UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

Title: BRIEFING ON MEDICAL USE OF BY-PRODUCT MATERIALS

Location: ROCKVILLE, MARYLAND

Date: JANUARY 19, 1989

Pages: 51 PAGES

NEAL R. GROSS AND CO., INC.

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Washington, D.C. 20005
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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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BRIEFING ON MEDICAL USE OF BY-PRODUCT MATERIALS

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PUBLIC MEETING

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Nuclear Regulatory Commission

One White Flint North

Rockville, Maryland

Thursday, January 19, 1989

The Commission met in open session, pursuant to notice, at 10:00 a.m., the Honorable LANDO W. ZECH, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

LANDO W. ZECH, Chairman of the Commission

KENNETH M.CARR, Member of the Commission

THOMAS M. ROBERTS, Member of the Commission

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

SAMUEL J. CHILK, Secretary

WILLIAM C. PARLER, General Counsel

ROBERT BERNERO, Deputy Office Director

HUGH THOMPSON, Office Director, NMSS

JAMES TAYLOR, Deputy Executive Director, Operations

RICHARD CUNNINGHAM, Division Director

NORMAN McELROY, Branch Chief

P R O C E E D I N G S

(10:00 a.m.)

CHAIRMAN ZECH: Good morning, ladies and gentlemen.

Commissioner Rogers and Commissioner Curtiss are on travel today and will not attend this meeting.

The purpose of today's briefing is to discuss the Nuclear Regulatory Commission's Medical Use Program. As part of an overall effort to direct more attention to the safe use of nuclear materials, a number of activities have been initiated for improving NRC oversight specifically in the area of medical use of byproduct materials.

The objective of NRC's program is to provide an integrated regulatory framework to reduce the risk that accompanies the medical use of byproduct material and to reduce non-compliance.

We will hear this morning from the Office of Nuclear Material Safety and Safeguards, on the status of activities underway in the Medical Use Program, including an update on the rulemaking effort to require licensees to have quality assurance programs.

During the briefing, I'd also like to ask the staff to address the specific comments made by Commissioner Rogers in his vote regarding the Medical

Use Program, which I believe you've been made aware of.

This is an information briefing this morning. Do any of my fellow Commissioners have any opening comments to make before we begin?

COMMISSIONER ROBERTS: No.

COMMISSIONER CARR: No.

CHAIRMAN ZECH: If not, Mr. Taylor, you may proceed.

MR. TAYLOR: Thank you, Mr. Chairman.

The briefing today will show you what the staff -- an outline of what the staff reported in a Commission paper to you, and showing the continued and increased staff attention to this important program. And, with that, I'll turn it over to Mr. Thompson.

MR. THOMPSON: Thank you, Mr. Taylor. Good morning, Mr. Chairman, Commissioners.

Certainly, the area of inspection activities, licensing activities, as well as the rulemaking activities that we have underway to improve the Commission's program and oversight of the medical regulated activities is one which we have given a lot of attention, a lot of activity, and we certainly appreciate the Commission support.

Today, we will give a status report of where we are in implementing some of the new initiatives, the

staffing activities, as well as identify what we see as some of the coming future areas of regulatory attention and concern with respect to making sure our program is prepared to address the challenges that we see.

Dick Cunningham, who is the Division Director of the Industrial and Medical Nuclear Materials Safety Division, and Norm McElroy are here to respond to any questions. Dick will be giving the briefing today.

CHAIRMAN ZECH: All right. Thank you very much. You may proceed.

MR. CUNNINGHAM: Thank you, Mr. Chairman.

I have a set of Vu-graphs which will be shown on the overheads also, and I believe they have been furnished to you and the Commissioners, and we start with the first Vu-graph.

(Slide)

This simply outlines the topics I propose to cover. First is just an overview of the industry, to remind you its size and scope, the resources we have devoted to the Medical Use Program and then, more importantly, the status of the Medical Use Program, progress we have made on the program that was submitted to you as SECY-88-77 -- I think it was dated June 7, 1988 -- and then, finally, I will address some areas of concern that we see emerging in medical programs.

May I have the next Vu-graph, please?

(Slide)

Very quickly, you've seen a chart similar to this before. To give you the size of the medical use that we regulate, there are about 7 million imaging procedures conducted per year. We reduced the number somewhat -- I believe it was 8 million in a previous report -- but these are estimates and that informational literature on the frequency of procedures cause us to reduce that somewhat.

Typically, an imaging dose results in about 2 rads to the target organ that's being imaged, and about a tenth of a rad, or 100 millirads whole-body exposure, effective whole-body exposure. So, it's somewhat less than that on radiation per year.

There are about 150,000 therapy procedures per year. These are large doses to kill cancer cells mainly. It involves about 5,000 rads to the target tumor, and very high doses to a localized area.

With respect to our licensees, there are about 2200 licensed hospitals under NRC jurisdiction, and about 4400 under the Agreement States. Private practice licenses, there are about 400 under NRC and about 600 under Agreement States.

May I have the next slide, please.

(Slide)

Misadministrations. In diagnostic misadministrations, you can see if you go across the chart, these are the number reported on an annual basis. The Calendar Year 88 is lower. I would like to take credit at this stage, for lowering the frequency of misadministrations, but I'm not prepared to do that at this time.

In April of '87, there was a modification of the misadministration reporting rule that set a dose threshold for reporting that might have changed the number some, in addition to which we don't have in our possession, in our compilation here, all the '88 reports because they have a 15-day period in which they can report. These are sent to the regions, and the regions accumulate these and send them to us per month. So, those data will change a little bit.

For the iodine misadministrations and therapy misadministrations, it appears to not change significantly from previous years.

Looking at the frequency for misadministrations, it's about 2-times 10 to the minus 4 is the frequency -- frequency of misadministrations per number of patients diagnosed or treated. That compares, incidentally, favorably with misadministrations as a

whole in medicine which, according to the literature, there are no formal reports, but there are some literature studies which indicate it's about 20 percent.

(Slide)

If I go to the next graph, we get into the resources. In a Program Development program that's here at headquarters, we have about 4 FTEs per year, and that remains constant.

In licensing, there's a slight reduction here because we're trying to shift resources to get more presence in the field through inspections, and we're trying to hold the line in licensing, itself, through increased efficiencies, and we're looking at initiatives to help the licensing process. So, we don't need to devote as many FTEs to licensing, and we can utilize those better in inspection.

You see the funds, $1.3 million -- that was initially targeted for the QA Rule, to do the initial round of inspections in the QA Rule. The Commission last year directed us to shift from a performance-based rule -- I'm sorry -- from a prescriptive-based rule to a performance-based rule which I will discuss later on, the progress on that.

In the meantime, we are using those resources to do two things that will help us in the QA, two

studies, one on voluntary standards, required voluntary standards through the industry, to see how we can make maximum use of these voluntary and required standards that are being used elsewhere, and to identify gaps where they may exist and where further work needs to be done, either by the medical community if we can get them to do it, or by us, if necessary.

The other study has to do with training. We have a Commission requirement to look at training across-the-board, not only physician training but the paramedical training, the technologist training, the medical physicist training, and to see the status of training, the status of credentialing, the status of state licensure requirements, to see how that fits, where the weaknesses are, and where we might best address our resources. So, that's another part of the study.

In the out-years, that money will be used for the initial round of inspections under the new QA Rules.

CHAIRMAN ZECH: Is that money that's used by contractor people?

MR. CUNNINGHAM: Yes, sir.

CHAIRMAN ZECH: All right.

MR. THOMPSON: Just kind of a baseline, Mr. Chairman, for last year we did about 2,000 licensing

case reviews and about 700 inspections of medical licensees. So, as you can see, we'll be increasing the emphasis on inspections as the Commission has directed, just to show you we are effectively getting out in the field, but there's still a lot of --

CHAIRMAN ZECH: Increasing it with your own FTE people --

MR. THOMPSON: That's correct.

CHAIRMAN ZECH: -- plus increasing it with contractor people. So, there is considerable increase.

MR. THOMPSON: Right. The key aspect on that contract is that once we have the new rule in place, we want to quickly go out and make sure all the hospitals have that improved QA program in place, and although we don't have normally enough inspection activities to go out to every facility every year, we want to make sure that that quality assurance program is in place where it needs to be.

CHAIRMAN ZECH: Very good.

MR. CUNNINGHAM: And this, incidentally, was one of the comments in Commissioner Rogers' statement, about increasing emphasis on inspection.

