POLICY ISSUE
(Information)

February 5, 1991 SECY-91-026

For: The Commissioners

From: James M. Taylor
Executive Director
for Operations

Subject: ANNUAL REPORT ON MEDICAL USE PROGRAM, FY 1990

Purpose: To provide an annual report on the medical use program.

Summary: In response to the Commission's request dated August 4, 1988 (Enclosure 1), the staff is providing an annual report on the Medical Use Program. This report discusses the implementation of the Five-Point Program previously described in SECY-88-77, points raised in the Commission's request dated March 29, 1990 (Enclosure 2), special-interest topics in the medical use of byproduct materials, and the medical use program's staffing and budget allocations.

Discussion: Background

In 1988, the staff provided the Commission with a Five-Point Program for improving the Nuclear Regulatory Commission's (NRC's) oversight of the medical use of byproduct material. The five points are: program development; inter-organization cooperation; staff development; oversight; and information. This paper describes the medical use program experience in FY90. The staff continues to use this program to improve the regulatory oversight of the medical use of byproduct material and identify fundamental needs and issues.

NOTE: TO BE MADE PUBLICLY AVAILABLE IN 10 WORKING DAYS FROM THE DATE OF THIS PAPER

Contact:
Josephine M. Piccone
(301) 492-1410

INDUSTRY CHARACTERIZATION

The NRC regulates medical use of byproduct material in approximately 1700 hospitals and 600 private-practice clinics. Agreement States account for an approximate 5000 additional medical use licenses. Medical use includes using radiopharmaceuticals to evaluate the presence and extent of disease, or to treat disease, and the use of sealed sources for diagnosis or cancer therapy. Approximately 7 million diagnostic procedures and 180,000 therapy procedures are performed nationwide each year.

PROGRAM DEVELOPMENT

Quality Assurance (QA) Rule

A proposed amendment to 10 CFR Part 35, requiring medical licensees to establish and implement a written basic QA program, was published for comment on January 16, 1990. The goal of the rule is to provide high confidence that errors in the medical use of byproduct material will be detected and corrected. A pilot program was conducted to: assist in determining the licensee's effectiveness in meeting the proposed rule; determine if the performance objectives of the proposed rule can spot mistakes that could lead to misadministrations, if not corrected; and aid in determining the impact of the proposed rule on current medical practice.

Five 1-day pilot pre-test workshops were held in March and April, 1990 with NRC and Agreement State licensees who volunteered to participate in the pilot program after being randomly selected. A total of 64 volunteers actually completed the pilot program conducted between May 14 and July 13, 1990. Five 2-day post-test workshops were held in August, September, and October 1990, to review the volunteers' experiences with the proposed rule and to receive and discuss their comments and suggestions on how to improve the proposed rulemaking. One aspect of this pilot program was the establishment of an NRC QA team to develop program evaluation (licensing) checklists and site evaluation (inspection) checklists. The QA team also considered the appropriateness and usefulness of the aforementioned developed guidance by evaluating the submitted QA programs of eighteen of the volunteer participants, with follow-up site visits. The results of these evaluations were presented to all the volunteers, at the post-test workshops. The staff held public meetings with the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM)in July 1990 to discuss the proposed rule. Other public meetings with other professional organizations such as American College of Radiology (ACR), American

Association of Physicists in Medicine (AAPM), National Council on Radiation Protection and Measurements (NCRP), American Society of Therapy, Radiology, and Oncology (ASTRO) and the Joint Commission on the Accreditation of Health Care Organizations (JCAHO) have been held in early FY91. Public workshops also have been held with the Agreement States.

There continues to be strong opposition to the rule from the SNM, ACNP and other professional organizations who question the need for such a rule in light of the low frequency of occurrence of misadministrations. A second question is the regulation of QA by the NRC. The term "quality assurance" has a meaning in the medical community which is associated with quality medical care and clinical practice issues which are addressed by JCAHO. There is also a concern or perception that the cost of the rule will be high, primarily due to the need for auditable records. The Advisory Committee on the Medical Use of Isotopes (ACMUI) has recommended removal of diagnostic procedures from the proposed rule while retaining requirements related to the administration of iodine-131 in quantities greater than 30 microcuries and therapy procedures. The staff is continuing to evaluate these concerns as part of the rulemaking process.

QA Contract

The QA Contract, "Quality Assurance in the Medical Use of Byproduct Materials," was awarded on September 23, 1990, to Science Applications International Corporation (SAIC) for a period of one year. The tasks covered by this contract include: identify the current regulations, standards, and guidelines that physicians, medical physicists and medical technologists involved with activities under NRC medical licenses are currently using for QA; review the inspections of radiology and nuclear medicine departments by the U. S. Department of Health and Human Services' Health Care Financing Administration (HCFA) and the Joint Commission on the Accreditation of Health Care Organizations (JCAHO) to determine their level of detail in review of QA for medical use of byproduct material; and review and analyze the completed NRC "Medical Use Quality Assessment" questionnaires. The "Medical Use Quality Assessment" questionnaire is a fifteen page questionnaire on medical use quality, which was used during unannounced inspections between July 1989 and June 1990. A report from SAIC is due September 23, 1991.

Dosimetry Assistance

The staff contracted with Oak Ridge Associated Universities' Radiopharmaceutical Internal Dose Information Center (RIDIC)

on September 5, 1990, to provide dose estimates to NRC for internal exposures received by individuals working for NRC licensees. The staff will use this information to evaluate the regulatory importance and medical significance of incidents. This assistance proved very valuable in helping the staff promptly respond to several significant incidents involving iodine.

Medical Training

A 1988 contract study, which examined training and experience criteria, credentialing programs, and State licensure for physicians, technologists, and ancillary medical personnel was completed in December 1989. Study findings, along with the public comments received in response to a Federal Register Notice (53 FR 18845) concerning training and experience criteria published on May 25, 1988, were analyzed and presented to the ACMUI as an agenda item during the meeting held on July 10, 1990. The ACMUI responded that the information gathered by the Office of Nuclear Materials Safety and Safeguards (NMSS) staff does not support the assumption that training and experience are significant factors in misadministrations. The ACMUI suggested that additional information be gathered to include the training and experience of all individuals involved with misadministrations, as well as other incidents uncovered during NRC inspections. Before recommending rulemaking, the staff needs more information about the relationship between the level of supervision provided by authorized users to technologists and the training and experience of the technologist. Similarly, the staff needs time to monitor the impact that current proposed rulemaking, regarding medical quality assurance, will have on misadministration or violations of NRC's requirements. Additional data will be gathered over the next two years and the results used in any decision to propose future rulemaking on this issue.

Human Factors

Human error is a significant contributor to medical use incidents. Reduction of such error requires detailed knowledge of the factors that cause it. NMSS has worked closely with the Office of Nuclear Regulatory Research (RES) over the last year, to initiate research projects designed to assist the staff in acquiring that knowledge for teletherapy and for brachytherapy using remote afterloaders. Those uses were selected because of the relative significance of errors associated with them. The projects include the following tasks:

1. Function and task analyses;
2. Human-machine interface evaluation;

3. Procedures evaluation;
4. Training and qualifications evaluation;
5. Organizational practices and policies evaluation;
6. Identification and prioritization of human factors problems (i.e., human errors that affect system performance) and identification and evaluation of alternative means for resolving those problems.

The contractors for the projects, CAE-Link Corporation (teletherapy) and Pacific Science and Engineering Group, Inc. (brachytherapy), are currently conducting the function and task analyses on which all other tasks will be based. Both projects are scheduled for completion in early FY92.

The staff has also encouraged medical industry groups and users of nuclear byproduct material to consider human factors as they attempt to improve safety in their facilities and operations. In mid-1990, Syncor International Corporation, the operator of a major chain of nuclear pharmacies, accepted that challenge. As a first step, Syncor has hired an experienced human factors consultant to work with its staff in developing a program to identify and resolve performance problems associated with human error.

About 400 diagnostic misadministrations of nuclear byproduct material are reported to NRC annually. In 1990, NMSS instituted a pilot project to evaluate information in those reports for insights into the causes of human errors that contribute to such misadministrations. The key element of the project is a computerized database. Data for 1989 are currently in the database because that was the last year for which all reports are available. Data for 1990 will be added in 1991. Up to seventy data elements are entered for each reported misadministration. Programming to summarize information in the database is underway. Early results indicate that the project may identify factors leading to human errors in nuclear medicine. The staff will assess the need for a continuing effort, once the pilot project is completed.

Devices or products employed in a number of fields benefit from the availability of human-machine interface design guidance tailored to the field. In 1988, the Association for the Advancement of Medical Instrumentation (AAMI) with NRC staff participation developed and published the first compilation of such guidance for medical devices. It is now revising that compilation.

Radiopharmacy Petition

A petition for rulemaking from the ACNP and the SNM was received in June 1989. The petitioners requested that NRC

change certain requirements regarding the preparation and use of radiopharmaceuticals. The staff discussed these issues during several meetings with the Food and Drug Administration. Pharmacy issues were discussed in separate meetings with the National Association of the State Boards of Pharmacy, the Ohio State Board of Pharmacy and the Illinois State Board of Pharmacy. An interim final rule was published in the Federal Register on August 23, 1990 (Enclosure 3) and is in effect until August 23, 1993. The interim final rule allows licensees to depart from the manufacturer's instructions for elution of generators, preparation of reagent kits, and indications of use for therapy radiopharmaceuticals provided certain conditions and limitations are met. During this time, the staff will collect information to determine whether to extend the interim period for the rule, make the rule permanent, or revise it, based on the nature of the reasons for, and frequency of, the departures. The remaining issues addressed in the petition are: use of radiopharmaceuticals for human research; use of radiolabeled biologics; and pharmacy preparation of drugs outside of the FDA Investigational New Drug (IND)/New Drug Application (NDA) framework. The staff is continuing to work on these remaining issues and will provide its proposed resolution for Commission consideration by November 1992.

The interim final rule has met with some resistance and criticism by members of the medical community. The SNM and ACNP have indicated that the rule has resulted in an overly burdensome recordkeeping requirement and that it too narrowly defines the basis for allowable departures. On September 20, 1990, Syncor International, Inc., filed before the Commission a Petition for Reconsideration and Stay of Action regarding the Interim Final Rule. On October 19, 1990, Syncor filed a lawsuit against the NRC challenging the interim final rule. Syncor International Corp. v. NRC # 90-1495 (D.C. Circuit). The staff and the Office of the General Counsel are evaluating the petition and subsequent documents submitted by Syncor.

