VOID SHEET

TO: License Fee Management Branch

FROM: Region IV

SUBJECT: VOIDED APPLICATION

Control Number: 418513

Applicant: V.A. Medical Center

Date Voided: 12/11/89

Reason for Void: Amendment 20 to NRC license 24-00144-05 authorized licensed material to be used at V.A. Medical Ctr in Grand Junction, Colorado.

Billie Gruszpecki 12/12/89
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 ☐ ML40 1/1

Processed by: _____

DEC 11 1989

Veterans Administration Medical Center
ATTN: W. T. Moore, M.D.
Chief of Staff
2121 North Avenue
Grand Junction, Colorado 81501

Gentlemen:

On November 28, 1989, the NRC issued Amendment 20 to NRC License 24-00144-05 (VA Medical Center, St. Louis, Missouri). This amendment authorized licensed material to be used at the VA Medical Center, Grand Junction, Colorado. Therefore, your facility has become an authorized place of use under the VA, St. Louis program.

Consistent with the above action, you will no longer need a separate NRC license and your renewal request dated February 21, 1989, to renew NRC License 05-08400-02, is hereby voided.

Sincerely,

Original signed by
R. J. Everett

R. J. Everett, Chief
Nuclear Materials Licensing Section

RIV:C/MNLS
RJEverett:nh
12/12/89

TECHNICAL ASSISTANCE REQUEST

DATE: March 14, 1989

TO: John H. Austin, Acting Chief
Medical, Academic, and Commercial Use Safety Branch, IMNS/NMSS

FROM: William L. Fisher, Chief, William L. Fisher
Nuclear Materials Safety Branch, Region IV

SUBJECT: REQUEST FOR TECHNICAL ASSISTANCE

__X__ Control Nos. 417504 and 418513 for VA Medical Centers in Cheyenne, Wy. and Grand Junction, Co.

Requested action:
_____ Custom source/device review
_____ Review and comment
_____ Provide policy guidance
__X__ Other (see remarks)

Remarks: At your request we have enclosed the letters from the VA Nuclear Network applicants that request an exemption from the regulations. These letters were not referred to NMSS because of the position taken in your memo dated October 6, 1988, which approved licensure of the Network. We have also enclosed copies of the latest deficiency letters to the hospitals dated January 25, 1989, and their revised applications dated February 8, 1989 (Grand Junction) and February 10, 1989 (Cheyenne).

To be completed by NMSS

Date:

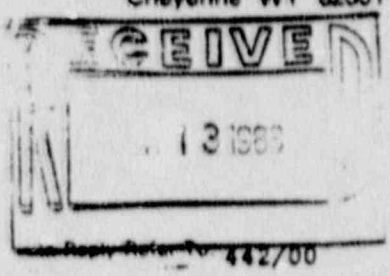
The above request has been received by NMSS/AB and assigned to _____ (name)

_____ (phone number). Please contact this individual for a status report if a response is not received by _____ (date).

Signature: _____
NMSS/AB Branch Chief

Medical and Regional
Office Center

2360 East Pershing Blvd.
Cheyenne WY 82001



Veterans Administration

June 10, 1988

Mr. Charles Cain
U.S. Nuclear Regulatory Commission
Material Radiation Protection Section
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

Dear Mr. Cain:

We are writing to formally request, pursuant to 10 CFR, Part 35.19, a specific exemption from the regulations of the Commission which have been interpreted by your office to preclude our further participation in the Nuclear Medicine Network for the purposes of providing diagnostic services to our patients.

We are further requesting that, if this matter is referred to the Advisory Committee on the Medical Uses of Isotopes (ACMUI), representatives of the Veterans Administration, as petitioners for the exemption, be permitted to present relevant material and answer the concerns of that committee.

The various materials previously submitted in connection with our license renewal will support our request for this exemption. If further information is required, please contact us.

Your consideration of this matter is appreciated.

Sincerely,

GEORGE H. ANDRIES, JR.
Center Director

Medical Center

2121 North Avenue
Grand Junction CO 81501

Veterans Administration

JUNE 2, 1988

In Reply Refer To: 575/00

Mr. Charles Cain
U.S. Nuclear Regulatory Commission
Material Radiation Protection Section
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

Dear Mr. Cain:

We are writing to formally request, pursuant to 10CFR Part 35.19, a specific exemption from the regulations of the Commission which have been interpreted by your office to preclude our further participation in the Nuclear Medicine Network for the purposes of providing diagnostic services to our patients.

We are further requesting that, if this matter is referred to the Advisory Committee on the Medical Uses of Isotopes (ACMUI), representatives of the Veterans Administration, as petitioners for the exemption, be permitted to present relevant material and answer the concerns of that committee.

The various materials previously submitted in connection with our license renewal will support our request for this exemption. If further information is required, please contact us.

Your consideration of this matter is appreciated.

Sincerely,

A. BOURRET
Medical Center Director

IE-1122

Medical Center
MS-16
2121 North Avenue
Grand Junction CO 81501

T2

Veterans Administration

February 8, 1989

In Reply Refer To: 575/11

Charles L. Cain
Chief, Nuclear Materials Licensing Section
U.S. Nuclear Regulatory Commission
811 Ryan Plaza Drive
Arlington, Texas 76001

RE: Control No. 418513

Dear Mr. Cain:

Enclosed is our revised renewal application for the medical use of byproduct materials. This revised application replaces and supersedes all previous submissions and represents the current description of our program for radiation safety and regulatory compliance.

In regard to the concerns you expressed and the information requested, these matters have been addressed in the body of the application as follows:

ITEM	REFERENCE
RG 10.8 Application format, Supporting information	Enclosed
Quarterly audits	Application, Item 10.1(a)
Audit format	Supporting information, Section 5
Authorized users	Application, Item 7.1 Supporting information, Section 2,3
Committee structure	Application, Item 10.1(d)
Committee meetings	Application, Item 10.1(e)
Management charge to RSO	Application, Item 10.1(b) Item 10.2 ALARA Program
RSO Qualifications	Supporting information, Section 4
Supervision	Application, Item 10.1(a),(c)
Previous submissions	This revised application supercedes pervious submissions

41851 23

U.S. Nuclear Regulatory Commission

We are pleased that you are continuing the review of our application and we trust that this updated informationn satisfies the remainder of your concerns.

Sincerely yours,

W. T. Moore, MD

W. T. MOORE, M.D.
Chief of Staff

Enclosure

2/15/84

JAMES A. FLETCHER, M.D.
Director, Nuclear Medicine Service (115)
Veterans Administration
Washington, DC 20420

RENEWAL APPLICATION FOR NRC MEDICAL USE LICENSE

Veterans Administration Medical Center
2121 North Avenue
Grand Junction, Colorado 81501

Revised February 3, 1989

NRC License Application - VA Medical Center, Grand Junction, CO

Item 5-RADIOACTIVE MATERIALS and Item 6-PURPOSE

Byproduct Material	Amount	Purpose
5.a Material in 35.100	as needed	Uptake, dilution and excretion
5.b Material in 35.200	as needed	Imaging and localization
5.c Material in 35.57	as needed	Calibration and reference sources

NRC License Application - VA Medical Center, Grand Junction, CO

Item 7-RESPONSIBLE INDIVIDUALS

7.1 Authorized Users for Medical Use

All medical use of materials will be performed by or under the supervision of Erica George, M.D. (ABNM 1972). Other Network nuclear physicians who may authorize, supervise and interpret diagnostic studies are:

James W. Fletcher, M.D.	ABMN 1972
James L. Littlefield, M.D.	ABNM 1980
Max S. Lin, M.D.	ABNM 1972
J. A. Fernandez-Pol, M.D.	ABNM 1975

Requests for clinical studies are reviewed, approved/disapproved, and doses and methods prescribed prior to performance of study.

Temporary authorized users may be designated under the provisions of Part 35.27, (a.,b. and c.)

7.2 Authorized Users for non-Medical Use

Not applicable, only Part 35 authorized materials will be used.

7.3 Radiation Safety Officer

The Radiation Safety Officer is designated as Sherrick Harmon. Training and experience, see attached supporting information.

NRC License Application - VA Medical Center, Grand Junction, CO

Item 8-TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

8.1 Training Program

We will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, Revision 2. Groups of workers who will receive training and the method, frequency, and content are identified below.

Group	Method	Frequency
Technicians, Nuclear Medicine	lecture, demonstration	2x annually

Content: Applicable sections of parts 19, 20 and 35, detailed procedures and methods of compliance.

Radiology Staff	lecture, written procs.	annually

Content: Location of use areas, security procedures.

Security Staff	lecture, written procs.	annually

Content: Package receipt, emergency response and procedures

Building Management	lecture, written procs.	annually

Identification of areas, cleaning procedures.

Supply Staff	lecture, written procs.	annually

Content: Procedures for receipt and delivery of packages.

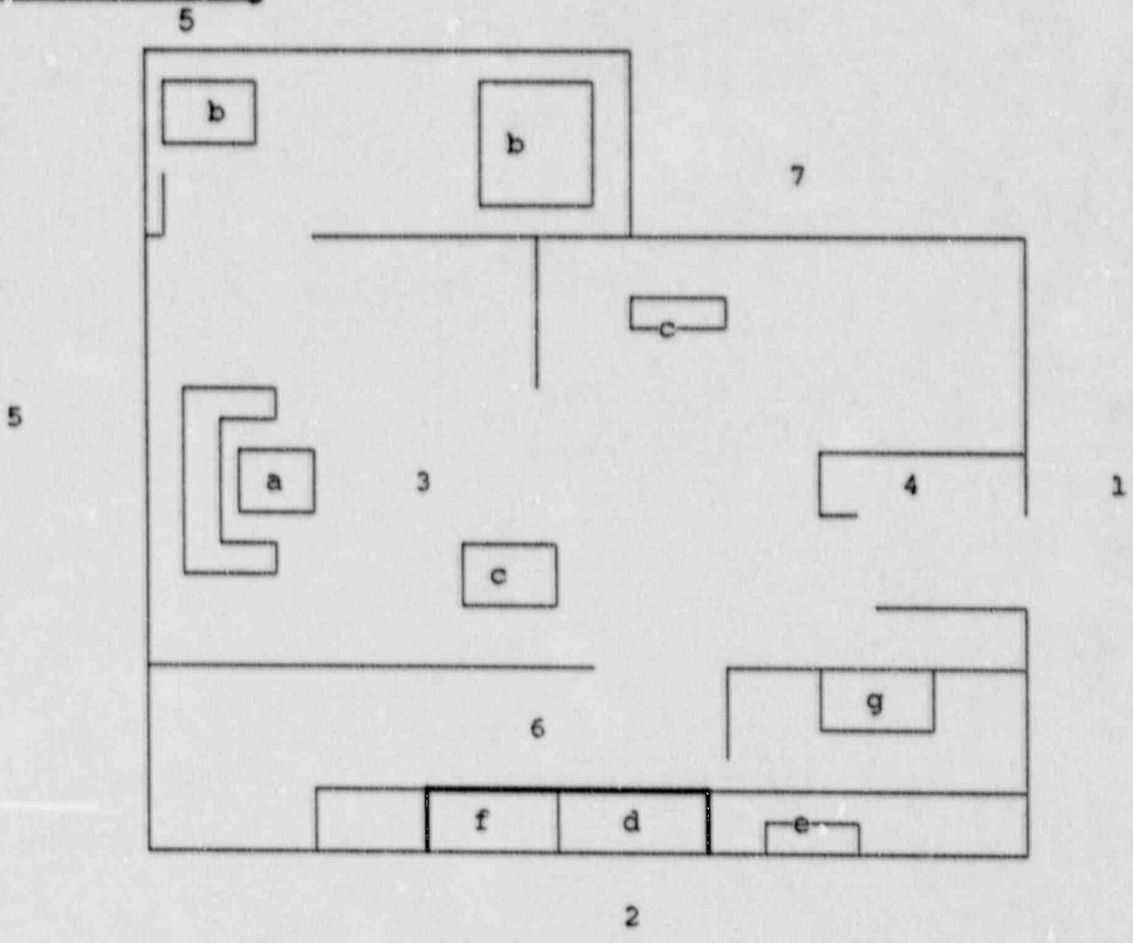
Operators/MAAs	lecture, written procs.	annually

Content: Package receipt, emergency contacts

NRC License Application - VA Medical Center, Grand Junction, CO

Item 9-FACILITIES AND EQUIPMENT

9.1 Annotated Drawing



Numbered Areas

1 - Hallway
2 - Radiology Exam
3 - Patient procedures*
4 - Patient injection

5 - Bldg. exterior
6 - Radiopharmacy*
7 - Pt. Toilet

* - restricted

Lettered Equipment

a - gamma camera
b - instrumentation
c - air exhaust (ceiling)
d - Pb shielding, generator, storage, waste
e - sink
f - vented dose prep, L-block
g - dose calibrator

9.2 Survey Meter Calibration

We will establish and implement the model procedure for calibrating survey instruments which was published in Appendix B to Regulatory Guide 10.8, Revision 2.

9.3 Dose Calibrator Calibration

We will establish and implement the model procedure for calibrating dose calibrator instruments which was published in Appendix C to Regulatory Guide 10.8, Revision 2.

9.4 Personnel Monitor Program

We will establish and implement the model procedure for personnel external exposure monitoring which was published in Appendix D to Regulatory Guide 10.8, Revision 2.

9.5 Imaging Equipment - Not Applicable

9.6 Other Equipment and Facilities

No radioactive materials other than those described in 10CFR Part 35 will be used in the Medical Center.

NRC License Application - VA Medical Center, Grand Junction, CO

Item 10-RADIATION SAFETY PROGRAM

10.1 Radiation Safety Committee/Radiation Safety Officer

We will issue the model Radiation Safety Committee Charter and Radiation Safety Officer Delegation of Authority that was published in Appendix F to Regulatory Guide 10.8, Revision 2. (see also 10.2, ALARA Program)

a. RSO Supervision

Administrative supervision is provided by the Chief Technologist, Radiology. This includes personnel management and non-technical evaluation in the area of radiation safety and nuclear medicine.

Technical supervision and evaluation of radiation safety activities is provided by Francis K. Herbig, Network Program Director and RSO, St. Louis VAMC. Evaluation of duties and performance is performed quarterly, written reports submitted and corrective actions monitored. Audits may also be performed by qualified physicians, health physics, radiopharmacy or other qualified technical personnel of the St. Louis VAMC.

The Radiation Safety Committee receives and reviews RSO reports and directs actions necessary for safety program compliance.

b. RSO Authority and Responsibilities

The Medical Center Director delegates to the RSO the operational responsibility, 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.

c. Technical Supervision

The technical quality and adequacy of diagnostic procedures is monitored by the supervisory Network physician. Repeated or unexplained problems are referred to the Quality Assurance Committee and corrective actions implemented if required. Technical supervision is also provided by the Radiation Safety Committee to assure that; (1) workers are instructed in the appropriate principles of radiation safety; (2) required instructions of the authorized users, and procedures established by the RSO and/or the RSO supervisor and the applicable NRC regulations and license conditions are followed; and (3) that periodic reviews are conducted of materials use and records.

d. Membership, Radiation Safety Committee

The following staff of the Medical Center are members of the Committee:

Name	Staff Position	Committee Position
R. Fulton, M.D.	Physician-in-Charge Radiology Service	Chairman
C. Sorrenson	Chief Technologist Radiology Service	Member
P. Hayes, RN	Staff Nurse	Nursing Rep.
S. Harmon	Chief Tech. NuclMed RadSafe Officer	RSO
W. Lawrance	Staff Engineer	Management Rep.
F. Herbig (ad hoc)	Program Director Nuclear Medicine Network	RadSafe Auditor

e. Radiation Safety Committee Meetings

Meetings of the RSC are regularly scheduled in each calendar quarter. Additional meetings may be called by the Chairman or RSO for consideration of safety related business. Any member of the Medical Center staff may petition for a meeting to bring radiation safety matters before the Committee.

10.2 ALARA Program (following pages)

ALARA PROGRAM
Veterans Administration Medical Center
Grand Junction, CO

1. Management Commitment

The management of the Grand Junction VA Medical Center is committed to the policy of keeping individual and collective radiation exposures ALARA. The management establishes and supports the necessary administrative and functional elements for radiation safety and promotes the concept of ALARA in the institution.

An annual formal review of the Radiation Safety Program will be conducted which includes operating procedures, past exposure records and inspections. This audit will establish that improvements have been sought, if necessary, and have been implemented where reasonable.

Modifications to operating procedures, equipment and facilities will be made where these will reduce exposures unless, in our judgment, the cost is unjustified. Where modifications were recommended but not implemented the reasons will be documented.

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

2. Radiation Safety Committee

The RSC performs a thorough review of the qualifications of all applicants proposing to use ionizing radiation in the medical center to ensure that the applicant takes appropriate measures to maintain exposure ALARA. This review requires that the applicant has established and justified systematized procedures for ALARA including the use of protective equipment.

The RSC delegates enforcement authority for ALARA to the Radiation Safety Officer and supports necessary assertion of this authority. In instances where actions and recommendations of the RSO are overruled or not supported the basis of this action will be documented.

The committee will require all users to review current procedures when filing for new authorizations and, if necessary, to develop or modify procedures to implement ALARA. The committee reviews on a quarterly basis all instances of occupational exposure exceeding established Investigation Levels and decides if action is warranted.

The committee annually reviews and evaluates the ALARA efforts of individuals charged with radiation safety responsibilities including authorized users, workers and the medical center management.

3. Radiation Safety Officer

The RSO will perform an annual review of all operational elements of the ALARA program. A quarterly review is conducted of occupational external and internal exposures and investigates or requires action where investigation Levels are exceeded. Facility survey records are reviewed quarterly to ensure ALARA. Known instances of deviation from good ALARA practices are also investigated to determine the cause and to require program changes.

An educational program is conducted to instruct personnel in the ALARA philosophy and to inform radiation workers and all involved medical center staff of the ALARA program efforts. The Radiation Safety Officer and staff cooperate with all users and workers to ensure development of ALARA procedures and receives and evaluates suggestions for improvement of ALARA practices.

4. Authorized Users and Occupationally Exposed Workers

Preliminary to any application for new procedures using ionizing radiation users will consult with the RSO concerning ALARA practices for the proposed use in order to develop and implement specific ALARA guidelines.

Authorized users are required to promote and explain the ALARA concept and ensure that supervised workers are trained in good radiation safety practices and their relationship to work procedures and conditions.

All occupationally exposed workers are required to report instances where it is believed that good ALARA practices are not promoted and followed.

5. Investigational Levels and Actions for External Exposure

	mREM/Quarter	
	Level I	Level II
A. Whole Body, head and trunk, blood forming organs, lens of eyes, gonads	125	375
B. Hands, forearms, feet and ankles	1875	5625
C. Skin of whole body	750	2250

The Radiation Safety Officer reviews records of personnel monitoring quarterly. The following actions are taken at the stated Investigation Levels.

	Exposure	Action
A.	Less than Level I	None
B.	Greater than Level I, less than Level II	Report exposure to RSC; RSC will evaluate the exposure conditions and record its action recommendation.
C.	Greater than Level II	RSO investigates and prepares a report for the RSC minutes including the exposure record, causes, actions taken and recommendations. Copies of minutes are received by the Medical Center Director.

In situations where exposures need to exceed Investigational Level I or II, these may be re-established at a higher level by action of the committee provided that all reasonable ALARA practices are enforced and the justification for new levels is recorded by the committee.

W. T. Moore, MD

W. Taft Moore, M.D.
Chief of Staff and
Acting Medical Center Director

10.3 Leak Testing

We will establish and implement the model procedure for leak-testing sealed sources that was published in Appendix H to Regulatory Guide 10.8, revision 2.

10.4 Safe Use of Radiopharmaceuticals

We will establish and implement the model safety rules published in Appendix I to Regulatory Guide 10.8, Revision 2.

10.5 Spill Procedures

We will establish and implement the model spill procedures published in Appendix J to Regulatory Guide 10.8, Revision 2.

10.6 Ordering and Receiving

We will establish and implement the model guidance for ordering and receiving radioactive material that was published in Appendix K to Regulatory Guide 10.8, Revision 2.

10.7 Opening Packages

We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, Revision 2.

10.8 Unit Dose Records

We will establish and implement the model procedure for a unit dose record system which was published in Appendix M.1 to Regulatory Guide 10.8, Revision 2.

10.9 Multidose Vial Records

We will establish and implement the model procedure for a multidose vial record system that was published in Appendix M.2 to Regulatory Guide 10.8, Revision 2.

10.10 Molybdenum Concentration Records

We will establish and implement the model procedure for measuring and recording Molybdenum concentration that was published in Appendix M.3 to Regulatory Guide 10.8, Revision 2.

10.11 Implant Source Use Records

Not Applicable

10.12 Area Survey Procedures

We will establish and implement the model procedure for area surveys that was published in Appendix N to Regulatory Guide 10.8, Revision 2.

10.13 Air Concentration Control

1. Worker Dose from Nobel Gases

We will collect spent noble gas in a shielded container and will establish and implement the model procedure for checking trap effluent that was published in Appendix O.3 to Regulatory Guide 10.8, Revision 2.

For estimation of worker dose from normal (20%) loss of activity from patients will follow the model procedure for calculating worker dose from nobel gases that was published in Appendix O.1 to Regulatory Guide 10.8, Revision 2. Calculations are available for inspection.

2. Worker Dose from Aerosols

Not applicable, aerosols will not be used.

3. Public Dose from Airborne Effluent

We will follow the model procedure for calculating airborne effluent concentration that was published in Appendix O.2 to Regulatory Guide 10.8, Revision 2. Calculations are available for inspection.

4. Spilled Gas Clearance Time

We will calculate the spilled gas clearance times according to the procedure that was published in Appendix O.4 to Regulatory Guide 10.8, Revision 2. Clearance times will be posted in the patient examination room.

10.14 Radiopharmaceutical Therapy

Not applicable, radiopharmaceutical therapy will not be performed.

10.15 Implant Therapy

Not applicable, implant therapy will not be performed.

10.16 Other Safety Procedures

Not applicable, only procedures authorized by 10CFR Part 35 will be performed.

NRC License Application - VA Medical Center, Grand Junction, CO

Item 11-WASTE MANAGEMENT

11.1 - Waste Disposal

We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, Revision 2.

11.2 - Other Waste Disposal

Not applicable, only procedures authorized by 10CFR Part 35 will be performed.

418513

Medical Use License Renewal
Supporting Information

Grand Junction VA Medical Center

February 3, 1989

1. Background:

Nuclear Medicine services have been provided to patients of the Grand Junction VA Medical Center under the aegis of the VA Nuclear Medicine Network since 1979. As a participant, patient imaging and diagnostic in-vivo examinations are performed at this medical center, data is acquired and stored on a digital computer system and transmitted to a central site at the VAMC in St. Louis, MO.

2. Medical Supervision:

Physician User: Erica A. George, M.D.
Medical Director, Nuclear Medicine Network
American Board of Nuclear Medicine - 1972

Dr. George serves as the Medical Director of the Nuclear Medicine Network. Her responsibilities include definition of standard operating procedures for all patient examinations, quality assurance/quality control programs, consultation with referring physicians, training, and definition and supervision of such other medical activities as are required by the program.

Dr. George is assisted by qualified, ABMN certified, nuclear medicine physicians at the central site (St. Louis VAMC) who review, interpret and report the clinical findings of patient examinations.

The qualified physician users at the central site exercise control and supervision of the medical uses of by-product materials in several important ways.

A. All procedures which may be provided to patients are defined and described in written procedure manuals which are used at all participating medical centers. These manuals specify all details of patient preparation, dosing, data acquisition, data processing and presentation which are required to complete the clinical procedures. The patient procedure manuals are supplemented by radiopharmacy manuals which specify all the requirements for preparation, measurement and quality control of radiopharmacy products in accord with the FDA approved package inserts and the applicable regulations of the NRC. Frequent review and revision, if necessary, of these procedure manuals is conducted by the physician staff.

B. Each request for any patient procedure is reviewed and approved, disapproved or modified by a qualified nuclear medicine physician prior to performance of an examination. If necessary, consultation with the primary physician is obtained. Based on the relevant clinical information, the reviewing physician specifically determines which patient procedure(s) will be performed, the radiopharmaceutical to be used, the dosage and route of administration. Variations in procedure may be directed to assure the adequacy of an examination. The written prescription is returned to the technologist prior to performance of the examination.

C. Review and interpretation of patient examinations routinely takes place within 12 working hours of the performance of the procedure. Certain examinations may require 'mid-stream' modification of procedures, depending on the progress of the examination and interim results. This is accomplished by transmission of data and/or consultation with the Nuclear physician. A verification of the prescription accompanies the clinical data. All work is reviewed for technical adequacy, conformance to the prescription and overall quality as well as the clinical diagnostic impression. Unusual or recurrent problems or deficiencies are reviewed by the physician quality assurance panel and appropriate corrective actions are taken.

D. Training is conducted in clinical procedures for the Nuclear Technologists as the needs are identified. This includes methods for introduction and performance of new procedures, evaluation of procedures and identification of important supplemental medical information which relates to the evaluation of results.

E. Dr. George works with the medical staff of the Grand Junction VAMC, through the Chief of Staff. Medical intervention and resolution of medical problems is a collaborative effort among the physicians responsible for patient care. Certain medical activities may be delegated to qualified individuals. The responsibility for Nuclear Medicine Services is not delegated.

These procedures constitute all of the supervision, review evaluation and control of procedures which is normally expected and exercised in a clinical diagnostic Nuclear Medicine setting, frequently exceed the medical supervision exercised in more conventional nuclear medicine settings and, far exceed the medical supervision, physician interaction and intervention that occurs in mobile nuclear medicine delivery systems.

3. Additional Qualified Users

In addition to Dr. George, other qualified users include:

James W. Fletcher, M.D.	ABNM 1972
Max S. Lin, M.D.	ABNM 1972
James L. Littlefield, M.D.	ABNM 1980
J. Albert Fernandez-Pol, M.D.	ABNM 1975

4. Radiation Safety Supervision

Radiation Safety Officer: Sherrick Harmon

Formal Training:

Time/Subjects: 200+ hours of training in:

(a) radiation physics and instrumentation
(b) radiation protection
(c) calculations relating to measurement and quantitation of radiation and radioactivity.
(d) radiation biology
(e) radiopharmaceutical chemistry

Location: Community College of Denver
Associate Degree - Nuclear Medicine
September,1974 - August, 1976

In-Service Training:

At least three times annually training a review is conducted by the Radiation Control Staff of the St. Louis VA Medical Center. Training includes techniques for safety measurements and quality control, safety evaluation, audit procedures and regulatory compliance. Typical sessions are four hours.

Experience: Full-time radiation safety technologist
Grand Junction VA Medical Center
March, 1981 - present

Duties: Safety and regulatory compliance for all authorized medical uses of byproduct materials including but not limited to: training ancillary personnel, surveys, wipe testing, instrument evaluation and testing, exposure review and evaluation, inventories, disposal and record keeping and compliance management.

The qualifications of the designated RSO exceed the requirements of 10CFR Part 35.900.

5. Quarterly Audit Format

RADIATION CONTROL FACILITY/USER INSPECTION

Authorized User:___ **Facility: ___** **Date:**

FINDINGS: This inspection was an examination of activities related to radiation safety policy and procedures, compliance with Federal regulations, the Radiation Control program, and the terms and conditions of the authorized use permit. The findings as a result of this inspection are:

___ No items of noncompliance found.

The following items of noncompliance were found:

	Area of Noncompliance	Specify
___	Posting/area signs/NRC-3	___
___	Posting emergency procedures	___
___	Labeling sources/waste	___
___	Permit/license not available	___
___	Rad Cntl Manual not available	___
___	Receipt, use, disposal records	___
___	Survey/wipe records	___
___	Quarterly inventories	___
___	Personnel monitoring	___
___	Failure to wear monitors	___
___	Monitor turnover	___
___	Use in unauthorized location	___
___	Safety procedures	___
___	Procedures for volatile nuclides	___
___	Safety equipment	___
___	Decontamination equipment	___
___	Survey procedures	___
___	Survey instruments	___
___	Unauthorized nuclide	___
___	Unauthorized user/worker	___
___	Initial worker training	___
___	Annual training	___
___	Awareness proc/hazards	___
___	Food/drink in work area	___
___	Spill/incident unreported	___
___	Dose calibrator geometry	___
___	Dose calibrator accuracy	___
___	Dose calibrator linearity	___
___	Dose calibrator constancy	___
___	Problem not reported to RCO	___
___	Sealed source wipe tests	___
___	Xenon trap check	___
___	Room exhaust calculations	___
___	Exhaust flow checks	___
___	Fume hood flow checks	___
___	Xenon use procedures	___
___	Injection procedures	___
___	Waste storage/segregation	___
___	Waste containers	___
___	Waste surveys	___
___	Waste disposal procedures	___
___	Area security	___

Authorized User: ___ **Date:** ^D

___ Other noncompliance/problem identification:

___

Survey/ Wipe Tests	Area	Survey Dose Rate	Wipe Test dpm/100cm^2
	Storage		
	Preparation	___	___
	Use areas	___	___
	Other (___)	___	___
		___	___

ALARA Data:	Worker	Qtr. Dose	Annual Dose
	.	.	.
	.	.	.
	.	.	.
	.	.	.

Monitor Report Date: .

Radiation Control Recommendations:

Immediate Action:

Long-term Compliance:

Surveyed by: _____

NMLS:CLC
Control No. 418513

JAN 25 1989

Veterans Administration Medical Center
ATTN: A. Bourret
Medical Center Director
2121 North Avenue
Grand Junction, Colorado 81501

Gentlemen:

This is in reference to the ongoing matter of the renewal of your byproduct material license for use in nuclear medicine.

We have completed review of your letter dated June 2, 1988, signed by A. Bourret, wherein you requested an exemption from NRC regulations to permit use of the VA Nuclear Medicine Network in lieu of a local authorized user physician. As a result of our review we have determined that your use of the Network is permitted contingent to your adherence to commitments and to your provision of additional information as described below.

1. Your letter dated May 23, 1988, signed by Francis K. Herbig, stated that a revised license renewal application would be forthcoming to NRC and would be prepared in accordance with Regulatory Guide 10.8, Revision 2 (August 1987). We have not yet received this application.

   This letter also included "Supporting Information" regarding use of the Network at the VA Medical Center at Cheyenne, Wyoming, as well as the identification and other information regarding the Radiation Safety Officer (RSO) at that facility. Such information was not provided for your own facility at Grand Junction.

   In your response to this letter you should provide a revised license application prepared in accordance with the guidelines described in Regulatory Guide 10.8 (copy enclosed). You should note that only diagnostic procedures may be authorized using the Network. Use of therapy procedures will require the use of an authorized user physician local to the Grand Junction area. The application should also include information similar to that previously provided by Mr. Herbig for the facility at Cheyenne.

2. In order to authorize use of the Network you should commit to sending from your St. Louis office an authorized user physician, to be named in the license, to the Grand Junction facility at least quarterly to audit program activities including the review of operating procedures. A written report of each audit, signed by the auditor, should be maintained on file at the Grand Junction facility for review by NRC inspectors. This report may be discarded following NRC inspector review.

RIV:C:NMLS
CLCain/jt
1/23/89

In your response, provide a detailed format for the quarterly audit and identify authorized user physician(s) that may conduct the audit. These physician(s) will be identified by name in the license.

3. Your application should clearly describe the structure of the Radiation Safety Committee required by 10 CFR 35.22. You should identify the title and location of each member and clarify the method by which regular meetings will be conducted.

4. Your application should identify the name of the RSO at Grand Junction and describe how the RSO meets the qualification requirements of 10 CFR 35.900. Your application should include the management statement to the RSO described in 10 CFR 35.23 and refer to the duties of the RSO as outlined in 10 CFR 35.21(b). A draft Regulatory Guide entitled "Qualifications for the Radiation Safety Officer in a Large-Scale Non-Fuel-Cycle Radionuclide Program" has been provided for guidance in this area.

5. Your application should describe the manner in which the RSO at Grand Junction will receive management supervision. You should distinguish between the supervision provided locally and that provided from the St. Louis office. Your response should address the stipulations in 10 CFR 35.25.

6. Indicate whether the other commitments identified in your letter dated April 30, 1987, signed by Francis K. Herbig, are still accurate.

In order to continue review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter. Please reply in duplicate and refer to Control No. 418513.

Sincerely,
Original signed by
C. L. Cain

Charles L. Cain, Chief
Nuclear Materials Licensing Section

Enclosures:
1. Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs," August 1987
2. Draft Regulatory Guide OP 722-4 "Qualifications for the Radiation Safety Officer in a Large-Scale Non-Fuel-Cycle Radionuclide Program," April 1982

cc: (see next page)

cc:
Veterans Administration Medical Center
ATTN: Francis K. Herbig
M/S 115AJC
918 N. Grand Avenue
St. Louis, Missouri 63106

Veterans Administration
ATTN: Dr. James W. Fletcher
Director, Nuclear Medicine Service (115)
810 Vermont Avenue NW
Washington, D.C. 20420

bcc w/o enclosures:
RDMartin
RLBangart
WLFisher
JHAustin
CLCain

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

October 6, 1988

10/17
Chuck:
Does this cause
any problems?
Bill
cc: Dale

MEMORANDUM FOR: William L. Fisher, Chief
Nuclear Materials and
Emergency Preparedness Branch, RIV

FROM: Vandy L. Miller, Chief
Medical, Academic, and Commercial
Use Safety Branch, NMSS

SUBJECT: TECHNICAL ASSISTANCE REQUEST DATED JUNE 21, 1988

This is in response to the above request which involves the use of the Veterans Administration's Nuclear Medicine Network in lieu of an authorized physician at the licensee's Cheyenne, Wyoming, Grand Junction, Colorado, and Fort Harrison, Montana, medical facilities.

Since the Fort Harrison, Montana, facility has obtained a qualified physician and since a license has been issued to the hospital it should no longer be of concern.

After a review of previous decisions and careful consideration of additional facts that relate to the operation of the Nuclear Medicine Network at the Cheyenne VAMC and Grand Junction VAMC facilities, it is decided to continue licensing these two facilities in the manner that they have been previously licensed. This decision is based on several considerations.

The facilities in question have been authorized to operate through the Nuclear Medicine Network for about eight to nine years. When they were granted this authorization, the safety and efficiency advantages and disadvantages of the proposed operation were carefully weighed. The facilities in question have operated during this time period in a satisfactory manner. They do not appear to perform any better or any worse than other Veteran's Administration or civilian hospitals. There does not appear to be any safety reason to consider limiting the facilities' authorization based on past performance.

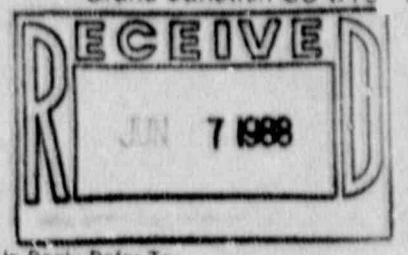
The key issue in this licensing action is the apparent lack of supervision for technologists. To demonstrate compliance with 10 CFR 35.25, "Supervision" (which requires instruction, compliance with instructions, and periodic review), the licensee and the authorized user must provide some mechanism for supervision other than daily personal presence, which is the normal mechanism for supervising. A quarterly visit to the hospital to review operating procedures in place would be acceptable. This authorization may not be expanded to include any therapy clinical procedure.

Presently, the staff is working on training requirements for physicians and ancillary personnel and a contract study for quality assurance in Nuclear Medicine activities. It is possible that the above initiatives may result in new policy decisions that will lead to a different operating definition of supervision requirements in the future and a reassessment of the network.

Norman L. Miller for

Vandy L. Miller, Chief
Medical, Academic, and Commercial
Use Safety Branch, NMSS

Medical Center
2121 North Avenue
Grand Junction CO 815



Veterans Administration

JUNE 2, 1988

In Reply Refer To: 575/00

Mr. Charles Cain
U.S. Nuclear Regulatory Commission
Material Radiation Protection Section
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

Dear Mr. Cain:

We are writing to formally request, pursuant to 10CFR Part 35.19, a specific exemption from the regulations of the Commission which have been interpreted by your office to preclude our further participation in the Nuclear Medicine Network for the purposes of providing diagnostic services to our patients.

We are further requesting that, if this matter is referred to the Advisory Committee on the Medical Uses of Isotopes (ACMUI), representatives of the Veterans Administration, as petitioners for the exemption, be permitted to present relevant material and answer the concerns of that committee.

The various materials previously submitted in connection with our license renewal will support our request for this exemption. If further information is required, please contact us.

Your consideration of this matter is appreciated.

Sincerely,

A. BOURRET
Medical Center Director

88-1122

Veterans Administration

In Reply Refer To: 657/115A

May 23, 1988

Mr. Charles Cain
U.S. Nuclear Regulatory Commission
Material Radiation Protection Section
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

Dear Mr. Cain;

We have revised in the Part 35/10.8 Rev 2 format the license renewal applications for the Cheyenne and Grand Junction VAMC programs. Additional information relative to your concerns about the medical supervision and radiation safety in VA Nuclear Medicine Network affiliated institutions is included. The revised applications will reach you shortly through the respective medical centers. I am enclosing a sample copy of the supporting information for your early consideration.

Briefly, our position holds that the medical supervision is more than sufficient to manage the program in the best interest of the patients. The Network is not simply an interpretation service. The responsibility for any aspect of services to the patients is not abrogated nor delegated in any way. With regard to the safety component of the program, we believe the designated RSOs meet all of the Part 35 requirements and, have consistently demonstrated their ability to perform as the individuals functionally responsible for regulatory compliance over a period of years. Their work in this regard is audited and evaluated at frequent intervals by qualified radiation safety personnel as well as the local committee and medical center management.

Additional economic information concerning the significance of Network operations is enclosed. From this you can appreciate the quantity and economic value of the services provided to veterans seeking medical care. Less obvious, but more important, is the fact that no participating medical center is in a fiscal position to purchase this level of service for its patients from alternative local sources.

We fully realize that this licensing environment is not explicitly covered by current regulatory positions. However, the use of modern telecommunications technology and especially the internal organization of the program permits the safe and effective delivery of patient services. Any reasonable license conditions in addition to the Part 35/10.8 requirements can be accommodated by the evaluation, oversight and supervisory controls already in place.

I can assure you that we share the same abiding concerns for the quality of service and the safety of our patients and staff that you must reflect in your licensing evaluations. If it will be of value, I will be pleased to visit your offices to discuss this matter further. You and/or your staff are also invited to visit St. Louis for an assessment and further assurances concerning any aspect of the program.

Yours truly,

Francis K. Herbig
Program Director

Enclosures

Copy: J.W. Fletcher, M.D.

Byproduct Materials License Renewal - Supporting Information
Cheyenne VA Medical Center

Background:

Nuclear Medicine services have been provided to patients of the Cheyenne VA Medical Center under the aegis of the VA Nuclear Medicine Network since 1979. As a participant, patient imaging and diagnostic in-vivo examinations are performed at this medical center, data is acquired and stored on a digital computer system and transmitted to a central site at the VAMC in St. Louis, MO.

Medical Supervision:

Physician User: Erica A. George, M.D.
Medical Director, Nuclear Medicine Network
American Board of Nuclear Medicine - 1972

Dr. George serves as the Medical Director of the Nuclear Medicine Network. Her responsibilities include definition of standard operating procedures for all patient examinations, quality assurance/quality control programs, consultation with referring physicians, training, and definition and supervision of such other medical activities as are required by the program.

Dr. George is assisted by qualified, ABMN certified, nuclear medicine physicians at the central site (St. Louis VAMC) who review, interpret and report the clinical findings of patient examinations.

The qualified physician users at the central site exercise control and supervision of the medical uses of by-product materials in several important ways.

A. All procedures which may be provided to patients are defined and described in written procedure manuals which are used at all participating medical centers. These manuals specify all details of patient preparation, dosing, data acquisition, data processing and presentation which are required to complete the clinical procedures. The patient procedure manuals are supplemented by radiopharmacy manuals which specify all the requirements for preparation, measurement and quality control of radiopharmacy products in accord with the FDA approved package inserts and the applicable regulations of the NRC. Frequent review and revision, if necessary, of these procedure manuals is conducted by the physician staff.

B. Each request for any patient procedure is reviewed and approved, disapproved or modified by a qualified nuclear medicine physician prior to performance of an examination. If necessary, consultation with the primary physician is obtained. Based on the relevant clinical information, the reviewing physician specifically determines which patient procedure(s) will be performed, the radiopharmaceutical to be used, the dosage and route of administration. Variations in procedure may be directed to assure the adequacy of an examination. The written prescription is returned to the technologist prior to performance of the examination.

C. Review and interpretation of patient examinations routinely takes place within 12 working hours of the performance of the procedure. Certain examinations may require 'mid-stream' modification of procedures, depending on the progress of the examination and interim results. This is accomplished by transmission of data and/or consultation with the Nuclear physician. A verification of the prescription accompanies the clinical data. All work is reviewed for technical adequacy, conformance to the

prescription and overall quality as well as the clinical diagnostic impression. Unusual or recurrent problems or deficiencies are reviewed by the physician quality assurance panel and appropriate corrective actions are taken.

D. Training is conducted in clinical procedures for the Nuclear Technologists as the needs are identified. This includes methods for introduction and performance of new procedures, evaluation of procedures and identification of important supplemental medical information which relates to the evaluation of results.

E. Dr. George works with the medical staff of the Cheyenne VAMC, through the Chief of Staff. Medical intervention and resolution of medical problems is a collaborative effort among the physicians responsible for patient care. Certain medical activities may be delegated to qualified individuals. The responsibility for Nuclear Medicine Services is not delegated.

These procedures constitute all of the supervision, review evaluation and control of procedures which is normally expected and exercised in a clinical diagnostic Nuclear Medicine setting, frequently exceed the medical supervision exercised in more conventional nuclear medicine settings and, far exceed the medical supervision, physician interaction and intervention that occurs in mobile nuclear medicine delivery systems.

Additional Qualified Users

In addition to Dr. George, other qualified diagnostic users include:

James W. Fletcher, M.D.	ABNM 1972
Max S. Lin, M.D.	ABNM 1972
James L. Littlefield, M.D.	ABNM 1980
J. Albert Fernandez-Pol, M.D.	ABNM 1975

Radiation Safety Supervision

Radiation Safety Officer: Glenn Janezich

Formal Training:

Time/Subjects - 200+ hours of training in:

(a) radiation physics and instrumentation
(b) radiation protection
(c) calculations relating to measurement and quantitation of radiation and radioactivity.
(d) radiation biology
(e) radiopharmaceutical chemistry

Location: Nuclear Medicine Institute
Cleveland, Ohio
May, 1983 - May 1984

In-Service Training:

At least three times annually training a review is conducted by the Radiation Control Staff of the St. Louis VA Medical Center. Training includes techniques for safety measurements and quality control, safety evaluation, audit procedures and regulatory compliance. Typical sessions are four hours.

Additional Training:

Radiation Safety Specialist Training
Oklahoma State University
March, 1988
One week

Experience: Full-time radiation safety technologist
Cheyenne VA Medical Center
December 1984 - present

Duties: Safety and regulatory compliance for all authorized medical uses of byproduct materia's including but not limited to: training ancillary personnel, surveys, wipe testing, instrument evaluation and testing, exposure review and evaluation, inventories, disposal and record keeping and compliance management.

The qualifications of the designated RSO exceed the requirements of 10CFR Part 35.900.

ECONOMIC IMPACT
NUCLEAR MEDICINE NETWORK

A modest cost study was conducted for the calendar year 1986 to compare the actual Network costs for participating Medical Centers with the costs if an equivalent number and mix of patient procedures were purchased through local medical facilities. Jefferson Barracks and Syracuse were excluded from the study since the Network use in these facilities is 'non-standard' in that JB is a division of a larger center and Syracuse is a part-time participant.

Cost projections for local purchase where made by using the actual procedure mix performed at the VA and the charge data obtained from a local referral center which provides Nuclear Medicine services. Ambulance costs were derived from the MAS Service of each VA and the cost for inpatient transportation calculated and added to the procedure cost to obtain a total purchase cost to the VA.

To determine actual Network costs, salaries, supplies, travel and phone charges were taken from fiscal data at each VA center, including the core facility at St. Louis. Maintenance was determined as a fixed percentage of new equipment cost and a straight-line 10 year depreciation of new equipment cost was included. From these data direct Network costs were calculated. The costs for operation of the St. Louis facilities were allocated to each participant on the basis of procedures performed and the total cost by Medical Center for Network participation was determined. Management and space overhead was not included.

Table 1 summarizes the cost elements, average values and cost avoidance for each Center. While it is tempting to claim the cost avoidance as an actual dollar saving, in fact it is unlikely that any participant would have Fee Basis dollars budgeted to cover the purchase of the quantity of service provided through the Network. Rather, it is likely that more patients received quality service through the Medical Center's association in the Network system.

The impact of any actions which disrupt or delay services provided to the Network participants will have a significant and adverse impact on the fiscal position of the referring centers in a period of constricted funding in all Federal programs and, especially, on the public health of the veteran population by making certain clinical procedures unavailable or inconvenient. This later consideration applies in particular to the most severely ill patients who cannot be transported safely to other facilities.

TABLE 1

NUCLEAR MEDICINE NETWORK COST ANALYSIS

Activity	Marion	PopBluff	Amarillo	GrandJct	Cheyenne	St. Louis
No. Patient Studies	1,560	822	689	327	487	
% Inpatients	89	84	64	79	80	
			*** COST OF SERVICES THROUGH LOCAL PURCHASE ***			
Cost Item						
Ambulance Trip ($)	202	60	191	214	250	
No. of Inpatients	1,388	690	441	258	390	
Ambulance Costs ($)	280,457	41,429	84,223	55,283	97,400	
Purchase of Procedures ($)	450,954	250,126	167,160	106,636	160,750	
Total Costs to Purchase ($)	731,411	291,555	251,383	161,919	258,150	
Average Cost to Purchase ($)	469	355	365	495	530	
			*** COST OF SERVICES THROUGH NETWORK ***			
Cost Item						
Salaries ($)	36,024	25,454	18,516	18,810	22,030	172,700
Supplies,Travel ($)	53,112	23,500	25,800	12,000	20,000	21,250
Maintenance ($)	16,400	16,400	16,400	16,400	16,400	22,400
Depreciation ($)	21,900	21,900	21,900	21,900	21,900	29,900
Telecommunications ($)	0	0	0	0	0	12,845
Total Cost thru Network ($)	127,436	87,254	82,616	69,110	80,330	259,095
Allocated St. Louis Costs ($)	104,038	54,820	45,950	21,808	32,479	
Total Cost thru Network ($)	231,474	142,074	128,566	90,918	112,809	
Average Cost thru Network ($)	148	173	187	278	232	
			*** SUMMARY ***			
Cost Avoidance/Procedure ($)	320	182	178	217	298	
Total Cost Avoidance ($)	499,937	149,481	122,817	71,001	145,341	

NMLS:JEW
Mail Control No. 418513

APR 27 1988

VA Medical and Regional Office Center
ATTN: A. Bourett
Medical Center Director
2121 North Avenue
Grand Junction, CO 81501

Gentlemen:

This refers to your correspondence dated December 3, 1984, requesting renewal of your byproduct material license for use in nuclear medicine. NRC issued a substantially revised regulation in regard to the medical use of byproduct material on October 16, 1986, which became effective on April 1, 1987. A copy of this regulation, 10 CFR Part 35, is enclosed.

You prepared your application for license renewal in accordance with Regulatory Guide 10.8, Revision 1, "Guide for the Preparation of Applications for Medical Programs." This Regulatory Guide has been superseded by the enclosed Revision 2 which provides the guidance needed by you in preparing an application in regard to the revised regulation. You should use this Guide in resubmitting your application for license renewal. We trust that your use of this Guide will help to acquaint you with the new requirements specified in 10 CFR 35. Your application should supply all of the information identified in the Guide and should not reference any previously submitted correspondence. Also enclosed is Form 313 for filing your application.