CHAIRMAN ZECH: Right. All right. Thank you.

MR. CUNNINGHAM: Okay. Now we get to the program itself, the Medical Use Program, the

developments that we're trying to do to upgrade the program. Certainly, this is a status report. We have a lot of work to do yet. We aren't there yet, but we are making progress.

That's slide 5. May I have slide 5 on there, please.

(Slide)

In SECY-88-77, we had a five-point program. The Commission agreed to that program, and provided additional comments, particularly Commissioner Rogers' comments, which we will include as we go along here and then address specifically.

The first one in the next slide, Chart 6, is the development of the regulatory framework, and the goal here is, of course, to improve the quality of medical use, and there are three points to that program -- the development of the QA Rule, which I am going to skip right at the moment because it requires another Vu-graph which follows, so if I could go to the second bullet right away -- develop the technical basis for determining whether changes need to be made in training -- I just discussed that.

The initial step there is the contract, to find out what training is out there, what training programs, what credentialing programs exist, how many

people are in those credentialing programs, and what state requirements are for licensure of technologists and paramedical personnel.

CHAIRMAN ZECH: How far along are you in that program? Have you chosen anybody for the contract yet?

MR. CUNNINGHAM: The contract is let. It is underway.

COMMISSIONER ROBERTS: Who is the contractor?

MR. CUNNINGHAM: Sanford Cohen and Associates.

CHAIRMAN ZECH: When will the study be completed?

MR. McELROY: We anticipate November, 1989, to have a final report submitted.

CHAIRMAN ZECH: All right.

MR. CUNNINGHAM: And then performance evaluation factors. You will recall, we have some general performance evaluation factors for materials licensees, and we are going to report to the Commission on that later this year, and they include things like management involvement, turn-over personnel, workload, radiation dose -- all to look at the safety of the operation, and these are general, cutting across the whole materials program.

What we have decided to do, though, for medical, is to develop a more specific set of

performance evaluation factors for medical licensing, and this will feed back into several aspects of our work.

Right at the moment, the status is, we have developed a questionnaire where we can start to gather data. The inspectors will gather data based on these questionnaires when they go out on inspection, related to existing quality assurance programs at medical institutions.

Right now, we've got to get OMB clearance to put that into effect. We have the questions in the hands of the inspectors, we are ready to go, but we do need OMB clearance in that, and we expect that very shortly. So, that program -- it's a database gathering of information, so we can use that in our development program as well as assisting inspectors recognizing where problems may develop in medical license programs. So, that is something new that has been added.

The next chart?

COMMISSIONER CARR: When do you expect to have those evaluation factors looked at, the list you're going to use?

MR. CUNNINGHAM: We have a questionnaire at this time.

MR. McELROY: Commissioner, we're in the

information-gathering mode. We've identified things that we think might indicate the level of quality of performance, but we aren't certain which are best correlated with performance, so I really can't respond to your question.

MR. THOMPSON: Our program is to come back to the Commission before the next fiscal year. Our intent right now -- my intent right now is to be back to the Commission about early August with what the performance evaluation factors should be.

If we get the information that would show and demonstrate the medical program factors ought to be modified or more focused, we will certainly inform you at that time. What I'm looking for is that by the first of the next fiscal year when we'll have additional resources, we have the performance evaluation inspection plan in place to be utilized for that next year.

So, I would anticipate dialogue with the Commission sometime probably the mid August-early September time frame is precisely where we are, and get your approval to implement those performance evaluation factors in the next year's -- fiscal year's inspection activities.

COMMISSIONER CARR: Well, I guess what I was curious about is, are we going to get any comments from

the medical profession on what factors we choose, or are we going to get some -- I hate to use the term "peer review", but it would be nice if we all agreed that, yes, this was a good set of factors.

MR. McELROY: Well, many of the parameters that we've identified are taken from the scientific literature prepared by the medical community, so I don't think there will be argument over the fact that these might be relevant, or related to quality of performance.

MR. THOMPSON: But we certainly would be using the advisory committee on medical -- you know, our medical advisory committee as one review of this activity.

CHAIRMAN ZECH: That's important, I think, to use those people and make sure they are involved. I am sure they would want to be involved in that.

All right, let's proceed.

MR. CUNNINGHAM: The next slide --

(Slide)

This is the QA Rulemaking. You will recall after the Commission met with members of our Medical Advisory Committee and representatives of the medical community, it was decided to change from a prescriptive type of QA Rule, to a more performance-based QA Rule,

with some guidance on what might constitute an adequate program, but allowing some flexibility in the medical use, with the licensees, so that they can fit a program that best meets their needs.

On that we have formed a subcommittee of our Medical Advisory Committee to assist us in this. And we did have a public meeting with the subcommittee on November 7, where medical organizations were represented. There still exists concern whether the staff is technically capable of preparing the QA Rule, but we feel with large involvement of the medical community, that we should be able to come up with something satisfactory, particularly since the rule itself will be a performance rule, with guidance on what constitutes a method of achieving adequate quality assurance based, to the extent it exists, on voluntary standards developed by the medical community.

CHAIRMAN ZECH: Well, that's an even more important reason why we should have our medical advisors involved in it, and to listen to their advice carefully.

MR. CUNNINGHAM: Yes, sir.

CHAIRMAN ZECH: Okay, thank you.

MR. CUNNINGHAM: In addition to that, we have scheduled, I believe it is June 30th, a meeting with a spectrum of medical licensees. We are trying to get a

cross-section of medical licensees together, to discuss and look at this problem again. And it is a round table type of thing, and look at our guidance that is evolving, and we will feed back that into our guidance role.

(Slide)

We plan to submit the rule to the Commission as scheduled, in April of '89. And from that point, we will then begin a pilot program as required by the Commission, to test out the implementation of the rule during the public comment period. And, again, feed back data from that into the final rule.

In addition to that, we are looking at the misadministration rule itself. This, again, was discussed by the Commission, and there is some direction in that in the SRM issued by the Commission. The term "misadministration" causes some problem to the medical community, because there is an indication of harm to patients in this, and it is somewhat objectionable because it gets tied up in -- there is a belief at least that it makes them more susceptible to malpractice suits.

In addition to that, there are questions about need for further reporting, particularly in one aspect of medical reporting, and that is what is termed the

"dose fractions". When you give therapy, you spread the therapy over a period with a prescription listing a final dose, but it might be broken up into 10 sessions, or so.

This was considered before by the Medical Advisory Committee, when the initial rule was proposed. And they wanted the final dose as a requirement for misadministration, if the final dose was off by a certain percentage, because in the course of treatment the physician, for medical reasons, may adjust the dose, depending on the patient's response. So they thought the final dose was the key.

However, we have seen instances of mistakes made in the dose fraction delivered. And we want to try to capture that in our misadministration rule.

So that is where we stand on this. We are looking at the misadministration rule.

(Slide)

Inter-organizational Cooperation.

CHAIRMAN ZECH: Before you go off that subject, what impact is that review having on your current enforcement cases?

MR. THOMPSON: The impact of the reporting requirement review?

CHAIRMAN ZECH: No, the impact of your

misadministration definition review.

MR. THOMPSON: Well, I think there is some confusion between the staff, and I guess differing views of what the appropriate interpretation is. We are working with OGC right now, with respect to a particular case that is before us. And once we get some clear guidance, we will put that out to the community. But it has some small impact. We don't have very many of these cases. As far as I know, we've gotten one, maybe two, since it has been in place. But it has got one particular case kind of held up right now.

MR. PARLER: Mr. Chairman.

CHAIRMAN ZECH: Yes, please.

MR. PARLER: I assume that the comment about clear guidance didn't refer to clear guidance from the legal office, which I am responsible for. There apparently is a problem with the definition. We shouldn't discuss the details too much because, as you indicated, there is a pending enforcement case and that would be an issue raised, depending upon which way we go now. Whether you go the legal advice way, or if you go the legal advice way, the staff side certainly can foresee, and properly foresee problems with that.

So my position is that we know what the problem is, and we should try to clarify it.

The question I have is -- and I would have to defer to the staff on this -- is whether the clarification can wait until the proposed rule, which would cover a number of things, or if it is significant enough, whether it should be clarified on a separate and faster track.

MR. CUNNINGHAM: So we will be looking at that as we go through --

CHAIRMAN ZECH: As an ongoing consideration, is what you are telling us, I believe.

MR. THOMPSON: That's correct.

