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NUCLEAR REGULATORY COMMISSION

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ANNUAL BRIEFING ON MEDICAL USE OF
BYPRODUCT MATERIAL

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PUBLIC MEETING

Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Tuesday, February 12, 1991

The Commission met in open session, pursuant to notice, at 1:30 p.m., Kenneth M. Carr, Chairman, presiding.

COMMISSIONERS PRESENT:

KENNETH M. CARR, Chairman of the Commission
KENNETH C. ROGERS, Commissioner
JAMES R. CURTISS, Commissioner
FORREST J. REMICK, Commissioner

STAFF SEATED AT THE COMMISSION TABLE:

SAMUEL J. CHILK, Secretary

WILLIAM C. PARLER, General Counsel

JAMES TAYLOR, Executive Director for Operations

HUGH THOMPSON, DEDO

LARRY CAMPER, Section Leader, Medical and Academic Section

RICHARD CUNNINGHAM, Director, Division of Ind. and Med. Nuclear Safety, NMSS

VANDY MILLER, A/D, State Agreements Programs

JOSEPHINE PICCONE, Senior Project Manager, Medical and Academic Section

P-R-O-C-E-E-D-I-N-G-S

1:30 p.m.

CHAIRMAN CARR: Good afternoon, ladies and gentlemen.

This is the NRC staff's annual briefing of the Commission on the medical use of byproduct material. The purpose of the briefing is for the staff to provide a programmatic overview of NRC's regulatory program for medical uses. Today's briefing provides an opportunity for the Commission to assess the status and effectiveness of NRC's current regulatory program to ensure the safety of medical uses of byproduct material.

Do my fellow Commissioners have any opening comments?

If not, Mr. Taylor, please proceed.

MR. TAYLOR: Good afternoon. With me today at the table, to my right, Hugh Thompson, my Deputy covering this area, and to his right Dick Cunningham from the Office of NMSS, Vandy Miller from the Office of GPA. To my left, Larry Camper and Josephine Piccone, both from NMSS. Mr. Bernero and Mr. Glenn, who were to be here today, are ill today.

In 1988, the staff provided the Commission with a five point program --

CHAIRMAN CARR: It's not a medical retribution anywhere, is it?

MR. TAYLOR: No.

MR. CAMPER: We don't believe so.

MR. TAYLOR: I think they're taking home remedies.

In 1988, the staff provided the Commission with a five point program for improving oversight of the medical use of byproduct material. In approving this plan, the Commission directed the staff to provide an annual briefing on this program. This is the third such briefing.

Since the last briefing, the staff has continued to pursue a number of significant initiatives across the five areas, including, first, continuation of efforts to promulgate the quality assurance role, including the pilot program; conducting studies of the cause of medical errors due to human factors; and has established a medical visiting fellows program.

In addition, the staff continues resolution of issues identified in the radiopharmacy petition filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine and continues to meet with and respond to recommendations

from our Advisory Committee on the Medical Use of Isotopes.

These issues, along with others, which were noted in the annual report on this program which we have recently provided to you, will now be discussed further by Larry Camper from NMSS.

MR. CAMPER: Thank you, Mr. Taylor.

As Mr. Taylor pointed out, Doctor Glenn was originally going to give this briefing. Mr. Bernero is absent. I'm getting over the tail end of the same thing, so this may become known as the influenza briefing of 1991. But hopefully we can cover everything that's important.

(Slide) May we have our first slide, please?

In looking at the annual briefing, the subject matter that we're going to discuss today was provided to you in a recent Commission paper identified as SECY-91-026. The format that we'll follow will be the same that you have seen before for this briefing. We will look at the five point program areas, those being program development, which of course is primarily focused upon improving licensee performance; interorganization cooperation, which focuses upon coordinating efforts with other

regulatory agencies; staff development, which emphasizes upgrading the depth of experience on our own staff; oversight, which of course is an increased presence; and information which is designed to improve communications.

(Slide) Next slide.

Under the category of program development, the first thing that's important to point out is a program for dosimetry assistance. In this regard, the staff has arranged and put in place a contract with Oak Ridge Associated Universities. The contract is primarily designed to look at internal exposures which are received by people in NRC licensing facilities and in some instances patients which are undergoing nuclear medicine procedures.

To a great degree at least, this was triggered by the event which occurred at Tripler Army Hospital in Hawaii. You may recall that in that case there was a significant exposure to the thyroid gland of a nursing infant.

This contract is approximately $100,000.00 in value. It is good through September of 1991. We do receive monthly reports from Oak Ridge as well as immediate reports or timely reports in those instances when we need to turn to them for assistance. And if

funds should be available, we have the opportunity to extend this contract.

COMMISSIONER REMICK: What is it they're actually doing in dosimetry there at Oak Ridge?

MR. CAMPER: Primarily they're looking at providing internal exposures as indicated by the episode that takes place. In the case of Tripler, for example, they were able to compute the thyroid dose delivered to the nursing infant. So, it will be variable, specific upon the radioisotope in question and the procedure in question. But the main thing is that we have the ability to receive a timely response by an organization of the stature of Oak Ridge.

CHAIRMAN CARR: So, it's a tasking contract?

MR. CAMPER: That's right, it is a tasking contract.

COMMISSIONER REMICK: Yes, but is it computational techniques or what? They aren't developing dosimeters, it's calculations. Is that it?

DOCTOR PICCONE: Yes.

MR. CAMPER: That's right.

COMMISSIONER CURTISS: We've been reporting medical misadministrations to the Congress in AO reports for some time. How have we evaluated

those questions before this contract?

MR. CAMPER: Well, if I understand your question, there has been a need -- we have perceived a need, particularly as a result of what happened at Tripler. Many of the cases that happen with misadministrations don't involve the degree of severity that occurred at Tripler. We have felt the need to enhance our capability as a result of that type of thing.

MR. THOMPSON: Specifically, I think, to the misadministrations, two reports are typically given. One, the licensee who has a responsibility to evaluate the dose, we will typically report that and confirm it with our own consultants or on staff calculations. We have the capability to do general scoping verification type calculations. I think the Oak Ridge dosimetry is just a clear improvement over that capability in a time fashion and with those that are particularly significant, like an infant. Those, I think, are dosimetry type calculations or dose calculations we really haven't had a lot of experience doing.

COMMISSIONER CURTISS: Okay. Good.

MR. CAMPER: And in the case of Tripler as well, the staff in Region V, as well as

Headquarters, did prepare some computations as to the expected dose to be delivered. But it is a need to further enhance that.

Okay. Under the area of human factors, human factors, of course, is a significant contributor to medical incidents, misadministrations and otherwise. If we're going to reduce such errors, we feel that there's a need to better understand the impact of the human factor arena. In this regard, we have contracts in place currently that look at teletherapy and remote brachytherapy functions. These are tasked analysis types of contracts and we hope that these will lay the groundwork for more programmatically directed regulations or studies in the future.

Under the area of quality assurance rule and pilot program, as well as radiopharmacy petition, we'll look at those more closely with individual slides.

COMMISSIONER REMICK: Two years ago NMSS hired their first human factors expert. Do we still have one at NMSS or do we have more than one?

MR. CAMPER: We have Doctor Dennis Serig, who has played an active role in monitoring and developing these contracts that are currently ongoing

and continues to do so.

COMMISSIONER REMICK: It seemed like you had a lot of work to do. Is he swamped or do we have any plans for adding personnel?

MR. CAMPER: I'm not aware of plans for adding, but we certainly have him very busy right now with the current contracts and, of course, it's interesting to point out that the medical community often says to us when we're discussing misadministrations that this is all about human error. So, it is certainly conceivable that what we're doing is very important.

MR. THOMPSON: He has developed for NMSS a human factors program plan that involves the Office of Research. So, he's not alone in evaluating the human factors questions that come up. In fact, we can use contractors. So, from where he started when I brought him over there a few years ago, which they were kind of like NRR before TMI, I'd say -- but it was a significant addition to the NMSS staff. We also do use him in some of the fuel cycle facilities, in some of the problems we have there. So, we do spread him fairly thinly and we continue to monitor him.

But the primary thrust of his expansion right now is with the Office of Research.

COMMISSIONER REMICK: Thank you.

MR. CAMPER: So, it does seem that he's very busy.

As I said, we'll talk about the quality assurance rule, the pilot program and the radiopharmacy petition with separate slides.

(Slide) Next slide, please.

The QA pilot program was conducted in conjunction with the quality assurance rulemaking that we're currently involved with. You may recall that the pilot program was designed to assist us in determining the licensee's effectiveness in meeting the proposed rule, to determine if performance objectives could spot mistakes which could lead to misadministrations if not corrected, and to aid in determining the impact of the proposed quality assurance rule on current medical practice.

The QA pilot program consisted of 64 volunteers, 23 of those being NRC licensees, 41 of those being agreement state licensees. They were selected on the basis of geography, urban versus rural, public versus private and the type of materials being used in each facility. In addition to this fact, there were 18 sites of the 64 volunteers that were visited by our QA team to evaluate directly

first-hand the impact of the QA rule on their programs.