You should note that you will no longer be able to use the Veterans Administration (VA) "Nuclear Medicine Network" to provide direct supervision over the nuclear medicine operations. The VA Network does not resolve the issue of providing effective on-site nuclear medicine supervision for radiation safety, regulatory compliance, management oversight and sustained quality assurance to the level and frequency required to assure patient and worker safety.

RIV:NMLS
JEWhitten
4/22/88

C:NMLS
CLCain
/ /88

In order to continue prompt review of your application, we request that you submit your response within 30 calendar days from the date of this letter. Please reply in duplicate and reference the mail control number indicated at the top of this letter. Your current license will not expire until final action has been taken on your renewal application.

Sincerely,

Original signed by
JACK E WHITTEN

Jack E. Whitten
Nuclear Materials Licensing Section

Enclosures:
1. Regulatory Guide 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs," (August 1987)
2. 10 CFR Part 35
3. Form 313

bcc w/o enclosures:
R. L. Bangart
C. L. Cain

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

APR 08 1988

EGM 88-04

Chuck
Date 4/8

MEMORANDUM FOR: William T. Russell, Regional Administrator, RI
J. Nelson Grace, Regional Administrator, RII
A. Bert Davis, Regional Administrator, RIII
Robert D. Martin, Regional Administrator, RIV
John B. Martin, Regional Administrator, RV

FROM: James Lieberman, Director
Office of Enforcement

SUBJECT: INFORMATION COPIES TO VA HEADQUARTERS

In an effort to improve coordination between NRC and the Veterans' Administration, and thereby improve the VA's management of nuclear medicine departments in its hospitals, NRC staff recently met with senior VA management personnel. At that meeting, the VA indicated a desire for closer involvement in what the NRC is doing concerning VA hospitals. We have discussed this with NMSS and concluded that the NRC should provide further information to VA Headquarters concerning VA licensees.

Therefore, to provide information at a higher level in the VA organization, please add the following individual to your distribution of any Inspection Report, Confirmatory Action Letter, Notice of Violation, or Order that you issue concerning a VA facility:

Dr. James W. Fletcher
Director, Nuclear Medicine Service (115)
Veterans' Administration
810 Vermont Ave. NW
Washington, D.C. 20420

James Lieberman, Director
Office of Enforcement

cc: J. Taylor, DEDRO
R. Cunningham, NMSS
Enforcement Coordinators
RI, RII, RIII, RIV, RV
OE Staff

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

MAR 3 0 1988

MEMORANDUM FOR: William L. Fisher, Chief
Nuclear Materials and Emergency
Preparedness Branch, Region IV

FROM: Vandy L. Miller, Chief
Medical, Academic and Commercial
Use Safety Branch, NMSS

SUBJECT: VETERANS ADMINISTRATION NUCLEAR NETWORK

This is in response to your request for additional technical assistance relative to the renewal of the by-product materials licenses currently held by the Veterans Administration Medical Centers in Cheyenne, Wyoming and Grand Junction, Colorado. We have reviewed the case, the previous technical assistance request, ACMUI Comments, previous policy guidance on the subject and the following comments are made:

1. The proposed V. A. Network does not resolve the issue of providing effective on-site nuclear medicine supervision for radiation safety, regulatory compliance, management oversight and sustained quality assurance to the level and frequency required to assure patient and worker safety.

2. The Veterans Administration Medical Center (VAMC) in St. Louis has not demonstrated that it exercises direct supervision over the nuclear medicine operations in either the Cheyenne or Grand Junction facilities. The Cheyenne and Grand Junction facilities are independent hospitals and retain their own management and medical staff.

3. VAMC St. Louis appears to function as a focal point for nuclear medicine resources and expertise for these and other medical centers. The service is analogous to a contract health physics service or consultative service for resolving medical questions. As such, the subject institutions do not appear to be under any legal obligation to follow the advice or suggestions of VAMC St. Louis. The NRC license remains the regulatory control at these institutions.

4. The only precedent that appears to be similar in concept is the VAMC St. Louis' direct support of other medical centers within its geographic area. These relationships have been recognized by amendment to the institution's NRC license. These were approved, in part, due to the supportive nature of the relationship and the close proximity of the satellite hospitals to VAMC St. Louis. Due to the larger distances between VAMC St. Louis and the Cheyenne and Grand Junction facilities it appears that VAMC St. Louis can do little more than offer "consultative" services on an infrequent basis to these hospitals at this time.

Because the proposed network does not appear to offer equivalent, or improved, safety and quality assurance standards over those offered by direct, day-to-day supervision, it is recommended that the licenses be renewed in accordance with current regulation and licensing policy.

Should the situation regarding the Veterans Administration's nuclear network program significantly change, their proposal should be reconsidered.

Please contact James H. Myers at FTS 492 - 0635 if you have further questions.

Vandy L. Miller, Chief
Medical, Academic, and Commercial
Use Safety Branch, NMSS

TECHNICAL ASSISTANCE REQUEST

DATE: December 7, 1987

TO: Vandy L. Miller, Chief, Medical, Academic, and Commercial Use Safety Branch, IMNS

FROM: Charles L. Cain, Chief, Nuclear Materials Licensing Section, Region IV

SUBJECT: REQUEST FOR TECHNICAL ASSISTANCE

__X__ Control Nos. 417504 and 418513 (enclosed)

__X__ See attached memo.

_____ Suggested change in licensing procedure (enclosed)

_____ Other

Requested action: _____ Custom source/device review

_____ Review and comment

__X__ Provide policy guidance - "Nuclear Medicine Network" Issue

_____ Other

Options:

1. Conversion to coverage under broad scope license (VA - St. Louis).
2. Allow licensees to use the "Nuclear Medicine Network" as requested.
3. Issue conventional licenses

To be completed by NMSS

Date:

The above request has been received by MA&CUS and assigned to _____ (name)

_____ (phone number). Please contact this individual for a status report if a response is not received by _____ (date).

Signature: _____
MA&CUS Branch Chief

DEC 11 1987

MEMORANDUM FOR: Vandy L. Miller, Chief
Medical, Academic, and Commercial Use Safety Branch, IMNS

FROM: William L. Fisher, Chief
Nuclear Materials and Emergency Preparedness Branch,
Region IV

SUBJECT: LICENSING OF VETERANS ADMINISTRATION (VA) NUCLEAR NETWORK IN CHEYENNE, WYOMING, AND GRAND JUNCTION, COLORADO

This is to request further Technical Assistance Review (TAR) relative to the renewal of licenses for VA Medical Centers in Cheyenne and Grand Junction. The review of these licensees has been complicated by the Part 35 revision and the licensees' request to function under the VA St. Louis broad scope license. We would welcome your analysis of this additional information. Enclosed are documents which bear on the review of these licenses.

We suggest the following as possible ways of handling these renewals:

a. Allow each licensee to become a satellite place of use under the VA St. Louis broad scope license, if this broad scope license is currently allowing this arrangement for other "Nuclear Medicine Network" users.

b. Allow the licensee to used the "Nuclear Medicine Network" concept under the conditions outlined in the VA St. Louis letter dated April 30, 1987.

c. Require each licensee to address all the requirements as outlined in Part 35 and Regulatory Guide 10.8, Revision 2 (i.e., issue licenses to each location in a conventional manner).

The following is a chronology of Region IV interaction with the subject licensees, the VA St. Louis, and NMSS in the process of attempting to complete these renewals.

VA - Cheyenne Renewal Chronology

May 9, 1985 - After reviewing the license renewal application at Jack Whitten's request, Pat Vacca contacted him via telephone to address the question of whether we should continue to accept the VA "Nuclear Medicine Network," authorized user arrangement between VA Cheyenne and VA St. Louis.

June 12, 1985 - Pat, after consulting with Vandy Miller, suggested that a TAR be submitted by Region IV.

NMLS RIV	C:NMLS RIV	NMEPB
JEWhitten;dp	CLCain	WLFisher
12/7/87	12/7/87	12/10/87

July 11, 1985 - TAR sent to NMSS for review and assistance. Cases were reviewed by ACMUI.

April 23, 1986 - TAR response received in RIV.

June 6, 1986 - Letter sent to VA Cheyenne outlining the ACMUI and NMSS collective findings, required actions, and suggestions relative to continued operation of the "Nuclear Medicine Network." Four additional items of concern were identified which affected the renewal action.

July 15, 1986 - Letter sent, at NMSS request, to Francis Herbig, VA St. Louis, with edited ACMUI comments.

September 12, 1986 - Letter from VA Cheyenne indicating a readiness to meet NRC requirements for an onsite physician. Licensee provided name of Dr. Surapanani for addition to license as an authorized user.

March 18, 1987 - Deficiency letter sent to VA requesting additional information on Dr. Surapanani's qualifications.

April 30, 1987 - Telecon between Jack Whitten and Francis Herbig specific to continued operation of the "Nuclear Medicine Network" under revised 10 CFR Part 35.

June 11, 1987 - Letter from VA Cheyenne to indicate that any further negotiations with NRC on renewal of license would be handled by Mr. Herbig.

Additional Correspondence for VA - Grand Junction

November 12, 1986 - Letter received responding to June 6, 1986, deficiency letter providing names of physicians, Dr. Fulton and Dr. Nichols as additions to license as authorized users.

November 21, 1986 - Telecon between Jack Whitten and Tast Moore, M.D., Chief of Staff, requesting additional information specific to Dr. Moore's qualifications.

March 18, 1987 - NRC letter sent to VA Grand Junction requesting additional information about Dr. Fulton's qualifications and the radiation safety committee composition.

March 26, 1987 - Letter from VA Grand Junction indicating our March 18, 1987, deficiency letter had been forwarded to Francis Herbig.

April 30, 1987 - Telecon between Jack Whitten and Francis Herbig about continued operation of the "Nuclear Medicine Network" under new 10 CFR Part 35.

May 4, 1987 - Letter received with comments specific to both VA Grand Junction and VA Cheyenne, with draft proposal outlining handling of nuclear medicine operations and the possibility of authorizing both sites as alternate locations under the VA St. Louis broad scope license.

June 5, 1987 - Letter from VA Grand Junction indicating that any further negotiations with NRC on renewal of license would be handled by Mr. Herbig.

Your assistance in dispositioning these cases will be appreciated.

Original Signed By:
WILLIAM L. FISHER

William L. Fisher, Chief
Nuclear Materials and Emergency
Preparedness Branch, Region IV

bcc:
J. Whitten
C. Cain
W. Fisher

Medical Center
2121 North Avenue
Grand Junction CO 81501

Veterans Administration

June 5, 1987

In Reply Refer To: 575/00

Mr. Jack E. Whitten
Nuclear Materials Safety Section
U. S. Nuclear Regulatory Commission
611 Ryan Plaza Drive
Arlington, TX 76011

Dear Mr. Whitten:

This is to confirm our intention to pursue renewal of our NRC Byproduct Materials License. We are asking that coordination and negotiation of the renewal be handled through Francis K. Herbig, the RSO and Program Director for the Nuclear Network, at the St. Louis VA Medical Center. At such time as you have reached an accord on the terms and conditions, we will submit confirmation of our agreement to those terms.

We are willing to continue our byproduct materials program either as a site of alternate use under the St. Louis Broad Scope license, or to delegate responsibility to qualified network physicians and RSO responsibility to the St. Louis Radiation Control Office.

Thank you for your continued support and interest in finding a satisfactory solution to an unusual licensing circumstance.

Sincerely yours,

A. Bourret

A. BOURRET
Medical Center Director

4775-16/71

FILE COPY

Veterans Administration

Medical Center St. Louis MO 63125

MAY - 4 1987

In Reply Refer To:

April 30, 1987

U.S. Nuclear Regulatory Commission
ATTN: Jack E. Whitten
Nuclear Materials Safety Section
611 Ryan Plaza Drive
Arlington, Texas 76011

Dear Jack;

Attached is a draft of the program which we believe most closely fits the way our program is conducted now and offers the most promise of satisfactory control and supervision. Basically, a participating medical center would be considered a site of alternate use under our broad license with the added requirement of some additional local control to assure full management participation.

Alternately, the participating medical centers (Directors with the concurrence of the Chiefs of Staff) could delegate clinical responsibility to the network physicians and radiation safety responsibility to the St. Louis RSO and staff.

Let me know what you think. This has gone on so long now that it is tempting to take the easy way; let's find the best way.

We want you to know that your efforts to help keep a good program going are appreciated.

Yours truly,

Francis K. Herbig

418513

DRAFT

Nuclear Regulatory Commission Licensing
VA Nuclear Medicine Network Medical Centers

1. Purpose and Scope

This part prescribes the conditions, requirements and provisions under which a VA Medical Center patient may receive the benefit of Nuclear Medicine procedures through the technology and professional expertise provided by the St. Louis Nuclear Medicine Network. These procedures may be performed at locations where a full complement of Nuclear Medicine staff is not available to the Medical Center and the clinical data is transmitted with a telecommunications system to physician experts at the St. Louis VA Medical Center (SLVAMC).

2. License Conditions

VA Medical Centers which participate as a clinical site for patient procedures in association with the SLVAMC Nuclear Medicine Network shall be designated as an alternate use site under the terms and conditions of the Broad Scope license issued to the SLVAMC.

3. Responsibility

3.1 The Chief of Nuclear Medicine, SLVAMC, recommends physicians for approval to the Radiation Safety Committee (RSC). The RSC reviews and approves or disapproves the qualifications. Physicians who will be assigned diagnostic clinical responsibilities in the Nuclear Medicine Network are approved by the St Louis RSC, and are required to meet the training and experience specifications of 35.910 and 35.920.

3.2 The Radiation Safety Officer recommends technical staff at the participating VAMC's as Assistant Radiation Safety Officers. These are individuals who by reason of training and experience can perform all necessary radiation safety procedures, recognize out-of-line situations, and take appropriate actions. Qualifications shall include satisfactory completion of one year in an approved NMT training program, or, certification by the NMTCB or ARRT, or, 3 years responsible experience. Should meet 10 CFR 35.900(b)(1)(2)

3.3 In consideration of additional sites for operation as Network medical centers, the RSC shall fully consider the current and future span of control, commitments and availability of staff to meet the clinical and safety requirements of the program.

3.4 When the RSC approves and accepts an additional site for Network operations, the NRC must be notified within 30 days.

2) License would have to be amended to include new site.

b) Using special condition similar to LCM allowing SLVAMC to add and drop new sites. or Special well-logging condition that allows same..

4. Delegation of Clinical Responsibility

4.1 The responsibilities delegated to approved physicians include:

(1) prior review, approval/disapproval of all requests for diagnostic patient studies,

(2) modification of clinical procedures consistent with the accepted practices,

(3) interpretation of clinical data and rendering a written report for the patient's chart and to the referring physician, and,

(4) consultation with referring physicians concerning nuclear medicine procedures.

4.2 The credentials and privileges of Nuclear Network physicians shall also be approved and recorded by the professional practice authority of the local VA Medical Centers.

4.3 Resident physicians in training at the SLVAMC may perform the above functions under the direct supervision of an approved physician.

4.4 In the event of equipment failures or other circumstances which preclude normal Network service for a medical center, a visiting authorized user may provide services if the conditions of 35.27 are fully met.

5. Delegation of Safety Responsibility

5.1 The St. Louis RSC and RSO delegate to the Assistant RSO responsibility to perform as necessary all required radiation safety procedures. All activities shall be fully documented as required by the NRC and hospital survey and accrediting offices and organizations.

5.2 The St. Louis RSO or a qualified designee will visit each participating VA medical center on a regular basis. Visits will ordinarily be four (4) times annually but never less than three times annually. During these visits laboratory records and procedures will be inspected and evaluated, training will be conducted and once annually a complete ALARA audit of the local program will be performed.

5.3 The physician member of the local radiation control subcommittee may be called upon for advice and assistance in matters pertaining to patient and staff safety. (see 6.1)

6. Local Control

6.1 Each participating VA Medical Center shall establish a committee concerned with matters of radiation safety. The committee will be administratively a subcommittee of the St. Louis RSC but in all other respects shall meet the administrative and oversight responsibilities specified in 35.22. The committee has full authority, organizational freedom and management prerogative to meet requirements of 35.23. For the purposes of this part the Assistant RSO serves as Radiation Safety Officer for the subcommittee.

6.2 In addition to the requirements of 35.22, one member of the committee shall be a physician who meets the training and experience requirements of Subpart J, 35.910 and 35.920. This member serves as a resource person for the committee and will advise and act on behalf of patient and staff safety.
(see 5.3)

6.3 The St. Louis Radiation Safety Office will submit reports of inspections and audits together will recommendations for consideration at each RSC subcommittee meeting.

6.4 The St. Louis Radiation Safety Officer will attend at least one local subcommittee meeting annually.

7. Scope of Remainder of Program

7.1 In all other respects the activities with byproduct materials at each participant VAMC shall be conducted in full compliance with the administrative, technical and safety requirements of 10 CFR Parts 19, 20 and 35.

FKH
May 1, 1987

375-16

Medical Center
2121 North Avenue
Grand Junction, CO 81501

I-1

Veterans Administration

March 26, 1987

Mr. Jack E. Whitten
Nuclear Materials Safety Section
Nuclear Regulatory Commission Region IV
611 Ryan Plaza Drive, Suite 1000
Arlington, TX 76011

SUBJECT: License Renewal Application

1. In reply to your letter of March 18, 1987 regarding our application for license renewal, I have taken the following actions.

a. A copy of your letter was forwarded to Mr. Fran Herbig, Director of the Nuclear Medicine Network in St. Louis, Missouri for his review.

b. Mr. Herbig indicated per a telephone conversation with this Medical Center that upon receipt of a copy of your letter, he would review your comments and contact you personally regarding this matter.

c. As Director of the VA Nuclear Medicine Network, we rely on Mr. Herbig for guidance in these special areas of licensing and I feel your office will receive a prompt reply from him upon receipt of your letter.

2. If I can be of any further service regarding this matter, please contact my office.

A. BOURRET
Medical Center Director

In Reply Refer To: 114

MAR 18 1987

Veterans Administration Medical Center
ATTN: A. Bourett
Medical Center Director
2121 North Avenue
Grand Junction, Colorado 81501

Gentlemen:

This is to confirm our telephone conversation on November 21, 1986, with W. T. Moore, M.D. in which we discussed the information we need to continue review of your application dated December 3, 1984.

The items specified below are those we discussed:

1. Radiation Safety Committee composition not in accordance with 10 CFR 35.11(b).

2. Dr. Fulton's legal name as it is listed on his certification certificates.

3. Copy of Dr. Fulton's nuclear medicine certification certificate.

If we do not receive a reply from you within 30 calendar days from the date of this letter, it may be necessary to deny your application for license renewal and to terminate your license. This action would require you to divest yourself of all licensed material in your possession.

Sincerely,
Original signed by
JACK E. WHITTEN

Jack E. Whitten
Nuclear Materials Safety Section

cc:
Veterans Administration Central Office
Director, Nuclear Medicine Service (115
810 Vermont Avenue, N.W.
Washington, DC 20420

RIV:NMSS
JEWhitten;df
3/16/87

C:NMSS
RJEverett
3/16/87

NRC FORM 218 (4-76) NRCM 0240 — U.S. NUCLEAR REGULATORY COMMISSION

TELEPHONE OR VERBAL CONVERSATION RECORD

DATE 11-21-86

TIME 9 ☑ A.M. ☐ P.M.

☐ INCOMING CALL ☑ OUTGOING CALL ☐ VISIT

PERSON CALLING	OFFICE/ADDRESS	PHONE NUMBER / EXTENSION

PERSON CALLED	OFFICE/ADDRESS	PHONE NUMBER / EXTENSION
Thst Moore, M.D.		FTS 322-0031

CONVERSATION

SUBJECT: Nuc Med Cert of Richard E. Fulton, III

SUMMARY

1. Send Copy of Certification of Dr. Fulton. for N.M.
2. R.S.C. as per 35.11(b).

(24x14)

Both - Review Item 132 with Dr Moore
Need letter
Have him call.

REFERRED TO: MS-15

ACTION REQUESTED

☐ ADVISE ME OF ACTION TAKEN.

INITIALS

DATE

ACTION TAKEN

INITIALS

DATE

NRC FORM 218 (4-76)

MS-16 Cont.

Medical Center

2121 North Avenue
Grand Junction CO 81501

Veterans Administration

November 12, 1986

In Reply Refer To: 575/00

Nuclear Regulatory Commission
Region IV
Suite 1000
611 Ryan Plaza Drive
Arlington, TX 76011

SUBJ: Renewal, Byproduct Material License 05-08400-02

1. We are writing to revise our recent communication regarding the renewal of our license which designated Dr. Sherman Nichols to become the responsible physician for supervisory, administrative and safety concerns within the Nuclear Medicine Service. The demands of clinical responsibilities in internal medicine preclude Dr. Nichols from assuming these responsibilities at this time.

2. Instead, Dr. Richard Fulton has agreed to accept these tasks. Dr. Fulton is board certified in diagnostic radiology and nuclear medicine and has 11 years of clinical nuclear medicine experience. He presently provides full-time clinical radiology service under contract to this medical center. Dr. Fulton, or one of his qualified associates, is available at the hospital or on-call for any situations which require consultation or corrective actions. Clinical nuclear medicine consultations, interpretations, technical and safety supervision will continue to be provided by the VA Nuclear Medicine Network staff based at the St. Louis VAMC.

3. We believe this arrangement will satisfy your expressed concerns regarding the availability of qualified professional staff locally. If you have further comments or suggestions, please contact us.

A. BOURRET
Medical Center Director

Richard E. Fulton, III, M.D.
P.O. Box 1628
Grand Junction, Co 81501

Radiology - Licensed 1972
ABP-
DR - 1975

FTS-322-0031

When was Dr Fulton certified in Nuc. Med?

4118513

YMS-16
T1

United States
Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive Suite 1000
Arlington, Texas 76011

Attention: Mr. Jack Whitten

Gentlemen:

We have reviewed your comments and sugggestions regarding the renewal of our materials license #24-08400-02 and agree to meet the your requirement for the availablity of a qualified physician in the event of an emergency situation in the Nuclear Medicine Service.

Dr. S. Nichols, a member of our full-time medicial staff has agreed to accept this responsibility. Dr. S. Nichols will receive the minimum 30 hours of radiation safety training conducted by the Network and Radiation Control staff at the St. Louis VA Medical Center. The training will include: radiation safety basis of regulatory requirements; routine safety practices; the ALARA program; analysis of potential hazards in Nuclear Medicine; evaluation of radiation exposure in emergency situations; analysis of procedures for minimizing exposure and contaminiation; measurement methods for determination of exposure and contaminations levels. We expect to complete this training by April 15, 1987 and will advise you of any changes in the program content or schedule.

Thank you for your continued interest and helpful suggestions for our program. We look forward to early renewal of our license and will continue to conduct our Nuclear Medicine program under the conditions of our existing license and in full compliance with the regulatory requirements.

Yours truly,

W. T. Moore, M.D.

Acting Director

41853

JUL 15 1986

NMSS:JEW
Mail Control Nos. 417504 and 418513

Veterans Administration Medical Center
Nuclear Medicine Service
ATTN: Francis Herbig
Radiation Control Director
115AJC
St. Louis, Missouri 63125

Gentlemen:

Please find enclosed copies of the edited letters, memos, and NRC staff telephone conversation records of ACMUI comments you requested in our telephone conversation of May 16 and 23, 1986.

As originally indicated to Grand Junction, Colorado, and Cheyenne, Wyoming, Veterans Administration Medical Centers in our letters dated June 6, 1986, and our telephone conversations of May 16 and 23, 1986, we would be pleased to discuss this authorized user matter or any other matter with you and your staff either by telephone or in a scheduled meeting. Should you wish a telephone conference call or a meeting, please contact me for coordination with NRC Washington, NRC Region IV, and all Veterans Administration staff to be included.

Sincerely,

Original Signed By
Jack E. Whitten

Jack E. Whitten
Nuclear Materials Safety Section

Enclosure:
As stated

RIV:NMSS
JEWhitten;df
7/8/86

C:NMSS
RJEverett
7/9/86

NMSS: JEW
Control No: 418513

JUN 6 1986

Veterans Administration Medical Center
ATTN: W. P. Freer, Director
2121 North Avenue
Grand Junction, CO 81501

Gentlemen:

This is in reference to your letter dated December 3, 1984, to renew License No. 05-08400-02. The Nuclear Regulatory Commission's (NRC's) staff recognizes that for several years your authorized physician-user, Dr. James M. Fletcher, has been normally located in St. Louis, Missouri, several hours flying time from your hospital, and has been visiting your hospital only a few times each year. We have been concerned about your situation for some time, believing that by any definition, the adequacy of supervision from such a distance is questionable. The NRC staff in our Washington, DC Headquarters' office expressed these concerns in a December 1981 meeting with representatives of the Veterans Administration (VA) Central Office and of the VA, St. Louis staff. Although these VA representatives seemed receptive to some NRC suggestions, it does not appear that the suggestions were implemented as your situation appears to be unchanged.

In connection with our review of your pending renewal application, we sought advice on your situation from NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) and our consultants. We asked the ACMUI members and our consultants for their views on the adequacy of the supervisory controls over your program and whether you had adequate justification for your non-traditional operation. In addition, we asked them for their suggestions about your program and any improvements they would recommend.

In general, the ACMUI members and our consultants thought that, although your system is "exemplary," telephone contacts, computer hookups, and occasional (2-4 times per year) visits to your facility by staff from VA, St. Louis cannot replace the "daily [in-person] contact needed for an efficient, effective, and safe nuclear medicine program." They believe that your situation is "not in the best interest of quality care" for your veteran patients.

They also believe that you should have (or be able to recruit) a physician whose training and experience meet NRC's criteria (as described in Appendix A of Enclosure 1 and in Enclosure 2), who can be at your facility within one hour and who will devote at least 25 percent FTE (i.e., full-time-equivalent) to your program. Several mentioned that physicians who have completed a residency program (e.g., radiology) within the last ten years should have most, if not all, of the training and experience needed to meet NRC's criteria. If additional training or experience or both were needed, they believe that it

NMSS
JEWhitten/cg
6/5/86

C:NMSS
RJEyer
6/5/86

could be obtained at a hospital in your community or at a VA hospital. If you are able to obtain the services of a properly qualified physician, you could still maintain consultative contact with VA, St. Louis in much the same way as VA, Amarillo. We believe that this is an opportune time for you to review your current situation and take steps both to improve it and to establish a traditional program supervised by a qualified physician-user who is in close proximity to your hospital. The following suggestions should be considered:

1. You should make new efforts to find a qualified physician to be an authorized user who is able to be physically present a reasonable percentage of the work day or work week.

2. If your efforts as suggested in Item 1 above are unsuccessful, then we remind you that, in the December 3, 1981, meeting with representatives of VA Central Office and VA, St. Louis, the NRC staff recommended that VA take steps to get authorized physician-users who can be at each (Cheyenne and Grand Junction) location on a routine basis. If VA proposed as a user a physician who did not clearly meet NRC's current training and experience criteria, the NRC staff offered to work with VA to decide on: (1) a mutually agreeable training program that might be needed to supplement that already received by the physician, and (2) a mutually agreeable schedule by which each location's operation would be supervised by a qualified physician in close proximity to the hospital. Although VA representatives seemed receptive to this approach, we are not aware of any action taken by the VA to implement this idea. The NRC staff stands by its December 1981 offer.

3. ACMUI members and our consultants suggested that, if you are unable to get a qualified physician in close proximity to your hospital to supervise your program, you could transfer patients needing nuclear medicine procedures to a local community hospital or to another VA hospital that operates a traditional nuclear medicine program.

If your efforts to find a properly qualified physician are successful, you should submit to us the name of the proposed physician-user and sufficient documentation of his or her training and experience to show that he or she meets NRC's criteria; see Appendix A of Enclosure 1 and also Enclosure 2. You may find it convenient to provide this information using Supplements A and B of Form NRC-313M; see Enclosure 3. In addition, you should specify: where this physician is normally located, the time needed for the physician to get to your hospital, the amount of time this physician will devote to supervising your nuclear medicine program, and when this physician will begin supervising your nuclear medicine program.

If you find a physician who does not clearly meet the appropriate NRC criteria, then you should submit not only the information requested in the paragraph

above, but also a proposed training program designed to provide the needed supplemental training, experience, or both, and a proposed schedule for completion of the training program.

Within 60 days of the date of this letter, please inform us of the results of your efforts to obtain a qualified physician in close proximity to your hospital to supervise your nuclear medicine program. Alternatively, you should describe other actions you have taken to ensure that your patients' nuclear medicine procedures are performed in a properly supervised program. Please submit your response in duplicate and refer to Control No. 418513.

Additional items of concern effecting your renewal issuance are as follows:

1. Your Radiation Safety Committee is not formulated in accordance with 10 CFR 35.11(b). Confirm that membership of the radiation safety committee will include at least the following: an authorized user for each type of use permitted by the license, a representative of the nursing staff, a representative of the institutions management, and the Radiation Safety Officer.

2. Your letter should have been signed by the hospital administrator. Please submit a letter from the hospital administrator indicating that he or she has reviewed the application and concurs in the statement and representations contained therein. Note also that the hospital administrator should sign all future correspondence, requests for amendment, renewal, etc.

If you believe that it would be helpful, we would be pleased to discuss this authorized user matter or another matter with you and your staff either by telephone, 817 860-8100/FTS 728-8100 or in a meeting.

Sincerely,

Original Signed By
R. J. Everett

R. J. Everett, Chief
Nuclear Materials Safety Section

Enclosures:
1. Regulatory Guide 10.8 (Rev. 1), October 1980
2. 47 FR 54376
3. Form NRC-313M

cc w/o enclosures:
Veterans Administration Central Office
Director, Nuclear Medicine
Service (115)
810 Vermont Avenue, N.W.
Washington, DC 20420

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

APR 21 [redacted]

MEMORANDUM FOR: Ramon E. Hall, Chief
Radiological and Safeguards Programs Branch
Division of Radiation Safety and Safeguards, R IV

FROM: Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and Material Safety, NMSS

SUBJECT: VETERANS ADMINISTRATION NUCLEAR NETWORK

In accordance with a request from Region IV staff prompted by two pending renewal applications, we asked the Nuclear Regulatory Commission's (NRC's) Advisory Committee on the Medical Uses of Isotopes (ACMUI) and consultants for their views on the Veterans Administration's (VA's) nuclear medicine network as it is operated at the VA Medical Center, Cheyenne, Wyoming (License No. 49-15495-01, Control No. 417504) and VA Medical Center, Grand Junction, Colorado (License No. 05-08400-02, Control No. 418513); see Enclosure 1.

Some of the ACMUI members and consultants have been slow in responding and we have followed up with telephone calls and accepted some comments by telephone. There are several members and consultants from whom we have not heard.

Enclosure 2 includes the comments we have received. From a review of these comments, you will note that a majority of those responding believe that there are inadequate controls in place to permit continuation of the VA's Cheyenne and Grand Junction operations without an authorized physician-user in close proximity to each location. Several members spoke of the need for an authorized physician-user to be physically present on a routine basis, not necessarily 40 hours per week, but a reasonable percentage of the time; one suggestion was at least 25% FTE (full-time-equivalent). Members indicated that telephone contacts, computer hook-ups, and visits 3-4 times per year are not an adequate substitute for routine, in-person supervision and direction of the nuclear medicine program (including the technologist's activities) and consultation with referring physicians.

The licensees' justification for not having a trained physician-user at each location was considered inadequate. Members thought that physicians with appropriate training and experience could be found within the community. Alternatively, they thought that VA could provide physicians currently on staff at each location (e.g., radiologists, internists) with the training and experience needed to qualify as authorized users. One member pointed out that any radiologist who completed his or her residency training within the last 10 years would have most, if not all, of the training and experience needed for NRC licensure. This member suggested that, if additional training or ex-

perience or both were needed, the physician could receive it at another institution, either in the local community or at another VA hospital.

Many members recommended following the approach outlined in Item 3 of Enclosure 1. However, since Enclosure 1 was prepared in October 1985, there have been changes that need to be considered. Although Section 35.38 of the proposed revision to 10 CFR Part 35 included requirements for the authorized physician-user to be immediately available by telephone and to be physically present within one hour, these requirements have been deleted from the final revision of 10 CFR Part 35 that was recently circulated for Headquarters' and Regional Offices' concurrence. The deletion was prompted by a desire to avoid regulating the specific details of delivery of medical care.

Enclosure 3 is a recent memorandum that discusses delegation of responsibilities by authorized physician-users. An enclosure to that document provides additional discussion of what constitutes "adequate supervision," and may be of interest to you.

We recommend that you contact the VA, Cheyenne and the VA, Grand Junction to express our concern about their situation, to describe the general nature of the comments we received from the ACMUI members and our consultants, and to make some suggestions for change. Enclosure 4 is suggested draft text for letters to be sent to the licensees. If you deem it appropriate, you could combine this text with other unresolved issues related to these two renewal applications.

The enclosed responses from ACMUI members and consultants should be filed in the official docket files on License Numbers 49-15495-01 and 05-08400-02. Please note that, although the general nature of the comments may be disclosed to the licensees, comments should not be attributed to any specific ACMUI member or consultant. If these responses are included with materials sent to DCS, be sure to insert NRC Form 190B before the responses to identify them for special handling so as to ensure that they are not available on publicly accessible microfiche; see Item 10 of Enclosure 3 to Policy and Guidance Directive FC 84-19, dated December 24, 1984.

If you or your staff have any questions on this matter, please contact me at FTS 427-4002 or Patricia Vacca at FTS 427-4112.

Sandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosures:
1. NRC memo dtd 10/4/85
2. ACMUI members' and consultant's comments
3. NRC memo w/enclosures dtd 4/14/86
4. Proposed draft letter

cc w/Enclosures 1 and 4 only:
J. Glenn, R I
J. Potter, R II
B. Mallett, R III
R. J. Everett, R IV
R. Thomas, R V
D. Nussbaumer, SP
N. McElroy, NMSS

Enclosure

1

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

OCT 04 1985

MEMORANDUM FOR: Members, Advisory Committee on the Medical Uses of Isotopes

Dr. Peter Almond, Consultant

CAPT William Briner, USPHS (Ret'd), Consultant

FROM: Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and Material Safety

SUBJECT: VETERANS ADMINISTRATION'S NUCLEAR MEDICINE NETWORK

We would like to obtain your comments and recommendations on the continuation of the Veterans Administration's (VA's) "nuclear medicine network," particularly as it applies to the VA, Cheyenne, Wyoming and VA, Grand Junction, Colorado. Enclosures 1-12 are copies of pertinent correspondence and other documents about these two licensees.

BACKGROUND

We have received requests from the VA hospitals in Cheyenne and Grand Junction asking that we renew their respective licenses. These hospitals have 176 and 152 beds, respectively. Their licenses are similar to other group medical licenses in many respects. However, these two licenses differ in that in both cases:

- The authorized physician-user is physically located at the VA, St. Louis;
- The "on-site" physicians at VA, Cheyenne and at VA, Grand Junction do not meet either the Nuclear Regulatory Commission's (NRC's) minimum training and experience criteria then in effect (Enclosure 13) or NRC's criteria of 30 hours of training in basic radioisotope handling techniques used for "on-site" physicians at hospitals served by mobile nuclear medicine service operations.
- The Radiation Safety Officer is a nuclear medicine technologist trained at VA, St. Louis;
- The staff of the VA, St. Louis visit each hospital several times a year to conduct training and audits. It is not clear that all of the visits by VA, St. Louis staff would be devoted to NRC-regulated activities; the visits may be related to such areas as diagnostic radiology.

The NRC staff had expressed concern over the type of operations conducted at VA, Cheyenne and VA, Grand Junction. We outlined what we believe are the responsibilities of the authorized physician-user (i.e., approval of procedures involving the administration of radiopharmaceuticals to patients; prescription of the radiopharmaceutical, activity, and route of adminstration; interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered). We asked how these responsibilities would be carried out at VA, Cheyenne and VA, Grand Junction. We were informed (see Enclosures 4 and 8) that an authorized physician-user at VA, St. Louis approves each proposed nuclear medicine procedure and specifies the radiopharmaceutical, activity and route of administration for each approved study. This communication is by telephone between the VA, St. Louis-trained nuclear medicine technologist and the authorized physician-user at VA, St. Louis. When the study is completed, the results are transmitted electronically to VA, St. Louis, where the images are interpreted by an authorized physician-user at VA, St. Louis and a hard copy of the results are sent to VA, Cheyenne or VA, Grand Junction, as appropriate.

Several years ago we expressed concern about the absence of a physican who met NRC's training and experience criteria as outlined in Enclosure 13. VA personnel indicated that they were unable to obtain the services of such a physician at VA, Cheyenne and VA, Grand Junction; such physicians could not be recruited as permanent VA staff nor could suitably qualified physicians in the community act as consultants to these two VA hospitals. We offered to discuss with VA personnel a training program for the "on-site" physicians at VA, Cheyenne and VA, Grand Junction that would fulfill the "spirit" of the Enclosure 13 criteria but that would recognize the previous experience of those physicians, the distances involved, time limitations, etc. However, we never received a proposal from VA personnel.

The current situation at these two VA hospitals, but especially VA, Grand Junction, has been of concern from an inspection standpoint. Enclosure 7, the basis on which the VA, Grand Junction's license was issued, does not make it clear that the hospital expected to participate in the VA, St. Louis' nuclear medicine network. At that time, NRC had internal documents (see Enclosures 10 and 12) that spoke to the staff's interpretation of adequate supervision by an authorized physician-user. However, these are not well-known to licensees and are not regulations. The question of what constitutes adequate supervision may be solved (or at least clarified) if the proposed revision of 10 CFR Part 35 becomes effective. Section 35.38 of the proposal (Enclosure 14) defines supervision and, among other things, would require that the authorized physician-user be available by telephone and be able to be physically present within one hour. If the proposed 10 CFR 35.38 becomes effective, it would appear to prohibit the VA, Cheyenne and VA, Grand Junction operations in that authorized physician-users located at VA, St. Louis could not reach Cheyenne or Grand Junction in less that one hour. Airline schedules indicate approximately three hours flying time between St. Louis and Cheyenne or Grand Junction with a minimum 40 minute layover in Denver. Of course, VA, Cheyenne and VA, Grand Junction could request an exemption from the provisions of 10 CFR 35.38.

In addition to our concerns about the VA, Cheyenne and the VA, Grand Junction, we are also concerned about the more generic aspects of this type of practice. We understand that there are similar types of operations (called "teleradiology") that cover diagnostic radiology, ultrasound, CAT scans as well as nuclear medicine. To what extent, if any, should we permit licensees other than VA hospitals to participate in a "nuclear medicine network?"

SPECIFIC QUESTIONS

Please answer the following questions and explain the rationale for your answers. For the purposes of our questions, please consider that the phrase "authorized physician-user on site" means a physician as defined in 10 CFR 35.3(a) (see Enclosure 15) who, as a minimum, has had training and experience as described in Enclosure 13 or Enclosure 16 who resides and works in the community in which the hospital is located and who is usually physically present at the hospital. If he is not physically present, he can be reached by telephone and can be physically present within one hour.

The following questions pertain to the specific cases of VA, Cheyenne and VA, Grand Junction.

1. Do you believe that adequate controls are in place to permit their continued participation in the VA St. Louis "nuclear medicine network" without an authorized physician-user on site? If you believe the controls are inadequate, what additional controls (other than having an authorized physician-user on site) would be sufficient to permit continued participation in the "nuclear medicine network"?

2. Do you believe that either VA hospital has adequate justification for not having an authorized physician-user on site? If you believe their justification is inadequate, what additional factors, of any, might change your view?

3. Our approach to these two hospitals may be to point out the provisions of the proposed 10 CFR 35.38, explain how that would affect them, suggest that they take steps to obtain an authorized physician-user on site and request that they provide either a date by which they will have such a physician or a schedule for providing appropriate training and experience to the untrained physicians currently at each location. Do you approve of this approach? Describe any suggestions you have about additional actions we should take or about any alternative approaches we should consider.

The following questions apply to other medical licensees.

4. If other licensees learn that NRC has permitted the VA, Cheyenne and VA, Grand Junction to participate in a "nuclear medicine network," the other licensees may want similar authorization. In fact, the Agreement State of Florida has received applications for licenses from several hospitals, each

of which wants as an authorized user a certain properly qualified physician who may be located as much as 50 miles from each hospital. This physician would not be physically present at any of the hospitals on a daily or weekly basis, but would conduct business via telephone, computer hook-up, etc. The Florida situation suggests the possibility for abuse (e.g., economic considerations leading to short cuts of "established procedures" for the physician to approve each test, etc.). Although possibilities for abuse exist in the VA situation, there are not the same economic factors in a government hospital as there are in a private practice or private hospital setting.

a. Do you believe any different considerations should apply to non-governmental medical licensees vs governmental medical licensees who wish to participate in "nuclear medicine network" operations? If so, what additional considerations should apply?

b. Assuming in the Florida case that the authorized physician-user is available by telephone and can get to each hospital within one hour, explain any objections you may have to these proposals.

5. If participation is a "nuclear medicine network" with an authorized physician-user on site is an acceptable practice, what are the key factors necessary to approval? The VA program involves: Board-certified physician-user; an ostensibly "well-trained" technologist; close communication between the physician-user and the technologist on each patient study; regularly-scheduled visits of the physician-user and his staff with the staff at the distant hospitals. Are all the points necessary for approval? If some may be omitted, which may be omitted? If some should be added, describe the additional points.

We would appreciate receiving your responses, comments and suggestions as soon as possible but not later than NOV 15 1985. If you have any questions on this matter, please contact Patricia Vacca of my staff at (301) 427-4112 or FTS 427-4112.

Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

OCT 0 4 1985

Enclosures:
1. VA Cheyenne ltr dtd 2/4/80 to NRC
2. VA Cheyenne ltr dtd 2/29/80 to NRC
3. NRC ltr dtd 4/10/80 to VA Cheyenne
4. VA Cheyenne ltr dtd 4/28/80 to NRC
5. VA Cheyenne ltr dtd 8/26/81 to NRC
6. VA Cheyenne ltr dtd 5/7/84 to NRC
7. VA Grand Junction application
8. VA Grand Junction ltr dtd 8/31/81 to NRC
9. NRC ltr dtd 5/20/82 to VA Grand Junction
10. Memo dtd 10/20/81 fm LBHigginbotham to VLMiller
11. Notes on St. Louis VA's Nuclear Network dtd 11/16/81
12. Memo dtd 11/18/81 fm VLMiller to LBHigginbotham
13. Appendix A of Reg. Guide 10.8 (Rev. 1)
14. Proposed revision to 10 CFR Part 35
15. Current 10 CFR Part 35
16. 47 FR 54376

Medical and Regional
Office Center

2360 East Pershing Blvd.
Cheyenne, WY 82001

Veterans
Administration

RECEIVED
FEB 11 PM 1 23

February 4, 1980

United States Nuclear Regulatory Commission
Washington, D.C. 20555

THRU: James J. Smith, M.D. (115)
Director, Nuclear Medicine Service
Department of Medicine and Surgery
Veterans Administration Central Office
Washington, D.C. 20420

Gentlemen:

We are writing to request amendment of our NRC medical by-product material license number 49-15495-01, expiration date May 31, 1984. The amendment should delete as user, Dr. Robert Nelson who has left this hospital.

Dr. Robert M. Donati will replace Dr. Nelson as the responsible user and medical supervisor of the laboratory. A copy of Dr. Donati's ABNM credentials is enclosed.

Mr. Vincent Glueck will serve as Radiation Safety Officer for the Nuclear Medicine Service at this Medical Center. A statement of his training and experience is enclosed.

Sincerely,

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FEB 8 1980
NUCLEAR MEDICINE S...
(115)

JOHN D. GRAVELEY
Acting Center Director

Enclosures: ABNM Credentials
Statement of training and experience

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FEB 0 8 1980

FEE EXEMPT

JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

02723

In Reply Refer To: 442/11

Encl 1 02723

THE AMERICAN BOARD OF NUCLEAR MEDICINE

INCORPORATED 1971

A CONJOINT BOARD ORGANIZED WITH THE SPONSORSHIP OF THE AMERICAN BOARD OF INTERNAL MEDICINE AMERICAN BOARD OF PATHOLOGY, AMERICAN BOARD OF RADIOLOGY AND THE SOCIETY OF NUCLEAR MEDICINE HEREBY CERTIFIES THAT

Robert M. Donati, M.D.

HAS MET THE REQUIREMENTS OF THIS BOARD AND IS CERTIFIED AS QUALIFIED TO PRACTICE AS A SPECIALIST IN ALL ASPECTS OF CLINICAL AND LABORATORY

NUCLEAR MEDICINE

INCLUDING BUT NOT LIMITED TO RADIOBIOASSAY, NUCLEAR IMAGING, IN VIVO MEASUREMENTS AND THERAPY WITH UNSEALED RADIONUCLIDES

Joseph F. Ross M.D.
CHAIRMAN

Tyree V. Kabrisky
SECRETARY

NUMBER 01071

DATE MAY 18, 1973

FORM NRC-313M-SUPPLEMENT A (8-78) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
RADIATION SAFETY OFFICER Vincent M. Glueck	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
ARRT	Nuclear Medicine	5/78
NMTCB	Nuclear Medicine	5/79

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	St. Francis Hospital 6/77-6/78 Cape Girardeau, MO Cochran VA Medical Ctr 8/78 St. Louis, MO	50	45 8
b. RADIATION PROTECTION	St. Francis Hospital 6/77-6/78 Cape Girardeau, MO Cochran VA Medical Ctr 8/78 St. Louis, MO	15	16
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	St. Francis Hospital 6/77-6/78 Cape Girardeau, MO	20	
d. RADIATION BIOLOGY	St. Francis Hospital 6/77-6/78 Cape Girardeau, MO	25	
e. RADIOPHARMACEUTICAL CHEMISTRY	St. Francis Hospital 6/77-6/78 Cape Girardeau, MO Cochran VA Medical Ctr 8/78 St. Louis, MO	25	16

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Groups	I, II, III	St. Francis Hospital Cape Girardeau, MO	6/77 - 6/78	Training
		Marion VA Medical Center Marion, IL	6/78 - 12/79	Clinical Nuclear Med.
		St. Louis VA Medical Ctr St. Louis, MO	8/78	Training

Medical and Regional
Office Center

2360 East Pershing Blvd.
Cheyenne, WY 82001

Veterans
Administration

February 29, 1980

United States Nuclear Regulatory Commission
Washington, D.C. 20555

THRU: James J. Smith, M.D. (115)
Director, Nuclear Medicine Service
Department of Medicine and Surgery
Veterans Administration Central Office
Washington, D.C. 20420

Gentlemen:

In reply to your recent inquiry concerning physician coverage of the Nuclear Medicine Laboratory of the Cheyenne VA Medical Center, please be advised that A. S. Aldrich, M.D., Chief of Staff, is the responsible physician for that service. Dr. Aldrich is available to advise on medical questions and handle medical emergencies that might arise in the laboratory. In his absence, L.G. Seidl, M.D., Chief, Medical Service will act in this capacity.

Dr. Robert Donati and the Nuclear Network staff are responsible for the details of Nuclear Medicine procedures. All requests for patient studies are reviewed and approved by him or his designee taking into account the medical problem and working diagnosis prior to scheduling the test. The specific procedure, radiopharmaceutical, dose, route of administration and special instructions are specified. Any questions concerning the test or its interpretation are resolved by consultation with the referring physician. Radiation Safety audits are conducted four times annually by the Network staff.

We trust this information will relieve your concern regarding the medical operation of our Nuclear Laboratory and we anticipate your favorable action on our request for amendment.