CHAIRMAN ZECH: All right, let's proceed.

MR. CUNNINGHAM: The next slide is inter-organizational cooperation. One of the problems we have with dealing with the medical community is that we have no single industry organization that we can deal with, no single point of contact. We have lots of interfaces. We don't have a NUMARC for instance, to deal with.

So we have a number of organizations we deal with. Most important is our sister agency, the FDA, and we have several interfaces with the FDA.

On a policy level, responsibility is divided between us and FDA, in many aspects of medical use of radioisotopes. So that we have good understanding among our staffs of what we do and what FDA does. We are

planning a seminar that will be held on January 27th, for our staff. This is a seminar conducted by FDA here. And we have people, our own staff here at headquarters as well as regional people, attending that meeting. And we will, in turn, give FDA a seminar on our program.

On a working day-to-day level, we have day-to-day contacts with FDA on a number of technical issues. FDA gets applications for new drugs that they want to distribute under FDA labels, and they consult with us on safety aspects of pharmaceuticals.

We, in turn, help them on problem reporting. FDA has responsibility for performance of equipment. And when we see cases where equipment isn't performing as it is supposed to, we tell this to FDA. And we also, because FDA doesn't know who has this equipment, we have assisted FDA from time to time in identifying users, so that notices can get out to users.

This was done in this past year on a failure of a component, the teletherapy unit, for example.

MR. THOMPSON: In fact we issue those notices, as I remember, to make sure our licensees are aware of--

MR. CUNNINGHAM: Yes, we take the information from FDA and issue the notices.

We have members of the staff assisting in development of voluntary standards. Some staff members

are members of standing committees, the US Pharmacopoeia on Radiopharmaceuticals, the medical physics group, the American Association of Physicists in Medicine were on their therapy -- Committee on Therapy Training and Medical Training. And we are on the Committee on the Society of Nuclear Medicine, in addition to which we are assisting in developing medical training programs through various medical organizations, particularly the Medical Physics Organization and the Society of Nuclear Medicine.

And we are also having these round tables, the first one of which I mentioned with this cross-section of medical users, to get some feedback into our QA role.

MR. THOMPSON: I just might note, on this medical training program, that's one of the key areas that our advisory committee on the medical practices has focused on -- the lack of that in the community, as well as the ability for us to assist them was, they thought an area that we can get a lot of payoff for just a small amount of effort.

So we really wanted to try to focus on being able to do that.

MR. CUNNINGHAM: Okay, if I could have the next slide.

(Slide)

Staff Development. This is a very important part of our program. We have recently hired staff, both in headquarters and in the regions, to implement this program, both for the development part and the licensing and inspection part.

In the regions, three of the four recently hired people in the regions are credentialed in the medical use of radioisotopes. That is they have worked in medical isotope laboratories and they have certification in nuclear medicine technology.

Similarly, in the staff, three or four of the recent hires are credentialed in medical use of radioisotopes. The one that is not is a PhD-level person that has worked for FDA, and has done medical research. In addition to which we just recently hired, and will expect to report on board soon an additional person, who is credentialed in medical use of radioisotopes.

We have a program underway, under development, some of which is underway, on refresher training through our TTC Center in Chattanooga. Examples, of course, are the medical use of byproduct material, that is under contract with MD Anderson Hospital. We are working to get a contract on radiation therapy. We have given lectures on transportation, because a large part of

transportation of medical isotopes and inspection procedures. And then we have the apprenticeship modules in our training for orientation of medical people on our regulations, regulatory guides, inspection manuals, so on and so forth.

We are also initiating the program, and we have agreement with a local hospital, and we are starting this with the regions, also. If you are credentialed in nuclear medicine, when you come to an organization such as ours, nuclear medicine is dynamic -- procedures change, new modalities are developed and so on, and so forth.

We are arranging for a week's visit to a hospital where they observe all the procedures, how they operate, "hands-in-pocket" type of observation, to keep up with medical technology at a hospital where patients are being treated.

And we think that this is important for our staff, to keep up with the medical field. In addition to which -- I don't have this as a bullet on the assignment, but we have a rotational assignment program, cutting across the materials program with regard to medical rotations. We have sent our headquarter's people out on inspections, but we aren't into the program as much as we will be this coming year on

rotational assignments.

Rotational assignments are being planned now, but first we are just in the hiring process, and in the orientation process with a lot of our new employees. So that is planned, and will come and we are doing it. That is one of the things mentioned in Commissioner Rogers' memorandum, also.

(Slide)

The next slide, oversight of the medical activities. There are two basic oversight programs. One is the AEOD program, in which we are heavily involved also in tracking trends in licensing, inspection, and misadministration reports.

In other words, when we go out on inspections, we look at frequency, types of violations that we see, to see whether or not this can be corrected by regulation, or generic trends of one sort or another, both just results of inspections, as well as misadministration reports.

The other is to certainly increase our oversight of medical licensees through increased inspection frequency. And I have that schedule on the next Vu-graph.

(Slide)

With the increased resources on inspections we

have broken these down into several categories. The first one is hospitals, and we have two types of hospitals: broad licensees that have large programs, mainly teaching hospitals, large hospitals, something like Walter Reed, as well as teaching hospitals.

Now, broad licensees have a lot more latitude in their programs. They are involved in research, and necessarily, they have more latitude with oversight of an in-house radioisotopes committee.

We are increasing the frequency of the broad scope licensees from two years to one year. Now, the reason for putting the emphasis on the broad scope licensees instead of the community hospital, if something goes wrong in the broad licensees it is usually a deterioration of the administrative oversight. And it has more broad implications than typically we find in the community hospital where the problem may be more narrowly focused, in addition to which, with the resources we have available, to make a significant difference.

If we put our resources in the community, we probably wouldn't change that from three to two years, or one year. So, we feel that that's an important one there.

MR. THOMPSON: We just wouldn't be able to

execute that one, if we change the frequency with the resources -- although you gave us additional resources, we just would not be able, as a category, to change that.

Obviously, where we have a problem with a community hospital, or anything like that, we will obviously increase the frequency at that particular hospital. But as a group, we are not prepared to change our major frequency at this time.

COMMISSIONER CARR: But you will be able to get them every three years?

MR. TAYLOR: Oh, yes.

MR. THOMPSON: That's correct. And we are looking at the -- the Commission asked us to look at the inspection frequency and utilizations, and obviously we will report back to you, whatever mechanisms we can, if we were to change frequencies. But right now that's how we applied the new resources.

MR. TAYLOR: As I recall, at the broad scope hospitals, too, we found in some cases, and have taken appropriate enforcement if the RSO, the radiation safety officer, isn't doing an appropriate job. It then begins to impact on broader programs in trying to keep the discipline. So, we've taken enforcement on that.

CHAIRMAN ZECH: I think your priority is

correct. The whole point here is whether the community -- the frequency at community hospitals is sufficient.

MR. THOMPSON: You've asked us to look at that aspect of it, with respect to this recent request.

CHAIRMAN ZECH: And that's what you are still looking at.

MR. THOMPSON: Right.

COMMISSIONER CARR: Were we making every three years in communities before?

MR. McELROY: I don't know, but I believe that is the case, but I am not absolutely certain.

COMMISSIONER CARR: My impression was that we were missing that one.

MR. THOMPSON: There may be some that are missing. I don't know that we are missing lots of them. And typically, they have some guidance that allows them to extend a year. So, you know, some facilities may not be met every year, but are probably met within a four-year period.

MR. CUNNINGHAM: But we have recently met with all the regions on this subject. And they are committed to maintaining these schedules at the present time.

CHAIRMAN ZECH: Good.

MR. CUNNINGHAM: I might mention cobalt therapy. The reason we go from three to one here, the

risk is higher, because you are delivering higher doses to patients. And in private practice we just want more presence in five years, and this is what we can get with the resources we have.

COMMISSIONER ROBERTS: Well, tell me, what is the population of the so-called "private practice"?

MR. CUNNINGHAM: Four hundred in NRC.

CHAIRMAN ZECH: Now, are the Agreement States going to have a comparable inspection frequency?

MR. CUNNINGHAM: I can't answer that. As I recall, Mr. Chairman, the Agreement States have -- I believe they might have done -- it varies from state to state, but I think there are some states that do more frequent inspections than we have in the past.

MR. THOMPSON: It's a broad spectrum. I think that is one of the questions you asked us to look at, how our inspection frequency compares with the Agreement States. But I think Dick is right, some states almost do an annual inspection of their licensees. Whereas we don't do that to the community hospitals at all.

