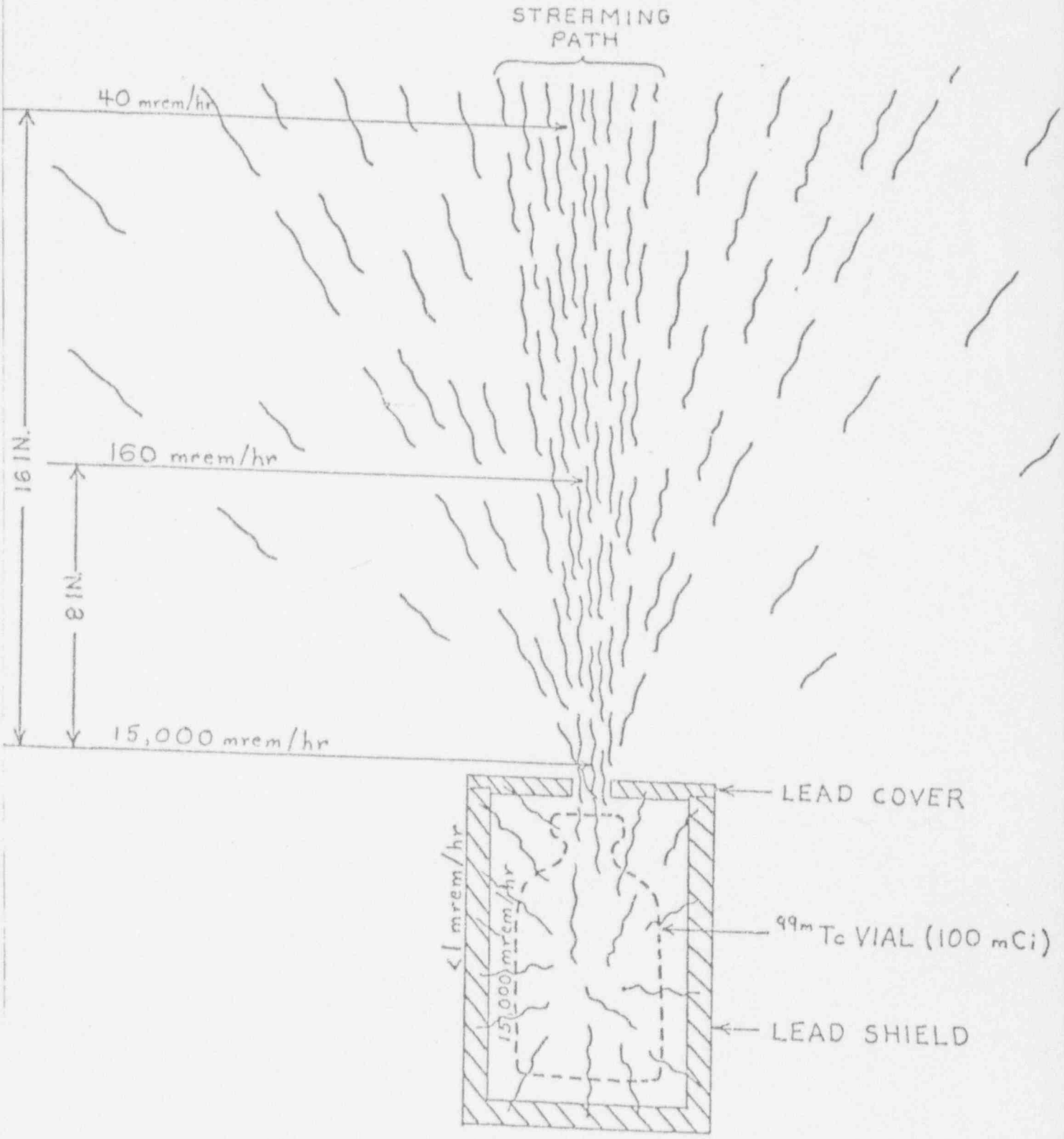
Procedure:	Radiation Exposure Rate (mR/hr)	
	Hand	Body
1. Unpacking and set-up of generator (3000 mCi)	250	30
2. Elution of Tc-99m	200	100
3. Transfer of eluate vial to shielded container (not using tongs)	*37,500 (292 mCi) *60,000 (400 mCi)	1000
4. Transfer of eluate to dose calibrator	*37,500 (292 mCi) *60,000 (400 mCi)	1000
5. Withdrawal of dose into syringe (Tc-99m) (unshielded syringe)	*10,000 (19 mCi)	< 1 (PB glass field)
6. Use of shielded syringe for withdrawal	* < 100	< 1
7. Transfer of syringe to calibrator	500 (20 mCi)	50

*TLD dosimeters

APPROXIMATE EXPOSURE RATES NEAR A SHIELDED VIAL

CONTAINING 100 mCi OF ^{99m}Tc

NOTE THE EFFECT OF DISTANCE AND SHIELDING ON DOSE RATE



To reduce hand exposure keep your hand out of the streaming path as much as possible and keep your hand as far away from the source (vial) as possible.

RADIATION PROTECTION SURVEY

January 29, 1975

		Radiation Exposure (mR/hr)	
A.	Technetium-99m generators		
1.	3000 mCi generator (Delivered by Monday/calibrated for Tuesday)	Body	30
		Hands	250
		Eyes/Thyroid	10
		Surface-top	200
2.	Elution of Tc-99m (400 mCi)	Body	10
		Hands	125
		Eyes/Thyroid	60
3.	Assay of Tc-99m eluate (400 mCi with shielded dose calibrator and 8 inch tongs)	Body	10
		Hands	640
		Eyes/Thyroid	10
B.	Patient dose preparation Technetium-99m		
1.	Withdrawal of 10 mCi of Tc-99m into a syringe from shielded 400 mCi eluate behind lead glass	Body	1
		Hands	400
		Eyes/Thyroid	1
2.	Assay of 10 mCi Tc-99m with a shielded (lead glass) dose calibrator	Body	0.5
		Hands	50
		Eyes/Thyroid	0.5

INJECTION OF DOSES

1) When injecting patients, TLD rings and gloves must be worn. Doses are to be administered only in approved, designated radiation use areas.

2) A leaded syringe shield should be used on all injecting syringes unless the use of the shield is contraindicated for that patient, (i.e. small children or chemotherapy patients with difficult veins).

3) Refer to the Nuclear Medicine Procedure Manual for specifics on injection techniques.

4) After injecting the patient, discard the spent syringe into a labelled lead pig. (This lead pig containing the contaminated syringe should be placed on a disposable pad for contamination control.)

5) The contaminated syringe should be returned to the Prep Lab as soon as possible, and disposed of into the appropriate radioactive waste/biohazard puncture-proof container.

6) The lead pig must be surveyed for contamination before re-use.

RECORDS AND REPORTS OF MISADMINISTRATIONS

(Part 35.33)

(a) When a misadministration involves any therapy procedure (I-131 therapy capsules, P-32 injections), the University will notify by telephone the NRC Regional Office (312-790-5500). Also to be notified are the referring physician of the affected patient and the patient or a responsible relative (or guardian), unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the discovery of the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, they shall be notified as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.

(b) Within 15 days after an initial therapy misadministration report to NRC, the University will report, in writing, to the NRC Regional Office initially telephoned and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified. The written report must include the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the patient or the patient's responsible relative (or guardian) were informed, and if not, why not. The report must not include the patient's name or other information that could lead to identification of the patient.

(c) When a misadministration involves a diagnostic procedure, the Radiation Safety Officer shall promptly investigate its cause, make a record for NRC review, and retain the record. The referring physician and the appropriate NRC Office will also be notified within 15 days if the misadministration involved the use of byproduct material not intended for medical use, administration of a dosage five-fold different from the intended dosage, or administration of byproduct material such that the patient is likely to receive an organ dose greater than 2 rem or a whole body dose greater than 500 millirem. Dosimetry tables in package inserts may be used, corrected only for amount of radioactivity administered, to determine whether a report is required.

(d) A record shall be retained of each misadministration for ten years. The record must contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence.

Report of a Misadministration

Involving a Therapy Procedure

Licensee: University of Minnesota
Department of Radiology
Division of Nuclear Medicine

Referring physician: _____

Description of event:

Effect on the patient:

Action taken to prevent reoccurrence:

Was the patient informed? If not, why not?

Signature: _____ Date: _____
(Radiation Safety Officer)

Signature: _____ Date: _____
(Physician)

Signature: _____ Date: _____
(Radiation Protection Committee Chair)

NRC FORM 473
(5-88)
10 CFR § 35.33

U.S. NUCLEAR REGULATORY COMMISSION
Approved by OMB
3150-0170
Expires 5-31-91

DIAGNOSTIC MISADMINISTRATION REPORT

(N1) LICENSEE NAME

(N2) LICENSE NUMBER

(N3) CITY

(N4) STATE

(N5) EVENT DATE — MONTH DAY YEAR

(N6) REPORT DATE — MONTH DAY YEAR

(N7) TYPE OF MISADMINISTRATION
- (01) WRONG RADIOPHARMACEUTICAL
- (02) DOSAGE DIFFERING FROM PRESCRIBED BY 50%
- (03) WRONG PATIENT
- (04) WRONG ROUTE

(N8) DID THE MISADMINISTRATION INVOLVE AN ISOTOPE OF IODINE
- (999) YES
- (111) NO

(N9) NUMBER OF PATIENTS WHO RECEIVED A MISADMINISTRATION UNDER THIS REPORT

(N10) INTENDED
- (05) NO CLINICAL PROCEDURE
- (06) NUCLEAR MEDICINE STUDY. Complete (N10A) INTENDED and (N11) GIVEN)
- (07) X-RAY STUDY
- (08) ULTRASOUND STUDY
- (09) CT STUDY
- (10) NMR STUDY
- (11) OTHER

(N10A) INTENDED				(N11) GIVEN			
MILLICURIES	ISOTOPE	CHEMICAL FORM	STUDY	MILLICURIES	ISOTOPE	CHEMICAL FORM	STUDY

(N12) PRECIPITATOR
- (71) REFERRING PHYSICIAN
- (72) WARD NURSE
- (73) WARD CLERK
- (74) NUCLEAR PHARMACY
  - NAME OF NUCLEAR PHARMACY
  - CITY
  - STATE
- (75) AUTHORIZED USER
- (76) HOT LAB TECHNOLOGIST
- (77) IMAGING TECHNOLOGIST
- (78) CLINIC RECEPTIONIST
- (79) SCHEDULING TECHNOLOGIST
- (80) PATIENT
- (81) OTHER

(N13) ERROR

HOT LAB
- (11) MISLABELED A SYRINGE
- (12) MISLABELED A VIAL OR VIAL SHIELD
- (13) RECONSTITUTED WRONG REAGENT KIT
- (14) PLACED RECONSTITUTED VIAL IN WRONG SHIELD
- (15) SELECTED WRONG VIAL WHEN DRAWING DOSAGE
- (16) SET DOSE CALIBRATOR IMPROPERLY
- (17) MISREAD DOSE CALIBRATOR
- (18) MISUNDERSTOOD RADIOPHARMACEUTICAL OR DOSAGE ORDER

REFERRAL
- (20) MISUNDERSTOOD REFERRING PHYSICIAN'S REQUEST
- (21) REQUESTED WRONG STUDY
- (22) REQUESTED STUDY FOR WRONG PATIENT

ADMINISTRATION
- (30) SELECTED WRONG PATIENT
- (31) ANSWERED WAITING ROOM PAGE INTENDED FOR OTHER PATIENT
- (32) BROUGHT WRONG PATIENT TO CLINIC
- (33) SELECTED WRONG SYRINGE FROM DOSAGE CART

OTHER
- (40) *Specify*

(N14) CONTRIBUTING FACTORS
- (80) STUDENT TECHNOLOGIST
- (81) NEW EMPLOYEE
- (82) FOREIGN LANGUAGE
- (83) PATIENT INCOHERENT OR UNCONSCIOUS
- (84) ID BRACELET NOT CHECKED
- (85) REQUISITION NOT CHECKED
- (86) PATIENT CHART NOT CHECKED
- (87) NEW PROCEDURE
- (88) HEAVY WORKLOAD
- (89) OTHER

(N15) ACTION TAKEN TO PREVENT RECURRENCE
- IMPLEMENT NEW PROCEDURES FOR
  - (C1) VERIFICATION OF REQUEST
  - (C2) RADIOPHARMACEUTICAL LABELING AND HANDLING
  - (C3) VERIFICATION OF PATIENT IDENTIFICATION
- (C4) REINSTRUCT PERSONNEL
- (C5) REPRIMAND PERSONNEL
- (C6) IMPROVE SUPERVISION OF PERSONNEL
- (C7) NO ACTION
- (C8) OTHER

(N16) EFFECT ON PATIENTS
- NONE APPARENT
- SEE ABSTRACT

(N17) ABSTRACT *(If more space is required, attach additional sheets.)*

RADIATION OFFICER (Printed Name) | SIGNATURE | TELEPHONE | DATE

NUCLEAR REGULATORY COMMISSION USE

(N18)	(N19) AS	(N20) REGIONAL LOG NUMBER	(N21) ACCESSION NUMBER	(N22) INITIALS	
(999) YES (111) NO					

NRC FORM 473 (5-88)

*From Nuclear Medicine's Quality Assurance Plan

GENERIC MONITORING RECORD

Part A

Patient Name:_____ Number:_____

INDICATORS

		Occurrence Date	Code
*1.	Admission for complications or adverse results of outpatient nuclear medicine study.		
2.	Consent not obtained for potentially hazardous (i.e. cardiac stress) study.		
3.	Unplanned return to repeat an incomplete or incorrectly performed procedure.		
4.	Administration of incorrect diagnostic or therapeutic dose of radiopharmaceutical.		
*5.	Cardiac or respiratory arrest in the nuclear medicine department.		
*6.	Transfer from general care to special care unit due to complication of the nuclear medicine procedure.		
*7.	Departmentally incurred patient incident (fall, equipment injury, etc.).		
8.	Utilization problem (repeat due to equipment failure, incorrect study, etc.)		
9.	Department problem (nursing errors, etc.)		
10.	Patient/family dissatisfaction (waiting time, treatment by personnel, etc.)		
11.	Examination Cancelled		
12.	Quality Assurance Standards met.		

*A significant complication and major incident report must also be completed.

DESCRIPTORS OF GENERIC MONITORS
Monitor Code for Part A

1. A. As on Part A

2. A. Missing
   B. Not signed by patient
   C. Risks not explained

3. A. Wrong area imaged
   B. Return for missed images
   C. Improper intensities
   D. Physician requested

4. A. Antibiotics or drugs not administered as ordered or on schedule because patient was in NM
   B. Incorrect therapeutic dose (mCi)
   C. Misadministration

5. A. Cardiac arrest
   B. Respiratory arrest

6. A. Transfer from general floor to CCU
   B. Transfer from CCU to ICU

7. A. Fall in department
   B. Equipment fell on patient
   C. IV infiltrated or discontinued while in NM
   D. Broken or malfunctioning equipment
   E. Infiltration of dose

8. A. Increased length of stay in hospital due to NM complication
   B. Repeat procedure due to equipment failure
   C. Repeat procedure due to technologist error
   D. Repeat procedure due to improper patient prep
   E. Incorrect images taken
   F. Images in wrong sequence (e.g., bone before liver/spleen)
   G. Poor study due to intensity, etc. (list study, camera)

9. A. Patient sent back to room
   B. Improper patient prep by nurses, floor, physician
   C. Wrong request
   D. Wrong patient name on request
   E. Medications not stopped
   F. No request in doctor's orders
   G. Patient waited more than 15 minutes to return to room
   H. Physician was late for stress testing

10. A. Waiting times too long
    B. Improper treatment by personnel

11. A. As on Part A

12. A. As on Part A

GENERIC MONITORING RECORD

Part B

(Complete if one or more occurrences are identified in Part A)

Patient Name:_____ Number:_____

Reason for Admission:_____

_____

_____

Date of Reporting:_____ Prepared by:_____

Criteria Number | Source Code*

Account of Occurrence(s)
(include date, time, specific location):

Source Code Key: 1 - medical record;
2 - direct observation;
3 - observation by other person (specify);
4 - other source (specify)

Date:_____

SIGNIFICANT COMPLICATIONS AND MAJOR INCIDENT REPORT

1. Name of Patient:_____
2. Hospital #:_____
3. Ordering Physician:_____
4. Type of Concern:

5. Procedure performed:_____
6. Was the study appropriate?
7. History of allergy:
8. Technologist comments:

9. Physician's comments:

10. Nurse comments:

11. Referring Physician:

12. Summary of events:

13. Recommendations:

DOSE CALIBRATOR

(Part 35.50)

All radiopharmaceuticals are required to be assayed for activity with a dose calibrator to an accuracy of 10%. In order to accomplish this, it is necessary to ascertain that the instrument is operating properly and accurately upon installation and periodically thereafter.

The following checks are required: constancy, accuracy, linearity and geometry.

I. Constancy Check

Frequency - Daily

Procedure:

A. Measure a check source on frequently used settings at the beginning of each day.

B. The reading MUST be within ± 5% of the previous reading of the stated activity, should it vary greater than this limit, service will be notified immediately.

C. Records shall be kept for 3 years, and must include: model and serial number of the dose calibrator used, the isotope of the check source, date, activity measured, initials of the technologist performing the test. (See example.)

INSTRUMENT CONSTANCY CHECK

Dose Calibrator Number: ______________

Check Source Used: ________________

Calibrator readings on:

Date	BKG	Cs^{137}	Tc^{99m}	I^{131}	Xe^{133}	In^{111}	Test	Tech. Initials

II. Calibration/Accuracy Check

Frequency: Upon installation, annually and following a repair.

Procedure:

A. Assay at least two sealed sources containing different isotopes.

B. Consider accurate if ± 5% of known sealed source activity.

C. Records must be kept for 3 years, and must include: model number and serial number of dose calibrator, model and serial numbers of each source used, identity and activity of radionuclide contained in sources, results of test, date of test, signature of the Radiation Protection Program Representative. (See the following example.)

Dose Calibrator

Accuracy Check/Calibration

DOSE CALIBRATOR

MODEL: _____ SERIAL NO.: _____

DATE: _____ QUARTER: _____

SOURCE # 1	SOURCE # 2	SOURCE # 3
_____ (isotope)	_____ (isotope)	_____ (isotope)
_____ (activity)	_____ (activity)	_____ (activity)
_____ (serial #)	_____ (serial #)	_____ (serial #)

RESULTS:

_____	_____	_____

Signature of RPP rep. _____

* Quality Control on Dose Calibrator:

DAILY:

1) Accuracy check ±5% (use sources ^{57}Co, ^{137}Cs, ^{133}Ba) (±5%)

2) Constancy check (use ^{137}Cs source)
Check ^{137}Cs, ^{99m}Tc, ^{131}I, ^{133}Xe, and ^{111}In

3) Potenometer Test (150 ± 5%)

4) Background

QUARTERLY:

1) Linearity Check

YEARLY:

1) Tc^{99m} Accuracy Check ±5%

*From the Nuclear Medicine Procedure Manual.

(Example of source used in Accuracy checks)

ISOTOPE: Cs-137
CALIBRATION DATE: 2/ 5/80
SOURCE CLBR SERIAL NO: CRC-10R 10989

SOURCE NUMBER: Amersham 3019MA
SOURCE ACTIVITY: 265.0 uCi

DATE	DAYS FROM CALIBRATION	ACTIVITY (uCi)	DOSE CALIBRATOR READING	ACCEPTABLE LIMITS (+/- 5%)	PERCENT DIFFERENCE
5-16-88	3023	218.88	219uCi	207.93 , 229.82	- BB
5-17-88	3024	218.86	219uCi	207.92 , 229.80	- RW
5-18-88	3025	218.85	219uCi	207.91 , 229.79	- RW
5-19-88	3026	218.83	219uCi	207.89 , 229.78	- RW
5-20-88	3027	218.82	219uCi	207.88 , 229.76	- RW
5-23-88	3030	218.78	218uCi	207.84 , 229.72	0.4% RW
5-24-88	3031	218.76	220uCi	207.83 , 229.70	0.6% RW
5-25-88	3032	218.75	219uCi	207.81 , 229.69	- RW
5-26-88	3033	218.74	218uCi	207.80 , 229.67	0.4% RW
5-27-88	3034	218.72	218uCi	207.79 , 229.66	0.4% RW
5-30-88	3037	218.68	Holiday	207.75 , 229.62	----
5-31-88	3038	218.67	218	207.73 , 229.60	- BB

JUNE

6- 1-88	3039	218.65	217uCi	207.72 , 229.59	0.8% RC
6- 2-88	3040	218.64	217uCi	207.71 , 229.57	0.8% RC
6- 3-88	3041	218.63		207.69 , 229.56	
6- 6-88	3044	218.58		207.66 , 229.51	
6- 7-88	3045	218.57		207.64 , 229.50	
6- 8-88	3046	218.56		207.63 , 229.48	
6- 9-88	3047	218.54		207.62 , 229.47	
6-10-88	3048	218.53		207.60 , 229.46	
6-13-88	3051	218.49		207.56 , 229.41	
6-14-88	3052	218.47		207.55 , 229.40	
6-15-88	3053	218.46		207.54 , 229.38	
6-16-88	3054	218.45		207.53 , 229.37	

Dose Calibrator

III. Test of Instrument Linearity

Frequency: Quarterly and upon installation.

Procedure:

1. Elute from generator the normal daily amount of Tc99m.
2. Assay the vial using various combinations of lead sleeves.
3. Calculate ratios and keep records as seen on the example record sheet.

OR

1. Assay approximately 100 mCi of Tc99m in the dose calibrator.
2. Assay the same vial of Tc99m at time intervals of 6, 24, 30 and 48 hrs after the initial assay.
3. Using the 30 hr activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hrs. Use the following table:

Assay Time	Correction Factor
0	32
6	16
24	2
30	1
48	0.125

4. Plot the measured net activity for each time interval vs. the predicted activity on log-log graph paper.
5. The activities plotted should be within ± 10% of the predicted curve if the instrument is linear and functioning properly. Errors greater than ± 10% indicate the need for repair or adjustments of the instrument.