INTER-ORGANIZATION COOPERATION

The Food and Drug Administration (FDA) regulates drugs and medical devices that are placed in interstate commerce. The staff initiated and has conducted office-level and day-to-day staff-level communications designed to ensure NRC and FDA cooperation and coordination.

Interagency staff meetings were held with both FDA's Center for Drug Evaluation and Research (CDER), and Center for Biologics and Evaluation and Research (CBER), to discuss and resolve issues of common interest that were addressed in the petition for rulemaking on the practice of pharmacy and medicine, which was submitted by the ACNP and SNM. Many of the requests in that petition concern NRC's interpretation of and reliance on FDA's radioactive drug and biologic regulations. Since the FDA regulates the manufacturer regarding labeling and package insert information, and not the end-user, it is reluctant to provide a definitive statement on adherence to the package insert information. The practice of medicine and pharmacy issues associated with end-use have contributed to FDA's inability to provide clear guidance. The staff will continue to work with FDA to resolve these issues.

The FDA's Center for Devices and Radiological Health (CDRH) and NRC are sharing information on incidents involving teletherapy units, brachytherapy sources, and brachytherapy remote afterloading devices. FDA field representatives accompanied NRC staff on one teletherapy inspection, in response to an unusual machine failure involving restart of the timer, caused by a static electricity problem.

The staff initiated contacts with the HCFA, and referred information on two medical events to HCFA, for its consideration for action. NRC staff investigated the aspects of the two events that pertained to NRC regulations. HCFA requested additional information and indicated that it would look into the non-radiation medical care issues, as part of its inspection process on quality of care.

The staff continues to assist and obtain constructive comments from organizations (Association for the Advancement of Medical Instrumentation, Human Factors Special Interest Groups on Medical Systems and the Functionally Impaired, and United States Pharmacopeial Convention) by participating in committee activities of these organizations. Liaisons for information flow are established with the ACNP, ACR, SNM, AAPM, and ASTRO. All of these organizations are on a mailing list for information notices, and the NMSS Licensee Newsletter.

NRC staff efforts to assist the U. S. Department of Veterans Affairs (VA) in the development and implementation of a Radiation Safety Audit Program are on-going. The VA abandoned its program to have the regional industrial hygienists audit the hospital radiation safety programs.

Instead the VA allocated training funds to provide approximately 60 physicians, health physicists, and technologists, who are radiation safety officers (RSOs) at smaller (non-broad scope) hospitals, with a two and a half day training session on radiation safety programs. The sessions focused on NRC's licensing, inspection, and enforcement policies, with specific workshops on practical issues and tasks facing the RSOs. Workshop topics included: "training; dose calibration; surveys and counting; volatile radionuclides; receiving and shipping; and use, spills and disposal." Both NRC staff and VA staff presented instruction. NRC staff is planning to continue meeting with VA Headquarters to focus attention on improving VA medical use programs.

STAFF DEVELOPMENT

Headquarters and the regions had continued success in recruiting individuals with medical use experience to work in the licensing and inspection programs in FY90. NMSS and the Regions have hired individuals with training and experience in nuclear medicine technology, medical health physics consulting, and medical physics, including individuals with NRC licensing and inspection experience. This varied and practical field experience provides a first-hand understanding of safety concerns and implementation problems associated with the medical use of byproduct material.

Both Headquarters and regional staff members continue to participate in the NRC rotational assignment program and in team inspections. This program has fostered a better understanding of regional licensing and inspection problems and Headquarters' programs and procedures.

ACMUI

The ACMUI was convened once last year. At a July public meeting, members commented on the ACNP-SNM petition, the QA rule, training and experience criteria, expanded membership, and meeting frequency.*

*In SECY-90-356 (October 18, 1990), the staff recommended changes in the composition of the ACMUI. In a Staff Requirements Memorandum dated December 10, 1990, the Commission approved the staff's plans to expand membership and recommended a balancing of representation on the Committee while minimizing the number of additional members. The Commission also instructed that members should be approved for a term of two years with an option for renewal of the appointment for an additional two years with Commission approval.

Medical Visiting Fellows Program

The staff is implementing the Medical Visiting Fellows Program (MVFP). The Federal Register Notice of June 7, 1990 (Enclosure 4) called for nominations of qualified physicians, radiopharmacists and other health professionals to participate in the MVFP. The staff submitted a Commission Paper on the implementation plan for the MVFP on August 8, 1990 (Enclosure 5.) A total of six physicians, three radiopharmacists, one RSO and one technologist submitted applications. From these candidates, the staff has selected one physician, and one radiopharmacist, both of whom have outstanding credentials, to be the first visiting fellows. Experience gained with the first two fellows will help provide a basis for future solicitations.

OVERSIGHT

The licensing and inspection functions are conducted by the regional offices, with guidance and oversight from Headquarters. The regions conduct approximately 1000 inspections of medical use licensees annually. Most medical use licensees are inspected every three years; broad scope, nuclear pharmacy and teletherapy licensees are inspected annually. The staff is currently working on inspection guidance to the regions which will change the inspection frequency for community hospitals from three years to two years, increasing NRC oversight of approximately 1400 medical use licensees. The staff continues to use notices of violation, civil penalties, and orders, as appropriate, to ensure compliance with regulations and license conditions.

BUDGET AND FULL-TIME EQUIVALENT UNITS (FTE)

The budget and FTE for the medical use program are described in Table 1.

The staff believes that this allocation of resources meets the needs of the medical use program with emphasis on inspection activities.

Table 1.

Resources for Medical Use Program[a,b]

Functional Areas	FY90		FY91		FY92		FY93	
	$	FTE	$	FTE	$	FTE	$	FTE
Program Development & Event Evaluation (HQ)	1038	8.2	1157	8.1	800	7.8	1050	8.0
Inspection and Event Evaluation (Regions)		20.5		23.2		24.5		25.3
Licensing (Regions)		8.4		7.7		8.5		8.5
Supervision (HQ & Regions)		4.7		4.9		5.2		5.3
TOTALS	1038	41.8	1157	43.9	800	46.0	1050	47.1

[a]Headquarters and regional staff resources are rounded to nearest tenth and do not include overhead.

[b]Most of the program support funds are for improving medical QA. Dollar resources are rounded in thousands of dollars.

INFORMATION

The staff visited Regions I, II, III and IV, in the summer 1990, to enhance communications between the regions and headquarters and described program goals, the workload tracking system, and an updated list of Medical and Academic Section contacts.

The staff has used a variety of communication methods to inform licensees of NRC's medical use program and potential safety problems. These have included: preparing and distributing the NMSS Licensee Newsletter, which includes information about misadministrations and enforcement actions; providing background information for newsletter articles published by medical organizations; increasing the distribution of information notices about operational issues; participating in scientific meetings; and specific portions of notices of rulemaking.

Staff members in all regions conducted workshops for licensees. Each workshop was designed to respond to medical use issues specific to the region, such as management and RSO responsibilities, training, surveys, and audits. The workshop program has been well-received by licensees and regional staff members, and will be continued.

A summary of the Staff workshops and presentations at outside meetings held in FY90 can be found in Enclosure 6. A listing of Federal Register Notices, information notices, and staff papers, regarding the medical use program, issued in FY90 (and in some previous years) can be found in Enclosure 7.

AREAS OF CONCERN

The staff believes that developments in the medical workforce, reimbursement by public and third-party carriers for medical services, new medical technology and aging equipment continue to be potential areas of concern.

Workforce

It appears that the body of fully qualified nuclear physicians and nuclear medicine and radiation therapy technologists will continue to decline because of a continued high attrition rate of better-trained and more-experienced personnel. Able candidates for physician and technologist training programs also continue to decline. This deteriorating situation creates the need for continued monitoring of nuclear medicine and radiation therapy training programs, to help ensure the continued safe medical use of byproduct material.

Health Care Reimbursement

Both public and private-sector third-party carriers have implemented stringent cost-control programs, effectively reducing resources and options throughout all facets of health care delivery, including nuclear medicine and radiation therapy. The staff expects that licensees, being forced to reduce costs, may find it harder to maintain staff and purchase equipment to implement the Commission's objective of safe medical use of byproduct material.

Medical Technology

As noted previously (SECY-90-047), the staff still anticipates that the key change in radiopharmaceutical uses will be the development and widespread use of radiolabeled monoclonal antibodies. Monoclonal antibodies may be labeled with radioisotopes not usually seen in nuclear medicine

departments (e.g. yttrium-90 and rhenium-86) and with much larger quantities of iodine-131 and phosphorus-32. To better understand this technology and its associated radiation protection issues, RES has contract projects concerned with the radiation protection aspects unique to monoclonal antibodies and recommended radiation protection requirements, adequacy of current regulatory criteria for release of patients, and protective measures for technologists and physicians. The medical section staff is providing technical review of these projects.

In radiation oncology, there has been increased use of high-dose-rate remote afterloading brachytherapy, stereotactic therapy, and computerized treatment planning and administration. Errors caused by misunderstood parameter definitions, unvalidated computer codes, code limitations, faulty treatment-plan software, faulty computer inputs or mechanical problems are likely to increase.

The staff is keeping abreast of the new developments in radiation oncology by recruiting experienced medical use personnel, by developing an enhanced awareness of the new technology, and by interacting with cognizant professional organizations. In May 1990, the staff visited Nucletron Corp., a vendor of remote afterloading brachytherapy devices, and in September 1990, attended a presentation by Elekta Instruments, Inc., on its stereotactic therapy device (Gamma Knife), for a general overview of these devices.

Through the Medical Visiting Fellows Program, the staff hopes to attract individuals knowledgeable in monoclonal antibodies and radiation oncology, who will provide input on new developments in these areas. Additionally, the staff is preparing statements of work for two contracts, covering QA concerns for gamma knives and brachytherapy remote afterloaders, including device review and registration requirements, quality control/calibration procedures for acceptance testing, routine calibration and spotchecks, and equipment service requirements and identification of critical components.

Some teletherapy devices have been in operation for over twenty years and are more prone to mechanical and electrical problems. Spare parts for these older units are becoming increasingly difficult and expensive to obtain and may render the units unserviceable. The staff, together with the FDA and Theratronics, a teletherapy device manufacturer, is monitoring developments in this area, to ensure continued safe medical use.