Sincerely,

JOHN D. GRAVELEY
Acting Center Director

for and in the absence of

MAR 1 8 1980

JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

03207
03207

RECEIVED
MAR - 1980
NUCLEAR MEDICINE SERVICE
(115)

COPIES SENT TO OFF. OF
INFO. Refer To:

FCMLB:MAL
030-09199
(03207)

APR 1 0 1980

Veterans Administration Hospital
ATTN: John D. Graveley
Acting Center Director
2360 East Pershing Boulevard
Cheyenne, WY 82001

Gentlemen:

This is in reference to your letter dated February 29, 1980, stating that A. S. Aldrich, M.D., Chief of Staff, or L. G. Seidl, M.D., Chief, Medical Service, will act as an onsite physician for your Nuclear Medicine Service in the absence of Robert M. Donati, M.D. Since Dr. Donati will not be physically present in your hospital during the performance of nuclear medicine procedures, in order t approve Dr. Aldrich and Dr. Seidl as onsite physicians, we need the following additional information:

1. Dr. Aldrich and Dr. Seidl should submit a complete description of their training in basic radiological handling techniques as requested in Item 4, Supplement A, Form NRC-313M. As a minimum, these physicians should have two hundred (200) hours of training.

2. Verify that Dr. Robert Donati or other physicians specifically listed on your license will be responsible for the details of the nuclear medicine procedures as outlined in your February 29, 1980 letter.

3. Submit the name and training and experience of your nuclear medicine technicians who will operate your Nuclear Medicine Department.

We will continue our review of your application upon receipt of this information. Please reply in duplicate and refer to Control No. 03207.

Sincerely,

Michael A. Lamastra
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Std. Br. Dist.
Enclosure: Form NRC-313M

Encl 3

CRESS:Wallace	cc: Central Veterans Administration Office	FCMLB		
MC#571452:gtw	ATTN: Dr. James D. Smith			
SURNAME	Nuclear Medicine Service (112-H)	MALamastra:gtw		
4/7/80 DATE	810 Vermont Avenue, N. W.	4/5/80		
	Washington, DC 20420			

NRC FORM 318 (6-77) ★ U. S. GOVERNMENT PRINTING OFFICE 1977—237—025

Medical and Regional
Office Center

2360 East Pershing Blvd.
Cheyenne, WY 82001

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ms

Veterans Administration

RECEIVED

MAY 5 1980 10 07

April 28, 1980

Mr. Michael A. Lamastra
Material Licensing Branch
Division of Fuel Cycle and Material Safety
United States Nuclear Regulatory Commission
Washington, D.C. 20555

Gentlemen:

Reference your Control Number 03207.

This letter is in response to your inquiry regarding the NRC license number 49-15495-01 at the Cheyenne VA Medical Center. This response will clarify and delineate responsibilities in the operation of our Nuclear Medicine Service.

a. All decisions regarding details of Nuclear Medicine procedures are made by Robert M. Donati, M.D., or his physician designee at the Nuclear Network facility at the St. Louis VA Medical Center. All requests for procedures are communicated to St. Louis and explicit approval for the test is obtained from a qualified Nuclear Medicine physician including radiopharmaceutical, dose, and any necessary additional instructions before the procedure is performed.

b. The Nuclear Medicine technologist, Mr. Vincent Glueck, is responsible for all matters relative to radiation safety on a continuing routine basis, and functions as the RSO for the facility. He assures compliance with all regulatory requirements and the personal safety of himself, patients and other individuals. A summary of his training and experience is attached.

c. Drs. Aldrich and Seidl have no responsibility for basic radiologic handling, but serve as medical support for the Nuclear Medicine Laboratory. They are available on an emergency basis in the event of, for example, an allergic reaction, cardiac or pulmonary arrest.

d. Additional support for the laboratory is derived from visits of specialists from the St. Louis hospital four times annually. During these visits, records and procedures are reviewed with respect to regulatory compliance as well as the quality of medical practice in Nuclear Medicine. Specific

In Reply Refer To: 442/11

Encl 4

educational programs are conducted for technical and professional staff relative to the proper and efficacious use of nuclear procedures.

e. We believe the procedures established to provide service to patients at this VA Medical Center through the St. Louis Network ensure a closer degree of supervision than that found in many hospitals where expert advice and assistance are available only on a part-time basis. Qualified physicians, physicists, radiopharmacists, chemists, engineers, educational specialists, and technicians are available on a full-time basis to support all nuclear medicine activities at this hospital.

f. If you feel that there is not sufficient administrative continuity to permit continued separate specific licensing of this hospital, then we suggest that the Cheyenne VA be added as an additional use site to the St. Louis VA Broad Medical License. The precedent for this has been established at the Jefferson Barracks, Marion, and Poplar Bluff VA Medical Centers. This has proven to be a feasible and effective means of assuring the quality of Nuclear Medicine service as your compliance staff will verify.

Thank you for your continued interest in our program.

JOHN D. GRAVELEY
Acting Center Director

Attachment

FORM NRC-313M-SUPPLEMENT A (9-78) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
RADIATION SAFETY OFFICER Vincent M. Glueck	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
AnRT	Nuclear Medicine	5/78
NMTCB	Nuclear Medicine	5/79

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	St. Francis Hospital 6/77-6/78 Cape Girardeau, MO Cochran VA Medical Ctr 8/78 St. Louis, MO	50	45 8
b. RADIATION PROTECTION	St. Francis Hospital 6/77-6/78 Cape Girardeau, MO Cochran VA Medical Ctr 8/78 St. Louis, MO	15	16
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	St. Francis Hospital 6/77-6/78 Cape Girardeau, MO	20	
d. RADIATION BIOLOGY	St. Francis Hospital 6/77-6/78 Cape Girardeau, MO	25	
e. RADIOPHARMACEUTICAL CHEMISTRY	St. Francis Hospital 6/77-6/78 Cape Girardeau, MO Cochran VA Medical Ctr 8/78 St. Louis, MO	25	16

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Groups	I, II, III	St. Francis Hospital Cape Girardeau, MO	6/77 - 6/78	Training
		Marion VA Medical Center Marion, IL	6/78 - 12/79	Clinical Nuclear Med.
		St. Louis VA Medical Ctr St. Louis, MO	8/78	Training

Medical and Regional
Office Center

2360 East Pershing Blvd.
Cheyenne, WY 82001

Veterans
Administration

Miller 49-15495-1

August 26, 1981

United States Nuclear Regulatory Commission
Washington, D. C. 20555

THRU: James J. Smith, M.D. (115)
Director, Nuclear Medicine Service
Department of Medicine and Surgery
Veterans Administration Central Office
Washington, D. C. 20420

Gentlemen:

Reference our letter dated February 29, 1980. This is to inform you E. W. Rideout, M.D., Chief of Staff, is now the responsible physician for our Nuclear Medicine Service. Dr. Rideout is available to advise on medical questions and handle medical emergencies that might arise in the Nuclear Medicine Laboratory. In his absence, L. G. Seidl, M.D., Chief, Medical Service, will act in this capacity.

Dr. Robert Donati and the Nuclear Network staff continue to be responsible for the details of Nuclear Medicine procedures as outlined in the referenced letter.

Sincerely,

JOHN D. GRAVELEY
Center Director

RECEIVED
AUG 2 8 1981
NUCLEAR MEDICINE SERVICE
(115)

FEE EXEMPT

AUG 2 8 1981
JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

Encl 5

In Reply Refer To:
442/11

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Veterans Administration

In Reply Refer To: 657/115A-JC

May 7, 1984

'84 MAY 16 P2:43

United States Nuclear Regulatory Commission
Washington, D.C. 20420

THRU: Medical Center Director (00)
Cheyenne VA Medcial Center

Director, Nuclear Medicine Service (115)
Veterans Administration Central Office

1. We are writing to request the renewal of our medical radionuclide by-product material license # 49-15495-01 which expires May 31, 1984. We have reviewed the terms, conditions and supporting information for the existing license and wish to have the license renewed as-is with the following minor changes:

a. The Capintec dose calibrator has been replaced with a Radix of similar design. Quality control procedures for accuracy, linearity, geometric efficency and reproducability are performed as required.

b. Survey instruments are calibrated annually at the facility in the St. Louis VAMC. The military procedures for calibration at Warren AFB do not meet the NRC requirements.

c. Licensed material in Groups I, II and III and Xenon-133 will be used under the supervision of James W. Fletcher, M.D. Dr. Fletcher is Chief, Nuclear Medicine Service, St. Louis VAMC and Medical Director of the Nuclear Medicine Network. Dr. Fletcher's ABNM Certification is enclosed.

2. In all other respects the by-product materials program remains the same. The Cheyenne Medical Center continues to participate in the Nuclear Medicine Network based in St. Louis. St. Louis staff visit the facility at least four times annually for training, safety inspection and participation in Radiation Safety Committee meetings. The ALARA program is fully implemented and effective.

3. Your consideration of this renewal request is appreciated. If further information is required you may contact me at 276-4359.

Francis K. Herbig

FRANCIS K. HERBIG
Program Director
Nuclear Medicine Network

III

Encl 6

Hospital Director Concurs

JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

5/10/84

1750

THE AMERICAN BOARD OF NUCLEAR MEDICINE

INCORPORATED 1971

A CONJOINT BOARD ORGANIZED WITH THE SPONSORSHIP OF THE AMERICAN BOARD OF INTERNAL MEDICINE, AMERICAN BOARD OF PATHOLOGY, AMERICAN BOARD OF RADIOLOGY AND THE SOCIETY OF NUCLEAR MEDICINE

HEREBY CERTIFIES THAT

James Warren Fletcher, M.D.

HAS MET THE REQUIREMENTS OF THIS BOARD AND IS CERTIFIED AS QUALIFIED TO PRACTICE AS A SPECIALIST IN ALL ASPECTS OF CLINICAL AND LABORATORY

NUCLEAR MEDICINE

INCLUDING BUT NOT LIMITED TO RADIOBIOASSAY, NUCLEAR IMAGING, IN VIVO MEASUREMENTS AND THERAPY WITH UNSEALED RADIONUCLIDES

Harold A. Blake
CHAIRMAN

Joseph F. Rosenthal
SECRETARY

NUMBER 02057

DATE MAY 5, 1972

1750

657/115JC

Veterans Administration

Medical Center
St. Louis, Missouri 63125

Official Business
Penalty for private use
$300

Postage and Fees paid
Veterans Administration
VA 601

U.S.MAIL

396-55

United States

Nuclear Regulatory Commission

Washington, D.C. 20420

42

FORM NRC-313M
(8-78)
10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE – MEDICAL

Approved:
GAO R0557

INSTRUCTIONS - *Complete items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Veterans Administration Medical Center
2121 North Avenue
Grand Junction, Colorado 81501

TELEPHONE NO.: AREA CODE (303) 242 0731

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

Same as 1.a.

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Robert E. Lindsey, Jr.
Medical Center Director
TELEPHONE NO.: AREA CODE (303) 242 0731

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*
- a. [X] NEW LICENSE
- b. [ ] AMENDMENT TO LICENSE NO. _____
- c. [ ] RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

James W. Fletcher, M.D.

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Timothy A. Egan

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES	X	1 mCi
10 CFR 35.100, SCHEDULE A, GROUP I	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II	X	AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III	X	1000 mCi
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
None			

Encl 7

FORM NRC-313M
(8-78)

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the applicat[illegible] the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. 1 Date: Nov. 1, 1977

7. MEDICAL ISOTOPES COMMITTEE		15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL *(Check One)*	
X	Names and Specialties Attached; and	X	Appendix G Rules Followed; or
X	Duties as in Appendix B; or *(Check One)*		Equivalent Rules Attached
	Equivalent Duties Attached	16. EMERGENCY PROCEDURES *(Check One)*	
8. TRAINING AND EXPERIENCE		X	Appendix H Procedures Followed; or
	Supplements A & B Attached for Each Individual User; and see attachment		Equivalent Procedures Attached
X	Supplement A Attached for RSO.	17. AREA SURVEY PROCEDURES *(Check One)*	
9. INSTRUMENTATION *(Check One)*		X	Appendix I Procedures Followed; or
X	Appendix C Form Attached; or		Equivalent Procedures Attached
	List by Name and Model Number	18. WASTE DISPOSAL *(Check One)*	
10. CALIBRATION OF INSTRUMENTS		X	Appendix J Form Attached; or
X	Appendix D Procedures Followed for Survey Instruments; or *(Check One)*		Equivalent Information Attached
	Equivalent Procedures Attached; and	19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS *(Check One)*	
X	Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	N/A	Appendix K Procedures Followed; or
	Equivalent Procedures Attached		Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT		20. THERAPEUTIC USE OF SEALED SOURCES	
X	Description and Diagram Attached	N/A	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM			Appendix L Procedures Followed; or *(Check One)*
X	Description of Training Attached		Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL		21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)	
X	Detailed Information Attached	X	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*		22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS	
		N/A	Detailed Information Attached
X	Appendix F Procedures Followed; or	23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b	
	Equivalent Procedures Attached	N/A	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	Landauer	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	Landauer	Monthly
		OTHER (Specify)		
c. WRIST	X	FILM	Landauer	Monthly
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

N/A

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY:

(2) LICENSE FEE ENCLOSED: $

b. APPLICANT OR CERTIFYING OFFICIAL (Signature)

Robert E. Lindsey, Jr.

(1) NAME (Type or Print)

Robert E. Lindsey, Jr.

(2) TITLE

Medical Center Director

c. DATE

8/1/79

FORM NRC-313M (8-78)

PRIVACY ACT STATEMENT

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

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

FORM NRC-313M-SUPPLEMENT A (6-78) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Timothy Austin Egan	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
The American Registry of Radiologic Technologists	Radiography Nuclear Medicine Technology #104707	June 1974 June 1975

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/ LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	Grady Memorial Hospital Atlanta, Georgia 1974-1975	350 hours	4 years as dept. head
b. RADIATION PROTECTION	Grady Memorial Hospital Atlanta, Georgia, 1974-1975	350 hours	4 years as dept. head
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Grady Hospital--Emory Univ. Atlanta, Georgia, 1974-1975	400 hours	4 years as dept. head
d. RADIATION BIOLOGY	Emory University Atlanta, Georgia, 1974-1975	300 hours	
e. RADIOPHARMACEUTICAL CHEMISTRY	Grady Memorial Hospital Atlanta, Georgia, 1974-1975	500 hours	4 years as dept. head

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I 131	500 uCi	Grady Hosp.-Emory Univ.	5 years	Diagnostic
I 131	300 MCi	Clayton General Hospital	5 years	Therapeutic
Tc99m	1 curie	"	5 years	Diagnostic
In111	50 MCi	"	5 years	Diagnostic
GA67	50 MCi	"	5 years	Diagnostic
I123	200 uCI	"	5 years	Diagnostic
YT	10 MCi	"	5 years	Diagnostic
Y90	10 MCi	Clayton General Hospital	1 year	Therapeutic

GRAND JUNCTION VA MEDICAL CENTER 8-1-79

Item 7 - Medical Isotope Committee

Member	Function	Specialty
Dorr H. Burns, M. D.	Chairman	Radiology
Ralph Pacini, M. D.	Member	Internal Medicine
Timothy A. Egan	Member	Radiation Safety/ Nuclear Technology
James W. Fletcher, M. D.	Member	Nuclear Medicine
Robert E. Lindsey, Jr.	Member*	Medical Center Director

*ex-officio

01799

GRAND JUNCTION VA MEDICAL CENTER 8-1-79

Item 8 - Training and Experience

1. Certification by the American Board of Nuclear Medicine is submitted as evidence that James W. Fletcher, M.D. has had adequate training and experience to use Groups I, II and III.

2. Supplement A is attached for Radiation Safety Officer.

THE AMERICAN BOARD OF NUCLEAR MEDICINE

INCORPORATED 1971

A CONJOINT BOARD ORGANIZED WITH THE SPONSORSHIP OF THE AMERICAN BOARD OF INTERNAL MEDICINE, AMERICAN BOARD OF PATHOLOGY, AMERICAN BOARD OF RADIOLOGY AND THE SOCIETY OF NUCLEAR MEDICINE HEREBY CERTIFIES THAT

James Warren Fletcher, M.D.

HAS MET THE REQUIREMENTS OF THIS BOARD AND IS CERTIFIED AS QUALIFIED TO PRACTICE AS A SPECIALIST IN ALL ASPECTS OF CLINICAL AND LABORATORY

NUCLEAR MEDICINE

INCLUDING BUT NOT LIMITED TO RADIOBIOASSAY, NUCLEAR IMAGING, IN VIVO MEASUREMENTS AND THERAPY WITH UNSEALED RADIONUCLIDES

CHAIRMAN

SECRETARY

NUMBER 02057

DATE MAY 5, 1972

GRAND JUNCTION VA MEDICAL CENTER 8-1-79

Item 9 INSTRUMENTATION

1. Survey meters

a. Manufacturer's name: Eberline Instruments

Manufacturer's model number: E-520, 177C Chamber

Number of instruments available: 1

Minimum range: 0 mr/hr to 0.2 mr/hr

Maximum range: 0 mr/hr to 2000 mr/hr

b. Laboratory monitor

Manufacturer's name: Victoreen, Inc.

Manufacturer's model number: 808D Vamp

Number of instruments available: 1

Ranges: 1 (logarithmic)

Minimum range: 0.1 mr/hr to 100 mr/hr

Maximum range: _____ mr/hr to _____ mr/hr

2. Dose calibrator

Manufacturer's name: Capintec

Manufacturer's model number: CRC-30

Number of instruments available: 1

3. Diagnostic instruments

Type of Instrument	Manufacturer's Name	Model No.
Large Field Gamma Camera	Picker	Dyna Camera 4/15
Multi Sample Counter	Picker	#630087 Compac 120
Xenon Ventilation System	Pulmonex (Atomic Products)	# 130-500

4. Other: Physiologic Synchronizer
Medical Data Systems Acquisition/Processing Computer
Gelman Chromatography System
Vial and Syringe Shields
Centrifuges

GRAND JUNCTION VA MEDICAL CENTER 8-1-79

Item 10 - Calibration of Survey Instruments

Survey instruments and laboratory monitors will be returned to the manufacturer annually for recalibration, adjustment and repair if necessary. Instruments are available through loan for interim use.

GRAND JUNCTION VA MEDICAL CENTER 8-1-79

Item 10 - CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test:

Check as appropriate:

__X__ First elution from new Mo-99/Tc-99m generator

or

_____ other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests:

Radionuclide**	Activity (mCi)	Accuracy
57 Co	1.0	±5%
133 Ba	0.25	±5%
137 Cs	0.20	±5%
other		

C. __X__ The procedures described in Appendix D Section 2 will be used for calibration of the dose calibrator

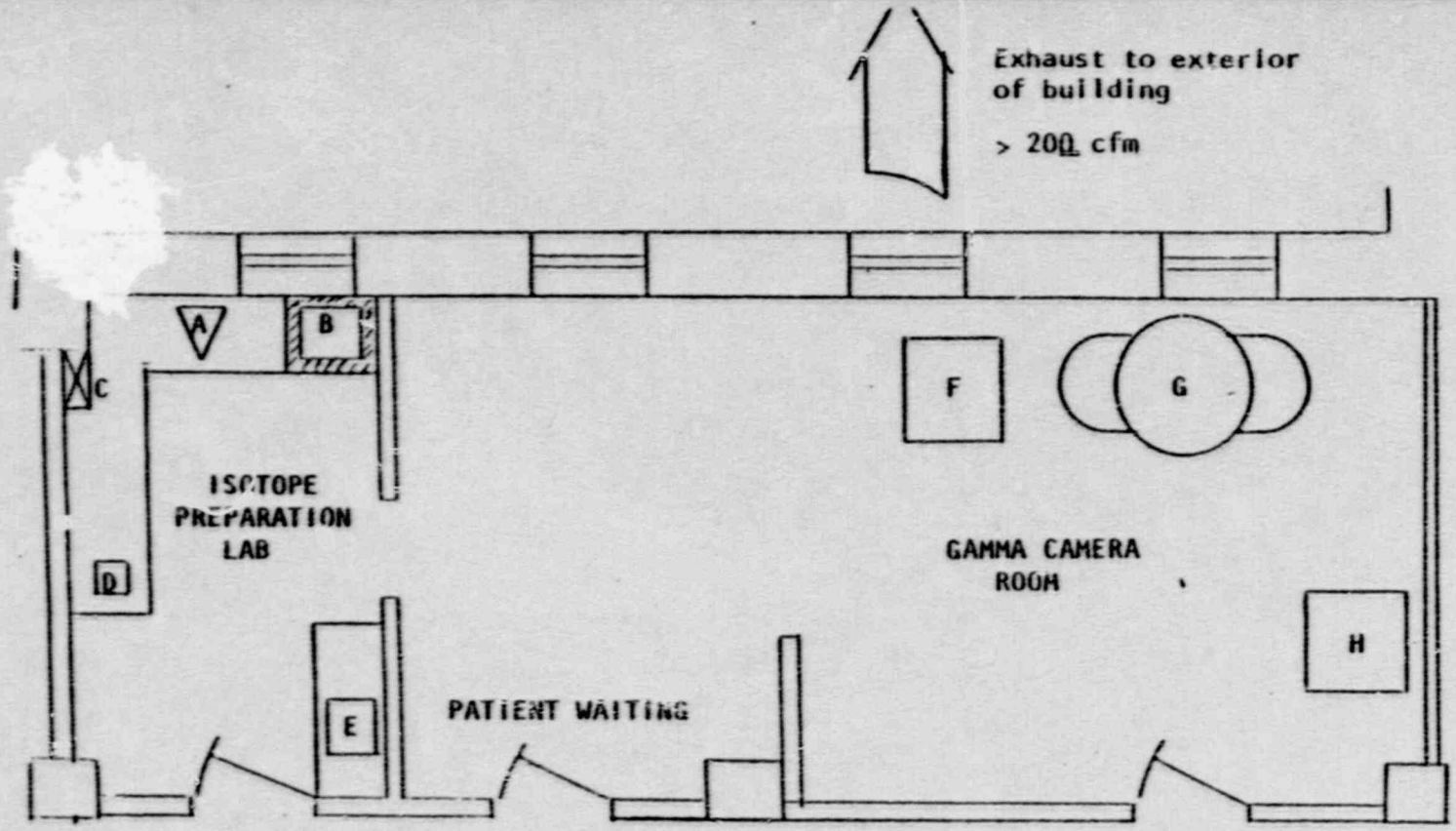
or

_____ Equivalent procedure are attached.

*Must be equivalent to the highest activity used.

**New England Nuclear, certified.

01703



A - Mo-Tc Generator
B - Isotope storage (2" lead)
C - Area monitor
D - Dose Calibrator
E - Sample counting
F - Xenon Apparatus
G - Gamma camera
H - Data system

GRAND JUNCTION VETERANS ADMINISTRATION MEDICAL CENTER

NUCLEAR MEDICINE LABORATORY

ROOMS 251, 252 & 253

Item 11

GRAND JUNCTION VA MEDICAL CENTER 8-1-79

Item 12 - Personnel Training

Training for the professional and technical staff of the Grand Junction VA Medical Center is conducted by the staff of the St. Louis VA Nuclear Medicine Service. This is carried out in two ways:

1. Grand Junction staff members are detailed to St. Louis for specialized training in particular areas of nuclear medicine. This training includes participation in conferences and courses conducted under the auspices of the Regional Medical Education Center at St. Louis and on-the-job training and work experience in the medical and technical aspects of the nuclear laboratory operations. Topics typically include:

Radiopharmacy - product preparation and quality control
Radioimmunoassay - test evaluation and quality control
Radiation Safety - survey techniques, emergency procedures, regulations
Clinical Applications - new test procedures, interpretation, integration of results
Instrumentation - calibration, testing, quality control
Laboratory Administration - procedures and record keeping

2. Two members of the St. Louis staff, usually one nuclear physician and one technical or scientific staff member visit the Grand Junction facility at regular 6-8 week intervals.

These visits provide in-service training opportunities in the topics outlined above for the technical laboratory staff. New procedures are introduced, current techniques are reviewed and quality control and records are critiqued in detail. Conferences are conducted for the Grand Junction medical staff where past cases are reviewed, current cases discussed and consultation provided. In-service lectures are given for nursing and para-medical personnel relative to patients receiving radionuclides. Procedures for receipt of radioactive materials are reviewed with receiving clerks and security staff.

3. Individuals working in or frequenting the restricted area receive specific instructions as required by 10 CFR 19, paragraph 12. This instruction is given as part of orientation for new employees and thereafter at least annually during ... service training.

Item 13

Ordering Radioactive Material

1. All orders for radioactive material in the Medical Center are originated in the Nuclear Medicine Service by persons familiar with the terms, conditions, and restrictions of the NRC license relative to which radionuclides may be ordered and possession limits which are applicable. Supply Service which processes orders checks requisitions for authorized signatures.

Receipt of Radioactive Material

1. Regular Hours (8:00 a.m. - 4:30 p.m., Monday - Friday)

   a. The receiving clerk inspects package, in particular noting the presence of substantial damage in transit to the outside container and wetness of the container due to leakage of the contents. If substantial damage or wetness is found, the receiving clerk shall request the delivery driver to remain and notify the Nuclear Medicine Service. A member of the nuclear medicine technical staff will report to the receiving area promptly, inspect and survey the package, driver and delivery vehicle as necessary.

   b. When receipt is routine (no damage noted) the receiving clerk will promptly schedule delivery to the Nuclear Medicine Laboratory. Shipment will not be held in the receiving and storage area.

2. Receipt of Material--4:30 p.m. - 8:00 a.m., Saturdays, Sundays and Holidays

   a. Carriers are instructed to make delivery to the Security Police Officer.

   b. The security officer on duty will carry out the procedures in 1a above.

   c. Following routine delivery, the security officer will immediately take the package to the Nuclear Medicine Laboratory, place the package on the stretcher inside the lab and lock the door. Packages will not be held in the security office.

3. These procedures are adopted by the Radioisotope Committee and promulgated as Medical Center policy by memorandum from the Director's Office.

GRAND JUNCTION VA MEDICAL CENTER 9-1-79

Item 18 - WASTE DISPOSAL PROCEDURES

1. Liquid Waste will be disposed of

_____ By commercial waste disposal service (See also No. 4 below)

__X__ In the sanitary sewer system in accordance with Section 20.303 of 10 CFR Part 20

_____ Other (specify): Held for decay as for solid wastes below

2. Mo-99/Tc-99m generators will be:

__X__ Returned to the manufacturer for disposal

_____ Held for decay until radiation levels are measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: This method of disposal may not be practical for generators containing long-lived radioactive contaminants)

_____ Disposed of by commercial waste disposal service (See also No. 4 below)

_____ Other (specify): _____

_____

3. Other Solid Waste will be:

__X__ Held for decay until radiation levels as measured with a low-level survey meter and with all shielding removed) have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash.

_____ Disposed of by commercial waste disposal service (See also No. 4 below)

_____ Other (specify): _____

_____

4. The commerical waste disposal service used will be: _____

_____

(Name) (City, State)

NRC/Agreement State License No. _____

Item 21 - Use of Xenon-133 Gas

A. Quantities

1. Patient information
   a. Number of studies per week - 4
   b. Average activity per patient - 10 mCi

2. Requested possession limit - 200 mCi

B Use and Storage Areas

1. Xe-133 will be stored in shielded shipping containers in the isotope storage area of the Nuclear Medicine Laboratory. The storage location is a cave constructed with 2x4x8 inch lead bricks. (See attached diagram)

2. Ventilation in the Nuclear Medicine Laboratory for intake and exhaust is shown in the attached diagram. There is no recirculation to the intake system. Positive exhaust of air to the outside is provided by an exhaust fan with capabilities of moving greater than 200 cubic ft/min.

3. Intake of air from the hospital distribution system is less than the rate of exhaust. Therefore, the laboratory will be at a negative pressure with respect to the remainder of the hospital. The exhaust system is operated at all times and a light adjacent to the exhaust fan switch indicates the exhaust is operating. Tests will be conducted quarterly and the results recorded to assure that the room ventilation system is working properly. The test will consist of an air velocity measurement at the opening of a hood of known cross-section placed over the exhaust fan.

C. Procedures for Routine Use

Xenon-133 will be stored until use as described in B.1. Patient studies are performed using the Pulmonex system (brochure attached). The system incorporates a shielded charcoal Xe trap which will be monitored externally at least weekly. Procedures for introduction of Xe, system operation and maintenance will be per the manufacturer's directions. Effluent from the trap will be monitored weekly. Nose clamps will be used on patients to reduce leakage. At the conclusion of each study room background will be monitored using the gamma camera.

D. Emergency Procedures

In the event of a major leakage a window air conditioner operated in exhaust mode will supplement the continuous exhaust system. The laboratory will be temporarily vacated. Depending on outside temperature, windows may be opened.

E. Air Concentrations

1. Restricted Area:

(Assume 20% leakage)

$$\text{Activity} = 1 \times 10^4 \frac{\text{uCi}}{\text{pt.}} \times 4 \frac{\text{pt.}}{\text{wk.}} = 4 \times 10^4 \frac{\text{uCi}}{\text{wk.}}$$

$$\text{Vol.} = \frac{\text{Activity} \times 0.2}{\text{permis. conc.}} = \frac{4 \times 10^4 \times 0.2}{1 \times 10^{-5}}$$

$$= 8.0 \times 10^3 \times 10^5 = 8 \times 10^8 \text{ ml/wk}$$

$$\text{Required Vent. Rate} = \frac{8 \times 10^8 \text{ ml/wk}}{2400 \text{ min/wk}} = 3.3 \times 10^5 \frac{\text{ml}}{\text{min}} = 12 \text{ cfm}$$

The exhaust system provides for exhaust of air of up to 200 cfm.

2. Concentration in Non-Restricted Area
(exhaust to outside of building)

Leakage Activity = 4×10^4 uCi/wk x 0.2 = 8×10^3 uCi

Vol. = 200 cf/min x 1.008×10^4 min/wk x 2.84×10^4 ml/cf

= 5.72×10^{10} ml

$$\text{Conc.} = \frac{8 \times 10^3 \text{ uCi}}{5.72 \times 10^{10} \text{ ml}} = 1.40 \times 10^{-7} \text{ uCi/ml}$$

(permissible concentration 3×10^{-7} uCi/ml)

F. Xenon Disposal

Xe-133 is absorbed on a charcoal trap contained within the Pulmonex delivery system.

(i) Leakage from the trap will be carried through an attached hose to an area adjacent to the intake of the outside exhaust fan. The 20% leakage factor used in the calculation of needed ventilation (see E above) includes trap leakage.

(ii) The performance of the charcoal trap will be monitored as follows:

a. The exhaust from the trap will be collected in a plastic bag of known volume during a patient procedure.

b. The collected exhaust will be counted in front of an uncollimated gamma camera crystal to obtain the count rate in that volume. (cpm/ml)

c. A standard will be prepared by introducing a known quantity of Xe into another bag of equal volume. Count rate for the standard will be determined cpm/uCi/ml.

d. The ratio of exhaust to standard will give the exhaust concentration in uCi/ml.

e. When the concentration exceeds 1×10^5 uCi/ml the trap will be replaced.

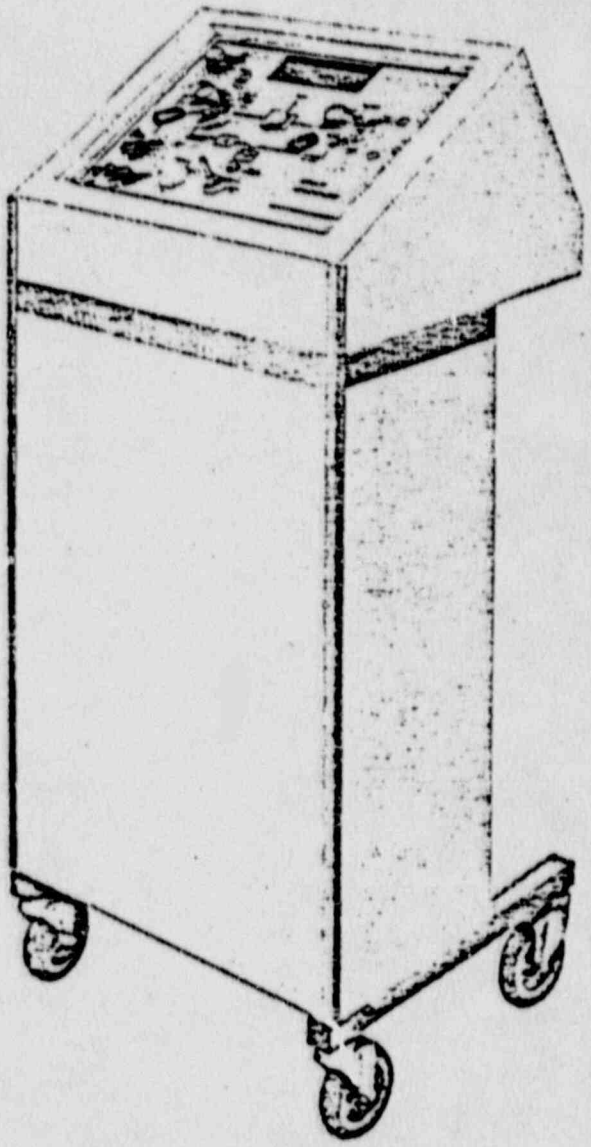
f. This procedure will be carried out monthly.

(iii) Saturated filters will be plugged and stored in a shielded area (see attached diagram) until monitoring indicates they are at background level.

Item 21

Atomlab

PULMONEX XENON SYSTEM



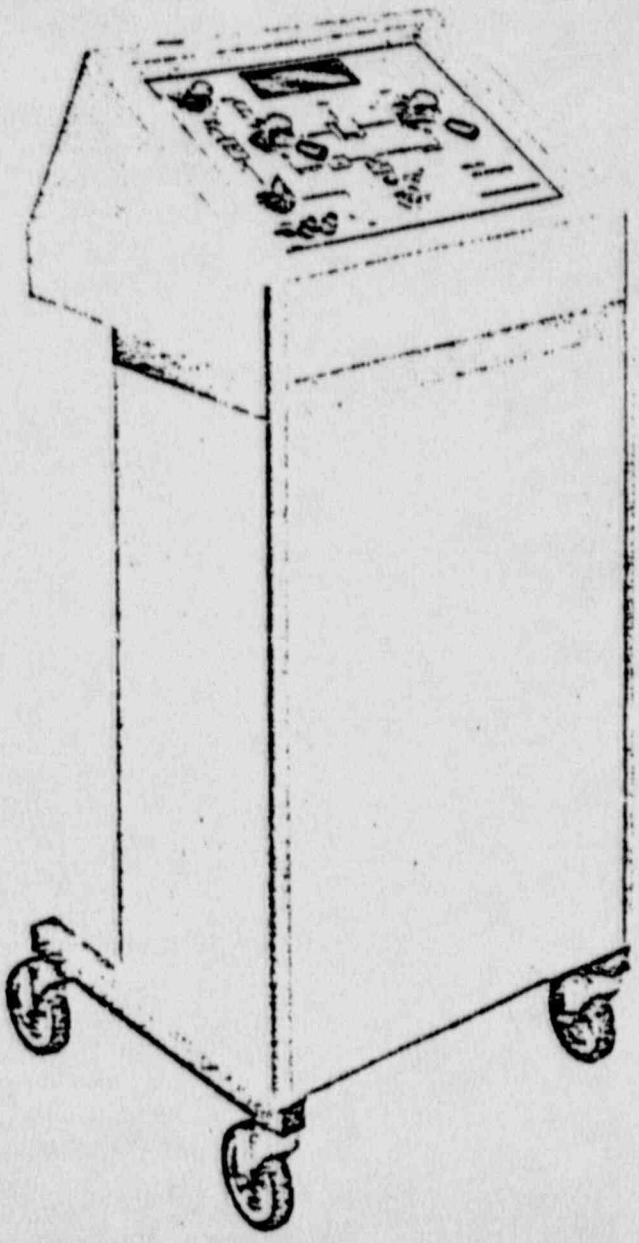
and integrated gas trap
for all
regional ventilation studies

Atomic Products Corporation

Center Moriches, New York 11934, U.S.A.
(516) 878-1074

AUTOMATIC

PULMONEX XENON SYSTEM



AUTOMATIC

Full-function xenon delivery system with built-in xenon gas trap for rebreathing, washout, perfusion and single breath studies on supine or seated patients.

- Complete easy-to-use system.
- Motor-driven circulator for resistance free patient breathing.
- Automatically timed washout.
- Adjustable air flow control.
- Accepts any commercial form of xen
- Rolls easily on large casters for positioning of supine or seated patie
- Lead glass window permits observati of patient breathing bag.
- Fully shielded.
- Carbon dioxide and moisture traps included.

Simple to operate • safe to use

Medical Center

2121 North Avenue
Grand Junction, CO 81501

Veterans Administration

August 31, 1981

U.S. Nuclear Regulatory Commission
Material Licensing Branch
Division of Fuel Cycle and Material Safety
Washington, DC 20555

Ref: License 05-08400-02

Gentlemen:

We are writing to request the amendment of condition 15 of our Materials License 05-08400-02. In the original application of November 1979, it was stated that visits would be made by the St. Louis VAMC Nuclear Medicine staff at six to eight week intervals for the purpose of medical consultation, supervision of laboratory management and audit of radiation safety practices in this facility. We request that the visit frequency be ammended to require four visits per year, ordinarily once each calendar quarter. We believe that this schedule is justified by the experience at the other VA facilities supported by the St. Louis staff, namely the Cheyenne, WY; Amarillo, TX; Poplar Bluff, MO and Marion, IL VA Medical Centers. In all instances, detailed inspections and training conducted at that frequency have been adequate to assure safe radiation practices. Funds for four visits in FY 82 have been approved by the VA Central Office. Failure to meet the six to eight week commitment was cause for a citation following a recent enforcement inspection.

During the enforcement visit, the inspector expressed concern over the fact that the nuclear medicine facility at this medical center is part of the nuclear network based in St. Louis. We wish to clarify this matter at this time.

Physician coverage of the Nuclear Medicine Laboratory is provided by Dr. Ralph Pacini, Chief of Medicine, who is available to advise on medical questions and handle medical emergencies that might arise in the laboratory. Dr. W. Taft Moore, Chief of Staff, is the administrative supervisor of the Radiology Service, including the Nuclear Medicine Laboratory.

Dr. James Fletcher and the nuclear network staff are responsible for the details of nuclear medicine procedures. All requests for patient studies are reviewed and approved by him or his designee taking into account the medical problem and working diagnosis prior to scheduling the test. The specific procedure, radiopharmaceutical, dose, route of administration and special instructions are specified and any questions concerning the test or its interpretation are resolved by consultation with the referring physician. As described above, safety audits and training will be conducted on-site four times annually.

Fred S

In Reply Refer To: 575/00

0890

U.S. Nuclear Regulatory Commission

Documentation of our ALARA program is enclosed for your files. This specifies the management and committee controls of our safety program.

If further information is required, please contact us.

Sincerely yours,

W. P. Freer

W. P. FREER
Medical Center Director

ALARA PROGRAM
(As Low As Is Reasonably Achievable)
Veterans Administration Medical Center
Grand Junction, Colorado

1. Management Commitment

The management of the Grand Junction VA Medical Center and its affiliated institutions are committed to the policy of keeping individual and collective radiation exposures ALARA. The management establishes and supports the necessary administrative and functional elements for radiation safety and promotes the concept of ALARA in these institutions.

An annual formal review of the Radiation Safety Program will be conducted which includes operating procedures, past exposure records and inspections. This audit will establish that improvements have been sought if necessary and have been implemented where reasonable.

Modifications to operating procedures, equipment and facilities will be made where these will reduce exposures unless, in our judgment, the cost is unjutified. Where modifications were recommended but not implemented the reasons will be documented.

2. Radiation Safety Committee

The RSC performs a thorough review of the qualifications of all applicants proposing to use ionizing radiation in the medical center to ensure that the applicant takes appropriate measures to maintain exposure ALARA. This review requires that the applicant has established and justified systematized procedures to ensure ALARA including the use of protective equipment.

The RSC delegates enforcement authority for ALARA to the Radiation Safety Officer and supports necessary assertion of this authority. In instances where actions and recommendations of the RSO are overruled or not supported the basis of this action will be documented.

The committee will require all users to review current procedures when filing for new authorizqtions and if necessary to develop or modify procedures to implement ALARA. The committee reviews on a quarterly basis all instances of occupational exposure exceeding established investigation levels and decides if action is warranted.

The committee annually reviews and evaluates the ALARA efforts of the radiation safety staff, authorized users, workers and the medical center management.

3. Radiation Safety Officer

The RSO will perform an annual review of all operational elements of the ALARA program. A quarterly review is conducted of occupational external and internal exposures and investigates or requires action where Investigation Levels are exceeded. Facility survey records are reveiwed quarterly to ensure ALARA. Known instances of deviation from good ALARA practices are also investigated to determine the cause and to require program changes.

The Radiation Safety staff conducts an educational program to instruct personnel in the ALARA philosophy and to inform workers of the ALARA program efforts.

The Radiation Safety Officer and staff cooperates with all users and workers to ensure development of ALARA procedures and receives and evaluates suggestions for improvement of ALARA practices.

4. Authorized Users and Occupationally Exposed Workers

Preliminary to any application for new procedures using ionizing radiation users will consult with the RSO concerning ALARA practices for the proposed use and develops and evaluates specific ALARA guidelines.

Authorized users are required to promote and explain the ALARA concept and ensure that supervised workers are trained in good radiation safety practices and their relationship to work procedures and conditions.

All occupationally exposed workers are required to report instances where it is believed that good ALARA practices are not promoted and followed.

5. Investigational Levels and Actions for External Exposure

		mREM/Quarter Level I	Level II
A.	Whole Body, head and trunk, blood forming organs, lens of eyes, gonads	125	375
B.	Hands, forearms, feet and ankles	1875	5625
C.	Skin of whole body	750	2250

The Radiation SAfety staff reviews records of personnel monitoring quarterly. The following actions are taken at the stated investigation Levels.

	Exposure	Action
A.	Less than Level I	None
B.	Greater than Level I Less than Level II	Report exposure to RSC; RSC will evaluate the exposure conditions and record its action and recommendation
C.	Greater than Level II	RSO investigates and prepares a report for the RSC minutes including the exposure record, causes, actions taken and recommendations. Copies of minutes are received by the Medical Center Director.

In situations where exposures need to exceed investigational Level I or II, these may be re-established at a higher level by action of the committee provided that all reasonable ALARA practices are enforcesd and the justification for new levels is recorded by the committee.

William P. Freer

William P. Freer
Medical Center Director

MAY 20 1982

FCML:WJW
030-17159
(08904)

Veterans Administration Medical Center
ATTN: Mr. W. P. Freer
Director
2121 North Avenue
Grand Junction, CO 81501

Gentlemen:

Enclosed is Amendment No. 01. to License No. 05-08400-02. We have amended your license to include the ALARA program. The other requested conditions in your letter dated August 31, 1981 were not considered, as these actions are tied into the current discussions with Dr. Jim Smith at VA Central regarding the use of VA's electronic nuclear medicine network.

Sincerely,

William J. Walker, Jr., Ph.D.
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosure: Amendment No. 01

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WJWalker FC Central File
NMSS r/f

FCML	FCML
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5/ /82	5/ /82

Encl 9

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

SSINS: 6920
TERA 0420

OCT 20 1981

MEMORANDUM FOR: Vandy L. Miller, Chief, Materials Licensing Branch, NMSS

FROM: Leo B. Higginbotham, Chief, Radiological Safety Branch, IE

SUBJECT: SUPERVISION OF DIAGNOSTIC MEDICAL PROGRAMS

The enclosed memo from our Region IV Office points out a problem regarding license conditions pertaining to supervision of diagnostic medical programs. In the instant case, it is apparent also that the license condition applicable to the Cheyenne WY and St. Louis, VA centers is in conflict with the guidance we issued in 1979 to our Regional Offices (See enclosed guide on license condition... "...used by or under the Supervision of ..."). Development of that guidance was coordinated informally with the NMSS staff prior to its issuance.

We understand that the license authorization similar to that for the Cheyenne facility has also been extended to several other VA facilities as well. In the Grand Junction case, apparently no such authorization had been sought or received.

We request that you review this matter. The apparent conflict between our guidance and the "multiple facility-central control" concept of the VA hospital situation should someway be resolved. If you are satisfied with the adequacy of the supervisory concept authorized at the Cheyenne facility and intend to continue the practice, we can accommodate that by a revision of our guidance. Consider however, the apparent difference in agency standards or restrictions that would be used for this aspect of regulating medical programs.

Leo B. Higginbotham, Chief
Radiological Safety Branch, IE

Enclosure: As stated

cc: J. H. Joyner, RI
A. F. Gibson, RII
L. R. Greger, RIII
G. D. Brown, RIV
H. E. Book, RV

Encl 10

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TEXAS 76011

JUL 31 1981

MEMORANDUM FOR: Al Grella, Chief, Fuel Cycle and Materials Safety Section, Radiation Safety Branch, IE

FROM: R. J. Everett, Chief, Materials Radiation Protection Section

SUBJECT: SUPERVISION OF DIAGNOSTIC MEDICAL PROGRAMS

We inspected the Veterans Administration Medical Center at Grand Junction, Colorado, on July 6 and 9, 1981. We found that the authorized user resides in St. Louis, Missouri. This physician prescribes radiopharmaceuticals, amount of dose, route of administration and reviews results of tests by phone and by mail. He has visited the facility one time since the license was issued on December 28, 1979. Other findings of the inspection indicated to us that the program is not being properly supervised. In our Enforcement Teleconference on July 24, 1981, the licensee expressed dismay that we would question this mode of operation since the issue had been previously discussed with NRC licensing and other VA Centers in the southwest are operating in a similar manner. For the Cheyenne, Wyoming VA facility, the licensee documented his proposed method of supervising use of licensed materials in a letter to Licensing, dated April 28, 1980, (attached). This letter was incorporated into the Cheyenne VA license. No such letter exists for the Grand Junction facility.

It is clear that the Cheyenne letter is in conflict with the IE interpretive guide, dated October 1, 1979, in that the authorized user is not "sufficiently close" to the place of use in order to provide reasonable supervision and approval of tests is vested in physicians not specified on the license.

There are several other VA Centers in Region IV that we expect to find operating similar to Cheyenne and Grand Junction. Therefore, we need a clear NRC position as to what is acceptable with regard to use and supervision of diagnostic medical programs.

Harold D. Bruner for
R. J. Everett, Chief
Materials Radiation Protection Section

Enclosure: As stated

Cheyenne, Wyoming

0948

April 28, 1980

Mr. Michael A. Lamastra
Material Licensing Branch
Division of Fuel Cycle and Material Safety
United States Nuclear Regulatory Commission
Washington, D.C. 20555

Gentlemen:

Reference your Control Number 03207.

This letter is in response to your inquiry regarding the NRC license number 49-15495-01 at the Cheyenne VA Medical Center. This response will clarify and delineate responsibilities in the operation of our Nuclear Medicine Service.

a. All decisions regarding details of Nuclear Medicine procedures are made by Robert M. Donati, M.D., or his physician designee at the Nuclear Network facility at the St. Louis VA Medical Center. All requests for procedures are communicated to St. Louis and explicit approval for the test is obtained from a qualified Nuclear Medicine physician including radiopharmaceutical, dose, and any necessary additional instructions before the procedure is performed.

b. The Nuclear Medicine technologist, Mr. Vincent Glueck, is responsible for all matters relative to radiation safety on a continuing routine basis, and functions as the RSO for the facility. He assures compliance with all regulatory requirements and the personal safety of himself, patients and other individuals. A summary of his training and experience is attached.

c. Drs. Aldrich and Seidl have no responsibility for basic radiologic handling, but serve as medical support for the Nuclear Medicine Laboratory. They are available on an emergency basis in the event of, for example, an allergic reaction, cardiac of pulmonary arrest.

d. Additional support for the laboratory is derived from visits of specialists from the St. Louis hospital four times annually. During these visits, records and procedures are reviewed with respect to regulatory compliance as well as the quality of medical practice in Nuclear Medicine. Specific

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educational programs are conducted for technical and professional staff relative to the proper and efficacious use of nuclear procedures.

e. We believe the procedures established to provide service to patients at this VA Medical Center through the St. Louis Network ensure a closer degree of supervision than that found in many hospitals where expert advice and assistance are available only on a part-time basis. Qualified physicians, physicists, radiopharmacists, chemists, engineers, educational specialists, and technicians are available on a full-time basis to support all nuclear medicine activities at this hospital.

f. If you feel that there is not sufficient administrative continuity to permit continued separate specific licensing of this hospital, then we suggest that the Cheyenne VA be added as an additional use site to the St. Louis VA Broad Medical License. The precedent for this has been established at the Jefferson Barracks, Marion, and Poplar Bluff VA Medical Centers. This has proven to be a feasible and effective means of assuring the quality of Nuclear Medicine service as your compliance staff will verify.

