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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 20, 1990

The Commission met in open session, pursuant to notice, at 2:00 p.m., Kenneth M. Carr, Chairman, presiding.

COMMISSIONERS PRESENT:

KENNETH M. CARR, Chairman of the Commission
THOMAS M. ROBERTS, Commissioner
KENNETH C. ROGERS, Commissioner
JAMES R. CURTISS, Commissioner

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STAFF SEATED AT THE COMMISSION TABLE:

SAMUEL J. CHILK, Secretary

WILLIAM C. PARLER, General Counsel

JAMES TAYLOR, Executive Director for Operations

ROBERT BERNERO, Director of Operations, NMSS

NORMAN McELROY, Section Leader, Medical and Academic Section, IMAB/NMSS

VANDY MILLER, A/D for State Agreements Program, GPA

JOHN GLENN, Chief, Medical and Commercial Use Safety Branch, IMAB/NMSS

JAMES MYERS, IMAB/NMSS

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

2:00 p.m.

CHAIRMAN CARR: Good afternoon, ladies and gentlemen.

This is the NRC staff's annual briefing to 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 of byproduct material. With more than 7,000 licensees performing over 7 million clinical procedures a year, the medical use area is one of the largest programs for radioactive material U.S. regulated by NRC and the agreement states.

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.

Commissioner Remick will not be with us today. He's on travel.

Do any of my fellow Commissioners have any opening comments?

If not, Mr. Taylor, please proceed.

MR. TAYLOR: Good afternoon, sir. With me at the table from the Office of NMSS, to my left, Mr.

Jim Myers, John Glenn, Bob Bernero, the Office Director, Norm McElroy, who I think you know, and Vandy Miller from the Office of State Programs.

The briefing today will discuss principally the implementation of a five point program which the staff previously submitted to the Commission in SECY-88-77 and will cover how the staff is trying to improve its oversight of the medical uses of byproduct material. We'll cover some special interest topics in that area and we'll briefly give you an overview in the staffing and budget allocations currently for that program.

With that introduction, I'll ask Mr. Glenn to proceed.

DOCTOR GLENN: Okay. Thank you very much.

(Slide) If I could have the first slide, please.

There's four topics that I want to cover today. The first one is just to briefly characterize or recharacterize the medical use industry. The second is to cover the medical use program, the five points that we initiated in our paper in 1988. Then some areas of concern in medical use. In some of these cases, we anticipate problems and I guess in some there are some opportunities. And then finally

the program resources will be the last topic that we discuss.

(Slide) The next slide, please.

Just a quick few comments on the industry just to remind you of some of the characteristics as has already been mentioned. There's seven million diagnostic procedures a year and around 150,000 therapy. I guess one point I would like to make, of course, is that the data we have in the medical program is relatively soft compared to what maybe you're used to in the reactor program. This is data that's inferred from various sources, articles, manuscripts and so forth. We don't have a hard count, of course, of how many procedures are actually performed each year.

Another point, I guess, is that we're regulating only a small part of the medical industry. There are over 100 million admissions into a hospital per year and certainly major areas of a hospital are not subject to our regulation.

There are approximately 2,200 hospitals that have NRC licensees as well as 400 private practices. Now, these numbers are hard because they come from our license management system database. As a rule of thumb, there are usually -- we usually can count on

there being about twice as many agreement state licensees as NRC licensees in this particular area. So, around 7,000 total medical licensees in the United States.

(Slide) The next slide, please.

This slide shows some data on misadministrations that have been reported to the NRC over the last four years. I'm not going to go into a lot of detail because on April 9th, AEOD will be giving a briefing to the Commission and we'll go into some of these findings in much more depth.

One thing I want to caution is not to make major assumptions based on the data that's shown here. There may appear to be trends, but they may not be real trends. One point to note is that in calendar year '87 there was a change in the reporting requirements for diagnostic misadministrations. So, what had to be reported changed just a little bit at that point, so there is a discontinuity in the data at that point.

COMMISSIONER ROGERS: Would that affect the -- might affect the '87, '88 numbers, comparative numbers or when did that go into effect?

DOCTOR GLENN: It actually went into effect in April of '87. So, it would have affected -- '86

would have been totally under the old system, '87 is a mixed year and then '88 and '89 would be under the new reporting requirements. In '89, although the year is finished, we probably don't have all the data in to AEOD at this point. So, that number will probably increase.