PROGRAM STATUS

The Five-Point Program, initiated in FY88 is being implemented. The results are increased NRC oversight of medical licensees through the regional inspection program; enhanced communications with the medical community and professional organizations; increased guidance to the regions on licensing and inspection issues; and tracking of current and projected medical concerns. The staff will continue the implementation of the Medical Use Program, as discussed in this paper.

Coordination: This paper has been coordinated with the Office of the General Counsel, and that office has no legal objection.

James M. Taylor
Executive Director
for Operations

Enclosures:
1. SRMs dtd 08/4/88 and 03/29/90
2. 55 FR 34513 (08/23/90)
3. 55 FR 23321 (06/07/90)
4. SECY-90-275 (08/08/90)
5. Staff Workshops and Participation in Outside Mtgs
6. Other NRC Documents Related to the Medical Use Program

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ENCLOSURE 1

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

OFFICE OF THE SECRETARY

ACTION - Thompson, NMSS

Cys: Stello
Taylor
Hoyle
Jordan, AEOD
McDonald, ARM
NMcElroy, NMSS
Regions

August 4, 1988

MEMORANDUM FOR: Victor Stello, Jr., Executive Director for Operations

FROM: Samuel J. Chilk, Secretary

SUBJECT: SECY-88-77 - MEDICAL USE PROGRAM

This is to advise you that the Commission (with all Commissioners agreeing) has approved proceeding with the staff's plan to provide improved regulatory oversight of the medical use of by-product material as revised in the June 7, 1988 memorandum from M. Thompson to S. J. Chilk subject to the following modifications:

1. The section titled "Regulation of Medical Service" in Enclosure 1 should be removed;

2. press releases for escalated enforcement actions should be sent to professional society newsletters (if this is not already done); and

3. the staff should provide the Commission with an annual briefing on the Medical Use Program.

(NMSS) (EDO) (SECY SUSPENSE: 12/88)

Commissioner Rogers noted that he believes that the medical misadministration of by-product material deserves further attention by the medical community. The current estimated rate of medical misadministrations, while small in comparison with other modalities of exposure to the public from by-product material employed in the commercial sector and from NARM, can be improved by a more effective and strengthened agency program. Therefore, he agrees with the objective of providing improved regulatory oversight of the medical use of by-product material.

Commissioner Rogers also noted that the staff's Five-Point Program could contain more specificity and diversity as to implementation. In particular he believes a resource allocation for regulating medical use of by-product material other than that proposed in Table 1 may be more effective in achieving these

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Rec'd Off. EDO Enclosure 1
Date 8-4-88

objections. A continuing emphasis on Regional inspection activities as proposed to Regional licensing activities will be necessary to achieve the oversight element of the Five-Point Program.

Examples of additional actions the staff should consider in the Inter-Organization Cooperation and Information Feedback elements of the Program include:

a. Encourage rotational assignments of Headquarters NMSS staff to the Regions for periods of several months, and shorter assignments by Region Inspectors to NMSS Headquarters staff for orientation and Program overview purposes.

b. Increased utilization of AEOD staff resources for periodic analyses of medical community performance and AEOD consideration of appropriate indicators of trends in performance.

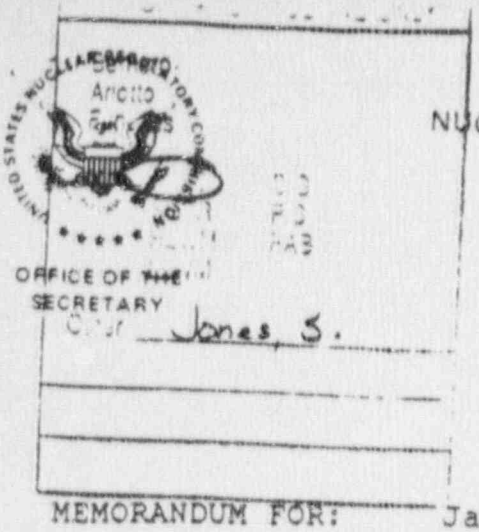
c. Exploration of further institutional ties to the medical community through establishment of a one year medical Visiting Fellows program within NMSS Headquarters. Budgetary support for an NRC Medical Fellow Program, selected by NMSS staff and the Advisory Committee on Nuclear Medicine might be possible through Health and Human Services and National Institutes of Health.

d. Active involvement of Commission offices, the EDO and Senior NRC staff members in communicating directly with the medical community (hospital administrators, physicians, medical schools, professional groups) as Commission representatives.

Commissioner Rogers requests that the staff add more flesh to the skeleton of the Five-Point Program, review the examples above and consider additional opportunities for achieving greater leverage in Program implementation. The Staff should report on these at its next briefing of the Commission.

Copies:
Chairman Zech
Commissioner Roberts
Commissioner Carr
Commissioner Rogers
OGC

ENCLOSURE 2



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

March 29, 1990

IN RESPONSE, PLEASE REFER TO: M900220

ACTION - [redacted]
Cys: Beckjord, RES
Taylor
Thompson
Blaha
Jordan, AEOD
Scroggins, OC

MEMORANDUM FOR: James M. Taylor
Executive Director for Operations

William C. Parler, General Counsel

FROM: Samuel J. Chilk, Secretary

SUBJECT: STAFF REQUIREMENTS - ANNUAL MEETING ON MEDICAL USE OF BYPRODUCT MATERIAL, TUESDAY, FEBRUARY 20, 1990, COMMISSIONERS' CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE MARYLAND (OPEN TO PUBLIC ATTENDANCE)

The Commission* was briefed by the staff on current issues associated with medical use of byproduct material. Chairman Carr commended staff for their efforts over the last year to improve NRC's regulation of such uses to ensure adequate protection of the public from unnecessary radiation exposure.

The Commission agreed that the staff should proceed with implementation of the visiting fellows program and inform the Commission when the action has been taken.

With regard to the pending petition for rulemaking from the American College of Nuclear Physicians and the Society of Nuclear Medicine about the practice of medicine and pharmacy, the Commission requested early resolution on whether a generic exemption or an interim rule is the most appropriate action to be taken.

The Commission also requested early recommendations on whether the membership of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) needs to be expanded as previously requested in the SRM dated 10/5/89 (SECY-89-263).

(Subsequently the staff submitted their recommendations in SECY-90-117.)

* Commissioner Remick was not present.

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Enclosure 2

The Commission urged the staff:

1. to seek opportunities to conduct extended facility visits to develop first-hand understanding of the safety needs and implementation difficulties associated with medical uses of byproduct material;

2. to solicit constructive comments from licensees, States, professional organizations, and other federal agencies on NRC's regulatory program in the medical use area;

3. to continue conducting workshops to inform licensees of NRC activities, sensitize licensees to NRC's concerns, and provide opportunity for feedback in the medical use area; and

4. to request sufficient resources in the next Five Year Plan to ensure adequate regulatory oversight of the medical uses of byproduct material in light of projected trends in the work force, health care reimbursement, and emerging technologies.

Chairman Carr requested that the distribution list for the NMSS newsletter include the members of the ACMUI and leaders of appropriate professional organizations.

Commissioner Curtiss suggested that charts used to indicate the number of medical misadministrations should have an added column which lists the number of medical events which are included in NRC's abnormal occurrence reports as a measure of the number of "significant" misadministrations.

cc: Chairman Carr
Commissioner Roberts
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick
GPA
ACRS
PDR - Advance
DCS - P1-24

ENCLOSURE 3

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30 and 35

RIN 3150-AD43

Authorization To Prepare Radiopharmaceutical Reagent Kits and Elute Radiopharmaceutical Generators; Use of Radiopharmaceuticals for Therapy

AGENCY: Nuclear Regulatory Commission.

ACTION: Interim final rule with request for comment.

SUMMARY: The Nuclear Regulatory Commission (NRC) is issuing an interim final rule amending its regulations related to the preparation and the therapeutic uses of radiopharmaceuticals. This interim rule allows licensees who elute generators and prepare reagent kits to depart from the manufacturer's instructions for elution and preparation in the package insert (a part of the Food and Drug Administration (FDA) approved labeling) provided the licensees meet certain conditions and limitations. The interim rule also permits NRC licensees using byproduct material in a radiopharmaceutical for a therapeutic use to depart from the package insert regarding indications and method of administration if certain requirements are met. This amendment is necessary to allow health professionals to provide diagnostic or therapeutic medical results not otherwise attainable or to reduce medical risks to particular patients because of their medical condition while continuing to protect public health and safety adequately. The interim rule applies only to radiopharmaceuticals for which the FDA has approved a "New Drug Application" (NDA).

DATES: *Effective date:* From August 23, 1990, to August 23, 1993.

Comment closing date: In view of the interim nature of this rulemaking, comments will be welcome at any time during the three-year period.

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. Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. on Federal workdays.

Copies of the regulatory analysis, environmental assessment, and the comments received on this rule may be examined at the Commission's Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the Regulatory Analysis are available from Dr. Anthony Tse, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: Dr. Tse, see **ADDRESSES** heading. Telephone (301) 492-3797.

SUPPLEMENTARY INFORMATION:

I. Background

A. Nuclear Medicine

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. An estimated 7 million diagnostic nuclear medicine procedures are performed in this country annually. In therapeutic nuclear medicine, radiopharmaceuticals are administered to treat various medical conditions (e.g., hyperactive thyroid). An estimated 30,000 therapeutic procedures are performed each year.

B. Regulatory Program and Policy Regarding Medical Use of Byproduct Materials

In a policy statement, "Regulation of the Medical Uses of Radioisotopes," published on February 9, 1979 (44 FR 8242), the NRC stated:

(1) The NRC will continue to regulate the medical uses [1] of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

(2) The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

(3) The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

The NRC has the authority to regulate medical use 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.

Under the Federal Food, Drug, and Cosmetic Act, as amended, the Food and Drug Administration (FDA) regulates drug research and the manufacturer and sale of drugs, including radiopharmaceuticals. FDA has regulated the safety and effectiveness of investigational radioactive drugs since 1975, when FDA revoked its 1963 exemption of radioactive drugs from the "Investigational New Drug" (IND) regulation. The NRC withdrew from regulating radioactive drug safety and efficacy to avoid dual Federal regulation, but continues to regulate the radiation safety of workers, patients, and the public.