In addition to this, this program which was conducted during May and July of 1990, there were pre and post-trial workshops associated with it. The post-trial workshops took place in Atlanta, Dallas, Chicago, Philadelphia and Washington, so that we were geographically reachable to a number of the participants. This undertaking, of course, was led by Research, with participation by NMSS as well as regional representatives. The workshops seem to be very beneficial. I personally attended a number of them, four of the five, and believe that we got a lot of very positive and worthwhile feedback from the participants.

(Slide) Next slide, please.

COMMISSIONER ROGERS: Just before you leave that slide --

MR. CAMPER: Yes, sir.

COMMISSIONER ROGERS: Did you feel that you got the breadth of diversity among the volunteers that you were seeking?

MR. CAMPER: Clearly, 64 can be viewed as a small number. But we did feel that the strata was representative. We did feel that we had a number of

private practice facilities, broad licensees, classic community hospitals. We felt that there was a good representation and we felt that we got feedback that represented their specific concerns.

For example, a private practice setting where there's one physician, for example, clearly looks at some of the management involvement and the need to audit and some concerns that go along with it quite differently than would, say, a broad licensee. So, yes, I would answer your question in the affirmative, that we did get a good representative sample.

The results of the program were interesting. Most of the volunteers had an existing QA program in place which addressed the majority of the objectives of the QA rule. The --

MR. THOMPSON: Just so you understand, we looked at two things. We looked at their program, we looked at their paper and then I think we went and looked at their implementation. So, I think when you say most of the volunteers at a program, this is just the paper portion, I believe, on it that they were looking at.

MR. CAMPER: The workshops were attended primarily by technologists and physicists. I do

recall that there were three physicians which attended. This is something that was pointed out to us during the recent ACMUI meeting in January. I will cover the ACMUI comments later as a distinct line item because they were important and many of them. But the participants, the majority of the participants in the workshop expressed a small incremental cost associated with implementing the pilot program. But again, some groups, and particularly the ACMUI, as well as some members of professional societies, have questioned this because of the record keeping associated with it. So, I would draw caution, if you will, to the small incremental cost line item and point out that this was expressed by the participants.

Similarly during these workshops, we got a number of suggestions on specific requirements to improve the rule and to further decrease the costs associated with the rule. I would characterize generally speaking the recommendations to improve the rule and further decrease the cost of the rule as being associated with whether or not we should include diagnostic materials uses in the quality assurance rule. Generally, the feedback seemed to be that if we were to not include diagnostic, that would be substantially reducing paperwork burden and related

cost.

COMMISSIONER REMICK: Is it safe to conclude that since most of those 64 had a QA program, that that's the case industry-wide or profession-wide or can't we tell?

MR. CAMPER: I would hesitate to draw that conclusion, certainly with regards to private practice scenarios. In the case of institutional settings, given the current status of quality assurance medicine and guidelines espoused by JCAHO and other certifying accredited bodies like American College of Radiology and what have you, I suspect that the answer would be generally yes, they would have similar programs in place. In the case of the private practice setting, I would be somewhat hesitant, although I'm sure that many of them, at last, adhere to standards espoused by the Society of Nuclear Medicine or the American College of Radiology. It's a question of degree and formality.

COMMISSIONER REMICK: Of the 64, you indicate they made suggestions on improving a rule. Did any of those 64 suggest that we not promulgate the final rule?

MR. CAMPER: Well, I'm sure if I were to go back and review the transcripts of the numerous

meetings, I would find comments to that effect in there, yes. Generally speaking, throughout these workshops, there is always some questions as to the efficacy for the rule, the rationale behind the rule.

CHAIRMAN CARR: At least 63 of them.

MR. CAMPER: Yes. One was positive, 63 were negative. No, but in all of these there was certainly some comments to that effect. But I would also, at the same time, have to characterize it though as most of them saying that it was not that much of a burden, either in terms of cost or manpower and that they felt in many cases it was an improvement of their programs.

I think, if nothing else, in some cases it caused them to go back and look at what they were doing and how they got to the end result. That was viewed as being positive. But certainly the comments were mixed.

(Slide) Next slide, please.

Another very sensitive issue that we're confronting at this point in time is the radiopharmacy petition. The petition, you may recall, was received by the Agency in June of 1989. It was filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. Staff chose to split this

particular effort on this petition into two components, one that we would carry through the regular rulemaking process and one that we would attempt to expedite in order to provide relief to the medical community.

At the time we were considering the tack for dealing with this petition. We did look at enforcement discretion. We did look at generic exemptions and we did, of course, look at immediately effective rules.

The interim final rule was approved by the Commission on the 25th of July 1990 and published in a Federal Register notice on the 23rd of August 1990. It was designed to provide relief to the medical community from strict adherence to package inserts in the area of elution of generators and preparation of reagent kits, as well as for indications for the use of radiopharmaceuticals in therapy.

The rule has been met with a mixed response. In some cases, we have been applauded for our efforts to expedite that part of the rule that dealt with the majority of nuclear medicine procedures affected. On the other hand, we have received some criticism from the medical community in the radiopharmacies with regards to the record keeping

component of the rule. The rule does carry with it a three year sunset provision and a record keeping requirement. Departures which are made under the rule must be directed by a physician, must be a physician directed deviation. They must be documented. The deviations are to reduce risk to a patient or provide benefit not otherwise obtainable. Some members of the medical community have argued that the latitude provided by the rule did not go far enough, that it is still too restrictive. There has been some concern expressed, particularly by the commercial radiopharmacies, that the rule may be too strictly enforced.

On the 20th of September, Syncor International Corporation, which is a large commercial radiopharmacy concern, did file a petition for consideration and stay of action regarding the interim rule, and subsequently on the 19th of October did file a lawsuit in the U.S. District Court of the District of Columbia. If there are any questions regarding those actions by Syncor, I would defer them to Mr. Treby, since we're currently in litigation with Syncor.

(Slide) The next slide, please.

The radiopharmacy petition, as I mentioned

a few moments ago, was divided into two components. The remaining components are certainly complicated and will require a great deal of effort to resolve. Those issues involve the use of radiopharmaceuticals for human research, the use of radio-labeled biologics, which are also sometimes known as PLAs or product license applications as identified by the FDA, and both of these categories have the potential to affect the broad spectrum of medical licensees authorized under Part 35.

The human research area would not necessarily provide diagnostic or therapeutic benefit. For example, it could be research into such things as physiological response to nutrition changes, as an example. With regards to human research also, there is a mechanism currently in place whereby community hospitals can obtain approval through the licensing process if they submit an adequate program under careful review and scrutiny by our license review staff, can be authorized to do human research. But, of course, if we were to pursue the rulemaking to authorize such, this would affect all or potentially affect all medical licensees. So you can certainly sense that there's a great deal of concern in that regard.

The area of radio-labeled biologics is an emerging area, primarily involving the use of monoclonal antibodies. Some of these monoclonal antibody procedures would involve isotopes that have a greater potential for harm. Some of these are alpha emitters, some of them are higher energy beta emitters, some of them have longer half lives and some of them involve larger quantities of isotopes that we're already familiar with, such as Iodine-131. We are currently working -- NMSS is currently working with the Office of Research through a contract to develop a NUREG identified as CR-4444 and entitled, "Radiation Safety Issues Related to Radio-Labeled Antibodies." Our effort there, of course, is to try to disseminate this information out to the medical community, the licensed community in a timely fashion to assist them with this emerging area and to help us in the future develop standard review plans and licensing guidelines that would be effective for dealing with this new area of medical use.

COMMISSIONER REMICK: How about our calculational capability for doses with those isotopes? Is that something that ORAU is working on or do we have that in-house capability, if these are in use already, these isotopes?

MR. CAMPER: Right. Within the reg. guide, the NUREG that I was referring to, there's a great deal of information about doses or doses associated with these isotopes and these procedures. That's one factor that's taking place. Similarly, we could turn to Oak Ridge if necessary to do dose calculations involving monoclonal procedures as well as other procedures that we're involved in. In fact, that may be very beneficial in the future.

MR. CUNNINGHAM: The Oak Ridge group was initially formed to do these kinds of calculations of reemerging technology to unique biological uptake sorts of things. They're very closely tied into the committee that's called the MODE Committee, an acronym I can't remember what it stands for, but it's the committee that deals mainly with biological uptakes and radiation dosimetry calculations.

COMMISSIONER CURTISS: The schedule here calls for you to go back to the Commission with a proposed rule?

MR. CAMPER: That's correct. Our schedule calls for us to come back to you by November of 1992 with our recommendations on the remaining issues in the petition. During that time, of course, we're going to be very busy. This is going to require a

great deal of interface with FDA and the Office of Research has a lead on the project and we'll be working closely with them.

The third one there in particular gets us into an area that is indeed very complex, the pharmacy preparation of radio-labeled drugs. What this really involves, if you will is the preparation of radiopharmaceuticals outside of the classical NDA IND framework. That is, a new drug application, investigation of new drug framework. It raises questions like what is the training and experience of the radiopharmacist that will prepare such compounds, what level of peer review and controls exist in smaller institutions as compared to the larger broad licensing institutions. Smaller hospitals may not necessarily trained radiopharmacists.