Formula:

$$\frac{\text{difference between PREDICTED \& MEASURED X 100}}{\text{PREDICTED}} = \text{\% of linearity}$$

(30 hour MEASURED activity X respective correction factor gives PREDICTED activity)

Records: Shall be kept for 3 years, and must include: model and serial numbers of dose calibrator checked, date, calculated and measured activities, signature of Radiaton Protection Program Representative.

Dose Calibrator

Linearity Check

DOSE CALIBRATOR

MODEL: _____ SERIAL NO.: _____

DATE: _____ QUARTER: _____

ISOTOPE: _____

	MEASURED ACTIVITY	CALCULATED ACTIVITY	% DIFFERENCE
100%	_____	_____	_____
0	_____	_____	_____
0 + A	_____	_____	_____
0 + B	_____	_____	_____
0 + A + B	_____	_____	_____
0 + C	_____	_____	_____
0 + A + C	_____	_____	_____
0 + B + C	_____	_____	_____
0 + A + B + C	_____	_____	_____

COMMENTS:

Signature of RPP rep. _____

Dose Calibrator

IV. Geometry Test

Frequency: Upon installation and following a repair.

Procedure:

A. See the next page for instructions.

B. Errors greater than ± 10% must be corrected mathematically.

C. Records must be retained for the duration of the use of the dose calibrator. Records must include: the model and serial numbers of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, date of test, and signature of a Radiation Protection Program Representative.

Geometric Variation Test

Assay a 30 ml vial containing Tc-99m in a volume of 1ml, then increase volume by steps to 2,4,8,10,20,25,30ml. The ratio of measured activities for each volume to the 10ml reference volume activity should be within ±2%. If outside this range, correction factors should be used. For instance, if activities of 4.12 mCi and 4.00 mCi are measured for 4ml and 10ml volumes, and 10ml is the reference volume selected, then the correction factor for 4ml volumes would be 4.00/4.12=0.97.

References:

T. Phan, R. Wasnich, Practical Nuclear Medicine

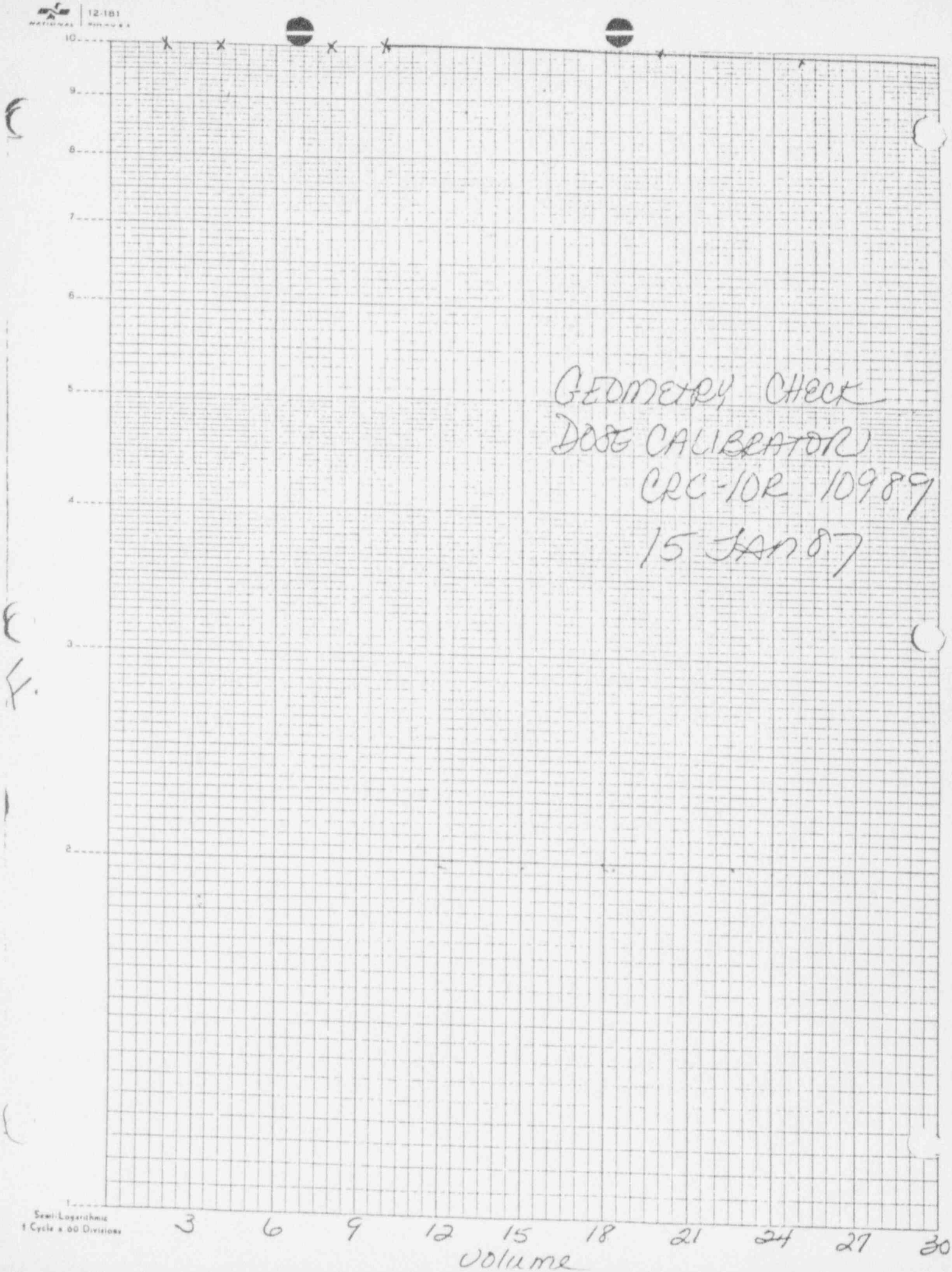
NUCLEAR PHARMACY
UNIVERSITY OF MINNESOTA
Division of Nuclear Medicine • Department of Radiology • University Hospitals
Box 382 Mayo Memorial Building • 420 Delaware Street S.E. • Minneapolis, Minnesota 55455

GEOMETRY CHECK

DOSE CALIBRATOR CRC-10R 10989

January 15, 1987

Volume	Assay	Correction Factor
2 ml	14.4 mCi	0.0
4 ml	14.4 mCi	0.0
8 ml	14.4 mCi	0.0
10 ml	14.4 mCi	Standard
20 ml	14.5 mCi	0.993
25 ml	14.6 mCi	0.986


12-181
10
9
8
7
6
5
4
3
2
1
GEOMETRY CHECK
DOSE CALIBRATOR
CRC-10R 10989
15 JAN 87
Semi-Logarithmic
1 Cycle x 60 Divisions
3
6
9
12
15
18
21
24
27
30
Volume

RADIATION PROTECTION PROGRAM RESPONSIBILITIES FOR THE NUCLEAR MEDICINE DEPARTMENT

I. Review Monthly Dosimetry Reports

- Investigate if ≥ 25% of monthly whole body or extremity limits (ALARA)
- Or if > 1.5 rem/month extremity
  > 100 mrem/month whole body

II. Survey Instrument Calibration (Part 35.51)

- once/year and following repair

III. Inventory and Leak-Testing of Sealed Sources (Part 35.59)

- Inventory quarterly all sealed sources
- Survey quarterly sealed source storage areas
- Leak test all sealed sources every 6 months

IV. Contamination Surveys (Part 35.70)

- Weekly

V. Monitoring of I-131 Therapy Patients (Part 35.75)

- Patients released only if exposure < 5 mR/hr at 1 meter or < 30 mCi
- Smear survey of patient room

VI. Control of Aerosols and Gases (Part 35.205)

- Check ventilation every six months

VII. Reports of Misadministrations (Part 35.33)

VIII. Annual Review of Nuclear Medicine Department

I. REVIEW OF MONTHLY DOSIMETRY REPORTS

(Part 35.21)

A. The Radiation Protection Program shall review the Nuclear Medicine Personnel dosimetry reports monthly, and sign the following review form. (See example form.)

B. Investigational Limits
An investigation shall be done if the dosimetry readings exceed 25% of the monthly limits, (ALARA) or if > 1.5 rem/month extremity or > 100 mrem/month whole body.

C. Investigations of personnel exposure exceeding the above limits shall include:

1) Date of investigation

2) Probable cause of exposure

3) Corrective action taken

(See example form.)

MONTHLY REVIEW OF NUCLEAR MEDICINE PERSONNEL DOSIMETRY REPORTS:

Month/Year:	Signature of Radiation Protection Program Representative:
June 1988	
July 1988	
Aug. 1988	
Sept. 1988	
Oct. 1988	
Nov. 1988	
Dec. 1988	
Jan. 1989	
Feb. 1989	
March 1989	
April 1989	
May 1989	
June 1989	
July 1989	
Aug. 1989	
Sept. 1989	
Oct. 1989	
Nov. 1989	
Dec. 1989	

INVESTIGATIONAL FORM
FOR NUCLEAR MEDICINE PERSONNEL
DOSIMETRY REPORTS EXCEEDING LIMITS:*

NAME: _____

DATE: _____

BADGE READINGS: Month: _____ _____ mrem whole body, _____rem extremities

EXPLANATION OF PROBABLE CAUSE OF EXPOSURE:

CORRECTIVE ACTION TO BE TAKEN:

_____
NUCLEAR MEDICINE PERSONNEL SIGNATURE

_____
RADIATION PROTECTION PROGRAM REPRESENTATIVE SIGNATURE

_____
RADIATION PROTECTION COMMITTEE CHAIR SIGNATURE

* An investigation shall be done if the dosimetry readings exceed 25% of the monthly ALARA limits, (> 1.5 rem/month extremity or > 100 mrem/month whole body.)

II. INSTRUMENT CALIBRATION

(Part 35.51)

A. The Radiation Protection Program will calibrate survey instruments for the Nuclear Medicine Department once per year. (The Nuclear Medicine Department is responsible for bringing instruments to the Radiation Protection Department for calibration.)

B. These records shall be kept for a minimum of 3 years.

C. Calibrate cutie pie instruments up to 1000 mR/hr.

D. Calibrate GM survey instruments up to 100 mR/hr.

E. Attempt to calibrate two separate readings on each scale.

F. Note on the instrument the exposure rate for the check source that can be used for daily accuracy checks.

G. Record calibration results (see example form) including date, description of source used, reference exposure rates, instrument readings and signature.

INSTRUMENT CALIBRATION FORM

Date: _____

Instrument Data: Model No. _____ Source Data: _____

Serial No. _____ Radioisotope _____

Probe _____ Activity _____

Instrument Owner: _____ Date of last cal. _____

Description of Calibration Procedure: _____

_____

_____

Calibration Performed By: _____

Calibration Data:

Reference Exposure Rate	Instrument Reading	
	Meter	Range/Scale

Check source: Isotope : _____

Activity : _____

Reference reading: _____

Exposure rate for the check source that can be used for daily accuracy checks: _____

COMMENTS:

III. INVENTORY AND LEAK-TESTING OF SEALED SOURCES

(Part 35.59)

A. All sealed sources will be leak-tested by the Radiation Protection Program before their initial use, and every six months thereafter.

B. Leak-tests include: date, model/serial number of each source, isotope, activity, result of leak test, measurement method used, signature. (See example form.)

C. If 0.005 uCi or more of removable contamination is found the source will immediately be removed from use and a report will be filed with the NRC.

D. The Radiation Protection Program will take inventory of all sealed sources quarterly including a survey of ambient dose rates.

E. This inventory includes: date, model/serial number of each source, isotope, activity, the measured dose rate in the storage room, signature. (See example form.)

F. All of these sealed source records will be kept for five years.

NUCLEAR MEDICINE
SEALED RADIATION SOURCES INVENTORY

Source Identification	Location	Isotope	Activity When New	Date When New
57727/76	V73	^{57}Co	5.4 mCi	5/85
2094 MA	V73	^{133}Ba	285.5 uCi	6/81
3327	V73	^{137}Cs	273 uCi	2/83
2891083A-65	2-446	^{57}Co	50 uCi	10/83
2093 ma	2-452	^{133}Ba	285.5 uCi	6/81
3019 ma	2-452	^{137}Cs	265 uCi	2/80
283899	2-452	^{57}Co	5.16 mCi	7/87
Rod	2-437	^{60}Co	0.110 uCi	4/72
NES1375 Rod	2-437	^{57}Co	0.101 uCi	12/81
G26 well ct std.	2-437	^{137}Cs	0.1 uCi	1/79
Rod	2.416	^{137}Cs	7.2 uCi	2/83
Rod	2-416	^{57}Co	7.5 uCi	3/83
445/221	2-450	^{57}Co	10.2 mCi	6/85
* 324539	2-452	^{57}Co	5.9 mCi	3/23/88
* 0338LN	2-416	^{153}Gd	1 Ci	3/18/88
* 324539 Rod	2-416	^{57}Co	8.35 uCi	3/23/88

James Tennison

April 18, 1988

* New

Quarterly Inventory of Sealed Sources

Sealed Source Identification:

Isotope: _____

Activity: _____

Serial/Model #: _____

Room #: _____

Room Plan:

Indicate: sealed source locations, measure the dose rate (mR/hr) at several points

Instrument used: _____

Signature: _____ Date: _____
(person completing inventory)

RPP rep. signature: _____ Date: _____

SEALED RADIATION SOURCE LEAK TEST REPORT FORM

Date of leak test: _____

Analysis Instrument: _____

	Source Model/Serial #	Location	Isotope	Activity (mCi)	Date*	Detector Used	Leak Test ** Results
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

* when new

** NAB - Not Above Background

Signature _____

(RPP Representative)

REMARKS:

IV. CONTAMINATION SURVEYS

(Part 35.70)

A. The Radiation Protection Program will survey the Nuclear Medicine Department for removable contamination once per week in the radioisotope use, administration and storage areas.

B. Each survey will include: date, plan of areas surveyed, results, instruments used, initials of person performing survey. (See example form.)

C. The Nuclear Medicine Department will be notified if any area surveyed exceeds 200 dpm/100 cm^2, so that they can take corrective action and decontaminate.

D. The Radiation Safety Officer will notify Nuclear Medicine personnel if any area exceeds the trigger level of 2000 dpm/100cm^2 for Tc-99m, or 200 dpm/100cm^2 for other radioisotopes, and access to the area will be restricted until decontamination takes place.

E. These records will be kept for 3 years.

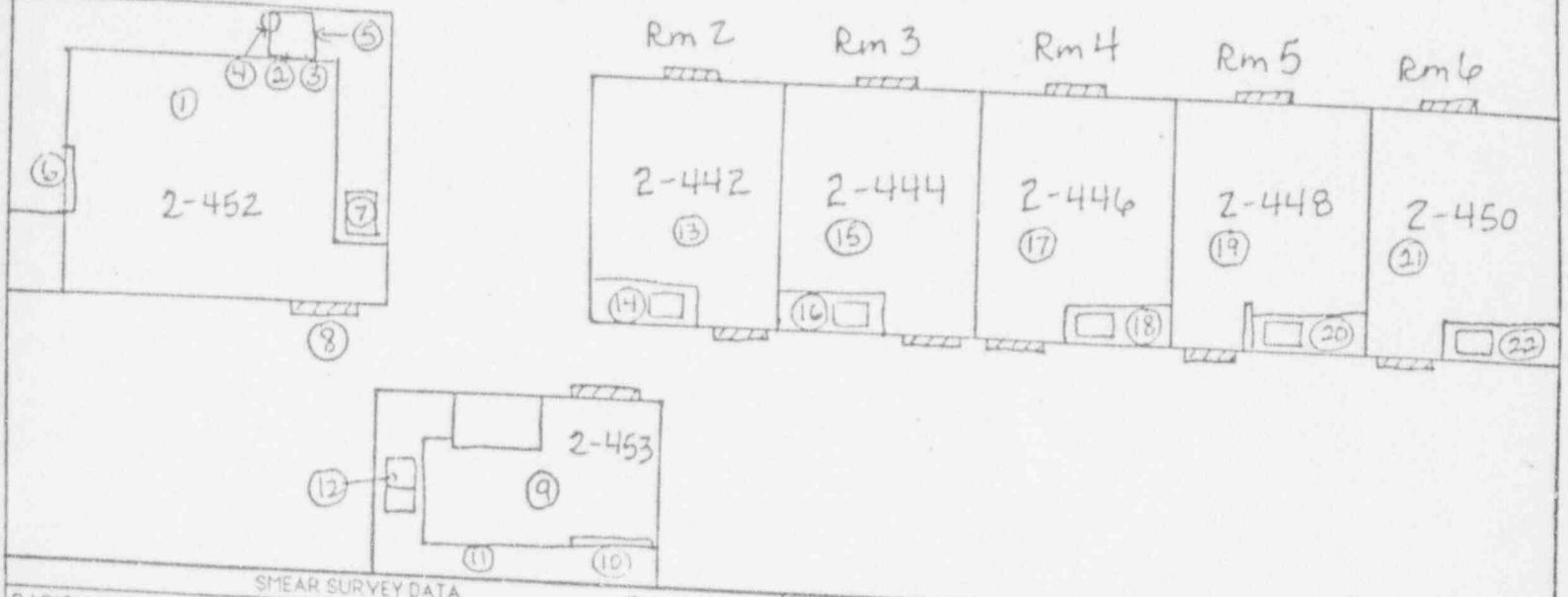
APPROVED USER: Dr. Boud[redacted]u | DEPT: [redacted]Nuclear Medicine

SURVEYED BY: Radiation Protection Program | SURVEY TYPE: Weekly | DATE

BUILDING: Health Science - Unit J | ROOM NUMBER: see below

MAP OF ROOM(S) - CLEARLY INDICATE ALL ROOM NUMBERS

Hot Lab



SMEAR SURVEY DATA

RADIOISOTOPE(S) ANALYZED:

% EFFICIENCY FOR RADIOISOTOPE(S):

INSTRUMENT USED:

BACKGROUND (CPM): | MDA (minimum detectable counts):

NO	LOCATION	CPM/100cm²
1	floor	
2	glass, outside	
3	glass, inside	
4	syringe bucket	
5	dose calibrator buttons	
6	hood	
7	sink	
8	hallway floor	
9	floor	
10	hood	
11	bench	
12	sink	
13	floor	
14	countertop / sink area	
15	floor	
16	countertop / sink area	
17	floor	
18	countertop / sink area	
19	floor	
20	countertop / sink area	
21	floor	
22	countertop / sink area	

COMMENTS

PORTABLE G-M SURVEY DATA

INSTRUMENT USED:

BACKGROUND (CPM) or (mr/hr):

NO	LOCATION	CPM/100cm² or (mr/hr)

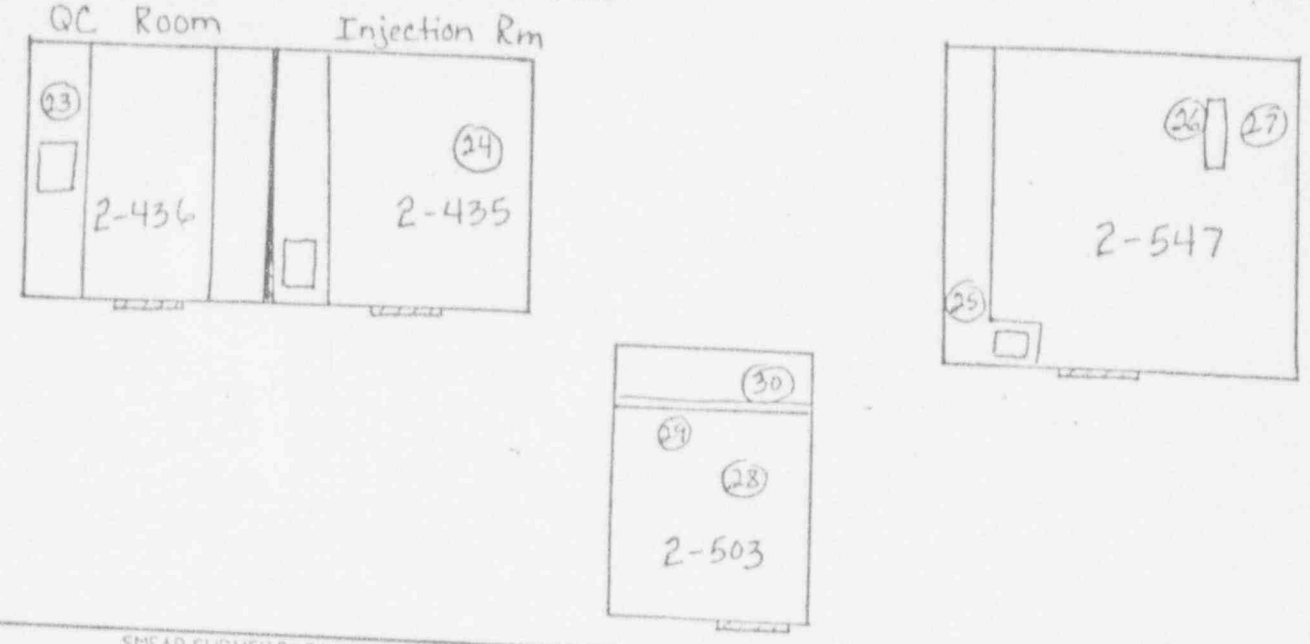
NO EATING, DRINKING, SMOKING, MOUTH PIPETTING OK?	Y	N	na
WASTE STORAGE OK?	Y	N	na
NEW H2O SOLUBLE SCINT. FLUID ?	Y	N	na
INVENTORY RECORDS OK?	Y	N	na
QUARTERLIES OK?	Y	N	na
NEW MANUAL IN LAB?	Y	N	na

APPROVED USER: Dr. Boudreau | DEPT: Nuclear Medicine

SURVEYED BY: Radiation Protection | SURVEY TYPE: Weekly | DATE

BUILDING: Health Science - Unit J | ROOM NUMBER: See below

MAP OF ROOM(S) - CLEARLY INDICATE ALL ROOM NUMBERS



SMEAR SURVEY DATA

RADIOISOTOPE(S) ANALYZED:

% EFFICIENCY FOR RADIOISOTOPE(S):

INSTRUMENT USED:

BACKGROUND (CPM): | MDA (minimum detectable counts):

NO	LOCATION	CPM/100cm²
23	countertop / sink area	
24	injection table arm	
25	countertop / sink area	
26	treadmill	
27	floor near treadmill / injection site	
28	floor	
29	top of waste cans	
30	Pb & generators	

Negative Pressure Checks

Rm #	Evac. times posted?	
Prep Lab.	Y	N
2-442 (Rm 2)	Y	N
2-446 (Rm 4)	Y	N
2-448 (Rm 5)	Y	N

PORTABLE G-M SURVEY DATA

INSTRUMENT USED:

BACKGROUND (CPM) or (mr/hr):

NO	LOCATION	CPM/100cm² or (mr/hr)

NO EATING, DRINKING, SMOKING, MOUTH PIPETTING OK?	Y	N	na
WASTE STORAGE OK?	Y	N	na
NEW H2O SOLUBLE SCINT. FLUID?	Y	N	na
INVENTORY RECORDS OK?	Y	N	na
QUARTERLIES OK?	Y	N	
NEW MANUAL IN LAB?	Y	N	na

COMMENTS

I-131 PATIENT THERAPY RECORD

Patient Name: _____

Room Number: _____ Station Number: _____

Dose Given: _____ mCi Date: _____ Time: _____

DOSE RATES AT ADMINISTRATION TIME:

Highest reading close to patient: _____ mR/hr

Bedside: _____ mR/hr

One meter from patient: _____ mR/hr

Room door: _____ mR/hr

At wall in room to the right: _____ mR/hr

At wall in room to the left: _____ mR/hr

Maximum contiguous unrestricted area: _____ mR/hr

---

*DOSE RATES AT ONE METER FROM PATIENT

ADMINISTERED ACTIVITY (mCi) / mR/hr @ 1m @ admin. time = RELEASE ACTIVITY (Must be below 30 mCi) / mR/hr @ 1m @ release (must be below 5mR/hr)

DATE:	TIME:	mR/hr:	mCi:

*Patient may not be released until < 5 mR/hr or < 30 mCi.