Each new drug approved for human use by the FDA, including radiopharmaceuticals, has labeling approved by FDA that includes a description of the drug, its pharmacology, indications for use, contraindications, warnings, adverse reactions, dosage and administration, and other information. The labeling of certain drugs, including some radiopharmaceuticals, includes manufacturer's instructions that specify the method of preparation. FDA reviews and approves the information in the labeling to ensure that it accurately reflects the data on safety and effectiveness on which the drug approval is based. NRC has, in the past, relied primarily on FDA's determination of a drug's safety and effectiveness when it is prepared and used according to the approved labeling, which some NRC regulations refer to as the package insert, as one means of ensuring protection of the public health and safety.

NRC regulations in 10 CFR 35.200(b) require medical use licensees to prepare radiopharmaceuticals in accordance with the manufacturer's instructions in the package insert (a part of the FDA-approved labeling). Similar requirements are placed on commercial nuclear pharmacies through NRC license conditions. Regulations in 10 CFR 35.300, "Use of Radiopharmaceuticals for Therapy," require, among other things, that the licensees comply with the package insert instructions regarding indications and method of administration for the therapeutic use of radiopharmaceuticals.

[1] "Medical use," as defined in 10 CFR 35.2, 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." "Medical use" includes the diagnostic and therapeutic use of radiopharmaceuticals in the practice of nuclear medicine, but does not include in vitro diagnostic tests.

II. Petition for Rulemaking Filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine

On June 8, 1989, the NRC docketed as PRM-35-9 a petition for rulemaking dated June 5, 1989, which was filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine (ACNP-SNM). The ACNP-SNM are composed of over 12,000 individuals who participate in the medical use of byproduct materials. Members include physicians, technologists, and nuclear pharmacists. As characterized by the petitioners, the physicians supervise the preparation and administration of radiopharmaceuticals to diagnose and treat patients. Also, technologists administer radiopharmaceuticals to diagnose and perform clinical procedures under the direction and supervision of an authorized user physician.[1] Nuclear pharmacists reconstitute radiopharmaceutical kits, compound radiopharmaceuticals, and dispense radiopharmaceuticals for medical purposes.

Among other things,[2] the petitioners requested that the NRC amend its regulations at 10 CFR part 35, "Medical Use of Byproduct Material," to recognize their appropriate practice of medicine and to allow (1) departures from the manufacturer's instructions for preparing diagnostic radiopharmaceuticals and (2) the use of radiopharmaceuticals for therapeutic indications and methods of administration not included in the package insert approved by the FDA.

The petitioners stated that, under current NRC regulations, members of the petitioning organizations believe they cannot appropriately practice their professions. The petitioners also stated that authorized user physicians cannot prescribe certain radiopharmaceuticals or routes of administration for proper patient care, even though they believe they are permitted to do so by the FDA and by their State medical licenses. According to the petitioners, nuclear pharmacists have been disenfranchised as a professional entity because activities that they believe are permitted by the FDA and by the States are not allowed under NRC regulations. The petitioners stated that, although a nuclear pharmacist is authorized by State license to prepare radiopharmaceuticals upon receipt of a prescription by an authorized user physician, current NRC regulations severely restrict their activity. The petitioners believe that their professional activities are curtailed by the limitations imposed by the NRC on nuclear physicians and pharmacists.

A notice of receipt of the petition, with a public comment period of 90 days was published in the **Federal Register** on September 15, 1989 (54 FR 38239). The Federal Register notice set forth the petitioners' proposed amendments to 10 CFR parts 30, 33, and 35, including the deletion of the restriction regarding the preparation of radiopharmaceuticals in § 35.200(b) and the deletion of the restriction in § 35.300, with respect to following the package insert instructions regarding indications and method of administration (54 FR 38240). The comment period closed on December 14, 1989, and 468 comment letters have been received.

Comments were received from many different sources such as hospitals, pharmacies, and medical associates. About 60 percent of the letters were similar to a form letter written for members of ACNP-SNM. These letters indicated agreement with the petition on all essential points. Fifteen percent of the comment letters were similar to a form letter written for the staff of Syncor International Corporation, also agreeing with the assertions in the petition. Twenty-five percent of the responses were letters from other individuals.

Most letters (99 percent) supported the petition and stated that the NRC should amend its regulations to relax its current restrictions on the practice of nuclear medicine and nuclear pharmacy. The majority of these letters did not provide specific supporting rationale. Some commenters provided rationale and examples of clinical cases that the commenters believe demonstrate how the relevant NRC regulations prevent physicians from providing proper care for their patients. The commenters stated that, although a licensee may request an exemption from specific requirements in the regulations on a case-by-case basis, this exemption process is time consuming and cumbersome. The commenters believe that a delay in order to obtain NRC approval for a particular departure from the package insert may, in some cases, jeopardize the patient's health. Some examples of clinical cases the commenters provided are described below:

(1) Licensees are not able to use Tc-99m macroaggregated albumin with high specific activity and low particle concentration to safely perform lung scans for patients who have pulmonary hypertension because the ranges of specific activity and particle concentration given in the package insert would be exceeded.

(2) Licensees are not able to add ascorbic acid as an antioxidant to Tc-99m-DTPA, which would increase stability and enhance image quality, because NRC regulations do not permit departure from the manufacturer's instructions for reconstituting reagent kits.

(3) When evaluating potential blood transfusions, licensees are not able to perform *in vivo* crossmatching using potential donar red cells radiolabeled with Tc-99m because this is not provided for in the package insert.

(4) Licensees are not able to use P-32 sodium phosphate to treat primary *Thrombocythemia* because this use is not specified in the package insert.

III. Need for a Rule

Information submitted by the ACNP-SNM in the petition for rulemaking and obtained during subsequent discussions with licensees indicates that the requirements in § 35.200(b) regarding preparation of radiopharmaceuticals and in § 35.300 regarding indications and method of administration for therapy procedures are preventing authorized user physicians from providing certain nuclear medicine clinical procedures. License conditions similar to § 35.200(b) currently placed on commercial nuclear pharmacies have the same effect. For some uncommon disease states or patient conditions, in order to provide proper patient care, it may be necessary to depart from the FDA-approved instructions to obtain diagnostic or therapeutic medical results not otherwise attainable or to reduce medical risks to particular patients because of their medical condition.

The NRC believes that continued application of these restrictions governing the preparation of radiopharmaceuticals and the indications and the method of administration for therapeutic use of radiopharmaceuticals would not permit proper patient care to be provided to some patients.

Under its 1979 Medical Use Policy Statement (44 FR 8242, February 9, 1979), the NRC stated that it would regulate the medical use of byproduct material in order to protect the health and safety of workers, patients, and the public. In general, NRC regulatory requirements are oriented to ensure that the properly prepared radiopharmaceutical is administered to the correct patient as prescribed by an authorized user

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[1] Whenever the term "authorized user physician" is used, it means the "authorized user" or the physician working under the supervision of the authorized user.

[2] The NRC is working to resolve the remaining issues identified in the petition.

physician. Aside from the requirements in § 35.200(b) and § 35.300, other requirements in part 35, such as the use of dose calibrators, are intended to ensure that the patient receives the prescribed dose. NRC's regulations need to provide a balance between adequate controls and avoidance of undue interference in medical judgments. The high level of public health and safety protection that accrues from following the FDA-approved instructions must be balanced with the need to depart from those instructions to obtain diagnostic or therapeutic results not otherwise attainable or to reduce patient risk in some uncommon disease states or patient conditions in order to provide proper patient care.

The diagnostic use of radiopharmaceuticals is, in most cases, an area of inherently low radiation risk to patients (Policy Statement, 44 FR 8242; February 9, 1979). Although there are greater risks inherent in the use of therapeutic levels of radioactive drugs, in light of the information provided with and gathered subsequent to the petition, the NRC does not believe that limiting the therapeutic use of radiopharmaceuticals in all cases to only the indications and methods of administration specified in the package insert is justified. Moreover, as stated in its 1979 Policy Statement, the NRC recognizes that physicians have the primary responsibility for the protection of their patients. The Commission believes that basic decisions concerning the diagnosis and treatment of disease are a part of the physician-patient relationship and are traditionally considered to be part of the practice of medicine.

The NRC has made a determination that continued application of the subject requirements, without exceptions, may adversely affect the public health and safety because the delivery of proper patient care may require, in certain instances, that some radiopharmaceuticals be prepared and administered in a manner different from that stated in the FDA-approved instructions. The NRC has reviewed the information on nuclear medicine clinical procedures and believes that adequate protection of the public health and safety can be maintained while, at the same time, providing proper patient care. Hence, the NRC is issuing an interim final rule that permits, on the direction of an authorized user physician, departures from the manufacturer's instructions in preparing radiopharmaceuticals and departures from package inserts for indication and method of administration for therapeutic use, provided a proper record of the departure is made. These records will be examined by the NRC to determine whether to extend the interim period for the rule, make the rule permanent, or revise it based on the nature of, reasons for, and frequency of departures. The NRC will provide FDA the opportunity to review this information.

Because these amendments involve relief from restrictions which if left in place could have an adverse impact on public health and safety, and because the NRC has received and considered public comments on the petition for rulemaking, good cause exists for omitting the notice of proposed rulemaking and the public procedures thereon as unnecessary and contrary to the public interest, and for making these amendments effective upon publication in the **Federal Register** without the customary thirty-day notice. This interim rule will terminate 3 years after the date of publication in the **Federal Register**.

IV. Future Agency Action

This interim rule amending 10 CFR parts 30 and 35 represents only one phase of NRC's resolution of the ACNP-SNM petition for rulemaking. During the 3-year period, the NRC may modify the interim rule or take other regulatory action it determines necessary to protect the public health and safety. Based on continued NRC analysis of the ACNP-SNM petition, the comments on petition and on this interim rule, experience with the implementation of this interim rule, and other information, the NRC may propose amendments to this rule or to other provisions of 10 CFR parts 30 and 35 as part of its resolution of all the issues raised in PRM-35-9.

V. Discussion

Section 35.200 Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies

The NRC believes that persons licensed by the NRC to elute generators and prepare reagent kits should not always be bound by the requirement specified in 10 CFR 35.200(b) to follow the manufacturer's instructions for radiophmaceuticals for which the FDA has approved an NDA. They should not be bound if they have a written directive (*e.g.*, prescription) made by an authorized user physician directing a specific departure for a particular patient, or patients, or for a radiopharmaceutical, and which includes (1) the specific nature of the departure, (2) a precise description of the departure, and (3) a brief statement of the reasons why the departure from the manufacturer's instructions would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. The NRC recognizes that the physician may face severe time constraints during an emergency; therefore, an exception has been provided in § 35.200(c). Under the exception, a written directive is not required before preparing the radiopharmaceutical if an authorized user physician determines that the delay in obtaining a written directive would jeopardize the patient's health. The written directive together with a statement of the emergency determination must be prepared with 3 working days of the emergency administration. The written directive and a record of the number of patient administrations under each departure must be retained by the licensee for a period of 5 years and made available for NRC inspection.