So, it does raise a host of questions about the practice of radiopharmacy which is a very complex area. Once we go beyond the NDA IND framework, we have to be very careful as we move ahead. So, the next two years will be very busy in that regard.

(Slide) Next slide, please.

To a lighter subject, that being interorganization cooperation, as I said earlier, this

primarily involves our interactions with other regulatory agencies. First is the Food and Drug Administration. We have developed a very good working rapport with FDA. We spent a lot of time interacting with that organization as we develop the interim final rule. Our life is somewhat complicated in dealing with the FDA though because FDA is reluctant to provide definitive answers regarding strict adherence to package inserts. So, we find ourselves, on one hand, trying to ensure that safety and efficacy concerns are met and that we take licensing actions that are appropriate, while at the same time trying to provide flexibility to the medical community to practice nuclear medicine and not hold them to some standard that may be unreasonable, the standard being the package insert.

So, our interactions with FDA the next couple of years in that area will be very crucial and very important.

CHAIRMAN CARR: Do we want to pin them down?

MR. CAMPER: Perhaps we do. It would certainly be nice if we could have FDA take some action with some of these things and provide some specific clarification --

CHAIRMAN CARR: Well, so far we've done this on an informal basis, I assume. Do you want the Commission to write them a letter and request they go on record?

MR. CAMPER: That may be helpful. We're dealing with some very complex issues right now in the radiopharmacy practice area that it would be helpful to get some input from FDA on, to know what their position is, in fact.

MR. THOMPSON: I believe earlier we've also gone formally with letters to and fro with the FDA. So I think there's an appropriate time for us to do that. Certainly on this petition we'll obviously work very closely and we'll want their position on the record with the FDA.

I think there is some tension within the medical community and FDA on some of this area also. So, there seems to be efforts on the part of the medical community to address where they're unhappy with the FDA. They come and try to --

CHAIRMAN CARR: Yes, that's why I asked the question. You don't want to go ask the question if you don't think you're going to like the answers though.

MR. THOMPSON: Well, that's true and I

think in most cases FDA has been very helpful. There was this radiopharmaceutical rulemaking that was a bit more difficult in getting resolution of the issues. I think it worked out well at the end, but there was some initial interaction with the FDA staff that created some concern on the staff part. But I certainly think we have no concern with getting a formal FDA and Commission support to get a position if we need one.

CHAIRMAN CARR: If you want help, holler.

MR. THOMPSON: Thank you.

MR. CAMPER: The next group, the Department of Health and Human Services, and in particular HCFA, is an area that we have had some cooperative interactions with in that in our inspection process if we find things that seem to be within the purview of HCFA as it relates to the quality of medical care, there have been instances when we have drawn to the attention of appropriate HCFA management that we have made such findings. Generally though, the radioisotope imaging area is such a small part of what HCFA is concerned about that there's not a great deal of concern there.

CHAIRMAN CARR: You're aware that I went to HCFA early on in the QA rule because one of the

complaints was that they didn't get reimbursed for money they put into QA, they only got reimbursed for treating patients, and asked them if they could do anything about taking a look at that. But I never got any feedback and I don't know whether you all explored that problem.

MR. CUNNINGHAM: We did meet with HCFA. I forget the person's name from HCFA, but it was a follow-up on your meeting.

CHAIRMAN CARR: Yes.

MR. CUNNINGHAM: Very clearly. Basically what they told us was that HCFA deals in billions and billions of dollars and they make big block budget things. The incremental cost of something like the QA rule would never be found in the budget that they'd handle and they'd probably not cut it that fine.

MR. THOMPSON: I think they also said that they support the concept of quality and so they didn't have any --

MR. CUNNINGHAM: Oh, yes.

CHAIRMAN CARR: I guess the question is if the hospital then filed it, would they pay it?

MR. CUNNINGHAM: Sir?

CHAIRMAN CARR: I guess if the hospital filed the claim, would they pay it is the question,

of course, in those billions and billions of dollars?

MR. CUNNINGHAM: And we got no answer to that question. Now, they might. I think it would have to depend on what the hospitals do. But we cannot get an answer to that specific question.

MR. PARLER: I would assume that the hospital would allocate such costs to each of the hundreds of thousands of patients whose bills are sent in. That's the way they would get their money back.

MR. CUNNINGHAM: Well --

MR. PARLER: At least from personal experience I can make that comment.

MR. CUNNINGHAM: Yes. HCFA does a periodic examination of the cost of specific kinds of procedures. Again, these procedures that we're talking about are rather small compared to cost of other procedures that HCFA deals with. So, it's somewhere down fairly low on the priority list. That's part of the problem.

CHAIRMAN CARR: And I think you're right, Counselor, on the -- what the problem is, from the hospital standpoint, is we have to add QA into this. It costs us money to put the QA in and hire somebody to do the record keeping or whatever, whatever additional costs even if they're minor. Their

complaint was, "We're not going to get reimbursed for them because it's going into that overhead claim and we only get paid by the procedures. So, we're going to have to heat that out of something else which will be health care." That was a pitch.

All right. Let's proceed.

MR. CAMPER: All right. The final category, agreement states, I think is certainly extremely important. We have had three separate meetings with representatives of the agreement states on the quality assurance rulemaking, the most recent being just last week on Thursday and Friday. We have received a great deal of input and recommendations from the agreement states on that rule.

We held one special topics workshop, one joint seminar and a number of general meetings with the agreement states area. I think that in the future the agreement states program area will continue to be an area of very big importance as we promulgate the remainder of our rules associated with the radiopharmacy petition and the like.

COMMISSIONER REMICK: Is it possible to generally categorize what the agreement states had to say?

MR. CAMPER: Yes, I could. Again,

recognize that we would be looking at several days of transcripts and it's always hard to extract something from that type of thing, but I think I would feel comfortable making two or three key observations. Let me use the last meeting as a primary example.

I would say that generally they tended to -- during the last meeting in San Francisco, we provided to the agreement states representatives the staff's draft regulatory language which we presented to the ACMUI in January and we also showed to them the ACMUI's reactions and their recommendations to that staff, the language. Generally speaking, the agreement states tended to agree with the ACMUI recommendations.

Early on, there were some comments, as there always are in these types of things, about questions regarding the need for the rule, the rationale behind the rule and certainly some comments and criticisms about the need for it to be compatible. I don't know how much of those are generally the question of state sovereignty and the question of whether we should be compatible and so forth, in general, if it was really about the rule. But there was some of that. But generally though, we did get very positive input from them on line by line item

review of the QA rule. They did tend to go along with the recommendations of the ACMUI.

In the final analysis, on Friday of the meeting, they caucused and we left the room and we came back in and they had two recommendations as a result of their caucus. They felt that during the meetings with the agreement state folks, as well as our meetings with the AAPM, the American College of Radiology, the Joint Committee, et cetera, et cetera, all the various groups we've gone to during the last ten months, a lot of very good ideas had surfaced. There probably were more good ideas out there and they recommended that we republish the rule, that we go out again for a round of public comment as opposed to publishing it as a final rule.

Secondly, they recommended that the rule, if it be compatible at all, that it be either a division 3 or a division 2 level of compatibility. Generally I would characterize interactions as very positive and worthwhile from a working standpoint. But they're clearly interested in the rule and they're clearly interested in having input.

(Slide) Next slide, please.

MR. TAYLOR: We haven't taken a position on those particular matters with the staff yet.

MR. CAMPER: We did make that clear, that we would take the message back, but we have no position yet.

Under the category of staff development, we are looking primarily at how we can increase our depth of experience and understanding of the medical community. Sometimes the medical community, rightly or wrongly, is prone to criticize us as not having a very good understanding of the medical industry. We think that we have developed a staff that does indeed have a good understanding of the medical community.

In fact, in the current staff at Headquarters, four of the six of us have either served as consultants, technologists, physicists or radiation safety officers or some combination of all the above in the medical setting, hands-on hospital setting. Review and polling of our regions indicates that there's another 28 individuals in the regions that have served as technologists, dosimetrists, physicists and so forth, bringing to a total of 32 people in Headquarters and in the regional offices that have had practical hands-on experience in the medical community.

We think this is a good thing because the medical community clearly is a unique community to

regulate. It is a complex technical community to regulate and it is a vocal community to regulate. We do feel that by having the kinds of people that we have on our staff, we can better understand the problems and we can better understand the concerns as a regulated community.

So, we think that we are in the right direction in this area.

COMMISSIONER REMICK: Along that line, I might say that I think about the first month that I was a Commissioner, I tagged along on an inspection and Josephine Piccone was the inspector. I came away feeling that I was very confident of the capability and professionalism of our inspection staff based on that So, I'd like to acknowledge that, Josephine.

MR. CAMPER: Well, thank you. We appreciate that. I'm very proud of our staff at Headquarters in particular since they're my immediate group. Their experience is very strong and they really do understand the problems of the medical community. So, we think that, as I said, is very positive.

Another effort that we've undertaken, of course, to improve our communications with the medical community, understand their problems better, is

through our visiting fellows program, which we're very excited about. I'm very pleased to inform you today that we have indeed identified our first two individuals that will participate in the medical visiting fellows program.