Thank you for your continued interest in our program.

JOHN D. GRAVELEY
Acting Center Director

Attachment

U. S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

INSPECTION AND ENFORCEMENT MANUAL

10 CFR 30
License Condition
re: supervision
Issue date: 10/1/79
SSINS: FFMSI 9320
9123
6100

INTERPRETIVE GUIDE

SUBJECT: LICENSE CONDITION,"...Used by or Under the Supervision of...."

A. PURPOSE AND BACKGROUND

To provide guidance for inspecting licensees to determine the extent and degree needed for compliance regarding supervision over the use of licensed materials.

B. APPLICABILITY

This guidance applies to all materials licensees except radiography; The requirements for licensee supervision of radiographic operations is defined in Part 34.

C. EXPLANATION

1. In developing the following interpretation with members of NRC staff and ELD, it was concluded that it is impractical to try to define numerical times and distances with respect to supervision availability, because of the wide variations in circumstances. Similarly, it is impractical to define the frequency of verbal orders or the performance of audits by supervision; these would depend in part on the degree of changes in operations, equipment, personnel, etc. Therefore, for these reasons and because the interpretation is necessarily broad, considerable judgment by the inspector(s) in implementing the guidance will continue to be required.

   a. An authorized user named on an NRC license is considered to be supervising the use of radioactive materials when he directs personnel in the conduct of operations involving the licensed material. This does not imply that the authorized user must be present at all times during the use of such materials. However, the authorized user/supervisor is responsible for assuring that personnel under his supervision have been properly trained and instructed.

   b. The authorized user/supervisor is therefore responsible for the supervision of operations involving the use of radioactive

materials whether he is present or absent. When absent, the authorized user should be available for consultation (by telephone) in a reasonable amount of time commensurate with the need for consultation, based on the adequacy of the training of those personnel under the user's supervision.

C. For medical programs, the supervising physician should be located sufficiently close to the hospital in the event he is needed to personally supervise a procedure or interpret the results of a procedure. "Sufficiently close" cannot be defined for the reasons stated above; but the supervisor should be in the same city as the activity or close to the city (if it is a small city or town) so that he can get to the facility in a reasonable period of time. (Many physicians use a "bell boy" beeper so that they can be alerted to call a hospital if needed.) A supervisor that goes on vacation or cannot be reached is not considered to be supervising. Further, for physicians licensed to supervise, it is necessary that they be available to interpret the results of a medical procedure, such as scans, whether or not they actually perform the scans, give injections, etc.

D. COORDINATION

This guidance has the concurrence of ELD (Joanna Becker), NMSS (Patricia Vacca).

E. REFERENCES

None

F. SUPERSESSION

None

G. CONTACT

FFMSI contact; J. R. Metzger

Leo B. Higginbotham
Assistant Director
Division of Fuel Facility and
Materials Safety Inspection
Office of Inspection and Enforcement

Date: 10/1/79

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Notes on St. Louis VA's Nuclear Network

As per November 5, 1981 telephone conversation with Helen Malaskiewicz, VA Central Office, St. Louis VA's "nuclear network" includes the following facilities:

1. Amarillo, Texas VA
2. Grand Junction, Colorado VA
3. Cheyenne, Wyoming VA
4. The facilities listed on St. Louis' license (i.e., Jefferson Barracks; Marion, IL; Poplar Bluff, MO)

I reviewed the licenses to determine what we understood from correspondence with the licensee regarding how each program operated. The results are as follows:

1. Amarillo VA

   a. Original application received February 15, 1979 states that person to contact re: application is F. Herbig. (Herbig is RSO at St. Louis VA.)

   b. The physician-users, Drs. Kalus and Dr. Epley, are physically located in Texas and, as far as we know, at the Amarillo facility.

   c. Item 12 of the application received February 15, 1979 indicates that St. Louis VA will provide training:

      (1) Amarillo staff will be detailed to St. Louis for training.

      (2) St. Louis staff (MD + technical or scientific person) to visit Amarillo every 6-8 weeks to conduct in-service training (e.g., new medical procedures, radiation safety).

   d. F. Herbig's June 28, 1979 letter indicates funding for training from St. Louis is for FY 80 only.

   e. CONCLUSIONS

      (1) Loose connection with VA St. Louis; "nuclear network: might be used primarily for consultation on "difficult" cases.

      (2) Appears to be no different from any other medical license.

2. Grand Junction (Colorado) VA

   a. Seems to be similar to Amarillo situation up to most recent inspection and amendment request.

Encl 11

b. Application received November 23, 1979 lists Medical Center Director as person to contact.

c. Application lists Dr. James Fletcher as user.- No indication that he is not physically located at Grand Junction. (However, he is at St. Louis VA.)

d. Item 12 of application is similar to the Amarillo application.-- i.e., St. Louis VA do provide training to Grand Junction staff.

e. CONCLUSION: At this time no different from any other medical license.

f. NOTE: Have amendment request dated August 31, 1981 to:

(1) Change frequency of visits by St. Louis VA staff for training purposes.

(2) "Clarify" that they are part of nuclear network.

As of November 6, 1981, no action taken on this request.

3. Cheyenne (Wyoming) VA

a. Up to Feb-March 1980 the license appeared to be normal medical license with Dr. Robert Nelson as authorized user.

b. By letter dated February 2, 1980, licensee advised us that:

(1) Dr. Nelson had left hospital

(2) Dr. Donati who is certified by ABNM would be new user.

(3) Vincent Glueck would be new Radiation Safety Officer. (Glueck is "certified" technologist, had training at St. Louis VA and worked for 1½ years at Marion, IL. VA, an authorized place of use on St. Louis VA's license.)

c. Amendment 06 issued March 5, 1980 named Dr. Donati as user in condition 12 and added February 4, 1980 letter to tie-down condition.

d. Licensee's letter dated February 29, 1980 indicated that NRC had questioned Dr. Donati as the user and begins describing how "nuclear network" would work between St. Louis VA and Cheyenne VA.

e. By letter dated April 10, 1980 NRC (Mike Lamastra) asked for additional information and licensee responded with more details in letter dated April 28, 1980.

f. Amendment 07 issued June 24, 1980 amended tie-down condition to add licensee's February 29, 1980 and April 28, 1980 letters.

g. Amendment 08 issued October 27, 1981 amended tie-down condition to add licensee's August 26, 1981 letter regarding change in on-site physician.

4. St. Louis VA

a. Until 1974 the license authorized use at the John Cochran Division, 915 North Grand Boulevard, St. Louis.

b. By letter dated April 5, 1974 licensee asked that authorized place of use be expanded to include Jefferson Barracks which became a division of the St. Louis VA. Condition 10 was amended on July 11, 1974.

c. Licensee applied for renewal on June 20, 1974. Record indicates that there was a meeting between NRC staff (Leo Wade was one person) and VA staff re: adding Marion, IL VA and Poplar Bluff, MO VA Hospitals as authorized places of use. March 26, 1975 letter says that the attachment to the letter provided information in response to a deficiency letter and information on activities at other two facilities. These attachments were missing from file and have been located; they include description of "nuclear network" and some procedures to be followed.

d. Renewed license was issued July 3, 1975 and authorized use at Jefferson Barracks, Poplar Bluff and Marion facilities.

e. Most recent inspection (1979) identified items of non-compliance at satellite facilities.

f. The more recent renewal application of December 23, 1980 and letter of April 9, 1981 do not indicate that activities at satellite facilities are any different from those at a typical nuclear medicine facility. Renewed license was issued June 12, 1981.

NOV 18 1981

MEMORANDUM FOR: Leo B. Higginbotham, Chief
Radiological Safety Branch
Division of Safeguards & Radiological Safety, IE

FROM: Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and Material Safety, NMSS

SUBJECT: AUTHORIZED USERS' SUPERVISION OF MEDICAL PROGRAMS

In accordance with my October 26, 1981 telephone conversation with Mr. Grella and other members of your staff, we agreed to answer your October 20, 1981 memorandum by considering two questions:

1. The specific question regarding the Veterans Administration's (VA) "nuclear network" involving their facilities at St. Louis, Missouri, Cheyenne, Wyoming and Grand Junction, Colorado.

2. The general question of our Branch's understanding of the two authorized user conditions (i.e., "Licensed material shall be used by _____" and "Licensed material shall be used by, or under the supervision of, _____") as they are used in medical licenses. Please note that our discussion of the more general question should be viewed as an interim response. We believe that the correct way to clarify NRC's position on this matter and to notify licensees of NRC's position is to define the meaning of these two license conditions in 10 CFR Part 35. Dr. William Walker, Leader of the Task Force working on the revision of 10 CFR Part 35, intends to include these definitions in the revised regulations.

Veterans Administration's "Nuclear Network"

To determine the extent of the VA's so-called "nuclear network", we contacted the VA Central Office in Washington, D.C. We learned that the "nuclear network" includes the following VA facilities: Amarillo, Texas; Grand Junction, Colorado; Cheyenne, Wyoming and those listed on the license issued to the St. Louis VA. We have found that as of November 10, 1981, only one specific license of limited scope (Cheyenne, Wyoming VA) differs from the normal nuclear medicine license.

Encl 12

In the case of the Cheyenne, Wyoming VA license, we approved Dr. Donati to act as authorized user (even though he is located in St. Louis) with the understanding that the facility has a qualified on-site radiation safety officer (Mr. Glueck) and that certain procedures will be followed. Condition 16. of the license approves Mr. Glueck and requires that the licensee follow the procedures set forth in his correspondence with us.

We believe that the licensee's correspondence clearly describes such matters as how patients will be selected, how doses will be prescribed, how test data will be evaluated and how the staff at the Cheyenne, Wyoming VA will interact with physicians at St. Louis VA. We recognize that this situation is different from other nuclear medicine facilities; however, we believe that the license contains sufficient commitments for proper inspection.

In the case of the VA hospital at Grand Junction, Colorado the existing license does not have Special provisions similar to those contained in the license for the VA at Cheyenne. We have an amendment request from the licensee at Grand Junction that seeks to "clarify" the licensee's participation in the "nuclear network". We have not acted on the licensee's request. As result of your memorandum we are reexamining our position in this matter and plan to confer with VA staff before proceeding. We will keep you informed of our decision in this matter.

The license for the VA Hospital at Amarillo seems to be similar to other nuclear medicine licenses. We have no reason to believe that the authorized physicians are not physically located at the Amarillo facility. From NRC's standpoint there does not appear to be any need for Amarillo to be connected to the "nuclear network". The connection may be for consultation on unusual cases.

The Type A License of Broad Scope for the VA Hospital at St. Louis was renewed in June 1981 based on an application dated December 23, 1980 and a letter dated April 9, 1981. From the information contained in these documents it appears that the Jefferson Barracks, Poplar Bluff (MO) and Marion (IL) facilities are additional places of use that are staffed with authorized users, paramedical personnel, etc. and that operate in the same manner as the main St. Louis facility (i.e., in the same manner as any other nuclear medicine licensee).

It should be noted, though, that attachments to the licensee's 1975 correspondence did provide information pertaining to the "nuclear network" and procedures to be followed. The most recent inspection of this license in 1979 revealed items of non-compliance associated with the licensee's activities at these satellite facilities.

General Discussion of Authorized User Conditions as Used on Medical Licenses

A person named as an authorized user on an NRC license is responsible for ensuring that radioactive materials are handled and used safely and in accordance with NRC regulations and the terms and conditions of the NRC license. For activities involving human use of licensed material, the person must be a physician (see 10 CFR 35.3).

As stated in Enclosure 1, the Commission recognizes the uniqueness of the medical licensee, specifies certain duties (see the proposed 10 CFR 35.32(b)) that the authorized physician-user must either perform himself or may delegate only to another physician and lists other activities (see the proposed 10 CFR 35.32 (c)) that the authorized physician-user may delegate to properly trained paramedical personnel. Note that, in the information preceding the proposed rule in Enclosure 1, the Commission states that it still considers the authorized physician-user to be the "user of radioisotopes" even though he may have delegated certain activities to paramedical personnel. We believe in the continued validity of the position expressed in Enclosure 1.

If we were to take the position that paramedical personnel should be considered as authorized users (i.e., for those activities listed in the proposed 10 CFR 35.32 (c)), then we would have to review the training and experience of these personnel. However, in the medical policy statement published in February 1979 (Enclosure 3) the Commission decided not to become involved in determining the adequacy of training of paramedical personnel.

A. "Licensed material shall be used by _____".

This condition is used on private practice licenses (i.e., those issued pursuant to 10 CFR 35.12). The authorized physician-user has all of the responsibilities of an authorized user on any NRC license. In addition, in his special position as a physician he has the responsibilities listed in the proposed 10 CFR 35.32(b). Also, as indicated in Enclosure 1, he may delegate certain activities to properly trained paramedical personnel. (In Regulatory Guide 10.8 (Revision 1) and the draft teletherapy guide being prepared by M. Wangler, RES, we have used the word "directs" to describe how the authorized user interacts with technologists or other paramedical personnel.)

B. "Licensed material shall be used by, or under the supervision of, _____"

This condition is used primarily on institutional licenses (i.e., licenses issued pursuant to 10 CFR 35.11). As explained in Enclosure 1, this condition provides a means whereby nonapproved physicians under the supervision of an authorized physician-user can obtain training (primarily clinical training) that may enable them to qualify as authorized users.

On licenses with this condition, the authorized physician-user has all of the duties and responsibilities outlined in A. above. In addition he may provide clinical training for nonapproved physicians and may delegate to them the activities listed in the proposed 10 CFR 35.32(b).

In general, we believe that physicians working "under the supervision of" an authorized physician-user should be physicians-in-training. However, for relatively short periods of time a physician may work "under the supervision of" an authorized user while the license is being amended to add his name as an authorized user. We believe that any other physicians involved with the use of radioactive materials should be added to the license.

What constitutes direction of technologists and/or supervision of nonapproved physicians?

We agree with your Interpretive Guide that the wide variety of circumstances found in medical programs makes it impractical to define supervision or direction in terms of numerical times and distances, frequency of written or oral orders, performance of audits, etc. We also agree that inspectors must excercise considerable judgment in implementing guidelines on this matter. Some factors that should be considered are as follows:

1. The authorized physician-user has the same responsibilities as an authorized user on a non-medical license, e.g., ensuring that radioactive materials are handled and used safely and in accordance with NRC regulations and terms of the NRC license; ensuring that personnel such as technologists and physician-trainees have appropriate training and instruction.

2. The authorized physician-user is expected to manage the medical program authorized by the license, to set up the clinical parameters to be used by the nonapproved physicians he supervises with regard to patient selection, dose selection, clinical interpretation and, at a minimum, to review closely the radiation safety procedures used by, and the diagnostic and/or therapeutic procedures performed by, the supervised physician trainee.

3. One of the authorized physician-users should be present on the licensee's premises for on-going and reasonable periods of time. For example, it is not acceptable for the physician-user simply to come in alone at night and read scans; he must have more involvement with the program.

4. If none of the authorized users is physically present on the premises where radioactive materials are used, then one of the users should be available by telephone and should be able to get to the licensee's facility within a short time to handle any emergency.

5. Authorized physician-users who are ill, on vacation, or otherwise unable to fulfill the responsibilities outlined in Item 1 above and in the proposed 10 CFR 35.32(b) should not be considered as supervising or directing other personnel. The "visiting physician" condition (Enclosure 2) has been added to institutional licenses to assist in these situations. Licensees who do not have this condition or whose proposed "visiting physician" does not meet all of the requirements specified in Enclosure 2 should have their licenses amended to add the new user(s).

6. We have recommended to licensees that a physician (not necessarily one of the authorized users) be readily accessible when radioisotopes are administered (e.g., to treat anaphylactic shock). This recommendation is in accordance with the proposed 10 CFR 35.32 (g); see Enclosure 1.

We hope that these comments will be helpful to you. We will keep you informed of our future decisions regarding the VA's "nuclear network" and expect that one or more IE staff working with the Part 35 Revision Task Force will be involved in clarifying these license conditions in the revised regulation.

Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosures:
1. 1973 Proposed Rule Change
2. "Visiting Physician" Condition
3. 1979 Medical Policy Statement

cc: John Cook
William J. Walker, Jr. Ph.D.
John Glenn, Ph.D.
Bruce Mallett Ph.D.

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APPENDIX A

ACCEPTABLE TRAINING AND EXPERIENCE FOR MEDICAL USES OF BYPRODUCT MATERIAL*

1. General Criteria

Any human use of byproduct material (i.e., the internal or external administration of byproduct material, or the radiation therefrom, to human beings) must be carried out by or under the supervision of a physician. As defined in paragraph 35.3(b) of 10 CFR Part 35, a *physician* means an individual licensed by a State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to dispense drugs in the practice of medicine.

Paragraph 35.11(d) of 10 CFR Part 35 provides that the Commission will approve a license application by an institution for medical use of byproduct material if it determines, among other things, that the physician designated as the individual user is adequately trained and experienced in (a) basic radioisotope handling techniques and (b) the clinical management of patients to whom radiopharmaceuticals have been administered. Similar criteria are established in paragraph 35.12(a)(4) of 10 CFR Part 35 for the approval of licenses for medical use of radiopharmaceuticals by individual physicians. Outlined below are training and experience criteria that the Commission, with the assistance of its Advisory Committee on the Medical Uses of Isotopes (ACMUI), has found acceptable for physicians who use radiopharmaceuticals.

This training and experience must have been obtained within a 5-year period preceding the date of the license application or must be supplemented by continuing education or experience. Also, the original training and experience should have been received in a formal residency program in an accredited medical institution. Each physician's training and experience are examined on a case-by-case basis. If a physician wishes to use radiopharmaceuticals but does not have the training and experience described, he may submit an application listing his specific qualifications and these will be reviewed by the Commission with the assistance of the ACMUI.

2. Training for Routine Diagnostic Procedures (Groups I-III)

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Groups I, II, and/or III in §35.100 of 10 CFR Part 35, a physician should have:

a. Training in basic radioisotope handling techniques applicable to the use of unsealed sources. This training should consist of lectures, laboratory sessions, discussion groups, or supervised experience in a nuclear medicine laboratory (i.e., on-the-job training in a formalized training program) in the following areas: (200 hours)**

   (1) Radiation physics and instrumentation (100 hours)

   (2) Radiation protection (30 hours)

   (3) Mathematics pertaining to the use and measurement of radioactivity (20 hours)

   (4) Radiation biology (20 hours)

   (5) Radiopharmaceutical chemistry (30 hours)

   (The hours listed next to each of the five subjects above are suggested values and should not be interpreted as specific requirements.)

b. Experience with the types and quantities of byproduct material for which the application is being made, or equivalent (500 hours). For authorization for Group III (generators and reagent kits), this experience should include personal participation in five procedures to elute Tc-99m, including testing of eluate, and five procedures to prepare radiopharmaceuticals from Group III reagent kits.

c. Supervised clinical training in an institutional nuclear medicine program (500 hours). The clinical training should cover all appropriate types of diagnostic procedures and should include:

   (1) Supervised examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed.

   (2) Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurement, and plotting data.

*Changes in these requirements are anticipated in the near future (after publication of this guide) and will be published in a revision to this guide.

**The hours are in terms of hours of class, laboratory, or clinical experience rather than semester hours.

Encl 13

(3) Followup of patients when required.

(4) Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc

Note A:

The requirements specified in Sections 2a, b, and c may be satisfied concurrently in a 3-month training program IF all three areas are integrated into the program.

Note B:

For each physician named in Item 4 of Form NRC-313M, complete Supplements A (Training and Experience) and B (Preceptor Statement) of Form NRC-313M. For each subject covered in basic training, state where the training was obtained, the dates, total number of hours, and type of training. Hours of training should be broken down into lecture or laboratory hours or on-the-job training (OJT). OJT must have been obtained in a formalized training program. Be sure that individual hours of training can be traced to the institution where the training was received. Each hour of training should be listed under only *one* subject category (i.e., the most applicable subject category).

Alternatives

Certification by (a) the American Board of Nuclear Medicine, or (b) the American Board of Radiology in Diagnostic Radiology with Special Competence in Nuclear Radiology will be accepted as evidence that a physician has had adequate training and experience to use Groups I, II, and III.

3. **Training for Specific Diagnostic Procedures**

A physician who wishes to be authorized for only one or two specific diagnostic procedures should have training in basic radioisotope handling techniques and clinical procedures commensurate with the procedures and quantities of byproduct material being requested. Such requests will be examined on a case-by-case basis by the Commission with the assistance of the ACMUI.

4. **Training for Therapy Procedures Involving Radiopharmaceuticals**

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Groups IV and/or V in §35.100 of 10 CFR Part 35, a physician should have:

a. Training in basic radioisotope handling techniques applicable to the use of unsealed sources for therapy procedures, including

(1) Radiation physics and instrumentation (25 hours)

(2) Radiation protection (25 hours)

(3) Mathematics pertaining to the use and measurement of radioactivity (10 hours)

(4) Radiation biology (20 hours)

(These requirements are in lieu of, not in addition to, those specified in Section 2a above.)

b. Clinical training in specific therapy procedures:

For Group IV

(1) I-131 for treatment of hyperthyroidism and/or cardiac conditions:

Clinical experience in the diagnosis of thyroid function and active participation in the treatment of *ten patients*.

(2) Soluble P-32 for treatment of polycythemia vera, leukemia, and/or bone metastases:

Active participation in the treatment of *three patients* with any combination of these three conditions.

(3) Colloidal P-32 for intracavitary treatment:

Active participation in the treatment of *three patients*.

For Group V

(1) I-131 for treatment of thyroid carcinoma:

Clinical experience in diagnosis of thyroid function, personal participation in the treatment of *ten patients* with hyperthyroidism and/or cardiac dysfunction, and active participation in the treatment of *three patients* with thyroid carcinoma.

(2) Colloidal Au-198 for intracavitary treatment:

Active participation in the treatment of *three patients*.

5. **Training for Therapy Procedures Involving Sealed Sources**

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Group VI in §35.100 of 10 CFR Part 35, a physician should have

a. Training in basic radioisotope handling techniques applicable (200 hours)

to the use of sealed sources for therapy procedures, consisting of lectures, laboratory sessions, discussion groups, or supervised experience in the following areas:

(1)	Radiation physics and instrumentation	(110 hours)
(2)	Radiation protection	(40 hours)
(3)	Mathematics pertaining to the use and measurement of radioactivity	(25 hours)
(4)	Radiation biology	(25 hours)

(The hours listed next to each of the four subjects above are suggested values and should not be interpreted as specific requirements.)

b. Experience with the types and quantities of radioactive material for which the application is made, or equivalent (500 hours).

c. Clinical training in Group VI procedures:

Active practice in therapeutic radiology with a minimum of 3 years experience of which at least 1 year should have been spent in a formal training program accredited by the Residency Review Committee of Radiology and the Liaison Committee on Graduate Medical Education.

As evidence of the foregoing training and experience, the applicant should complete Supplements A and B of Form NRC-313M. Supplement B should be completed and signed by each preceptor-physician under whom the applicant-physician gained experience *or* training. Submission of letters of evaluation from each preceptor-physician on behalf of the applicant-physician should be included with the application. These letters of evaluation should describe the scope and extent of the applicant-physician's training and experience and should include an appraisal of the applicant-physician's competency to use Group VI sources independently for therapy procedures.

Note:

Evidence of certification by the American Board of Radiology in Radiology or Therapeutic Radiology, certification as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR) or Canadian certification from the Royal College of Physicians and Surgeons (RCPS) in therapeutic radiology may be submitted in lieu of the information requested in Sections 5a through c above. Physicians certified by the FFR or FRCR must also submit evidence of specialization in radiotherapy. Evidence of previous approval by the NRC or an Agreement State may also be submitted in lieu of the information requested above. In this case, the applicant should specify the number of the NRC license or submit a copy of the Agreement State license on which the applicant-physician was specifically listed as an authorized user.

6. **Training for Physicians Wishing to Use Sr-90 Ophthalmic Eye Applicators Only**

To qualify as adequately trained to use or supervise the use of an Sr-90 eye applicator only, a physician should submit:

a. Evidence of certification by the American Board of Radiology in radiology or therapeutic radiology, or

b. Evidence of:

(1) Active practice in therapeutic radiology or ophthalmology, and

(2) Training in basic radioisotope handling techniques, including (24 hours)

(a)	Radiation physics and instrumentation	(6 hours)
(b)	Radiation protection	(6 hours)
(c)	Mathematics pertaining to the use and measurement of radioactivity	(4 hours)
(d)	Radiation biology	(8 hours)

This information may be submitted on Supplement A of Form NRC-313M. The hours listed next to each of the four subjects are suggested minimum values and should not be interpreted as specific requirements.

(3) Evidence of active participation in the treatment of *five patients* (to be submitted on Supplement B (Preceptor Statement) of Form NRC-313M).

"Active participation" should include supervised examination of patients, collaboration and calculations concerning the dose to be used, administration of the dose to the patient, and followup and study of patient case histories.

federal register

Friday
July 26, 1985
50 FR 30516

Part IV

Nuclear Regulatory Commission

10 CFR Parts 30, 31, 32, 35 and 40
Medical Use of Byproduct Material;
Proposed Rule

Encl 14

UNITED STATES
NUCLEAR REGULATORY COMMISSION
Office of Public Affairs
Washington, D.C. 20555

No. 85-98
Tel. 301/492-7715

FOR IMMEDIATE RELEASE
(Friday, July 19, 1985)

NRC PROPOSES TO SIMPLIFY MEDICAL LICENSING PROCEDURES

The Nuclear Regulatory Commission is proposing to revise its regulations to simplify and make more efficient the regulatory process for the medical uses of radioisotopes.

The NRC issues licenses to medical facilities and individual physicians for the use of radioactive materials to diagnose and to treat patients. Specific licenses are issued for one or more of six groups of medical uses organized in ascending order of radiation hazard potential, each containing related diagnostic or therapeutic procedures. A separate license is issued for teletherapy units. Applicants for specific licenses must submit a substantial amount of information to show that all radiation safety requirements will be met, including a description of the procedures used in meeting the requirements. The Commission's radiation safety review covers three general areas: radiological-health and safety procedures; personnel training and experience; and facilities and equipment.

Due to the rapid evolution in the medical use of radioisotopes over the last thirty years, current requirements are found throughout the regulations, regulatory guides, standard license conditions and other sources. Therefore, the primary purpose of the proposed revision is to consolidate the requirements. Under the proposal, all requirements would be clarified and published in one place, Part 35 of NRC regulations, which would serve to regulate the day-to-day uses of medical radioisotopes. The revised regulation would give both licensees and NRC staff a clearer basis for licensing, operation, and inspection activities.

A draft regulatory guide for medical programs has been prepared. It contains a model procedure acceptable to NRC for meeting each of the medical use requirements. Licensees could use the model procedure for meeting the requirements or could prepare their own procedures.

If applicants submit their own radiation safety procedures, the NRC staff will continue to review them to determine whether they are adequate to meet the requirements of the regulations. However, to permit licensees to make prompt use of new safety methods and to adjust their radioisotope programs to meet new needs caused by changes in demand for patient care services or patient load,

licensees would be able to modify their procedures without NRC review provided the regulations are met. Modifications would require approval of the licensee's Radiation Safety Officer, and at a hospital, its Radiation Safety Committee.

Some types of program changes which would still require a formal NRC review and license amendment include new physician user, new medical use, and new location of use.

The proposed revision to Part 35 of NRC regulations is being published for public comment in the Federal Register on July 19, 1985. Comments should be submitted within 120 days (by November 18) to the Office of the Secretary, Nuclear Regulatory Commission, Washington, D. C. 20555, Attention: Docketing and Service Branch.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 31, 32, 35, and 40

Medical Use of Byproduct Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to revise its regulations to modify the process for licensing and regulating the medical use of radioactive byproduct material. The proposed revision would primarily affect hospitals, clinics, and individual physicians.

By clarifying and consolidating all the essential radiation safety requirements that are now contained in the regulations, license conditions, regulatory guides, and staff positions, the proposed regulation provides a single source of requirements related specifically to medical use of byproduct materials. The proposed regulation also provides flexibility for licensees to update their day-to-day radiation safety procedures. The revision of the regulations would provide a more efficient method for regulating the medical uses of byproduct material.

DATE: Comment period expires November 18, 1985. 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 filed on or before this date.

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

Copies of the preliminary regulatory analysis and the comments received may be examined at the Commission's Public Document Room at 1717 H Street NW., Washington, DC. Single copies of the preliminary regulatory analysis and environmental impact assessment are available from Norman L. McElroy, Office of Nuclear Material Safety and Safeguard, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 427-4108.

FOR FURTHER INFORMATION CONTACT: Norman L. McElroy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 427-4108.

SUPPLEMENTARY INFORMATION:

Byproduct Material in Medicine

Use for Patient Care

Radioactive materials are used in drugs in the field of nuclear medicine. Drugs labeled with radioisotopes are known as radiopharmaceuticals. In diagnostic nuclear medicine, patients receive these materials by injection, inhalation, or oral administration. Physicians use radiation detection equipment to visualize the distribution of a radioactive drug within the patient. Using this technology, it is possible to locate tumors, assess organ function, or monitor the effectiveness of a treatment. In therapeutic nuclear medicine, larger quantities of radiopharmaceuticals are administererd to treat hyperactive thyroid conditions and certain forms of cancer. An estimated 15 to 20 million nuclear medicine procedures are performed in this country annually.

Sealed radioactive sources that produce high radiation fields are used in radiation therapy to treat cancer. A radioactive source in a teletherapy machine can be adjusted to direct a radiation beam to the part of the patient's body to be treated. An estimated 2 million teletherapy treatments are performed annually by NRC licensees. Smaller, less radioactive sealed sources are designed to be implanted directly into a tumor area or applied on the surface of an area to be treated. This procedure is known as brachytherapy. NRC licensees perform approximately 10,000 brachytherapy treatments annually.

Sealed radioactive sources can also be used in machines that are used for diagnostic purposes. The source provides a beam of radiation that is projected through the patient. A device on the other side of the patient detects the amount or spatial distribution of radiation that goes through the patient. This can provide information about tissues within the patient. This is a relatively new development in the field of medicine and the NRC has no estimate of the number of these diagnostic procedures performed annually.

State and Federal Regulation

Twenty-seven states, known as Agreement States, have assumed responsibility for regulating certain radioactive materials within their respective borders by agreement with the NRC. (This kind of agreement is authorized by the Atomic Energy Act.) They issue licenses for the medical use of byproduct material. In non-Agreement States, the NRC issues licenses to medical institutions (mostly hospitals and clinics) and to individual physicians. These licenses authorizes certain diagnostic and therapeutic uses of radioactive materials.

NRC's Regulatory Program

Policy Regarding the Medical Use of Byproduct Material

In a policy statement published in 1979 (44 FR 8242), the NRC noted that it regulates the medical use of byproduct material as necessary to provide for the radiation safety of workers and the general public, regulates the radiation safety of patients where justified by the risk to patients, and minimizes its intrusion into medical judgements affecting patients, and into other areas traditionally considered to be the practice of medicine. The NRC does have the authority to regulate the medical use of byproduct material to protect the health and safety of patients, but also recognizes that physicians have the primary responsibility for the protection of their patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

This revision retains NRC's current balance between adequate controls and avoidance of undue interference in medical judgments. Too much regulation could result in poorer health care delivery to patients. Insufficient regulation could result in the unwarranted or unsafe use of radiation.

Current Licensing Practice

The current regulations in 10 CFR Part 35, "Human Uses of Byproduct Material," provide for general and specific licenses for medical use.

The general license in current § 35.31 authorizes physicians to use small quantities of prepackaged, individual dosages of byproduct materials. Physicians simply submit a registration Form NRC-482 to NRC. A validated copy with a registration number is returned to the applicant.

Most medical institutions and physicians who use byproduct material need more byproduct material than can be permitted under the general license program. A specific license, which authorizes a larger inventory of byproduct material and a wider variety of uses, may be issued for one or more of six types of medical use, defined as Groups I–VI in the current § 35.100. Each group is comprised of a number of diagnostic or therapeutic procedures that have been grouped together because they require similar physician training and radiation safety

precautions for safe use. A separate specific license may also be issued for use of a teletherapy unit. Applications for a specific license are much more detailed than a general license application and actually contain the applicant's step-by-step radiation safety procedures, which are reviewed and approved individually by NRC.

The NRC has issued 650 general licenses, and in 1983 received seventeen new applications. NRC currently has about 2500 specific medical licensees (2200 hospitals and 300 physicians in private practice). In 1983, the NRC received 143 new applications for specific licenses, 647 license renewal applications, and 1,772 license amendment requests for a total of 2,562 licensing actions.

To help licensees design their radiation safety programs, the NRC has published many NUREG reports and regulatory guides that contain radiation safety guidance. These publications address three general areas: radiological health and safety, personnel training and experience, and facilities and equipment. Experience has shown that if licensees follow the guidance in the publications, the medical use of byproduct material generally poses no hazard to workers and the public.

Problems with Current Practice

The General License. The general license program is based on the fact that the quantities and forms of material that are authorized by a general license present a very low health risk. The NRC believes it is no longer efficient to issue medical general licenses. The tests authorized under § 35.31 have been superseded by newer procedures with greater diagnostic accuracy. These developments have been reflected by a significant decrease in applications for general licenses. As noted above, although NRC has on file 650 in-vivo general licenses under § 35.31, only seventeen new applications were received by NRC in 1983.

To determine the status of general license use, the staff performed a telephone survey of 10 percent of the current registrants. The survey results indicated that less than 9 percent of all the current registrants still use material under a general license; many are now using byproduct material under a specific license. Because of the low level of use of the general license, the NRC has concluded that it no longer serves a useful role in licensing the medical use of byproduct material.

The Specific License. Because of the potential radiation hazard to workers and the public, the specific license program incorporates three regulatory features: case-by-case review of applications, on-site inspections, and periodic license renewals.

A major problem with the current licensing program is that radiation protection requirements are not located in one document. Requirements are scattered in the regulations, Inspection and Enforcement (IE) orders that modify a license or group of licenses, and in conditions attached to individual licenses. Suggestions for good practice are contained in NRC regulatory guides and technical reports (NUREG's). For example, Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," and NUREG–0267, "Principles and Practices for Keeping Occupational Radiation Exposure at Medical Institutions As Low As Reasonably Achievable," contain many recommendations that the NRC believes are important for the safe use of byproduct material. The revision of Part 35 incorporates those recommendations, and also corrects the piecemeal fashion in which the regulations have been amended over the years to address specific problems.

When preparing a specific license application for review under the current licensing program, the applicant must include sufficient information to assure NRC reviewers that byproduct material will be used safely. Applicants include, as an integral part of the application package, copies of their proposed step-by-step radiation safety procedures. In many cases, the procedures are edited versions of procedures described in Regulatory Guide 10.8.

When NRC receives the application, a licensing reviewer evaluates the applicant's training and experience, facility, equipment, and radiation safety procdures in detail. If the application is found to be incomplete or inadequate, a "deficiency letter" is sent to the applicant explaining what additional information is needed. Review of the application is not resumed until a written response from the applicant has been received. Staff studies indicate that about 40 percent of all applicants receive either a deficiency letter or a phone call for additional information. The need for deficiency letters stems from two sources. Guidance on what is needed to get a license is unclear and scattered in various documents. Application review practice must be conservative because the application and license comprise the basis for regulatory control. Deficiency letters are costly for the NRC and the applicant and greatly increase the time needed to complete licensing actions.

When the application, including any additional submitted information, is approved, the NRC issues a specific license that grants the authority for medical use of byproduct material in accordance with the program described in the application. Requirements in addition to those contained in the regulations are frequently incorporated in the license as conditions of use. Since the licensee must comply with conditions specified in the license, the license, rather than the regulations, is frequently used to regulate radiation safety in the day-to-day use of byproduct material.

The specific license is valid for five years. The license must be amended before methods of use or procedures may be added or changed, or before permitting additional physicians to use materials. Amendments to a specific license involve an application, review, and approval process similar to that for new licenses. Renewals are treated in the same manner as new license applications.

This regulatory process was appropriate during the evolution of the use of byproduct material in medicine. Radiation safety problems were not well defined, regulatory requirements had not caught up with developing technology, physician training curricula had not been established, and there were no formal training programs for nuclear medicine technologists. Therefore, it was necessary to regulate by reviewing each individual radiation safety program to ensure that the applicant had adequate personnel, facilities, and equipment.

Proposed Revision of the Regulatory Program

Overview

NRC intends to modify its regulation of the medical use of byproduct material. The Commission plans to revise the regulations to provide a single source of requirements specifically related to medical use of byproduct materials, and within the boundaries set by the regulations, allow medical licensees to modify their radiation safety procedures, facilities, and equipment so they can make prompt use of new safety methods and also meet new needs caused by changes in demand for various patient care services or in patient load. The proposed revision of 10 CFR Part 35 is consistent with the Commission's general policy on medical use of byproduct material issued February 9, 1979 (44 FR 8242). It states "NRC will continue to regulate the medical uses of radioisotopes, as necessary, to provide for the radiation

safety of workers and the general public."

Codification of Requirements in the Regulations

NRC proposes to simplify regulation of medical licensees by incorporating all medical use requirements in 10 CFR Part 35. These regulations would become the primary means of regulating the medical use of byproduct material. General safety requirements for worker instruction, worker safety, noncompliance reports, and materials licensing that are in Parts 19, 20, 21, and 30 will also continue to apply to Part 35 licensees. The current license application process will be unchanged. The applicant prepares a complete Form NRC-313. That form asks for the following information: the name and mailing address of the applicant; the location of use; a person who can be contacted about the application; what materials are requested; the purpose (in this case, "medical use"); the training and experience of the authorized users and Radiation Safety Officer; the worker radiation safety training program; facilities and equipment; the radiation safety program; and waste management. Licensees would not face significant new regulatory burdens because, in most cases, these requirements are currently imposed as license conditions. Under the proposed revision, the license would authorize medical use of byproduct materials for specified types of use. A licensee's day-to-day uses would be controlled by the regulations. This would simplify inspections for NRC because inspectors would only need to be familiar with one set of regulations rather than a different set of license conditions and radiation safety procedures at each facility.

License Application, Issuance, and Authority and Responsibility

New revisions of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," and Draft Regulatory Guide TM 606-4, "Guide for the Preparation of Licenses in Medical Teletherapy Programs," will contain instructions on the type and extent of information that must be submitted based on what byproduct materials the applicant has requested. They will also contain model procedures that the applicant can use to develop site-specific procedures. (Consistent with current practice, applicants will alternatively be allowed to simply certify that they will follow the model procedure developed by NRC staff with public comment and published in a regulatory guide to meet a certain requirement. This method significantly reduces the amount of time NRC must spend reviewing procedures.) The applicant mails the completed application, with application fee, to the NRC office identified on the form.

The NRC staff will continue to review the application to determine whether the applicant's radiation safety program is sufficient to meet the requirements of the regulations. After completing the review, if the applicant's program appears incomplete or inadequate, NRC will issue a deficiency letter that describes the apparent shortcomings in the applicant's program and requests clarification or correction. If the applicant's response to the deficiency letter is satisfactory (or if no deficiency letter was needed), the license will be issued.

Licensees will be free to modify their procedures after conducting a required internal review and approval process. At medical institutions, the Radiation Safety Committee would review and approve a modified procedure before it could be implemented. At non-institution facilities, the Radiation Safety Officer (RSO) and management would review and approve changes. This will allow each licensee to make prompt use of new safety methods and to adjust radiation safety procedures to meet new needs caused by changes in demand for patient care services or patient load. A list of radiation safety topics that should be considered when reviewing proposed changes will be published as an appendix in Regulatory Guide 10.8. The right to modify procedures does not relieve the licensee from the requirement to comply with the regulations. This regulatory scheme would *not* incorporate the current requirement that licensees use byproduct material in accordance with the statements made in the application.

This proposed regulatory program, which gives more discretionary authority, and concomitant responsibility, to the licensee, represents a change in the policy that has guided NRC's regulation of medical licensees for several years. The NRC particularly invites comment on whether this change is appropriate at this time, and whether or not it will benefit licensees, workers, and the public.

The proposed regulations require specific training and experience for the use of material in each use group. Proposed authorized user physicians and qualified teletherapy calibration experts (identified in current Part 35 as qualified experts) will have to submit summaries of their training and experience. This is currently required for authorized users and Radiation Safety Officers, but would be a new requirement for qualified teletherapy calibration experts, whose credentials are currently reviewed by the licensee. The staff will review those individuals' training and experience against the standards in the regulation before authorizing them to work under the license. (Also consistent with current practice, any individual who does not meet the standards may ask for an exemption from the training and experience requirements. The NRC staff will review the individual's training and experience with the assistance of its Advisory Committee on the Medical Use of Isotopes, and may issue the exemption as a license condition.)

Enforcement

Under this regulatory scheme, a licensee will be cited for failure to meet the requirements of the regulations or license conditions (which would list, for example, authorized users, locations of use, authorized methods of use, authorized byproduct material and inventory limits, and other site-specific limitations), failure to have on hand the written procedures required by the regulations, failure to follow the procedures on hand, failure to have the records required by the regulations, or failure to follow technically valid procedures (examples: Using an instrument that doesn't work, not determining instrument detection efficiency, not allowing an instrument enough time to respond, or making unsubstantiated assumptions in calculations). Use of material can be authorized either by license or by virtue of working under supervision; use without authorization would be a violation of the regulations and the Act, which would subject the user to an enforcement action.

Amendments

As mentioned above, under the current regulatory scheme, the licensee is required to handle material exactly according to the radiation safety procedures submitted with the application. The NRC frequently receives requests for permission to modify day-to-day radiation safety procedures. Because the regulations will now contain sufficient prescriptive and performance criteria on which to base enforcement actions, the NRC would allow a licensee to change its radiation safety procedures without preparing a formal amendment request, paying an amendment fee, and awaiting NRC approval. This would *not* relieve the licensee from the regulatory requirement

to comply with the regulations in Part 35 or in other parts of 10 CFR Chapter I.

Four types of program changes will still require formal license amendments:

(1) *New users.* The NRC will review the training and experience of each proposed authorized user, Radiation Safety Officer, and qualified teletherapy calibration expert as described above before listing the individual on a license.

(2) *New type of use.* A licensee's request to add a type of use (for example, adding radiopharmaceutical therapy to a license that authorizes radiopharmaceuticals for imaging) to an existing license will be handled as a new application. The authorized user's training and experience will be reviewed for adequacy with respect to the new type of use, and procedures that must be submitted in support of the request will be reviewed for completeness and adequacy with respect to the new type of use before the amendment is issued.

(3) *New method of use.* Two developments may occur but only one type of license amendment will be needed:

(a) If a new radioactive material becomes available, and the radiation safety procedures needed for its safe use are identical to the procedures already established for an already established and authorized use (for example, a new imaging agent administered by intravenous injection), no license amendment will be required. Instead, the new material will be added by rulemaking to the list of materials in the appropriate use group specified in the regulations. The NRC will mail to licensees a notice that says those who are authorized to use material in that group may begin using the new material on the effective date of the final rule that adds the new material to the regulations.

(b) If a new radioactive material becomes available but its safe use depends on following a new procedure that current licensees have not submitted and NRC has not reviewed, two actions will be taken.

(i) The new material will be added by rulemaking to the appropriate use group in the regulations but authorization to use it will be limited to persons who were licensed after it was added to the use group and who have submitted the new procedure for review in their application packages.

(ii) NRC will mail to current licensees a notice that says they may apply for authorization to use the new material. With that notice, NRC will also supply a model procedure, which would become a new appendix in Regulatory Guide 10.8, for the new material. Those licensees who want to use the new material will have to submit a request for amendment which includes a proposed procedure that will be reviewed by NRC for completeness and adequacy.

(4) *New location of use.* Two types of amendment may be needed:

(a) A request to leave one location of use and begin working in a new location, for example when moving a private practice to a new office or when moving into a new hospital building, will have to be supported by a complete new application package.

(b) Some licensees receive packages, prepare radiopharmaceuticals, and package waste at a central facility, but actually use the byproduct material at satellite locations. This might be a mobile nuclear medicine service that provides diagnostic services at clients' facilities such as clinics, small hospitals, or nursing homes, or it may be a licensee that has a principal facility and outlying clinics. If the licensee has been approved to offer service at satellite locations, a request to add another satellite location will only have to identify the new location. (Due to the training, space, and equipment commitments needed for safety during therapy procedures, the NRC will generally not authorize licensees to perform therapies at satellite locations. This type of request will be handled on a case-by-case basis.)

Renewals

The NRC license is valid for five years. If a person wants to continue using byproduct material the license must be renewed. The renewal application must completely describe the entire radiation safety program just as a new application does. If a previously submitted radiation safety procedure, facility description, or equipment list still accurately reflects that part of the licensee's program, the renewal applicant may simply make a clear reference to the previous submission. If the licensee has changed a procedure, is using different areas of use, or is using different equipment, a complete new description of the particular procedure, area of use, or equipment must be submitted. The licensee may also take this opportunity to identify new authorized users or request authorization for new types or methods of use.

Summary of Changes Proposed in the Regulatory Program

In summary, the regulation will be amended to require that licensees meet standards that are currently imposed by license conditions. The NRC will continue to review user training and experience. The NRC will review site-specific radiation safety procedures for completeness and adequacy and issue deficiency letters if necessary, but will allow licensees to change procedures that were submitted in support of the application after conducting an internal radiation safety review of each change. However, the right to change procedures does not relieve the licensee from the requirement to comply with the regulations. Amendment requests will generally be reviewed just as new applications are reviewed, but they may incorporate by reference the original application and any previous amendments.

Notes

Word Usage

In preparing the proposed revision of Part 35, one goal was to remove language that might be misinterpreted. The following words used in the revision may require clarification.

1. *Licensee.* The person (individual, partnership, corporation, or agency) listed on the license as the "licensee" is responsible for compliance with regulations and license conditions. The licensee may effect compliance through full-time or part-time employees, contracts with consultants or service organizations, or other business arrangements. The word "licensee" is used throughout the regulation to stress the fact that, no matter which method is used, the licensee is legally responsible in case of non-compliance.

2. *Type of use* and *group.* In the current Part 35 there are six "groups" of use described in § 35.100. Each group is comprised of a set of medical procedures that require similar training and equipment for radiation safety purposes. The word "group" has not been used in the proposed revision in order to avoid confusion between the old and new Part 35. The revision uses the phrase "type of use" for this concept. Some types of use are amalgamations of old groups, and some types are new. The six types of use are: (1) Uptake, dilution, and excretion—Subpart D; (2) imaging and localization—Subpart E; (3) radiopharmaceutical therapy—Subpart F; (4) brachytherapy—Subpart G; (5) sealed sources for diagnosis—Subpart H; and (6) teletherapy—Subpart I.

3. *Method of use* and *procedure.* The word "procedure" is frequently used in supporting documentation for by product materials programs. Sometimes it refers to a specific set of steps that must be taken to effect an end, for example a procedure for ordering and

receiving packages. Sometimes it is used to indicate a type of medical examination or treatment, for example a thyroid uptake study or a cesium implant therapy, without indicating the amount of byproduct material used or the specific steps taken in handling it. The word may also be used to indicate the number of patients cared for over a period of time, for example an average workload of fifteen procedures each day. In order to avoid confusion, the phrase "method of use" appears in the proposed revision. Each type of use is comprised of several methods of use. Each method of use should identify, explicitly or by context, the radionuclide, its chemical and physical form, method of administration, and purpose (diagnosis or therapy).

4. *Dose* and *dosage*. In pharmacy, the word "dose" is used to indicate the amount of chemical administered; in radiation biology it is used to indicate the amount of ionizing energy absorbed per unit mass; and in radiation safety it is used as a shorthand term to indicate a worker's exposure to radiation. In order to avoid confusion, the word "dosage" is used in the proposed revision to indicate quantities of radioactivity that are measured with the base unit Curie. The word dose is used to indicate quantities of radiation absorbed dose or dose equivalent that are measured with the base unit rad or rem.