This interim rule does not address departures from "Investigational New Drug" (IND) generator elution instructions or IND protocol directions for reagent kit preparation because the departures may compromise the scientific integrity of the clinical investigation. Therefore, licensees must continue to follow the IND generator elution instructions and IND protocol directions for reagent kit preparation.

Section 35.300 Use of Radiopharmaceuticals for Therapy

For a radiopharmaceutical for which the FDA has approved an NDA, the amendments to § 35.300 would permit a licensee, under certain circumstances, to use therapeutic radiopharmaceuticals for indications or a method of administration not specified in the package insert. Specifically, these uses would be permitted if an authorized user physician makes a record of the departure which includes the specific nature of the departure and a brief statement of the reasons why the departure would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. A record of the departures from indications and method of administration and a record of the number of patient administrations under each departure must be retained in an auditable form and be available for inspection for 5 years. If a kit or generator for a radiopharmaceutical for therapy were approved by FDA (through an NDA), this interim rule does not

authorize departures from the manufacturer's instructions for eluting the generator or preparing the therapy kit.

Section 30.34 Terms and Conditions of Licenses

Commercial nuclear pharmacies are licensed pursuant to 10 CFR part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." These licensees are required by a license condition similar to § 35.200(b) to elute generators and prepare reagent kits in accordance with the manufacturer's instructions. The NRC believes that authorized users obtaining radiopharmaceuticals from commercial nuclear pharmacy licensees should not be bound by this restriction in the commercial nuclear pharmacy license. Therefore, the NRC is amending 10 CFR 30.34, "Terms and Conditions of Licenses," to permit actions within the scope of those permitted by the new § 35.200(c). For situations not within the scope of the amended § 30.34, a commercial nuclear pharmacy licensee may file an application to have its license amended to permit specific departures from the manufacturer's instructions for identified products.

Under the interim rule, commercial nuclear pharmacy licensees would no longer be bound by the requirement in their licenses to follow the manufacturer's instructions for a radiopharmaceutical for which the FDA has approved an NDA if they have a written directive made by an authorized user physician directing a specific departure for a particular patient, or patients, or for a radiopharmaceutical, and which includes the specific nature of the departure, a precise description of the departure, and why the departure from the manufacturer's instructions would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. As in § 35.200(c), there is an exception to the requirement for a written directive before preparing the radiopharmaceutical in an emergency situation if an authorized user physician determines that a delay in obtaining the written directive would jeopardize the patient's health. In this case, the commercial nuclear pharmacy licensee shall obtain the written directive from the authorized user physician within 3 working days of the prescribed departure. The directive must contain information regarding the emergency and all other required information. Licensees shall keep those records in an auditable form and available for inspection for 5 years.

These amendments to § 30.34 take precedence over the restrictive conditions (*i.e.*, on eluting generators and preparing reagent kits for NDA radiopharmaceuticals) in the licenses of commercial nuclear pharmacies. Therefore, those parts of the license conditions no longer apply during the 3-year period when the interim rule is in effect. This interim rule does not address departures from IND generator elution instructions or IND protocol directions for reagent kit preparation, thus licensees shall continue to follow the IND instructions.

Continuing Applicability of Regulatory Requirements

The NRC notes that this interim rule does not relieve licensees from the requirements to comply with other applicable NRC, FDA, and other Federal or State regulations or NRC orders or license conditions concerning possession or use of byproduct material for medical use or other purposes as specified in 10 CFR parts 30, 32, 33, and 35. Moreover, if a radioactive biologic receives a product license approval (PLA), this interim rule does not authorize departures from the manufacturer's instructions for preparing the biologic. In addition, if a kit or generator for a radiopharmaceutical for therapy receives an approved NDA, this interim rule does not authorize departures from the manufacturer's instructions for eluting the generator or preparing the therapy kit. Neither of these approvals exists at this time and neither is authorized by current regulations.

Radiation Safety Responsibilities of Medical Use Licensees

NRC medical use licensees are required by § 35.21 to appoint a Radiation Safety Officer (RSO) responsible for implementing the licensee's radiation safety program. The licensee is required, through the RSO, to 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. Nothing in this rulemaking relieves the licensee from complying with the requirements of § 35.21.

In accordance with 10 CFR 35.22, NRC medical institution licensees are required to establish a Radiation Safety Committee (RSC) to oversee the use of byproduct material. The duties of the RSC are specified in § 35.22(b) and include reviews, on the basis of safety, of numerous aspects of a licensee's use of byproduct material. Nothing in this rulemaking relieves the licensee from complying with the requirements of § 35.22.

VI. Administrative Statements

Finding of No Significant Environmental Impact: Availability

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 these amendments are not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required. This interim rule amends NRC regulations to permit licensees who elute generators and prepare reagent kits to depart from the manufacturer's instructions if those persons have a written directive made by an authorized user physician that requests a specific departure for a particular patient, or patients, or for a radiopharmaceutical. This directive must provide the specific nature of the departure, a precise description of the departure, and the reasons why the departure from the manufacturer's instructions would obtain medical results, diagnostic or therapeutic, not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. The amendment does not address departures from IND generator elution instructions or IND protocol directions for reagent kit preparation. The NRC is also modifying its regulations to permit, if certain requirements are met, the therapeutic use of radiopharmaceuticals without following the package instructions regarding indications and method of administration. The interim rule does not affect the exemption in 10 CFR part 20 for the intentional exposure of patients to radiation for the purpose of medical diagnosis and therapy.

Although the rule may cause some patients to be exposed to higher or lower levels of radiation than otherwise expected, those exposures would be given to obtain medical results not otherwise attainable or to reduce other risks to the patient. It should be noted that current requirements do not limit the radiation dose prescribed by the authorized user physician for either diagnosis or therapy. The amendments would not relieve licensees from meeting the requirements in 10 CFR parts 20 and 35 that restrict radiation exposure to medical care personnel in the restricted area or to the general public in the unrestricted area, or radioactive effluent releases. It is expected that there would be no

significant change, either increase or decrease, in radiation exposure to the public or to the environment beyond the exposures currently resulting from deliver the dose to the patient.

The Environmental Assessment and Finding of No Significant Impact is available for inspection at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the Assessment are available from Dr. Tse (see **ADDRESSES** heading).

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These requirements were approved by the Office of Management and Budget approval numbers 3150–0010 and 3150–0017.

Public reporting burden for this collection of information is estimated to average .05 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB–7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–3019 (3150–0017 and 3150–0010), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The Commission has prepared a regulatory analysis for these amendments. The analysis examines the benefits and impacts considered by the NRC. The regulatory analysis is available for inspection at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC. Single copies are available from Dr. Tse (see **ADDRESSES** heading).

The Commission requests public comments on the regulatory analysis. Comments are welcome at any time during the three-year period that the interim final rule is in effect. Comments on the analysis may be submitted to the NRC as indicated under the **ADDRESSES** heading.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to these amendments because they do not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalty, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 35

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

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 30 and 35.

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for part 30 is revised to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 68 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 30.3, 30.34(b), (c), (f), (g), and (i), 30.41(a) and (c), and 30.53 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 30.6, 30.9, 30.34(g), 30.36, 30.51, 30.52, 30.55, and 30.56(b) and (c) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. In § 30.34, paragraph (i) is added to read as follows:

§ 30.34 Terms and conditions of licenses.

* * * * *

(i)(1) From August 23, 1990, to August 23, 1993, each licensee eluting generators and processing radioactive material with diagnostic reagent kits for which the Food and Drug Administration (FDA) has approved a "New Drug Application" (NDA) may depart from the manufacturer's elution and preparation instructions (for radiopharmaceuticals authorized for use pursuant to § 35.200) provided that:

(i) The licensee has a written directive made by an authorized user physician that directs a specific departure for a particular patient, or patients, or for a radiopharmaceutical, and which includes the specific nature of the departure, a precise description of the departure, and a brief statement of the reasons why the departure from the manufacturer's instructions for preparing the radiopharmaceutical would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. The licensee shall keep the written directive and record of the number of prescriptions dispensed under the departure in an auditable form and available for inspection for 5 years; or

(ii) An authorized user physician determines, in accordance with § 35.200(c), that a delay in preparing the radiopharmaceutical in order to make a written directive would jeopardize the patient's health because of the emergent nature of the patient's medical condition. In this case, the licensee shall obtain the written directive made by the authorized user physician which contains the notation regarding the emergency and all the information specified in paragraph (i)(1)(i) of this section within 3 working days after the prescribed departure. The licensee shall keep these records in an auditable form and available for inspection for 5 years.

(2) The actions authorized in paragraph (i)(1) of this section are permitted notwithstanding more restrictive language in license conditions unless those license conditions specifically reference § 30.34(i).

(3) Nothing in this section relieves the licensee from complying with other applicable NRC, FDA, and other Federal or State regulations governing the elution of generators and preparation of reagent kits.