So they probably have a --

CHAIRMAN ZECH: But we ought to be concerned, perhaps, about those states that don't do it as frequently as, perhaps, we think they should. That's what I hoped you looked at.

MR. TAYLOR: We ought to be prepared next time to give you that.

CHAIRMAN ZECH: Well, I hope you will look at that aspect of it. Because the Agreement States, as you say, they vary, and I am aware of that, too. And there may be good reasons to do it somewhat differently, but I just think we should be concerned about doing it with sufficient frequency of inspections. So we should look at that, and I hope you will get back to us on that.

MR. THOMPSON: Will do.

(Slide)

MR. CUNNINGHAM: The next Vu-graph is Information Exchange. We have a number of initiatives going. In this past year, calendar '88, we've used association newsletters. The Society of Nuclear Medicine Newsline, which is I believe a quarterly--

MR. McELROY: That's published monthly.

MR. CUNNINGHAM: -- a monthly newspaper distributed to members. There were six articles on enforcement actions and rules in those papers.

And then there is a publication called Nuclear Licensing Reports, in which there were two articles on rulemaking.

We have issued information notices, two information notices on the cause of misadministration.

We spoke at 14 scientific meetings with the medical community. We are planning workshops, four workshops in this coming year with medical licensees. And we have initiated the NMSS Newsletter. We have had three editions of that newsletter.

In those newsletters we have had six enforcement case reports, five reports on misadministration, and an article on a problem in a device that was a broken braechio radiotherapy afterloader, equipment problem, and an article on the rulemaking on quality assurance. So, we are getting out in our publications and speaking on those points.

MR. TAYLOR: I think the workshops are probably the most effective of these avenues. Obviously, meeting with the scientific community, professional meetings is another way, but the workshops you get the licensees there with the key regulatory staff, and a sufficient number that issues, I think, are appropriately addressed.

And I look forward to that, and I think we are probably going to ask some of the Commissioners if they would like to participate in some of the future workshops, as their schedules permit. Certainly I, and Bob Bernero intend to follow that activity very carefully.

CHAIRMAN ZECH: All right, let's proceed.

(Slide)

MR. CUNNINGHAM: Finally, on page 13, or graph 13, we have listed some areas emerging on concerns in medical use. The first one that seems to be of emerging concern is radiopharmacy. We have had rules that are long-standing, which require medical users to use radiopharmaceuticals that are approved by FDA, either under an IND, investigational new drug application, or an NDA, which is their final licensure labeling of the drug.

There appears to be a problem emerging by the medical community, representatives of the medical community, saying this prohibits the hospital radiopharmacy from making drugs and using drugs as they need them.

Now, our rules have been long-standing, but this appears to be an emerging problem. We don't know the dimensions of the problem, but we need to address it. We want to give hospitals the flexibility they need to manage their patients, and at the same time we want to have a high level of protection that is equivalent to what FDA regulates.

I might add here that FDA does not regulate the hospital radiopharmacies. Pharmacies in hospitals

are licensed by the state, but as nearly as we can tell, they really don't look at what happens in a radiopharmacy. So on the one hand we have -- we want to give the flexibility the community feels it needs, and on the other hand we want to make sure that what is done meets with appropriate standards of quality.

Another problem we see emerging is computerized treatment planning. Therapy is done by computers. And mistakes in computer programming can not only result in a misadministration to one patient, but to a series of patients before the error is found.

We have had two recent examples of that here in the United States, and I am aware of one that occurred in England, although I do not have the details of the thing.

So we have a machine-man interface here that is a problem, and we are seeing more of this. And we feel that this is a problem that demands attention.

Availability of trained technologists in the medical community. The average career of a medical technologist is about five years. And there are a variety of reasons for this. In therapy particularly it is a very emotional kind of job. They have burnout, the pay -- there is not too much opportunity for the technologist's advancement in pay. And there are a

variety of factors for high turnover.

Coupled with that there are declining resources for training courses conducted by hospitals to train technologists. HCFA, this is the Health Care --

MR. McELROY: Health Care Finance Administration, part of Health and Human Services Department.

MR. CUNNINGHAM: -- prescribes what medical fees may be paid for certain types of illness through medical care. Excluded from the cost of medical care is any provisions for training. In other words, it is just the hands-on treatment of the patient, and it doesn't include these kinds of things. And now hospitals are having a hard time funding those.

So we are seeing problems with getting highly trained, well trained people emerging because of this kind of problem. And that will come up more in the study that I talked about earlier.

Monoclonal antibodies. This is something that is being developed, where you label an antibody that seeks out cancer cells in the body. This is something new. If it develops as some people project it will develop, it may be an important break through in cancer treatment. The problem though is that it involves large quantities of Iodine-131, perhaps labeled in

hospitals, a labeling procedure which is relatively inefficient, which is going to result in iodine going somewhere, either trapped, or perhaps up the stack. And we have those kinds of problems.

In addition to which some of the labels may be alpha emitters. Now, as you all know, alpha emitters are, in general, more radio toxic than some other kinds of isotopes. And alpha emitters heretofore haven't been used in nuclear medicine laboratories. So we have a plain health-physics problem that we are going to be faced with, if this becomes popular. Because if it does become an approved practice and it gets out of the research stage, we can envision most hospitals wanting to use this for management of cancer patients.

And then we have the low-level waste problem that is emerging. At the moment two states are being excluded from access to waste disposals grounds because they haven't met their commitments under the Low-Level Waste Policy Act, and these are Vermont and New Hampshire. New Hampshire is an agreement state, and Vermont is not an agreement state and they do have hospitals there. We have a couple of hospitals in New Hampshire, two federal hospitals. So we have a problem there with waste.

We also have the mixed waste problem, the

pathological waste issues to deal with at the same time. So this is an emerging problem, also. It might get worse as other states don't meet the second round of commitments under the Nuclear Waste Policy Act in a couple of years.

So these are problems that we are trying to deal with, track and keep on top of.

MR. THOMPSON: Particularly in that case, we are working with Region I to identify and survey the licensees that are our responsibility, there in Vermont, to identify what the problems are, if any, and what steps need to be taken.

COMMISSIONER CARR: But they are only excluded from --

MR. THOMPSON: So far, but it is anticipated that the other cited states will likely send letters in.

COMMISSIONER CARR: Well, that remains to be seen whether they want to cut off their money, or not. They get to charge them more if they are not meeting their requirements.

MR. CUNNINGHAM: This concludes the Vu-graph presentation, Mr. Chairman.

MR. THOMPSON: Did you want to see if any of the issues of Commissioner Rogers need to be further addressed, then?

MR. CUNNINGHAM: Yes.

COMMISSIONER CARR: Are we taking care of some of those foreseeable problems in our five-year plan? Or are you going to staff up to take care of some of those? I mean, if we can see them this far ahead, we might as well face the issue.

MR. McELROY: If I may interject on one of them. The availability of medical technologists is not peculiar to radiation medicine, it is running the gamut throughout all medical care. I think two Sundays ago in the Washington Post there were five pages of advertisements for nurses. There was one page of advertisements for radiation technologists. So, it goes far beyond the portion of the hospital activity that we regulate.

That's a very large problem and I am not sure how we could impact on that. I would mention in passing, regarding the computerized treatment planning process, the American Association of Physicists in Medicine has already established a committee that is developing a program that will allow end users to actually validate codes that are purchased. We will be participating in that committee, to make sure that the man-machine interface is dealt with properly, to ensure that users don't misunderstand what parameters mean.

COMMISSIONER CARR: And they didn't get a code that wasn't right when they got it.

MR. McELROY: Right.

MR. THOMPSON: Part of that, also, will be addressed as we get experience with the QA Rules. Part of quality assurance is having some assurance that the computer treatment aspect is properly checked out, verified, prior to its being implemented and adopted.

I would say in the training technologist area that it is kind of beyond our control in that aspect, but to the extent that we can participate in working with the professional societies, in conducting training, we intend to continue that. But that's one that we just wanted to identify to the Commission, as an area that the industry is experiencing difficulties.

It kind of goes into the inspection frequency. You know, if you have a high turnover of your trained technologists, it would imply that you may, in fact, have an inspection and have people who never know what the NRC really is, if we don't come out but once every three or four years. So, that was one of the areas that we have been trying to increase our inspection frequency at those types.