One is a physician by the name of Doctor Myron Polycobe. Doctor Polycobe is an experienced senior nuclear medicine physician who's ending his active career as a practicing physician. He will go into retirement and then join us sometime in the very near future. Amongst his numerous credentials, at one point in time he was president of the American College of Nuclear Physicians. So, he's certainly highly viewed by his colleagues.

Similarly, we are bringing on board a radiopharmacist, a gentleman by the name of Mark Rotman, who is currently actively involved in the radiopharmacy program at NIH. So, he is on the leading edge of changes involving radiopharmaceuticals, particularly those that relate to monoclonal antibodies, radio-labeled biologics.

These individuals have accepted. We are currently in the final stages of negotiation with regards to start-up dates and what have you. But we expect to have them on within the next few months.

Both of these individuals, we think, will be very helpful to us, in fact as we look at issues like human factors and misadministrations and supervision of physicians by preceptoring physicians and, of course, in the case of the radiopharmacist, as we look at the question of radio-labeled biologics.

So, I think our task in front of us now when these individuals are on board is to define clear and concise projects that will be meaningful to them and will assist us in our efforts in the future. So, we're very excited about this program.

CHAIRMAN CARR: I guess I don't understand why it's going to take three more months if we've already --

MR. CAMPER: I think in the case of Mr. Rotman, he's very close, being at NIH. In the case of Doctor Polycobe, I think it's a question of when he retires and is available.

MR. CUNNINGHAM: Doctor Polycobe is going to retire June 30. So, it has to be sometime after June 30. In the case of Doctor Rotman --

CHAIRMAN CARR: July 1st?

MR. CUNNINGHAM: He has to get across the country. In the case of Doctor Rotman, as a matter of fact I tried to call him yesterday and there isn't

-- it's a question of releasing him from NIH. He's in the Public Health Service, so the transfer is not a problem. It's a question of NIH being able to substitute somebody when he comes over here. I think that's the most difficult problem.

CHAIRMAN CARR: Now, did we set this up for a year from the time they're on board or from the time we pick them out?

MR. CUNNINGHAM: We have set it -- well, it would be from the time they're on board. That's what we have in mind.

MR. THOMPSON: And I believe we have an option for a renewal.

CHAIRMAN CARR: Okay.

MR. CAMPER: Finally, under the category of staff development is the expansion of the experience of the ACMUI. We currently have out a Federal Register notice dated the 24th of December which closes on the 22nd of this month, calling for nominations to the ACMUI. That Federal Register notice asked for a nomination in the area of patients rights advocacy, medical regulation by the states, and we're also attempting to replace one of our brachytherapy physicians.

Concurrent with that, we are soliciting

nominations from the Commissioner of the FDA and the Public Health Service. Next year we plan to go out with a Federal Register notice to solicit nominations for representative of hospital management and of medical research.

So, we believe that the undertaking that we now have in the area of the ACMUI will not only broaden the experience of the ACMUI but will also serve to provide the Commission with balanced input on issues confronting the medical regulation area.

CHAIRMAN CARR: What kind of response did you get to the December notice?

MR. CAMPER: Thus far we have, I believe, either two or three nominations. Characteristically though, they tend to come in at the 11th hour.

(Slide) Next slide.

Under the area of oversight, our goal, of course, is to identify early developing problems. In that regard, we expect to conduct approximately 1,000 medical inspections in fiscal year '90. We expect that next year the number of inspections will increase primarily because of our increased frequency of the inspections at community hospitals. We continue to analyze misadministration reports and developing trends. We interact on a monthly basis with AEOD to

review this area.

Then the coordination and technical assistance to regions is an area that we have continued to devote increasing amounts of energy to. We do this through monthly conference calls with the regions, through the National Program Review which is taking place later this month and next month, through accompanied inspections, through final guidance to the regions and through a great number of response to written requests for assistance on licensing issues, so-called technical assistance requests.

In addition to that, I have personally gone out to all five regions and expressed our interest in improving the level of communication between Headquarters and the regional offices. I have given them an overview of the major program areas affecting the medical use area and research area and I found this to be very well received. They appreciate the fact that Headquarters is paying attention to the regions.

CHAIRMAN CARR: Are we still using the indicator checklist? Do we have a checklist that kind of indicated you might have problems -- depending on the answers to these questions, you might --

MR. THOMPSON: The performance evaluation

factors.

CHAIRMAN CARR: Whatever we call them.

MR. THOMPSON: PEFs. I believe that's what we called it. I'm not real sure exactly what that is.

Dick, do you know that one?

MR. CUNNINGHAM: Glen?

Glen Sjoblom from the staff can tell us.

MR. SJOBLOM: If I understand the question, yes, we are still continuing the use of the performance evaluation factors.

CHAIRMAN CARR: Are all the regions using it?

MR. SJOBLOM: Yes, and for more than just medical, for all of our larger facilities that we inspect. Basically, these are subjective factors --

CHAIRMAN CARR: Oh, yes, it's just a heads-up on that.

MR. SJOBLOM: -- which many times conform the underlying causes when a licensee gets into trouble. If a radiation safety officer is assigned duties which take him away from his principle safety mission, then that can result in lack of oversight of the program. That's just one example. Inadequate staff, although that's hard to judge, can also be a

cause. In adequate review of procedures by the isotope committee can be another one.

CHAIRMAN CARR: I understand the purpose in what was in it. I just wondered if all the regions are using it. Did the agreement states pick up on it at all?

MR. SJOBLOM: Some of the agreement states participated in the pilot program and are using it, I understand. It is a permanent part of our manual Chapter 2800 at this time.

CHAIRMAN CARR: Okay.

MR. THOMPSON: Vandy, do you have anything you want to add on the agreement states?

MR. MILLER: Well, he's exactly right. We've provided the results of the pilot program they did early and left it up to the agreement states to take it as far as they wanted.

CHAIRMAN CARR: Sure. Okay. But it's still available then.

Okay. Let's proceed.

COMMISSIONER CURTISS: On the increased inspection of the community hospitals, can you give me a feel for what that means in terms of staff impact? How from -- from three to two, what are we talking about in terms of increased impact on regional

inspection forces?

MR. CAMPER: We do have a slide that comes later that talks about the FTE issue.

COMMISSIONER CURTISS: Okay.

MR. CAMPER: Perhaps we'll answer your question at that time.

(Slide) Slide number 11, please.

Okay. This slide depicts the number of misadministrations reported by NRC licensees. I would draw a certain amount of caution to the numbers because -- particularly under the calendar year '90. We view this as incomplete data because we have not yet received medical license event reports from all the regions. So, I would caution you about that.

But generally, you can see that the number of diagnostic misadministrations has remained constant and flat, similarly with Iodine-131, and I would point out that the Iodine-131 category is of course diagnostic and therapeutic uses of Iodine-131.

The category of therapy, at least on initial glance, can be somewhat alarming when you see 18. This may be a trend, but again I would caution you that numbers are small and we'd be hesitant to draw hasty conclusions.

The number of licensees involved continues

to be constant and relatively small in number. And of these in 'endar year '90, 14 of them have qualified as meeting the abnormal occurrence criteria.

CHAIRMAN CARR: Now, that's only our licensees. Do we now get reports from the agreement states?

MR. CAMPER: I'm not aware of reports from agreement states.

Vandy, do you have that?

MR. MILLER: Yes. Let me comment on this.

You recall back in April of '90, this was the time for the misadministration reporting to be a matter of compatibility with the states. Now, we have plans out how they are supposed to provide their data and, to my knowledge, it is getting to AEOD. I have not seen any analysis of the agrement states up to this point, however.

CHAIRMAN CARR: Okay. Well, maybe you could send up a paper kind of combining the things if you've got them.

MR. TAYLOR: We'll follow-up on that and get it to you, depending upon the state of the data.

CHAIRMAN CARR: If there are three to one as many as we've got, then these numbers could be a little less than --

MR. TAYLOR: We'll give you another base.

MR. CAMPER: (Slide) Slide 12, please.

Trying to get briefly to Commissioner Curtiss' question, we do have a slide for that. Clearly, this is not a budget briefing, so the numbers we're showing you are trends only and informational in nature, but at least you can get some feel for what's going on in the resource area.

A couple of comments regarding the dollar amounts in fiscal year '91 and fiscal year '92. The $1,157,000.00, the greatest part of that is earmarked for contracts associated with risk-assessment as it relates to brachytherapy, teletherapy, and the gamma knife. We do have $100,000.00 of that money earmarked for the fellows program.

Under the $800,000.00 in fiscal year '92, the majority of that, $700,000.00 of it or so, is identified and related to a contract for assistance in conducting quality assurance-related inspections relative to the implementation of the quality assurance rule.

We are seeing a steady increase under the category of inspection and event evaluation in the regions. Basically, we've gone from 20.5 to 23.2 for fiscal year '91 and approximately another person

gained in fiscal year '92, so we are seeing that type of increase in manpower to increase our frequency of inspection. These numbers, of course, are pure FTE components and don't consist of any overhead.