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

3. The authority citation for part 35 is revised to read as follows:

Authority: Secs. 81, 101, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 35.11, 35.13, 35.20 (a) and (b), 35.21 (a) and (b), 35.22, 35.23, 35.25, 35.27 (a), (c) and (d), 35.31 (a), 35.49, 35.50 (a)–(d), 35.51 (a)–(c), 35.53 (a)–(h), 35.59 (a)–(c), (e)(1), (g) and (h), 35.60, 35.61, 35.70 (a)–(f), 35.75, 35.80 (a)–(e), 35.90, 35.92(a),

35.120, 35.200 (b) and (c), 35.204 (a) and (b), 35.205, 35.220, 35.300, 35.310(a), 35.315, 35.320, 35.400, 35.404(a), 35.406 (a) and (c), 35.410(a), 35.415, 35.420, 35.500, 35.520, 35.605, 35.606, 35.610 (a) and (b), 35.615, 35.620, 35.630 (a) and (b), 35.632 (a)–(f), 35.634 (a)–(e), 35.636 (a) and (h), 35.641 (a) and (b), 35.643 (a) and (b), 35.645 (a) and (b), 35.900, 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960, 35.961, 35.970, and 35.971, are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 35.14, 35.21(b), 35.22(b), 35.23(b), 35.27 (a) and(c), 35.29(b), 35.33 (a)–(e), 35.36(b), 35.50(e), 35.51(d), 35.53(c), 35.59 (d) and (e)(2), 35.59 (g) and (i), 35.70(g), 35.80(f), 35.92(b), 35.200(c), 35.204(c), 35.300(b), 35.310(b), 35.315(b), 35.404(b), 35.406 (b) and (d), 35.410(b), 35.415(b), 35.610(c), 35.615(d)(4), 35.630(c), 35.632(g), 35.634(f), 35.636(c), 35.641(c), 35.643(c), 35.645, and 35.647(c) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

4. In § 35.8, paragraph (b) is revised to read as follows:

§ 35.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 35.12, 35.13, 35.14, 35.21, 35.22, 35.23, 35.27, 35.29, 35.31, 35.33, 35.50, 35.51, 35.53, 35.59, 35.60, 35.61, 35.70, 35.80, 35.92, 35.200, 35.204, 35.205, 35.300, 35.310, 35.315, 35.404, 35.400, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, and 35.647.

* * * * *

5. In § 35.200, paragraph (c) is added to read as follows:

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

* * * * *

(c)(1) From August 23, 1990, to August 23, 1993, a licensee may depart from the manufacturer's instructions for eluting generators and preparing reagent kits for which FDA has approved an NDA, provided that the licensee has a written directive made by an authorized user physician that directs a specific departure for a particular patient, or patients, or for a radiopharmaceutical, and which includes the specific nature of the departure, a precise description of the departure, and a brief statement of the reasons why the departure from the manufacturer's instructions for preparing the radiopharmaceutical would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. If the authorized user physician determines that a delay in preparing the radiopharmaceutical in order to make a written directive would jeopardize the patient's health because of the emergency nature of the patient's medical condition, the radiopharmaceutical may be prepared without first making a written directive. The authorized user physician shall make notation of this determination in the written directive within 3 working days after the prescribed departure.

(2) The licensee shall keep the written directive and a record of the number of patient administrations under the departure in an auditable form and available for inspection for a period of 5 years.

(3) Nothing in this section relieves the licensee from complying with other applicable NRC, FDA, and other Federal or State regulations governing the elution of generators and preparation of reagent kits.

6. In § 35.300, the existing text is designated as paragraph (a) and a new paragraph (b) is added to read as follows:

§ 35.300 Use of radiopharmaceuticals for therapy.

* * * * *

(b)(1) From August 23, 1990, to August 23, 1993, a licensee may depart from the package insert instructions regarding indications or method of administration for a radiopharmaceutical for which FDA has approved an NDA, provided that the authorized user physician makes a record of the departure which includes the specific nature of the departure and a brief statement of the reasons why the departure would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition. Licensees are not authorized to depart from the manufacturer's instructions for eluting a generator or preparing any kit for a radiopharmaceutical for therapy.

(2) The licensee shall obtain this record within 3 working days of the administration and keep this record and a record of the number of patient administrations under the departure in an auditable form and available for inspection for 5 years.

(3) Nothing in this section relieves the licensee from complying with other applicable NRC, FDA (including requirements governing the submission of an IND), and other Federal or State regulations governing the use of radiopharmaceuticals for therapy.

Dated at Rockville, Maryland, this 17th day of August 1990.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 90–19901 Filed 8–22–90; 8:45 am]

BILLING CODE 7590–01–M

ENCLOSURE 4

Nominations for Visiting Fellows Program

AGENCY: Nuclear Regulatory Commission.

ACTION: Call for nominations.

SUMMARY: The Nuclear Regulatory Commission (NRC) is inviting nominations of physicians, having expert qualifications in the medical specialty fields of Nuclear Medicine or Radiation Oncology, to apply as Visiting Fellows. Others having expert qualifications in related fields such as Diagnostic Radiological Physics, Therapeutic Radiological Physics or Radiopharmacy are also invited to apply.

SUPPLEMENTARY INFORMATION:

Objectives. NRC is seeking to expand its understanding of the regulated community by creating a program for Visiting Fellows. The objectives of this program are to improve NRC's knowledge of the medical community; to keep abreast of new technology and developments in the diagnostic and therapeutic uses of isotopes; to develop an awareness of the socio-economic factors governing health care; to develop and sustain a base of experienced individual familar with the regulatory environment; to improve NRC's regulatory process; and to develop medical use regulations that minimally intrude into medical practice. The program is open to physicians interested in seeking an appointment for individual sabbatical pursuits. Other specialists on sabbatical, or those who wish to engage in post-doctroal research, will also be considered. Individuals participating in the Visiting Fellows Program (VFP) would join NRC, for approximately one year, to undertake activities consistent with the interests and needs of NRC and with the individual's training and experience; and that will result in a clearly defined assignment useful to NRC's medical regulatory program.

The number of appointments made will depend on the range of skills embodied in the nominations, individual interests and the needs of NRC

In addition to a specific assignment or research project, it is anticipated that the Fellow would attend meetings of NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI); Federal, State, and local agencies; professional organizations; and groups, to participate in discussions on issues related to medical affairs and radiation medicine. The selectee may also participate in public meetings and seminars sponsored by NRC for exchanging information and discussing issues, of mutual interest, that will benefit the regulation of medical practice. A collateral NRC goal is to create a cadre of individual with knowledge and experience in the regulation of the medical use of isotopes; therefore, it is likely that former Fellows may be asked to participate, from time to time, in NRC-sponsored meetings and seminars after their appointments and, to provide advice and consultation about the regulated program.

Therefore, NRC is primarily soliciting nominations of physicians involved with the medical use of radioisotopes, but will be pleased to receive nominations of other radiation health professionals and medical radiation specialists to serve in the VFP.

Appointment Method. Appointments will be made by means of Intergovernmental Personnel Act assignment, reimbursable detail, or professional term appointment, depending on the selectee's situation.

Term of Appointment. The term of appointment will be approximately one year. Appointments may be lengthened, depending on the depth and scope of the Fellow's project, to approximately two years.

Compensation. Visiting Fellows will receive compensation commensurate with their experience, salary history and federal pay guidelines while serving their appointment. Visiting Fellows will be reimbursed for official travel and relocation expenses.

Duty Location and Travel. Visiting Fellows may be assigned to any Office in NRC, including Office of the Commissioners, consistent with the interests and needs of NRC and the individual's training and experience. The duty location is at NRC Headquarters, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. It is anticipated that there will be some travel associated with this position.

Eligibility Requirements. NRC is an equal opportunity employer. Nominees must be U.S. citizens. Nomiees must also satisfy applicable NRC security, conflict of interest, and drug-free work place standards. Eligibility is open to physicians specializing in Nuclear Medicine or Radiation Oncology, Diagnostic Radiological Physicists, Therapeutic Radiological Physicists and Radiopharmacists. Other nominees, will also be considered based on the needs of NRC and the individual's interests.

How to Nominate. Candidates may be nominated by professional groups, medical societies, government agencies, or may be self-nominated. Nominations must provide the nominee's current address and telephone number and include a resume describing the educational and professional qualifications of the nominee. A brief statement of the individual's professional objectives should also be included.

Where to Submit Nominations. Submit nominations to: Secretary of the Commission, ATTN: Visiting Fellows Management Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Date Nominations Are Due. Nominations are due to the Secretary of the Commission by August 31, 1990.

FOR FURTHER INFORMATION, CONTACT: James H. Myers, Medical, Academic, and Commercial Use Safety Branch, Mail, Stop: 6H3, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-0637.

Dated At Rockville, Maryland, this 31st day of May, 1990.

For the Nuclear Regulatory Commission.

John E. Glenn,

Chief, Medical, Academic, and Commercial Use Safety Branch, Division of Industrial and Medical Nuclear Safety, NMSS.

[FR Doc. 90-13231 Filed 6-6-90; 8:45 am]

BILLING CODE 7590-01-M

ENCLOSURE 5

SECY File

POLICY ISSUE
(Information)

August 8, 1990 SECY-90-275

For: The Commissioners

From: James M. Taylor
Executive Director
for Operations

Subject: IMPLEMENTATION OF THE MEDICAL VISITING FELLOWS PROGRAM

Purpose: This paper informs the Commission about the implementation and administration of the Medical Visiting Fellows Program (MVFP) described in SECY-89-295. Enclosure 1 is a Federal Register Notice dated June 7, 1990, outlining a number of program items designed to initiate implementation of the MVFP, and soliciting nominations. Enclosure 2 contains a summary of key milestones associated with the administration of the MVFP, their expected completion dates, and lead Offices.

This paper also responds to comments from the Commissioners contained in a memorandum from Samuel J. Chilk, of October 20, 1989, regarding the development of the MVFP. The responses of the staff are found in Enclosure 3.

Discussion: The U.S. Nuclear Regulatory Commission (NRC) intends to expand its understanding of the regulated community through a MVFP. The objectives of this program are to improve NRC's knowledge of the medical community; to keep abreast of new technology and developments in the diagnostic and therapeutic uses of isotopes; to develop an awareness of the socio-economic factors governing health care; to develop and sustain a base of experienced individuals familiar with the regulatory environment; to improve NRC's regulatory process; and to develop medical use regulations that minimally intrude into medical practice. The program is primarily seeking physicians with expert backgrounds in nuclear medicine or radiation oncology. Others, having expert qualifications in related fields such as diagnostic radiological physics, therapeutic radiological physics, or radiopharmacy are also invited to apply as Medical Visiting Fellows.

Contact: Janet Schlueter, NMSS
492-0633

Nominees might be on sabbatical or interested in conducting graduate, post-graduate, or post-doctural research, or job related work consistent with the needs and interests of the NRC.

A collateral NRC goal is to create a cadre of individuals with knowledge and experience in the regulation of the medical use of isotopes. As a result, the NRC will likely ask former Fellows to participate, from time to time, in meetings and seminars to provide advice and consultation about the regulated program, the MVFP, or related areas of interest. The staff will incorporate language into each individual's MVFP agreement indicating that the Fellow should be willing to meet and confer with the NRC and other Fellows in future meetings and seminars at the request of the Commission.