5. *Record* and *report*. A record is a user-retrievable notation or complete document. It may consist of something as small as a check-mark on a form or something as extensive as a survey of a newly installed teletherapy unit with appended calculations to demonstrate compliance with the limits on exposure in uncontrolled areas. A report is a transfer of information which might be made face to face, by telephone, telegram, computer link, or hard copy transmittal.

6. *Test* and *check*. For many pieces of equipment, drafting committees comprised of industry experts have prepared standards of performance and complete calibration protocols. If a piece of equipment is subjected to the protocol in the calibration laboratory and meets all the standards, then the ability of the equipment to perform as expected in normal field use is assured. In the proposed revision this concept of complete examination is referred to as a "test." During field use it is common practice to subject a piece of equipment to a quick examination to determine whether it is working. This procedure does not examine all parameters of equipment performance. In the proposed revision this concept of perfunctory examination is referred to as a "check."

7. *Location of use, facility,* and *area of use*. The phrase "location of use" is used to describe the building or buildings (typically identified by a single street address) where byproduct material is used. The word "facility" connotes a room or contiguous rooms where byproduct material is used, such as a nuclear medicine clinic comprised of an office, an imaging room, and a dosage preparation and waste storage room. The phrase "area of use" connotes the space used by worker when performing a specific task connected with receiving, handling, or storing byproduct material.

8. *Chemical form*. The current regulation requires that if a radiopharmaceutical is used for indications other than those described in the package insert, the user must nevertheless follow instructions on chemical and physical form, dosage, and route of administration. The proposed revision has deleted the word chemical in its restatement of this requirement because to change the chemical form would be to create a radiopharmaceutical other than the one received from the authorized distributor. Deletion of this word in the proposed revision does not authorize Part 35 licensees to manufacture radiopharmaceuticals.

9. *Available for use*. In many cases the regulation states an equipment possession requirement because the piece of equipment is considered by experts to be an integral part of the radiation safety program. In a few cases the need for a piece of equipment is sporadic and normally scheduled weeks in advance. For example, a licensee who has a diagnostic sealed source in a device (see § 35.500) usually only needs a survey instrument when receiving or returning a radioactive source; there is no need to have the instrument on hand every day. The phrase "available for use" is intended to connote that the licensee either may possess equipment or contract for measurement services, but is not required to have regular day-to-day possession of the described equipment.

10. *Dedicated check source*. A long-lived radioactive source can be used to check the day-to-day constancy of an instrument. The *same* source (a "dedicated" source) must be used every day so that the user knows what reading to expect from the instrument. The source may also be used for other purposes.

11. *Operable*. The word "operable" is not used in the proposed regulation because every piece of equipment must be operable. If a piece of equipment is not operable or reliable, whether due to old or absent batteries, incomplete or improper maintenance, damage, inappropriate use, or improper use, it cannot be used to meet a regulatory requirement because there is no assurance that it accomplished the task for which it was used.

12. *Implement*. This verb is used with its ordinary definition, which is "to carry out, accomplish, or ensure fulfillment of."

13. *Promptly*. This word is used with its ordinary definition, which is "performed readily or immediately."

Record Retention

The Commission requires that licensees make and retain records as evidence of compliance with regulations and license conditions. A review of records during inspections is the least burdensome way that the Commission may be assured that the licensee has developed and implemented a radiation safety program. However, permanent retention of all required records, or retention between inspections, would be unreasonable and would run counter to recent guidance to regulatory agencies that was issued by the Office of Management and Budget. Therefore the Commission has, in the proposed revision, generally adhered to the following policy.

1. For recurring records that are created on a daily basis, for example end-of-day surveys, and for most non-recurring, sporadic, or periodic records, such as individual patient dosage measurements or survey instrument calibrations, the Commission has made a judgment that records retention for two years provides adequate evidence of compliance with requirements.

2. In a few cases a record is only created once or the Commission considers the record to be essential evidence of compliance with regulations that, if not followed, might cause an immediate discernible impact on a worker or member of the public (for example, requirements for the geometry test for a dose calibrator and the teletherapy dosimetry equipment calibration, respectively). In those cases the Commission has made a judgment that retention for the duration of use of the equipment or of the license is necessary.

Effect on Broad Licensees

In addition to the more common "group" licenses which the NRC issues that authorize by product material for uses described in the groups, the NRC has also issued about 100 broad licenses

under Part 33 that include medical use. They are issued to large medical/academic institutions that have had several years experience using radioactive materials.

About 50 of the medical use broad licenses that have been issued vest in each institution's Radiation Safety Committee the authority to permit medical practitioners to use byproduct material for both patient care and medical research, to permit individuals to use byproduct material for research in test tubes and animals, and to review the facilities and radiation safety procedures that these individuals will use. Before NRC issues a broad license it reviews the applicant's administrative and safety procedures, the training and experience of the Radiation Safety Officer and of each individual member of the Committee, and the standards and management procedures it will use when reviewing permit requests. This type of license is needed to allow for the orderly evolution of the medical sciences. The NRC will continue to review Committee member qualifications on a case-by-case basis because the size and individuality of each broad licensee program precludes the preparation of generic prescriptive qualifications. These licensees would be required to comply with the proposed prescriptive and performance criteria of Part 35, but would be exempted from the training and experience requirements of Subpart J and the authorized materials and authorized use restrictions in proposed §§ 35.49, 35.100, 35.200, 35.300, 35.400, and 35.500.

The other 50 medical broad licenses that have been issued are similar to the license described above, except that the Committee only has the authority to permit individuals to use material in test tube and animal research, and only authorizes medical use in accordance with the groups in current § 35.100. The NRC would continue to review the training and experience of medical practitioners before allowing them to use material for medical use. Because control of medical use in these cases is the same as that exercised over the more common group licensees, the basis for a determination of compliance will be the same as that described below for group licensees.

Because, whether at a group or broad license facility, teletherapy is separately licensed "for treatment of humans" and because the NRC reviews qualifications of proposed users and safety procedures, no significant inconsistencies with current teletherapy programs or new teletherapy programs are expected.

Transition Policy for General Licensees

The general license in current § 35.31 has been eliminated from the proposed regulations. In the future, all medical use will be specifically licensed. Current general licensees, all of whom are physicians, will receive a specific license that will be incorporated into NRC's filing system for keeping track of specific licensees. However, they will be limited to the methods of use described in the current § 35.31, and relieved, by license condition on a pre-printed license, from the requirements that are more burdensome than the current general licensee requirements. The only action general licensees will need to take is to respond affirmatively to an NRC notice that asks if they want to continue to have an NRC license that is limited to the methods of use authorized by the current general license.

The Commission proposes, under § 170.11(b), to continue to exempt these licensees from application and renewal fees as long as their programs are limited to the material uses described in current § 35.31. Under the new specific licensing system, former general licensees that want to make any changes in their programs, amend their licenses, or transfer them to other physicians, will have to apply under the new licensing scheme and will be subject to all the fees that apply to other specific licensees.

The Commission proposes to waive fees to former general licensees for the following reasons. General licensees do not now pay fees. About 90% of the 600 or so general licensees are inactive. Each year NRC receives only a very few requests for general licenses under § 35.31. There would be no NRC review time needed and only a minor NRC administrative cost to process these licenses. It would be unfair to charge these licensees the fees listed in 10 CFR Part 170, and it would be more costly for NRC to alter that fee structure than to grant the exemption.

The current Part 35 also grants a general license for in vitro work described in § 31.11 to group licensees without requiring that they submit an in vitro registration form. Under the proposed regulation, applicants would have to specifically request this authorization as a line item on their applications. Part 31 will be amended to continue the in vitro authorization for current medical licensees until their licenses are renewed. In either case, the use of § 31.11 materials within the inventory limits of that section will only be subject to the requirements of § 31.11.

Transition Policy for Specific Licensees

Under the current regulatory program, the license document with the appended application is used to regulate each individual licensee. Because the requirements in the proposed revision were taken from commonly used topical license conditions and regulatory guidance that most licensees have incorporated into their applications, the Commission does not expect any significant inconsistencies between current licensee radiation safety programs and radiation safety programs of applicants that apply after the effective date of the proposed regulations. Therefore, current licensees will normally be cited if they do not comply with the new regulations. However, because each current licensee's radiation safety program was reviewed individually and license conditions were tailored to meet the licensee's individual needs, there may be an occasional inconsistency between a license condition and the regulation (for example, a license may require survey instrument calibration biennially, but the proposed regulation would require calibration annually). There is no health and safety reason to undo these licenses to effect compliance with the regulation. To impose the regulation in addition to or in lieu of the license conditions would not provide for significant additional health and safety. The Commission therefore proposes to resolve possible temporary inconsistencies between license conditions and the regulation by providing in the regulation a transition period between the effective date of the final rule and the expiration date of each license. During this transition period, if there is an inconsistency between a provision in a license (issued prior to the regulation) and the regulation, the proposed regulation states that the license condition would take precedence over the regulation. Because the license conditions were reviewed from the perspective of overall safety and approved by the NRC, the inconsistency would not result in an increased risk to workers or the public.

In addition to the topical license conditions mentioned above (for example, sealed source leak test requirements, special bioassay requirements, radioactive patient surveys and release limits, or waste disposal restrictions), each specific license has an encompassing license condition that requires each licensee to possess and use licensed material in accordance with the statements, representations, and procedures contained in the license application and

in letters of clarification. Despite this encompassing condition, licensees would be allowed to make changes in their radiation safety programs; permissible changes would be restricted to those identified in § 35.36, and the licensee would have to conduct the internal review required by that section.

In the case of record retention, the regulation will generally take precedence because, in the past, the Commission has not offered much guidance on this topic. Many applicants have either not specified a period of retention or have incorporated a single, all encompassing record retention phrase "until the Commission authorizes their disposal," rather than shouldering the burden of justifying to NRC a shorter period. If a record is substantively the same as a record described in the proposed regulation and the licensee has not stated a retention period for that specific record, licensees could adopt the retention period stated in the final rulemaking. However, licensees would still have to comply with any record retention period required by a topical license condition or another Part (for example Part 20) of the regulations. (For example, surveys that provide the basis for occupational dose records or measurements of effluent release are governed by Part 20.)

NRC does not currently review qualified teletherapy calibration expert credentials, and does not identify the Radiation Safety Officer on the license. Under this proposal, NRC would begin to review their credentials and identify both of them just as it does now for authorized users. To add current licensees to this new scheme, licensees would be required to submit their credentials for review and approval when the next amendment or renewal request is required. These individuals would be identified on the next license amendment.

The NRC particularly requests public comment on this transition policy and would like to know if licensees envision problems of interpretation or compliance that the staff might not foresee.

Discussion of Proposed Regulations

The primary purpose in initiating this revision to the regulations is to simplify the regulatory process by providing licensees with a single source of requirements for the medical use of byproduct material. Radiation protection standards now contained in several existing regulations, inspection and Enforcement orders that modify a single license or group of licenses, technical reports (NUREGs), standard conditions of licenses, and regulatory guides would be consolidated into a concise set of regulations. The requirements that apply to all licensees appear first, followed by the specific requirements for each of the six basic types of use.

In the proposed regulation, items of general information, general administrative requirements, and general technical requirements are addressed first in Subparts A through C, respectively. Subparts D through I contain the additional technical requirements that apply to licensees for each of the six new types of use. Subpart J lists the training and experience requirements, and Subpart K lists the penalties for violations of the regulations.

In order to maintain consistency among the various parts of NRC's regulations, conforming amendments have been made to the affected sections of Parts 30, 31, 32, and 40. These conforming amendments can be found immediately after the revised Part 35. A section-by-section discussion of the proposed revision of Part 35 follows.

Title

The title of Part 35 has been changed from "Human Uses of Byproduct Material" to "Medical Use of Byproduct Material" to better reflect the scope of the part.

Authority

This listing provides notice of the statutory basis for the regulations. It also provides notice that the NRC may initiate criminal prosecution of persons who knowingly and willfully do not comply with the prescriptive requirements issued under section 161b or the recordkeeping and reporting requirements issued under section 161o.

Subpart A—General Information

Section 35.1 Purpose and scope.

The regulations in this part apply to all persons licensed by the Commission to intentionally administer byproduct material or the radiation from byproduct material to humans, and to individuals working under their supervision.

Section 35.2 License required.

This section requires that persons have a license issued by the Commission or an Agreement State before they handle byproduct material for medical use. The Commission uses the specific licensing process to limit the use of byproduct material to persons who have the equipment, facilities, training, and experience needed to ensure its safe use. Individuals who are working under the supervision of an authorized user do not need a license document, but this does not relieve them of the requirement to conduct their work in accordance with requirements of the license and the regulations of this chapter. The licensee remains responsible for the noncompliance of such agents or employees, and may be subject to sanctions for their failure to comply.

Section 35.8 Information collection requirements: OMB Approval.

This section provides notice that the Office of Management and Budget has reviewed and approved the information collection requirements contained in this part.

Section 35.13 Definitions.

The term "Agreement State" applies to those states that have entered into an agreement with NRC to assume responsibility for regulating the use of byproduct material within their borders.

The word "ALARA" was added to identify the acronym for the phrase "as low as reasonably achievable."

The term "area of use" was added to identify a place in which byproduct materials are received, used, or stored. The term is used in § 35.36 to authorize licensees to use byproduct materials in rooms, suites, or building wings not identified in the application.

The term "authorized user" was added to identify individuals who are identified by name on a license and who are authorized by the Commission or an Agreement State to administer byproduct material, or the radiation therefrom, to humans for medical care, and supervise its use by others.

The term "dentist" we added to identify a group of practitioners licensed by the States who might use byproduct materials in their practice.

The term "medical use" was included to help identify the scope of this part. The word "intentional" was included in the definition to make it clear that occupational and nonoccupational exposures under the regulations of Part 20, accidental exposures, and unwanted exposures from other sources of radiation (e.g., nuclear powered cardiac pacemakers, smoke detectors, and radioactive waste) are not considered medical use. The phrase "in the practice of medicine in accordance with a license" was included to make it clear that NRC recognizes that States may have different diffinitions of medical practice or different levels of control and that licensees should not interpret that NRC license as a pre-emption of State medical regulations or an attempt to direct the States' regulation of medical practice.

The word "medical institution" was added to identify organizations in which the radiation safety program depends on the cooperation of individuals from several different departments.

The word "management" was added to identify the individual responsible for defining the licensee's policies and allocating personnel, budget, and space resources.

The word "misadministration" was included to define those instances in which a mistake has been made in the medical use of byproduct material. The definitions are the same as those in the current § 35.41.

The term "mobile nuclear medicine service" was added to describe the transport of byproduct material for the purpose of offering diagnostic nuclear medicine services at addresses other than the principal business address of the licensee.

The word "output" was added to describe the amount of radiation in a teletherapy beam.

The word "physician" was included to identify individuals licensed by the States to practice medicine and therefore eligible to use byproduct meterial in the practice of medicine.

The word "podiatrist" was added to identify a group of practitioners licensed by the States who might use byproduct materials in their practice.

The term "qualified teletherapy calibration expert" was included to replace the term "qualified expert" which is used in the current § 35.24. The new term better reflects the training, experience, and responsibilities of the individual who is responsible for calibrating a licensee's teletherapy unit.

The term "Radiation Safety Officer" was added to identify the individual named on a license and who is responsible for managing the licensee's radiation safety program.

The term "sealed source" was included to identify byproduct material that is specially encapsulated to prevent leakage or escape during use and storage. It is the same definition as use in § 30.4.

The term "visiting authorized user" was added to identify individuals listed as authorized users on one license who, while working for another licensee on a temporary or occasional basis, use byproduct material under the restrictions of the temporary employer's license, which does not identify the visitor as an authorized user. This authorization is based on a frequently used topical license condition.

Section 35.16 Application for license, amendment, or renewal.

At an institution, only management may apply for a license; individual physicians would be listed on that license as authorized users. An individual physician may not apply for use within a medical institution (an organization that provides various medical services). This requirement reflects the need for coordination with other employees who may not be under the administrative control of the authorized user. For use sited outside a medical institution, such as for private practice or mobile service, any person may apply. An application must be filed on Form NRC-313 because it elicits information in an orderly manner that will allow for uniformity in application review procedures.

Teletherapy applications must be submitted separately because the scope and nature of information needed is much different than that needed for the other types of medical use. This requirement does *not* imply that the applicant should have two separate safety programs.

This section also reflects the Commission's decision to delegate to Regional Administrators some licensing functions which, until recently, were conducted in the headquarters. This program was described in Federal Register notices published May 27, 1982 (47 FR 23138), April 14, 1983 (48 FR 16030), May 9, 1984 (49 FR 19630), and April 15, 1985 (50 FR 14892).

Section 35.17 License amendments.

The Commission requires that the licensee obtain an amendment for any changes in the byproduct material program that might increase the potential for radiation exposure to workers and the general public, or make it difficult for the Commission to conduct its inspection program. The Commission has determined that certain changes are potentially significant for the following reasons and thus will require an amendment:

(1) The NRC must be assured that the licensee has adequate training and experience and facilities before authorizing a change in the type or method of medical use or amount of byproduct material used. Such a change might also indicate a need for increased inspection frequency.

(2) The use of byproduct material at an address not identified on the license would make it impossible for the Commission to make unannounced inspections. The Commission relies on the unannounced inspection to assure day-to-day compliance. For the purpose of this part, the phrase "location of use" refers to a building. (Moving from one room to another within a building would not constitute a change in location of use.)

(3) The Commission must be assured that the training and experience of Radiation Safety Officers, authorized users, and qualified teletherapy calibration experts is sufficient to assure that they are able to understand and follow regulations for the safe use of byproduct material.

Section 35.18 Notifications.

A notification requirement was added to require the licensee to notify the Commission if an authorized user, Radiation Safety Officer or qualified teletherapy calibration expert is no longer affiliated with the licensee's byproduct material program. Without this notice the NRC would not have assurance that the collective training and experience of the licensee's remaining personnel is adequate to ensure the safe use of byproduct material for all the types of use authorized by the license. The Commission has made a judgment that notification within 30 days is sufficient because technicians who have worked under the supervision of the authorized user can adequately ensure the safe receipt and proper storage of byproduct material. However, absence of an individual to oversee a byproduct material program may increase the probability of an accumulation of unused byproduct material or unauthorized use of material. This presents an unacceptable potential hazard.

Section 35.28 License issuance.

The Commission has selected a license term of five years. A shorter term would not benefit the public health and safety because past experience indicates that medical programs do not generally change significantly over that period of time. A shorter term may unduly interfere in patient care because the licensee would spend an inordinate amount of time requesting renewals. A longer term may occasionally result in unintentional abandonment of the license.

The applicant must use Form NRC-313 to provide for an orderly safety review of the applicant's program. The Commission will apply certain standards when reviewing an application so as to ensure that the safety of workers and the public will not be compromised if the license is granted. The staff must be assured that the applicant's proposed equipment and

facilities are adequate to protect health and minimize danger to life or property (§ 30.33(a)(2)), and that the authorized users are qualified by training and experience to use the material for the purposes listed in the application in such a manner as to protect health and minimize danger to life or property (§ 30.33(a)(3)), and that applicant has established procedures adequate to assure that safe use of byproduct material.

Concerning fees, Congress has directed that agency services, such as licensing and inspection, must be self-sustaining to the extent possible.

Section 35.29 Specific exemptions.

As part of an application or amendment request, a person may request an exemption from any requirement of this part. The NRC occasionally receives requests for exemptions from procedural, equipment, or training standards. The Commission may allow the exemption if the applicant can show that it will not compromise the health and safety of workers and the public.

Subpart B—General Administrative Requirements

Section 35.30 ALARA program.

An ALARA program is a management tool needed to assure that all reasonable efforts are made to assure that safe use of byproduct material. (See 'Management Organization and Administration for ALARA' by Kathren, *Health Physics*, Vol. 42, No. 2, February 1982, p. 119–131, and 'Radiation Safety in a Nuclear Medicine Department,' by Gandsman et al., *Health Physics*, Vol. 38, No. 3, March 1980, p. 399–406.) In an institution many workers from different departments might be occasionally exposed to byproduct material. The Commission has made a judgment that a formal ALARA program is the only management tool that can ensure a cooperative effort to reduce individual and collective dose and ensure regular safety reviews. Specific requirements usually considered part of an ALARA program are required by §§ 35.31 and 35.32.

The annual briefing of management by the Radiation Safety Officer on the byproduct material program is intended to assure that licensee management knows what kinds of byproduct material are used in which departments, which workers are involved, its use, the regulatory requirements that govern its use, and current and potential radiation safety problems. Management needs this information to ensure that its decisions do not inadvertently result in activities contrary to the regulations or license conditions.

In this proposed rulemaking the Commission has not required non-institutional licensees, such as one or a few physicians in private practice, to have a formal ALARA program because, for those licensees, the physician authorized user is usually also the Radiation Safety Officer, management, and the line manager. Hence, any formal ALARA report requirement would consist of the physician reporting to himself. However, the Commission would appreciate comments as to whether *all* medical licensees should have a formal ALARA program. If so, should small licensees conduct an internal annual review or should that review be conducted by someone who is not associated with the licensee's program on a day-to-day basis? Commenters are reminded that the exhortation in 10 CFR 20.1(c) to make every reasonable effort to maintain radiation exposures and releases of radioactive materials ALARA applies to medical licensees.

Section 35.31 Radiation Safety Officer.

The Radiation Safety Officer is an individual with special expertise who is needed to coordinate the safe use of byproduct material in accordance with the license and the Commission's regulations.

Section 35.32 Radiation Safety Committee.

The proposed Part 35 requires institutional licensees to establish a Radiation Safety Committee to oversee the use of byproduct material. The committee is required because, in an institution, radiation safety for *all* workers (users and ancillary staff) and the public depends on the cooperation of employees from administratively separate departments. Without the benefit of committee discussion, authorized users may not be aware of radiation safety problems outside their own department that are caused by their patients, packages, or waste. The Committee's deliberations will provide management and authorized users with information that is needed to optimize allocation of resources available for radiation safety. A Committee is not required for licensees that are not medical institutions because such organizations generally do not have the multi-armed, multi-tiered management structure typical of medical institutions. In non-institutions the authorized user is likely to be part of management and a line supervisor for ancillary workers; therefore a formal committee structure would serve no useful purpose. A similar requirement was published as a proposed rule on April 9, 1979 (44 FR 21023), and as a final rule on September 13, 1982 (47 FR 40149).

Committee membership must include a physician identified on the institution's license as an authorized user of byproduct material for each type of use permitted by the license, the institution's Radiation Safety Officer, a representative of the institution's management, and a representative of the nursing service.

Institutions that only request a license for diagnostic sealed sources will be exempted from this requirement by license condition because the radiation safety program would not depend on the cooperation of individuals from several different departments. Packages would arrive infrequently, there would be no chance of contaminating an entire room or suite, no radioactive waste, no radioactive patients, and little chance of loss of material.

To assure the safety of workers and the public in light of site-specific exigencies, the Committee must review on the basis of safety: (1) The qualifications of each individual to be listed as an authorized user, and (2) each proposed method of use. In its reviews, the Committee should consider compliance with NRC regulations, special physical or chemical containment problems, the amount of byproduct material that will be used, and the relative hazard of the material, all in light of the licensee's facility and staff.

The Committee must review occupational exposures quarterly. A more frequent review would inappropriately emphasize normal and expected statistical variations in exposure data. A less frequent review would not provide for timely notice of unnecessary or unnecessarily high doses.

The quarterly review should be guided by two trigger levels for individual doses. The lower level would be a minimum level below which no action need be taken. Above the minimum level, the source of exposure should be determined and consideration given to methods of reducing the exposure rate. The higher level should trigger immediate intervention by the Radiation Safety Officer to reduce the exposure. The committee should review the appropriateness and completeness of the intervention, and should develop a permanent solution to maintain doses at a lower level.

The annual review of the safety program is needed to determine its adequacy in light of the current and projected use of all byproduct material. In the Commission's judgment, a review at least once each year is adequate to

assure that exposures remain ALARA considering the few program adjustments typically made during any single year. More time between reviews might not permit the committee to make timely recommendations for reducing unnecessary worker, public, or patient exposure by, for example, changing space allocation, purchasing new equipment, or changing procedures.

Section 35.33 Requirement for authority and statement of responsibilities.

To ensure that material is used safely, the Radiation Safety Officer and Radiation Safety Committee need a clear statement of their duties from management so that questions about authority, responsibility, and jurisdiction do not keep these individuals from acting.

Section 35.34 Visiting authorized user.

The uninterrupted provision of medical care occasionally requires a visiting authorized user to work for a host licensee when its permanent staff may be unable to do so. This was allowed in the past by a standard license condition. If the licensee had a copy of another licensee's NRC license that listed the visitor as an authorized user, the visitor could work under the license for sixty days each year without requesting a license amendment. The scope of this concept has been expanded to allow NRC licensees to employ Agreement State authorized users. Because the visiting authorized user's training and experience has been reviewed for health and safety consideration by a regulatory agency, this short-term authorization will not pose an undue risk to public health and safety. The purpose of written permission is to assure that the required records have been reviewed and found complete.

When exercising this privilege, host licensees should identify each individual method of use authorized by their license, each individual method of use authorized by the visitor's license, and each individual method of use that the visitor will be allowed to do at the host facility. Note that in some cases the Agreement States' groups, schedules, or subparts do not correspond to those of the NRC. The visitor can only do those procedures authorized by *both* licenses.

Section 35.36 Mobile nuclear medicine service administrative requirements.

Mobile nuclear medicine service has been limited to diagnostic medical use because the inherent hazard of therapeutic amounts of byproduct material makes it unsuitable for use in locations where the licensee might not have clear and direct control over personnel, facilities, or equipment. The Commission will continue, on a case-by-case basis, to authorize provision of low level radiopharmaceutical therapy by mobile nuclear medicine services. These licensees are required to have a letter of permission from the management of each client to assure that the client management is aware of and in agreement with the medical use of byproduct material within the facility.

Mobile service may not be provided to licensed clients because, in case of a spill or dose rates above regulatory limits, the responsibility for corrective action may be clouded.

Section 35.38 Radiation safety program changes.

This section allows the licensee to make changes in the radiation safety program that was described in the application if the changes are within the requirements of the regulation. The purpose of this authorization is to allow the licensee to respond to changes in staff levels, available equipment, or patient load that may require reallocation of floor space, or to make changes that may be necessary for patient care, administrative, radiation safety, or economy needs. Before implementing any change, the licensee must make a record of safety matters that were considered when planning the change. The record will be used during unannounced inspections to determine whether the licensee has made changes that are contrary to the regulations, license conditions or orders, and during termination surveys to provide an indication of every area where material was used.

The Commission notes that this change in the current licensing process under which *all* radiation safety program changes must be approved by license amendment, recognizes that, in the end, public health and safety is based on three features: (1) NRC regulates who may use byproduct material for medical use by listing authorized users on the license; (2) NRC regulates the degree of hazard, balanced with medical needs, by only allowing certain chemical and physical forms for medical use; and (3) NRC regulates where byproduct material may be used to allow for unannounced inspections of licensee radiation safety programs. This proposal would retain those regulatory features by requiring licensees to receive a license amendment before using material for new clinical methods of use not permitted by the license; before permitting new authorized users to use material; before receiving more material or different kinds of material than permitted by the license; and before using material at locations not listed on the license. These are major changes in a licensee's radiation safety program for which a license amendment would still be required (see § 35.17). Under this proposal all other changes (such as selecting replacement equipment, re-arranging the nuclear medicine clinic, switching from one service contractor to another, or switching to an alternative equipment quality assurance procedure) would be minor changes.

The Commission would appreciate comments on this major/minor dividing line or threshold. Is this dividing line clear and complete? Are there other features that should be considered as major changes, or are some of these major changes really not important to health and safety? Is there some other dividing line, either fixed or flexible, that would clarify which changes are really not important to health and safety and may therefore be made by the licensee? Alternatively, should the Commission continue to require licensees to submit all radiation safety program changes for agency approval?

Section 35.37 Records and reports of misadministrations.

The proposed Part 35 retains the misadministration definitions and reporting and recordkeeping requirements of the current Part 35. A discussion of these requirements appears at 45 FR 31701, published May 14, 1980.

Although the Commission has not revised its misadministration reporting and recordkeeping requirements, it would like to take this opportunity to ask for public comment on these requirements based on the experience gained since the requirements were first published in final form five years ago. For both diagnostic and therapeutic misadministrations, are the current requirements adequate to protect the public health and safety or should they be made more or less stringent? Should the regulations require prompt notification of the patient who received the misadministration? Do the regulations provide the public with a clear notice of the Commission's role when there is misadministration? Should the Commission take enforcement action against licensees who misadminister by product material or radiation to patients? If so, what type of enforcement action should be taken?

Section 35.38 Supervision.

The authorized user is allowed to use byproduct material in the practice of medicine. Frequently, specific tasks may be delegated (under §§ [illegible]) and 35.38) to individuals with less training and experience. However, it is necessary that a qualified individual instruct them, oversee their work on a frequent basis, and be available to promptly respond in unusual or emergency situations. The regulation requires that supervised individuals comply with instructions, procedures, and the regulations.

The NRC has not specified which tasks may be delegated to whom because the practice of medicine is regulated differently in each State and because medical services must also be responsive to each community's particular needs. The NRC particularly requests comment on whether special training elements should be clearly identified for certain tasks that are delegated or whether the general guidance is sufficient.

Section 35.49 Suppliers.

In order to authorize only the use of materials reviewed by the government for safety and effectiveness considerations, authorized users may use only byproduct material that has been manufactured and distributed under procedures that were reviewed for safety by the NRC, the Food and Drug Administration (FDA), or an Agreement State.

The NRC will continue its current practice of allowing, on a case-by-case basis, re-transfer of radiopharmaceuticals between Part 35 licensees if an applicant specifically requests an exemption from this section and shows the exemption is in the public interest.

Subpart C—General Technical Requirements

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

A dose calibrator is needed to ensure that the dosage of material given is the dosage that was prescribed. It must be tested for accuracy, the ability to exactly measure a specified quantity, and linearity, the ability to exactly measure a range of quantities. The requirements are generally consistent with the recommendations of the American National Standards Institute. (See ANSI N42.13–1978). Copies may be purchased by contacting Sales Department, American National Standards Institute, 1430 Broadway, New York, NY 10018. In the interest of economy and efficiency, the NRC uses voluntary national standards in its regulatory program if they provide adequate assurance of safety.) The activity levels of the accuracy check sources were chosen because a lower activity would invalidate the accuracy test due to expected statistical fluctuations, and a higher activity would present an unnecessary source of radiation exposure to workers. The radionuclides required reflect the fact that dose calibrators are not as accurate as might be expected for the photon energies commonly used for imaging (see "Joint NCDRH and State Quality Assurance Surveys in Nuclear Medicine," HHS Publication FDA 83–8209). The linearity test should only be done over the range between highest individual dosage measured and 10 microcuries to ensure that the dosage given is the dosage that was prescribed. It is not necessary to test for linearity for all amounts that might be measured, for example the first elution from a fresh generator or a multidose vial, because this would subject the worker to unnecessary radiation dose. Dosages below 10 microcuries cannot be accurately measured on a conventional dose calibrator because they are so tiny. Also, these dosages present only a trivial risk to the patient and therefore need not be so accurately measured. The geometry test assures that the shape of the syringe or vial containing the byproduct material does not affect the dosage measurement. The daily constancy check assures that the dose calibrator has worked consistently since it was last tested.

Licensees whose level or scope of use does not indicate need for a dose calibrator may request an exemption from this section. The request should be supported by a description of an alternative method that the licensee will use to measure radiopharmaceutical dosages.

Section 35.51 Calibration and check of survey instruments.

The 1000 mR/hr limit was chosen because that is the highest radiation exposure rate that is likely to be encountered in the medical environment. The calibration frequency and the other prescriptive and performance requirements in this section are generally consistent with ANSI N323–1978.

Section 35.53 Measurement of radiopharmaceutical dosages.

This section requires that the licensee assay the radioactivity of each radiopharmaceutical dosage before it is administered to a patient and keep a record of the assay results. This is required to ensure that the patient receives the intended dosage. The time at which the measurement must be made has been purposefully omitted to allow for flexibility in licensee's procedures.

A similar requirement was published as a proposed rule on September 1, 1981 (46 FR 43840). The comment period on the proposed rule expired November 30, 1981. The NRC is incorporating the dosage measurement proposal in this revision. The proposed Part 35 dosage measurement requirement differs from the 1981 proposal in its recordkeeping requirement. The Part 35 proposal requires the dosage measurement record to include the patient's name, and identification number if one has been assigned, and prescribed dosage. This information was not required by the 1981 proposal.

Section 35.56 Authorization for calibration and reference sources.

These sources are needed to check and test radiation instruments and to mark images. They represent a small radiation hazard in relation to the amount of radioactivity used in patient care. The activity level was chosen to allow licensees to have a range of sources with several energies and half-lives available.

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

The user must follow the manufacturer's instructions because they have been reviewed for safety considerations by the Commission or an Agreement State.

The six-month test interval has been recommended by the National Council on Radiation Protection and Measurements (NCRP)[1] in Report No. 57, "Instrumentation and Monitoring Methods for Radiation Protection." More frequent testing is inconsistent with ALARA considerations because it would cause worker dose when making the test but provides only a slightly greater probability of finding a leaking source. The test procedures described are intended to maximize the probability of detecting contamination from a leaking source. Report No. 57,

[1] The National Council on Radiation Protection and Measurements (NCRP) is a nonprofit corporation chartered by Congress in 1964 to draft proposed recommendations on protection against radiation and on radiation measurements, quantities, and units, particularly those concerned with radiation protection. Copies of reports may be purchased by contacting NCRP Publications, P.O. Box 30175, Washington, DC 20014.

Section 3.3.5.3 recommends a minimum detectable limit of 0.005 microcuries for equipment used to measure leak test samples. This level is also consistent with the requirements of other parts of the current regulations (see, for example, §§ 31.5 and 34.25), and is only slightly higher than the minimum detectable activity exhibited by instrumentation available to licensees. The Commission has made a judgment that this level provides the most conservative detection level technically achievable at a reasonable cost. It is noted that this requirement would reduce the current permissible amount of detectable contamination from teletherapy sources ten-fold, from 0.05 microcuries to 0.005 microcuries for purpose of consistency.

The Commission has made a judgment that the exempted sources do not present a contamination hazard because of the small amount of radioactivity in the sources, the method in which they are constructed, or the small hazard of the byproduct material. To conduct a physical inventory more frequently than quarterly is inconsistent with ALARA exposure goals. To inventory less frequently may, in case of a misplaced source, allow an unacceptable radiation exposure to go on for too long without detection. The radiation survey ensures that sources are safely stored.

Section 35.80 Syringe shields.

Syringes that contain byproduct material can be an external radiation source and should therefore be shielded at all times. In some cases the use of a shield when making an injection could interfere significantly with the injection. This would jeopardize patient benefit. In such cases the higher radiation exposure to the hands that is received by the technician who does not use a syringe shield is warranted. A shield need not be used when the risk of spoiling the injection is greater than the benefit of reduced worker exposure.

The NRC considered requiring the use of syringe shields when drawing individual dosages from multi-dose vials. That requirement is not included in this proposed revision because it appears that the increased handling required to remove the shield when measuring the dosage may actually increase radiation dose to the hands. However, the NRC is soliciting comments on whether syringe shields should be used when drawing individual dosages.

Section 35.81 Vial shields.

A vial radiation shield can significantly reduce the radiation exposure to the fingers and hands of an individual handling a vial of byproduct material.

Section 35.82 Syringe labels, and § 35.83 Vial shield labels.

Some misadministrations have been caused by accidentally transposing vials or syringes. The proper labelling of containers will help to avoid this type of mistake.

Section 35.70 Surveys for contamination and ambient radiation exposure rate.

Since radiopharmaceuticals are frequently handled, it is plausible that a syringe or some radioactive waste may be misled. This would result in unnecessary radiation exposure to workers and the public. The exposure rate survey will bring this to the attention of workers. The weekly exposure rate survey of waste storage areas will ensure that exposure rates in that area will be monitored so that special steps can be taken if greater than average use of radiopharmaceuticals results in higher than average exposure rates in the waste storage area.

The Commission knows that a removable contamination wipe test made several days after spillage of a short-lived radiopharmaceutical will probably not detect any contamination. The periodic contamination survey serves as a check of workers' physical control of radiopharmaceuticals. If contamination is found, it indicates that controls or safety measures may be inadequate or are not always being used.

Section 35.75 Release of patients containing radiopharmaceuticals or permanent implants.

A patient whose body contains byproduct material is a source of external radiation and can be a source of radioactive contamination. The patient should not be released from the clinic or hospital until the residual radioactivity in the patient is at an acceptable level. The Commission proposes to allow patient release limits based on residual activity in the patient or exposure rate at a specified distance from the patient at the licensee's option. The 30 millicuries burden limit is based on a recommendation of the NCRP and current licensing practice. The 5 mR/hr at one meter limit is based on the exposure rate from 30 millicuries of iodine-131, the most commonly used therapeutic radiopharmaceutical; some individuals believe that the exposure rate is more relevant and easier to measure. The Commission believes that either limit provides an adequate measure of safety for the general public, and that further reductions in public exposure are not reasonably achievable considering the cost and potential for detrimental effect from an unnecessarily long hospital confinement.

Section 35.80 Mobile nuclear medicine service technical requirements.

The Commission has limited radiopharmaceutical transportation by these licensees to unit dosage and multi-dose vials of prepared radiopharmaceuticals.

The Commission did not authorize transportation of generators because they are needed by persons who do not have daily access to prepared radiopharmaceuticals. That lack of access would be contrary to the geographic proximity required by § 35.36.

The service must remove all radioactive waste generated during the use of byproduct material at a client location of use because the Commission has no assurance that the client is equipped to safely receive and process radioactive waste. Because there is no assurance that the licensee can control access to areas of use while working in a facility that is under another person's administrative control, client facilities should be considered as unrestricted areas, and the licensee must therefore constantly exercise physical control of byproduct material.

Equipment checks are needed to assure the proper function of equipment after transport and before byproduct material is handled. A survey is needed to assure that all byproduct material has been removed from the client location of use. The mobile nuclear medicine service must carry a calibrated survey meter to monitor exposure and contamination in case of any accident that may result in a release of byproduct material.

Section 35.90 Storage of volatiles and gases.

Some radiopharmaceuticals present an inhalation or immersion source (e.g., volatile iodine-131 and xenon-133 respectively). The chance of exposure can be reduced by storing these materials in a fume hood or multiple barriers (such as a folded plastic bag within a folded plastic bag).

Section 35.92 Decay-in-storage.

For most hospital radiopharmaceutical waste, decay to background levels is essentially complete over a period of days or months. The waste disposal requirements of § 20.301, directed

primarily at longer half-lived material, are not necessary for short half-lived radiopharmaceutical waste. Therefore, short half-lived waste can be exempted from the requirements of § 20.301. A decay period of ten half-lives was chosen because it represents a thousand-fold reduction in radioactivity. This ensures that, in most cases, byproduct material will have decayed to levels below those in § 30.71, which are quantities that, under certain ordinary conditions, are exempt from a requirement for a specific license. The regulation would only allow decay-in-storage for radioactive material with a half-life of 65 days or less because storage for the required ten half-lives would be in excess of 650 days and more appropriately considered permanent storage. (Consistent with current practice, the Commission will consider, on a case-by-case basis, requests to decay longer-lived material or to decay for fewer half-lives.) Waste must be monitored to assure that long-lived waste was not accidentally mixed with short-lived waste and that no waste has been added to the container since it was sealed. When the waste is monitored, neither the waste nor the survey instrument may have any radiation shielding because it might hide the presence of long-lived byproduct material in the waste. The requirement to remove or obliterate radiation labels is in § 20.205(f)(4) and is included here for completeness. Generator columns must be individually monitored because they contained larger amounts of radioactivity and also may have small amounts of long-lived contaminants.

Subpart D—Uptake, Dilution, and Excretion

Section 35.100 Use of radiopharmaceuticals for uptake, dilution and excretion studies, and § 35.200 Use of radiopharmaceuticals, generators, and reagent kits for imaging and localization studies (§ 35.200 is also discussed later).

Drugs approved for human use by the FDA have a label or package insert that specifies the FDA-approved use, physical form, route of administration, and dosage range. NRC relies primarily on FDA's determination of a radioactive drug's safety and effectiveness when it is used according to the package insert. By restricting the physician to the FDA-approved physical form, route of administration, and dosage range, NRC assures the safety of the public while allowing the physician flexibility regarding the choice of the clinical procedure.

The Commission notes that the FDA is considering a change in its regulations for reviewing the safety of investigational new drugs and new uses of approved drugs (see 48 FR 26720, published June 9, 1983). The Commission may revise its regulations regarding investigational new drugs and new uses of approved drugs after reviewing FDA's final rulemaking.

The FDA also authorizes the Radioactive Drug Research Committee (RDRC) at an institution to review and approve the use of radioactive materials for medical use research purposes. The Commission believes that the guidelines used by the FDA when reviewing the credentials of the RDRC members, and the guidelines that the FDA requires the RDRC to use when evaluating research proposals, are adequate to assure the safety of workers and the public without unduly restricting medical research. Therefore, the Commission will continue to allow, on a case-by-case basis, licensees to administer radiopharmaceuticals authorized by an RDRC in accordance with FDA regulations. This authorization was not included in the regulation because only a few licensees request it.

The radiopharmaceuticals listed in § 35.100 were taken from those listed in the current §§ 35.31 and 35.100(a). Those listed in § 35.200 were taken from current §§ 35.100 (b) and (c). Mercury-203 was not included in the proposed revision because the Commission believes that there are other radiopharmaceuticals available that provide equivalent diagnostic information with much less radiation dose to the patient.

Manufacturers are currently distributing generally licensed radiopharmaceuticals under a license issued pursuant to § 32.70. If this revision is adopted by the Commission, these manufacturers would have to apply for a license amendment to distribute radiopharmaceuticals pursuant to § 32.72.

Section 35.120 Possession of survey instrument.

A low level survey instrument is needed to check areas of use for contamination. Since the total amount of radioactivity used for uptake, dilution, and excretion studies is relatively small, the Commission does not believe the licensee needs an ionization survey instrument to measure dose rates.

Subpart E—Imaging and Localization

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

Xenon-133 as a gas or as saline solution has been added to this group. Manufacturers are currently distributing the product under a license issued pursuant to Part 30. If this revision is adopted by the Commission, these manufacturers would have to apply for a license amendment to distribute xenon pursuant to § 32.72.

Through continuing medical research, new uses may be found for existing approved radiopharmaceuticals. These new uses, which may require a different dosage, route of administration, or physical form, may not appear on the manufacturer's label or package insert instructions. It was such a situation that resulted in a petition filed by Dr. George V. Taplin (Docket No. PRM-35-1) requesting an exemption for Tc-99m pentetate as an aerosol for lung function studies. A proposed rule was published on April 13, 1982 (47 FR 15798). The comment period on this proposed rule expired June 14, 1982, and 35 comments were received. The NRC adopted the rule in final form without change on February 4, 1983 (48 FR 5217); the preamble of the final rule also described how to apply for future exemption requests. The NRC is incorporating this regulation into this revision of Part 35 without soliciting public comment because of the recentness of the rulemaking and because there are no substantive changes to the rule as adopted.

Section 35.204 Permissible molybdenum-99 concentration.

Technetium-99m is produced when molybdenum-99 undergoes radioactive decay. When the technetium is separated from the molybdenum, unwanted molybdenum may appear as a contaminant in the technetium solution. The permissible concentration of molybdenum-99 was chosen to be consistent with the permissible concentration listed in the United States Pharmacopeia (USP), the nationwide standard for all pharmaceuticals used in the practice of medicine. It is the judgment of the Commission that the USP standard provides an adequate level of safety and to require a different standard would be confusing and unproductive. Since diagnostic dosages of technetium-99m are generally 30 millicuries or less, the maximum permissible level of molybdenum-99 in such a dosage would result in a patient

receiving an undesired 4.8 microcuries of molybdenum-99. The molybdenum would be taken up primarily by the liver. The dose to the liver would be about 0.2 rads as a result of the molybdenum concentration. The Commission has made a judgment that, by holding the permissible concentration to the required level, the resulting radiation dose is insignificant compared to the radiation dose which would be received by the patient due to the administration of the technetium.

The licensee that elutes the generator must measure and keep a record of the molybdenum concentration. Persons who receive prepared radiopharmaceuticals do not have to make this measurement because the person who prepared it would have made the measurement (see the conforming amendment to § 30.34).

Section 35.205 Control of aerosols and gases.

The Commission believes that a system that provides for the collection or controlled dispersal of aerosols and gases is needed to reduce exposure to workers and the public. If control is by dispersal in the atmosphere, licensees should note §§ 20.105 and 20.106, which limit the amount of radioactivity in the effluent stream.

Unlike solid and liquid byproduct materials authorized by this part, gases usually cannot be contained or recovered after a spill. To reduce exposure to workers and the public after a spill, exhaust and dispersal in the atmosphere is commonly used. However, because conventional room ventilation rates are seldom sufficient to clear spilled gas in a timely fashion, the licensee must follow special, room-specific safety measures in case of a gas spill. When making the required exhaust calculation, the licensee must assume that the largest single gas container handled in the area is completely spilled, and may use either ambient or emergency air exhaust rates.

Section 35.220 Possession of survey instruments.

The licensee needs a low level survey instrument to check for contamination and an ionization type instrument to measure dose rates in areas where large amounts of radioactive material are stored.

Subpart F—Radiopharmaceuticals for Therapy

Section 35.300 Use of radiopharmaceuticals for therapy.

The radiopharmaceuticals listed in § 35.300 were taken from those listed in the current §§ 35.100 (d) and (e). The drugs have been approved for medical use by the FDA.

Section 35.310 Safety instruction, and § 35.410 Safety instruction.

In the hospital setting, the use of byproduct material presents special training problems which are not addressed in Part 19 because they are unique to the medical environment. For example, visitor control in a hospital cannot be accomplished by physical barriers which might impede the delivery of emergency medical care to patients. After administration, the byproduct material is contained in an ambulatory human.

Therefore, the Commission has made a judgment that worker instruction in addition to that required by Part 19 is necessary. (This parallels special instruction required, for example, for radiographers and radiographers' assistants pursuant to § 34.31 of the Commission's regulations.)

Section 35.315 Safety precautions.

Because of the special contamination hazards of radiopharmaceutical therapy patients, a private room with private sanitary facilities is needed to protect members of the public, who might be visiting nearby patients, from unnecessary exposure to radiation. The RSO must be notified in case of the patient's death or medical emergency in order to determine whether special contamination control procedures must be implemented.

Section 35.320 Possession of survey instruments.

The licensee needs a low level survey instrument to check for contamination and an ionization type instrument to measure dose rates in areas where large amounts of radioactive material are stored.

Subpart G—Sources for Brachytherapy

Section 35.400 Use of sources for brachytherapy.

This section identifies brachytherapy sources that may be used for medical use. The list was taken from the current § 35.100(e), which is a list of sources commonly used for patient care.

Section 35.404 Release of patients treated with temporary implants.

A responsibility of the Commission is to restrict the movement of byproduct material when the public exposure would be increased. Brachytherapy sources for temporary implants have high levels of radiation, and remain radioactive for a long period of time. Loss of control of these sources and their release to unrestricted areas may result in potentially lethal radiation exposure to members of the public. The Commission has made a judgment that temporary confinement of the implant patient is necessary to ensure public safety. Section 35.404 requires that the licensee prevent the patient from leaving the hospital or clinic until all temporary implant sources have been removed. The records required by this section may be amalgamated with the records required by § 35.406; there is no need for duplication.

Section 35.406 Brachytherapy sources inventory.

Because of the particular hazard of brachytherapy sources due to their high activity and small size, the Commission believes that an inventory procedure that requires a physical count and a radiation survey log entry each time sources are handled with help to ensure that if a source is misplaced its absence will quickly become apparent to the licensee, which can then promptly begin a search for the source.