The other numbers, licensing and supervision, have remained relatively flat or have increased in proportion to the manpower component for supervisors.

(Slide) Okay. Next slide, please.

Information exchange, of course, continues to be a worthwhile goal to acquaint everyone with what we're doing in the medical area. We take a lot of pride, in fact, in the efforts that we have conducted in this particular arena.

We've had 24 presentations to professional groups, the complete spectrum of professional groups. I've mentioned some of them already, the American College of Radiology, the American Association of Physicists in Medicine, the Endocurie Therapy Society, the Joint Commission and so forth. So, a lot of effort has gone into that area during fiscal year '90.

We held four workshops for licensees, which were very favorably received. Licensees like the idea that we go out and talk to them and explain to them some of the complications associated with the

medical area.

The NMSS Newsletter, we have expanded its circulation to include the members of the ACMUI and professional organizations. The Commission had requested that we do this previously, so now those folks are on our mailing list as well.

And then we have met with eight professional societies, including the American College of Nuclear Physicians and the Society of Nuclear Medicine as recently as July of last year to discuss the quality assurance rulemaking. So, a great deal of effort has gone into information exchange and it seems to be well-received.

(Slide) Next slide.

Before talking specifically about the staff's interpretation of the recommendations of the ACMUI -- and I do characterize that carefully, because, again, looking at two days of transcripts and a very dynamic fluid process -- I do want to make a comment or two about the ACMUI in general, if I may.

The first is that the ACMUI has become a very active committee once again and we're very proud of that. The Committee met in July of last year and then again held a two day meeting on the 14th and 15th of January of this year.

The dynamics associated with the ACMUI is difficult to define in a few words. It's a very interesting group, highly experienced, highly qualified, very prone to give you their opinion and what-have-you and this is very worthwhile. One of the most difficult tasks in that whole process is for the chairman to try to reach some consensus of the Committee and to try to put it into a framework that we as the staff --

CHAIRMAN CARR: Tell me about it.

MR. CAMPER: You do understand -- that the staff can use, of course, to come away and make this thing work. And in that regard, I would like to commend publicly the work of Doctor Barry Seigle. He did an absolute yeoman's job in both of the meetings in doing that for us and has done an absolutely superb job as Chairman of the Committee. I think he set a standard that will be tough to follow in the future, but we really do appreciate the efforts of Doctor Seigle and all the Committee for that matter.

Let me then, having said that, try to turn to the recommendations of the ACMUI during the last meeting. Many of these, of course, deal with the quality assurance rulemaking. We spent a day and a half of that meeting, almost, talking about the QA

rule. We did go through the staff's draft regulatory language for the rule line item by line item. It generated considerable input in recommendations.

At the present time, the staff is developing a draft final rule that will incorporate a number of the recommendations of the ACMUI as well as the other groups that we met with. We're not seeking Commission direction at this time, but we will be bringing to you the draft final rule sometime in late March and will present a paper specific to that topic, at which time we expect to receive a great deal of questions and comments and what-have-you.

With regards to the recommendations of the ACMUI themselves, they recommended that the area of diagnostics, the use of diagnostic radiopharmaceuticals be dropped from the quality assurance rulemaking. They pointed out that it would be far more appropriate to focus upon the use of Iodine-131 in quantities of 30 microcuries or greater and therapy procedures than it would be to focus upon diagnostics, because that small percentage of procedures is where the greatest potential for patient harm existed. They felt that by dropping diagnostic from the QA rule we would not dilute the efforts of the medical community in dealing with the QA rule and

that their limited resources could be better applied to those areas where the potential for greatest harm exists.

COMMISSIONER REMICK: So, their recommendation is based primarily on the potential consequences of a misadministration? Because, when I look at the numbers you have in one of the previous tables the percentage of misadministrations in therapy is about the same as in diagnostics, so I assume that it must be because they see a potential consequence?

MR. CAMPER: That's essentially correct. They feel that the deleterious effects associated with the majority of diagnostic misadministrations is --

CHAIRMAN CARR: That's BRC.

MR. CAMPER: It's BRC, that's right. It's a good way to characterize it. They feel like it's not a significant issue.

They also made comments that now we've had some eight or nine or ten years of data and we've got a pretty good idea of what goes on in diagnostic misadministrations. It hasn't changed a whole lot. By and large it's pilot error. It really isn't necessary, primarily because of the consequences.

They also advocated in the staff draft regulatory language we use the term "event,"

"reportable event," "diagnostic event," "reportable diagnostic event," "therapy event," and "therapy diagnostic event," as opposed to the use of the term "misadministration." We did of course caution at the outset that this language was by no means anything other than a staff draft regulatory language and that the use of the term "misadministration" had a history and it was established and please don't jump to the conclusion that we were moving away from that term.

However, they did advocate the use of the term "event" rather than misadministration. Primarily, they feel that it is less burdensome as a practicing physician to say that something is a reportable event to the Nuclear Regulatory Commission than it is to use a term like misadministration which may be construed by the lay public as having some malpractice implication, so they did feel strongly that the use of the term "event" was preferable to the use of the term "misadministration."

MR. CUNNINGHAM: You may recall that a couple of years ago we proposed to use the term "event," rather than "misadministration."

CHAIRMAN CARR: I remember it well.

MR. CUNNINGHAM: The Commission did not accept that, but the Commission also instructed the

staff to go and speak with various professional organizations in the medical community and explore this further. That's what we have done and almost universally they would much prefer it to be called an "event," rather than "misadministration."

CHAIRMAN CARR: I can even understand why.

COMMISSIONER REMICK: Has anybody looked to see if there might even be a better word?

CHAIRMAN CARR: I guess we could call them "violations."

MR. TAYLOR: I think there was some discussion, wasn't there? I mean, they principally centered into this type of choice, though.

MR. CUNNINGHAM: They centered into this type of choice. Of course, we in the draft language that we used in the proposed -- in the QA rule that they looked at we used the word "event," so it really did not stimulate exploring other kinds of words. It was something between "event" and "misadministration."

MR. CAMPER: Okay. The final point on this particular slide was they suggested that if there is to be a diagnostic event or a reportable diagnostic event, that it really should be tied to some harm criteria rather than some percentage of error criteria. We currently are trying to better

understand and take a look at what "harm" might mean. We are considering the use of outside organizations to explore that possibility, but primarily we need to attempt to better define what harm might be.

CHAIRMAN CARR: It's interesting they did that instead of the potential for harm.

MR. CAMPER: That's true. That's true.

CHAIRMAN CARR: We don't do that in the rest of our regulation. You don't have to harm somebody to get tagged.

MR. CAMPER: True.

(Slide) Okay. Next slide, please.

Their recommendations continued, there were two lesser recommendations regarding the quality assurance rule and one was that there be a summary report provided to the patient rather than an expansive technical report. They felt that the patients did not need to have that depth of information and that the summary report would be adequate.

They also supported the change of the rule title. In the presentation of the draft regulatory language, we entitled the rule "The Program for the Prevention, Detection, and Correction of Events and Reportable Events." They tended to advocate the use

of that title.

MR. CUNNINGHAM: I might add here, we have been calling it the QA Rule. But, in speaking with the various professional groups and so forth, they have a problem calling it the QA Rule because there are so many different QA procedures in hospitals that it gets mixed up with JCAHO QA and HCFA QA and internal QA, so they want to call it something different. We looked at the --

CHAIRMAN CARR: "Procedural compliance," how does that sound to them?

MR. CUNNINGHAM: I'll write it down, sir.

MR. TAYLOR: Most of us will have trouble remembering that -- an acronym or something.

MR. CUNNINGHAM: What we were looking at is the headings in Part 35 for the various sections and get something that is consistent and compatible with that. We haven't centered in -- we haven't --

MR. TAYLOR: I think we have to digest that a little more so we all have an easily-spoken common language.

MR. CAMPER: To add to that, they certainly did point out that the use of the term "quality assurance" has an established meaning and has a long history in the practice of medicine, that there

are standards, for example, in place by the Joint Commission for Accreditation of Hospitals which embodies the concept of quality assurance and that what we were doing here or were attempting to do is really very specific. It did not readily lend itself to the use of the term "quality assurance."

And then finally, they had a major recommendation that was nonrelated to the QA Rule and that was they felt that the staff's proposed two year term for the ACMUI was too short. They felt that this was not enough time for an individual to become familiar with the process and to make a reasonable contribution.

CHAIRMAN CARR: How often to they meet?

MR. CAMPER: They're meeting at least twice per year. The next meeting is scheduled for May in order to put them onto a May and October cycle.

That concludes the slides and the information we wanted to present to you today in a formal fashion. We feel that a great deal of progress has been made in the medical and academic area. The five point program initiated in fiscal year '88 is being implemented. The results are increased NRC oversight of medical licenses through the regional inspection program, enhanced communications with the

medical community and professional organizations, and increased guidance to the regions on licensing and inspection issues and tracking of current and projected medical concerns.

In summary, then, the five point program is in place and is working. Again, we feel that a great deal of progress has been made. We do face some very difficult issues in the future as we look at the radiopharmacy petition and the outcome of the interim final rule that we think is going to be a very interesting area for the Commission for the next two or three years.