COMMISSIONER CARR: Well, I guess my problem was, it looks like we are going to need to train our own

people, as well. And we may want to do increased inspections as some of these problems pop up.

MR. THOMPSON: That's true. And one of the things, like the monoclonal antibodies, I think we obviously have to monitor where the state of the medical community is going, so that our regulatory program stays consistent with that. That's precisely right.

COMMISSIONER CARR: And the five-year plan is a good mechanism for doing that.

MR. THOMPSON: That's right, and that's why we have the developmental resources -- you will notice, we have four FTEs to maintain that type of problematic development and monitoring. And the Commission has given us resources for that.

CHAIRMAN ZECH: All right.

MR. CUNNINGHAM: Turning to Commissioner Rogers' memorandum and the SRM -- I don't have a Vu-graph on this, but very quickly, Commissioner Rogers made several recommendations. He emphasized the need for inspection presence at licensee sites. And I have discussed our inspection program. And then he gave examples of additional actions.

The first one is to encourage rotational assignments, I've addressed that. We are going to do that. But we are right now in the hiring-orientation

phase and development phase. But we have that schedule, starting with Norm going out to one of the regions.

Increased utilization of AEOD staff resources for periodic analysis of the medical community performance. There are two things, AEOD has two staff members to cut across all materials licensing.

Now, we are doing two things: I had mentioned the performance evaluation factors, where we are trying to get specific ones for medical licensing. That will feedback into this trend analysis, too. So that is a precursor to doing that. In addition to which one of the two members of the AEOD staff that recently went over there is a staff member that is very experienced in medical programs, both licensing and inspection. And has experience in nuclear medicine laboratories.

The problem with that is AEOD hired her away from us. So, we had to replace her. But that is being beefed up there.

MR. THOMPSON: And I would also note that monthly we hold meetings to go over all of the incidents that have occurred, you know, in the past, and review that. We involve the AEOD staff, in trying to identify any particular areas that it might be useful for them to take a more detailed look at. And they have been able to do that in response to the incidents that we review on a

monthly basis.

MR. CUNNINGHAM: An example of that is we have asked AEOD to look at end uses of equipment, like teletherapy units when they are out.

Exploration of further institutional ties, and Commissioner Rogers suggested that we look into a fellow program, where we could have a fellow somehow associated with our program. And we have preliminary work on that. We have more work to do, but Norm has been in contact with George Washington University, and they are starting a fellowship.

MR. THOMPSON: The University is starting a PhD program in medical physics. This would turn out very well trained physicists, the kind of person we are looking for, to have in as many hospitals as possible, particularly in radiation therapy.

In developing that program they are looking for work assignments for their PhD candidates, and of course looking for whatever financial support that is available to develop that program.

I indicated that we were interested in working with them, but of course have not made any commitments at this time.

CHAIRMAN ZECH: On that issue, I think it would be helpful to the Commission for you to continue

looking into it, and get a paper to the staff -- from the staff to the Commission on that particular suggestion of Commissioner Rogers. I think we would all be interested in seeing what we could do in that regard, or whether we should do it, or not.

But it will be resources involved and I think that should come to the Commission. If you would do that, I would appreciate it.

All right, let's continue.

MR. McELROY: And finally, more active involvement of Commission offices, the EDO and senior staff members. Well, senior staff members have been involved.

In the past, you, Mr. Chairman, gave an opening paper at one workshop, that was a while ago. We have four workshops planned, at least in three of those we would hope to invite Commissioners and Chairman to give a talk. And we are also going to explore with your assistance first, with some of your assistants perhaps, giving a talk at one of the annual meetings of the major society. I think that would be helpful to our program, in addition to continuing to go out to hospitals. I think that's very helpful.

I mean, the word gets around that you go to these hospitals. It isn't just the single hospital that

you go to, I think that that's very helpful and important.

CHAIRMAN ZECH: Well, keep the Commission informed on that. I know that there is interest, as far as the Commission is concerned on following through and supporting that. I intend to do that myself for the next few months, to the extent that I can. And I think the other Commissioners, also, should be given that opportunity. So, we do want to support that program, and please keep us informed.

MR. CUNNINGHAM: I think that covers-- Commissioner Rogers made general statements that we should put more flesh on the skeleton of the staff paper that went out in June, SECY-77-88, I believe it was-- 88-77. That was the purpose of this briefing, and there is a subsequent paper that will go out.

You can see how the program is emerging now and being fleshed out.

CHAIRMAN ZECH: He mentioned also the Advisory Committee on Nuclear Waste, and make sure that they are informed, and kept involved in this whole implementation of the program. And I presume you intend to do that.

MR. CUNNINGHAM: Yes.

CHAIRMAN ZECH: All right, thank you.

MR. THOMPSON: I think that completes our

briefing today. We would be glad to respond to any particular questions you have, Mr. Chairman.

CHAIRMAN ZECH: Thank you very much.

Questions from my colleagues -- Commissioner Roberts?

COMMISSIONER ROBERTS: No.

CHAIRMAN ZECH: Commissioner Carr.

COMMISSIONER CARR: I don't have any questions. I would like to commend you on the program, I think you are making progress. I think the newsletters are a valuable piece, I am proud to see that those are going out. Also, the AEOD training film on misadministration which you mentioned in the newsletter, I didn't know that was coming up. It may be helpful. I am going to look at it one of these days.

But I think the info exchange is very good. I think it is an important program. As I say, we injure more people in this area than we have in reactors, so we can't afford to neglect that. So I would say proceed with all due haste.

CHAIRMAN ZECH: Just a couple of comments. Commissioner Carr mentioned earlier the five-year plan, and I hope that you will look at that five-year plan, and recognize that it is the vehicle for the Commission to provide the guidance to the staff that we want you to

look at carefully. And if you see that you can't execute some program that we are trying to emphasize-- and this is certainly one of them -- be sure you get back to the Commission, so we are aware of that.

MR. TAYLOR: Yes, sir, the EDO has set up, in the next month, or so, a meeting of the Steering Committee, to look at the five-year plan. And the intent of that then is to reach into areas that --

CHAIRMAN ZECH: That's the idea, and to come back to us if you see some things there that are problems.

MR. TAYLOR: Right -- and we will work with the offices, and come back to the Commission with suggested adjustments. That will be in the next month or two.

CHAIRMAN ZECH: All right, thank you.

Concerning the Agreement States, I do think it is important that they are aware of, and following closely the actions we are taking here at NRC headquarters to give more emphasis to these programs that we have discussed here today, in the area of nuclear materials licensing, and in particular the hospital programs.

COMMISSIONER ROBERTS: If I may, doesn't that lead to the question is it possible that the NRC could

learn from some of the Agreement States?

MR. CUNNINGHAM: I think there is no question that we can learn from each other. On the point though, we have given several talks. We have an agreement state training workshop. We have met with -- I am trying to scan here -- but we did meet with the agreement state-- the radiation control program officers.

MR. McELROY: The Conference of Radiation Control Program Directors annual meeting included some discussion on medical use regulation, inspection frequencies and so on.

CHAIRMAN ZECH: Commissioner Roberts makes a good point, some of the Agreement States may have more aggressive programs in this area than we do.

COMMISSIONER ROBERTS: It is my understanding that is an accurate statement.

CHAIRMAN ZECH: And we should learn from that, and consider that. And I think that is an important point. By the same token, I think they should certainly all be aware of our efforts to try to upgrade our inspection and oversight activities in this area. I think the point is well taken that those who have more aggressive programs than we have, we should look at that very carefully, too, and learn from them, also.

How about the Food and Drug Administration,

you did mention them. It seems to me that there is considerable parallel in some of our responsibilities. I wonder, do you know if they have a quality assurance program, like we are talking about?

MR. McELROY: They have a very stringent product monitoring program -- you have all heard of recalls of medical products, and that is the oversight program.

CHAIRMAN ZECH: You've looked at that carefully, I mean, we can learn from them in that regard, too. And I hope you have done that.

MR. McELROY: We are working together with them. The regulatory framework is somewhat different, because they are dealing with a smaller population of very large manufacturers, whereas we have many, many licensees scattered across the country.

CHAIRMAN ZECH: I recognize that, but our public health and safety responsibilities at least have a similar relationship, have some relationship. And it seems to me that even though of course there are differences, many of the same principles are involved. And I hope that we are working closely with them and learning from them.

In the area of quality assurance, as you point out, they have had a program -- do have a program, it is

my understanding, for some time in that regard.