Section 35.415 Safety precautions.

Because of the high exposure rates around implant patients, a private room is needed to protect members of the public, who might be visiting nearby patients, from unnecessary exposure to radiation. The RSO must be notified in case of the patient's death or medical emergency to ensure that control of implant sources is retained.

Section 35.420 Possession of survey instrument.

The licensee needs a high level survey instrument to measure exposure rates in storage areas around a patient's room, and to check to be sure all sources have been removed from the patient before release from confinement.

Subpart H—Sealed Sources for Diagnosis

Section 35.500 Use of sealed sources for diagnosis

This is a new type of use group established to incorporate the recent development of medical devices that use a sealed source of byproduct material to create a beam of ionizing radiation. These devices are now available to persons licensed to use materials listed in § 35.100(f). Because the devices represent a lower level of hazard than the other sources in that group, the Commission has determined that these devices should comprise a new group.

Section 35.620 Availability of survey instrument.

The licensee needs a survey instrument to measure the exposure rates around a packaged sealed source that was just received or that is to be returned to the manufacturer, and to survey for contamination in case of an accident that might have compromised the integrity of the sealed source. However, because a source exchange is an infrequent and scheduled event, and because a hazardous accident would be a very rare occurrence, the Commission believes that it is sufficient, for safety purposes, to require the licensee to make arrangements to borrow or rent an instrument or contract with a measurement service when measurements are necessary.

Subpart I—Teletherapy

Section 35.600 Use of a sealed source in a teletherapy unit.

This is a new type of use group established to deal with a well-established type of use. Safety measures that now apply to all licensees within this group have been used over the years and are reflected in these proposed regulations.

Section 35.605 Maintenance and repair restrictions, and § 35.645 Five-year inspection (§ 35.645 is also discussed later).

These sections provide notice that only specially licensed persons may maintain, adjust, or repair teletherapy units because this type of work requires special training and equipment in order to be done safely. This work is licensed under Part 30 of the Commission's regulations.

Section 35.606 Amendments.

Amendments are required for items identified in paragraphs (a) through (e) because any change described in these paragraphs could easily result in an increase in radiation levels in excess of the levels authorized in § 20.105. The service of a qualified teletherapy calibration expert is an essential element in ensuring the safe use of a teletherapy unit. The Commission has made a judgment that only an individual with special training and experience can determine the operating characteristics of the licensee's teletherapy unit and should therefore be identified on the license.

Section 35.610 Safety instructions.

Emergency instructions must be posted to remind individuals of the proper steps to be taken in case of an emergency and to identify individuals to be notified in an emergency. The Commission believes this is also an appropriate place to remind workers that it is important to ensure that only the patient is in the room before turning the unit on. The reminder is necessary because it is possible that when two workers are stationed on one teletherapy unit one worker may inadvertently turn the unit on when the other worker is still in the treatment room, or a worker may turn the unit on to check its operation after a patient or co-worker has entered the treatment room without telling the worker at the control console.

The special instruction for teletherapy workers is needed because this is the one type of medical use of byproduct material in which a worker or member of the public could receive a high, whole body dose in a matter of minutes if the source were not used safely.

Section 35.615 Doors, interlocks, and warning systems.

NCRP Report No. 57, "Instrumentation and Monitoring Methods for Radiation Protection," on page 42, states that a survey of a new teletherapy facility must determine that . . ." All entrances into the irradiation rooms or other high radiation areas are provided with barriers equipped with interlocks that are not dependent on the operation of a single circuit, and that will interrupt radiation production when the barrier is opened." There have been incidents in irradiation facilities in which personnel were unnecessarily exposed to radiation because door interlocks or alarms were intentionally bypassed for convenience. See, for example, cases 19, 21, and 28 in NUREG/BR-0001, "Case Histories of Radiography Events," vol. 1, 1980. If the interlocks and warning systems had not been bypassed, personnel would not have been irradiated. The Commission, however, has made a judgment that the dual warning system of a door interlock and a radiation monitor in the teletherapy room obviates the need for the dual circuit door interlock recommended in the report.

The beam condition indicator light will indicate to workers about to enter the room whether the unit is turned on or off.

Section 35.620 Possession of survey instrument.

The licensee needs a survey instrument on hand as a backup room monitoring device in case the radiation monitoring device fails.

Section 35.621 Radiation monitoring device.

The radiation monitoring device is needed to indicate radiation levels in the teletherapy room if the interlocks or the warning systems fail. Individuals may be unnecessarily exposed following the failure of the source retraction mechanism coupled with a failure of the primary beam condition indicator system. Therefore, § 35.621 requires licensees to install a permanent radiation monitor in each teletherapy room, to check its operation before using the teletherapy unit, and to use portable survey instrument or personal audible alarm dosimeter if the monitor is inoperable. Similar requirements were published as a proposed rule on April 28, 1982 (47 FR 18131), and were adopted in a final rule published January 18, 1983 (48 FR 2116).

Section 35.622 Viewing system.

If a patient moved during a therapy administration, this could result in a radiation dose to healthy tissue and no dose to the treatment area. Therefore, a viewing system is needed to monitor the orientation of the patient and the teletherapy unit to assure the prescribed application of radiation.

Section 35.630 Dosimetry equipment.

Dosimetry equipment is needed to measure radiation output. In order to help assure accuracy the equipment must be calibrated. The equipment requirements are the same as the current §§ 35.22 and 35.23. This section also contains the proposed resolution of the petition filed by the American Association of Physicists in Medicine, Petition Docket No. PRM 35-4 (see 47 FR 4311, January 28, 1982). Currently, regulations require that primary dosimetry equipment be calibrated every two years. The petitioner requested that this two year requirement be relaxed to four years if, two years after calibration, the primary dosimetry system is intercompared with a system that was calibrated within the past two years, and the results of the intercomparison indicate that the calibration factor used to convert an instrument reading to a dose measurement had not changed by more than two percent. (Intercomparison meetings are occasionally scheduled by several qualified teletherapy calibration experts within a geographic area. Each expert takes a dosimetry system of similar metrological quality to the meeting. Each dosimetry system in turn is exposed to the same radiation dose from a teletherapy unit. The response of each dosimetry system can then be

compared to the response of the other systems. If each system measures the same radiation dose in rads, this provides assurance that each system is working properly. Note that when instruments of *different* metrological quality are exposed to the same radiation dose, it is referred to as a comparison rather than an intercomparison.) This suggestion has been incorporated into these proposed regulations. The petitioner also asked that the licensee be required to make quarterly constancy checks to assure the consistency of operation of the dosimetry system. The Commission did not incorporate this suggestion because it is not aware of any scientific study that shows that such checks, when made with currently available equipment, are capable of detecting small but significant changes in calibration. Therefore, the Commission has no basis to assume that periodic constancy checks would necessarily provide increased assurance of proper operation.

Section 35.632 Full calibration measurements.

Full calibrations are needed to ensure that the given dose is the same as the prescribed dose. The required frequency of full calibrations remains unchanged from that of the current Part 35. The test for timer accuracy has been clarified to include on-off error. The accuracy of localization devices that are used to position the teletherapy patient has been added to minimize the risk of unintentional irradiating healthy tissue. The function of mechanical and electrical interlocks that are used to limit the directions in which the beam can be aimed, and thereby reduce the exposure rate in uncontrolled areas, has also been added. The licensee need no longer perform all measurements with a calibrated dosimetry system. Instead, the calibrated dosimetry system need only be used for one representative measurement, and then a relative exposure rate measurement system can be used to complete the calibration. This would allow for use of computer-controlled dosimetry systems that are capable of making precise relative measurements but are not suitable for making absolute output measurements.

The Commission proposes to allow licensees to use either the currently required calibration procedure or a new procedure that was recently published. The new procedure is generally considered more scientifically rigorous, but the Commission believes that either procedure provides an adequate measure of teletherapy dose rate.

The exposure rate from a radioactive source goes down as time progresses due to source radioactive decay. To ensure accurate dose delivery, the regulation requires that licensees mathematically take this into account in calculating patient doses. The regulation requires that the licensee use time *periods of not longer* than one month when making decay calculations. This will ensure that the actual dose does not differ from the calculated dose by more than one percent due to this decay error.

Section 35.633 Periodic spot-checks, and § 35.642 Safety checks for teletherapy facilities.

A monthly spot-check is required by § 35.22 of the current regulations to ensure that the teletherapy unit is giving the expected radiation dose. The following changes from current requirements have been made. Timer accuracy has been clarified to include on-off error. The accuracy of localization devices has been added. Error in either may result in incorrect administration of radiation. The qualified teletherapy calibration expert must review the results of the spot-check measurements within fifteen days, and must notify the licensee in writing of the results of the monthly check, to assure the licensee and the Commission that the check results were reviewed by a qualified individual. The Commission has made a judgment that a response period of less than fifteen days would be unreasonably expensive.

A requirement to check certain safety systems in the teletherapy facility has been added. These checks are needed to assure that safety systems required by other sections of the regulations are working properly. They need not be performed by the qualified teletherapy calibration expert. Devices that are not working must be promptly repaired in order to assure safety in the teletherapy facility. In case of failure of the viewing system, the regulation would allow the physician to decide whether treatments should be interrupted. This would *not* relieve the licensee from the requirement to promptly repair the viewing system. The regulation would require that the teletherapy unit not be used in case of door interlock failure because that is the mechanism that protects workers and the public from unintentional irradiation. However, the Commission invites comment as to whether additional administrative procedures or personal supervision would provide an acceptable balance of worker safety and medical use needs.

Section 35.641 Radiation surveys for teletherapy facilities.

The Commission has used these maximum and average permissible source leakage radiation levels for several years as license conditions. They are consistent with guidance from the NCRP in its Report No. 33, "Medical X-ray and Gamma-ray Protection for Energies up to 10 MeV-Equipment Design and Use," Section 4.2.2. The Commission has made a judgment that they are sufficiently restrictive to keep exposures as low as reasonably achievable. The required location of the collimators during the head leakage survey is a new specification. It is based on the fact that, for individuals who receive most of their radiation dose from working around a source in the "off" position, the collimators will normally be at the setting used for the last treatment.

Section 35.643 Modification of teletherapy unit or room before beginning a treatment program.

The section is needed to require that licensees take prompt action to reduce exposure rates in uncontrolled areas that may be caused by errors in design or construction of the teletherapy facility.

Section 35.644 Reports of teletherapy surveys, checks, tests, and measurements.

Given the potential for high exposure to workers and the public from improperly installed teletherapy units, the radiation survey information required by § 35.644 is needed to assure that teletherapy units have been properly installed and are sufficiently shielded to ensure compliance with the exposure limits of Part 20.

Section 35.645 Five-year inspection.

Many licensees replace teletherapy sources at five year intervals. Requiring a mechanical check at five year intervals helps to assure that the source exposure mechanism is in good working order and will not stick in the exposed position. The mechanic who exchanges sources and inspects units can remove the source, inspect the drawer mechanism, and then install the new source. More frequent checks would require greater time near a very radioactive source. Less frequent checks would not be sufficient to assure the continuous proper operation of the exposure mechanism. The identification information in the record is needed to establish which unit was inspected, when, and by whom. The remaining information is needed so the Commission may determine that the inspection was of sufficient depth to assure the health and safety of workers and the public.

Subpart J—Training and Experience Requirements

A combination of theoretical and practical training and experience is necessary to assure the safe use of byproduct material. The criteria in this subpart were developed by the staff with the advice of the Advisory Committee on the Medical Use of Isotopes (ACMUI). The requirements for the Radiation Safety Officer have not been published before. The requirements for authorized users are similar to those published as an amendment to Appendix A of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Programs," in the Federal Register on December 2, 1982 (47 FR 54376). The requirements for the qualified teletherapy calibration expert are similar to those required of a qualified expert pursuant to the current § 35.24.

Consistent with current practice, if individuals do not meet the training and experience standards, the NRC will review their credentials with regard to the materials requested and these standards and make authorizations on a case-by-case basis.

The Commission has received and is reviewing suggested alternative training standards for some methods of use. The review is being handled as a separate project. If any changes in training standards come out of that project, they will be published for public comment and incorporated into this subpart or elsewhere, as appropriate.

Sections 35.900(a), 35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.941(a), 35.950(a), 35.960(a), and 35.961(a), concerning certification.

The Commission has made a judgment that in some cases, certification by an appropriate professional board provides proof of adequate training and experience because the criteria which must be met to attain certification are more stringent than the training and experience required by the Commission.

Section 35.900(c) Authorized user as a Radiation Safety Officer.

The training and experience required by the Commission includes safety considerations for the byproduct material that the authorized user may use. Therefore, authorized users are qualified to oversee the safe use of byproduct material that they are authorized to use pursuant to the conditions of the license.

Sections 35.900(b), 35.910(b), 35.920(b), 35.930(b), 35.940(b), 35.941(b), 35.950(b), 35.960(b), and 35.961(b) Training and experience.

The criteria identified in these sections were developed by the staff with the assistance of the ACMUI over the past several years. The Commission has made a judgment that, for each type of use, the training and experience described is necessary to ensure the safe use of byproduct material. The duration of training and experience is usually specified in classroom (not credit) hours. Training may be received as part of a formal program at an accredited university, at a proprietary school, from an equipment or radiopharmaceutical manufacturer, or elsewhere. NRC will carefully review this information before listing an individual on a license. Supervised work experience must be received at an institution under an authorized user preceptor because usually only such an individual is qualified to teach the clinical use of byproduct material, and, if the experience were not received at an institution, the student would be less likely to receive experience with all the methods of use commonly used or all the management problems associated with the safe handling of byproduct material.

Sections 35.910(c) and 35.920(c) Integrated programs.

The Accreditation Council for Graduate Medical Education (ACGME) reviews and approves training programs for physicians. Approval of these training programs is based, in part, on adequate radiation safety content. The Commission has made a judgment that individuals who have successfully completed an approved training program have received sufficient training and experience to use byproduct material safely.

Sections 35.901 and 35.970 Current Radiation Safety Officers and Authorized users.

The staff has reviewed and found acceptable the training and experience of each individual who is currently listed as a Radiation Safety Officer or an authorized user. Further review of the credentials of these individuals is unnecessary.

Section 35.971 Physician training exception.

In addition to the ACGME, the American Board of Radiology, the American Board of Osteopathic Radiology, and the American Board of Nuclear Medicine review and approve nuclear medicine training programs for physicians. These three boards independently arrived at the conclusion that, while currently acceptable, a three month training program may not allow sufficient time in the future to provide the training and experience needed to develop a satisfactory level of expertise in nuclear medicine, including radiation safety. All three boards and the ACGME have therefore extended their training programs to six months duration for those who begin their training after June 30, 1984. The Commission has made a judgment that, in the meantime, individuals who have successfully completed an approved three month training program have received sufficient training and experience to use byproduct material safely.

Section 35.972 Recentness of Training.

Radiation safety regulations and practices may be expected to change with time. The Commission has made a judgment that training received within the five years preceding submittal of an application is sufficiently up-to-date to assure the safe use of byproduct material. If an individual received training more than five years before the application and has not had continuing involvement in the field, training must be repeated.

Subpart K—Enforcement

Section 35.990 Violations.

This section gives notice that the Commission will initiate legal proceedings if necessary to enforce requirements.

Section 35.999 Resolution of conflicting requirements during transition period.

As discussed before, to allow for an orderly transition from licenses granted under the present regulations to licenses granted under the new regulations if there is a conflict between the final rule and a licensee's radiation safety program as described in the statements, representations, and procedures submitted in support of the license request, and if the license was issued before the effective date of the final rule and has not been renewed, the requirements and authorizations of the licensee's radiation safety program will take precedence over the final rule. However, if the licensee exercises its right to make a radiation safety program change as authorized under § 35.36, the changed procedure must be in accord with the revised regulation.

Conforming Amendment

Section 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

Many medical use licensees now use byproduct material for in vitro work under the provisions of current §§ 31.11 and 35.14(c). The proposed conforming amendment grandfathers them. In the future, new and renewal applicants will have to specifically request permission to use § 31.11 materials as a separate line item on their applications. The use of materials listed in § 31.11 within the inventory limits of that section would only be subject to the requirements of that section; consistent with current regulations, the use of materials listed in § 31.11 will *not* be subject to the requirements of Parts 19, 20, 21, and 35 except for the Mock Iodine-125 disposal, loss or theft, and notification clause of § 31.11(f).

Derivation Table

The following derivation table identifies the origin of each section of the proposed regulations. Sources of the proposed regulations include 10 CFR Parts 19, 30, and 35, Federal Register Notices (FR), frequently used license conditions, licensing staff policy, current regulatory guides (RG), Office of Inspection and Enforcement bulletins, the United States Pharmacopeia, and new text prepared by staff.

New Section Number	Origin
Subpart A—General Information	
35.1 Purpose and scope	35.1 revised.
35.2 Licenses required	35.2 revised.
35.8 Reporting recordkeeping, and application requirements OMB Approvals.	New text.
35.10 Definitions:	
Agreement State	35.2.
ALARA	Appendix.
Authorized users	Term used on licenses.
Dentist	New term.
Medical institution	Do.
Misadministration	Do.
Medical use	35.2(a) revised.
Misadministration	35.41.
Mobile nuclear medicine service.	New term.
OMBA	Do.
Physician	35.2(b) revised.
Podiatrist	New term.
Qualified teletherapy calibration expert.	Do.
Radiation Safety Officer	Term used on licenses.
Sealed source	35.4(c) variation.
Visiting authorized user	New term, similar to "visiting authorized user" license condition.
35.13 Application for license, amendment, or renewal.	35.4 revised.
35.17 License amendments	New text compare 30.38.
35.18 Notifications	New text.
35.20 Licensee education	New text compare 70.20.
35.25 Specific exemptions	New text, compare 30.11.

New Section Number	Origin
Subpart B—General Administrative Requirements	
35.30 ALARA program	New text, see RG 10.8 Appendix S revised.
35.31 Radiation Safety Officer	RG 10.8.
35.32 Radiation Safety Committee.	35.11(b) revised.
35.33 Requirements for authority and assignment of responsibilities.	New text.
35.34 Visiting authorized user	Licensee condition.
35.35 Mobile nuclear medicine service administrative requirements.	Licensing policy.
35.36 Radiation safety program changes.	New item.
35.37 Records and reports of misadministrations.	35.42.
35.38 Supervision	Expansion from RG 10.8 p. 3.
35.40 Suppliers	35.14 revised.
Subpart C—General Technical Requirements	
35.50 Possession, use, calibration, and check of dose calibrators.	RG 10.8 Appendix D revised, and new text.
35.51 Calibration and check of survey instruments.	RG 10.8 Appendix D1 revised, and new text.
35.52 Measurement of radiopharmaceutical dosages.	Proposed rulemaking 35 (5 146 FR 43640, September 1, 1981).
35.56 Authorization for calibration and reference sources.	35.14(d) revised.
35.59 Requirements for possession of sealed sources.	35.14(b)(1)(i), 35.14(f) revised.
35.60 Syringe shields	Inspection and Enforcement letter April 18, 1979.
35.61 Vial shields	Inspection and Enforcement letter April 18, 1979.
35.62 Syringe labels	New text.
35.63 Vial shield labels	Do.
35.70 Surveys for contamination and prompt notification exposure rate.	RG 10.8 Appendix I revised.
35.75 Release of patients containing radiopharmaceuticals or permanent implants.	New text.
35.80 Mobile nuclear medicine service technical requirements.	Licensing policy.
35.90 Storage of wastes and waste.	RG 10.8 Appendix M revised.
35.92 Decay-in-storage	Licensee condition.
Subpart D—Uptake, Dilution, and Excretion	
35.100 Use of radiopharmaceuticals, for uptake, dilution, and excretion studies.	35.31 and 35.100 (f) revised.
35.120 Possession of survey instruments.	RG 10.8 page 6.
Subpart E—Imaging and Localization	
35.200 Use of radiopharmaceuticals, generators, and reagent kits, for imaging and localization studies.	35.100 (b) and (d) revised.
35.204 Permissible molybdenum-99 concentration.	US Pharmacopeia.
35.206 Control of contrasts and gases.	RG 10.8 Appendix M revised.
35.220 Possession of survey instruments.	RG 10.3 page 6.
Subpart F—Radiopharmaceuticals for Therapy	
35.300 Use of radiopharmaceuticals for therapy.	35.100 (VI and (V) revised.
35.310 Safety instruction	19.12 revised.
35.315 Safety precautions	RG 10.8 Appendix K.
35.320 Possession of survey instruments.	RG 10.8 page 6.
Subpart G—Sources for Brachytherapy	
35.400 Use of sources for brachytherapy.	35.100 (VI revised.
35.404 Release of patients treated with temporary implants.	35.14(a)(5)(vi) revised.
35.406 Brachytherapy sources inventory.	RG 8.10 page 6.

New Section Number	Origin
35.410 Safety instruction	19.12 revised.
35.415 Safety precautions	RG 10.8 Appendix L.
35.420 Possession of survey instruments.	New text.
Subpart H—Sealed Sources for Diagnosis	
35.500 Use of sealed sources for diagnosis.	New text.
35.520 Possession of survey instruments.	New text.
Subpart I—Teletherapy	
35.600 Use of a sealed source in a teletherapy unit.	New text.
35.605 Maintenance and repair restrictions.	Licensee condition.
35.610 Amendments	New text.
35.615 Safety instruction	Licensee condition and new text.
35.615 Doors, shielding, and warning systems.	Licensee condition.
35.620 Possession of survey instruments.	New text.
35.631 Radiation monitoring device.	35.20 (48 FR 21116, June 10, 1983).
35.632 Viewing system	Licensee condition.
35.633 Dosimetry equipment	35.22, 35.23 revised.
35.632 Full calibration measurements.	35.21 revised.
35.633 Periodic spot-checks	35.22 revised and license condition.
35.641 Radiation surveys for unattended teletherapy.	Licensee condition.
35.642 Safety checks for teletherapy facilities.	Licensee condition.
35.643 Modification of teletherapy unit or room before beginning a treatment program.	New text.
35.644 Reports of teletherapy surveys, checks, tests and measurements.	Licensee condition.
35.645 Post-visit inspection	Licensee condition.
Subpart J—Training and Experience Requirements	
35.900 Radiation Safety Officer	New text.
35.901 Training for experienced Radiation Safety Officer.	Do.
35.910 Training for uptake, dilution, and excretion studies.	Do.
35.920 Training for imaging and localization studies.	Revision of Federal Register Notice (47 FR 53478, Dec. 2, 1982).
35.930 Training for therapeutic use of radiopharmaceuticals.	Revision of Federal Register Notice (47 FR 53478, Dec. 2, 1982).
35.940 Training for therapeutic use of brachytherapy sources.	Revision of Federal Register Notice (47 FR 53478, Dec. 2, 1982).
35.941 Training for ophthalmic use of strontium-90.	Revision of Federal Register Notice (47 FR 53478, Dec. 2, 1982).
35.950 Training for use of sealed sources for diagnosis.	New text.
35.960 Training for teletherapy	Revision of Federal Register Notice (47 FR 53478, Dec. 2, 1982).
35.961 Training for qualified teletherapy calibration expert.	35.24 revised.
35.970 Training for experienced authorized users.	New text.
35.971 Provision training in a three month program.	Do.
35.972 Requirements of training	Revision of Federal Register Notice (47 FR 53478, Dec. 2, 1982).
Subpart K—Enforcement	
35.990 Violations	New text.
35.999 Possession of conflicting requirements during transition period.	Do.

Administrative Statements

Finding of No Significant Environmental Impact: Availability

The Commission is proposing to completely revise the regulations

governing the medical use of byproduct material. The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that promulgation of this regulation is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. The radiation levels and release of byproduct material authorized by this proposed revision are consistent with the Commission's other regulations and internationally accepted standards. Most radiation experts agree that levels and releases that are within these regulations and standards will not have a significant effect on the quality of the human environment. The assessment analyzes the possible impact of release of radioactive patients, the transportation of byproduct material for medical use, storage, and control of aerosols and gases, waste disposal by decay-in-storage, and dose rates outside teletherapy rooms. The environmental assessment and finding of no significant impact on which this determination is based are available for public inspection at the NRC Public Document Room, 1717 H Street NW, Washington, DC. Single copies of the evironmental assessment and finding of no significant impact are available from Mr. McElroy (See "For further information contact:" heading).

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection in the NRC Public Document Room, 1717 H Street NW, Washington, DC Single Copies of the analysis may be obtained from Mr. McElroy (see "For further information contact:" heading).

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted as indicated in the ADDRESSES heading.

Regulatory Flexibility Certification

Based on the information available at this stage of the rulemaking proceeding, in accordance with section 605(b) of the Regulatory Flexibility Act of 1980, the Commission certifies that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. The NRC has issued approximately 2500 medical licensees under 10 CFR Part 35. Of these, approximately 2200 are held by institutions, and approximately 300 by individual physicians. Most of the institutional licensees are community hospitals. The Small Business Administration size standards, 13 CFR Part 121, (49 FR 5037; February 8, 1984) classify a hospital or physician's office as a small entity if its average gross annual receipts do not exceed $3.5 million. Under these size standards, some NRC medical licensees could be considered "small entities" for purposes of the Regulatory Flexibility Act.

The number of medical licensees that would fall into the small entity category does not constitute a substantial number for purposes of the Regulatory Flexibility Act.

The primary objective of the proposed rule is to simplify the medical licensing process by consolidating requirements without lessening the protection necessary for public health and safety. This will be accomplished through incorporation of frequently used license conditions into the regulations and the elimination or modification of requirements that are not essential to the protection of public health and safety. These steps will make it easier for a licensee to determine what is required to obtain a license and what is required of licensees. Therefore, there should not be a significant economic impact on these small entities.

The Commission has prepared a preliminary regulatory analysis for this proposed regulation which contains information concerning the anticipated economic effect of this regulation on licensees and presents the basis for the Commission's belief that the proposed regulation would not result in 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).

Because of the widely differing conditions under which licensees covered by this proposed regulation operate, the Commission specifically seeks public comment from small entities. Any small entity subject to this regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates:

(1) The licensee's size in terms of annual income or revenue, number of employees and, if the licensee is a treatment center, the number of beds and patients treated annually;

(2) How the proposed regulation would result in a significant economic burden on the licensee as compared to that on a larger licensee;

(3) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities;

(4) The benefits that would be gained or the detriments that would be avoided to the licensee, if the proposed regulations were modified as suggested by the Commenter; and

(5) How the regulation, as modified, would still adequately protect public health and safety.

List of Subjects

10 CFR Part 30

Byproduct material, Government contracts, Intergovernmental relations, Isoptes, 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 proposing to adopt the following revision of 10 CFR Part 35 and the following amendments to 10 CFR Parts 30, 31, 32, and 40.

1. 10 CFR Part 35 is revised to read as follows:

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

Sec.

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); §§ 35.2, 35.17, 35.30 (a) and (b), 35.31 (a) and (b), 35.32, 35.33, 35.34(a), 35.38(a), 35.38, 35.49, 35.50 (a)–(d), 35.51 (a)–(d), 35.57 (a) and (b), 35.59 (a)–(c), (e)(1), (g) and (h), 35.60, 35.61, 35.62, 35.63, 35.70 (a)–(f), 35.75, 35.80 (a)–(e), 35.90, 35.92(a), 35.100(b), 35.120, 35.200 (b) and (c), 35.204 (a) and (b), 35.205, 35.220, 35.310(a), 35.315, 35.320, 35.400, 35.406(a), 35.408 (a) and (c), 35.410(a), 35.415, 35.420, 35.500, 35.520, 35.605, 35.608, 35.610 (a) and (b), 35.615, 35.620, 35.621 (a)–(d), 35.621 (f) and (g), 35.622, 35.630 (a) and (b), 35.632 (a)–(f), 35.633 (a)–(i), 35.641 (a) and (b), 35.642 (a) and (b), 35.643 (a) and (b), 35.645 (a) and (b), 35.920, 35.910, 35.920, 35.930, 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 §§ 35.13, 35.30(c), 35.31(b), 35.32(b), 35.33(b), 35.34 (c) and (c), 35.35(b), 35.36(b), 35.37 (a)–(d), 35.53(e), 35.51(e), 35.53(c), 35.59 (d) and (e)(2), 35.59 (g) and (i), 35.70(g), 35.80(f), 35.92(b), 35.206(c), 35.210(b), 35.215(b), 35.606(b), 35.608 (b) and (d), 35.410(b), 35.415(b), 35.610(c), 35.621(e), 35.630(c), 35.632(g), 35.633(j), 35.641(c), 35.642(c), 35.643(c), 35.644 and 35.645(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 License required.

(a) No person shall 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 and 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 § 35.38, unless prohibited by license condition.

§ 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-

(b) The approved information collection requirements contained in this part appear in §§ 35.16, 35.17, 35.18, 35.30(c), 35.31(b), 35.32(a), 35.33(b), 35.34(c), 35.35(b), 35.36, 35.37(a)-(d), 35.50(e), 35.51(e), 35.53(c), 35.59 (d), (e), (g), and (i), 35.62, 35.63, 35.70(g), 35.80(f), 35.92(b), 35.204(c), 35.310, 35.315, 35.404(b), 35.406, 35.410(b), 35.606, 35.610, 35.621(e), 35.630(c), 35.632(g), 35.633 (e), and (j), 35.641(c), 35.642(c), 35.643(c), 35.644, and 35.645(c).

§ 35.13 Definitions.

"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" means as low as reasonably achievable.

"Area of use" means a portion of a physical structure 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.

"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 on humans.

"Management" means the chief executive officer.

"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.

"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 therapeutic dosage of a radiopharmaceutical differing from the prescribed dosage by more than 10 percent; or

(6) A therapeutic 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.

"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 on humans.

"Qualified teletherapy calibration expert" means the individual identified as the qualified teletherapy calibration expert on a Commission license.

"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.

"Visiting authorized user" means an authorized user who is not identified on the license of the host.

§ 35.16 Application for license, amendment, or renewal.

(a) For use sited in a medical institution, only the institution's management may apply. For 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 Regulatory Guide 10.8 Revision 2, "Guide for the Preparation of Applications for Medical Programs." 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 contained in Regulatory Guide 10.—, "Guide for the Preparation of Applications for Teletherapy Programs." A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

(d) An applicant shall mail the completed request as directed below.

(1) If the applicant is a Federal agency in Region I or is located in Connecticut, the District of Columbia, Delaware, Maine, Massachusetts, New Jersey, Pennsylvania, or Vermont, it shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region I, Material Licensing, 631 Park Avenue, King of Prussia, Pennsylvania 19406.

(2) If the applicant is a Federal agency in Region II or is located in Virginia, West Virginia, Puerto Rico, or the Virgin Islands, it shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region II, Material Licensing Section, 101 Marietta Street, Suite 2900, Atlanta, Georgia 30323.

(3) If the applicant is a Federal agency in Region III or is located in Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, or Wisconsin, it shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region III, Material Licensing Section, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

(4) If the applicant is a Federal agency in Region IV or is located in Oklahoma, Montana, South Dakota, or Wyoming, it shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region IV, Material Licensing Section, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011.

(5) If the applicant is a Federal agency in Region V or is located in Alaska, Hawaii, or Guam, it shall mail or deliver the completed application form to U.S. Nuclear Regulatory Commission, Region V, Material Licensing Section, 1450 Maria Lane, Suite 210, Walnut Creek, California 94596.

(e) If the applicant is located in a State, territory, or possession that is not mentioned in paragraphs (d) (1) through (5) of this section, it shall:

(1) Mail the completed application form, to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, or

(2) Deliver the completed application form to the Commission offices at:

(i) 1717 H Street NW., Washington, DC, or

(ii) 7915 Eastern Avenue, Silver Spring, Maryland.

§ 35.17 License amendments.

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

(a) Before it uses byproduct material for a method or type of medical use not permitted by the license issued under this part;

(b) Before it permits anyone, except a visiting authorized user described in § 35.34, to work as an authorized user under the license;

(c) Before it changes Radiation Safety Officers or Qualified Teletherapy Calibration Experts;

(d) Before it receives byproduct material in excess of the amount authorized on the license; and

(e) Before it adds to or changes the location or locations of use or mailing address identified on the license.

§ 35.18 Notifications.

A licensee shall notify the Commission by letter within thirty days when an authorized user, Radiation Safety Officer, or Qualified Teletherapy Calibration Expert, permanently discontinues performance of duties under the license. It shall mail the report to the appropriate address identified in § 35.16.

§ 35.20 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 § 35.16;

(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 for the protection of the public health and safety; and

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

§ 35.29 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.

Subpart B—General Administrative Requirements

§ 35.30 ALARA program.

(a) Each medical institution licensee shall implement a program to maintain individual and collective dose equivalents as low as reasonably achievable.

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

(1) Management, the Radiation Safety Officer, and all authorized users must participate in the establishment, implementation, and operation of the program as required by the regulations or requested by the Radiation Safety Committee.

(2) The program must include an annual review by the Radiation Safety Committee of the types and amounts of byproduct material used, occupational dose reports or summaries, 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 individuals make every reasonable effort to maintain individual and collective occupational dose as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

(c) A licensee shall retain a written description of the ALARA program for the duration of the license. The written description must include:

(1) A commitment by management to keep individual and collective occupational dose as low as reasonably achievable;

(2) A requirement that the Radiation Safety Officer brief management once each year on the byproduct material program;

(3) Personnel exposure investigational levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and

(4) 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 or recurrence.

§ 35.31 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, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Establish 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) For medical use not at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management; and

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

§ 35.32 Radiation Safety Committee.

Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of byproduct material. Management may establish more than one committee to meet these responsibilities.

(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, 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 § 35.30(b)(2).

(5) The Committee must 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) Be responsible for monitoring the institutional program to maintain individual and collective doses as low as reasonably achievable;

(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 Qualified Teletherapy Calibration Expert before submitting a license application or request for amendment or renewal;

(3) Review on the basis of safety and approve or disapprove each proposed method of use of byproduct material;

(4) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with byproduct material;

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

(7) Review annually, with the assistance of the Radiation Safety Officer, the byproduct material program; and

(8) Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.

§ 35.23 Requirement for authority and statement of responsibilities.

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

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide solutions; and

(3) Verify implementation of solutions.

(b) A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee.

§ 35.24 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 Commission or Agreement State license 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 a Commission or Agreement State license 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 copies of the records specified in this section for two years after the visiting authorized user's last use of licensed material unless the visiting authorized user has been listed as an authorized user on the licensee's license.

§ 35.26 Mobile nuclear medicine service administrative requirements.

(a) The Commission will only license mobile nuclear medicine service in accordance with Subparts D, E and H of this part and § 31.11 of this chapter to serve clients who do not have a Commission or Agreement State license for the materials listed in those Subparts.

(b) Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of byproduct material.

§ 35.30 Radiation safety program changes.

(a) A licensee may change the radiation safety procedures and equipment that are used to meet regulatory requirements and that were described in the application for license, renewal, or amendment. The licensee may also receive, use, and store licensed material (except teletherapy sources) in areas of use that were not identified in the application for license, renewal, or amendment.

(b) A licensee shall retain for the duration of the license a record of each change. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, equipment descriptions, or area floor plans, 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.

§ 35.37 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 licensee shall notify, in writing, the referring physician and the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. Licensee reports of diagnostic misadministrations are due within 10 days after the end of the calendar quarters (defined by March, June, September and December) in which they occur. These written reports must include the licensee's name; the referring physician's name; a description of the event; the effect on the patient; and the action taken to prevent recurrence. The report should not include the patient's name or other information that could lead to identification of the patient.

(d) Each licensee shall retain for ten years a record of each misadministration. 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 physican), the patient's social security number, a brief description of the event, the effect on the patient, and the action taken to prevent recurrence.

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

§ 35.38 Supervision.

A licensee who permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by § 35.2(b) shall:

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

(2) Review the supervised individual's use of byproduct material and the records kept to reflect this use;

(3) Require the authorized user to be immediately available by telephone to the supervised individual; and

(4) Require the authorized user to be able to be physically present and available to the supervised individual on one hour's notice. The supervising authorized user need not be present for each use of byproduct material.

(b) Require the supervised individual receiving, possessing, using or transferring byproduct material under § 35.2(b) to:

(1) Follow the instructions of the supervising authorized user;

(2) Follow the procedures established by the Radiation Safety Officer; and

(3) Comply with the regulations of this part and the license conditions with respect to the use of byproduct material.

§ 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) 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-emiyting 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 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.

(b) To satisfy the requirements of paragraph (a) of this section, the licensee shall:

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

(2) Calibrate two 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.

(c) To satisfy the requirements of paragraph (b) of this section, the licensee shall:

(1) Consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 10 percent; and

(2) Consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent if a correction chart or graph is conspicuously attached to the instrument.

(d) A licensee shall check each survey instrument for proper operation with the dedicated check source before and after each use. The licensee is not required to keep records of these checks.

(e) The licensee shall retain a record of each calibration required in paragraph (a) of this section for two years. To satisfy the requirements of this paragraph, the record must include:

(1) A description of the calibration procedure; and

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

(b) Assay before medical use the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries or less of a photon-emitting radionuclide 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 measurement.

§ 35.59 Authorization for calibration and reference sources.

Any person authorized by § 35.2 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 5 millicuries each;

(b) Any byproduct material listed in §§ 53.100 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 the teletherapy source test sample 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 two 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 Nuclear Regulatory Commission Regional Office listed in Appendix D of Part 20 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 materials 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 estimated 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 survey with a low range survey meter quarterly 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 exposure rate at several points in each area expressed in millirem per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the Radiation Safety Officer.

§ 35.60 Syringe shields.

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

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

§ 35.61 Vial shields.

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

§ 35.62 Syringe labels.

A licensee shall conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical's abbreviation or with the type of diagnostic study or therapy procedure to be performed.

§ 35.63 Vial shield labels.

A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

§ 35.70 Surveys for contamination and ambient radiation exposure rate.

(a) A licensee shall survey with a low range survey meter 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 low range survey meter 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 measure exposure rates as low as 0.1 milliroentgen per hour.

(d) A licensee shall establish radiation exposure rate action levels for the surveys required by paragraphs (a) and (b) of this section and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if an exposure rate exceeds an action 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 200 disintegrations per minute.

(g) A licensee shall establish removable contamination action levels for the surveys required by paragraph (e) of this section and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds the action 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 action level established for each area, the measured exposure rate at several points in each area expressed in millirem per hour or disintegrations per minute, the model number of 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 exposure rate from the patient is less than 6 milliroentgens 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 exposure rate from the patient is less than 6 milliroentgens per hour at a distance of one meter.

§ 35.80 Mobile nuclear medicine service technical requirements.

A licensee providing mobile nuclear medicine service shall:

(a) Transport to each location of use only syringes or vials containing prepared radiopharmaceuticals;

(b) Bring into each location 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 a location 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 location of use;

(e) Carry a calibrated survey meter in each vehicle that is being used to transport byproduct material, and, before leaving a client location of use, survey all radiopharmaceutical areas of use with a low range 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 exposure rate at several points in each area of use expressed in millirem per hour, the model number of 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 a fume hood or in a container with two barriers against release.

§ 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 low range survey meter set on its most sesitive 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) For paragraph (a) of this section, the licensee shall retain a record of each disposal for two years. The record must include the date of the disposal, the date on which the byproduct material was placed in storage, the model number of the survey instrument used, the background radiation exposure rate, the radiation exposure 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) A licensee may use the following prepared radiopharmaceuticals for diagnostic studies involving the measurement of uptake, dilution, or excretion:

(1) Iodine-131 as sodium iodide, iodinated human serum albumin (IHSA), labeled rose bengal, or sodium iodohippurate;

(2) Iodine-125 as sodium iodide or iodinated human serum albumin (IHSA);

(3) Cobalt-58 as labeled cyanocobalamin;

(4) Cobalt-60 as labeled cyanocobalamin;

(5) Chromium-51 as sodium chromate or labeled human serum albumin;

(6) Iron-59 as citrate;

(7) Technetium-99m as pertechnetate;

(8) 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).

(b) A licensee using a radiopharmaceutical listed in paragraph (a) of this section for a clinical procedure other than one specified in the product label or package insert instructions for use shall comply with the product label or package insert instructions regarding physical form, route of administration and dosage range.

§ 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 low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen 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 the following radiopharmaceuticals, generators, and reagent kits for imaging and localization studies:

(1) Molybdenum-99/technetium-99m generators for the elution or extraction of technetium-99m as pertechnetate;

(2) Technetium-99m as pertechnetate;

(3) Prepared radiopharmaceuticals and reagent kits for the preparation of the following technetium-99m labeled radiopharmaceuticals:

(i) Sulfur colloid;

(ii) Pentetate sodium;

(iii) Human serum albumin microspheres;

(iv) Polyphosphate;

(v) Macroaggregated human serum albumin;

(vi) Etidronate sodium;

(vii) Stannous pyrophosphate;

(viii) Human serum albumin;

(ix) Medronate sodium;

(x) Gluceptate sodium;

(xi) Oxidronate sodium;

(xii) Disofenin; and

(xiii) Succimer.

(4) Iodine-131 as sodium iodide, iodinated human serum albumin, macroaggregated iodinated human serum albumin, colloidal (microaggregated) iodinated human serum albumin, rose bengal, or sodium iodohippurate;

(5) Iodine-125 as sodium iodide or fibrinogen;

(6) Chromium-51 as human serum albumin;

(7) Gold-198 in colloidal form;

(8) Mercury-197 as chlormerodrin;

(9) Selenium-75 as selenomethionine;

(10) Strontium-85 as nitrate;

(11) Ytterbium-169 as pentetate sodium;

(12) Xenon-133 as a gas or saline solution;

(13) 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 using the radiopharmaceuticals listed in paragraph (a) of this section for clinical procedures other than those specified in the product label or package insert shall comply with the product label or package insert regarding physical form, route of administration, and dosage range.

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

(d) The following radiopharmaceuticals, when used for the listed clinical procedures, are not subject to the restrictions in paragraph (b) of this section:

(1) Technetium-99m pentetate as an aerosol for lung function studies.

§ 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 preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract.

(c) A licensee who 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 date of the test, and the initials of the individual who performed the test.

§ 35.206 Control of aerosols and gases.

(a) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by §§ 20.103 and 20.106 of this chapter.

(b) 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.

(c) A licensee shall only administer radioactive aerosols and gases in rooms

that are at negative pressure compared to surrounding rooms.

(d) 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 area of use 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 and the measured available air exhaust rate.

(e) A licensee shall post the calculated time at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

(f) A licensee shall check the operation of collection and ventilation systems 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 low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour and a portable ion chamber radiation survey instrument that has a scale with a full-scale deflection of 1 roentgen per hour.

Subpart F—Radiopharmaceuticals for Therapy

§ 35.300 Use of radiopharmaceuticals for therapy.

A licensee may use the following prepared radiopharmaceuticals:

(a) Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma;

(b) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases;

(c) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;

(d) Gold-198 as colloid for intracavitary treatment of malignant effusions;

(e) 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).

§ 35.310 Safety instruction.

(a) A licensee shall provide oral and written radiation safety instruction for all personnel caring for the patient undergoing radiopharmaceutical therapy. 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) A licensee shall provide each individual hospitalized for radiopharmaceutical therapy a private room with a private sanitary facility.

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

(c) A licensee shall post the patient's door with a "Radioactive Materials" sign and note in the patient's chart where and how long visitors may stay in the patient's room.

(d) The authorized user and Radiation Safety Officer must specifically authorize visits by individuals under age 18 on a case-by-case basis.

(e) The licensee shall 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 low range survey meter set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste.

(f) The licensee shall survey the patient's room and private sanitary facility for removable contamination 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.

(g) Within three days after administering a therapeutic dosage of iodine-131, the licensee shall measure the thyroid burden of each individual who helped prepare or administer 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.

§ 35.320 Possession of survey instruments.

A licensee authorized to use byproduct material for radiopharmaceutical therapy shall have in its possession a portable low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour and a portable ion chamber radiation survey instrument that has a scale with a full scale deflection of 1 Roentgen 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 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 exposure rate from the patient expressed as millirem per hour and measured within one meter of the patient, and the initials of the individual who made the survey.

§ 35.406 Brachytherapy sources inventory.

(a) Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately 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 room number of use or patient's name, 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 room number of use or patient's name, 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 oral and written 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) The licensee shall provide a private room to each individual hospitalized for implant therapy.

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

(c) A licensee shall post the patient's door with a "Radioactive Materials" sign and note in the patient's chart where and how long visitors may stay in the patient's room.

(d) The authorized user and Radiation Safety Officer must specifically authorize visits by individuals under age 18 on a case-by-case basis.

§ 35.420 Possession of survey instrument.

A licensee authorized to use byproduct material for implant therapy shall have in its possession a portable ion chamber radiation survey instrument that has a scale with a full scale deflection of 1 Roentgen 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 as a sealed source in a device for bone mineral analysis;

(b) Americium-241 as a sealed source in a device for bone mineral analysis; and

(c) Iodine-125 as a sealed source in a portable device for imaging.

§ 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 low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour or a portable ion chamber radiation survey instrument that has a scale with a full scale deflection of 1 Roentgen 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 the following sources.

(a) Cobalt-60 as a sealed source; and

(b) Cesium-137 as a sealed source.

§ 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 install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or 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 Amendments.

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 and individual not listed on the licensee's license to perform the duties of the qualified teletherapy calibration expert.

§ 35.610 Safety instruction.

(a) A licensee shall post written 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 Doors, interlocks, and warning systems.

(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.

§ 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 low level radiation survey instrument whose most sensitive scale has a full-scale deflection of not more than 1 milliroentgen per hour or a portable ion chamber radiation survey instrument that has a scale with a full scale deflection of 1 Roentgen per hour.

§ 35.621 Radiation monitoring device.

(a) A licensee shall install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

(b) Each radiation monitor must be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels must be observable by an individual entering the teletherapy room.

(c) Each radiation monitor must be equipped with an emergency power supply separate from the power supply to the teletherapy unit. This emergency power supply may be a battery system.

(d) Each radiation monitor must be checked for proper operation each day before the teletherapy unit is used for treatment of patients.

(e) A licensee shall maintain a record of the check required by paragraph (d) of this section for two years. The record must include the date of the check, notation that the monitor indicates when the source is and is not exposed, and the initials of the individual who performed the check.

(f) If a radiation monitor is inoperable for any reason, 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 for proper operation at the beginning of each day of use.

(g) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

§ 35.622 Viewing system.

A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

§ 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 factors that were deduced, 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.

§ 35.633 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 accuracy;

(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 then be made using 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. 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 8401, Washington, DC. 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.

(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 a qualified teletherapy calibration expert.

(g) A licensee shall retain a record of each calibration for the duration of the license. 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, the measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, and the signature of the qualified teletherapy calibration expert.

§ 35.633 Periodic spot-checks.

(a) A licensee authorized to use teletherapy units for medical use shall perform spot-checks on each teletherapy unit once in each calendar month.

(b) To satisfy the requirement of paragraph (a) of this section, measurements must include determination of:

(1) Timer accuracy;

(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; 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).

(c) A licensee shall use the dosimetry system described in § 35.630(b) to make the measurement required in paragraph (b)(5) of this section.

(d) A licensee shall perform measurements required by paragraph (a) of this section in accordance with procedures established by the qualified teletherapy calibration expert. That individual need not actually perform the spot-check measurements.

(e) A licensee shall have the qualified teletherapy calibration expert review the results of each spot-check within 15 days. The qualified teletherapy calibration expert 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.

(f) A licensee authorized to use a teletherapy unit for medical use shall perform spot-checks of each teletherapy facility once in each calendar month.

(g) To satisfy the requirement of paragraph (f) of this section, checks must 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.

(h) A licensee shall lock the control console in the off position if any door interlock malfunctions. The licensee may not use the unit until the interlock system is repaired.

(i) A licensee shall promptly repair any system identified in paragraph (g) of this section that is not operating properly.

(j) A licensee shall retain a record of each spot-check required by paragraphs (e) and (f) of this section for two years. The record must include the date of the spot-check, the manufacturer's names, 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, the measured timer accuracy, 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 measured timer accuracy for a typical treatment time, the calculated on-off error, the estimated 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.