Instrument used: _____

Signature of surveyor: _____

APPROVED USER:

SURVEYED BY: | DEPT:

BUILDING: | SURVEY TYPE: I-131 Therapy Close-Out | DATE

ROOM NUMBER:

MAP OF ROOM(S) – CLEARLY INDICATE ALL ROOM NUMBERS

SMEAR SURVEY DATA

RADIOISOTOPE(S) ANALYZED:

% EFFICIENCY FOR RADIOISOTOPE(S):

INSTRUMENT USED:

BACKGROUND (CPM): | MDA (minimum detectable counts):

NO.	LOCATION	CPM/100cm²
1	Floor at room doorway	
2	Floor near bedside	
3	Food table	
4	Telephone	
5	Call button	
6	Light switch	
7	Chair arms	
8	Room door handle	
9	Bathroom door handle	
10	Bathroom floor	
11	Sink	
12	Sink vanity top	
13	Sink faucet handles	
14	Toilet seat	

COMMENTS:

PORTABLE G-M SURVEY DATA

INSTRUMENT USED:

BACKGROUND (CPM) or (mr/hr):

NO	LOCATION	CPM/100cm² or (mr/hr)
1.	Pillow Y N	
2.	Mattress Y N	
3.	Bed Linen Y N	
4.	Disposable solid waste Y N	
	⇑	
	Do these items need to be held for decay?	
	Rad. Signs Removed?	Y N
	NO EATING, DRINKING, SMOKING, MOUTH PIPETTING OK?	Y N na
	WASTE STORAGE OK?	Y N na
	NEW H2O SOLUBLE SCINT. FLUID?	Y N na
	INVENTORY RECORDS OK?	Y N na
	QUARTERLIES OK?	Y N na
	NEW MANUAL IN LAB?	Y N na

APPROVED USER:

SURVEYED BY: | DEPT:

BUILDING: | SURVEY TYPE: I-131 Therapy Close-Out | DATE

ROOM NUMBER:

MAP OF ROOM(S) – CLEARLY INDICATE ALL ROOM NUMBERS

SMEAR SURVEY DATA

RADIOISOTOPE(S) ANALYZED:

% EFFICIENCY FOR RADIOISOTOPE(S):

INSTRUMENT USED:

BACKGROUND (CPM): | MDA (minimum detectable counts):

NO.	LOCATION	CPM/100cm²
1	Floor at room doorway	
2	Floor near bedside	
3	Food table	
4	Telephone	
5	Call button	
6	Light switch	
7	Chair arms	
8	Room door handle	
9	Bathroom door handle	
10	Bathroom floor	
11	Sink	
12	Sink vanity top	
13	Sink faucet handles	
14	Toilet seat	

PORTABLE G-M SURVEY DATA

INSTRUMENT USED:

BACKGROUND (CPM) or (mr/hr):

NO	LOCATION	CPM/100cm² or (mr/hr)
1.	Pillow Y N	
2.	Mattress Y N	
3.	Bed Linen Y N	
4.	Disposable solid waste Y N	
	⇑	
	Do these items need to be held for decay?	
	Rad. Signs Removed?	

	Y	N	
NO EATING, DRINKING, SMOKING, MOUTH PIPETTING OK?	Y	N	na
WASTE STORAGE OK?	Y	N	na
NEW H2O SOLUBLE SCINT. FLUID?	Y	N	na
INVENTORY RECORDS OK?	Y	N	na
QUARTERLIES OK?	Y	N	na
NEW MANUAL IN LAB?	Y	N	na

COMMENTS

V. MONITORING OF I-131 THERAPY PATIENTS

(Part 35.75 and 35.315)

(1) Each patient receiving I-131 therapy doses will be provided a private room with a private restroom;

(2) The RPP representative will post the patient's door with a "Caution Radioactive Materials" sign and a "Caution Radiation Area" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room;

(3) Visits by individuals under age 18 will be authorized only on a patient-by-patient basis with the approval of the health care staff after consultation with the Radiation Safety Officer;

(4) Promptly after administration of the dosage, the dose rates will be measured in contiguous restricted and unrestricted areas with a radiation survey instrument to demonstrate that dose rates are less than 2 mR/hr in these areas. The RPP will retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who conducted the survey. (See example form.)

(5) The RPP will monitor material and items removed from the patient's room to determine if their radioactive content cannot be distinguished from the natural background radiation level using a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or if they should be handled as radioactive waste.

(6) The nursing station will provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient from the hospital. An estimate of the time that these precautions should remain in effect will be given by the physician in charge of the patient and is included as part of the patient radiation pamphlet.

(7) The RPP will survey the patient's room and private restroom for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room will not be reassigned until removable contamination is less than 200 disintegrations per minute above background per 100 square centimeters; and

(8) The Radiation Safety Officer will be notified immediately if the patient dies or has a medical emergency.

(9) The patient will not be released until the measured dose rate from the patient is less than 5 millirems per hour at 1 meter, or the activity in the patient is less then 30 mCi.

Radiation Protection

Department of Environmental Health and Safety

Boynton Health Service
University of Minnesota
Minneapolis, Minnesota 55455

For information on Radiation Protection call 626-6002

In case of Radiation Emergency dial 1 2 3

RADIATION PROTECTION INSTRUCTIONS FOR NURSES CARING FOR PATIENTS WHO RECEIVE ^{131}I THERAPY

There is no need to be alarmed when assigned to the care of a patient receiving radioiodine therapy, as one may work safely around sources of ionizing radiation, provided proper precautions are taken.

Proper care may be provided to the patient while maintaining the radiation exposure received by the nursing staff within the protection limits. Nurses who care for radioiodine therapy patients must read and understand the attached instructions. If there are questions concerning these instructions, contact the nursing supervisor or the Radiation Protection Program (626-6002). The following is a brief review of basic principles of external and internal radiation exposure control.

External Radiation Exposure Control

External exposure results when an individual is exposed to ionizing radiation emitted by a source located outside of the individual's body. The distance one works from an external radiation source and the time spent near the source contribute to the degree of exposure one will receive. The nurse should keep in mind that she/he should spend only the time necessary near the patient and should work at as great a distance as possible without sacrificing quality of care. If the working time is reduced and the distance increased, the exposure will consequently be less. If a nurse can administer care to a patient at two feet instead of one foot, her/his exposure will be only one fourth as great. To carry this further, if the nurse were five feet from the patient, her/his exposure would be only one twenty-fifth as great as at one foot from the patient, and at ten feet it would be one-hundredth as great. This is not meant to discourage the nurse from going close to the patient, but rather to show the importance of distance in radiation protection. Time is also an important factor in that the exposure received by the nurse will be twice as great if she/he spends ten minutes at the bedside as it would be if she/he were there only five minutes.

Internal Radiation Exposure Control

Internal radiation exposure results when radioactive material, in this case ^{131}I, is taken into an individual's body by the routes of inhalation, ingestion, and/or through breaks in the skin. Unsealed radioactive materials, such as those used in ^{131}I therapy, present not only an external radiation exposure potential, but also present a potential for personnel and area contamination. The primary sources of ^{131}I contamination in the patient's room result from contaminated urine and saliva which will contain appreciable amounts of ^{131}I. Special precautions, as outlined in the attached instructions, must be followed to prevent contamination of the hands and clothing of personnel who care for the patient.

Keep in mind that past experience tells us that with normal care to the patient, the hazard to the nurse will be well within protection limits. However, we need your full cooperation in following the attached instructions in order that the hospital area may remain free of contamination and that radiation exposures to all concerned will be kept as low as reasonably achievable.

(ATTACH THESE PROCEDURES TO THE COVER OF THE PATIENT'S CHART)

Instructions for Nurses Caring for Patients Receiving ^{131}I Therapy

The Division of Nuclear Medicine is responsible for calling the Radiation Protection Program (RPP) when a patient is scheduled for ^{131}I therapy. The RPP will provide film badge monitoring for the nursing staff, and will also provide a shielded radioactive urine container to be located in the patient's bathroom.

Staff Precautions

All persons who enter the patient's room should be given the following instructions:

1. Spend as little time in the room as is necessary to provide proper care.
2. Spend no more time at the patient's bedside than is absolutely necessary.
3. Wear disposable gloves at all times in the room and wash hands thoroughly after removal of gloves. Gloves should be placed in the designated disposal bag located in the room.
4. Custodial services should not be provided until after the Radiation Protection Program staff have decontaminated the room.
5. All staff persons who enter the room must wear a film badge.

Room Assignment

The hospital policy on room assignment for patients who receive ^{131}I therapy provides that these patients are to be located in specially designated rooms. These rooms are to be designated single patient rooms.

The Radiation Protection Program staff will make radiation exposure measurements in the patient's room following ^{131}I administration and will record these measurements on the radiation protection survey form which will be attached to the patient's chart. The Radiation Protection Program is responsible for preparing the patient's room for ^{131}I therapy. This room preparation includes the application of protective covering to the floor area around the toilet and sink, under the urine container, walk area from bed to bathroom, etc.

Posting of Patient Room

Radiation caution signs are to be posted on the door of the patient's room (Caution Radiation Area and Caution Radioactive Material) by the Radiation Protection Program staff and are not to be removed until the patient is discharged and Radiation Protection Program staff have made a final radiation survey of the patient's room. The appropriate radiation caution signs will be provided to the nursing station by the Radiation Protection Program.

Personnel Monitoring

The RPP will provide film badges for each individual caring for the patient. Individuals who wear a film badge monitor must complete a request card listing the required information. The request card and film badge must be returned to the Radiation Protection Program upon release of the patient, or completion of the patient therapy. It is important that each individual wear only the film badge dosimeter assigned to her or him.

Radiation Exposure to Fertile and Pregnant Women

Based on the recommendation of the National Council on Radiation Protection (NCRP), and on a recent regulatory guide of the Nuclear Regulatory Commission, it is recommended that pregnant women should limit their radiation dose to 500 mrem or less during the entire period of gestation. The reason for the recommendation is the increased sensitivity of the human embryo and developing fetus to radiation damage; this is particularly true during the first trimester of pregnancy. Because a woman often does not know she is pregnant during the period of greatest radiation sensitivity for the fetus (first trimester) the regulatory guide implies that each fertile woman be informed of the recommendation to limit her exposure to 500 mrem or less during the gestation period. It is the policy of the University that pregnant women not be assigned to care for patients where ionizing radiation is involved. Also, pregnant women should not be allowed to visit in a patient's room.

Baths

The patient should have a bath prior to administration of ^{131}I therapy to eliminate the need for a bath during therapy. The radiation levels around the patient during therapy are high and would unnecessarily expose the staff person assisting with the bath.

Linen

All the patient's linen shall be put in a properly labeled laundry bag and placed in the far corner of the room, or in the private bath if such is provided. The Radiation Protection Program may modify this procedure.

No bedding, clothing or any other materials are to be removed from the patient's room without first being monitored by the Radiation Protection Program staff person. Disposable gloves should be worn by the nurse and her/his hands should be washed after changing linen. Gloves should be placed in the designated disposal bag in the room.

Dietary

The ^{131}I will be found in the saliva; consequently, paper plates and cups and disposable knives and forks should be used. Food and beverages remaining in the dishes, as well as the paper dishes, may be disposed of in the regular manner and should not be kept in the room.

Facial tissue, etc., which have come in contact with the person's mouth should be placed in a plastic bag. A plastic bag should be taped to the bedside stand for collecting these potentially contaminated materials. All radioactive bags and other containers must be labeled with Caution Radioactive Material signs and left in the patient's room.

Excrement

The patient is to be instructed concerning the need for care in transfer of the urine to the collection container to minimize spillage. The patient should wash his or her hands thoroughly following toilet use.

The urine will be grossly contaminated and every precaution must be taken to prevent spillage and contamination of the hands or clothing. A large mouth urine bottle for

Excrement (cont.)

collection of the contaminated urine will be provided by the RPP. This container should be kept in the patient's bathroom. A disposable plastic toilet insert should be used to facilitate urine collection, and the urine emptied into the collection bottle. The patient must be instructed not to overfill the container and to notify the nursing staff when the container is nearly full. The nursing staff will contact the Radiation Protection Program for instructions. Fecal contamination of the urine must be prevented.

If a catheter is used, the urine will be collected in a non-breakable bottle, which should be placed in a tray to collect the urine in case the bottle should break. The catheter should be kept after use for disposal.

Lab Work

All body fluid samples (blood, urine, spinal, abd., etc.) withdrawn from an ^{131}I therapy patient are to be considered radioactive. These samples must be labeled with radiation caution tape before they leave the station. Contact the Radiation Protection Program at 626-6002 before any sample that might be contaminated with ^{131}I leaves the station.

Because of the excretion route of ^{131}I from the body, additional radiation protection precautions may be necessary for urine samples that are taken from the patient within four days after administration. If it is necessary to collect a urine sample within this period, contact the Radiation Protection Program for instructions and monitoring of the sample before it is sent to the laboratory.

Visitors

Visitors should sit as far from the patient as possible (not closer than 6 feet). The nurse will instruct visitors in proper precautions. Nothing in the room should be handled by visitors. No pregnant visitors or persons under 18 years of age are to be allowed in the patient's room. Visiting time must be limited to 1/2 hour per day.

Procedures for Transport of ^{131}I Therapy Patients

The Division of Nuclear Medicine has indicated that ^{131}I patients must be scanned prior to release from the hospital. This procedure will normally be conducted immediately preceding patient release. The following will be the procedure for transporting the patient from the nursing station to the Nuclear Medicine Clinic:

1. The Radiation Protection Program staff member will notify the Nuclear Medicine Clinic when the patient's ^{131}I dose has decreased to a level which will allow patient release.
2. The Nuclear Medicine Clinic will call the station and request that the patient be brought to the clinic for the scan.
3. A staff person on the station will be responsible for transporting the patient. The patient may be released directly from the Nuclear Medicine Clinic.
4. A wheel chair should be used to transport the patient and must be labeled with a Caution Radiation Area sign, which may be hand-held by the patient and should be clearly visible. The patient should also be instructed to thoroughly wash his or her hands prior to transport.

Transport (cont.)

5. The staff person must wear a film badge dosimeter while transporting the patient, and should walk as far behind the wheel chair as possible to maximize the distance from the patient.
6. When using the elevator, the staff person should allow no other individual on the elevator with the patient.
7. In the event that the Nuclear Medicine Clinic must scan the patient before the ^{131}I activity has decreased to the patient discharge level, it will be necessary for the station staff person to return to the clinic and transport the patient back to the station following the same procedures as listed above.

Final Survey of the Patient's Room

The Radiation Protection Program staff will measure the radiation level from the patient and determine when the residual ^{131}I activity in the patient is at 30 millicuries. The RPP will inform the Division of Nuclear Medicine, which will instruct the station relative to the discharge of the patient.

When the patient is discharged, the Radiation Protection Program staff person will make a complete contamination survey of the patient's room. The room must not be assigned to another patient until after it has been decontaminated by the Radiation Protection Program. A copy of the final room survey will be kept on file by the RPP.

Radiation Isolation

If the patient remains in the hospital for an extended period of time, radiation isolation may be discontinued based on radiation exposure measurements made by Radiation Protection Program staff.

Emergency Procedures

In cases of the following emergencies, contact both the Radiation Protection Program (626-6002) and the Division of Nuclear Medicine (626-3205). If the emergency occurs after normal working hours, call the University emergency notification number, 123 and inform the operator that you have a radiation emergency. Give your name, station, patient room number, a telephone number at which you may be reached, and a brief description of the emergency.

1. If the patient should vomit following the administration of the ^{131}I.
2. If radioactive urine is spilled or if the collection container is broken.
3. In the event of emergency surgery for the patient.
4. In the event of death of the patient.
5. In the event that a patient needs to be resuscitated (refer to the appropriate section of station manual).

Do not attempt to clean up urine spills or vomitus, but restrict access to the spill area.

If questions arise regarding these ^{131}I therapy procedures, please contact the Radiation Protection Program at 626-6002.

VI. CONTROL OF AEROSOLS AND GASES

(Part 35.205)

A. All Nuclear Medicine Rooms in which radioactive gases are used (Xe-133) must be under negative pressure. The RPP will check negative pressure in use areas monthly (see weekly contamination survey form).

B. The Radiation Protection Program will measure the ventilation rates in administration rooms of aerosols and gases every six months with a velometer. (See following form.) The Radiopharmaceutical Prep Lab. hood will also be checked every six months.

VENTILATON RATES
IN RADIOACTIVE GAS USE AREAS

Room Number:	Velometer reading:
PREP LAB	_____fpm
2-442 (RM 2)	_____fpm
2-446 (RM 4)	_____fpm
2-448 (RM 5)	_____fpm
_____	_____fpm
_____	_____fpm
_____	_____fpm

Comments:

Signature of RPP rep._____ Date:_____

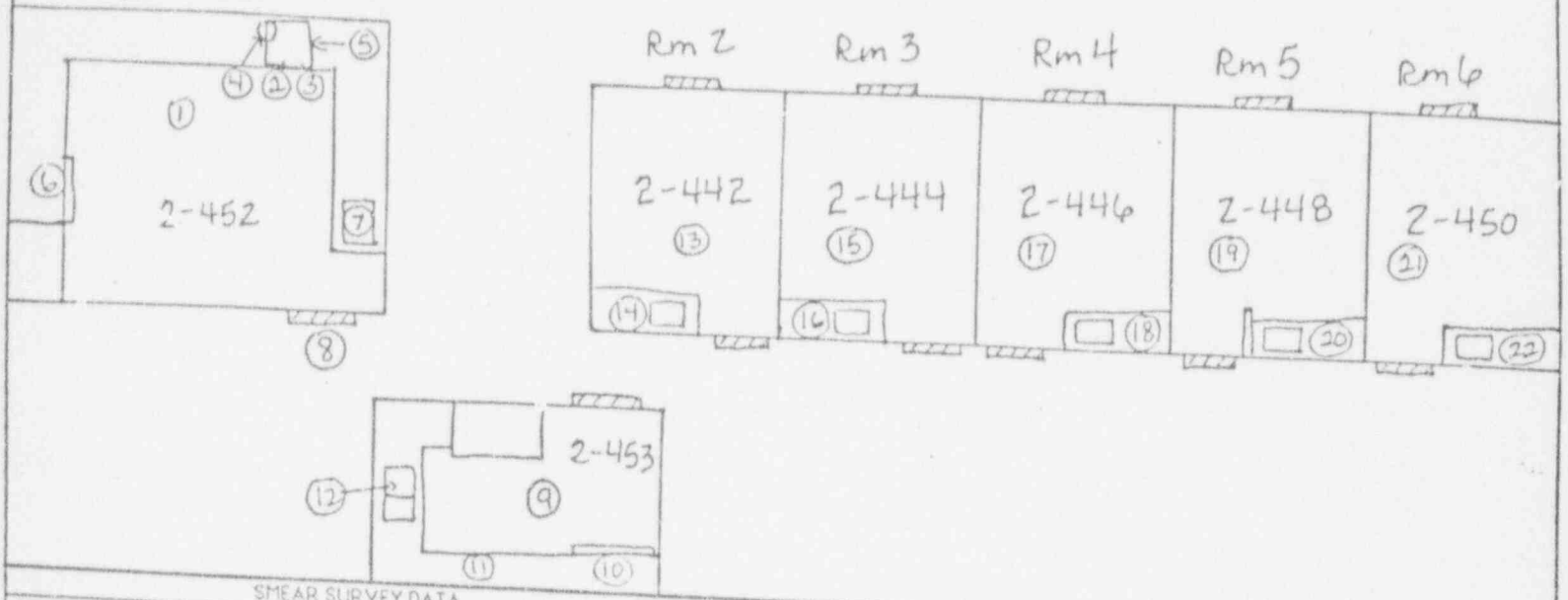
APPROVED USER: Dr. Boud[redacted]u | DEPT: [redacted]Nuclear Medicine

SURVEYED BY: Radiation Protection Program | SURVEY TYPE: Weekly | DATE

BUILDING: Health Science - Unit J | ROOM NUMBER: see below

MAP OF ROOM(S) - CLEARLY INDICATE ALL ROOM NUMBERS

Hot Lab



SMEAR SURVEY DATA

RADIOISOTOPE(S) ANALYZED:

% EFFICIENCY FOR RADIOISOTOPE(S):

INSTRUMENT USED:

BACKGROUND (CPM): | MDA (minimum detectable counts):