I would like to take this opportunity, if I may, to thank my staff and all of those who helped in putting together all the background information. As you can certainly appreciate, a great deal of work goes into it and I commend them for their efforts.

If there are any other questions, that is all we have.

CHAIRMAN CARR: Commissioner Remick?

COMMISSIONER REMICK: Two questions.

Alert our General Counsel, my first question is not intended to have anything to do with the suit, but I notice that Syncor International had hired an outside consulting firm to look at some of

the human factors considerations. Is there any feedback from that effort that we know of, what they were able to find?

MR. CUNNINGHAM: I think it's too early -- some time ago. But their hiring that consultant is clearly a result of Dennis' work with Syncor in bringing this to their attention and some of the benefits that can be derived from that.

COMMISSIONER REMICK: But there are no findings yet that we're aware of?

MR. CUNNINGHAM: Not that I'm aware of.

COMMISSIONER REMICK: Okay.

MR. THOMPSON: We'll look at that and make sure. If there are some, we'll provide them to the Commission.

COMMISSIONER REMICK: Okay.

In the paper you also indicate that there's a fairly high rate of attrition of nuclear physicians and technologists. Is there any specific reason why that's true nationwide?

MR. CAMPER: Primarily, the attrition deals with technologists, although I'm not readily in command of the numbers for physicians going into nuclear medicine as a specialty as compared to bygone days. I certainly am more familiar, though, with the

technologist aspect of it, the clinical aspect of it.

I would say that the answer involves a number of things. First of all, I think that there is a problem in that the older more experienced technologists at some point in their career aspire to loftier positions that are economically more feasible, pay them more money and the like and provide a higher level of professional participation. Many of them go off into the regulatory arena. Some of them go off into sales. Some of them go into other levels of management within the hospital and that type of thing.

I think that a significant problem exists this time around, though, in that the front-end problem is severe in that not as many individuals are going into the schools of technology. There simply aren't as many schools of nuclear medicine technology, for example, as there used to be. Enrollment in many cases is down. There are a number of reasons for this. I think some of it is generic to the health care industry in that with the reimbursement crisis that's going on today in health care and with some of the concerns the public has about such things as AIDS, for example, I don't think health care is as attractive as it once was as a career. I think that's very unfortunate, because it's obviously very

necessary and very important to all of us.

So, I think we have on one hand the continuing high rate of attrition of the experienced people with a decrease in the number of individuals going into the field on the front end. I think we have a very serious shortage that will continue to be in place for a long time. Of course, a question that raises for us as individuals who look at this as regulators and that is who is performing the medical imaging procedures and who is handling the radioactive materials on a day to day basis and it's something that we are looking at in some of our current endeavors in the training area. And as time marches on over the next couple of years we hope to have a better handle on that question.

COMMISSIONER REMICK: What's the typical level of education training of the technologist? Is this a two year or a four year program?

MR. CAMPER: Well, it ranges from minimally two years, typically either a certificate or an associate degree in nuclear medicine technology, up to and including a bachelor of science degree in nuclear medicine technology or some similar identified regimen.

There was a move several years ago to move

away from a two year associate degree certificate program and move toward a bachelors degree program because they felt that elevated the overall quality of the practice of nuclear medicine technology. That certainly was pursued. One can ask the question of whether or not that is necessary in terms of producing the numbers of players that you'd like to see. Many individuals can go pursue a two year associate degree with minimal cost. There are some scholarships available. Community colleges are less expensive and can produce a viable working technologist that's capable of certification and capable of doing a very good job. So, that area right now has a dynamics to it as we speak in terms of looking at whether or not two years is sufficient or four years is sufficient.

COMMISSIONER REMICK: Thank you.

CHAIRMAN CARR: Sounds like the degreed operator all over again.

COMMISSIONER REMICK: Yes, it does.

CHAIRMAN CARR: Commissioner Curtiss?

COMMISSIONER CURTISS: I just had two quick questions on the -- their both on the ACMUI recommendations. You talked about your position on a couple of them. Did you have any preliminary thoughts on the first suggestion to drop the

diagnostic and to focus on therapeutic or is it too early to --

MR. CAMPER: Yes and no. Yes in a sense that the quality assurance team, the rule writing team, is about to meet later this week to try to go back and revisit and absorb all the things we've looked at and learned through all the various meetings, including the ACMUI. So, I don't want to say anything that would be premature, having not had that group get together as a group, but I think that there is a -- at least, in my interpretation, there's a general sense amongst the QA team and amongst the management that I've talked with that the idea of eliminating diagnostics and focusing upon Iodine-131 of quantities greater than 30 microcuries and therapy would be an appropriate thing to do. It would capture those areas of greatest concern, of greatest harm, and perhaps if there is to be a diagnostic component included it should be tied to some dose threshold that made some sense scientifically.

COMMISSIONER CURTISS: Just out of curiosity, have we reported any events that would not be captured under that approach as abnormal occurrences in our periodic reports?

MR. CAMPER: If I understand you, you're

saying if we establish some threshold --

CHAIRMAN CARR: Previously.

COMMISSIONER CURTISS: Yes, previously.

MR. TAYLOR: I think we'd have to go look at that.

CHAIRMAN CARR: Have we reported any diagnostics as an abnormal --

MR. CUNNINGHAM: Iodine diagnostics.

MR. THOMPSON: If the iodine was going to be included --

COMMISSIONER CURTISS: That would be covered?

CHAIRMAN CARR: Only if it's over 30.

MR. CUNNINGHAM: I think that in the diagnostics, except for Iodine, you really have to work to get an effective dose equivalent higher than 500 millirem. Most of them are below that. So, if you make a mistake in the procedure, administer the wrong radiopharmaceutical, you're still going to be below the 500 millirem.

CHAIRMAN CARR: Makes our BRC number look kind of puny, doesn't it?

MR. CUNNINGHAM: Well, in a lot of them we might be below 100 millirem.

COMMISSIONER CURTISS: Well, check on it.

I'd be curious, if you can take a look.

CHAIRMAN CARR: Well, that's what I say, but, I mean, we're talking hundreds of millirems here and we're not supposed to worry about that. I'm having trouble getting ten millirem okayed.

COMMISSIONER CURTISS: I agree with ten.

MR. TAYLOR: We'll check that.

COMMISSIONER CURTISS: One other quick question. If I recall correctly, the ACMUI folks recommended that we await receipt of the NCRP comments before proceeding with the rule. Can you give us a brief status report on where the NCRP initiative stands and what your thoughts are on that?

MR. CAMPER: I think the best way to handle that would be -- is John Telford --

John, would you care to comment?

Research is actively involved in that particular project, so John is the best person.

MR. TELFORD: John Telford, Office of Research.

We are pursuing an effort to establish a formal contract with NCRP for this particular work. We have engaged in informal discussions with NCRP. We think that the results that we could expect, say, next month, if we're lucky with our contracting

efforts, would be helpful in making a scientific basis that we could use to compare what we now have of half rem whole body and two rem any organ to find out if we can use something that has a more scientific basis that would be something you might call a measurable effect.

So, I think it will be useful in two ways. One would be in comparing what we have now. And, two, if the staff really wants to have a threshold connected to, say, events for diagnostic procedures, it may be useful to establish something.

COMMISSIONER CURTISS: Did I understand you to say the results of the NCRP's efforts would be in next month?

MR. TELFORD: I would cross my fingers.

COMMISSIONER CURTISS: But it's a real possibility --

MR. TELFORD: As a draft commentary.

COMMISSIONER CURTISS: -- that their comments would be available in time that we could plug them into the initiative. Okay.

CHAIRMAN CARR: Well, I didn't understand about the contract.

COMMISSIONER CURTISS: Yes, that's what threw me.

CHAIRMAN CARR: They're doing this project on their own, aren't they?

MR. TELFORD: We are attempting to pay them for it, a small amount of money but money nevertheless. You're correct in that they have money that we give them on a grant basis from a sister branch and they are pursuing any work that they so desire under that grant. That's correct.

MR. CUNNINGHAM: This is not commenting on the whole rule. This is on a very specific part of it.

COMMISSIONER CURTISS: On the significance of --

MR. CUNNINGHAM: Yes.

CHAIRMAN CARR: Health significance of medical misadministrations, but I thought that was something they started. Did we ask them to do it?

MR. TELFORD: The ACNP and SNM, both those societies made a formal request to NCRP to undertake this kind of study. We also discussed with them on an informal basis if they would be interested in doing that, because they are an independent body established by Congress to provide advice to agencies and they are without any bias and so it seems like a very good idea.

CHAIRMAN CARR: Well, I don't have any problem with the idea. It's the paying them for it that bothered me.

COMMISSIONER CURTISS: How much are we paying them?

MR. TELFORD: Approximately $50,000.00.

COMMISSIONER CURTISS: That's all I had. I was just curious to know that we'll have the input from that in a fashion where we can feed it into what you'll be submitting to the Commission on the subject that they're looking at.