Individuals participating in the MVFP would join the NRC for approximately one year, to undertake activities consistent with the interests and needs of the NRC and the individual's professional experience. Appointments may be lengthened upon mutual agreement by tne NRC and the Fellow.

The key elements associated with administration of the MVFP have been designed to ensure that the program is meaningful for both the Fellows and the Commission. The following paragraphs describe the process that the staff will follow to implement and administer the program:

Procedures for receipt of nomination packets

The NMSS Project Manager will receive and log the nomination packets. The Project Manager will review each packet for completeness and forward a letter acknowledging receipt of the packet to the applicant in a timely manner.

Evaluation panel

The NMSS Office Director will establish an evaluation panel and appoint its members. The panel will consist of three to five individuals from higher-level NRC managemen representing several agency Offices, and the Project Manager. The NMSS Office Director will chair the panel. As an early and integral part of the panel's evaluation, the Office of the General Counsel will be consulted and will provide advice on all prospective candidates with regard to conflict of interest issues.

Review of nomination packets by the panel

Within 30 days of the close of the nomination period described in the Notice, the evaluation panel will complete a review of each applicant, primarily on the basis of the packet submitted.

Coordination with the agency host Office for the development of the work project or product

Within 60 days of the close of the nomination period described in the Notice, the panel will identify prospective candidates, if any. As a result, during initial negotiations with the appropriate host Office, the panel will identify each work project, and if applicable, an expected product. The host Office is not limited to NMSS and might include other Offices, such as, the Office of Nuclear Regulatory Research. The development of each work project will be based on the individual applicant's professional experience and the needs of the Commission at that time. For example, in one project a Fellow could investigate the emerging trends in Nuclear Medicine, or Radiation Therapy and related radiological safety considerations. A few examples of new trends of interest include the following: the use of monoclonal antibodies in diagnostic and therapeutic administrations; the use of high activity brachytherapy afterloaders; and the use of the gamma knife device for the treatment of intracranial tumors. An example of a work product, might be an analysis of the status of monoclonal antibody research, research issues that need to be resolved before it achieves wide-spread use, projections as to when this might be achieved, identification of licensing issues for routine use that need to be resolved, and proposed special licensing requirements such as, training, radiation safety precautions, quality assurance requirements, etc.

Negotiations with selected individual(s)

The development of a work project and product will include an interview of candidates by the NMSS Office Director and others as deemed appropriate, and an initial negotiation with each prospective candidate. The host Office and the Office of Personnel will submit specific guidelines which will be tailored to incorporate expertise offered by each individual. In addition, during the interview the Office of Personnel will explain NRC procedural commitments (e.g. drug testing).

Recommendations forwarded to EDO for approval

The panel will submit to the EDO, for approval, those candidates it recommends within 90 days of the close of the nomination period identified in the Federal Register Notice.

Candidate selection and notification process

Upon EDO approval, the staff will notify the candidate(s) in order to proceed with final negotiations with the host Office and the Office of Personnel.

Commencement of term of appointment
The Project Manager will continue to participate by ensuring that the Office of Personnel and the host Office complete placement of each Fellow, handling the responsibility for all daily administrative matters, and identifying a host Office staff member to coordinate the work project and product, if appropriate.

Solicitation of additional candidates
The staff will periodically publish Federal Register Notices announcing a call for nominations for the MVFP. The timing of these Notices will be determined by the timing of the end date of each Fellow, the number of Fellows currently participating in the MVFP, the needs of the Commission at that time, and the availability of qualified applicants.

Actions Taken: The Federal Register Notice published on June 7, 1990, announcing a call for nominations of Fellows, described a number of program items designed to initiate implementation of the MVFP. These items include the following: Objectives of MVFP, Appointment Method, Term of Appointment, Compensation, Duty Location and Travel, Eligibility Requirements, How to Nominate, Where to Submit Nominations, and Date Nominations Are Due. The call for nominations closes August 31, 1990.

In addition to publication of the Federal Register Notice on June 7, 1990, copies of the Notice have been distributed to all medical use program licensees. Copies have also been given to the Office of State Programs for distribution to Agreement States and Agreement State licensees. To ensure wide distribution, the staff sent copies to approximately 200 organizations and individuals who may have an interest in the MVFP, and placed copies in professional journals such as Scanner, published by the American College of Nuclear Physicians and Newsline, published by the Society of Nuclear Medicine. Copies of the Notice were also made available at the Society of Nuclear Medicine's 37th Annual Meeting, June 19 to 22, 1990, held in Washington, D.C.

As a result of this Federal Register Notice, the receipt of nomination packets has commenced. Consequently, the program is underway with the staff focus primarily on administration of the MVFP. However, at present, the staff has no indication of the kind or number of nominations it will receive. Therefore, the number of candidates selected will depend on the range of disciplines involved, and the types of activities that can be assigned.

Coordination: This paper has been coordinated with the Office of the General Counsel, and that office has no legal objection.

James M. Taylor
Executive Director
for Operations

Enclosures:
1. FRN
2. Key Milestones of program mgmt.
3. Responses to comments from the OCM contained in a memo of 10/20/89.

DISTRIBUTION:
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Nominations for Visiting Fellows Program

AGENCY: Nuclear Regulatory Commission.

ACTION: Call for nominations.

SUMMARY: The Nuclear Regulatory Commission (NRC) is inviting nominations of physicians, having expert qualifications in the medical specialty fields of Nuclear Medicine or Radiation Oncology, to apply as Visiting Fellows. Others having expert qualifications in related fields such as Diagnostic Radiological Physics, Therapeutic Radiological Physics or Radiopharmancy are also invited to apply.

SUPPLEMENTARY INFORMATION:

Objectives. NRC is seeking to expand its understanding of the regulated community by creating a program for Visiting Fellows. The objectives of this program are to improve NRC's knowledge of the medical community; to keep abreast of new technology and developments in the diagnostic and therapeutic uses of isotopes; to develop an awareness of the socio-economic factors governing health care; to develop and sustain a base of experienced individual familar with the regulatory environment; to improve NRC's regulatory process; and to develop medical use regulations that minimally intrude into medical practice. The program is open to physicians interested in seeking an appointment for individual sabbatical pursuits. Other specialists on sabbatical, or those who wish to engage in post-doctroal research, will also be considered. Individuals participating in the Visiting Fellows Program (VFP) would join NRC, for approximately one year, to undertake activities consistent with the interests and needs of NRC and with the individual's training and experience; and that will result in a clearly defined assignment useful to NRC's medical regulatory program.

The number of appointments made will depend on the range of skills embodied in the nominations, individual interests and the needs of NRC

In addition to a specific assignment or research project, it is anticipated that the Fellow would attend meetings of NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI); Federal, State, and local agencies; professional organizations; and groups, to participate in discussions on issues related to medical affairs and radiation medicine. The selectee may also participate in public meetings and seminars sponsored by NRC for exchanging information and discussing issues, of mutual interest, that will benefit the regulation of medical practice. A collateral NRC goal is to create a cadre of individual with knowledge and experience in the regulation of the medical use of isotopes; therefore, it is likely that former Fellows may be asked to participate, from time to time, in NRC-sponsored meetings and seminars after their appointments end, to provide advice and consultation about the regulated program.

Therefore, NRC is primarily soliciting nominations of physicians involved with the medical use of radioisotopes, but will be pleased to receive nominations of other radiation health professionals and medical radiation specialists to serve in the VFP.

Appointment Method. Appointments will be made by means of Intergovernmental Personnel Act assignment, reimbursable detail, or professional term appointment, depending on the selectee's situation.

Term of Appointment. The term of appointment will be approximately one year. Appointments may be lengthened, depending on the depth and scope of the Fellow's project, to approximately two years.

Compensation. Visiting Fellows will receive compensation commensurate with their experience, salary history and federal pay guidelines while serving their appointment. Visiting Fellows will be reimbursed for official travel and relocation expenses.

Duty Location and Travel. Visiting Fellows may be assigned to any Office in NRC, including Office of the Commissioners, consistent with the interests and needs of NRC and the individual's training and experience. The duty location is at NRC Headquarters, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. It is anticipated that there will be some trave associated with this position.

Eligibility Requirements. NRC is an equal opportunity employer. Mominees must be U.S. citizens. Nomiees must also satisfy applicable NRC security, conflict of interest, and drug-free work place standards. Eligibility is open to physicians specializing in Nuclear Medicine or Radiation Oncology, Diagnostic Radiological Physicists, Therapeutic Radiological Physicists and Radiopharmacists. Other nominees, will also be considered based on the needs of NRC and the individual's interests.

How to Nominate. Candidates may be nominated by professional groups, medical societies, government agencies, or may be self-nominated. Nominations must provide the nominee's current address and telephone number and include a resume describing the educational and professional qualifications of the nominee. A brief statement of the individual's professional objectives should also be included.

Where to Submit Nominations. Submit nominations to: Secretary of the Commission, ATTN: Visiting Fellows Management Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Date Nominations Are Due. Nominations are due to the Secretary of the Commission by August 31, 1990.

FOR FURTHER INFORMATION, CONTACT: James H. Myers, Medical, Academic, and Commercial Use Safety Branch, Mail, Stop: 6H3, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-0637.

Dated At Rockville, Maryland, this 31st day of May, 1990.

For the Nuclear Regulatory Commission.

John E. Glenn,

Chief, Medical, Academic, and Commercial Use Safety Branch, Division of Industrial and Medical Nuclear Safety, NMSS.

[FR Doc. 90-13231 Filed 6-6-90; 8:45 am]

BILLING CODE 7590-01-M

ENCLOSURE 1

KEY MILESTONES OF MEDICAL VISITING FELLOWS PROGRAM (MVFP) AND RESPONSIBLE OFFICE

Objective	Office	Completion Date*
Draft Federal Register Notice and submit to EDO	NMSS	May 1, 1990
Federal Register Notice approved	EDO	May 30, 1990
Federal Register Notice published	Fed. Reg.	June 7, 1990
MVFP Commission Paper due NMSS	NMSS	July 19, 1990
MVFP Commission Paper due EDO	NMSS	July 26, 1990
MVFP Appointment Panel Identified	NMSS/OP	August 15, 1990
Nominations Close	NMSS	August 31, 1990
Nomination Assessment Begins	NMSS/OP	September 3, 1990
Interviews with selectee(s) and initial negotiations	NMSS/OP	October 31, 1990
Nomination Assessment Closes	NMSS/OP	November 15, 1990
Panel recommendations forwarded to EDO for approval	EDO	November 30, 1990
Notification of selectee	NMSS/EDO	December 31, 1990
Selectee acceptance, project definition, final negotiation and clearance processing	NMSS/OP	January 31, 1991
Fellow on Board	OP	To Be Determined

* Note: All dates are representative and may change due to programmatic needs.