NO	LOCATION	CPM/100cm²
1	floor	
2	glass, outside	
3	glass, inside	
4	syringe bucket	
5	dose calibrator buttons	
6	hood	
7	sink	
8	hallway floor	
9	floor	
10	hood	
11	bench	
12	sink	
13	floor	
14	countertop / sink area	
15	floor	
16	countertop / sink area	
17	floor	
18	countertop / sink area	
19	floor	
20	countertop / sink area	
21	floor	
22	countertop / sink area	

COMMENTS

PORTABLE G-M SURVEY DATA

INSTRUMENT USED:

BACKGROUND (CPM) or (mr/hr):

NO	LOCATION	CPM/100cm² or (mr/hr)

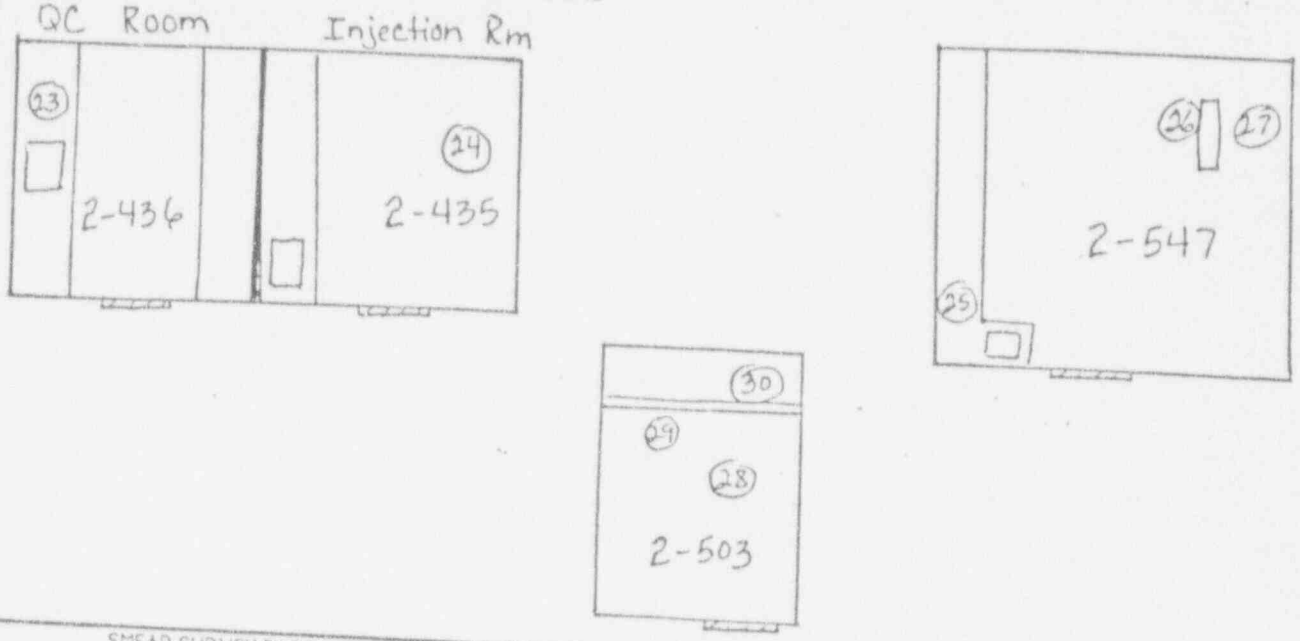
NO EATING, DRINKING, SMOKING, MOUTH PIPETTING OK?	Y	N	na
WASTE STORAGE OK?	Y	N	na
NEW H2O SOLUBLE SCINT. FLUID ?	Y	N	na
INVENTORY RECORDS OK?	Y	N	na
QUARTERLIES OK?	Y	N	na
NEW MANUAL IN LAB?	Y	N	na

APPROVED USER: Dr. Boudreau | DEPT: Nuclear Medicine

SURVEYED BY: Radiation Protection | SURVEY TYPE: Weekly | DATE

BUILDING: Health Science - Unit J | ROOM NUMBER: See below

MAP OF ROOM(S) - CLEARLY INDICATE ALL ROOM NUMBERS



SMEAR SURVEY DATA

RADIOISOTOPE(S) ANALYZED:

% EFFICIENCY FOR RADIOISOTOPE(S):

INSTRUMENT USED:

BACKGROUND (CPM): | MDA (minimum detectable counts):

NO	LOCATION	CPM/100cm²
23	countertop / sink area	
24	injection table arm	
25	countertop / sink area	
26	treadmill	
27	floor near treadmill / injection site	
28	floor	
29	top of waste cans	
30	Pb & generators	

Negative Pressure Checks

Rm #	Evac. times posted?	
Prep Lab.	Y	N
2-442 (Rm2)	Y	N
2-446 (Rm4)	Y	N
2-448 (Rm5)	Y	N

PORTABLE G-M SURVEY DATA

INSTRUMENT USED:

BACKGROUND (CPM) or (mr/hr):

NO	LOCATION	CPM/100cm² or (mr/hr)

NO EATING, DRINKING, SMOKING, MOUTH PIPETTING OK?	Y	N	na
WASTE STORAGE OK?	Y	N	na
NEW H2O SOLUBLE SCINT. FLUID?	Y	N	na
INVENTORY RECORDS OK?	Y	N	na
QUARTERLIES OK?	Y	N	1
NEW MANUAL IN LAB?	Y	N	na

COMMENTS

EVACUATION TIME = 30 MINUTES

In the event of an accidental release of Xe-133, close all doors and evacuate this room for 30 minutes. Restrict access. Radiation exposure rate measurements must be made upon re-entry. Do not re-enter unless the exposure reading is below 0.5 mR/hr. Call the Radiation Protection Program at 626-6002 for assistance.

*This sign is posted in rooms were Xe-133 is used.

VII. REPORTS OF MISADMINISTRATIONS

(Part 35.33)

A. In the event of a misadministration involving a therapeutic or a diagnostic procedure, the Radiation Safety Officer (RSO) will immediately investigate the cause.

B. The RSO will make a record for NRC review (see the following example).

C. If required by the regulations of Part 35.33 the NRC will be notified.

D. The case will be reviewed and, if necessary, action will taken to prevent a recurrence.

E. All records of misadministrations will be retained for 10 years.

NRC FORM 473
(5-88)
10 CFR § 35.33

U.S. NUCLEAR REGULATORY COMMISSION
Approved by OMB
3150-0130
Expires 5-31-91

DIAGNOSTIC MISADMINISTRATION REPORT

(N1) LICENSEE NAME

(N2) LICENSE NUMBER

(N3) CITY

(N4) STATE

(N5) EVENT DATE — MONTH DAY YEAR

(N6) REPORT DATE — MONTH DAY YEAR

(N7) TYPE OF MISADMINISTRATION
- (01) WRONG RADIOPHARMACEUTICAL
- (02) DOSAGE DIFFERING FROM PRESCRIBED BY 50%
- (03) WRONG PATIENT
- (04) WRONG ROUTE

(N8) DID THE MISADMINISTRATION INVOLVE AN ISOTOPE OF IODINE
- (999) YES
- (111) NO

(N9) NUMBER OF PATIENTS WHO RECEIVED A MISADMINISTRATION UNDER THIS REPORT

(N10) INTENDED
- (05) NO CLINICAL PROCEDURE
- (06) NUCLEAR MEDICINE STUDY (Complete (N10A) INTENDED and (N11) GIVEN)
- (07) X-RAY STUDY
- (08) ULTRASOUND STUDY
- (09) CT STUDY
- (10) NMR STUDY
- (11) OTHER

(N10A) INTENDED				(N11) GIVEN			
MILLICURIES	ISOTOPE	CHEMICAL FORM	STUDY	MILLICURIES	ISOTOPE	CHEMICAL FORM	STUDY

(N12) PRECIPITATOR
- (71) REFERRING PHYSICIAN
- (72) WARD NURSE
- (73) WARD CLERK
- (74) NUCLEAR PHARMACY
  - NAME OF NUCLEAR PHARMACY
  - CITY
  - STATE
- (75) AUTHORIZED USER
- (76) HOT LAB TECHNOLOGIST
- (77) IMAGING TECHNOLOGIST
- (78) CLINIC RECEPTIONIST
- (79) SCHEDULING TECHNOLOGIST
- (80) PATIENT
- (81) OTHER

(N13) ERROR

HOT LAB
- (11) MISLABELED A SYRINGE
- (12) MISLABELED A VIAL OR VIAL SHIELD
- (13) RECONSTITUTED WRONG REAGENT KIT
- (14) PLACED RECONSTITUTED VIAL IN WRONG SHIELD
- (15) SELECTED WRONG VIAL WHEN DRAWING DOSAGE
- (16) SET DOSE CALIBRATOR IMPROPERLY
- (17) MISREAD DOSE CALIBRATOR
- (18) MISUNDERSTOOD RADIOPHARMACEUTICAL OR DOSAGE ORDER

REFERRAL
- (20) MISUNDERSTOOD REFERRING PHYSICIAN'S REQUEST
- (21) REQUESTED WRONG STUDY
- (22) REQUESTED STUDY FOR WRONG PATIENT

ADMINISTRATION
- (30) SELECTED WRONG PATIENT
- (31) ANSWERED WAITING ROOM PAGE INTENDED FOR OTHER PATIENT
- (32) BROUGHT WRONG PATIENT TO CLINIC
- (33) SELECTED WRONG SYRINGE FROM DOSAGE CART

OTHER
- (40) Specify

(N14) CONTRIBUTING FACTORS
- (80) STUDENT TECHNOLOGIST
- (81) NEW EMPLOYEE
- (82) FOREIGN LANGUAGE
- (83) PATIENT INCOHERENT OR UNCONSCIOUS
- (84) ID BRACELET NOT CHECKED
- (85) REQUISITION NOT CHECKED
- (86) PATIENT CHART NOT CHECKED
- (87) NEW PROCEDURE
- (88) HEAVY WORKLOAD
- (89) OTHER

(N15) ACTION TAKEN TO PREVENT RECURRENCE
- IMPLEMENT NEW PROCEDURES FOR
  - (C1) VERIFICATION OF REQUEST
  - (C2) RADIOPHARMACEUTICAL LABELING AND HANDLING
  - (C3) VERIFICATION OF PATIENT IDENTIFICATION
- (C4) REINSTRUCT PERSONNEL
- (C5) REPRIMAND PERSONNEL
- (C6) IMPROVE SUPERVISION OF PERSONNEL
- (C7) NO ACTION
- (C8) OTHER

(N16) EFFECT ON PATIENTS
- NONE APPARENT
- SEE ABSTRACT

(N17) ABSTRACT *(If more space is required, attach additional sheets.)*

RADIATION OFFICER (Printed Name) | SIGNATURE | TELEPHONE | DATE

NUCLEAR REGULATORY COMMISSION USE

(N18)	(N19) AS	(N20) REGIONAL LOG NUMBER	(N21) ACCESSION NUMBER	(N22) INITIALS
(999) YES (111) NO				

Report of a Misadministration

Involving a Therapy Procedure

Licensee: University of Minnesota
Department of Radiology
Division of Nuclear Medicine

Referring physician: _____

Description of event:

Effect on the patient:

Action taken to prevent reoccurrence:

Was the patient informed? If not, why not?

Signature: _____ Date: _____
(Radiation Safety Officer)

Signature: _____ Date: _____
(Physician)

Signature: _____ Date: _____
(Radiation Protection Committee Chair)

VIII. ANNUAL REVIEW

The Radiation Protection Program will conduct an annual audit of the Nuclear Medicine Department. This annual compliance meeting with Nuclear Medicine staff will include suggestions for maintaining exposure rates ALARA, continuing education, and a review of dosimeter readings. A record of the summary of each annual review will be retained in this manual.

NUCLEAR MEDICINE DEPARTMENT
ANNUAL REVIEW

Are the following records up-to-date?:

Training Records	Y	N
Log of Receipt of Radioactive Materials	Y	N
Delivery Records	Y	N
Shipment Surveys	Y	N
Non-Tc Dispensing Records	Y	N
Daily Surveys	Y	N
Radiopharmaceutical Records	Y	N
Dose Calibrator Records:		
Daily constancy check	Y	N
Quarterly accuracy check	Y	N
Quarterly linearity test	Y	N
Dosimetry Reports ALARA	Y	N
Survey Meters Calibrated	Y	N
Quarterly Inventory of Sealed Sources	Y	N
Sealed Source Leak Tests	Y	N
Weekly Smear Surveys	Y	N

COMMENTS:

Signature of RSO: _____ Date: _____

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUN 2 4 1988

TO: Medical Use Licensees

FROM: Vandy L. Miller, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

SUBJECT: DIAGNOSTIC MISADMINISTRATION REPORT FORM, NRC FORM 473

This is to inform medical use licensees of the development and availability of NRC Form 473. Medical use licensees must use this form to report diagnostic misadministrations.

When it approved the revision of 10 CFR Part 35, the Commission directed the staff to develop a form for reporting diagnostic misadministrations. The revised rule, without an NRC form number, became effective in April, 1987. The Office of Management and Budget has approved the form and the form number was recently announced in the Federal Register. A copy of the Federal Register notice announcing the form and a copy of the form are enclosed for your convenience.

Please note that the use of NRC Form 473 is required for reporting diagnostic misadministrations. You may refer to 10 CFR 35.33(c), also enclosed, for this requirement.

If you have additional questions concerning the use of NRC Form 473, please contact Jim Myers at (301)-492-0637.

Vandy L. Miller, Chief
Medical, Academic and Commercial
Use Safety Branch,
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosures:
1. NRC Form 473
2. Federal Register Notice (53 FR 21627)
3. 10 CFR 35.33(c)

NRC FORM 473
(5-88)
10 CFR § 35

U.S. NUCLEAR REGULATORY COMMISSION
Approved by OMB
3150-0110
Expires 5/31/91

DIAGNOSTIC MISADMINISTRATION REPORT

(N1) LICENSEE NAME

(N2) LICENSE NUMBER

(N3) CITY

(N4) STATE

(N5) EVENT DATE — MONTH DAY YEAR

(N6) REPORT D — MONTH DAY YEAR

(N7) TYPE OF MISADMINISTRATION
- (01) WRONG RADIOPHARMACEUTICAL
- (02) DOSAGE DIFFERING FROM PRESCRIBED BY 50%
- (03) WRONG PATIENT
- (04) WRONG ROUTE

(N8) DID THE MISADMINISTRATION INVOLVE AN ISOTOPE OF IODINE
- (999) YES
- (111) NO

(N9) NUMBER OF PATIENTS WHO RECEIVED A MISADMINISTRATION UNDER THIS REPORT

(N10) INTENDED
- (05) NO CLINICAL PROCEDURE
- (06) NUCLEAR MEDICINE STUDY (Complete (N10A) INTENDED and (N11) GIVEN)
- (07) X-RAY STUDY
- (08) ULTRASOUND STUDY
- (09) CT STUDY
- (10) NMR STUDY
- (11) OTHER

(N10A) INTENDED				(N11) GIVEN			
MILLICURIES	ISOTOPE	CHEMICAL FORM	STUDY	MILLICURIES	ISOTOPE	CHEMICAL FORM	STUDY

(N12) PRECIPITATOR
- (71) REFERRING PHYSICIAN
- (72) WARD NURSE
- (73) WARD CLERK
- (74) NUCLEAR PHARMACY
  - NAME OF NUCLEAR PHARMACY
  - CITY
  - STATE
- (75) AUTHORIZED USER
- (76) HOT LAB TECHNOLOGIST
- (77) IMAGING TECHNOLOGIST
- (78) CLINIC RECEPTIONIST
- (79) SCHEDULING TECHNOLOGIST
- (80) PATIENT
- (81) OTHER

(N13) ERROR

HOT LAB
- (11) MISLABELED A SYRINGE
- (12) MISLABELED A VIAL OR VIAL SHIELD
- (13) RECONSTITUTED WRONG REAGENT KIT
- (14) PLACED RECONSTITUTED VIAL IN WRONG SHIELD
- (15) SELECTED WRONG VIAL WHEN DRAWING DOSAGE
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- (17) MISREAD DOSE CALIBRATOR
- (18) MISUNDERSTOOD RADIOPHARMACEUTICAL OR DOSAGE ORDER

REFERRAL
- (20) MISUNDERSTOOD REFERRING PHYSICIAN'S REQUEST
- (21) REQUESTED WRONG STUDY
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ADMINISTRATION
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OTHER
- (40) Specify

(N14) CONTRIBUTING FACTORS
- (80) STUDENT TECHNOLOGIST
- (81) NEW EMPLOYEE
- (82) FOREIGN LANGUAGE
- (83) PATIENT INCOHERENT OR UNCONSCIOUS
- (84) ID BRACELET NOT CHECKED
- (85) REQUISITION NOT CHECKED
- (86) PATIENT CHART NOT CHECKED
- (87) NEW PROCEDURE
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(N15) ACTION TAKEN TO PREVENT RECURRENCE
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  - (C2) RADIOPHARMACEUTICAL LABELING AND HANDLING
  - (C3) VERIFICATION OF PATIENT IDENTIFICATION
- (C4) REINSTRUCT PERSONNEL
- (C5) REPRIMAND PERSONNEL
- (C6) IMPROVE SUPERVISION OF PERSONNEL
- (C7) NO ACTION
- (C8) OTHER

(N16) EFFECT ON PATIENTS
- NONE APPARENT
- SEE ABSTRACT

(N17) ABSTRACT (If more space is required, attach additional sheets.)

RADIATION OFFICER (Printed Name) | SIGNATURE | TELEPHONE | DATE

NUCLEAR REGULATORY COMMISSION USE

(N18)	(N19) AS	(N20) REGIONAL LOG NUMBER	(N21) ACCESSION NUMBER	(N22) INITIALS
(999) YES (111) NO				

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

Diagnostic Misadministration Report Form

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations for the medical use of byproduct material to indicate the form to be used for reporting diagnostic misadministrations. This action is intended to inform the public of the development and availability of the form that medical licensees must use to meet this reporting requirement.

EFFECTIVE DATE: June 9, 1988.

ADDRESSES: A copy of Form NRC 473 may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, DC. Single copies are available from James H. Myers, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492–0635.

FOR FURTHER INFORMATION CONTACT: James H. Myers, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492–0635.

SUPPLEMENTARY INFORMATION: The NRC amended its regulations for the medical use of byproduct material to require licensees to report certain diagnostic misadministrations to the NRC on a special NRC form. This matter was discussed in the final rule revising 10 CFR Part 35 (51 FR 36932, October 16, 1986).

The NRC staff has developed the form, and the Office of Management and Budget (OMB) has approved its use. The NRC is amending its regulations to insert the form number in the regulatory text. A copy of the form will be mailed to NRC medical use licensees.

This amendment is a minor administrative change to an existing final rule. It merely adds the form number for an NRC form to the codified rule. The number had been omitted because OMB had not completed its review. Based on this, good cause exists to find that the notice and public procedure provisions of the Administrative Procedure Act are unnecessary pursuant to the exemption provision found in 5 U.S.C. 553(b)(B). Therefore, the amendment is effective upon publication in the Federal Register.

Administrative Statements

Environmental Impact: Categorical Exclusion.

The NRC has determined that this regulation is the type of action described in categorical exclusion 10 CFR 51.22(c)(3). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget under OMB Number 3150–0140.

List of Subjects in 10 CFR Part 35

Byproduct material, Drugs, Health facilities, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

Regulatory Text

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553 the NRC is adopting the following amendment to 10 CFR Part 35.

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

1. The authority citation for Part 35 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

§ 35.33 [Amended]

2. In § 35.33, paragraph (c) is amended by removing footnote 1 and by inserting "Form NRC 473" in place of "Form NRC ___" in the second sentence.

Dated at Rockville, MD, this 27th day of May 1988.

For the Nuclear Regulatory Commission.

Victor Stello, Jr.,

Executive Director for Operations.

[FR Doc. 88–12965 Filed 6–8–88; 8:45 am]

BILLING CODE 7590-01-M

§ 35.33 Records and reports of misadministrations.

(a) When a misadministration involves any therapy procedure, the licensee shall notify by telephone the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian), unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.

(b) Within 15 days after an initial therapy misadministration report to NRC, the licensee shall report, in writing, to the NRC Regional Office initially telephoned and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee under paragraph (a) of this section. The written report must include the licensee's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report must not include the patient's name or other information that could lead to identification of the patient.

(c) When a misadministration involves a diagnostic procedure, the Radiation Safety Officer shall promptly investigate its cause, make a record for NRC review, and retain the record as directed in § 35.33(d). The licensee shall also notify the referring physician and the appropriate NRC Office specified in § 30.6 of this part in writing on Form NRC——— within 15 days if the misadministration involved the use of byproduct material not intended for medical use, administration of a dosage five-fold different from the intended dosage, or administration of byproduct material such that the patient is likely to receive an organ dose greater than 2 rem or a whole body dose greater than 500 millirem. Licensees may use dosimetry tables in package inserts, corrected only for amount of radioactivity administered, to determine whether a report is required.

(d) Each licensee shall retain a record of each misadministration for ten years. The record must contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence.

(e) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients, or responsible relatives (or guardians).

the license, showing for each sealed source the following information:

* * * * *

29. In § 34.28, paragraph (b) is revised to read as follows:

§ 34.28 Inspection and maintenance of radiographic exposure devices, storage containers, and source changers.

* * * * *

(b) The licensee shall conduct a program for inspection and maintenance of radiographic exposure devices, storage containers, and source changers at intervals not to exceed three months or prior to the first use thereafter to ensure proper functioning of components important to safety. The licensee shall retain records of these inspections and maintenance for three years.

30. In § 34.29, paragraph (c) is revised to read as follows:

§ 34.29 Permanent radiographic installations.

* * * * *

(c) The alarm system must be tested at intervals not to exceed three months or prior to the first use thereafter of the source in the installation. The licensee shall retain records of these tests for three years.

31. In § 34.32, the introductory paragraph is revised to read as follows:

§ 34.32 Operating and emergency procedures.