Although it may be different in a way from what you are doing, there are things in that program, I think, that might apply to our regulatory practices. And I hope that we are taking a good look at their regulatory practices, so that we can benefit from their experience in this regard.

MR. CUNNINGHAM: Mr. Chairman, I think there is no question that we have looked, and we are continuing to look and work with FDA on this. The difference is they regulate drugs and we regulate people who administer drugs.

MR. THOMPSON: Not only, Dick, they do have a voluntary QA program that they put out. It is not, you know, so that the institutions can select the portion of the QA program. They don't have an inspection program, like we do, but I think we certainly are aware of their QA program that they have published.

MR. CUNNINGHAM: One of the things in QA, of course, we have added to our staff a human factors person. And that is, I think, a very important contribution, that is heavily engaged in this. And it isn't only FDA QA, it is other people's QA, too. Because when you get to human factors, the kinds of things that happen are -- there are similarities,

whether it is medicine, or other places. So we have to look more than just at FDA, or some of these other places, and we are trying to do that.

CHAIRMAN ZECH: Well, I hope you are doing that, but also I hope you are looking at the Food and Drug Administration.

MR. CUNNINGHAM: Yes, sir.

CHAIRMAN ZECH: Well, I, too, would like to commend you for what you are doing. It is clear that we are putting added emphasis on this, not only in our own resources, or our own people, but also planning to add contractual support in the future. I think the consistency of your inspections and the inspections themselves, looking at the quality of your inspection, and all, is awfully important.

I do think that working with our medical advisory committee and listening to them carefully is important. Our regulatory responsibilities for public health and safety in this particular field are very real. And as we know, the potential for injuring people in this area is, as we know, more in evidence than has occurred in the past, more perhaps than even in the-- to a great extent in the reactor nuclear power plant area.

And, therefore, it behooves us to give this

field attention, and to follow through with a good program of inspection and enforcement, when warranted. And so I think you are doing the right thing. And this is what the Commission has had in mind. And I am pleased to see that we are seeing some added emphasis and resources placed on this important area.

So, I would like to commend the staff for your efforts in this regard, and ask you to keep up the pace you are on, keep up the momentum. And we will expect to be briefed periodically by the staff on this important program.

Do any of my fellow Commissioners have any additional comments to make, before we conclude?

COMMISSIONER CARR: One comment on your redefinition of misadministration. I would like a chop on that before we put it out -- redefine misadministration so it is not one.

(Laughter)

COMMISSIONER ROBERTS: A rose by any other name is still a rose.

CHAIRMAN ZECH: Yes, I think it is very important that that come to the Commission, and let us get involved in that important policy matter.

Any other comments?

(No response)

CHAIRMAN ZECH: All right, thank you very much. We stand adjourned.

(Whereupon, at 11:13 a.m., the meeting was adjourned)

CERTIFICATE OF TRANSCRIBER

This is to certify that the attached events of a meeting of the U.S. Nuclear REgulatory Commission entited:

TITLE OF MEETING: Briefing on Medical Use of By-Produce Materials

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: January 19, 1989

was 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.

Phyllis Young

PHYLLIS YOUNG
Reporter and transcriber

BRIEFING ON MEDICAL USE OF BYPRODUCT MATERIALS

JANUARY 19, 1989

TOPICS

- THE MEDICAL USE INDUSTRY
- PROGRAM RESOURCES
- NRC'S MEDICAL USE PROGRAM
- AREAS OF CONCERN IN MEDICAL USE

SLIDE 1

INDUSTRY CHARACTERIZATION

- o CLINICAL PROCEDURES PER YEAR NATIONWIDE
  - 7 MILLION IMAGING
  - 150 THOUSAND THERAPY
- o LICENSEES

	NRC	AGREEMENT STATES
HOSPITALS	2200	4400
PRIVATE PRAC.	400	600

SLIDE 2

MISADMINISTRATIONS REPORTED BY NRC LICENSEES

	CY86	CY87	CY88*	EST FREQ
DIAGNOSTIC	433	409	259	.0002
I-131	5	5	4	
THERAPY	7	9	8	.0002
LICENSEES INVOLVED	369	348	237	15%

* REPORTED AS OF JANUARY 9, 1989

NMSS MEDICAL USE PROGRAM RESOURCES

	FY88	FY89	FY90	FY91
PROG DEV	4 FTE	4 FTE $1.3 M	4 FTE	4 FTE
LIC	10 FTE	9 FTE	9 FTE	11 FTE
INSP	15 FTE	23 FTE	23 FTE $2 M	24 FTE $2 M

NRC'S MEDICAL USE PROGRAM (SECY-88-77)

- Program Development-Regulatory Framework
- Interorganization Cooperation
- Staff Development
- Oversight-Monitoring Medical Use Activities
- Information Exchange

PROGRAM DEVELOPMENT-REGULATORY FRAMEWORK

GOAL: IMPROVED QUALITY IN MEDICAL USE

- DEVELOP QA RULE, REGULATORY GUIDE
- DEVELOP TECHNICAL BASIS FOR DETERMINING WHETHER CHANGES ARE NEEDED IN TRAINING LICENSEE STAFF
- DEVELOP PERFORMANCE EVALUATION FACTORS SPECIFIC TO MEDICAL USE

QA RULEMAKING

- o PERFORMANCE-ORIENTED QA RULE
  - ACMUI SUBCOMMITTEE MEETING
  - MEET WITH SPECTRUM OF MEDICAL LICENSEES
  - FEEDBACK TO REGULATORY GUIDE
  - SUBMIT PROPOSED RULE TO COMMISSION APRIL 1989
  - PILOT PROGRAM TO TEST IMPLEMENTATION
- o REVIEW "MISADMINISTRATION" TERM AND REPORTING REQUIREMENT
- o SUBMIT FINAL QA RULE APRIL 1990

INTER-ORGANIZATION COOPERATION

- o Coordinate Regulatory Framework with FDA
  - Policy
  - Technical Issues
  - Problem reporting
- o Assist in Development of Applicable Voluntary Standards (USP, AAPM, SNM)
- o Assist in Developing Medical Training Programs
- o Roundtables

STAFF DEVELOPMENT

- o RECENTLY HIRED PERSONNEL HAVE MEDICAL USE BACKGROUNDS
- o PROVIDING REFRESHER TRAINING
  - REVISING TTC COURSES ON NUCLEAR MEDICINE, RADIATION THERAPY
  - ARRANGE OBSERVATION DETAIL FOR STAFF AT A NEARBY HOSPITAL

OVERSIGHT-MONITORING MEDICAL USE ACTIVITIES

- Track Trends in Licensing, Inspection, Misadministration Reports
- New Inspection Schedule

SLIDE 10

INSPECTION FREQUENCY (YEARS)

	FY88	FY89	BASIS
HOSPITALS			
- BROAD SCOPE	2	1	RISK
- COMMUNITY	3	3	RESOURCES
COBALT THERAPY	3	1	RISK
PRIVATE PRACTICE	5	4	PRESENCE

INFORMATION EXCHANGE

- o USED ASSOCIATION NEWSLETTERS (8)
- o ISSUED INFORMATION NOTICES (2)
- o SPOKE AT SCIENTIFIC MEETINGS (14)
- o WILL HOLD WORKSHOPS WITH LICENSEES (4)
- o INITIATED NMSS NEWSLETTER (3)

AREAS OF CONCERN IN MEDICAL USE

- o RADIOPHARMACY
- o COMPUTERIZED TREATMENT PLANNING
- o AVAILABILITY OF TRAINED TECHNOLOGISTS
- o MONOCLONAL ANTIBODIES
- o LOW-LEVEL WASTE

SLIDE 13

RESERVE SLIDES FOR

BRIEFING ON MEDICAL USE OF

BYPRODUCT MATERIALS

JANUARY 19, 1989

ORGANIZATIONS AFFECTING LICENSEES

- o FEDERAL AGENCIES - 5
- o SCIENTIFIC OR PROFESSIONAL - 13
- o CREDENTIALING OR ACCREDITING - 9
  - PHYSICIANS
  - TECHNOLOGISTS
  - PROGRAMS

RESERVE SLIDE 9.0

FEDERAL AGENCIES

- o NUCLEAR REGULATORY COMMISSION
- o HEALTH AND HUMAN SERVICES
  - HEALTH CARE FINANCING ADMINISTRATION
  - FOOD AND DRUG ADMINISTRATION
- o ENVIRONMENTAL PROTECTION AGENCY
- o DEPARTMENT OF TRANSPORTATION
- o DEPARTMENT OF LABOR (OSHA)