§ 35.641 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 to verify that:

(1) The maximum and average radiation levels 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 milliroentgens per hour and 2 milliroentgens 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 quantities in restricted areas adjacent to the treatment room are not likely to cause personnel exposures in excess of the limits specified in § 20.101 of this chapter; and

(ii) Radiation quantities in unrestricted areas adjacent to the

treatment room 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 quantity 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.

§ 35.642 Safety checks for teletherapy facilities.

(a) A licensee shall promptly check all systems listed in § 35.633(g) 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 § 35.633(g), 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.

§ 35.643 Modification of teletherapy unit or room before beginning a treatment program.

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:

(a) Either equip the unit with stops or add additional radiation shielding to ensure compliance with § 20.105(b);

(b) Perform the survey required by § 35.641 again; and

(c) Include in the report required by § 35.644 the results of the initial survey, a description of the modification made to comply with paragraph (a) of this section, and the results of the second survey; or

(d) Request and receive a license amendment under § 20.105(a) of this part that authorizes radiation levels in unrestricted areas greater than those permitted by § 20.105(b).

§ 35.644 Reports of teletherapy surveys, checks, tests, and measurements.

A licensee shall mail an original and a copy of the records required in §§ 35.641, 35.642, 35.643, and the output from the teletherapy source expressed as Roentgens per hour at a distance of one meter from the source and determined during the full calibration required in § 35.632, to the appropriate Commission Regional Office listed in § 35.16 of this part within thirty days following completion of the action that initiated the record requirement.

§ 35.645 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.

(d) Amendment to teletherapy licenses that extended the time interval for the inspection and servicing requirement of paragraph (a) of this section that were in effect on March 4, 1983 remain in effect and are not rescinded by this section.

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:

(a) Be certified by:

(1) American Board of Health Physics in Comprehensive Health Physics;

(2) American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics; or

(3) American Board of Nuclear Medicine Science in Nuclear Medicine Science; or

(b) Have had 200 hours of classroom and laboratory training and one year of experience as follows:

(1) 100 hours of radiation physics and instrumentation;

(2) 30 hours of radiation protection;

(3) 20 hours of mathematics pertaining to the use and measurement of radioactivity;

(4) 20 hours of radiation biology;

(5) 30 hours of radiopharmaceutical chemistry; and

(6) One year of full time experience in radiation safety 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 for those byproduct material uses that come within the Radiation Safety Officer's responsibilities.

§ 35.901 Training for experienced Radiation Safety Officer.

An individual identified as a Radiation Safety Officer on a Commission or Agreement State license on [*insert effective date of final rule*] who oversees only the use of byproduct material for which the licensee was authorized on that date 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 listed 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 with special competence in nuclear radiology by the American Board of Radiology; or

(3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or

(b) Has completed 80 hours of instruction in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and 40 hours of supervised clinical experience.

(1) To satisfy the basic instruction requirement, the classroom and laboratory instruction must include:

(i) 25 hours of radiation physics and instrumentation;

(ii) 25 hours of radiation protection;

(iii) 10 hours of mathematics pertaining to the use and measurement of radioactivity;

(iv) 10 hours of radiation biology; and

(v) 10 hours of radiopharmaceutical chemistry.

(2) To satisfy the requirement for supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and must include:

(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 listed 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 with special competence in nuclear radiology by the American Board of Radiology; or

(3) Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or

(b) Has completed 200 hours of instruction in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience and 500 hours of supervised clinical experience.

(1) To satisfy the basic instruction requirement, the classroom and laboratory training must include:

(i) 100 hours of radiation physics and instrumentation;

(ii) 30 hours of radiation protection;

(iii) 20 hours of mathematics pertaining to the use and measurement of radioactivity;

(iv) 30 hours of radiopharmaceutical chemistry; and

(v) 20 hours of radiation biology.

(2) To satisfy the requirement for supervised work experience, training must be under the supervision of an authorized user at a medical institution and must include:

(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 emergency procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

(3) To satisfy the requirement for supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and must include:

(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 a radiopharmaceutical listed in § 35.300 for therapy to be a physician who:

(a) Is certified in nuclear medicine by the American Board of Nuclear Medicine; or

(b) Has completed 80 hours of instruction in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(i)

(i) 25 hours of radiation physics and instrumentation;

(ii) 25 hours of radiation protection;

(iii) 10 hours of mathematics pertaining to the use and measurement of radioactivity; and

(iv) 20 hours of radiation biology;

(2) To satisfy the requirement for supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and must include:

(i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals;

(ii) Use of soluble phosphorus-32 for the treatment of polycythemia vera, leukemia, or bone metastases in 3 individuals;

(iii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals; and

(iv) Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in 3 individuals.

§ 35.940 Training for therapeutic use of brachytherapy sources.

Except as provided in § 35.970, the licensee shall require the authorized user using 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 a 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 completed 200 hours of instruction in basic radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of three years of supervised clinical experience.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(i) 110 hours of radiation physics and instrumentation;

(ii) 40 hours of radiation protection;

(iii) 25 hours of mathematics pertaining to the use and measurement of radioactivity; and

(iv) 25 hours of radiation biology.

(2) To satisfy the requirement for supervised work experience, training must be under the supervision of an authorized user at an institution and must include:

(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) Using administrative controls to prevent the misadministration of byproduct material; and

(v) Using emergency procedures to control byproduct material.

(3) To satisfy the requirement for a period of supervised clinical experience, training must include 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. The supervised clinical experience must include:

(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 using only strontium-90 ophthalmic radiotherapy to be a physician who:

(a) Is certified in radiology or therapeutic radiology by the American Board of Radiology; or

(b) Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction 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.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(i) 8 hours of radiation physics and instrumentation;

(ii) 8 hours of radiation protection;

(iii) 4 hours of mathematics pertaining to the use and measurement of radioactivity; and

(iv) 8 hours of radiation biology.

(2) To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training must be under the supervision of an authorized user at a medical institution and must include the use of strontium-90 for the ophthalmic treatment of five individuals that includes

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Followup and review of each individual's case history.

§ 35.990 Training for use of sealed sources for diagnosis.

Except as provided in § 35.970, the licensee shall require the authorized user using a sealed source in a device listed in § 35.300 to be a physician, dentist, or podiatrist who:

(a) Is certified in

(1) Radiology, diagnostic radiology with special competence in nuclear 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 completed 8 hours of instruction in basic radioisotope handling techniques specifically applicable to the use of the device. To satisfy the requirement for instruction, the training must include:

(1) 3 hours of radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(2) 3 hours of radiation biology; and

(3) 2 hours of radiation protection and training in the use of the device for the purposes authorized by the license.

§ 35.960 Training for teletherapy.

Except as provided in § 35.970, the licensee shall require the authorized user using 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 completed 200 hours of instruction in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

(1) To satisfy the requirement for instruction, the classroom and laboratory training must include:

(i) 110 hours of radiation physics and instrumentation;

(ii) 40 hours of radiation protection;

(iii) 25 hours of mathematics pertaining to the use and measurement of radioactivity; and

(iv) 25 hours of radiation biology.

(2) To satisfy the requirement for supervised work experience, training must be under the supervision of an authorized user at an institution and must include:

(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.

(3) To satisfy the requirement for a period of supervised clinical experience, training must include 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. The supervised clinical experience must include:

(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 qualified teletherapy calibration expert.

The licensee shall require the qualified teletherapy calibration expert to:

(a) Be 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) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a qualified teletherapy calibration expert at a medical institution. To satisfy this requirements, the neophyte qualified teletherapy calibration expert must have performed the tasks listed in §§ 35.59, 35.632, 35.633, and 35.641 of this part under the supervision of a qualified teletherapy calibration expert during the year of work experience.

§ 35.970 Training for experienced authorized users.

Physicians, dentists, or podiatrists identified as authorized users for the human use of byproduct material on a Commission or Agreement State license on [*insert effective date of final rule*] 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 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 continuing 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;

(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 violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954.

(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 section 161, and cited in the authority citation at the beginning of this part for the purposes of section 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 [*insert effective date of final rule*] and has not been renewed, then the requirements in the license will 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, as amended (42 U.S.C. 2201); sec. 201, 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 in the practice of medicine.

* * * * *

(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 on humans.

(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 on humans.

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 maintain the records required by § 35.204.

PART 31—GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

5. The authority citation for Part 31 continues to read as follows:

Authority: Sec. 161, as amended (42 U.S.C. 2201); sec. 201, as amended (42 U.S.C. 5481).

6. 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) No person shall receive, acquire, possess, use, or transfer byproduct material pursuant to 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;

(2) Has a license that authorizes the medical use of byproduct material and that expires before (*insert five years after effective date of final rule*); or

(3) Has a license that authorizes the medical use of byproduct material and also authorizes the use of byproduct material consistent with the requirements of this section.

* * * * *

PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIALS

7. The authority citation for Part 32 continues to read as follows:

Authority: Sec. 161, as amended (42 U.S.C. 2201); sec. 201, as amended (42 U.S.C. 5481).

§ 32.70 [Removed]

8. Section 32.70 is removed.

9. In § 32.72 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 group licenses.

(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 radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed to use byproduct material listed in §§ 35.100, 35.200, or 35.300, as appropriate, or under an equivalent license of an Agreement State.

* * * * *

10. 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.

* * * * *

11. 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 (name of source or device) is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed to use byproduct material identified in §§ 35.58, 35.400, or 35.500, as appropriate, or under an equivalent license of an Agreement State.

* * * * *

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

12. The authority citation for Part 40 continues to read as follows:

Authority: Sec. 161, as amended (42 U.S.C. 2201); sec. 201, as amended (42 U.S.C. 5481).

13. 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, D.C., this 22nd day of July 1985.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 85–17233 Filed 7–25–85; 8:45 am]

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

DEC 07 1982

TO ALL MEDICAL LICENSEES AND COMMENTERS

Enclosed is a Federal Register notice that concerns revised training and experience criteria for physicians who request authorization to use reactor produced radioactive isotopes (byproduct material) in nuclear medicine procedures, including cardiovascular nuclear medicine.

This notice is of primary interest to cardiology and nuclear medicine (radiology) physicians, especially those involved with physician training programs.

The effective date of the revision is July 1, 1984. This revision does not affect physicians who are currently authorized to perform nuclear medicine procedures, nor those who begin their training prior to the effective date.

Handy L. Miller

Handy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosure: Federal Register
Notice

Revised Training and Experience Criteria for Nuclear Medicine Physicians

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of revised training and experience criteria for physicians who apply for authorization to perform nuclear medicine procedures.

SUMMARY: The Nuclear Regulatory Commission is publishing revised training and experience criteria for physicians who request authorization to use reactor-produced radioactive isotopes (byproduct material) in nuclear medicine procedures. This revision increases the minimum time appropriate for a physician to obtain acceptable training and experience for authorization to perform diagnostic nuclear medicine studies.

EFFECTIVE DATE: July 1, 1984. This revision does not affect physicians who begin their nuclear medicine training prior to the effective date.

FOR FURTHER INFORMATION CONTACT: Joseph DelMedico, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards.

U.S. Nuclear Regulatory Commission, Washington, D.C., 20555, 301–427–4082.

SUPPLEMENTARY INFORMATION: NRC is revising Appendix A of Regulatory Guide 10.8. Appendix A concerns training and experience criteria for physicians who apply for authorization to use byproduct material in medical diagnosis and therapy. Regulatory Guide 10.8 describes the type and extent of information needed by the Nuclear Regulatory Commission (NRC) staff to evaluate an application for a specific license for the possession of byproduct material and its use in or on humans. This type of license is provided for under 10 CFR Part 35, "Human Uses of Byproduct Material." The revision of Appendix A is based upon the recommendation of NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI).

Essentially, the revised criteria indicate that physicians who apply for authorization to use byproduct material for diagnostic nuclear medicine studies, including cardiovascular nuclear medicine studies, should have a minimum of six months of special education, training, and experience in these uses. The previous criteria indicated a minimum of three months.

The revison does not affect physicians who are presently authorized to perform nuclear medicine procedures, nor physicians who begin their nuclear medicine training prior to the effective date. The effective date was chosen so as to allow the various training programs sufficient time to restructure their curricula.

Background

The revised Appendix A evolved from proposals initiated by the medical community to reflect the training believed necessary for a physician to use licensed materials safely and to protect workers, patients, and the public from unnecessary radiation exposure. This topic was discussed at public meetings held on January 18, 1980, August 18, 1980, and August 31, 1981. Information concerning these meetings was published in the **Federal Register** prior to each meeting (44 FR 73170, 45 FR 42904, and 46 FR 32354). Transcripts of these meetings are available from NRC's Public Document Room at 1717 H Street, NW., Washington, D.C.

A **Federal Register** notice that the new criteria were under consideration and that public comments were invited was published on January 22, 1982 (47 FR 3228). The Commission received 232 comment letters, of which 159 supported the new criteria, 36 expressed support but suggested specific changes, and 33 expressed opposition. Most of the opposing comments either supported or actually enclosed a copy of the position taken jointly by the American College of Cardiology (ACC) and the American Heart Association (AHA). All comments were carefully considered and, wherever possible, the new criteria were changed to take them into account. Copies of the comment letters are available for inspection at NRC's Public Document Room.

Discussion of Public Comments

A. Comments of an Editorial Nature

All comments of an editorial nature were accommodated in the new criteria. These changes included: (a) Revision of Section VII.A to eliminate confusion concerning colloidal gold 198, which is currently not in use; (b) modification of Section IX to include all of the radiation therapy certification boards listed in Table 1; (c) mention of the accrediting authority for osteopathic training in Table 3; (d) inclusion of xenon 133 studies in the training criteria; (e) use of the term "cardiovascular nuclear medicine" in place of the less descriptive "nuclear cardiology;" (f) modifications to emphasize that the new criteria represent the minimum that NRC finds acceptable; and (g) revision of the **Federal Register** notice to stress that the new criteria will not affect physicians who are currently authorized to perform nuclear medicine studies or physicians who begin their training prior to the effective date.

B. Comments Concerning Table 1

A number of commenters questioned why certain medical specialty certification boards were or were not included in Table 1, and whether certain procedures should or should not be authorized on the basis of various board certifications. Each individual board initiates action to become accepted by providing evidence of adequate training for certain procedures. The board sends the Commission evidence of eligibility requirements, accreditation programs, and examination procedures which assure that NRC's criteria will be met. Additional boards may be included at any time provided that they approach NRC and present this information. These submissions are examined by the staff and by appropriate members of the ACMUI. A recommendation is made to the full ACMUI at an open public meeting. The boards listed in Table 1 met the requirements specified above.

C. Comments Calling for More Stringent Criteria

Over 50 commenters stated that six months of training was minimum or not enough. Some recommended that only board-certified physicians should be authorized. Many of the commenters noted that six months of specific study in nuclear medicine may not allow enough time to satisfy the radiation safety training as well as the clinical requirements of that specialty. The increasing complexity of the field, especially as related to equipment and clinical procedures, was cited by several commenters. In determining that the published criteria are justified, the staff took into account the facts that these criteria received strong support during the public meetings and that no significant new information has been presented to support a period of training longer than six months. Commenters are therefore referred to the meeting transcripts.

D. Comments Concerning Documentation of Training and Experience

Comment: A number of comments concerned the method for documenting training and experience. One commenter suggested that NRC issue certificate-type credentials to all qualified physicians. The commenter stated that the certificate would be convenient for physicians changing jobs. The premise was that a physician, once licensed, could thereafter show a new employer or radiation safety committee the certificate as evidence that NRC accepted his credentials.

Response: The staff feels that the current Supplements A and B of Form NRC 313M are adequate for documenting training and experience. Physicians authorized as users on NRC licenses may make copies of the license to present to a new employer as evidence of such approval.

E. Comments Concerning the Medical Competence of Physician-Users

Comment: Several commenters asked NRC to notify physican and hospital licensees that NRC authorization relates only to radiation safety and not to medical competence.

Response: In 1979, the NRC published "Regulation of the Medical Uses of Radioisotopes: Statement of General Policy" (44 FR 8242). The third and final specific area in the policy stated, "The NRC will minimize intrusion into medical judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine." The staff has and will

continue to interpret this to mean NRC approval of a physician to use byproduct materials in humans for treatment and diagnosis relates to radiation safety and to training sufficient to avoid unwarrented radiation exposure to the physician, medical workers and the public, inlcuding patients. Such authorization does not imply a standard for professional clinical achievement as would be evidenced by a medical specialty board certification. Further clarification of NRC's position is being considered in connection with a separate revision to Part 35 of Title 10, Code of Federal Regulations. This revision is under way at the present time.

F. Comments Opposing the New Criteria

The concerns of those who object to the criteria (as paraphrased by the NRC staff) and the staff response are summarized below:

Comment: The current criteria have been more than adequate in protecting the public; therefore, there is no basis for an increase.

Response: The current criteria have been adequate because they have been revised whenever necessary to keep pace with developments in nuclear medicine, a rapidly expanding, technology based clinical specialty. In 1972, the Atomic Energy Commission, NRC's predecessor agency, had physician training criteria that involved only 30 hours of training in basic radioisotope handling techniques. Since that time, the criteria have been revised and increased three separate times. Transcripts of NRC's ACMUI meetings show that each change was made in response to the increasing complexity of the field, not in response to accidents or incidents.

The transcripts of the public meetings concerning the present changes indicate that there has been an increase in the complexity of the diagnostic interpretation of nuclear medicine studies and that this has resulted in a concomitant increase in the portion of the time that is allotted to this aspect of training during the three month programs. It is apparent from the transcripts that, in order to stay within the three month limit, many programs have made proportionate decreases in the aspects of training involving basic radioisotope handling techniques and actual experience handling unsealed radioactive materials. In order to maintain the previous level of training in these last two areas, the increase to program of six months duration is justified.

The concept of concurrent training in three month programs originated because such programs were offered as part of the residency training leading to certification by the American Board of Radiology (ABR). The ABR and AOBR programs have recognized the need for a minimum of six months of training and experience and have voluntarily taken action to restructure their programs accordingly. The new programs will be in place by July 1, 1984. NRC's action will maintain its criteria equal to the minimum standards set by the profession.

Comment: Technetium 99m is the only NRC-licensed material used in cardiovascular nuclear medicine studies and its properties make it uniquely safe for handling and use; therefore, an increase in the training and experience criteria is unwarranted.

Response: The criteria in Section V of Appendix A apply to physicians who use or supervise the use of molybdenum 99/technetium 99m generators and reagent kits to prepare Tc-99m labeled radiopharmaceuticals. These materials do present serious safety hazards if they are misused or improperly supervised. Tc-99m radiopharmaceuticals are also available in prepared, unit dose form, ready for patient injection. If a physician wishes to use this form for one or two types of diagnostic studies and accepts a limited possession limit, he or she may apply under the provisions of Appendix A, Section VI.

Comment: Through their training and experience with cardiac catherization and angiocardiography, cardiologists are already familiar with the principles of radiation exposure.

Response: Any hours of training that are specifically applicable to basic handling techniques using unsealed radioisotopes may be included in the physician's application to NRC.

Comment: There are important risks if cardiovascular nuclear medicine studies are performed by physicians who lack formal training in cardiovascular hemodynamics, coronary artery disease physiology, exercise testing and exercise physiology, arrhythmia detection, and cardiopulmonary resuscitation.

Response: The implication here is that NRC should not allow physicians with little or no training in cardiovascular disease to perform cardiovascular nuclear medicine studies. Training and experience criteria set by NRC relate specifically to safe handling of the reactor-produced radioisotopes that are used during the medical procedure. NRC does not regulate the quality of medical practice. Matters of medical competence have traditionally been addressed by the State medical licensing authorities and by peer review groups and professional societies within the medical profession. As stated previously, NRC published its decision to minimize intrusion into areas traditionally considered to be a part of the practice of medicine in 1979 (44 FR 8242).

Comment: If the training and experience criteria are increased to six months, the only aspect that would be augmented for cardiologists would be in the area of interpretation of scans.

Response: NRC believes that actual experience handling unsealed radioactive materials (Item B of Table 2, Appendix A) should be augmented. Presently there is little incentive for a physician-in-training to acquire such experience. It is the physician, however, who is listed on the NRC license as the authorized user and who may be listed as the radiation safety officer. The physician is responsible for the use of the material. To fulfill this responsibility, the physician must have had adequate "hands-on" experience during the training period.

Comment: Additional requirements will serve to discourage persons well trained in cardiology from participating in cardiovascular nuclear medicine and will therefore deprive the public of the expertise that cardiologists lend to these studies.

Response: The NRC licensing process does not prohibit cardiologists or any other physicians from being present, providing patient care, and participating in the diagnosis during cardiovascular nuclear medicine procedures. The license specifies only what physician (or physicians) may use or supervise the use of the radioactive material that is needed to perform the procedure. In many hospitals, these procedures are performed as a coordinated effort between the nuclear medicine physician and the cardiologist.

The revision to Appendix A of Regulatory Guide 10.8 is printed in its entirety below:

Appendix A—Acceptable Training and Experience for Medical Uses of Byproduct Material

I. General Criteria

Paragraphs 35.11 and 35.12 of 10 CFR Part 35 provide that the Commission will approve a license application for medical use if it determines, among other things, that the physician designated as the individual user has adequate experience in the proposed use, the handling and administration of isotopes, and where applicable, the

clinical management of radioactive patients. In addition, § 30.33 of 10 CFR Part 30 requires that applicants be qualified by training and experience to use licensed material for the purpose requested in the application.

This appendix outlines training and experience criteria that the Commission, with the assistance of its Advisory Committee on the Medical Uses of Isotopes (ACMUI), has found acceptable for physicians [1] who wish to use byproduct material for human use.[1] We recommend that this training and experience be obtained in a formal, accredited training program for resident physicians.

Physician training and experience can be examined on a case-by-case basis. A physician wishing to use radioactive material but not having the training and experience described, may submit an application listing specific qualifications; and these will be reviewed by the Commission with the assistance of the ACMUI.

II. Acceptance of Medical Specialty Board Certification

Certification by the medical specialty boards listed in Table 1 will be accepted as evidence that a physician has had adequate training and experience for the corresponding procedures listed in the table.

III. Documenting Training and Experience

Supplements A and B of Form NRC 313M are used to document training and experience. Physicians who wish to qualify on the basis of board certification need only complete Items 1, 2, and 3 on Supplement A. Other applicants should submit Supplements A and B with all items completed. A separate Supplement B form should be completed and signed by each preceptor who provided training or supervised experience.

IV. Time Limitation on Acceptable Training and Experience

Training and experience must have been obtained within five years of the date of the application, or else the applicant must demonstrate continuing involvement in the procedures since the time of training.

V. Training for Routine Diagnostic Procedures (Groups I–III,[2] Including Cardiovascular Nuclear Medicine)

To qualify as adequately trained to use byproduct material listed in Groups I, II, and III of § 35.100, 10 CFR Part 35, a physician should have the training and experience listed in Table 2.

VI. Training for Specific Diagnostic Procedures

A physician who wishes to be authorized for only one or two specific diagnostic procedures should have training in basic radioisotope handling techniques and clinical experience commensurate with the types, quantities and uses of byproduct material being requested. Such requests will be examined case-by-case by the Commission with advice from the ACMUI.

VII. Training for Therapy Procedures Involving Radiopharmaceuticals (Groups IV and V)

A. Physicians who meet the criteria for Groups I–III may qualify to perform specific therapy procedures with the following clinical experience:

1. I–131 for treatment of hyperthyroidism and/or cardiac conditions:

Clinical experience in the diagnosis of thyroid function and active participation in the treatment of ten patients.

2. Soluble P–32 for treatment of polycythemia vera, leukemia, and/or bone metastases:

Active participation in the treatment of three patients with any combination of these three conditions.

3. Colloidal P–32 for intracavitary treatment:

Active participation in the intracavitary treatment of three patients using colloidal forms of either P–32 or Au–198

4. I–131 for treatment of thyroid carcinoma:

Clinical experience in diagnosis of thyroid function, personal participation in the treatment of ten patients with hyperthyroidism and/or cardiac dysfunction, and active participation in the treatment of three patients with thyroid carcinoma.

5. Colloidal Au–198 for intracavitary treatment:

Active participation in the intracavitary treatment of three patients using colloidal forms of either Au–198 or P–32.

B. To perform *only* Group IV and V therapy procedures, physicians who do *not* meet the criteria for Groups I–III need to obtain the specific clinical experience listed in VII. A. above and, as a minimum:

	Hours
Training in basic radioisotope handling techniques specifically applicable to the use of unsealed sources for therapy procedures, including	80
1. Radiation physics and instrumentation	25
2. Radiation protection	25
3. Mathematics pertaining to the use and measurement of radioactivity	10
4. Radiation biology	20

VIII. Training for Therapy Procedures Involving Sealed Sources (Group VI)

To qualify as adequately trained to use byproduct material listed in Group VI of § 35.100, 10 CFR Part 35, a physician should have the training and experience listed in Table 3.

When a physician is not board certified in one of the radiation therapy specialties listed in Table 1, his or her training will be reviewed with the assistance of the ACMUI. In addition to Supplements A and B as described in Section III. above, the applicant should submit letters of evaluation from each physician who served as preceptor. These letters of evaluation should describe the scope and extent of the applicant's training and experience and should state whether, in the opinion of the preceptor, the applicant is fully qualified to independently perform Group VI therapy procedures.

IX. Training for Physicians Wishing To Use SR–90 Eye Applicators Only

To qualify as adequately trained to use a Sr–90 eye applicator only, a physician should submit evidence of certification by one of the radiation therapy specialty boards listed in Table 1 or, as a minimum, evidence of:

A. Active practice in therapeutic radiology or opthalmology.

	Hours
B. Training in basic radioisotope handling techniques, including	24
a. Radiation physics and instrumentation	6
b. Radiation protection	6
c. Mathematics pertaining to the use and measurement of radioactivity	4
d. Radiation biology	8

This information should be submitted on Supplement A of Form NRC–313M. The hours listed next to each of the four subjects are suggested minimum values and should not be interpreted as specific requirements.

C. Active participation in the treatment of five patients (to be submitted on Preceptor Statement, Form NRC 313M, Supplement B).

"Active participation" should include supervised examination of patients, collaboration and calculations concerning the dose to be administered, administration of the dose to the patient, followup and study of patient case histories.

[1] As defined in 10 CFR 35.3

[2] Physicians authorized for Group II or III may also use Xenon-133.

TABLE I.—ACCEPTANCE OF MEDICAL SPECIALTY BOARD CERTIFICATION

Board	Specialty	Procedures
American Board of Nuclear Medicine	Nuclear Medicine	Groups I–V.
American Board of Radiology	Diagnostic Radiology with Special Competence in Nuclear Radiology	Groups I–III
	Radiology	Group VI.
	Therapeutic Radiology	Group VI.
American Osteopathic Board of Radiology	Diagnostic Radiology	Groups I–III.
	Radiology [1]	Groups I–III.
	Radiation Oncology	Groups V & VI.
British Faculty of Radiology [1] [2]	Radiology	Group VI.
British Royal College of Radiology [1]	Radiology	Group VI.
Canadian Royal College of Physicians and Surgeons.	Therapeutic Radiology	Group VI.

[1] Board examination must have been passed within five years prior to the date of the application, or else the physician must demonstrate continuing involvement in the procedures since the time of the board certification.
[2] Applicants must also submit evidence of specialization in radiotherapy.

Table 2.—Miminum Acceptable Training for Routine Diagnostic Procedures (Groups I–III)

Concurrent Training in Six month Programs. The criteria specified below may be satisfied concurrently in a formal intergrated six-month training program. Note, however, that all of the requirements in Sections A., B. and C. must be fully intergrated into the program. Physicians who do not recieve their training in such a program should obtain the specified number of hours in each area:

	Hours
A. Training in basic radioisotope handing techniques specifically applicable to the use of unsealed sources. This training should consist of lectures, laboratory sessions, discussion groups, and supervised experence in a nuclear medicine laboratory in the following areas	200
1. Radiation physics and instrumentation	100
2. Radiation protection	30
3. Mathematics pertaining to the use and measurement of radioactivity	20
4. Radiation biology	20
5. Radiopharmaceubical chemistry	30

The hours listed next to each of the five subects above are suggested values and should not be interperted as specific requirements.

B. Experience handling unsealed radioactive materials under the supervision of a qualified instructor (500 hours). This experience should cover the types and quantities of byproduct material requested in the application and should include:

1. Ordering, recieving and unpackaging radioactive materials safely, including performance of the related radiation surveys.

2. Calibration of dose calibrators and diagnostic instrumentation, and performance of operational checks on survey meters.

3. Calculation, preparation and calibration of patient doses, including radiation safety considerations.

4. Administration of doses to patients, including proper use of syringe shields.

5. Appropriate internal control procedures to prevent the misadministration of materials to patients.

6. Emergency procedures to handle and contain spilled materials safely, including related decontamination procedures.

7. Elution of Tc–99m from generator systems, assay and testing of the eluate for Mo–99 and alumina contamination, and processing the eluate with reagent kits to prepare Tc–99m labeled radiopharmaceuticals. (Required when physicians apply for Group III authorization.)

C. Supervised clinical training in an institutional nuclear medicine (or cardiovascular nuclear medicine) program (500 hours). The clinical training should cover all appropriate types of diagnostic procedures and should include:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed.

2. Selection of the proper radiopharmaceutical and dosage, calculation of the related radiation dose and collaboration in the interpretation of the radioisotope test results.

3. Follow-up of patients when required.

4. Study and discussion of case histories with preceptor to establish the most appropriate diagnostic procedures, limitations, contraindications, etc.

Table 3.—Minimum Acceptable Training for Therapy Procedures Involving Sealed Sources (Group VI)

To qualify as adequately trained to use byproduct material listed in Group VI of § 35.100, 10 CFR Part 35, a physician should have:

	Hours
A. Training in basic radioisotope handing techniques specifically applicable to the use of sealed sources for therapy procedures consisting of lectures, laboratory sessions, discussion groups, and supervised experience in the following areas	200
1. Radiation physics and instrumentation	110
2. Radiation protection	40
3. Mathematics pertaining to the use and measurement of radioactivity	25
4. Radiation biology	25

The hours listed next to each of the four subjects above are suggested values and should not be interpreted as specific requirements.

B. Experience handling sealed radionuclide therapy sources under the supervision of a qualified instructor (500 hours). This experience should cover the types and quantities of byproduct material requested in the application and should include:

1. Ordering, receiving, and unpackaging sealed sources safely, including performance of the related radiation surveys.

2. Performance of operational checks on ion chambers and survey meters.

3. Safe handling of sealed sources during preparation, insertion and removal.

4. Quality control and emergency procedures.

C. Clinical training in Group VI procedures: Active practice in therapeutic radiology with a minimum of 3 years experience of which at least 1 year should have been 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.

Dated at Silver Spring, Md this 27th day of September 1982.

For the Nuclear Regulatory Commission.

Richard E. Cunningham,

Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards.

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PART 35

HUMAN USES OF BYPRODUCT MATERIAL

Sec.

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); Section 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); §§ 35.2, 35.14 (b), (e) and (f), 35.21(a), 35.22(a), 35.24, and 35.31 (b) and (c) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.14(b)(5) (ii), (iii) and (v) and (f)(2), 35.27 and 35.31(d) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

§ 35.1 Purpose and scope.

This part prescribes regulations governing the licensing of byproduct material for human uses. It includes special requirements for issuance of specific licenses authorizing human use of byproduct material, general licenses for human use of byproduct material of specified types and forms, and certain regulations governing the holders of such specific and general licenses. The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of Part 30 of this chapter apply to applications and licenses subject to this part.

§ 35.2 License requirements.

No person subject to the regulations in this chapter shall receive, possess, use, or transfer byproduct material for any human use except in accordance with a specific or general license issued pursuant to the regulations in this part and Parts 30 and 32 or 33 of this chapter.

§ 35.3 Definitions.

As used in this part:

(a) "Human use" means the internal or external administration of byproduct material, or the radiation therefrom, to human beings;

(b) "Physician" means an individual licensed by a State or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to dispense drugs in the practice of medicine.

§ 35.4 Application form for specific licenses.

Applications for specific licenses for human use under §§35.11, 35.12, and 35.13 shall be filed on form NRC-313M, "Application for Materials License Medical."

SPECIFIC LICENSES

§ 35.11 Specific licenses for human use of byproduct material in institutions.

An application by an institution for a specific license for human use of byproduct material will be approved if:

(a) The applicant satisfies the general requirements specified in §30.33 of this chapter;

(b) The applicant has appointed a radiation safety committee to oversee the use of licensed material throughout the institution and to review the institution's radiation safety program. Membership of the committee must include at least the following: an authorized user for each type of use permitted by the license, a representative of the nursing staff, a representative of the institution's management, and the Radiation Safety Officer;

(c) The applicant possesses adequate facilities for the clinical care of patients;

(d) The physician designated on the application as the individual user has substantial experience in the proposed use, the handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients; and

(e) If the application is for a license to use unspecified quantities or multiple types of byproduct material, the applicant has previously received a reasonable number of licenses for a variety of byproduct materials for a variety of human uses.

§ 35.12 Specific licenses to individual physicians for human use of byproduct material.

(a) An application by an individual physician or groups of physicians for a specific license for human use of byproduct material will be approved if:

(1) The applicant satisfies the general requirements specified in §30.33 of this chapter;

(2) The application is for use in the applicant's practice in an office(s) outside a medical institution;

(3) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and

(4) The applicant has extensive experience in the proposed use, the handling and administration of radioisotopes, and where applicable, the clinical management of radioactive patients. (The physician(s) shall furnish suitable evidence of such experience with the application. A statement from the medical isotope committee in the institution where the applicant acquired experience, indicating its amount and nature, may be submitted as evidence of such experience.)

(b) The Commission will not approve an application by an individual physician or group of physicians for a specific license to receive, possess or use byproduct material on the premises of a medical institution unless:

(1) The use of byproduct material is limited to:

(i) The administration of radiopharmaceuticals for diagnostic or therapeutic purposes;

(ii) The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;

(iii) The performance of in vitro diagnostic studies; or

(iv) The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation, and diagnostic instrumentation;

(2) The physician brings the byproduct material with him and removes the byproduct material when he departs. (The institution cannot receive, possess or store byproduct material other than the amount of material remaining in the patient); and

(3) The medical institution does not hold a byproduct material license under §35.11.

§ 35.13 Specific licenses for human use of byproduct material in sealed sources.

An application for a specific license for use of a sealed source for human use will be approved if:

(a) The applicant satisfies the general requirements specified in §30.33 of this chapter; and

(b) The applicant or, if the application is made by an institution, the individual user (1) has specialized training in the therapeutic use of the radioactive device considered (teletherapy unit, beta applicator, etc.) or has experience equivalent to such training; and (2) is a physician.

§ 35.14 Specific licenses for certain groups of medical uses of byproduct material.

(a) Subject to the provisions of paragraphs (b), (c), and (d) of this section, an application for a specific license pursuant to §35.11, §35.12, or §35.13 for any medical use or uses of byproduct material specified in one or more of Groups I to VI, inclusive, of §35.100 will be approved for all of the uses within the group or groups which include the use or uses specified in the application if:

(1) The applicant satisfies the requirements of §35.11, §35.12, or §35.13;

(2) The applicant, or the physician designated in the application as the individual user, has adequate clinical experience in the types of uses included in the group or groups;

(3) The applicant or the physicians and all other personnel who will be involved in the preparation and use of the byproduct material have adequate training and experience in the handling of radioactive material appropriate to their participation in the uses included in the group or groups;

(4) The applicant's radiation detection and measuring instrumentation is adequate for conducting the procedures involved in the uses included in the group or groups;

(5) The applicant's radiation safety operating procedures are adequate for handling and disposal of the radioactive material involved in the uses included in the group or groups;

(b) Any licensee who is authorized to use byproduct material pursuant to one or more groups in §§35.14(a) and 35.100 is subject to the following conditions:

(1) For Groups I, II, IV, and V no licensee shall receive, possess, or use byproduct material except as a radiopharmaceutical manufactured in the form to be administered to the patient, labeled, packaged, and distributed in accordance with:

(i) A specific license issued pursuant to §32.72 of this chapter; or

(ii) A specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations; or

(iii) An application filed with the Atomic Energy Commission pursuant to §32.72 of this chapter or with an Agreement State pursuant to equivalent State regulations on or before October 15, 1974 for a license to manufacture and distribute a radiopharmaceutical that the applicant distributed commercially on or before August 16, 1974, on which application the Atomic Energy Commission or the Nuclear Regulatory Commission or the Agreement State has not acted.

(2) For Group III, no licensee shall receive, possess, or use generators or reagent kits containing byproduct material or shall use reagent kits that do not contain byproduct material to prepare radiopharmaceuticals containing byproduct material, except:

(i) Reagent kits not containing byproduct material that are approved by the Commission or the Atomic Energy Commission or an Agreement State for use by persons licensed pursuant to this §35.14 and Group III of Schedule A, §35.100 or equivalent Agreement State regulations; or

(ii) Generators or reagent kits containing byproduct material that are manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to §32.73 of this chapter or by an Agreement State pursuant to equivalent State regulations; or

(iii) Generators or reagent kits that the manufacturer distributed on or before August 16, 1974 for which an application for license or approval was filed with the Atomic Energy Commission pursuant to §32.73 of this chapter or with an Agreement State pursuant to equivalent State regulations on or before October 15, 1974 on which application the Atomic Energy Commission or the Nuclear Regulatory Commission or the Agreement State has not acted.

(3) For Group VI no licensee shall receive, possess, or use byproduct material except as contained in a source or device that has been manufactured, labeled, packaged, and distributed in accordance with:

(i) A specific license issued pursuant to §32.74 of this chapter; or

(ii) A specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations; or

(iii) An application filed with the Atomic Energy Commission pursuant to §32.74 of this chapter or with an Agreement State pursuant to equivalent State regulations on or before October 15, 1974 for a license to manufacture a source or device that the applicant distributed commercially on or before August 16, 1974 on which application the Atomic Energy Commission or the Nuclear Regulatory Commission or the Agreement State has not acted.

(4) For Group III, any licensee using generators or reagent kits shall:

(i) Elute the generator, or process radioactive material with the reagent kit, in accordance with instructions approved by the Nuclear Regulatory Commission or an Agreement State and furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit;

(ii) Before administration to patients, assay each elution or extraction of technetium-99m from a molybdenum-99/technetium-99m generator to be used to determine either the total molybdenum-99 activity or the concentration of molybdenum-99. This testing shall be conducted according to written procedures and by personnel who have been specifically trained to perform the test;

(iii) Prohibit the administration to patients of technetium-99m containing more than 1 microcurie of molybdenum-99 per millicurie of technetium-99m, or more than 5 microcuries of molybdenum-99 per administered dose, at the time of administration; and

(iv) Maintain for 3 years for Commission inspection records of the molybdenum-99 test conducted on each elution from the generator.

(5) For Group VI any licensee who possesses and uses sources or devices containing byproduct material shall:

(i) Cause each source or device containing more than 100 microcuries of byproduct material with a half-life greater than thirty days, except iridium-192 seeds encased in nylon ribbon, to be tested for contamination and/or leakage at intervals not to exceed six months or at such other intervals as are approved by the Nuclear Regulatory Commission or an Agreement State and described by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure which accompanies the source or device. Each source or device shall be so tested prior to its first use unless the supplier furnishes a certificate that the source or device has been so tested within six months prior to the transfer;

(ii) Assure that the test required by paragraph (b)(5)(i) of this section is capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the source or from the surfaces of the device in which the source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission;

(iii) If the test required by paragraph (b)(5)(i) of this section reveals the presence of 0.005 microcurie or more of removable contamination, immediately withdraw the source from use and cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with the appropriate Nuclear Regulatory Commission Inspection and Enforcement Regional Office listed in Appendix D of Part 20 of this chapter, describing the equipment involved, the test results, and the corrective action taken.

Copies of such report shall be sent to the Director of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555;

(iv) Follow the radiation safety and handling instructions approved by the Nuclear Regulatory Commission or an Agreement State and furnished by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure that accompanies the source or device, and maintain such instruction in a legible and conveniently available form;

(v) Conduct a quarterly physical inventory to account for all sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the Commission and shall include the quantities and kinds of byproduct material, location of sources and devices, and the date of the inventory;

(vi) Assure that needles or standard medical applicator cells containing cobalt-60 as wire are not opened while in the licensee's possession unless specifically authorized by a license issued to him by the Atomic Energy Commission or the Commission;

(vii) Assure that patients treated with cobalt-60, cesium-137 or iridium-192 implants remain hospitalized until a source count and a radiation survey of the patient confirm that all implants have been removed.

≫ (6) Except for those radiopharmaceuticals listed in paragraph (b)(7) of this section, for Groups I, II, and III any licensee using byproduct material for clinical procedures other than those specified in the product labeling (package insert) shall comply with the product labeling regarding:

(i) Chemical and physical form;

(ii) Route of administration; and

(iii) Dosage range.

(7) The following radiopharmaceutical(s) when used for the listed clinical procedure(s), are not subject to the restrictions in paragraph (b)(6) of this section:

(i) Technetium-99m pentetate as an aerosol for lung function studies.

(8) Radioactive aerosols must be administered 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.

(c) Any licensee who is licensed pursuant to paragraph (a) of this section for one or more of the medical use groups in §35.100 also is authorized to use byproduct material under the general license in §31.11 of this chapter for the specified in vitro uses without filing Form NRC-483 as required by §31.11(b); *Provided*, That the licensee is subject to the other provisions of §31.11.

(d) Any licensee who is licensed pursuant to paragraph (a) of this section for one or more of the medical use groups in §35.100 also is authorized, subject to the provisions of paragraphs (e) and (f) of this section, to receive, possess, and use for calibration and reference standards:

(1) Any byproduct material listed in Group I, Group II, or Group III of Schedule A, §35.100, with a half-life not longer than 100 days, in amounts not to exceed 15 millicuries total;

(2) Any byproduct material listed in Group I, Group II, or Group III of Schedule A, §35.100 with half-life greater than 100 days in amounts not to exceed 200 microcuries total;

(3) Technetium-99m in amounts not to exceed 30 millicuries;

(4) Any byproduct material, in amounts not to exceed 3 millicuries per source, contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with:

(i) A specific license issued by the Commission pursuant to §32.74 of this chapter; or

(ii) A specific license issued to the manufacturer by an Agreement State pursuant to equivalent State regulations; or

(iii) An application filed with the Atomic Energy Commission pursuant to §32.74 of this chapter or with an Agreement State pursuant to equivalent State regulations on or before October 15, 1974 for a license to manufacture a source that the applicant distributed commercially on or before August 16, 1974, on which application the Atomic Energy Commission or the Nuclear Regulatory Commission or the Agreement State has not acted.

(e)(1)(i) Any licensee who possesses sealed sources as calibration or reference sources pursuant to paragraph (d) of this section shall cause each sealed source containing byproduct material, other than hydrogen-3, with a half-life greater than thirty days in any form other than gas to be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the sealed source shall not be used until tested, *Provided, however*, That no leak tests are required when:

(*a*) The source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material, or

(*b*) The sealed source is stored and is not being used; such sources shall, however, be tested for leakage prior to any use or transfer unless they have been leak tested within six months prior to the date of use or transfer.

(2) The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

(3) If the leak test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Parts 20 and 30 of this chapter. A report shall be filed within 5 days of the test with the appropriate Nuclear Regulatory Commission Inspection and Enforcement Regional Office listed in Appendix D of Part 20 of this chapter, with a copy to the Director of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555,† describing the equipment involved, the test results, and the corrective action taken;

(f) Any licensee who possesses and uses calibration and reference sources pursuant to paragraph (d)(4) of this section shall:

(1) Follow the radiation safety and handling instructions approved by the Atomic Energy Commission, the Commission, or an Agreement State and furnished by the manufacturer on the label attached to the source, or permanent container thereof, or in the leaflet or brochure that accompanies the source, and maintain such instruction in a legible and conveniently available form.

(2) Conduct a quarterly physical inventory to account for all sources received and possessed. Records of the inventories shall be maintained for inspection by the Commission and shall include the quantities and kinds of byproduct material, location of sources, and the date of the inventory.

†Amended 41 FR 16464.

Special Requirements for Teletherapy Licensees

§ 35.21 Requirement to perform full calibration measurements of teletherapy units.

(a) Any licensee authorized under § 35.13 to use teletherapy units for treating humans shall cause full calibration measurements to be performed on each teletherapy unit:

(1) Prior to the first use of the unit for treating humans;

(2) Prior to treating humans:

(i) Whenever spot-check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last full calibration corrected mathematically for physical decay;

(ii) Following replacement of the radiation 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) Full calibration measurements required by paragraph (a) of this section shall include determination of:

(1) The exposure rate or dose rate to an accuracy within ±3 percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;

(2) The congruence between the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence upon the orientation of the useful beam;

(4) Timer accuracy; and

(5) The accuracy of all distance measuring devices used for treating humans.

(c) Full calibration measurements shall be made in accordance with the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine (*Physics in Medicine and Biology*, Vol. 16, No. 3, 1971, pp. 379-396).[1]

(d) The exposure rate or dose rate values determined in paragraph (b)(1) of this section shall be corrected mathematically for physical decay for intervals not exceeding one month.

(e) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (d) of this section shall be performed by an expert qualified by training and experience in accordance with § 35.24.

§ 35.22 Requirement to perform periodic spot-check measurements of teletherapy units.

(a) Any licensee authorized under § 35.13 to use teletherapy units for treating humans shall cause spot-check measurements to be performed on each teletherapy unit at intervals not exceeding one month.

(b) Spot-check measurements required by paragraph (a) of this section shall include determination of:

(1) Timer accuracy;

(2) The congruence between the radiation field and the field indicated by the light beam localizing device;

(3) The accuracy of all distance measuring devices used for treating humans;

(4) The exposure rate, dose rate, or a quantity related in a known manner to these rates for one typical set of operating conditions; and

(5) The difference between the measurement made in paragraph (b)(4) 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).

(c) Spot-check measurements required by paragraph (a) of this section shall be performed in accordance with procedures established by an expert qualified by training and experience in accordance with § 35.24. (A qualified expert need not actually perform the spot-check measurements.) If a qualified expert does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a qualified expert within 15 days.

§ 35.23 Requirement to calibrate instruments used for full calibration and spot-check measurements.

(a) Full calibration measurements required by § 35.21 shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.

(b) Spot-check measurements required by § 35.22 shall be performed using a dosimetry system that has been calibrated in accordance with paragraph (a) of this section. Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with paragraph (a) of this section. This alternative calibration method shall have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.

§ 35.24 Qualified expert.

The licensee shall determine if a person is an expert qualified by training and experience to calibrate a teletherapy unit and establish procedures for (and review the results of) spot-check measurements. The licensee shall determine that the qualified expert:

(a) Is certified by the American Board of Radiology in Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics; or

(b) Has the following[1] minimum training and experience:

(1) A Master's or Doctor's degree in physics, biophysics, radiological physics or health physics;

(2) One year of full-time training in therapeutic radiological physics; and

(3) One year of full-time experience in a radiotherapy facility including personal calibration and spot check of at least one teletherapy unit.

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[1] This incorporation by reference provision was approved by the Acting Director of the Federal Register on August 6, 1976. Copies are available for inspection or may be obtained from U.S. Nuclear Regulatory Commission, Public Document Room, 1717 H Street, NW., Washington, D.C. 20555.

[1] Licensees that have their teletherapy units calibrated by persons who do not meet these criteria for minimum training and experience may request a license amendment excepting them from the requirements of § 35.24. The request, accompanied by the appropriate amendment fee (§ 170.31 of 10 CFR Part 170), should include the name of the proposed qualified expert, a description of his training and experience including information similar to that specified in § 35.24(b), reports of at least one calibration and spot-check program based on measurements personally made by the proposed expert within the last 10 years, and written endorsement of the technical qualifications of the proposed expert from personal knowledge by a physicist certified by the American Board of Radiology in one of the specialties listed in § 35.24(a). The individual's qualifications will be evaluated by NRC's consultants in medical physics. The amendment request should be addressed to: License Management Branch, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

§ 35.28 Requirements to install a permanent radiation monitor in teletherapy rooms and to use portable survey instruments or audible alarm dosimeters.