The licensee shall retain a copy of current operating and emergency procedures as a record until the Commission terminates the license that authorizes the activity for which the procedures were developed and, if superseded, retain the superseded material for three years after each change. These procedures must include instructions in at least the following:

* * * * *

32. In § 34.33, paragraphs (b) and (e) are revised to read as follows:

§ 34.33 Personnel monitoring.

* * * * *

(b) Pocket dosimeters must be read and exposures recorded daily. The licensee shall retain each record of these exposures for three years after the record is made.

* * * * *

(e) Reports received from the film badge or TLD processor must be retained for inspection until the Commission terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

33. The authority citation for Part 35 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

34. A new § 35.5 is added to read as follows:

§ 35.5 Maintenance of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

§ 35.27 [Amended]

35. Section 35.27 paragraph (c) is amended by changing "two years" to "three years."

§ 35.29 [Amended]

36. Section 35.29, paragraph (b) is amended by changing "two years" to "three years."

§ 35.50 [Amended]

37. Section 35.50, paragraph (e) introductory text is amended by changing "two years" to "three years."

§ 35.51 [Amended]

38. Section 35.51, paragraph (d) introductory text is amended by changing "two years" to "three years."

§ 35.53 [Amended]

39. Section 35.53, paragraph (c) introductory text is amended by changing "two years" to "three years."

§ 35.59 [Amended]

40. Section 35.59, paragraph (i) is amended by changing "two years" to "three years."

§ 35.70 [Amended]

41. Section 35.70, paragraph (h) is amended by changing "two years" to "three years."

§ 35.80 [Amended]

42. Section 35.80, paragraph (f) is amended by changing "two years" to "three years."

§ 35.92 [Amended]

43. Section 35.92, paragraph (b) is amended by changing "two years" to "three years."

§ 35.204 [Amended]

44. Section 35.204, paragraph (c) is amended by changing "two years" to "three years."

§ 35.310 [Amended]

45. Section 35.310, paragraph (b) is amended by changing "two years" to "three years."

§ 35.315 [Amended]

46. Section 35.315, paragraph (a)(4) is amended by changing "two years" to "three years."

§ 35.404 [Amended]

47. Section 35.404, paragraph (b) is amended by changing "two years" to "three years."

§ 35.406 [Amended]

48. Section 35.406, paragraph (d) is amended by changing "two years" to "three years."

§ 35.410 [Amended]

49. Section 35.410, paragraph (b) is amended by changing "two years" to "three years."

§ 35.415 [Amended]

50. Section 35.415, paragraph (a)(4) is amended by changing "two years" to "three years."

§ 35.610 [Amended]

51. Section 35.610, paragraph (c) is amended by changing "two years" to "three years."

§ 35.615 [Amended]

52. Section 35.615, paragraph (d)(4) is amended by changing "two years" to "three years."

§ 35.634 [Amended]

53. Section 35.634, paragraph (c) is amended by changing "two years" to "three years."

54. Section 35.634, paragraph (f) is amended by changing "two years" to "three years."

§ 35.636 [Amended]

55. Section 35.636, paragraph (c) is amended by changing "two years" to "three years."

UNIVERSITY OF MINNESOTA
TWIN CITIES

Department of Environmental Health and Safety
Boynton Health Service, Room W-140
410 Church Street S.E.
Minneapolis, Minnesota 55455
(612) 373-3167

July 18, 1986

Dr. William Adam
Materials Licensing Section
Region III USNRC
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Dr. Adam:

In response to your request for additional information pertaining to our April 1, 1986 letter for amendment of NRC License #22-00218-29 (Control #81042), the following information is provided concerning use of Xe-133 in the new University of Minnesota Nuclear Medicine facilities.

The assure that air concentrations of radioactive gases (e.g., Xe-133) are within MPC limits, air measurements were made in all rooms in the new Nuclear Medicine imaging areas where Xe-133 patient studies may be conducted. These rooms are 2-442, 2-444, 2-446, 2-448, 2-450 and 2-547 Unit J. All rooms are under negative air pressure and contain a single 8" x 8" duct in which air is continuously flowing. During patient studies a flexible tube with a collection hood is attached to this duct and is placed in the patient's breathing zone to collect Xe-133 gases that may escape. Air flow measurements were made using a TSI Model 1650 air velometer. Each duct measured an average air flow volume of 222 ft^3/min. All calculations were made assuming a maximum load of 5 patients/month and a maximum activity of 20 mCi/patient.

The six ducts are individually connected to a central exhaust system which is single stacked to the roof. Release fractions to unrestricted and restricted areas were conservatively estimated as one.

Using the above-mentioned assumptions, the Xe-133 concentration in unrestricted areas was calculated to be 6.06×10^{-8} µCi/ml or nearly five times below the current MPC value for unrestricted areas (see attachment). Xe-133 concentration in restricted areas was 1.52×10^{-6} µCi/ml or approximately six times below the current MPC value for restricted areas (see attachment).

In the event the entire activity in a standard Xe-133 vial is accidentaly released (20 mCi), personnel will be instructed to evacuate the area, all doors will be closed and the area secured to restrict access. Assuming a total room volume of 2448 ft^3 (16 ft x 18 ft x 8.5 ft), the room would be restricted for approximately 20 min. to allow for the Xe-133 to be vented from the room via the room exhaust duct. Radiation exposure rate measurements will be made in the area before personnel are allowed to reenter.

If you have any questions, or if you need additional information, please contact me.

KN:bc
cc: Merle Loken, M.D., Ph.D.
Jim Tennison

Sincerely,
Kevin Nelson
Radiation Protection Officer

Xe-133 Unrestricted Area Calculation

The concentration of Xe-133 in unrestricted areas was determined by the following formula:

$$C = \frac{A}{V} f$$

where C = the average concentration in μCi/ml

A = maximum activity used per year

= 5 patients/month x 12 months x 20 mCi/patient

= 1200 mCi or 1.2×10^{6} μCi Xe-133

V = airflow per year

$$= 500 \text{ ft/min-duct} \times 0.67 \text{ ft.} \times 0.67 \text{ ft.} \times 6 \text{ ducts} \times \frac{1.484 \times 10^{10} \text{ ml/yr}}{1 \text{ ft}^3/\text{min}}$$

$= 1.98 \times 10^{13}$ ml/yr

f = release fraction

= 1

$$C = \frac{1.2 \times 10^{6} \text{ μCi}}{1.98 \times 10^{13} \text{ ml/yr}}$$

$= 6.06 \times 10^{-8}$ μCi/ml

Xe-133 Restriced Area Calculation

The concentration of Xe-133 in restricted areas was determined by the following formula:

$$C = \frac{A}{V} f$$

where

C = the average concentration in μCi/ml

A = maximum activity used per week

= 60 patients/yr x 1 year/52 weeks x 20000 μCi/patient

≅ 23,000 μCi/week

V = airflow per week

$$= 500 \text{ ft/min} \times 0.67 \times 0.67 \text{ ft} \times \frac{6.797 \times 10^{7} \text{ ml/40 hrs}}{\text{ft}^3/\text{min}}$$

$= 1.51 \times 10^{10}$ ml/wk

f = escape fraction

= 1

$$C = \frac{23{,}000 \text{ μCi/wk}}{1.51 \times 10^{10} \text{ ml/wk}} \quad (1)$$

$= 1.52 \times 10^{-6}$ μCi/ml

Proposed Rules

Federal Register
Vol. 52, No. 241
Wednesday, December 16, 1987

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

Control of Aerosols and Gases

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations governing the medical uses of byproduct material by removing the requirement that radioactive aerosols be administered to patients only in rooms that are at negative pressure relative to surrounding rooms. The proposed rule, developed in response to PRM-35-6, would allow the use of radioactive aerosols in locations such as intensive care units, critical care units, and patients' rooms. Evaluation of potential radiation hazards to hospital personnel showed minimal risk when a radioactive aerosol is used with a closed, shielded system either vented to the outside atmosphere through an air exhaust or a system which provides for collection and disposal of the aerosol. The proposed rule would allow physicians greater latitude in administering necessary clinical procedures to their patients. The proposed amendment clarifies that the requirement that certain medical procedures be performed only in rooms at negative pressure relative to surrounding rooms applies to radioactive gases but not to radioactive aerosols.

DATE: Comment period expires January 15, 1988. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Deliver comments to: Room 1121, 1717 I Street, NW., Washington, DC, between 7:30 a.m. and 4:15 p.m. weekdays.

FOR FURTHER INFORMATION CONTACT: Judith Foulke, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 443-7681.

SUPPLEMENTARY INFORMATION:

Background

In 1983, NRC began authorizing medical licensees to administer radioactive aerosols (see 48 FR 5217; February 4, 1983) to patients for diagnosing lung disease. The only safety measure required specific to this clinical procedure was that the licensee had to administer the radioactive aerosol "with a closed, shielded system that either is vented to the outside atmosphere through an air exhaust or provides for collection and disposal of the aerosol." (see 10 CFR 35.14(b)(8)). In a complete revision of 10 CFR Part 35, effective April 1, 1987, NRC added the requirement that aerosols be administered only in rooms that are at negative pressure (see § 35.205(b), 51 FR 36932; October 16, 1986). In response to a letter received in February 1987 that stated that application of the requirement would have a negative impact on health care delivery, medical licensees were temporarily exempted from the requirement in § 35.205(b) (see 52 FR 9292; March 24, 1987).

Petition for Rulemaking

On March 9, 1987, Mallinckrodt, Inc., submitted a petition for rulemaking which was docketed PRM-35-6 on March 11, 1987. A copy of the petition may be obtained from the Rules and Procedures Branch, Division of Rules and Records, Office of Administration and Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555. The petitioner requests that the Commission remove the requirement that radioactive aerosols be administered in rooms that are at negative pressure relative to surrounding rooms.

The petitioner submitted literature showing that, for many hospitals, TC-99m DTPA aerosol is the preferred lung ventilation imaging procedure. For critically ill patients who cannot be moved, it has been the only lung imaging technique available. If use of aerosols is restricted to negative pressure rooms, these patients would be deprived of the benefits of lung imaging.

The petitioner described a typical radioactive aerosol delivery system. Because the only radiation safety hazard is leakage of the aerosol, three potential leakage points external to the shield were identified in drawings. Two leakage points require patient compliance for safety; the frequencies of patient non-compliance based on clinical experience were 10% and 5%. Corresponding durations of leakage were 2-3 exhalations and 1-2 exhalations. These numbers were used to calculate the average administration loss per patient. This quantity was used to calculate the maximum number of clinical procedures that could be performed in an average room per week without exceeding the maximum permissible concentration for Tc-99m in an unrestricted area. The very large number (238) of treatments possible before exceeding the maximum permissible concentration greatly exceeds the busiest work load of 30 studies per week in a large hospital. The third potential leakage point is the junction between the manifold and the plastic patient breathing tube. Leakage has been found to be negligible during routine, proper use.

Conclusion

The NRC has examined Mallinckrodt's petition and supporting information and made a determination to grant the petition. The requirement for administering radioactive aerosols in rooms at negative pressure relative to their surroundings may adversely affect the public health and safety. Some patients requiring the clinical procedure cannot be moved safely to an appropriate room or another hospital that has the required facilities. These patients would not be able to be treated unless the restriction on the negative pressure is removed. Calculations show that worker health and safety does not require negative pressure rooms for administration of radioaerosols.

The NRC notes that relief from the negative pressure requirement of § 35.205(b) does not relieve licensees from the requirements to comply with other NRC regulations, orders, or license conditions limiting maximum permissible air concentrations in controlled and uncontrolled areas.

UNIVERSITY OF MINNESOTA
TWIN CITIES

Department of Environmental Health and Safety
Boynton Health Service, Room W-140
410 Church Street S.E.
Minneapolis, Minnesota 55455
(612) 373-3167

April 1, 1986

U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Section
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Gentlemen:

This letter is to inform you of a change in the location of Nuclear Medicine within the University Hospital. As of April 18, 1986, the Division will be relocated to facilities in the recently completed University Hospital (Unit J). Attached is a copy of the section of the second floor Unit J plan which shows the rooms (shaded areas) which the Division of Nuclear Medicine will occupy.

In addition to the rooms shown on the floor plan, Room 2-416 (across corridor #2-041 from Room 2-435) will also be assigned to this Division as a Bone Mineral Analysis Room. Room 2-503 is a locked storage room which will be used as the radioactive materials shipment receipt and holding area for the Division. The Hospital Information Desk will have delivery personnel place radioactive material shipments in this room and will notify Nuclear Medicine personnel of the receipt of shipments. The Radiation Protection Program will conduct an initial survey of all rooms and areas surrounding radioactive material use areas as soon as the move to the new location is completed.

The current use areas will remain posted and will be surveyed as use areas during the transition period. Following the completion of the move, the second floor Mayo use area will be closed-out and a final survey made of all rooms prior to removal of caution signage by the Radiation Protection Program.

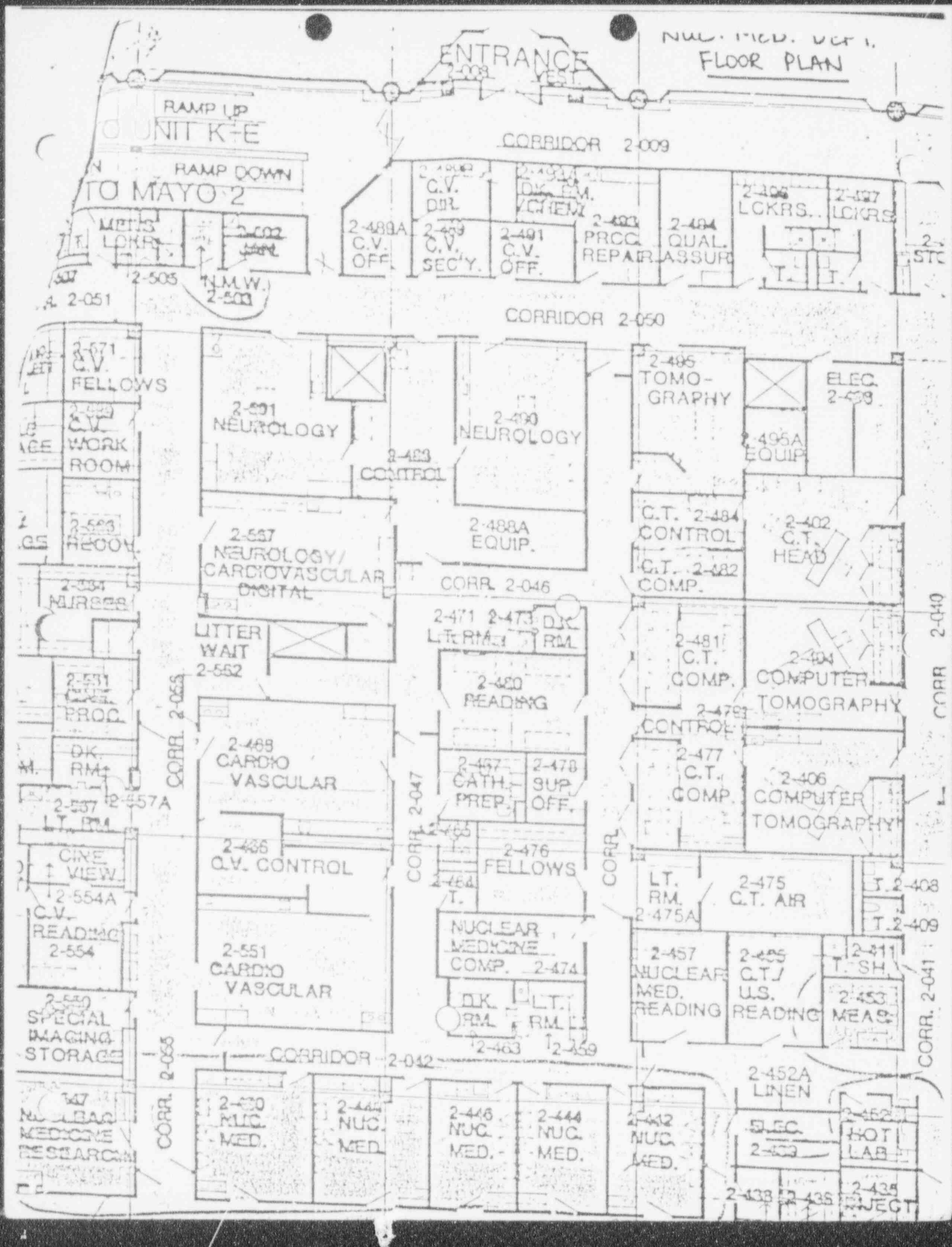
If you require any additional information, please contact me.

Sincerely,

Jerome W. Staiger

Jerome W. Staiger
Radiation Protection Officer

JWS:bc
Enclosure
cc: Dr. Eugene Gedgaudas
Dr. Merle Loken
Jim Tennison


NUC. MED. DEPT.
FLOOR PLAN
ENTRANCE
2-008
RAMP UP
UNIT K-E
RAMP DOWN
TO MAYO 2
MEN'S LOKR.
2-502
2-505
W.M.W.
2-503
2-051
CORRIDOR 2-009
C.V. DIR.
2-489A C.V. OFF.
2-489 C.V. SEC'Y.
2-491 C.V. OFF.
PRCC REPAIR
QUAL. ASSUR
LCKRS.
LCKRS
CORRIDOR 2-050
2-671 C.V. FELLOWS
C.V. WORK ROOM
2-563 RECOV.
2-554 NURSES
2-531 PROC.
DK. RM.
2-557A
2-557 LT. RM.
CINE VIEW
2-554A C.V. READING
2-554
2-550 SPECIAL IMAGING STORAGE
2-491 NEUROLOGY
2-490 NEUROLOGY
2-493 CONTROL
2-488A EQUIP.
2-557 NEUROLOGY/ CARDIOVASCULAR DIGITAL
LITTER WAIT
2-552
CORR. 2-046
2-471 2-473 DK. LT. RM.
2-420 READING
2-469 CARDIO VASCULAR
2-436 C.V. CONTROL
2-551 CARDIO VASCULAR
2-457 CATH. PREP.
2-478 SUP. OFF.
2-455
2-476 FELLOWS
2-454
T.
NUCLEAR MEDICINE COMP. 2-474
DK. RM.
LT. RM.
2-463
2-459
CORR. 2-055
CORR. 2-047
CORR.
2-495 TOMO-GRAPHY
ELEC. 2-499
2-495A EQUIP.
C.T. 2-484 CONTROL
2-402 C.T. HEAD
C.T. 2-482 COMP.
2-481 C.T. COMP.
2-404 COMPUTER TOMOGRAPHY
2-479 CONTROL
2-477 C.T. COMP.
2-406 COMPUTER TOMOGRAPHY
LT. RM. 2-475A
2-475 C.T. AIR
T. 2-408
T. 2-409
2-457 NUCLEAR MED. READING
2-455 C.T./ U.S. READING
2-411 T. SH.
2-453 MEAS.
CORR. 2-040
CORR. 2-041
CORRIDOR 2-012
2-452A LINEN
2-452
ELEC. 2-433
HOT LAB
2-438
2-435
INJECT.
2-430 NUC. MED.
2-444 NUC. MED.
2-446 NUC. MED.
2-448 NUC. MED.
2-442 NUC. MED.
CORR. 2-065

and if Rm 2-416 is used for Nuc Med exams

copy to Rick + Tom

"Mobile nuclear medicine service" means the transportation and medical use of byproduct material.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

"Podiatric use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of podiatry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

"Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

"Radiation Safety Officer" means the individual identified as the Radiation Safety Officer on a Commission license.

"Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

"Teletherapy physicist" means the individual identified as the teletherapy physicist on a Commission license.

"Visiting authorized user" means an authorized user who is not identified as an authorized user on the license of the licensee being visited.

§ 35.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.12, 35.13, 35.14, 35.21, 35.22, 35.23, 35.27, 35.29, 35.31, 35.33, 35.50, 35.51, 35.53, 35.59, 35.60, 35.61, 35.70, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, and 35.647.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved as follows:

(1) In § 35.12, Form NRC-313 is approved under control number 3150-0120.

§ 35.11 License required.

(a) A person shall not manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) of this section.

(b) An individual may receive, possess, use, or transfer byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.25, unless prohibited by license condition.

§ 35.12 Application for license, amendment, or renewal.

(a) If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, and 35.500 of this part must be made by filing an original and one copy of Form NRC-313, "Application for Materials License." For guidance in completing the form, refer to the instructions in the most current versions of the appropriate Regulatory Guides. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(c) An application for a license for medical use of byproduct material as described in § 35.600 of this part must be made by filing an original and one copy of Form NRC-313. For guidance in completing the form, refer to the instructions in the most current version of the appropriate Regulatory Guide. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(d) For copies of regulatory guides, application forms, or to submit an application or an amendment request, refer to § 30.6 of this chapter.

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment:

(a) Before it receives or uses byproduct material for a clinical procedure permitted under this Part but not permitted by the license issued pursuant to this part;

(b) Before it permits anyone, except a visiting authorized user described in § 35.27, to work as an authorized user under the license;

(c) Before it changes Radiation Safety Officers or Teletherapy Physicists;

(d) Before it orders byproduct material in excess of the amount, or radionuclide or form different than authorized on the license; and

(e) Before it adds to or changes the areas of use or address or addresses of use identified in the application or on the license.

§ 35.14 Notifications.

A licensee shall notify the Commission by letter within thirty days when an authorized user, Radiation Safety Officer, or Teletherapy Physicist permanently discontinues performance of duties under the license or has a name change, or when the licensee's mailing address changes. The licensee shall mail the report to the appropriate address identified in § 30.6 of this chapter.

§ 35.18 License issuance.

The Commission shall issue a license for the medical use of byproduct material for a term of five years if:

(a) The applicant has filed Form NRC-313 "Application for Materials License" in accordance with the instructions in § 35.12;

(b) The applicant has paid any applicable fee as provided in Part 170 of this chapter;

(c) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this Chapter for the protection of the public health and safety; and

(d) The applicant meets the requirements of Part 30 of this chapter.

§ 35.19 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The Commission will review requests for exemptions from training and experience requirements with the assistance of its Advisory Committee on the Medical Uses of Isotopes.

Subpart B—General Administrative Requirements

§ 35.20 ALARA program.

(a) Each licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA.

(b) To satisfy the requirement of paragraph (a) of this section:

(1) At a medical institution, management, the Radiation Safety Officer, and all authorized users must participate in the program as requested by the Radiation Safety Committee.