CHAIRMAN CARR: You'll get it like you got the NCRP data for the last effort that we waited on for a year and --

COMMISSIONER CURTISS: We'll cross our fingers, I guess.

MR. TAYLOR: We don't want to wait that long.

COMMISSIONER CURTISS: Okay. That's all I have.

CHAIRMAN CARR: They have a history of not meeting their dates, in my opinion.

COMMISSIONER ROGERS: Yes. There were a few issues that were raised in the petition that didn't get addressed in the interim final rule and I

wondered if you received any comments on any of those issues and whether you have anything to say about those comments.

MR. CAMPER: Yes, we had received some comments regarding the issues that were addressed and those that were not. Basically with regards to the ones that were addressed in the interim rule, as I indicated somewhat earlier, generally there has been a great deal of concern about the record keeping requirements as being overly burdensome, about the costs associated with that and the fact that perhaps we didn't go far enough in providing them relief.

With regards to those items that were not covered thus far, questions and comments such as, "It's really not that complicated. Why didn't you do it all at one time?" "Does it really take two years," so many of the things that we want to do are already established and it really shouldn't be that much of a problem to put them into place regulatorily speaking.

But generally, we feel that the remaining issues, as I indicated, are very complex and very complicated and the two years is a reasonable time frame. If we were going to provide relief to the medical community in short order, it was absolutely

necessary to segregate the issues and to focus upon those which provided the greatest relief and that being the elution of generators and preparation of reagent kits and things that affected the largest number of studies. These remaining issues are complex and will take some time.

There are certain segments of the medical community that would have liked to seen it dealt with in its entirety in a very fast manner. But given the complexity and the nature of the number of things, that simply wasn't possible.

COMMISSIONER ROGERS: Is there any way to characterize or summarize the support within the regulated community that has come for the QA rule?

MR. CAMPER: The support for?

COMMISSIONER ROGERS: For. There's a lot against, I know.

MR. CAMPER: Yes. I think that a number of physicians and radiopharmacists recognize that we did take a step to provide relief. I think that they sense -- a positive comment that I have heard is this, that, "We sense that you, the NRC, is now becoming aware of the practice of nuclear medicine, the practice of radiopharmacy and you've taken at least the first step in the right direction. You didn't go

far enough. You didn't give us enough latitude, but you at least took a step in the right direction. We're staying tuned to see to it now the remaining issues. Will you be as aggressive, will you come through on these remaining issues as you have at least thus far?"

So, generally, I think there has been -- I've certainly heard positive comments that "Yes, you have taken a step in the right direction. Now you need to broaden it and now you really need to change your language so that as nuclear physicians and as pharmacists we can practice nuclear medicine and radiopharmacy unencumbered by some unnecessary regulatory criteria. So, you've taken a step in the right direction."

MR. CUNNINGHAM: I think it was significant what the ACMUI did in this past meeting. As you know, they've been rather negative on this QA rule over the years. There was a motion on the floor to vote that the ACMUI as a committee voted against the QA rule flat out. That motion was defeated because there were the majority of the committee who felt that there was a need for the therapy part of the QA rule, so that if you retained the therapy part, that carried the day. There was a majority that felt

that there is a need for this and it would serve a useful purpose for the therapy part. Clearly, the Committee as a whole did not want the diagnostic part in the QA rule.

MR. THOMPSON: And I would say there was one other thing that kind of indicated support for the theory and the approach of the quality assurance. In the pilot program, when we went and looked at both the program as it was described and the program as it was implemented, we found that the implementation was, in fact, better than the paper describing the program, so that in practice many of the facilities, in fact, did more of what we were looking for in the QA program than they would have actually had their paper written on.

Of course, obviously, in a license amendment type of review process, if we'd had questions about were you going to implement that, that type of clarification would have been expanded and put in the program, so the program would have been complete. But I was very encouraged by the significant implementation as it currently exists in the medical community of a QA program which we would have found addressing most of, if not in some cases all of the areas that we were looking for a QA program

to be implemented.

MR. TAYLOR: You've gotten answers on the QA. Larry brought up -- some of his comments were directed toward the interim final rule package insert.

MR. CAMPER: Yes.

COMMISSIONER REMICK: May I just follow up?

Hugh, I'm not quite sure I understand what you're saying. Are you saying that their implementation regardless of our rule was better than their procedures might indicate or their implementation was better because of our QA rule, they exceed what they had before?

MR. THOMPSON: I think it's the former. They have in place -- we were out looking at what their program would have described and in the pilot program of what our QA program would have been so that we wanted to see how much it would have cost to implement it. Their description of that program, as I understand it, and I think John or Larry can correct me, their description of their program was not as robust as it would have been if we'd gone through a licensing review program. But their implementation, in fact, was closer to what we would have expected. So, it was better implemented than it was described

on paper.

MR. CAMPER: That's correct. The QA team that went to 18 site visits found generally that programs were there, they were in place. They did not describe them very well in the questionnaire, but on site visit demonstrated that they were indeed in place.

COMMISSIONER REMICK: I see. Thank you.

COMMISSIONER ROGERS: Well, I just wanted to commend first the staff for the briefing because I think it was an excellent presentation, very clear and very complete. And for the efforts over the past year in the various activities that have been going on, training workshops, interaction with other agencies, and staff development, all very important. But as we know, this is a very prickly area and it's one that --understandably so, I think in some ways. We deal here with a somewhat different kind of professional than we deal with in nuclear reactor area.

It requires patience and sensitivity to getting to understand each other so that we can accomplish what we feel is necessary without an undue trampling upon professional sensitivities. I think that you've been working very hard at that. I can

sense it through what's happened over the last year or so and I want to commend the staff for its patience in what I'm sure at times have been somewhat difficult retorts that have come back from that community.

But I think we're all trying to work towards a safety goal and that's one that is certainly defensible and certainly one that is our responsibility and I want to commend you for your hard work and patience and fortitude. Thank you.

MR. CAMPER: Appreciate that.

MR. TAYLOR: Commissioner, I might add I spent several hours at an ACMUI meeting. It was an eye-opener to hear this professional viewpoint at that type of meeting for someone who comes from the reactor side.

CHAIRMAN CARR: Well, I'd certainly echo his comments. I would -- but my experience in this Agency, I must admit that between the medical uses and the radiographers, we've hurt more people than we have in reactors. So that's probably why I -- if you just look at how many people do we injure sometime, that's the why I've really had kind of a closeness in my attention to this item.

I've just got a few questions. I understand we got a contract with SAIC and that

doesn't mature until next September. What are you going to do with the results of that?

MR. CAMPER: Well, I happen to have Doctor Piccone with me who's the project manager for that particular contract.

CHAIRMAN CARR: Okay.

MR. CAMPER: So, I'll let her --

CHAIRMAN CARR: I wouldn't want Josie to go away without talking.

MR. CAMPER: -- Josie answer that question and give her a chance to --

DOCTOR PICCONE: Well, primarily, the results of the contract will be used to formalize some of the informal discussions that have been going on with the QA team with some of the professional organizations on the existing quality assurance regulations or suggestions requirements. The task with SAIC that does look at existing programs with other organizations is due to us by the end of March. So, we will have that at a time to look at, certainly to at least review with the rulemaking.

The remainder of the tasks with SAIC have to do with reviewing a quality assessment questionnaire that was used by NRC in inspections for about a year to analyze those results and see what we

can get from them. It primarily focused on -- it did try to focus on what quality assurance is in institutions at the present time, but had a tremendous focus on equipment, age of equipment, model number and whatever. So, I think we'll have more of a feel for the state of the art that is in existence.

They are also developing a survey that we can use to see what quality assurance programs are out with licensees now, whose recommendations they are using, are these mandatory or voluntary recommendations that they are following in their institution, and just what areas are covered now in the quality assurance program? Surely, some of that information and the information they glean from the professional organizations can be used in our regulatory guide effort and revising that regulatory guide and possibly the rule at a future time.

CHAIRMAN CARR: Okay. Now, are they just looking at NRC licensees or are they working with state licensees to agreement states?

DOCTOR PICCONE: Well, they're not looking at any licensees at this point. They're meeting with professional organizations. They've gone to one or two licensees who have large therapy programs to get an idea of their quality assurance program.

The survey, that is meant for NRC licensees.

CHAIRMAN CARR: Okay. There's been a lot of discussion about training and how much training is required. Have you all determined whether there's a correlation between the occurrence of medical misadministrations and the training or credentials of the users who commit these problems?

MR. CAMPER: We're currently looking at that issue. We did present to the ACMUI during its meeting last July the results of a contract study conducted by Cohen and Associates that looked at the various standards and organizations that have something to do with the training and experience and standards within the practice of medicine in the nuclear arena.

In fact, when we presented this information to the ACMUI, the ACMUI said, "Well, fine, but you have not shown us what the correlation is, if any, between the number of misadministrations that occur and other enforcement events." In fact, they challenged us to do that.

One of the things that we're looking at over the next couple of years is to try to modify the misadministration reporting form so that some

indicator is provided for the level of training and experience of the individual that committed the misadministration. Perhaps in time, if enough of these are collected, we will draw some correlation between the level of training and experience in those individuals that commit misadministrations, or for that matter some other enforcement activity.