(a) Each licensee authorized under § 35.13 to use teletherapy units for treating humans shall install a permanent radiation monitor in each teletherapy room for continous monitoring of beam status.

(b) Each radiation monitor must be capable of providing visible notice of a teletherapy unit malfunction that may result in an exposed or partially exposed source. The visable indicator of high radiation levels must be located so as to be observable by a person entering the treatment room.

(c) Each radiation monitor must be equipped with an emergency power supply separate from the power supply to the teletherapy unit. This emergency power supply may be a battery system.

(d) Each radiation monitor must be tested for proper operation each day before the teletherapy unit is used for treatment of patients.

(e) If a radiation monitor is inoperable for any reason, any person entering the teletherapy room shall use a properly operating portable survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may have resulted in an exposed or partially exposed source. Survey instruments or dosimeters must be tested daily before use.

[49 FR 2115]

§ 35.29 Inspection and servicing of the source exposure mechanism; relief granted by certain license conditions.

(a) The licensee shall cause each teletherapy unit used to treat humans to be fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) Inspection and servicing of the teletherapy unit shall be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) Amendments to teletherapy licenses in effect as of March 4, 1983, which extended the time interval for the inspection and servicing requirement of paragraph (a) of this section shall remain in effect and are not rescinded by this section.

§ 35.27 Records.

The licensee shall maintain, for inspection by the Commission, records of the measurements, tests, corrective actions, inspection and servicing of the teletherapy unit, and instrument calibrations made under §§ 35.21 through 35.28 and records of the licensee's evaluation of the qualified expert's training and experience made under § 35.24.

(a) The following records must be preserved for five years after completion of the full calibration or after inspection and servicing:

(1) Full calibration measurements reports made under § 35.21.

(2) Records of calibration of the instruments used to make these measurements under § 35.23.

(3) Records of inspection and servicing of the teletherapy unit under § 35.28.

[49 FR 2115]

(b) Records of (1) spot-check measurements and corrective actions under § 35.22 and (2) calibration of instruments used to make spot-check measurements under § 35.23, shall be preserved for two years after completion of the spot-check measurements and corrective actions.

(c) Records of the licensee's evaluation of the qualified expert's training and experience under § 35.24 shall be preserved for five years after the qualified expert's last performance of a full calibration on the licensee's teletherapy unit.

General Licenses

[50 FR 9185]

§ 35.31 General license for medical use of certain quantities of byproduct material.

(a) A general license is hereby issued to any physician to receive, possess, transfer, or use for any of the following stated diagnostic uses, in accordance with the provisions of paragraphs (b), (c), and (d) of this section, the following byproduct materials in capsules, disposable syringes or other forms of prepackaged individual doses:

(1) Iodine-131 as sodium iodide (NaI^{131}) for measurement of thyroid uptake;

(2) Iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(3) Iodine-125 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume;

(4) Cobalt-58 for the measurement of intestinal absorption of cyanocobalamin;

(5) Cobalt-60 for the measurement of intestinal absorption of cyanocobalamin;

(6) Chromium-51 as sodium radiochromate for determination of red blood cell volumes and studies of red blood cell survival time.

Note: Section 32.70 of this chapter requires manufacturers of radiopharmaceuticals which are under the general license in this paragraph to include the following statement in the label affixed to the container or in the leaflet or brochure which accompanies the radiopharmaceutical:

This radioactive drug may be received, possessed, and used only by physicians licensed to dispense drugs in the practice of medicine. Its receipt, possession, use, and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of manufacturer)

(b) No physician shall receive, possess, use, or transfer byproduct material pursuant to the general license established by paragraph (a) of this section until he has filed Form NRC-482, "Registration Certificate—Medical Use of Byproduct Material Under General License" with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C., 20555, and received from the Commission a validated copy of the Form NRC-482 with registration number assigned. The registrant shall furnish on Form NRC-482 the following information and such other information as may be required by that form.

(1) Name and address of the registrant;

(2) A statement that the registrant is a duly licensed physician authorized to dispense drugs in the practice of medi-

[50 FR 9185]

cine, and specifying the license number and the State in which such license is valid; and

(3) A statement that the registrant has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use byproduct material under the general license of §35.31 of this chapter and that he is competent in the use of such instruments.

(c) A physician who receives, possesses, or uses a pharmaceutical containing byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:

(1) He shall not possess at any one time, pursuant to the general license in paragraph (a) of this section, more than:

(i) 200 microcuries of iodine-131,

(ii) 200 microcuries of iodine-125,

(iii) 5 microcuries of cobalt-58,

(iv) 5 microcuries of cobalt-60, and

(v) 200 microcuries of chromium-51.

(2) He shall store the pharmaceutical until administered in the original shipping container or a container providing equivalent radiation protection;

(3) He shall use the pharmaceutical only for the uses authorized by paragraph (a) of this section;

(4) He shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age;

(5) He shall not transfer the byproduct material to a person who is not authorized to receive it pursuant to a license issued by the Commission or an Agreement State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.

(d) The registrant possessing or using byproduct material under the general license of paragraph (a) shall report in duplicate to the Director of Nuclear Material Safety and Safeguards any changes in the information furnished by him in the "Registration Certificate—Medical Use of Byproduct Material Under General License," Form NRC-482. The report shall be submitted within 30 days after the effective date of such change.

(e) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of Parts 19, 20, and 21* of this chapter with respect to the byproduct materials covered by the general license.

*Amended 42 FR 28891.

Misadministration Reports and Records

§ 35.41 Definition of a misadministration.

For this part, misadministration means the administration of:

(a) A radiopharmaceutical or radiation from a sealed source other than the one intended;

(b) A radiopharmaceutical or radiation to the wrong patient;

(c) A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;

(d) A diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent;

(e) A therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent; or

(f) A therapeutic 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.

§ 35.42 Reports of therapy misadministrations.

(a) *Immediate telephone report.* When a misadministration involves any therapy procedure, the licensee shall notify, by telephone only, 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 personally informs the licensee either that he will inform the patient or that, in his medical judgment, telling the patient or the patient's responsible relative (or guardian) would be harmful to one or the other, respectively. These notifications shall 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) *Written report.* Within 15 days after the 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 shall 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 shall not include the patient's name, or other information which could lead to identification of the patient.

§ 35.43 Reports of diagnostic misadministrations.

When a misadministration involves a diagnostic procedure, the licensee shall notify, in writing, the referring physician and the appropriate NRC Regional Office listed in Appendix D of Part 20 of this chapter. Licensee reports of diagnostic misadministrations are due within 10 days after the end of the calendar quarters (defined by March, June, September, and December) in which they occur. These written reports shall include the licensee's name; the referring physician's name, a description of the event; the effect on the patient; and the action taken to prevent recurrence. The report should not include the patient's name or other information which could lead to identification of the patient.

§ 35.44 Records of all misadministrations.

Each licensee shall maintain for Commission inspection, records of all misadministrations of radiopharmaceuticals or radiation from teletherapy or brachytherapy sources. These records shall 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, a brief description of the event, the effect on the patient, and the action taken to prevent recurrence. These records shall be preserved until the Commission authorizes their disposition.

§ 35.45 Rights and duties of licensees.

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

**Amended 45 FR 19829

SCHEDULES

§ 35.100 Schedule A—Groups of medical uses of byproduct material.

(a) *Group I.* Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion. This group does not include imaging or localization studies.

(1) Iodine-131 as sodium iodide, iodinated human serum albumin, labeled rose bengal, triolein, or sodium iodohippurate;

(2) Iodine-125 as sodium iodide, iodinated human serum albumin, oleic acid or sodium iothalamate;

(3) Cobalt-58 as labeled cyanocobalamin;

(4) Cobalt-60 as labeled cyanocobalamin;

(5) Chromium-51 as sodium chromate or labeled human serum albumin;

(6) Iron-59 as citrate;

(7) Technetium-99m as pertechnetate; and

(8) Any byproduct material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution or excretion for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

(b) *Group II.* Use of prepared radiopharmaceuticals for diagnostic imaging and localization studies

(1) Iodine-131 as sodium iodide, iodinated human serum albumin, macroaggregated iodinated human serum albumin, colloidal (microaggregated) iodinated human serum albumin, rose benegal or sodium iodohippurate;

(2) Iodine-125 as sodium iodide or fibrinogen;

(3) Chromium-51 as human serum albumin;

(4) Gold-198 in colloidal form;

(5) Mercury-197 as chlormerodrin;

(6) Mercury-203 as chlormerodrin;

(7) Selenium-75 as selenomethionine;

(8) Strontium-85 as nitrate;

(9) Technetium-99m as pertechnetate, sulfur colloid or macroaggregated human serum albumin;

(10) Ytterbium-169 as pentatate sodium;

(11) Indium-113m as chloride;

(12) Any byproduct material in a radiopharmaceutical prepared from a reagent kit listed in paragraph (a)(4) of this section; and

(13) Any byproduct material in a radiopharmaceutical and for a diagnostic use involving imaging or localizing for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

(c) *Group III.* Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing byproduct material for certain diagnostic studies.

(1) Molybdenum-99/technetium-99m generators for the elution of technetium-99m as pertechnetate;

(2) Technetium-99m as pertechnetate for use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m as provided in paragraphs (c)(4) and (5) of this section;

(3) Tin-113/indium-113m generators for the elution of the indium-113m as chloride;

(4) Reagent kits for preparation of technetium-99m labeled:

(i) Sulfur colloid;

(ii) Pentatate sodium;

(iii) Human serum albumin microspheres;

(iv) Polyphosphates;

(v) Macroaggregated human serum albumin;

(vi) Etidronate sodium;

(vii) Stannous pyrophosphate;

(viii) Human serum albumin;

(ix) Medronate sodium;

(x) Gluceptate sodium;

(xi) Oxidronate sodium;

(xii) Dizofenin;

(xiii) Succimer;

(xiv) Albumin colloid; and

(5) Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing byproduct material for which generator or reagent kit a "Notice of Claimed Investigational Exemption of a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

(d) *Group IV.* Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety:

(1) Iodine-131 as iodide for treatment of hyperthyroidism** and cardiac dysfunction;

(2) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases;

(3) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;

(4) Any byproduct material in a radiopharmaceutical and for a therapeutic use not normally requiring hospitalization for purposes of radiation safety for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

**Amended 40 FR 26679.

(e) *Group V.* Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety:

(1) Gold-198 as colloid for intracavitary treatment of malignant effusions;

(2) Iodine-131 as iodide for treatment of thyroid carcinoma;

(3) Any byproduct material in a radiopharmaceutical and for a therapeutic use normally requiring hospitalization for radiation safety reasons for which a "Notice of Claimed Investigational Exemption for a New Drug" (IND) has been accepted by the Food and Drug Administration (FDA).

(f) *Group VI.* Use of sources and devices containing byproduct material for certain medical uses:

(1) Americium-241 as a sealed source in a device for bone mineral analysis;

(2) Cesium-137 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(3) Cobalt-60 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

(4) Gold-198 as seeds for interstitial treatment of cancer;

(5) Iodine-125 as a sealed source in a device for bone mineral analysis;

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

(7) Strontium-90 sealed in an applicator for treatment of superficial eye conditions;

(8) Iodine-125 as seeds for interstitial treatment of cancer.

(9) Iodine-125 as a sealed source in a portable device for bone imaging and foreign body detection.

NOTE.—The reporting and record keeping requirements contained in this part have been approved by the General Accounting Office under B-180225 (R0068), (R0334).

School of Medicine
James Graham Brown Cancer Center
Louisville, Kentucky 40292
(502) 588-5054

Enclosure 2

UNIVERSITY of LOUISVILLE

85 DEC -4 P2:51

MEMORANDUM

TO: Vandy L. Miller
Material Licensing Branch
Division of Fuel Cycle and Material Safety

FROM: Peter R. Almond
Consultant

DATE: November 6, 1985

SUBJECT: Veteran Administration's Nuclear Medicine Network

I have reviewed your inquiry about Veterans Administration's Nuclear Medicine Network.

My initial reaction was to recommend that both sites (Chyenne and Grant Junction) meet the requirements of Section 35.38 of the proposed revision of the regulations, i.e. that the authorized user must be able to be physically present within one hour. However, I would not object to the situation remaining as is, if the on site physicians were to meet NRC criteria of 30 hour training in basic radiosotope handling techniques.

The fact that neither physician meets the training requirement and that the authorized user is several hours away, presents a very real problem---not the least of which is that it sets a very dangerous precedent.

In answers to your specific question therefore:

1) No, I do not believe adequate controls are in place to permit the continued use of the network. I would be satisfied if the on site physician had adequate training. In this case, I would accept the 30 hours as required for mobile nuclear medicine service operations even though the authorized user is more than one hour away. Alternatively, transferring the license to an authorized user one hour away would be satisfactory.

2) It is easy to sympathize with the V.A. since it is obviously a real problem for them to get an authorized physician-user on site. However, the safety of the patient and public must be safeguarded and the solution is not to come up with an appropriate justification to allow the situation to continue, but to change the situation.

3) I believe this is the best solution to this problem, if the V.A. will go along with training the present staff.

4) a. I don't believe any different considerations should apply to government and non-government institutions. As stated above the NRC concern here is to safeguard the patient and public's safety---regardless of other factors. NRC is not authorized to regulated economic considerations.

b) I have no objections.

5) There appears to be a typo error in this question. Should it read "...with an authorized physician-user off-site...". If this is the case, then he must be available to be physically present within one hour. If is is on-site, then the program appears perfectly adequate.

I have also reviewed the revised 10 CFR Part 35 pertaining to medical use of byproduct material and I have no specific comments to make.

I believe it fulfills it's purpose of consolidating all the requirements into one document and as such, will be very useful.

In paragraph 35.406 (b) 2 and 3, I would suggest a minor change to read in both "...the room number of use and patient's name,...".

In paragraph 35.400 A (d), is iridium wire going to be added to the seeds? If it is, the paragraph should read:

(d) Iridium-192 as seeds encased in nylon ribbon or as a sealed source in wire for interstitial treatment of cancer.

In paragraph 35.400 A (a), should sphere's be added to the Cs-137 source? If so the paragraph should read:

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

PRA:paw/052

V. P. COLLINS, M.D.

Rec'd 11/26/85

November 22, 1985

Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and Material Safety
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Miller:

The following opinions are offered in answer to the questions posed in the memorandum on the subject Veteran Administration's Nuclear Medicine Network.

1. Adequate controls seem to be in place, with a qualified nuclear medicine technician who has been trained at least in part at the Network Center in St. Louis.
   There is daily contact with the physician in charge in St. Louis for approval of the tests requested and for transmission of results and interpretations.
   There is periodic inspection by a physicist and/or qualified physician on a monthly basis.
   I see no need for the requirement that licensee be available within one hour. The only real emergency would be an anaphylactic reaction to an intravenous injection. This would be handled immediately by an onsite physician who need not be trained in nuclear medicine.
   In the event of spill or contamination the licensee in charge in St. Louis would be immediately notified. His immediate presence would not contribute to the clean-up.
   In the event of a misadministration of agent or dose for diagnostic test, the prompt presence of the licensee would not correct this. His orders by telephone would provide any action immediately necessary and subsequent visit would be made as indicated.

2. The justification for the network management of the nuclear medicine service in either V.A. Hospital is the need for the service in that hospital and the lack of an available qualified licensee. The only alternative would appear to be be discontinuance of the service. This seems an inappropriate action. The network service for just this purpose is functioning for other centers presumably in a satisfactory fashion and with no record of misadministration.

9000 Westheimer, Suite 53 **Center for Zetetics** Houston, Texas 77063
713 / 780 - 0588

3. It seems entirely appropriate to continue to seek an authorized physician user on site or alternatively, to have a schedule for providing appropriate training experience to physicians at each location. In any event the longer the network arrangement is functioning under close supervision, the more effective it should become to the satisfaction of all concerned, from the point of view of medical service provided and the overall safety of the program.

4. The system has the potential for being a satisfactory mechanism for providing nuclear medicine service to more hospitals who are unable to maintain an on site trained licensee. I see no objection to permitting or promoting extension of diagnostic nuclear medicine services by network, where none might otherwise be available. It seems to me to be overly apprehensive to be concerned for the possibility of "abuse". Contrary, in today's atomsphere of cost control in all branches of medical practice, the system may represent a positive economic benefit to patients and institutions. I believe the same considerations could apply to governmental or nongovernmental medical licensees. I personally have had some 20 years experience in operating a network for consultation, treatment planning and supervision of radiotherapy across the southwest and I know we have been able to provide radiation therapy in hospitals in remote communities that has been the equivalent of what they might receive in medical centers at only a fraction of the cost of transportation, and housing far from home.
As explained above I do not consider that the presence of the authorized physician user within one hour, represents an essential safety factor in carrying on a service of this type.

5. The essential factors for operation of a nuclear medicine network would be, -

   a. In the center, an authorized physician user with appropriate communication technology for transmission of information including images.

   b. A certified nuclear medicine technologist who has spent an indoctrination period of 2 weeks in the network center under the observation of the physician licensee.

   c. Each patient study would be communicated to the physician user in the form of a daily schedule followed by the results of the studies on completion of the schedule. The interpretation or confirmation of each study would be by the physician-user in the network center and then transmitted back to the participating hospital.

d. Orders, receipt of orders and disposal of any waste would be approved by the physician user in the network center.

e. The certified nuclear medicine technologist might act as radiation safety officer. Inspection of the department and its records would be carried out on a monthly basis by either a physicist or a physician from the network center.

f. The licensed physician user of the network center should be carried as a member of the staff of the participating hospital, providing a monthly report of activities of the nuclear medicine department to the chief of staff and administrative office.

g. A member of the staff of the participating hospital should be appointed as liason officer to the nuclear medicine service for medical consultation.

Sincerely,

V. P. Collins

VPC:jl

CONVERSATION RECORD

TIME | DATE 1/6/86

TYPE ☐ VISIT ☐ CONFERENCE ☐ TELEPHONE ☐ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Dr Goodrich	ACMI Member	814-453-6711

SUBJECT VA Nuclear Network described in our 10/4/85 memo.

ROUTING	
NAME/SYMBOL	INT

SUMMARY Scalled to see if Dr Goodrich had rec'd our 10/4/85 memo. He had but had not yet had a chance to respond. I read him the questions on pp 3-4 of the memo & his oral responses were as follows.

Q1.a. – No; this practice is not in the best interest of quality care for veterans

Q1.b – There is no substitute for an on-site physician here

Q2 – NO. It is inconceivable that there is no qualified physician in Cheyenne & Grand Junction. Dr Goodrich presumed that ~~[illegible]~~ equivalents to in nuclear medicine or nuclear radiology were available

Q3 – VA could send patients to a local hospital or to another VA hospital that has appropriate supervisory review

Q4a – The concept does not provide good medical care for patients served by either govt. or non-govt.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE

ACTION TAKEN

SIGNATURE	TITLE	DATE

CONVERSATION RECORD

TIME | DATE 1/6/86

TYPE ☐ VISIT ☐ CONFERENCE ☐ TELEPHONE ☐ INCOMING ☐ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO.
Dr Goodrich		

SUBJECT VA Nuclear Network (cont'd)

ROUTING	
NAME/SYMBOL	INT

SUMMARY

Medicine. Telemetry is "not good enough" - haven't saved the patient unnecessary radiation exposure.

Q4.b - Physician-user does not see ORIGINAL documents (e.g., scans); physician-user must make routine visits & be physically present (hopefully visits are daily)

Q5 - Current practice at Cheyenne & Grand Junction VA Hospitals are NOT ACCEPTABLE

[This conversation record was prepared from notes made on 1/6/86 during the telephone conversation]

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
	Patricia A Vacca	4/14/86

ACTION TAKEN

SIGNATURE	TITLE	DATE

CONVERSATION RECORD

TIME | DATE 2/6/86

TYPE: ☐ VISIT ☐ CONFERENCE ☒ TELEPHONE ☐ INCOMING ☒ OUTGOING

Location of Visit/Conference:

ROUTING: NAME/SYMBOL | INT

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU: Dr Green

ORGANIZATION (Office, dept., bureau, etc.): ACMUI Member

TELEPHONE NO: 608-263-8500

SUBJECT: VA Nuclear Network described in our 10/14/85 memo.

SUMMARY: I called Dr Green at the Univ of Wisconsin Hosp spending a sabbatical & asked if he had rec'd our 10/14/85 memo. He said that he had but he had not had a chance to respond in writing.

We discussed the concept and he expressed the following views:

1. "If something goes wrong, NRC will have egg on its face"
2. "It's hazardous as hell"
3. The controls are inadequate
4. It is "too sloppy; it is "no way to supervise"

[This conversation record was prepared from notes made during the 2/6/86 telephone conversation]

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE Patricia Waco | DATE 4/14/86

ACTION TAKEN

SIGNATURE | TITLE | DATE

Rec'd 11/25/85

Danbury Hospital
The Community Health Center
Danbury, CT 06810 Tel. 203-797-7000

Department of Laboratory Medicine

A World Health Organization
Collaborating Center
For Nuclear Medicine

November 15, 1985

MEMORANDUM FOR: Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and Material Safety

FROM: N. E. Herrera, M.D.
Member, Advisory Committee on the Medical Uses of Isotopes

SUBJECT: VETERANS ADMINISTRATION'S NUCLEAR MEDICINE NETWORK

Question 1. Do you believe that adequate controls are in place to permit their continued participation in the VA-St.Louis "Nuclear Medicine Network", etc. From the information provided on the nuclear medicine network, I feel that such a network should only be used as a supportive measure providing additional expertise that would not otherwise be available to hospitals. However, I do not feel that this replaces the need that there be an authorized physician-user on site, or one available in the immediate vicinity that could be on site within one hour's notice. The depth of professional support and the mechanism for peer review provided by the network is exemplary. However, in my opinion, it cannot replace the daily contact needed to insure an efficient, effective and safe nuclear medicine program. This can only be accomplished by having knowledgeable personnel present or immediately available.

Question 2. Do you believe that either VA Hospital has adequate justification for not having an authorized physician-user on site? etc. I do not believe that either VA Hospital has given adequate justification for not having an authorized physician-user on site. There are three possible situations which would make me feel that such an on-site authorized user may not be necessary. First, if there were an authorized physician-user in the vicinity who could respond to problems at the institution, this would probably be adequate.

Second, if the Radiation Safety Officer at the institution were a full time individual, well qualified in the aspects of radiation physics and radiation safety, I would feel much more comfortable about the situation, though possibly not entirely happy. Third, and this probably should be done in conjuction with the second reason, I would tend to look more favorably upon their request if the credentials of the Radiation Safety Officer were better, and if one or more of the physicians at the insitution would take minimum recommended 30 hours of training in basic radiation safety, as put forth by the NRC.

Question 3. Our approach to these two hospitals may be to point out the provisions of the proposed 10-CFR 35.38, etc. I feel that reference should definitely be made to these proposed regulations. Not only should reference be made to them, but they should be made as a condition for the license. I feel that the two hospitals have been given adequate time towards having a physician receive some basic training in radiation protection and safety. Therefore, the insitution should be required to have such an arrangement similar to the new proposed regulations within a relatively short time span. Their continued disregard to the suggestions of the NRC should not be allowed to continue indefinitely.

Question 4.a: I do not feel that different considerations should apply for government and non-government hospitals. This would constitute a double standard which will sooner or later lead to problems of interpretation and/or implementations of NRC regulations and basic radiation safety principles like in the case of Florida.

b. If physician user is available and can get to the hospitals within an hour I would have no objections provided there is appropriate documentation of compliance with the regulations.

Question 5. I believe the key factors should be those that ensure that an appropriate program of Quality Assurance and Radiation Safety exists and is complied with.

This implies in my mind that in addition to an authorized physician user, there should be a duly qualified radiation safety officer, a technologist certified by an appropriate organization such as The Nuclear Medicine Technology Certification Board and documented evidence that the above program exists. Therefore in my opinion all the points mentioned should be necessary for approval and none should be omitted.

N. E. Herrera

N. E. Herrera, M.D.
Member, Advisory Committee
on the Medical Uses of
Isotopes

HARVARD MEDICAL SCHOOL

BRIGHAM AND WOMEN'S HOSPITAL

DEPARTMENT OF RADIOLOGY
DIVISION OF NUCLEAR MEDICINE

'85 NOV 13 P2:47

B. LEONARD HOLMAN, M.D.
PROFESSOR OF RADIOLOGY
DIRECTOR OF CLINICAL
NUCLEAR MEDICINE

75 FRANCIS STREET
BOSTON, MASSACHUSETTS 02115
(617) 732-6290

November 1, 1985

Vandy Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety
United States Nuclear
Regulatory Commission
Washington, D.C. 20555

Dear Mr. Miller:

With regard to your letter concerning the VA's nuclear medicine network, I would first like to comment on the general concept of information networks and their potential impact on regulatory supervision. It is clear from the VA experience that the current guidelines were not developed to take into account the capabilities of telecommunications and the added set of problems that this technology will place on regulatory function. The VA experience has shown that, even when the program is established with the most commendable of goals, serious operational problems arise which jeopardize the network. The dangers of such a program are even more imposing when the element of economic gain are introduced. It is very clear that a network program would be far less expensive than an on-site fully trained nuclear medicine physician. In a cost-driven system, hospitals might opt for the network even though an on-site program is far superior in terms of patient care and radiation safety. I am therefore against the network concept in general unless strict regulatory guidelines can be worked out to prevent abuse and to assure minimal standards of radiation safety.

With respect to your specific questions, it is clear that adequate controls are not in place in the VA network. There is insufficient documentation in place to support the quality assurance program that was promised. For example, their is an inconsistency between the number of visits by

the St. Louis staff to the various sites and the number of visits that were promised. The nature and content of quality assurance programs have been left poorly defined as have the individuals ultimately responsible for such programs. Can radiation safety and radiation emergencies be handled properly by telephone without direct physician supervision? Are all cases, in fact, screened by the St. Louis VA before injection? The room for abuse in this type of system is enormous. I therefore suggest that an authorized nuclear medicine user be on-site and that the system be applied, as with the Amirillo VA, for consultation, but not for primary patient care.

The argument that an authorized physician is not available on-site is weak since all JCHA approved hospitals must arrange for nuclear medicine services either on site or under the supervision of an authorized user.

The hospitals should be instructed to obtain an authorized physician user on-site and to provide a timetable for obtaining one.

As pointed out earlier, I am very much against authorizing blanket approval for off-site practice by telecommunications, because the opportunities for abuse are enormous without very specific, targeted regulations in place. I am equally opposed to operating a primary nuclear medicine facility by telephone even if the physician can reach the premises within one hour. These situations should be judged on very strict criteria to insure that the off-site operation is both necessary and safe and that adequate safeguards have been instituted to insure safety and that enforcement of these safeguards is properly documented.

The issue in question five is not the points necessary for maintaining a network system but, rather, the difficulty for even the St. Louis network to verify and document compliance with those points. I would add the need to fully document the responsibility of each member in the network and to document the procedures with respect to radiation safety and radiation emergencies.

The issue of telecommunications in medical practice will not disappear and the long range goals of the Commission should be to establish the conditions under which

could be effectively carried out and to set up guidelines and regulations to prevent its abuses (with respect to radiation safety).

Sincerely,

B. Leonard Holman, M.D.

BLH:hcm

The University of Alabama in Birmingham
School of Medicine/Department of Medicine
Division of Cardiovascular Disease
Gerald M. Pohost, M.D., Director
205/934-3624

November 8, 1985

Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and Material Safety
United States Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Miller:

The situation you describe regarding the two VA hospitals and their licensure for medical use of isotopes is interesting, indeed. The authorized physician-user is highly competent but located at least three hours by commercial air carrier from the hospitals. Nevertheless, interpretation is performed by this physician.

There are two issues that should be addressed. The first is the relationship between NRC licensures and clinical skills of the physician in image interpretation. I do not believe that a relationship between qualifications for licensure and interpretative skill has been demonstrated or should be anticipated. In the present cases, I believe that the interpretations rendered by the highly skilled off-site physician satisfy the clinical interpretative needs which I would consider essentially independent of licensure. Regarding the issue of radiation safety, I would consider that a well qualified radiation safety officer (physicist, physician or even technologist) should satisfy the immediate needs of these VA hospitals. I realize that these comments may come as somewhat of a different approach to more traditional NRC methods, but the need for medical care delivery seems to outweigh the potential problems of a non-physician overseeing the operation of the laboratory with a skilled expert interpreting the studies.

Of course, every attempt should be made to recruit a locally positioned physician licensee to oversee the NRC mandate of safety. However, the NRC should consider the inevitable solution to such problems of licensing nonphysicians to manage radiation safety in conjunction with a non-licensed but respected patient-oriented physician such as an internist.

Very truly yours,

Gerald M. Pohost, M.D.

original to V.L. Miller

MASSACHUSETTS GENERAL HOSPITAL ◆ HARVARD MEDICAL SCHOOL

DEPARTMENT OF RADIOLOGY
Division of Radiological
Sciences and Technology
EDWARD W. WEBSTER, Ph.D.
Professor of Radiology (Physics)

Mailing Address:
Massachusetts General Hospital
Boston, Massachusetts 02114
(617) 726-8326 / 3078

January 14, 1986

Material Licensing Branch
Division of Fuel Cycle
and Material Safety
U. S. Nuclear Regulatory Commission
Mail Stop 39655
Washington, DC 20555

Re: VA Nuclear Medicine Network

Attention: Vandy L. Miller

Dear Mr. Miller:

I am sorry it has taken me since late October to read and digest the material you assembled on the above problem, and come to some conclusions about the issues. In arriving at those conclusions, I have found it helpful (in maintaining consistency) to have just completed my review of the new proposals for physician training (N. McElroy).

The concepts advanced by the VA network in connection with the Grand Junction and Cheyenne hospitals include the following elements:

1. A physician-user who resides and works in another state, 3 or 4 hours away from the network hospitals by air, whose duties primarily consist of ordering specific nuclear medicine examinations by telephone and reading and reporting the results via tele-transmission; and who seldom visits the nuclear medicine facilities involved.

2. A non-physician user (N. M. Technologist) who runs the day-to-day operation including dispensing, calibrating, presumably administering the doses, and securing the images before transmission. This person is effectively in charge of the radiation safety program.

3. One or more on-site physicians whose primary role appears to be the handling of medical emergencies with little or no input to the conduct of the nuclear medicine examinations.

These notions strike me as aborting many of the requirements for training and experience of nuclear medicine physicians. It seems to me ludicrous that the professional organizations in nuclear medicine, radiology and cardiology can speak so vehemently about the physician needs for basic science, radiobiology, and radiation safety training when the job of the "physician-user" in such a network has need only to specify the particular test and to have skills in interpretation. Indeed it suggests to me that the only NRC requirements for the physician in this case would be evidence of relevant clinical skills, while a new class of "non-physician user" would be created for all the other skills relating to radiopharmaceuticals, radiation safety and imaging technology!

Therefore since we have worked so long and hard on assembling the manifold criteria for the physician-user, it seems logical to me to insist that:

(1) There must be a physician meeting the NRC training standards in residence at each licensed medical center.

(2) That this physician should actively operate the nuclear medicine program, including ultimate responsibility for radiation safety in the N.M. Department, on a day-to-day basis. In this view that physician should be physically present in the licensed medical facility at least 3 times per week for a minimum of 10 hours.

(3) That this physician should attend the meetings of the Radiation Safety Committee in the institution.

My answers to the questions regarding Cheyenne and Grand Junction posed in your letter of October 4 are as follows:

Q1. Controls are inadequate. A physician meeting NRC training requirements should be available on at least a 25% FTE basis.

Q2. The VA could change its ground rules and recruit a part-time NM physician from the local community.

Q3. With all the consistency I can muster, I approve of the approach described, either for a part-time NM physician as above or for a special training program for one or more physicians presently on the staff.

Q4. I am against spreading the culture of "nuclear-medicine-practice-via-long-distance-telephone," unless the physicians so employed spend some part of each week at the facility as noted in my general Item 2 above.

(a) There should be no difference between governmental and non-governmental institutions in this regard.

(b) In the Florida case the physician presence must be routine. He is required on-site for a variety of reasons, not the least being his supervisory responsibilities (for which he is supposed to be trained and licensed) and his contact with other physicians who refer patients to his service.

Q5. The "physician-user" in this question corresponds to the standard noted for the VA, except that "close communication" should involve the physical presence of both in the same place for a significant part of the working week, visits on a weekly basis as noted above, real in-person responsibility for the operation of the NM laboratory and medical service.

I say again, if a physician-user does not have to be in the NM area interacting with the NM techs, ordering, supervising, etc., then why specify such detailed training on non-medical matters in the classroom and for hands-on experience? The "network" as described earlier envisages a different world. If this is to be, then forget all that "unnecessary" training and demand the safety training primarily (or only) for the NM technologists.

I wonder how the nuclear medicine physicians on ACMUI have voted.

Sincerely,

E. W. Webster

E. W. Webster, Professor

EWW/bh

WESTLAND MEDICAL CENTER
2345 Merriman Road Westland, Michigan 48185 (313) 467-2300

November 14, 1985

Mr. Vandy L. Miller
Chief, Material Licensing Branch
Division of Fuel & Cycle Material Safety
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Miller:

This letter is in response to your directive of October 4, this year in regards to Veteran"s Administration's Nuclear Medicine network. Unfortunately, we were not privy to all of the decisions, both financial and political, that were manifest for the NRC to initially authorize the concept for the VA systems in and around the St. Louis Hospital; however, it seems that in attempting to solve one problem, a situation has been created that is an anathema, both from a regulatory safety standpoint, as well as from the judicious use of radionuclides in the clinical medicine setting. I can think of no other setting in the practice of medicine where the responsible physician of a service is physically over 1,000 miles from the site of patient responsibility. To perpetuate this concept would fly directly in the face of all of the Nuclear Regulatory and Joint Commission regulations relative to quality control, as well as the Alara concept. Now that government immunity is being challenged legally the potential ramifications of the "network" seems unconscienable, particularly as it concerns the Cheyenne and Grand Junction VA institutions. I will hereby comment on each of the specifics of your memo:

I. Participation in the VA St Louis "Nuclear Medicine Network;"

A. I cannot comprehend how a physician authorized user can control activities in an institution over 1,000 miles away. It is of interest that some large teaching hospitals that have a compliment of physicists, physicians; and a Nuclear Medicine section that is well staffed, have been sighted for varying elements of noncompliance. To maintain compliance with three visits yearly, to me seems void of pragmatism. I can think of no adequate set of controls that would allow these hospitals to continue in the St. Louis VA network.

B. An example might illustrate the problems that I foresee. In many Nuclear Medicine settings currently, elements of Nuclear cardiology represents 30-50% of the studies performed. In the VA system, where the patients tend to be more chronically ill and older, it is conceivable that many of their studies would be either with stress thallium or exercise MUGA. Both of these studies virtually demand that a trained physician is in attendance at the performance of these studies. Nowhere in the information afforded to me was there an indication that there would be any physician

in the scanning area for the performance of these studies. The information afforded from the Cheyenne and Grand Junction Hospitals suggested that the chiefs and assistant Chiefs of Medicine would be on call in case of emergency; how these studies can be handled from St. Louis begs a pragmatic answer.

C. It is not clear from the information provided who is in charge of safety and quality control when Mr. Gluick is on vacation, leave, or attending meetings. If an emergency such as spillage, mis-administration or other contamination were to happen in his absence it seems that there would be no qualified person aboard to handle the emergency and/or report the same. Nowhere in their documents is there an authorized visiting RSO. Other questions in this vein arise, but they are more clinically applicable than safety quality control.

2. Justification for authorized physician user on site.

I do not believe that either hospital has justification for not having an authorized physician user on site. My reason for this statement is that they obviously must have a Radiologist on board. Most Radiologists have had training in Nuclear Medicine. It would seem that the Radiologist or an internist could be trained to adequately assume the responsibility of an authorized physician user. The statement "VA personnel indicated that they were unable to obtain the services of such a physician at VA Cheyenne and VA Grand Junction; such physicians could not be recruited as permanent VA staff nor could suitably qualified physicians in the community as a consultant to these VA Hospitals," is an absolute cop-out and borders on the untruth. Any Radiologist trained within the last ten years during residency had most of the training needed for certification; if not, certainly could be sent TDY in the VA system to receive whatever additional training is necessary to provide Nuclear Medicine Services. Sixty-five percent of Nuclear Medicine today is under the aegis of Radiology because of that element of training in their residency. Hence, I am not able to support VA's point of view.

3. I approve of NRC approach, suggesting that the hospitals provide appropriate training and experience for physicians of board, probably Radiologists, or possibly Internists.

4. I believe that the consideration relative to establishment of the "Nuclear Medicine Network" should be uniform for both government and non-governmental licencies. I think that the present request of the two VA Hospitals depict the extent to which some licencees may go to avoid developing the in-house safety and quality control assurances required both by NRC and JACH.

I am more sympathetic with the authorized physican user who may be involved with two hospitals within 50 miles of each other, particularly if the physician has the wherewithall to interact on a daily basis with the technicians and physicians who offer referrals, but not in the situation where all business is conducted via telephone or computer hook-up. I think that there are specific businesses where this type of approach might be used, but would have to be reviewed on an individual basis with commitment from the authorized physician user to be responsible for both the quality control and safety assurances, as well as for the consultative and legal aspects of the Nuclear Medicine Section.

5. As mentioned in the foregoing, I do not think that participation in the Nuclear Medicine Network, particularly as proposed by the Cheyenne and Grand Junction VA program is an acceptable practice.

In summary, I cannot approve the Nuclear Medicine Network proposal of the Cheyenne and Grand Junction VA Hospitals. I feel that it is possible for them to recruit or train staff for this function. I feel to further expand the Nuclear Medicine Network concept tends to fly in the face of the Alara concept, safety concept and quality control concepts promulgated by the NRC and Joint Commission of Hospital Accreditation.

Respectfully submitted,

David H. Woodbury, M.D.
Nuclear Medicine Dept.

ENCLOSURE 4

DRAFT TEXT FOR LETTERS TO VA, CHEYENNE AND VA, GRAND JUNCTION

Gentlemen:

This is in reference to your application dated _____ to renew License No. _____. The Nuclear Regulatory Commission's (NRC's) staff recognizes that for several years your authorized physician-user, Dr. _____, has been normally located in St. Louis, Missouri, at least three hours flying time from your hospital, and has been visiting your hospital only a few times each year. We have been concerned about your situation for some time, believing that by any definition, the adequacy of supervision from such a distance is questionable. The NRC staff in our Washington, DC Headquarters' office expressed these concerns in a December 1981 meeting with representatives of the Veterans Administration (VA) Central Office and of the VA, St. Louis staff. Although these VA representatives seemed receptive to some NRC suggestions, it does not appear that the suggestions were implemented because your situation appears to be unchanged.

In connection with our review of your pending renewal application, we sought advice on your situation from NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) and our consultants. We asked the ACMUI members and our consultants for their views on the adequacy of the supervisory controls over your program and whether you had adequate justification for your non-traditional operation. In addition, we asked them for their suggestions about your program and any improvements they would recommend.

In general, the ACMUI members and our consultants thought that, although your system is "exemplary," telephone contacts, computer hook-ups, and occasional (2-4 times per year) visits to your facility by staff from VA, St. Louis cannot replace the "daily [in-person] contact needed for an efficient, effective, and safe nuclear medicine program." They believe that your situation is "not in the best interest of quality care" for your veteran patients.

They also believe that you should have (or be able to recruit) a physician whose training and experience meet NRC's criteria (as described in Appendix A of Enclosure 1 and in Enclosure 2), who can be at your facility within one hour and who will devote at least 25% FTE (i.e., full-time-equivalent) to your program. Several mentioned that physicians who have completed a residency program (e.g., radiology) within the last ten years should have most, if not all, of the training and experience needed to meet NRC's criteria. If additional training or experience or both were needed, they believe that it could be obtained at a hospital in your community or at a VA hospital. If you are able to obtain the services of a properly qualified physician, you could still maintain consultative contact with VA, St. Louis in much the same way as VA, Amarillo.

We believe that this is an opportune time for you to review your current situation and take steps both to improve it and to establish a traditional program supervised by a qualified physician-user who is in close proximity to your hospital. The following suggestions should be considered:

1. You should make new efforts to find a qualified physician to be an authorized user who is able to be physically present a reasonable percentage of the work day or work week.

2. If your efforts as suggested in Item 1 above are unsuccessful, then we remind you that, in the December 3, 1981 meeting with representatives of VA Central Office and VA, St. Louis, the NRC staff recommended that VA take steps to get authorized physician-users who can be at each (Cheyenne and Grand Junction) location on a routine basis. If VA proposed as a user a physician who did not clearly meet NRC's current training and experience criteria, the NRC staff offered to work with VA to decide on: (1) a mutually agreeable training program that might be needed to supplement that already received by the physician, and (2) a mutually agreeable schedule by which each location's operation would be supervised by a qualified physician in close proximity to the hospital. Although VA representatives seemed receptive to this approach, we are not aware of any action taken by the VA to implement this idea. The NRC staff stands by its December 1981 offer.

3. ACMUI members and our consultants suggested that, if you are unable to get a qualified physician in close proximity to your hospital to supervise your program, you could transfer patients needing nuclear medicine procedures to a local community hospital or to another VA hospital that operates a traditional nuclear medicine program.

If your efforts to find a properly qualified physician are successful, you should submit to us the name of the proposed physician-user and sufficient documentation of his or her training and experience to show that he or she meets NRC's criteria; see Appendix A of Enclosure 1 and also Enclosure 2. You may find it convenient to provide this information using Supplements A and B of Form NRC-313M; see Enclosure 3. In addition, you should specify: where this physician is normally located, the time needed for the physician to get to your hospital, the amount of time this physician will devote to supervising your nuclear medicine program, and when this physician will begin supervising your nuclear medicine program.

If you find a physician who does not clearly meet the appropriate NRC criteria, then you should submit not only the information requested in the paragraph above, but also a proposed training program designed to provide the needed supplemental training, experience, or both, and a proposed schedule for completion of the training program.

Within 60 days of the date of this letter, please inform us of the results of your efforts to obtain a qualified physician in close proximity to your hospital to supervise your nuclear medicine progam. Alternatively, you should describe other actions you have taken to ensure that your patients' nuclear medicine procedures are performed in a properly supervised program. Please submit your response in duplicate and refer to Control No. _____.

If you believe that it would be helpful, we would be pleased to discuss this matter with you and your staff either by telephone (insert FTS and commercial telephone numbers) or in a meeting.

Sincerely,

(insert appropriate signature block)

Enclosures:
1. Regulatory Guide 10.8 (Rev. 1), Oct. 1980
2. 47 FR 54376
3. Form NRC-313M

cc w/o enclosures:
(Insert name of VA coordinator.
Although we have not received official notice
of a change, we believe that Dr. Donati of the
VA, St. Louis has replaced Dr. James Smith as
the coordinator. Please contact P. Vacca
for up-to-date name before mailing this letter.)

TECHNICAL ASSISTANCE REQUEST

DATE: JUL 11 1985

TO: Vandy Miller, Chief, Material Licensing Branch, NMSS

Chief, Material Certification and Procedures Branch, NMSS

FROM: R. J. Everett, Chief, Nuclear Materials Safety Section (TXC for

SUBJECT: REQUEST FOR TECHNICAL ASSISTANCE

attached

__X__ Control No. 18513 & 17504 (enclosed)

__X__ Letter(s) dated: 18513 - See attached backup material
17504 - See attached backup material

_____ Suggested change in licensing procedure (enclosed)

__X__ Other (see remarks)

letter dated 5/7/84
" " 8/26/81
" " 4/28/80
" " 7/10/80
" " 2/4/80
notes " 11/16/81
letter " 2/29/80
" " 8/31/81
application rcvd 11/23/79

Requested action: _____ Custom source/device review

_____ Review and comment

_____ Provide policy guidance

_____ Other (see remarks)

Remarks: Transmit to ACMUI for review of "Nuclear Medicine Network" system protocol. To be determined: continued acceptance of "Nuclear Medicine Network" system in lieu of having a qualified user onsite at Grand Junction and Cheyenne VAMC's.

To be completed by NMSS

Date:

The above request has been received by MLB/MCPB and assigned to _____ (name)

_____ (phone number). Please contact this individual for a status report if a response is not received by _____ (date).

Signature: _____
FCML/FCMC Branch Chief

JAN 07 1985

FCML:FAS

V. A. Medical Center
ATTN: Francis K. Herbig
Program Director/KSO
N Nuclear Medicine Network
2121 North Avenue
Grand Junction, Colorado 81501

Docket No. _____

License No. 030-17159

Control No. 05-08400-02
18513

SUBJECT: LICENSE RENEWAL APPLICATION

Gentlemen:

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Any correspondence regarding the renewal application should reference the control number specified and your license number.

Sincerely,

Material Licensing Branch
Francis A. St. Mary
Division of Fuel Cycle and
Material Safety

Medical Center St. Louis MO 63125

Veterans Administration

In Reply Refer To:

December 3, 1984

United States Nuclear Regulatory Commission
Washington, D.C. 20420

THRU: Medical Center Director (00)
Grand Junction CO

Director, Nuclear Medicine Service (115)
Veterans Administration Central Office

1. We are writing to request the renewal of our medical radionuclide by-product material license # 05-08400-02 which expires December 30, 1984. We have reviewed the terms, conditions and supporting information for the existing license and wish to have the license renewed as-is with the following minor changes:

a. Survey instruments are calibrated annually at the facility in the St. Louis VAMC.

b. Licensed material in Groups I, II and III and Xenon-133 are used under the supervision of James W. Fletcher, M.D. Dr. Fletcher is Chief, Nuclear Medicine Service, St. Louis VAMC and Medical Director of the Nuclear Medicine Network.

c. Sherrick Harmon will have day to day responsibility for radiation safety activities subject to review during quarterly visits. His credentials on NRC-313M (p5) are enclosed.

2. In all other respects the by-product materials program remains the same. The Grand Junction Medical Center continues to participate in the Nuclear Medicine Network based in St. Louis. St. Louis staff visit the facility at least four times annually for training, safety inspection and participation in Radiation Safety Committee meetings. The ALARA program is fully implemented and effective.

3. Your consideration of this renewal request is appreciated. If further information is required you may contact me at 276-4359.

FRANCIS K. HERBIG
Program Director/RSO
Nuclear Medicine Network

encl.

18513

JAMES J. SMITH, M. D. (115)
Director, Nuclear Medicine Service
VA Central Office
Washington, D.C. 20420

FORM NRC-313M SUPPLEMENT A (8-78) — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
Sherrick S. Harmon	

3. CERTIFICATION

SPECIALTY BOARD (A)	CATEGORY (B)	MONTH AND YEAR CERTIFIED (C)
Nuclear Medicine Technology Certification Board	Nuclear Medicine Technology #000077	06/1978

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING (A)	LOCATION AND DATE (S) OF TRAINING (B)	TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) (C)	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) (D)
a. RADIATION PHYSICS AND INSTRUMENTATION	General Rose Memorial Hospital /University of Colorado Medical Center - 9/74-9/76	200	600
b. RADIATION PROTECTION	General Rose Memorial Hospital /University of Colorado Medical Center - 9/74 - 9/76	150	600
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	University of Colorado Medical Center - 9/74 - 9/76	150	450
d. RADIATION BIOLOGY	University of Colorado Medical Center - 9/74 - 9/76	150	300
e. RADIOPHARMACEUTICAL CHEMISTRY	General Rose Memorial Hospital /University of Colorado Medical Center - 9/74 - 9/76	300	600

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

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{99m}Tc	1 curie	General Rose Memorial Hospital/VA Medical Ctr	7 years	Diagnostic
^{131}I	200mCi	Iowa City, Reno, Gr. Jct.	" "	"
67Ga	50mCi	" " "	" "	"
201Tl	10mCi	" " "	" "	"
57 Co	50mCi	" " "	" "	"
133XeGas	25mCi	" " "	" "	"

18513