(2) For licensees that are not medical institutions, management and all authorized users must participate in the program as requested by the Radiation Safety Officer.

(c) The program must include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA, a review of summaries of the types and amounts of byproduct material used, occupational doses, changes in radi-

ion safety procedures and safety easures, and continuing education id training for all personnel who ork with or in the vicinity of byprod- t material. The purpose of the view is to ensure that licensees make reasonable effort to maintain indi- lual and collective occupational ses ALARA.

5.21 Radiation Safety Officer.

a) A licensee shall appoint a Radi- on Safety Officer responsible for plementing the radiation safety pro- m. The licensee, through the Radi- on Safety Officer, shall ensure that liation safety activities are being rformed in accordance with ap- oved procedures and regulatory re- irements in the daily operation of licensee's byproduct material pro- m.

b) The Radiation Safety Officer ll:

) Investigate overexposures, acci- ts, spills, losses, thefts, unauthor- receipts, uses, transfers, disposals, administrations, and other devi- ns from approved radiation safety ctice and implement corrective ac- s as necessary;

) Establish, collect in one binder or and implement written policy and edures for:

) Authorizing the purchase of by- duct material;

) Receiving and opening packages yproduct material;

i) Storing byproduct material;

) Keeping an inventory record of oduct material;

Using byproduct material safely;

) Taking emergency action if con- of byproduct material is lost;

i) Performing periodic radiation ys;

ii) Performing checks of survey in- nents and other safety equip-

Disposing of byproduct material;

Training personnel who work in equent areas where byproduct rial is used or stored;

Keeping a copy of all records eports required by the Commis- egulations, a copy of these regu- s, a copy of each licensing re- and license and amendments, and the written policy and procedures required by the regulations.

(3) Brief management once each year on the byproduct material program;

(4) Establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure;

(5) Establish personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence;

(6) For medical use not at a medical institution, approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety with the advice and consent of management; and

(7) For medical use at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

§ 35.22 Radiation Safety Committee.

Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of byproduct material.

(a) Each Committee must meet the following administrative requirements:

(1) Membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) The Committee must meet at least quarterly.

(3) To establish a quorum and to conduct business, at least one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

(4) The minutes of each Radiation Safety Committee meeting must include:

(i) The date of the meeting;

(ii) Members present;

(iii) Members absent;

(iv) Summary of deliberations and discussions;

(v) Recommended actions and the numerical results of all ballots; and

(vi) ALARA program reviews described in § 35.20(c).

(5) The Committee must promptly provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

(b) To oversee the use of licensed material, the Committee must:

(1) Review recommendations on ways to maintain individual and collective doses ALARA;

(2) Review, on the basis of safety and with regard to the training and experience standards in Subpart J of this part, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer, or a Teletherapy Physicist before submitting a license application or request for amendment or renewal;

(3) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under § 35.31 of this Part;

(4) Review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of all personnel working with byproduct material;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving byproduct material with respect to cause and subsequent actions taken; and

(6) Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

§ 35.23 Statements of authority and responsibilities.

(a) A licensee shall provide the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, sufficient authority, organizational freedom, and management prerogative, to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions; and

(3) Verify implementation of corrective actions.

(b) A licensee shall establish and state in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, and retain the current edition of these statements as a record until the Commission terminates the license.

§ 35.25 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by § 35.11(b) of this part shall:

(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material;

(2) Require the supervised individual to follow the instructions of the supervising authorized user, follow the procedures established by the Radiation Safety Officer, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material; and

(3) Periodically review the supervised individual's use of byproduct material and the records kept to reflect this use.

(b) A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

§ 35.27 Visiting authorized user.

(a) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for sixty days each year if:

(1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

(2) The licensee has a copy of a license issued by the Commission or an Agreement State, or a permit issued by a Commission or Agreement State broad licensee that is authorized to

permit medical use, that identifies the visiting authorized user by name as an authorized user for medical use; and

(3) Only those procedures for which the visiting authorized user is specifically authorized by the license or permit are performed by that individual.

(b) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in paragraph (a) of this section.

(c) A licensee shall retain the records specified in this section for two years after the visiting authorized user's last use of licensed material, but may discard the records if the visiting authorized user has been listed as an authorized user on the licensee's license.

35.29 Administrative requirements that apply to the provision of mobile nuclear medicine service.

(a) The Commission will license mobile nuclear medicine service only in accordance with Subparts D, E and F of this part and § 31.11 of this chapter.

(b) Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of byproduct material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for two years after the last provision of service.

(c) If a mobile nuclear medicine service provides services that the client is not authorized to provide, the client is responsible for assuring that services are conducted in accordance with the regulations in this chapter while the mobile nuclear medicine service is under the client's direction.

(d) A mobile nuclear medicine service may not order byproduct material to be delivered directly from the manufacturer or distributor to the client's address of use.

35.31 Radiation safety program changes.

A licensee may make minor changes in radiation safety procedures that are not potentially important to safety, i.e., ministerial changes, that are described in the application for license, renewal, or amendment except for those changes in §§ 35.13 and 35.606 of this part. Examples of such ministerial changes include: editing of procedures for clarity or conformance with local drafting policy or updating names, telephone numbers, and addresses; adoption of model radiation safety procedures published in NRC Regulatory Guides; replacement of equipment; reassignment of tasks among employees; or assignment of service contracts for services such as personnel dosimetry, radiation safety equipment repair or calibration, waste disposal, and safety surveys. A licensee is responsible for assuring that any change made is in compliance with the requirements of the regulations and the license.

(b) A licensee shall retain a record of each change until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

§ 35.33 Records and reports of misadministrations.

(a) When a misadministration involves any therapy procedure, the licensee shall notify by telephone the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian), unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.

(b) Within 15 days after an initial therapy misadministration report to NRC, the licensee shall report, in writing, to the NRC Regional Office initially telephoned and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee under paragraph (a) of this section. The written report must include the licensee's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report must not include the patient's name or other information that could lead to identification of the patient.

(c) When a misadministration involves a diagnostic procedure, the Radiation Safety Officer shall promptly investigate its cause, make a record for NRC review, and retain the record as directed in § 35.33(d). The licensee shall also notify the referring physician and the appropriate NRC Office specified in § 30.6 of this part in writing on Form NRC——[1] within 15 days if the misadministration involved the use of byproduct material not intended for medical use, administration of a dosage five-fold different from the intended dosage, or administration of byproduct material such that the patient is likely to receive an organ dose greater than 2 rem or a whole body dose greater than 500 millirem. Licensees may use dosimetry tables in package inserts, corrected only for amount of radioactivity administered, to determine whether a report is required.

(d) Each licensee shall retain a record of each misadministration for ten years. The record must contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence.

(e) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients, or responsible relatives (or guardians).

§ 35.49 Suppliers.

A licensee may use for medical use only:

(a) Byproduct material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to the regulations in Part 30 and §§ 32.72, 32.73, or 32.74 of this chapter or the equivalent regulations of an Agreement State;

(b) Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval by the Commission pursuant to § 32.73 or an Agreement State under equivalent regulations for the preparation of radiopharmaceuticals for medical use; and

(c) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to Part 30 of this chapter or the equivalent regulations of an Agreement State.

Subpart C—General Technical Requirements

§ 35.50 Possession, use, calibration, and check of dose calibrators.

(a) A medical use licensee authorized to administer radiopharmaceuticals shall have in its possession a dose calibrator and use it to measure the amount of activity administered to each patient.

(b) A licensee shall:

[1] The staff is developing this form and will make it available before the effective date of this regulation. A notice of its availability will be published in the FEDERAL REGISTER.

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this paragraph, the check must be done on a frequently used setting with a sealed source of not less than 10 microcuries of radium-226 or 50 microcuries of any other photon-emitting radionuclide;

(2) Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within 5 percent of its stated activity, whose activity is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries; and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(c) A licensee shall also perform appropriate checks and tests required by this section following adjustment or repair of the dose calibrator.

(d) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(e) A licensee shall retain a record of each check and test required by this section for two years unless directed otherwise. The records required in paragraphs (b)(1) through (b)(4) of this section must include:

(1) For paragraph (b)(1) of this section, the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check;

(2) For paragraph (b)(2) of this section, the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the signature of the Radiation Safety Officer;

(3) For paragraph (b)(3) of this section, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer; and

(4) For paragraph (b)(4) of this section, the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the signature of the Radiation Safety Officer.

§ 35.51 Calibration and check of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part before first use, annually, and following repair. The licensee shall:

(1) Calibrate all scales with readings up to 1000 millirem per hour with a radiation source;

(2) Calibrate two separated readings on each scale that must be calibrated; and

(3) Conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(b) When calibrating a survey instrument, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

(c) A licensee shall check each survey instrument for proper operation with the dedicated check source each day of use. A licensee is not required to keep records of these checks.

(d) A licensee shall retain a record of each survey instrument calibration for two years. The record must include:

(1) A description of the calibration procedure; and

(2) The date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

§ 35.53 Measurement of radiopharmaceutical dosages.

A licensee shall:

(a) Measure the activity of each radiopharmaceutical dosage that contains more than 10 microcuries of a photon-emitting radionuclide before medical use;

(b) Measure the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries or less of a photon-emitting radionuclide before medical use to verify that the dosage does not exceed 10 microcuries;

(c) Retain a record of the measurements required by this section for two years. To satisfy this requirement, the record must contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) Patient's name, and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 10 microcuries;

(4) Date and time of the measurement; and

(5) Initials of the individual who made the record.

§ 35.57 Authorization for calibration and reference sources.

Any person authorized by § 35.11 of this Part for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, and reference use:

(a) Sealed sources manufactured and distributed by a person licensed pursuant to § 32.74 of this chapter or equivalent Agreement State regulations and that do not exceed 15 millicuries each;

(b) Any byproduct material listed in §§ 35.100 or 35.200 with a half-life not longer than 100 days in individual amounts not to exceed 15 millicuries;

(c) Any byproduct material listed in §§ 35.100 or 35.200 with a half-life longer than 100 days in individual amounts not to exceed 200 microcuries each; and

(d) Technetium-99m in individual amounts not to exceed 50 millicuries.

§ 35.59 Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall:

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State and described in the label or brochure that accompanies the source.

(c) To satisfy the leak test requirements of this section, the licensee must:

(1) Take a wipe sample from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate or wash the source in a small volume of detergent solution and treat the entire volume as the sample;

(2) Take teletherapy and other device source test samples when the source is in the "off" position; and

(3) Measure the sample so that the leakage test can detect the presence of 0.005 microcuries of radioactive material on the sample.

(d) A licensee shall retain leakage
est records for five years. The records
ust contain the model number, and
rial number if assigned, of each
urce tested, the identity of each
urce radionuclide and its estimated
tivity, the measured activity of each
st sample expressed in microcuries, a
scription of the method used to
easure each test sample, the date of
e test, and the signature of the Ra-
ation Safety Officer.

(e) If the leakage test reveals the
esence of 0.005 microcurie or more
removable contamination, the li-
nsee shall:

(1) Immediately withdraw the sealed
urce from use and store it in accord-
ce with the requirements in Parts 20
d 30 of this chapter; and

(2) File a report within five days of
e leakage test with the appropriate
RC Office listed in § 30.6 of this
apter, with a copy to Director of In-
ction and Enforcement, U.S. Nucle-
Regulatory Commission, Washing-
n, DC 20555, describing the equip-
nt involved, the test results, and
e action taken.

f) A licensee need not perform a
kage test on the following sources:

1) Sources containing only byprod-
material with a half-life of less
n 30 days;

2) Sources containing only byprod-
material as a gas;

3) Sources containing 100 microcur-
or less of beta or gamma-emitting
terial or 10 microcuries or less of
ha-emitting material;

i) Sources stored and not being
d. The licensee shall, however, test
h such source for leakage before
use or transfer unless it has been
kage-tested within six months
ore the date of use or transfer; and

) Seeds of iridium-192 encased in
n ribbon.

) A licensee in possession of a
ed source or brachytherapy source
l conduct a quarterly physical in-
ory of all such sources in its pos-
ion. The licensee shall retain each
ntory record for five years. The in-
ory records must contain the
el number of each source, and
l number if one has been as-
d, the identity of each source ra-
uclide and its nominal activity,
the location of each source, and the signature of the Radiation Safety Officer.

(h) A licensee in possession of a sealed source or brachytherapy source shall measure the ambient dose rates quarterly in all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(i) A licensee shall retain a record of each survey required in paragraph (h) of this section for two years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the survey instrument used, and the signature of the Radiation Safety Officer.

§ 35.60 Syringe shields and labels.

(a) A licensee shall keep syringes that contain byproduct material to be administered in a radiation shield.

(b) To identify its contents, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

(c) A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit and shall require each individual to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient.

§ 35.61 Vial shields and labels.

(a) A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

(b) To identify its contents, a licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation.

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

(a) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

(c) A licensee shall conduct the surveys required by paragraphs (a) and (b) of this section so as to be able to detect dose rates as low as 0.1 millirem per hour.

(d) A licensee shall establish radiation dose rate trigger levels for the surveys required by paragraphs (a) and (b) of this section. A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds a trigger level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

(f) A licensee shall conduct the surveys required by paragraph (e) of this section so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute.

(g) A licensee shall establish removable contamination trigger levels for the surveys required by paragraph (e) of this section. A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds the trigger level.

(h) A licensee shall retain a record of each survey for two years. The record must include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

(a) A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:

(1) The measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter; or

(2) The activity in the patient is less than 30 millicuries.

(b) A licensee may not authorize release from confinement for medical care of any patient administered a permanent implant until the measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter.

§ 35.80 Technical requirements that apply to the provision of mobile nuclear medicine service.

A licensee providing mobile nuclear medicine service shall:

(a) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(b) Bring into each address of use all byproduct material to be used and, before leaving, remove all unused byproduct material and all associated waste;

(c) Secure or keep under constant surveillance and immediate control all byproduct material when in transit or at an address of use;

(d) Check survey instruments and dose calibrators as described in §§ 35.50 and 35.51, and check all other transported equipment for proper function before medical use at each address of use;

(e) Carry a radiation detection survey meter in each vehicle that is being used to transport byproduct material, and, before leaving a client address of use, survey all radiopharmaceutical areas of use with a radiation detection survey meter to ensure that all radiopharmaceuticals and all associated waste have been removed;

(f) Retain a record of each survey required in paragraph (e) of this section for two years. The record must include

he date of the survey, a plan of each rea that was surveyed, the measured ose rate at several points in each area f use expressed in millirem per hour, ie instrument used to make the rvey, and the initials of the individ- l who performed the survey.

5.90 Storage of volatiles and gases.

A licensee shall store volatile radio- armaceuticals and radioactive gases the shipper's radiation shield and ntainer. A licensee shall store a ulti-dose container in a fume hood ter drawing the first dosage from it.

5.92 Decay-in-storage.

a) A licensee may hold byproduct terial with a physical half-life of s than 65 days for decay-in-storage fore disposal in ordinary trash and exempt from the requirements of 0.301 of this chapter if it:

1) Holds byproduct material for ay a minimum of ten half-lives;

2) Monitors byproduct material at container surface before disposal ordinary trash and determines that radioactivity cannot be distin- shed from the background radi- n level with a radiation detection ey meter set on its most sensitive e and with no interposed shielding;

) Removes or obliterates all radi- n labels; and

) Separates and monitors each gen- or column individually with all ra- ion shielding removed to ensure it has decayed to background ra- ion level before disposal.

) A licensee shall retain a record of disposal permitted under para- h (a) of this section for two years. record must include the date of lisposal, the date on which the by- uct material was placed in stor- the radionuclides disposed, the y instrument used, the back- nd dose rate, the dose rate meas- at the surface of each waste con- r, and the name of the individual performed the dis; osal.

Subpart D—Uptake, Dilution, and Excretion

§ 35.100 Use of radiopharmaceuticals for uptake, dilution and excretion studies.

A licensee may use any byproduct material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

§ 35.120 Possession of survey instrument.

A licensee authorized to use byproduct material for uptake, dilution, and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour.

Subpart E—Imaging and Localization

§ 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

(a) A licensee may use any byproduct material in a diagnostic radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing byproduct material for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

(b) A licensee shall elute generators and prepare reagent kits in accordance with the manufacturer's instructions.

§ 35.204 Permissible molybdenum-99 concentration.

(a) A licensee may not administer to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate or extract.

(c) A licensee that must measure molybdenum concentration shall retain a record of each measurement for two years. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries, the measured activity of the molybdenum expressed in microcuries, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the initials of the individual who made the measurement.

§ 35.205 Control of aerosols and gases.

(a) A licensee that administers radioactive aerosols or gases shall do so in a room with a system that will keep airborne concentrations within the limits prescribed by §§ 20.103 and 20.106 of this chapter. The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(b) A licensee shall administer radioactive aerosols and gases in rooms that are at negative pressure compared to surrounding rooms.

(c) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a spill to reduce the concentration in the room to the occupational limit listed in Appendix B to Part 20 of this chapter. The calculation must be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust rate.

(d) A licensee shall make a record of the calculations required in paragraph (c) of this section that includes the assumptions, measurements, and calculations made and shall retain the record for the duration of use of the area. A licensee shall also post the calculated time and safety measures to be instituted in case of a spill at the area of use.

(e) A licensee shall check the operation of collection systems each month, and measure the ventilation rates available in areas of use each six months.

§ 35.220 Possession of survey instruments.

A licensee authorized to use byproduct material for imaging and localization studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart F—Radiopharmaceuticals for Therapy

§ 35.300 Use of radiopharmaceuticals for therapy.

A licensee may use any byproduct material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The licensee shall comply with the package insert instructions regarding indications and method of administration.

§ 35.310 Safety instruction.

(a) A licensee shall provide radiation safety instruction for all personnel caring for the patient receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75 of this chapter. To satisfy this requirement, the instruction must describe the licensee's procedures for:

(1) Patient control;

(2) Visitor control;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer in case of the patient's death or medical emergency.

(b) A licensee shall keep for two years a list of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

§ 35.315 Safety precautions.

(a) For each patient receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75 of this chapter, a licensee shall:

(1) Provide a private room with a private sanitary facility;

(2) Post the patient's door with a "Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room;

(3) Authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of part 20 of this chapter, and retain for two years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(5) Either monitor material and items removed from the patient's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale in use with no interposed shielding, or handle them as radioactive waste.

(b) Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient.

Survey the patient's room and adjacent sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters; and

Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by § 20.401(c)(1) a record of each thyroid burden measurement, its date, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient dies or has a medical emergency.

§ 35.320 Possession of survey instruments.

A licensee authorized to use byproduct material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart G—Sources for Brachytherapy

§ 35.400 Use of sources for brachytherapy.

A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

(a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

(d) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(e) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

(f) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer.

§ 35.404 Release of patients treated with temporary implants.

(a) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The licensee may not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

(b) A licensee shall retain a record of patient surveys for two years. Each record must include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirem per hour and measured at one meter from the patient, the survey instrument used, and the initials of the individual who made the survey.

§ 35.406 Brachytherapy sources inventory.

(a) Promptly after removing them from a patient, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.

(b) A licensee shall make a record of brachytherapy source use which must include:

(1) The names of the individuals permitted to handle the sources,

(2) The number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage;

(3) The number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

(c) Immediately after implanting sources in a patient the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

(d) A licensee shall retain the records required in paragraphs (b) and (c) of this section for two years.

§ 35.410 Safety instruction.

(a) The licensee shall provide radiation safety instruction to all personnel caring for the patient undergoing implant therapy. To satisfy this requirement, the instruction must describe:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions in case of a dislodged source;

(3) Procedures for patient control;

(4) Procedures for visitor control; and

(5) Procedures for notification of the Radiation Safety Officer if the patient dies or has a medical emergency.

(b) A licensee shall retain for two years a record of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

§ 35.415 Safety precautions.

(a) For each patient receiving implant therapy, a licensee shall:

(1) Not quarter the patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirements of § 20.105(b) of this chapter at a distance of one meter from the implant;

(2) Post the patient's door with a "Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room;

(3) Authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the Radiation Safety Officer; and

(4) Promptly after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Part 20 of this chapter, and retain for two years a record of each survey that

significant additional costs to any licensees. It is available for public inspection in the NRC Public Document Room at 1717 H Street NW., Washington, DC. Single copies are available from Mr. McElroy (see "FOR FURTHER INFORMATION CONTACT:" heading).

Resolution of Petition for Rulemaking PRM 35–2

The American Association of Physicists in Medicine filed a petition regarding dosimetry equipment calibration frequency (Petition Docket No. PRM 35–2; see 47 FR 4311, January 29, 1982). This rulemaking resolves that petition in § 35.630 Dosimetry equipment. The petition is granted essentially as recommended by the petitioner.

List of Subjects

10 CFR Part 30

Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 31

Byproduct material, Labeling, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment.

10 CFR Part 32

Byproduct materials, Labeling, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

Byproduct material, Drugs, Health devices, Health professions, Incorporation by reference, Medical devices, Nuclear materials, Occupational safety and health, Penalty, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Government contracts, Hazardous materials—transportation, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Source material, Uranium.

Under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553 the NRC is adopting the following revision of 10 CFR Part 35 and the following amendments to 10 CFR Parts 30, 31, 32, and 40.