Similarly, we are pondering whether or not we could, during the inspection process, take a look at the level of training and experience of the individuals and in those cases particularly where there are violations which occur and those which resulted in enforcement action, is there some correlation we can draw between the level of training experience and the events which occur.

It's a complicated area. How do you quantitate something like that? How do you clearly define something like that? But it is an area that if we're ever going to get to the bottom of the adequacy of training and experience as it relates to such events, we've got to take a look at it. So, we are currently pursuing such an endeavor.

CHAIRMAN CARR: Okay. How about enforcement actions in the medical area over the last few years? Are they directly proportional to the

amount of inspection we're doing or what kind of trails do you got?

MR. CAMPER: I have some notes here that in physical year '90 we conducted approximately 1,000 inspections. We had 57 enforcement conferences. There were 28 simple penalties imposed, two orders, 17 notices of violations, two letters, CALs, and eight were unresolved.

CHAIRMAN CARR: Is that trend increasing?

MR. CUNNINGHAM: It's my guess that it is.

CHAIRMAN CARR: Is that because we're looking more or --

MR. CUNNINGHAM: We're looking more frequently and we're looking in greater depth. So, I don't have the data to compare it, but --

MR. TAYLOR: I think others have that sense. We can get those numbers.

CHAIRMAN CARR: Well, we ought to start tracking them, I think --

MR. TAYLOR: As they're collected, we can give it to you.

CHAIRMAN CARR: -- so we get a feel for --

MR. TAYLOR: We have that data.

CHAIRMAN CARR: Pretty soon we would hope

that if we look more they'll start going to other way.

MR. SJOBLOM: I'd like to maybe add --

CHAIRMAN CARR: Want to identify yourself for the recorder, please?

MR. SJOBLOM: Glen Sjoblom, NMSS.

In the NMSS Newsletter two times ago, in fact, there was a graph that showed the number of materials enforcement and showed that both radiography and medical were on the up-trend. We think part of this has to do with our more in-depth inspections in the last two or three years.

You also recall that 10 CFR Part 35 went into effect a couple of years ago and there is a learning curve the licensees are on. There is a theory at least that once we inspect them all once, and that should occur like this year, after that rule went into effect, that perhaps that enforcement frequency might go down. That's not at all certain, but there's the possibility that that might exist, that might occur.

CHAIRMAN CARR: Well, we're going to have a perturbation in that bubble because we've delegated enforcement to the regions, I guess, in this area. So, we're going to have to factor that in. Have you see any impact on delegation of the enforcement?

MR. THOMPSON: We've not seen any impact per se that we have not taken many enforcement actions that have been delegated to the regions, but we obviously monitor that process very carefully and we'll continue to put that in our report to the Commission on enforcement actions.

CHAIRMAN CARR: Okay. Well, I want to thank the staff for this informative briefing and commend them for their efforts over the last year to continue improvements in the regulatory oversight of the medical use of byproduct material. Staff efforts are particularly commendable in support of the pilot program for the quality assurance rule, the Advisory Committee on Medical Uses of Isotopes, the development of the informative video on nuclear medicine safety, and coordination with other government agencies, states and professional societies involved with medical uses.

I'm also looking forward to the contributions that our new visiting fellows will make in assisting the staff both here and in the regions in addressing emergent issues and trends that may affect the safety of medical uses.

I encourage the staff to continue its efforts to solicit constructive comments from

licensees, states, professional societies, and other federal agencies on how the medical program should be improved.

I also encourage the staff to seek timely and effective ways to communicate with the licensees at the working level on the causes of medical misadministrations and emerging safety issues in the medical use program.

The NRC, the agreement states and the licensees share the important responsibility of ensuring protection of the public from unnecessary radiation associated with the medical uses of byproduct material.

We must continue to pursue this goal by striving to improve our regulatory program within available resources and without imposing any unnecessary burden on the medical community and the public.

Do my fellow Commissioners have any additional comments?

If not, we stand adjourned.

(Whereupon, at 3:05 p.m., the above-entitled matter was adjourned.)

CERTIFICATE OF TRANSCRIBER

This is to certify that the attached events of a meeting of the United States Nuclear Regulatory Commission entitled:

TITLE OF MEETING: ANNUAL BRIEFING ON MEDICAL USE OF BYPRODUCT MATERIAL

PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: FEBRUARY 12, 1991

were transcribed by me. I further certify that said transcription is accurate and complete, to the best of my ability, and that the transcript is a true and accurate record of the foregoing events.

Carol Lynch

Reporter's name: Peter Lynch

MEDICAL USE OF BYPRODUCT MATERIAL ANNUAL BRIEFING

February 12, 1991

John E. Glenn

Larry W. Camper

Contact: Josie Piccone, 492-1410

NRC's MEDICAL USE PROGRAM

- Program Development
- Inter-organization Cooperation
- Staff Development
- Oversight
- Information

PROGRAM DEVELOPMENT

- Dosimetry Assistance
- Human Factors
- Quality Assurance Rule/Pilot Program
- Radiopharmacy Petition

QA PILOT PROGRAM

- 64 Volunteers
  - 23 NRC Licensees
  - 41 Agreement State Licensees
- Pre- and Post-trial Workshops

PILOT PROGRAM RESULTS

- Most Volunteers had Existing QA Programs Which Addressed Objectives of the Proposed Rule
- Incremental Cost Small
- Suggestions on Specific Requirements to Improve Rule and Further Decrease Costs

RADIOPHARMACY PETITION

- History
- Interim Final Rule Permits Departures from Package Inserts:
  - for eluting generators and preparing kits
  - indications for use of radiopharmaceuticals in therapy

RADIOPHARMACY PETITION

- Remaining Issues:
  - Use of radiopharmaceuticals for human research
  - Use of radiolabeled biologics
  - Pharmacy preparation of radiolabeled drugs

INTER-ORGANIZATION COOPERATION

- The Food and Drug Administration (FDA)
- The U.S. Department of Health and Human Services' Health Care Finance Administration (HCFA)
- Agreement States

STAFF DEVELOPMENT

- GOAL: Increased Depth of Expertise in Medical Issues
- Most Members of Medical and Academic Section Have Worked in a Hospital
- Medical Visiting Fellows Program
  - Physician / Radiopharmacist
- Expand Experience Base of ACMUI

OVERSIGHT

- GOAL: Early Identification of Developing Problems
- Approximately 1000 inspections in FY '90
- Analysis of Misadministration Reports and Developing Trends
- Coordination and Technical Assistance to the Regions

MISADMINISTRATIONS REPORTED BY NRC LICENSEES

	CY87	CY88	CY89	CY90
Diagnostic	409	386	397	400*
I-131	5	7	10	10*
Therapy	9	12	10	18**
Licensees Involved	348	344	326	325*
AO Reports	8	7	8	14***

* Estimated ** Incomplete data *** 1, 2, & 3 Qtr

RESOURCES FOR MEDICAL USE PROGRAM

FUNCTIONAL AREAS	FY90 $	FY90 FTE	FY91 $	FY91 FTE	FY92 $	FY92 FTE
Program Dvlpmt & Event Eval. (HQ)	1038	8.2	1157	8.1	800	7.8
Inspec. & Event Eval. (Rgns)		20.5		23.2		24.5
Licensing (Rgns)		8.4		7.7		8.5
Supervision (HQ & Rgns)		4.7		4.9		5.2
TOTALS	1038	41.8	1157	43.9	800	46.0

INFORMATION EXCHANGE

- GOAL: Widespread Notice of NRC Activities

  -24 Presentations to Professional Groups

  - 4 Workshops for Licensees

  - NMSS Newsletter

  - Meetings with 8 Professional Societies

RECOMMENDATIONS OF ACMUI

- Drop Diagnostic QA to Focus on Iodine and Therapy QA
- Use of Event Instead of Misadministration
- Use Diagnostic Event Reporting Criteria Based on Harm

RECOMMENDATIONS CONTINUED

- Provide Summary Report to Patient Rather Than Technical Report
- Supports Change of Rule Title
- 2-Year ACMUI Term Too Short

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
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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 opportunity 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 sterectactic 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 componen.

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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ASLBP
ASLAP
SECY

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 H. 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

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

Jones, S.

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.

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.

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[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.

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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 466 comment letters have been received.

Comments were received from many different sources such as hospitals, pharmacies, and medical associates. About 80 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

...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

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 486 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 radiopharmaceuticals 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, 88 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 purpose 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, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 35.11, 35.13, 35.20 (a) and (b), 35.21 (a) and (b), 35.22, 35.23, 35.25, 35.27 (a), (c) and (d), 35.31 (a), 35.49, 35.50 (a)–(d), 35.51 (a)–(c), 35.53 (a)–(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, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, and 35.647.

* * * * *

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 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 particpate, 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. 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 the 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 management 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.

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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 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 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 open to physicians interested in seeking an appointment for individual sabbatical pursuits. Other specialists on sabbatical, or those who wish to engage in post-doctoral 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 Personnal 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.

Joan E. Glenn,

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

[FR Doc. 90-13271 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 collat[illegible]al 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 progra 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