ENCLOSURE 2

STAFF RESPONSES TO COMMENTS FROM THE COMMISSIONERS
CONTAINED IN A SECY MEMORANDUM DATED OCTOBER 20, 1989

Comment No. 1:

The staff is encouraged to pursue potential assignments for a Visiting Fellow in areas of emerging medical technologies and procedures where the Commission needs to concentrate efforts to ensure that the regulations are adequate for future medical applications.

STAFF RESPONSE:

As directed by the Commission, the staff has pursued potential assignments for the MVFP. The staff has discussed the matter with representatives of professional societies, Federal agencies and services, and individual physicians. The staff believes that there are several types of individuals willing to participate in the MVFP. There are projects that may be undertaken that are consistent with the individual's training and experience and the interests and needs of the NRC. For example, the Commission could benefit from a nuclear medicine or radiation therapy physician's knowledge and experience in the area of quality assurance, monoclonal antibody therapy, gamma knife therapy, or high activity brachytherapy afterloaders. A nuclear medicine physician, or a radiopharmacist, could work on a project related to physician-ordered modifications of the radiopharmaceutical manufacturer's instructions for the reconstitution of reagent kits or the use of radiopharmaceuticals. These individuals could also address the issue of compounding radiopharmaceuticals. The Commission could also benefit from the work of a medical radiation physicist for teletherapy units and/or brachytherapy devices.

Comment No. 2:

The fellows program should contain language that states that it is the Commission's expectation that a fellowship recipient will be willing to participate in possible future meetings and seminars sponsored by the NRC for the purposes of maintaining contact with the alumni of the program and exchanging professional information of mutual interest. Over time a group of past fellowship holders could be a very valuable information resource to the NRC and it seems appropriate to ask potential fellowship candidates to make a non-binding commitment to meet and confer, from time to time, with the NRC and other fellows.

STAFF RESPONSE:

The staff has addressed this area of concern by establishing a collateral MVFP goal to create a cadre of individuals with knowledge and experience in the regulation of the medical use of isotopes. Therefore, former Fellows will be asked to participate, from time to time, in meetings and seminars, after their appointments end, to provide advice and consultation about the regulated program. The staff will incorporate language into the MVFP agreement, indicating that the Fellow is willing to meet and confer with the NRC, and other Fellows, in the future.

Comment No. 3:

The U.S. Public Health Service should be included as one of the organizations participating in the program. As a federally funded, non-profit, service-oriented entity, their members could provide a unique perspective on the practice of medicine.

STAFF RESPONSE:

The staff contacted members of the U.S. Public Health Service (USPHS) and discussed the concept of the MVFP. Although the USPHS physicians could provide a unique perspective on the practice of medicine, most USPHS physicians are not specialized in nuclear medicine or radiation oncology. USPHS physicians may, however, be able to contribute to projects related to broad issues such as industrial hygiene, referring physicians, Federal medical programs, and emergency medical response capabilities in incidents involving nuclear materials.

Comment No. 4:

Since the paper mentions that the program costs are expected to be accommodated through reallocations of planned program support funds, the Commission should be informed on whether the "user-fee" concept applies and if so, how.

STAFF RESPONSE:

Most of the costs for the MVFP are expected to be accommodated through reallocations of planned program support funds. Fellows will not work on fee-chargeable casework, but they may follow such work in parallel as part of their work activity. Individuals participating in the MVFP would join the NRC, to undertake activities consistent with the interests and needs of

the NRC and the individual's training and experience. Their participation will result in a clearly defined project, or assignment, useful to the NRC's medical regulatory program. Work assignments involving fee-chargeable casework would appear to be inconsistent with established goals of the MVFP.

Comment No. 5:

The staff is encouraged to pursue the offer of key medical use organizations to provide short-term sabbatical positions for NRC staff in order to provide enhanced understanding of the regulated industry as well as valuable current experience.

STAFF RESPONSE:

The staff believes that the offer of key medical organizations to provide short-term sabbatical positions for NRC staff at the facilities of NRC medical licensees needs further evaluation. The staff believes that the goals of enhancing the NRC staff members' understanding of the regulated industry and maintaining current knowledge of clinical practice can be partially achieved through selective recruiting, additional staff training, and attendance at national or local medical society meetings and short, one-day to two-week, observation visits arranged with nearby medical institutions. The benefits to NRC of establishing short-term sabbaticals for staff members, must be balanced against the possibility of creating conflict-of-interest situations for individual staff members. The staff recommends continued discussion with the medical organizations, participating medical institutions, the Advisory Committee on the Medical Use of Isotopes (ACMUI), Office of Personnel (OP), Office of the General Counsel (OGC), and NMSS to more fully develop this issue.

ENCLOSURE 6

Staff Workshops and Participation in Outside Meetings

1989

OCTOBER

Headquarters, Presentation on Medical Licensing and Inspection, American College of Cardiology, Bethesda, Maryland
Headquarters, Army Industrial Hygiene Annual Meeting, Aberdeen, Maryland
Region I, Workshop, "Medical Initiatives," Rockport, Maine
Region III, Presentation at Annual Agreement State Meeting, Kansas City, Missouri
Region III, Presentation at Evanston-Glenbrook Hospital, Chicago, Illinois

NOVEMBER

NMSS and GPA, Joint Special Topics Workshop, Downer's Grove, Illinois
Region I, Presentation to Technologist Section, Mid-Eastern Chapter, Society of Nuclear Medicine, Philadelphia, Pennsylvania
Region III, Presentation at NRC Agreement States Sponsored Course, Emmitsburg, Maryland
Region V, Meeting with Hawaii Department of Health Officials on Quality Assurance, Honolulu, Hawaii
Region V, Workshop, Oakland, California
Region V, Presentation at ASNT, Dublin, California

DECEMBER

Headquarters, Presentation to Mid-Atlantic Chapter, American Association of Physicists in Medicine, Annapolis, Maryland
Region II, Workshop, Richmond, Virginia

1990

FEBRUARY

Region III, Presentation to Health Physics students from Wayne State University, Detroit, Michigan
Region III, Presentation to Harper Grace Hospital, Detroit, Michigan

MARCH

Region V, Presentation at Letterman Army Medical Center, San Francisco, California
Headquarters, Presentation to Nuclear Medicine Technologists at Northport VAMC, Northport, New York
Headquarters, Presentation to American Association of Physicists in Medicine, Houston, Texas

Enclosure 6

APRIL

Headquarters and RIII, Presentation at IAEA Training Course, Argonne National Laboratory, Illinois

MAY

Region III, Presentation at Michael Reese Hospital, Chicago, Illinois

JUNE

Region III, Medical Workshop, Downers Grove, Illinois
Region V, Presentation at Hawaiian Chapter of Society of Nuclear Medicine Technologists, Honolulu, Hawaii
Region V, Workshop, Honolulu, Hawaii
Region III, Presentation on "Impact of Part 35" at Health Physics Annual Meeting, Anaheim, California
Headquarters, Presentation at Society of Nuclear Medicine Annual Meeting, Washington, DC
Headquarters, Presentation to American Association of Medical Dosimetrists, Denver, Colorado

JULY

Region III, Presentation at Argonne National Laboratory on "Uses of Radioactive Material," Illinois

AUGUST

NMSS and GPA, Joint Seminar, Arlington, Texas

SEPTEMBER

Region III, Presentation at Great Lakes Chapter of Health Physics Society, Royal Oak, Michigan
Headquarters, Regions II and IV, Presentations at V.A. Workshop for V.A. Radiation Safety Officers, Little Rock, Arkansas

ENCLOSURE 7

OTHER NRC DOCUMENTS RELATED TO THE MEDICAL USE PROGRAM

Federal Register Notices

44 FR 8242, "Regulation of the Medical Use of Radioisotopes; Statement of General Policy," February 9, 1979.

51 FR 36932, "Medical Use of Byproduct Material; Final Rule," October 16, 1986.

53 FR 18845, "Medical Use of Byproduct Material; Training and Experience Criteria," May 25, 1988.

52 FR 36942, "Basic Quality Assurance in Radiation Therapy," and 52 FR 36949, "Comprehensive Quality Assurance in Medical Use and a Standard of Care," October 2, 1987.

54 FR 22444, "Indemnification of Licensees that Manufacture, Produce, Possess, or Use Radiopharmaceuticals or Radioisotopes for Medical Purposes," May 24, 1989.

54 FR 36239, "Petition for Rulemaking; Notice of Receipt," September 15, 1989.

55 FR 23321, "Nomination for Visiting Fellows Program," June 7, 1990.

55 FR 34513, "Authorization to Prepare Radiopharmaceutical Reagent Kits and Elute Radiopharmaceutical Generators; Use of Radiopharmaceuticals for Therapy," August 23, 1990.

Staff Papers

SECY-88-77, "Medical Use Program," March 14, 1988.

SECY-89-006, "Annual Report on Medical Use Program," January 12, 1989.

SECY-89-105, "Price-Anderson Negotiated Rulemaking," April 3, 1989.

SECY-89-171, "Proposed Amendments to 10 CFR Part 35 to Require a Basic Quality Assurance Program and to Modify Reporting and Recordkeeping Requirements," June 7, 1989.

SECY-89-269, "Proposed Amendments to 10 CFR Part 35 to Require a Basic Quality Assurance Program and to Modify Reporting and Recordkeeping Requirements," August 30, 1989.

SECY-89-295, "Medical Community Performance and Visiting Fellows Programs," September 21, 1989.

SECY-90-047, "Annual Report on Medical Use Program, 1989," February 14, 1990.

SECY-90-275, "Implementation of the Medical Visiting Fellows Programs," August 8, 1990.

Information Notices

IN 89-12 Dose Calibrator Quality Control

IN 89-60 Maintenance of Teletherapy Units

In 89-85 EPA's Interim Final Rule on Medical Waste Tracking and Management

IN 90-58 Improper Handling of Opthalmic Strontium-90 Beta Radiation Applicators

IN 90-59 Errors in the Use of Radioactive Iodine-131

In 90-71 Effective use of Radiation Safety Committees to Exercise Control over Medical Use Programs