VII. Text of Final Regulations

1. 10 CFR Part 35 is revised to read as follows:

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

Subpart A—General Information

Subpart B—General Administrative Requirements

Subpart C—General Technical Requirements

Subpart D—Uptake, Dilution, and Excretion

Subpart E—Imaging and Localization

Subpart F—Radiopharmaceuticals for Therapy

Subpart G—Sources for Brachytherapy

Subpart H—Sealed Sources for Diagnosis

Subpart I—Teletherapy

Subpart J—Training and Experience Requirements

Subpart K—Enforcement

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 35.11, 35.13, 35.20(a) and (b), 35.21(a) and (b), 35.22, 35.23, 35.25, 35.27(a), (c) and (d), 35.31(a), 35.49, 35.50(a)–(d), 35.51(a)–(c), 35.53(a) and (b), 35.59(a)–(c), (e)(1), (g) and (h), 35.60, 35.61, 35.70(a)–(f), 35.75, 35.80(a)–(e), 35.90, 35.92(a), 35.120, 35.200(b), 35.204(a) and (b), 35.205, 35.220, 35.310(a), 35.315, 35.320, 35.400, 35.404(a), 35.406(a) and (c), 35.410(a), 35.415, 35.420, 35.500, 35.520, 35.605, 35.606, 35.610(a) and (b), 35.615, 35.620, 35.630(a) and (b), 35.632(a)–(f), 35.633(a)–(i), 35.636(a) and (b), 35.641(a) and (b), 35.643(a) and (b), 35.645(a) and (b), 35.900, 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960, 35.961, 35.970, and 35.971 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.14, 35.21(b), 35.22(b), 35.23(b), 35.27(a) and (c), 35.29(b), 35.33(a)–(d), 35.36(b), 35.50(e), 35.51(d), 35.53(c), 35.59(d) and (e)(2), 35.59(g) and (i), 35.70(g), 35.80(f), 35.92(b), 35.204(c), 35.310(b), 35.315(b), 35.404(b), 35.406(b) and (d), 35.410(b), 35.415(b), 35.610(c), 35.615(d)(4), 35.630(c), 35.632(g), 35.634(j), 35.636(c), 35.641(c), 35.643(c), 35.645, and 35.647(c) are issued under sec. 161o, 68 Stat. 950 as amended (42 U.S.C. 2201(o)).

Subpart A—General Information

§ 35.1 Purpose and scope.

This part prescribes requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of Parts 19, 20, 21, 30, 71, and 170 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.

§ 35.2 Definitions.

"Address of use" means the building or buildings that are identified on the license and where byproduct material may be received, used, or stored.

"Agreement State" means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

"ALARA" (as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical:

(1) Consistent with the purpose for which the licensed activity is undertaken,

(2) Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and

(3) In relation to utilization of nuclear energy in the public interest.

"Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing byproduct material.

"Authorized user" means a physician, dentist, or podiatrist who is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material.

"Brachytherapy source" means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.

"Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.

"Dental use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of dentistry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

"Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

"Management" means the chief executive officer or that person's delegate or delegates.

"Medical Institution" means an organization in which several medical disciplines are practiced.

"Medical use" means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

"Ministerial change" means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements should apply in the case at hand.

"Misadministration" means the administration of:

(1) A radiopharmaceutical or radiation from a sealed source other than the one intended;

(2) A radiopharmaceutical or radiation to the wrong patient;

(3) A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;

(4) A diagnostic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 50 percent;

(5) A therapy dosage of a radiopharmaceutical differing from the prescribed dosage by more than 10 percent; or

(6) A therapy radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.

"Mobile nuclear medicine service" means the transportation and medical use of byproduct material.

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

"Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

"Podiatric use" means the intentional external administration of the radiation from byproduct material to human beings in the practice of podiatry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

"Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

"Radiation Safety Officer" means the individual identified as the Radiation Safety Officer on a Commission license.

"Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

"Teletherapy physicist" means the individual identified as the teletherapy physicist on a Commission license.

"Visiting authorized user" means an authorized user who is not identified as an authorized user on the license of the licensee being visited.

§ 35.8 Information collection requirements: OMB approval.

(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements in this part under control number 3150-0010.

(b) The approved information collection requirements contained in this part appear in §§ 35.12, 35.13, 35.14, 35.21, 35.22, 35.23, 35.27, 35.29, 35.31, 35.33, 35.50, 35.51, 35.53, 35.59, 35.60, 35.61, 35.70, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, and 35.647.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved as follows:

(1) In § 35.12, Form NRC-313 is approved under control number 3150-0120.

§ 35.11 License required.

(a) A person shall not manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) of this section.

(b) An individual may receive, possess, use, or transfer byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.25, unless prohibited by license condition.

§ 35.12 Application for license, amendment, or renewal.

(a) If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, and 35.500 of this part must be made by filing an original and one copy of Form NRC-313, "Application for Materials License." For guidance in completing the form, refer to the instructions in the most current versions the appropriate Regulatory Guides. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(c) An application for a license for medical use of byproduct material as described in § 35.600 of this part must be made by filing an original and one copy of Form NRC-313. For guidance in completing the form, refer to the instructions in the most current version of the appropriate Regulatory Guide. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(d) For copies of regulatory guides, application forms, or to submit an application or an amendment request, refer to § 30.6 of this chapter.

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment:

(a) Before it receives or uses byproduct material for a clinical procedure permitted under this Part but not permitted by the license issued pursuant to this part;

(b) Before it permits anyone, except a visiting authorized user described in § 35.27, to work as an authorized user under the license;

(c) Before it changes Radiation Safety Officers or Teletherapy Physicists;

(d) Before it orders byproduct material in excess of the amount, or radionuclide or form different than authorized on the license; and

(e) Before it adds to or changes the areas of use or address or addresses of use identified in the application or on the license.

§ 35.14 Notifications.

A licensee shall notify the Commission by letter within thirty days when an authorized user, Radiation Safety Officer, or Teletherapy Physicist permanently discontinues performance of duties under the license or has a name change, or when the licensee's mailing address changes. The licensee shall mail the report to the appropriate address identified in § 30.6 of this chapter.

§ 35.18 License issuance.

The Commission shall issue a license for the medical use of byproduct material for a term of five years if:

(a) The applicant has filed Form NRC-313 "Application for Materials License" in accordance with the instructions in § 35.12;

(b) The applicant has paid any applicable fee as provided in Part 170 of this chapter;

(c) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this Chapter for the protection of the public health and safety; and

(d) The applicant meets the requirements of Part 30 of this chapter.

§ 35.19 Specific exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The Commission will review requests for exemptions from training and experience requirements with the assistance of its Advisory Committee on the Medical Uses of Isotopes.

Subpart B—General Administrative Requirements

§ 35.20 ALARA program.

(a) Each licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA.

(b) To satisfy the requirement of paragraph (a) of this section:

(1) At a medical institution, management, the Radiation Safety Officer, and all authorized users must participate in the program as requested by the Radiation Safety Committee.

(2) For licensees that are not medical institutions, management and all authorized users must participate in the program as requested by the Radiation Safety Officer.

(c) The program must include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA, a review of summaries of the types and amounts of byproduct material used, occupational doses, changes in radiation safety procedures and safety measures, and continuing education and training for all personnel who work with or in the vicinity of byproduct material. The purpose of the review is to ensure that licensees make a reasonable effort to maintain individual and collective occupational doses ALARA.

Annual refresher

Quarterly staff mtgs ?

§ 35.21 Radiation Safety Officer.

(a) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.

(b) The Radiation Safety Officer shall:

(1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Establish, collect in one binder or file, and implement written policy and procedures for:

(i) Authorizing the purchase of byproduct material;

(ii) Receiving and opening packages of byproduct material;

(iii) Storing byproduct material;

(iv) Keeping an inventory record of byproduct material;

(v) Using byproduct material safely;

(vi) Taking emergency action if control of byproduct material is lost;

(vii) Performing periodic radiation surveys;

(viii) Performing checks of survey instruments and other safety equipment;

(ix) Disposing of byproduct material;

(x) Training personnel who work in or frequent areas where byproduct material is used or stored;

(xi) Keeping a copy of all records and reports required by the Commission regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations.

(3) Brief management once each year on the byproduct material program;

(4) Establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure;

(5) Establish personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence;

(6) For medical use not at a medical institution, approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety with the advice and consent of management; and

(7) For medical use at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

§ 35.22 Radiation Safety Committee.

Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of byproduct material.

(a) Each Committee must meet the following administrative requirements:

(1) Membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) The Committee must meet at least quarterly.

(3) To establish a quorum and to conduct business, at least one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

(4) The minutes of each Radiation Safety Committee meeting must include:

(i) The date of the meeting;

(ii) Members present;

(iii) Members absent;

(iv) Summary of deliberations and discussions;

(v) Recommended actions and the numerical results of all ballots; and

(vi) ALARA program reviews described in § 35.20(c).

(5) The Committee must promptly provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

(b) To oversee the use of licensed material, the Committee must:

(1) Review recommendations on ways to maintain individual and collective doses ALARA;

(2) Review, on the basis of safety and with regard to the training and experience standards in Subpart J of this part, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer, or a Teletherapy Physicist before submitting a license application or request for amendment or renewal;

(3) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under § 35.31 of this Part;

(4) Review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of all personnel working with byproduct material;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving byproduct material with respect to cause and subsequent actions taken; and

(6) Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

§ 35.23 Statements of authority and responsibilities.

(a) A licensee shall provide the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, sufficient authority, organizational freedom, and management prerogative, to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions; and

(3) Verify implementation of corrective actions.

(b) A licensee shall establish and state in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, and retain the current edition of these statements as a record until the Commission terminates the license.

§ 35.25 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by § 35.11(b) of this part shall:

(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material;

(2) Require the supervised individual to follow the instructions of the supervising authorized user, follow the procedures established by the Radiation Safety Officer, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material; and

(3) Periodically review the supervised individual's use of byproduct material and the records kept to reflect this use.

(b) A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

§ 35.27 Visiting authorized user.

(a) A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for sixty days each year if:

(1) The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

(2) The licensee has a copy of a license issued by the Commission or an Agreement State, or a permit issued by a Commission or Agreement State broad licensee that is authorized to permit medical use, that identifies the visiting authorized user by name as an authorized user for medical use; and

(3) Only those procedures for which the visiting authorized user is specifically authorized by the license or permit are performed by that individual.

(b) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in paragraph (a) of this section.

(c) A licensee shall retain the records specified in this section for two years after the visiting authorized user's last use of licensed material, but may discard the records if the visiting authorized user has been listed as an authorized user on the licensee's license.

§ 35.29 Administrative requirements that apply to the provision of mobile nuclear medicine service.

(a) The Commission will license mobile nuclear medicine service only in accordance with Subparts D, E and H of this part and § 31.11 of this chapter.

(b) Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of byproduct material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for two years after the last provision of service.

(c) If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for assuring that services are conducted in accordance with the regulations in this chapter while the mobile nuclear medicine service is under the client's direction.

(d) A mobile nuclear medicine service may not order byproduct material to be delivered directly from the manufacturer or distributor to the client's address of use.

§ 35.31 Radiation safety program changes.

(a) A licensee may make minor changes in radiation safety procedures that are not potentially important to safety, i.e., ministerial changes, that were described in the application for license, renewal, or amendment except for those changes in §§ 35.13 and 35.606 of this part. Examples of such ministerial changes include: editing of procedures for clarity or conformance with local drafting policy or updating names, telephone numbers, and addresses; adoption of model radiation safety procedures published in NRC Regulatory Guides; replacement of equipment; reassignment of tasks among employees; or assignment of service contracts for services such as personnel dosimetry, radiation safety equipment repair or calibration, waste disposal, and safety surveys. A licensee is responsible for assuring that any change made is in compliance with the requirements of the regulations and the license.

(b) A licensee shall retain a record of each change until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

§ 35.33 Records and reports of misadministrations.

(a) When a misadministration involves any therapy procedure, the licensee shall notify by telephone the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. The licensee shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian), unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the licensee shall notify them as soon as practicable. The licensee is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this.

(b) Within 15 days after an initial therapy misadministration report to NRC, the licensee shall report, in writing, to the NRC Regional Office initially telephoned and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously notified by the licensee under paragraph (a) of this section. The written report must include the licensee's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the licensee informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report must not include the patient's name or other information that could lead to identification of the patient.

(c) When a misadministration involves a diagnostic procedure, the Radiation Safety Officer shall promptly investigate its cause, make a record for NRC review, and retain the record as directed in § 35.33(d). The licensee shall also notify the referring physician and the appropriate NRC Office specified in § 30.6 of this part in writing on Form NRC——[1] within 15 days if the misadministration involved the use of byproduct material not intended for medical use, administration of a dosage five-fold different from the intended dosage, or administration of byproduct material such that the patient is likely to receive an organ dose greater than 2 rem or a whole body dose greater than 500 millirem. Licensees may use dosimetry tables in package inserts, corrected only for amount of radioactivity administered, to determine whether a report is required.

(d) Each licensee shall retain a record of each misadministration for ten years. The record must contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence.

(e) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, patients, or responsible relatives (or guardians).

§ 35.49 Suppliers.

A licensee may use for medical use only:

(a) Byproduct material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to the regulations in Part 30 and §§ 32.72, 32.73, or 32.74 of this chapter or the equivalent regulations of an Agreement State;

(b) Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval by the Commission pursuant to § 32.73 or an Agreement State under equivalent regulations for the

[1] The staff is developing this form and will make it available before the effective date of this regulation. A notice of its availability will be published in the Federal Register.

preparation of radiopharmaceuticals for medical use; and

(c) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to Part 30 of this chapter or the equivalent regulations of an Agreement State.

Subpart C—General Technical Requirements

§ 35.50 Possession, use, calibration, and check of dose calibrators.

(a) A medical use licensee authorized to administer radiopharmaceuticals shall have in its possession a dose calibrator and use it to measure the amount of activity administered to each patient.

(b) A licensee shall:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this paragraph, the check must be done on a frequently used setting with a sealed source of not less than 10 microcuries of radium-226 or 50 microcuries of any other photon-emitting radionuclide;

(2) Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within 5 percent of its stated activity, whose activity is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries; and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(c) A licensee shall also perform appropriate checks and tests required by this section following adjustment or repair of the dose calibrator.

(d) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(e) A licensee shall retain a record of each check and test required by this section for two years unless directed otherwise. The records required in paragraphs (b)(1) through (b)(4) of this section must include:

(1) For paragraph (b)(1), the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check;

(2) For paragraph (b)(2), the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the signature of the Radiation Safety Officer;

(3) For paragraph (b)(3), the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer; and

(4) For paragraph (b)(4), the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the signature of the Radiation Safety Officer.

§ 35.51 Calibration and check of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part before first use, annually, and following repair. The licensee shall:

(1) Calibrate all scales with readings up to 1000 millirem per hour with a radiation source;

(2) Calibrate two separated readings on each scale that must be calibrated; and

(3) Conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

(b) When calibrating a survey instrument, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.

(c) A licensee shall check each survey instrument for proper operation with the dedicated check source each day of use. A licensee is not required to keep records of these checks.

(d) A licensee shall retain a record of each survey instrument calibration for two years. The record must include:

(1) A description of the calibration procedure; and

(2) The date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.

§ 35.53 Measurement of radiopharmaceutical dosages.

A licensee shall:

(a) Measure the activity of each radiopharmaceutical dosage that contains more than 10 microcuries of a photon-emitting radionuclide before medical use;

(b) Measure the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries or less of a photon-emitting radionuclide before medical use to verify that the dosage does not exceed 10 microcuries;

(c) Retain a record of the measurements required by this section for two years. To satisfy this requirement, the record must contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

(2) Patient's name, and identification number if one has been assigned;

(3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 10 microcuries;

(4) Date and time of the measurement; and

(5) Initials of the individual who made the record.

§ 35.57 Authorization for calibration and reference sources.

Any person authorized by § 35.11 of this Part for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, and reference use:

(a) Sealed sources manufactured and distributed by a person licensed pursuant to § 32.74 of this chapter or equivalent Agreement State regulations and that do not exceed 15 millicuries each;

(b) Any byproduct material listed in §§ 35.100 or 35.200 with a half-life not longer than 100 days in individual amounts not to exceed 15 millicuries;

(c) Any byproduct material listed in §§ 35.100 or 35.200 with a half-life longer than 100 days in individual amounts not to exceed 200 microcuries each; and

(d) Technetium-99m in individual amounts not to exceed 50 millicuries.

§ 35.59 Requirements for possession of sealed sources and brachytherapy sources.

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.

(b) A licensee in possession of a sealed source shall:

(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and

(2) Test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State and described in the label or brochure that accompanies the source.

(c) To satisfy the leak test requirements of this section, the licensee must:

(1) Take a wipe sample from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate or wash the source in a small volume of detergent solution and treat the entire volume as the sample;

(2) Take teletherapy and other device source test samples when the source is in the "off" position; and

(3) Measure the sample so that the leakage test can detect the presence of 0.005 microcuries of radioactive material on the sample.

(d) A licensee shall retain leakage test records for five years. The records must contain the model number, and serial number if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries, a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer.

(e) If the leakage test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall:

(1) Immediately withdraw the sealed source from use and store it in accordance with the requirements in Parts 20 and 30 of this chapter; and

(2) File a report within five days of the leakage test with the appropriate NRC Office listed in § 30.6 of this chapter, with a copy to Director of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, describing the equipment involved, the test results, and the action taken.

(f) A licensee need not perform a leakage test on the following sources:

(1) Sources containing only byproduct material with a half-life of less than 30 days;

(2) Sources containing only byproduct material as a gas;

(3) Sources containing 100 microcuries or less of beta or gamma-emitting material or 10 microcuries or less of alpha-emitting material;

(4) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leakage-tested within six months before the date of use or transfer; and

(5) Seeds of iridium-192 encased in nylon ribbon.

(g) A licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all such sources in its possession. The licensee shall retain each inventory record for five years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer.

(h) A licensee in possession of a sealed source or brachytherapy source shall measure the ambient dose rates quarterly in all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(i) A licensee shall retain a record of each survey required in paragraph (h) of this section for two years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the survey instrument used, and the signature of the Radiation Safety Officer.

§ 35.60 Syringe shields and labels.

(a) A licensee shall keep syringes that contain byproduct material to be administered in a radiation shield.

(b) To identify its contents, a licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's name.

(c) A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit and shall require each individual to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient.

§ 35.61 Vial shields and labels.

(a) A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

(b) To identify its contents, a licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation.

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

(a) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

(c) A licensee shall conduct the surveys required by paragraphs (a) and (b) of this section so as to be able to detect dose rates as low as 0.1 millirem per hour.

(d) A licensee shall establish radiation dose rate trigger levels for the surveys required by paragraphs (a) and (b) of this section. A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds a trigger level.

(e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

(f) A licensee shall conduct the surveys required by paragraph (e) of this section so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute.

(g) A licensee shall establish removable contamination trigger levels for the surveys required by paragraph (e) of this section. A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds the trigger level.

(h) A licensee shall retain a record of each survey for two years. The record must include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the

detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

§ 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

(a) A licensee may not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:

(1) The measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter; or

(2) The activity in the patient is less than 30 millicuries.

(b) A licensee may not authorize release from confinement for medical care of any patient administered a permanent implant until the measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter.

§ 35.80 Technical requirements that apply to the provision of mobile nuclear medicine service.

A licensee providing mobile nuclear medicine service shall:

(a) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

(b) Bring into each address of use all byproduct material to be used and, before leaving, remove all unused byproduct material and all associated waste;

(c) Secure or keep under constant surveillance and immediate control all byproduct material when in transit or at an address of use;

(d) Check survey instruments and dose calibrators as described in §§ 35.50 and 35.51, and check all other transported equipment for proper function before medical use at each address of use;

(e) Carry a radiation detection survey meter in each vehicle that is being used to transport byproduct material, and, before leaving a client address of use, survey all radiopharmaceutical areas of use with a radiation detection survey meter to ensure that all radiopharmaceuticals and all associated waste have been removed;

(f) Retain a record of each survey required in paragraph (e) of this section for two years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who performed the survey.

§ 35.90 Storage of volatiles and gases.

A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container. A licensee shall store a multi-dose container in a fume hood after drawing the first dosage from it.

§ 35.92 Decay-in-storage.

(a) A licensee may hold byproduct material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of § 20.301 of this chapter if it:

(1) Holds byproduct material for decay a minimum of ten half-lives;

(2) Monitors byproduct material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding;

(3) Removes or obliterates all radiation labels; and

(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal.

(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section for two years. The record must include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Subpart D—Uptake, Dilution, and Excretion

§ 35.100 Use of radiopharmaceuticals for uptake, dilution and excretion studies.

A licensee may use any byproduct material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

§ 35.120 Possession of survey instrument.

A licensee authorized to use byproduct material for uptake, dilution, and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour.

Subpart E—Imaging and Localization

§ 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies.

(a) A licensee may use any byproduct material in a diagnostic radiopharmaceutical or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing byproduct material for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

(b) A licensee shall elute generators and prepare reagent kits in accordance with the manufacturer's instructions.

§ 35.204 Permissible molybdenum-99 concentration.

(a) A licensee may not administer to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate or extract.

(c) A licensee that must measure molybdenum concentration shall retain a record of each measurement for two years. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries, the measured activity of the molybdenum expressed in microcuries, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the initials of the individual who made the measurement.

§ 35.205 Control of aerosols and gases.

(a) A licensee that administers radioactive aerosols or gases shall do so in a room with a system that will keep airborne concentrations within the limits prescribed by §§ 20.103 and 20.106 of this chapter. The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(b) A licensee shall administer radioactive aerosols and gases in rooms that are at negative pressure compared to surrounding rooms.

(c) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a spill to reduce the concentration in the room to the occupational limit listed in Appendix B to Part 20 of this chapter. The calculation must be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust rate.

(d) A licensee shall make a record of the calculations required in paragraph (c) of this section that includes the assumptions, measurements, and calculations made and shall retain the record for the duration of use of the area. A licensee shall also post the calculated time and safety measures to be instituted in case of a spill at the area of use.

(e) A licensee shall check the proper operation of collection systems each month, and measure the ventilation rates available in areas of use each six months.

§ 35.220 Possession of survey instruments.

A licensee authorized to use byproduct material for imaging and localization studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart F—Radiopharmaceuticals for Therapy

§ 35.300 Use of radiopharmaceuticals for therapy.

A licensee may use any byproduct material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The licensee shall comply with the package insert instructions regarding indications and method of administration.

§ 35.310 Safety instruction.

(a) A licensee shall provide radiation safety instruction for all personnel caring for the patient receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75 of this chapter. To satisfy this requirement, the instruction must describe the licensee's procedures for:

(1) Patient control;

(2) Visitor control;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer in case of the patient's death or medical emergency.

(b) A licensee shall keep for two years a list of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

§ 35.315 Safety precautions.

(a) For each patient receiving radiopharmaceutical therapy and hospitalized for compliance with § 35.75 of this chapter, a licensee shall:

(1) Provide a private room with a private sanitary facility;

(2) Post the patient's door with a "Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room;

(3) Authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Part 20 of this chapter, and retain for two years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(5) Either monitor material and items removed from the patient's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste.