RESERVE SLIDE 9.1

PROFESSIONAL

- AMER ASSO OF PHYSICISTS IN MED
- AMER COLL OF MEDICAL PHYSICISTS
- AMER COLL OF RADIOLOGY
- SOC OF NUCLEAR MEDICINE
- AMER COLL OF NUCLEAR PHYSICIANS
- AMER SOC OF THER RADN ONCOLOGISTS
- COLL OF AMER PATHOLOGISTS

RESERVE SLIDE 9.2

SCIENTIFIC

- RADIOLOGIC SOCIETY OF NORTH AMERICA
- UNITED STATES PHARMACOPOEIA
- NATL COUNCIL ON RADN PROT AND MSMNTS
- AMER ROENTGEN RAY SOCIETY

RESERVE SLIDE 9.3

ADMINISTRATIVE

- o Asso of Community Cancer Centers
- o Asso of Hospital Radiology Admin
- o Soc of Radn Oncology Admin

RESERVE SLIDE 9.4

CREDENTIALING FOR PHYSICIANS

- AMER BD OF RADIOLOGY
- AMER BD OF NUCLEAR MEDICINE
- AMER OSTEOPATHIC BD OF NUC MEDICINE
- AMER OSEOPATHIC BD OF RADIOLOGY

RESERVE SLIDE 9.5

CREDENTIALING FOR SCIENTISTS AND TECHNOLOGISTS

- AMER BD OF SCIENCE IN NUC MEDICINE
- AMER REGISTRY OF RADIOLOGIC TECHS
- NUC MED TECHNOLOGY CERT BD
- STATES (14)

RESERVE SLIDE 9.6

PROGRAM ACCREDITATION

- COMM ON ALLIED HEALTH EDUCATION AND ACCREDITATION
- JOINT COMM ON THE ACCREDITATION OF HEALTHCARE ORGANIZATIONS

RESERVE SLIDE 9.7

POLICY ISSUE
(Information)

January 12, 1989 SECY-89-006

For: The Commissioners

From: Victor Stello, Jr.
Executive Director for Operations

Subject: ANNUAL REPORT ON MEDICAL USE PROGRAM

Purpose: To provide an annual report on the Medical Use Program.

Summary: The Commission asked the staff to provide an annual report on the Medical Use Program. This report describes the implementation of the Five Point Program (SECY-88-77) for improving NRC's oversight of medical use, resources, and areas of concern in the medical use of byproduct materials.

Discussion:

Background

In response to the Commission's interest in matters concerning medical use, the staff provided the Commission a Five Point Program for improved NRC oversight of the medical use of byproduct material (see SECY-88-77). The purpose of the program is to provide an integrated regulatory framework to reduce the risk that accompanies the medical use of byproduct material, and to reduce non-compliance. The program was designed to maximize the use of other voluntary programs already in place. The program addressed: 1. Program Development, 2. Inter-Organization Cooperation, 3. Staff Development, 4. Oversight, and 5. Information.

The implementation of these five integrated initiatives, the budget, and problem areas are discussed below.

Industry Characterization

NRC regulates medical use of byproduct material in about 2,000 hospitals and 400 private practice clinics. This represents about one-third of medical use licensees; the other two-thirds are in the Agreement States. Medical use includes the administration of millicurie dosages of radiopharmaceuticals to diagnose the presence and extent of disease or treat disease, and the use of sealed sources for cancer therapy. About seven million diagnostic procedures and 150,000 therapy procedures are performed nationwide each year.

Contact:
Norman L. McElroy, NMSS
49-23417

Five Point Program

The Five Point Program described an integrated approach to regulating NRC's medical use licensees. It was designed to optimize the use of Agency resources by working with other organizations. The original program submitted in SECY-88-77 was of necessity general, while the staff identified fundamental needs and issues. The details of implementation are described below.

Program Development. The staff is developing a flexible, performance-based rule to require medical use licensees to have quality assurance programs. This rule will heighten the medical community's attention to detecting and reducing the chance of misadministrations. The staff has let a contract to study training and experience criteria, credentialing programs, and state licensure of medical personnel. The results may indicate a need for rulemaking in this area. In accordance with Section 19 of the Price-Anderson Amendments Act of 1988, the staff is participating in a negotiated rulemaking to determine the feasibility of indemnifying radiopharmaceutical licensees under Price-Anderson. These rules will be submitted as separate papers.

The staff believes that human error is a large contributor to mistakes in medical use. The staff's plan for identifying and addressing human factors concerns in the medical environment has been given high priority. The plan will include human factors input to all medical use program activities, with coordination between NMSS, RES, and AEOD as well as outside organizations. Information collection on the factors will begin in February 1989. This supplements the general performance evaluation factors program applicable to all materials licensees.

Inter-Organization Cooperation. The other key Federal agency that regulates safety in medical care is the Food and Drug Administration (FDA). It regulates drugs and medical devices that are placed in interstate commerce. The staff initiated and has conducted office-level communications designed to ensure that NRC and FDA will work together.

The first programmatic step will be an FDA seminar at NRC headquarters in January 1989 to describe the FDA regulatory program for pharmaceuticals; a similar seminar is being planned for medical devices. In return, NRC will present a seminar on its medical use regulatory program in 1989. These seminars are designed to educate each agency's staff in the programs and procedures of the other agency.

The staff has already developed contacts at FDA that have helped resolve several technical questions posed by NRC licensees. In

return, NRC helped FDA track down some teletherapy units that required a special inspection for mechanical safety.

The staff is working with other organizations (Society of Nuclear Medicine, American Association of Physicists in Medicine, and United States Pharmacopoeial Convention) by participating in committee activities. Liaisons for information flow are established with the American College of Nuclear Physicians, the American College of Radiology, and the American College of Medical Physics. All these organizations are on a mailing list for regional and headquarters Public Affairs press releases and Office Information Notices.

Staff Development. Within headquarters, over the last year, the staff has recruited from outside four individuals with extensive medical use experience and one with extensive FDA and medical research experience. The regions have recruited four new individuals with extensive medical use experience to work in the licensing and inspection programs, and are in the process of further reinforcing the medical use program by reallocating available resources.

To ensure that headquarters staff retains its expertise in medical use, the staff has arranged for annual one-week refresher visits at a local Federal hospital that provides both diagnostic and therapy services. Both headquarters and regional staff members are encouraged to participate in the Agency rotational assignment program to develop more complete understanding of the Agency programs and procedures.

Oversight. The licensing and inspection functions are conducted by the regional offices with guidance and oversight from headquarters. With the additional staff resources provided by the Commission, the staff has increased the inspection frequency of medical use licensees. Almost all medical use licensees will be inspected at least each three years; broad scope and teletherapy licensees will be inspected annually. The staff will continue to use Notices of Violation, Civil Penalties, and Orders as appropriate.

The headquarters staff currently audits licensing actions for national uniformity, and is developing a computer program to log and sort licensing and licensing-related actions. Based on this information, the staff may identify licensee actions that should not require NRC approval, thus reducing NRC's caseload. The staff plans to develop a similar program for inspection information. Changes would probably require minor amendments to the medical use regulations.

The staff is preparing a contract for FY89 that includes a review of other required and voluntary programs that NRC may

rely on to provide adequate assurance of public health and safety in medical use of byproduct material. Reliance on such programs may provide the potential for reducing NRC's inspection caseload and targeting its resources on problem cases and initiatives with nationwide impact.

The Office for Analysis and Evaluation of Operational Data will continue to evaluate misadministration reports to look for opportunities to improve oversight and identify trends.

Information. 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: preparation and industry-wide distribution of an NMSS Licensee Newsletter that includes information about misadministrations and enforcement actions; providing background information for association newsletter articles; widening the distribution of Information Notices; participating in scientific meetings; and commenting on a nuclear pharmacy textbook chapter on radiation safety that is in preparation. Staff members in Regions I, II, III, and V are developing workshops for licensees to explain the medical use regulatory program. Each workshop has been designed to respond to medical use issues specific to the region.

The Commission's demonstration of interest in the Medical Use Program, as indicated by participation in NRC workshops and visits to licensees, has been beneficial. The upcoming regional workshops provide another opportunity for Commission participation.

Budget

The budget for the medical use program is described in Table 1.