(6) Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient.

(7) Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters; and

(8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by § 20.401(c)(1) a record of each thyroid burden measurement, its date, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient dies or has a medical emergency.

§ 35.320 Possession of survey instruments.

A licensee authorized to use byproduct material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart G—Sources for Brachytherapy

§ 35.400 Use of sources for brachytherapy.

A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

(a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

(d) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

(e) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

(f) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer.

§ 35.404 Release of patients treated with temporary implants.

(a) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to

confirm that all sources have been removed. The licensee may not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

(b) A licensee shall retain a record of patient surveys for two years. Each record must include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirem per hour and measured at one meter from the patient, the survey instrument used, and the initials of the individual who made the survey.

§ 35.406 Brachytherapy sources inventory.

(a) Promptly after removing them from a patient, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.

(b) A licensee shall make a record of brachytherapy source use which must include:

(1) The names of the individuals permitted to handle the sources;

(2) The number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage;

(3) The number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

(c) Immediately after implanting sources in a patient the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

(d) A licensee shall retain the records required in paragraphs (b) and (c) of this section for two years.

§ 35.410 Safety instruction.

(a) The licensee shall provide radiation safety instruction to all personnel caring for the patient undergoing implant therapy. To satisfy this requirement, the instruction must describe:

(1) Size and appearance of the brachytherapy sources;

(2) Safe handling and shielding instructions in case of a dislodged source;

(3) Procedures for patient control;

(4) Procedures for visitor control; and

(5) Procedures for notification of the Radiation Safety Officer if the patient dies or has a medical emergency.

(b) A licensee shall retain for two years a record of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

§ 35.415 Safety precautions.

(a) For each patient receiving implant therapy, a licensee shall:

(1) Not quarter the patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirements of § 20.105(b) of this chapter at a distance of one meter from the implant;

(2) Post the patient's door with a "Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room;

(3) Authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the Radiation Safety Officer; and

(4) Promptly after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of Part 20 of this chapter, and retain for two years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

(5) Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.

(b) A licensee shall notify the Radiation Safety Officer immediately if the patient dies or has a medical emergency.

§ 35.420 Possession of survey instrument.

A licensee authorized to use byproduct material for implant therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Subpart H—Sealed Sources for Diagnosis

§ 35.500 Use of sealed sources for diagnosis.

A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

(a) Iodine-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis; and

(b) Iodine-125 as a sealed source in a portable imaging device.

§ 35.520 Availability of survey instrument.

A licensee authorized to use byproduct material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour. The instrument must have been calibrated in accordance with § 35.51 of this part.

Subpart I—Teletherapy

§ 35.600 Use of a sealed source in a teletherapy unit.

The regulations and provisions of this subpart govern the use of teletherapy units for medical use that contain a sealed source of cobalt-60 or cesium-137.

§ 35.605 Maintenance and repair restrictions.

Only a person specifically licensed by the Commission or an Agreement State to perform teletherapy unit maintenance and repair shall:

(a) Install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source; or

(b) Maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

§ 35.606 License amendments.

In addition to the changes specified in § 35.13 of this part, a licensee shall apply for and must receive a license amendment before:

(a) Making any change in the treatment room shielding;

(b) Making any change in the location of the teletherapy unit within the treatment room;

(c) Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(d) Relocating the teletherapy unit; or

(e) Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

§ 35.610 Safety instruction.

(a) A licensee shall post instructions at the teletherapy unit console. To satisfy this requirement, these instructions must inform the operator of:

(1) The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption;

(2) The procedure to be followed if:

(i) The operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and

(ii) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.

(b) A licensee shall provide instruction in the topics identified in paragraph (a) of this section to all individuals who operate a teletherapy unit.

(c) A licensee shall retain for two years a record of individuals receiving instruction required by paragraph (b) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

§ 35.615 Safety precautions.

(a) A licensee shall control access to the teletherapy room by a door at each entrance.

(b) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that will:

(1) Prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;

(2) Turn the primary beam of radiation off immediately when an entrance door is opened; and

(3) Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

(c) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.

(d) A licensee shall install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(1) A radiation monitor must provide visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source, and must be observable by an individual entering the teletherapy room.

(2) A radiation monitor must be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

(3) A radiation monitor must be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

(4) A licensee shall maintain a record of the check required by paragraph (d)(3) of this section for two years. The record must include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.

(5) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in paragraph (d)(4) of this section.

(6) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(e) A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

§ 35.620 Possession of survey instrument.

A licensee authorized to use byproduct material in a teletherapy unit shall have in its possession either a portable radiation detection survey instrument capable of detecting dose rate over the range 0.1 millirem per hour to 100 millirem per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1,000 millirem per hour.

§ 35.630 Dosimetry equipment.

(a) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

(1) The system must have been calibrated by the National Bureau of Standards or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or

(2) The system must have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by the National Bureau of Standards or by a calibration laboratory accredited by the AAPM. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

(b) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of this section.

the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

§ 35.632 Full calibration measurements.

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

(1) Before the first medical use of the unit; and

(2) Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one year.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of:

(1) The output within ±3 percent for the range of field sizes and for the distance or range of distances used for medical use;

(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer constancy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in *Physics in Medicine and Biology* Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in *Medical Physics* Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984 p. 213. (Both of these references have been approved for incorporation by reference by the Director of the Federal Register. Copies of the documents are available for inspection or may be obtained from the U.S. Nuclear Regulatory Commission, Public Document Room, 1717 H Street NW., Washington, DC 20555. Copies of the documents are also on file at the Office of the Federal Register, 1100 L Street NW., Room 8301, Washington, DC 20408. A notice of any change in the material will be published in the Federal Register.)

(e) A licensee shall correct mathematically the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding one month for cobalt-60 or six months for cesium-137.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the licensee's teletherapy physicist.

(g) A licensee shall retain a record of each calibration for the duration of use of the teletherapy unit source. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer linearity and constancy, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

§ 35.634 Periodic spot-checks.

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

(1) Timer constancy, and timer linearity over the range of use;

(2) On-off error;

(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;

(4) The accuracy of all distance measuring and localization devices used for medical use;

(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b) of this part; and

(6) The difference between the measurement made in paragraph (b)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with procedures established by the teletherapy physicist. That individual need not actually perform the spotcheck measurements.

(c) A licensee shall have the teletherapy physicist review the results of each spot-check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for two years.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month that assure proper operation of:

(1) Electrical interlocks at each teletherapy room entrance;

(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) A licensee shall arrange for prompt repair of any system identified in paragraph (d) of this section that is not operating properly, and shall not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section for two years.

The record must include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of timer linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

§ 35.636 Safety checks for teletherapy facilities.

(a) A licensee shall promptly check all systems listed in § 35.634(d) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by § 35.606 (a)–(d).

(b) If the results of the checks required in paragraph (a) of this section indicate the malfunction of any system specified in § 35.634(d), the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(c) A licensee shall retain for two years a record of the facility checks following installation of a source. The record must include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors, and the signature of the Radiation Safety Officer.

§ 35.641 Radiation surveys for teletherapy facilities.

(a) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by § 35.606 (a)–(d), the licensee shall perform radiation surveys with a portable radiation measurement survey instrument calibrated in accordance with § 35.51 of this part to verify that:

(1) The maximum and average dose rates at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 10 millirem per hour and 2 millirem per hour, respectively; and

(2) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

(i) Radiation dose quantities per unit time in restricted areas are not likely to cause personnel exposures in excess of the limits specified in § 20.101 of this chapter; and

(ii) Radiation dose quantities per unit time in unrestricted areas do not exceed the limits specified in § 20.105(b) of this chapter.

(b) If the results of the surveys required in paragraph (a) of this section indicate any radiation dose quantity per unit time in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the off position and not use the unit:

(1) Except as may be necessary to repair, replace, or test the teletherapy unit shielding or the treatment room shielding; or

(2) Until the licensee has received a specific exemption pursuant to § 20.501 of this chapter.

(c) A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record must include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

§ 35.643 Modification of teletherapy unit or room before beginning a treatment program.

(a) If the survey required by § 35.641 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by § 20.105(b) of this chapter, before beginning the treatment program the licensee shall:

(1) Either equip the unit with stops or add additional radiation shielding to ensure compliance with § 20.105(b);

(2) Perform the survey required by § 35.641 again; and

(3) Include in the report required by § 35.645 the results of the initial survey, a description of the modification made to comply with paragraph (a)(1) of this section, and the results of the second survey.

(b) As an alternative to the requirements set out in paragraph (a) of this section, a licensee may request a license amendment under § 20.105(a) of this chapter that authorizes radiation levels in unrestricted areas greater than those permitted by § 20.105(b). A licensee may not begin the treatment program until the license amendment has been issued.

§ 35.645 Reports of teletherapy surveys, checks, tests, and measurements.

A licensee shall mail a copy of the records required in §§ 35.636, 35.641, 35.643, and the output from the teletherapy source expressed as roentgens or rads per hour at one meter from the source and determined during the full calibration required in § 35.632, to the appropriate Commission Regional Office listed in § 30.6 of this chapter within thirty days following completion of the action that initiated the record requirement.

§ 35.647 Five-year inspection.

(a) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing for the duration of the license. The record must contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

Subpart J—Training and Experience Requirements

§ 35.900 Radiation Safety Officer.

Except as provided in § 35.901, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.32 to be an individual who:

(a) Is certified by:

(1) American Board of Health Physics in Comprehensive Health Physics;

(2) American Board of Radiology;
(3) American Board of Nuclear Medicine;
(4) American Board of Science in Nuclear Medicine; or
(5) Board of Pharmaceutical Specialties in Nuclear Pharmacy; or
(b) Has had classroom and laboratory training and experience as follows:
(1) 200 hours of classroom and laboratory training that includes:
(i) Radiation physics and instrumentation;
(ii) Radiation protection;
(iii) Mathematics pertaining to the use and measurement of radioactivity;
(iv) Radiation biology; and
(v) Radiopharmaceutical chemistry; and
(2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material; or
(c) Be an authorized user identified on the licensee's license.

§ 35.901 Training for experienced Radiation Safety Officer.

An individual identified as a Radiation Safety Officer on a Commission or Agreement State license before October 1, 1986 need not comply with the training requirements of § 35.900.

§ 35.910 Training for uptake, dilution, and excretion studies.

Except as provided in §§ 35.970 and 35.971, the licensee shall require the authorized user of a radiopharmaceutical in § 35.100(a) to be a physician who:
(a) Is certified in:
(1) Nuclear medicine by the American Board of Nuclear Medicine;
(2) Diagnostic radiology by the American Board of Radiology; or
(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:
(1) 40 hours of classroom and laboratory training that includes:
(i) Radiation physics and instrumentation;
(ii) Radiation protection;
(iii) Mathematics pertaining to the use and measurement of radioactivity;
(iv) Radiation biology; and
(v) Radiopharmaceutical chemistry; and
(2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes:
(i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
(iii) Administering dosages to patients and using syringe radiation shields;
(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and
(v) Patient followup; or
(c) Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.920 Training for imaging and localization studies.

Except as provided in § 35.970 or 35.971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in § 35.200(a) to be a physician who:
(a) Is certified in:
(1) Nuclear medicine by the American Board of Nuclear Medicine;
(2) Diagnostic radiology by the American Board of Radiology; or
(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:
(1) 200 hours of classroom and laboratory training that includes:
(i) Radiation physics and instrumentation;
(ii) Radiation protection;
(iii) Mathematics pertaining to the use and measurement of radioactivity;
(iv) Radiopharmaceutical chemistry; and
(v) Radiation biology; and
(2) 500 hours of supervised work experience under the supervision of an authorized user that includes:
(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
(iii) Calculating and safely preparing patient dosages;
(iv) Using administrative controls to prevent the misadministration of byproduct material;
(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
(vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and
(3) 500 hours of supervised clinical experience under the supervision of an authorized user that includes:
(i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
(ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
(iii) Administering dosages to patients and using syringe radiation shields;
(iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and
(v) Patient followup; or
(c) Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.

§ 35.930 Training for therapeutic use of radiopharmaceuticals.

Except as provided in § 35.970, the licensee shall require the authorized user of radiopharmaceuticals in § 35.300 to be a physician who:
(a) Is certified by:
(1) The American Board of Nuclear Medicine; or
(2) The American Board of Radiology in radiology or therapeutic radiology; or
(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:
(1) 80 hours of classroom and laboratory training that includes:
(i) Radiation physics and instrumentation;
(ii) Radiation protection;
(iii) Mathematics pertaining to the use and measurement of radioactivity; and
(iv) Radiation biology; and

(2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes:

(i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and

(ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.

§ 35.932 Training for treatment of hyperthyroidism.

Except as provided in § 35.970, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection,

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

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.

§ 35.934 Training for treatment of thyroid carcinoma.

Except as provided in § 35.970, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows:

(a) 80 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology; and

(b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid arcinoma in 3 individuals.

§ 35.940 Training for use of brachytherapy sources.

Except as provided in § 35.970, the licensee shall require the authorized user of a brachytherapy source listed in § 35.400 for therapy to be a physician who:

(a) Is certified in:

(1) Radiology or therapeutic radiology by the American Board of Radiology;

(2) Radiation oncology by the American Osteopathic Board of Radiology;

(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:

(1) 200 hours of classroom and laboratory training that includes:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology;

(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Checking survey meters for proper operation;

(iii) Preparing, implanting, and removing sealed sources;

(iv) Maintaining running inventories of material on hand;

(v) Using administrative controls to prevent the misadministration of byproduct material; and

(vi) Using emergency procedures to control byproduct material; and

(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:

(i) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(ii) Selecting the proper brachytherapy sources and dose and method of administration;

(iii) Calculating the dose; and

(iv) Post-administration followup and review of case histories in collaboration with the authorized user.

§ 35.941 Training for ophthalmic use of strontium-90.

Except as provided in § 35.970, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

(a) 24 hours of classroom and laboratory training that includes:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology;

(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

(1) Examination of each individual to be treated;

(2) Calculation of the dose to be administered;

(3) Administration of the dose; and

(4) Followup and review of each individual's case history.

§ 35.950 Training for use of sealed sources for diagnosis.

Except as provided in § 35.970, the licensee shall require the authorized user of a sealed source in a device listed in § 35.500 to be a physician, dentist, or podiatrist who:

(a) Is certified in:

(1) Radiology, diagnostic radiology, or therapeutic radiology by the American Board of Radiology;

(2) Nuclear medicine by the American Board of Nuclear Medicine; or

(3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

(b) Has had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:

(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
(2) Radiation biology;
(3) Radiation protection; and
(4) Training in the use of the device for the uses requested.

§ 35.960 Training for teletherapy.

Except as provided in § 35.970, the licensee shall require the authorized user of a sealed source listed in § 35.600 in a teletherapy unit to be a physician who:
(a) Is certified in:
(1) Radiology or therapeutic radiology by the American Board of Radiology;
(2) Radiation oncology by the American Osteopathic Board of Radiology;
(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
(b) Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:
(1) 200 hours of classroom and laboratory training that includes:
(i) Radiation physics and instrumentation;
(ii) Radiation protection;
(iii) Mathematics pertaining to the use and measurement of radioactivity; and
(iv) Radiation biology;
(2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes:
(i) Review of the full calibration measurements and periodic spot checks;
(ii) Preparing treatment plans and calculating treatment times;
(iii) Using administrative controls to prevent misadministrations;
(iv) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
(v) Checking and using survey meters; and
(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:
(i) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;
(ii) Selecting the proper dose and how it is to be administered;
(iii) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and
(iv) Post-administration followup and review of case histories.

§ 35.961 Training for teletherapy physicist.

The licensee shall require the teletherapy physicist to be an individual who:
(a) Is certified by the American Board of Radiology in:
(1) Therapeutic radiological physics;
(2) Roentgen ray and gamma ray physics;
(3) X-ray and radium physics; or
(4) Radiological physics; or
(b) Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed one year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a teletherapy physicist at a medical institution that includes the tasks listed in §§ 35.59, 35.632, 35.634, and 35.641 of this part.

§ 35.970 Training for experienced authorized users.

Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material on a Commission or Agreement State license issued before April 1, 1987 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of Subpart J.

§ 35.971 Physician training in a three month program.

A physician who, before July 1, 1984, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program need not comply with the requirements of §§ 35.910 or 35.920.

§ 35.972 Recentness of training.

The training and experience specified in this subpart must have been obtained within the five years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

Subpart K—Enforcement

§ 35.990 Violations.

(a) An injunction or other court order may be obtained to prohibit a violation of any provision of:
(1) The Atomic Energy Act of 1954, as amended;
(2) Title II of the Energy Reorganization Act of 1974, as amended; or
(3) Any rule, regulation, or order issued under these Acts.
(b) A court order may be obtained for the payment of a civil penalty imposed for violation of:
(1) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 under section 234 of the Atomic Energy Act of 1954, as amended;
(2) Section 206 of the Energy Reorganization Act of 1974;
(3) Any rule, regulation, or order issued under these Acts;
(4) Any term, condition, or limitation of any license issued under these Acts; or
(5) Any requirement for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.
(c) Any person who willfully violates any provision of the Atomic Energy Act of 1954, as amended, or any rule, regulation, or order issued under the Act may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both as provided by law. Regulations issued under the Act include regulations issued under sec. 161, and cited in the authority citation at the beginning of this part for the purposes of sec. 223.

§ 35.999 Resolution of conflicting requirements during transition period.

If the rules in this part conflict with the licensee's radiation safety program as identified in its license, and if that license was approved by the Commission before April 1, 1987 and has not been renewed since April 1, 1987, then the requirements in the license will apply. However, if that licensee exercises its privilege to make minor changes in its radiation safety procedures that are not potentially important to safety under § 35.31 of this chapter, the portion changed must comply with the requirements of this Part. At the time of license renewal and

thereafter, these admendments to this Part shall apply.

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

2. The authority citation for Part 30 continues to read as follows:

Authority: Sec. 161, Pub. L. 83–703, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, Pub. L. 93–438, 88 Stat. 1242, as amended (42 U.S.C. 5841).

3. Section 30.4 is amended by revising paragraphs (h) and (l) to read as follows and by adding new paragraphs (y) and (z) as follows:

§ 30.4 Definitions.

* * * * *

(h) "Medical use" means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

* * * * *

(l) "Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine;

* * * * *

(y) "Dentist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

(z) "Podiatrist" means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

4. Section 30.34 is amended by revising paragraph (g) to read as follows:

§ 30.34 Terms and conditions of licenses.

* * * * *

(g) A licensee may prepare technetium-99m radiopharmaceuticals only with technetium-99m that contains less than 0.15 microcuries of molybdenum-99 per millicurie of technetium-99m. The licensee shall perform tests and retain the records required by § 35.204.

PART 31—GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

5. The authority citation for Part 31 is revised to read as follows:

Authority: Secs. 81, 161, 183, 68 Stat. 935, 948, 954, as amended (42 U.S.C. 2111, 2201, 2233); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842).

Section 31.5 is also issued under sec. 274, 73 Stat. 688 (42 U.S.C. 2021).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 31.5(c)(1)–(3) and (5)–(9), 31.8(c), 31.10(b), and 31.11(b), (c), and (d) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 31.5(c)(4), (5), and (9), 31.11(b) and (e) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201o).

6. The authority citations following §§ 31.2, 31.5, 31.6, 31.7, 31.8, 31.10 and 31.11 are removed.

7. Section 31.11 is amended by revising paragraph (b) to read as follows:

§ 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

* * * * *

(b) A person shall not receive, acquire, possess, use, or transfer byproduct material under the general license established by paragraph (a) of this section unless that person:

(1) Has filed Form NRC–483, "Registration Certificate—In Vitro Testing with Byproduct Material Under General License," with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 and received from the Commission a validated copy of Form NRC–483 with a registration number assigned; or

(2) Has a license that authorizes the medical use of byproduct material that was issued under Part 35 of this chapter.

* * * * *

PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIALS

8. The authority citation for Part 32 continues to read as follows:

Authority: Sec. 161, Pub. L. 83–703, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec 201, Pub. L. 93–438, 88 Stat. 1242, as amended (42 U.S.C. 5841).

§ 32.70 [Removed]

9. Section 32.70 is removed.

10. In § 32.72 the section heading, the introductory text of paragraph (a), and paragraph (a)(4)(i) are revised to read as follows:

§ 32.72 Manufacture and distribution of radiopharmaceuticals containing byproduct material for medical use under Part 35.

(a) An application for a specific license to manufacture and distribute radiopharmaceuticals containing byproduct material for use by persons authorized pursuant to Part 35 of this chapter will be approved if:

* * * * *

(4) * * *

(i) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay, and the label, or the leaflet or brochure that accompanies each package, contains a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the radiopharmaceutical to persons licensed to use byproduct material listed in §§ 35.100, 35.200, or 35.300, as appropriate, and to persons who hold an equivalent license issued by an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

* * * * *

11. In § 32.73 paragraph (a)(5)(ii) is revised to read as follows:

§ 32.73 Manufacture and distribution of generators or reagent kits for preparation of radiopharmaceuticals containing byproduct material.

(a) * * *

(5) * * *

(ii) A statement that this generator or reagent kit (as appropriate) is approved for distribution to persons licensed by the U.S. Nuclear Regulatory Commission to use byproduct material identified in § 35.200 or under an equivalent license of an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

* * * * *

12. In § 32.74 the introductory text of paragraph (a) and paragraph (a)(3) are revised to read as follows:

§ 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to Part 35 of this chapter for use as a calibration or reference source or for the uses listed in §§ 35.400 and 35.500 of this chapter will be approved if:

* * * * *

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of

assay, and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use byproduct material identified in §§ 35.58, 35.400, or 35.500, as appropriate, and to persons who hold an equivalent license issued by an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

* * * * *

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

13. The authority citation for Part 40 continues to read as follows:

Authority: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841).

14. Section 40.4 is amended by revising paragraph (g) to read as follows:

§ 40.4 Definitions.

* * * * *

(g) "Physician" means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine;

* * * * *

Dated at Washington, DC, this 7th day of October 1986.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 86-23168 Filed 10-15-86; 8:45 am]

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