The staff believes that this allocation of resources best meets the competing needs of coordination with other organizations, and emphasizes inspection activities.

Table 1. Resources for Medical Use Program[1]

	FY88	FY89	FY90	FY91
Program Development (HQ)	4 FTE	4 FTE $1.3 M[2]	4 FTE	4 FTE
Licensing (Regions)	10 FTE	9 FTE	9 FTE	11 FTE
Inspection (Regions)	15 FTE	23 FTE	23 FTE $2.0 M[2]	24 FTE $2.0 M[2]

[1]Staff resources do not include overhead.
[2]Technical assistance funding for improving quality assurance at medical use licensees.

Areas of Concern

The staff believes that developments in medical technology and the medical workforce pose the two most significant potential areas of concern.

Medical Technology. The staff anticipates that the key change in radiopharmaceuticals will be the development and widespread use of radiolabeled monoclonal antibodies coupled with the use of curie amounts of I-131. In sealed source therapy, there will be increased use of computerized treatment planning with the chance of unvalidated codes and human error caused by misunderstood parameter definitions and code limitations. The staff is keeping abreast of these developments by recruiting experienced medical use personnel and participating in committee work.

Workforce. It appears that the pool of trained nuclear medicine and radiation therapy technologists is becoming smaller in the face of continued need for radiation medicine workers. This may create the need for more NRC assistance in medical community training programs to help ensure continued safe medical use of byproduct material.

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

Note: The staff will continue the implementation of the Medical Use Program as discussed in this paper.

Victor Stello, Jr.
Executive Director for Operations

Enclosures:
1. Staff Requirements Memorandum dated August 4, 1988
2. Key Initiatives
3. Staff Participation in Outside Meetings
4. Other NRC Documents Related to the Medical Use Program

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ENCLOSURE 1

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

OFFICE OF THE
SECRETARY

ACTION - Thompson, NMSS

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

August 4, 1988

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

FROM: Samuel J. Chilk, Secretary

SUBJECT: SECY-88-77 - MEDICAL USE PROGRAM

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

Enclosure 1

Rec'd Off. EDO
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

KEY INITIATIVES

This enclosure provides a brief description of several staff initiatives undertaken to provide increased assurance of public health and safety in medical use.

Program Development

Price-Anderson for Radiopharmaceutical Licensees. In Section 19 of the Price-Anderson Amendments Act of 1988, Congress directed the NRC to conduct a negotiated rulemaking to determine whether to enter into indemnity agreements with persons licensed by the Commission or an Agreement State for the manufacture, production, possession, or use of radiopharmaceuticals for medical use. The staff has begun the negotiated rulemaking process. In addition to NRC, two other parties, each representing manufacturers or radiopharmacies, have identified themselves as interested. Those two parties seek indemnification because of their belief that certain radiation releases would not be covered by their existing comprehensive general liability insurance due to the attachment of nuclear and pollution exclusions to their insurance policies, and they cannot find adequate special nuclear liability insurance to fill in this gap in coverage. The NRC staff believes that these operations do not pose a significant risk to public health and safety and that a number of issues related to the legal authority of the NRC to indemnify Agreement State Licensees or to protect against releases of naturally-occurring or accelerator-produced radioactive material (NARM) need to be resolved before federal indemnification could be found to be appropriate. The convenor's report is due to the Commission in March 1989. The Office of the General Counsel is managing this project.

Basic Quality Assurance in Medical Use. In response to several misadministrations reported over the years, the Commission directed the staff to prepare a rule that would require quality assurance programs. A prescriptive rule was published for comment October 2, 1987. Widespread, adverse comment was received from the

medical community. The Commission directed the staff to prepare a performance-based rule that provides greater flexibility for licensees, a regulatory guide, and a pilot program to test the workability of the rule. The rule is due to the Commission in April, 1989. The Office of Nuclear Regulatory Research is managing this project.

Training and Experience Criteria. The staff prepared a proposed rule that would have changed NRC's training and experience criteria for physician users. In light of misadministration reports on hand, the Commission directed the staff to study training and experience criteria for all individuals who participate in medical use; this includes technologists, technicians, physicists, and dosimetrists. A contractor has been selected to study standards for training programs, accreditation and certification, and other applicable regulations. The contractor's report is due November 1989. The staff will review the report and make a recommendation to the Commission on whether training and experience criteria should be changed. The Office of Nuclear Material Safety and Safeguards is managing this project.

Inter-Organization Cooperation

Food and Drug Administration (FDA). The FDA regulates the safety and effectiveness of pharmaceuticals, biologics and medical devices in interstate commerce. The staff has established contacts in key areas of mutual interest. Requests for clarification and technical assistance have been shared, and each agency has notified the other of events that may be of enforcement interest. Training seminars on each agency's statutory authority and regulatory program are being planned.

Veteran's Administration (VA). The staff has identified the Veteran's Administration system of medical centers as a large organization that provides, as Commissioner Rogers noted (Enclosure 1, page 2) an opportunity for "achieving greater leverage in Program Implementation." Division-level staff met with their counterparts last April to discuss NRC's heightened interest in Medical Use. Last May, the staff provided a one-day seminar on NRC's regulatory program at a national meeting of VA safety staff.

Society of Nuclear Medicine (SNM). Last July, the staff met with the president-elect of the Society of Nuclear Medicine (SNM) to discuss NRC's role in regulating the medical use of byproduct material, mechanisms for improving medical use, and continuing education. SNM demonstrated interest in having NRC assistance in the design and implementation of its education programs. Further informal discussions are planned. The staff will participate in committee work and programs as requested.

Staff Development

Increased Resources. The FY89 budget included an increase of eight FTE in the regions for medical program improvements. Each region was authorized to recruit one medical program specialist. This initiative was taken to emphasize the agency's commitment to improve the medical use program. The remaining three vacancies were filled by re-allocation of existing resources.

Continuing Education. Continuing education for materials staff is part of an NMSS office-wide initiative to identify and fulfill training needs. In addition to general courses on radiation science, licensing and inspection methods, and radiation safety methodology, the office has developed courses for NRC staff on the medical use of radiation to ensure that staff is able to properly apply NRC regulations in the medical setting.

Oversight

Performance Evaluation Factors. The staff has developed a draft set of performance evaluation factors that are specific to the medical use of byproduct material. Data will be collected during regular, unannounced compliance inspections. The staff will correlate the data with misadministration reports and compliance inspection citations to determine which factors can be used to identify licensees with increased potential for problems.

Information

Topical Reports. The two primary vehicles the staff is using to get safety information to licensees are NRC Information Notices and providing speakers at

regional and national meetings. See Enclosure 3 for a listing of specific presentations.

Continuing Education. The Society of Nuclear Medicine (SNM) has asked the staff to provide technical assistance in developing materials for a one-day safety course that individual licensees could provide at in-house, regional, and national meetings. SNM would develop the lecture notes and handouts with NRC assistance, and update them regularly.

Document Name:
ANNUAL RPT MED USE ENCL 2

Requestor's ID:
DEKLE

Author's Name:
McElRoy

Document Comments:
WFN 12/22/88 - ECS revisions

ENCLOSURE 3

STAFF PARTICIPATION IN OUTSIDE MEETINGS

The staff has made presentations about the medical use program at the following meetings this calendar year:

- Agreement State Training Workshop, December 1988.
- Mid-Eastern Chapter (Technologist Section), Society of Nuclear Medicine, November 1988.
- Army Industrial Hygiene Annual Meeting, October 1988.
- Ohio Radioactive Material Users Groups, Inc., October 1988.
- Health Physics Society, July 1988.
- Society of Nuclear Medicine, June 1988.
- American College of Medical Physics, June 1988.
- Conference of Radiation Control Program Directors, May 1988.
- Delaware Valley American Association of Physicists in Medicine/Health Physics Society joint meeting, May 1988.
- National meeting of Veterans Administration safety staff, May 1988.
- Greater New York Chapter of the Society of Nuclear Medicine, March 1988.
- Cleveland Area Medical Physics Society, February 1988.
- Christiana Hospital Continuing Education Program, January 1988.
- Central Pennsylvania Chapter, Society of Nuclear Medicine, January 1988.

Enclosure 3

ENCLOSURE 4

OTHER NRC DOCUMENTS RELATED TO THE MEDICAL USE PROGRAM

Federal Register Notices

44 FR 8242, "Regulation of the Medical Uses 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.

Staff Papers

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