Now, if you notice, we broke it out into three categories, diagnostic, iodine 131 and therapy. They're not reported in that fashion. They're reported either as diagnostic or therapy. It did break out the iodine 131 as being of interest because although some of those misadministrations are diagnostic, because iodine is involved and a small amount of iodine going to the thyroid results in a very large dose, we're more concerned about those misadministrations than other diagnostic misadministrations.

Because of the way we've broken it out, the iodine misadministrations are being double counted here. So, they would appear either as diagnostic or therapy as well as being in the iodine 131 column.

We're also particularly interested in iodine because, as we'll discuss later, some of the new technologies involve the use of iodine and so we may be seeing more problems there if we don't get a good

grip on it.

(Slide) The next slide.

Just briefly, these are the five points in the medical use program and we will be discussing each one of these five points.

(Slide) If I could have the next slide.

The first area we're discussing is program development. There has been a fair amount of activity in this area, rulemaking, contracts to gather information, characterize what's going on in the industry a little bit better and some other initiatives that we've begun. I think certainly one of the major areas that has been involving the time of the medical staff has been the QA rule and the regulatory guide.

Certainly in the near future, a major activity for the staff is going to be the implementation of the pilot program. Over the period of from about April to August, we're hoping to see whether licensees can implement the program as published in the proposed rule and the regulatory guide and the staff will actually be making site visits to about 18 different institutions who will be implementing this rule.

At the same time, for about eight months,

the staff has been asking questions about quality assurance programs as they currently exist at medical licensees, that questionnaire. The data is being gathered. It has not been analyzed yet. That's another initiative we have in order to understand the QA program.

One area that we're particularly interested in and at least beginning to look at is human factors since human error is a major contributor to misadministrations. Very rarely is it caused by equipment or other kinds of failure, but usually by human failure.

We're starting to look into human factors. We don't know yet what the payoff will be, but we are letting initial contracts in the areas of human factors as applied to teletherapy, remote brachytherapy and computer planning of treatments. So, we'll be doing initial studies in those three areas. We'll see what we get and whether to proceed further and faster in those particular areas.

(Slide) Now, the next slide, please.

The second area that we were interested in emphasizing in our five point program was inter-organizational cooperation. There are quite a few federal agencies and professional, scientific and

other kinds of professional organizations that we have been interacting with. There are no particular issues to raise in this area. We feel that we have gotten excellent cooperation from those institutions that we've been dealing with and we feel that the interactions have been quite useful to us.

(Slide) The next slide, please.

CHAIRMAN CARR: I think you're running one slide behind on the screen.

DOCTOR GLENN: Could I see the slide that's there now?

MR. McELROY: No, it's the next slide.

DOCTOR GLENN: The next slide.

MR. McELROY: And the next.

DOCTOR GLENN: The next slide. There. Okay. Thank you.

The next area was staff development and as an immediate result of the beginning the program in FY'88, the regions were authorized to each go out and hire an additional inspector to add to the staff provided that person did have medical experience. We have continued as those people leave and we replace staff, to make sure that we're hiring people who do have experience in the medical area who will be able to understand the issues and help us improve our

regulation of the medical program.

During '89, we added people who had backgrounds in dosimetry, therapy dosimetry, nuclear medicine technology and health physics consulting at medical institutions. So we're continuing to make sure that the people we hire to work in the medical program do have that kind of background.

CHAIRMAN CARR: How big a group is out there to hire from?

DOCTOR GLENN: It depends upon the specialty we're looking at. Certainly with nuclear medicine technology, it's a rather large group and it's limited mainly by the educational background of the people who are in that area. We would also, of course, like to get medical physicists and people like that. We're limited there quite a bit by what we can offer in terms of salary. Dosimetry, it's a matter of -- it's a much smaller group to recruit from and we have to look a little bit harder to find those kind of people.

COMMISSIONER ROGERS: What are the professional credentials or academic credentials, say, of the people that you've been able to hire recently?

DOCTOR GLENN: This year?

COMMISSIONER ROGERS: Roughly.

DOCTOR GLENN: I think for the three that I

mentioned, I think it's one bachelors degree and two masters degrees. Now, we do have Ph.D.s in the medical program as well. So, we hire from a mixture of experiences and academic backgrounds.

One thing, of course, that we try to do is to keep our own people's skills up. One thing that AEOD was able to do for us this year was to modify the teletherapy and nuclear medicine courses that are offered through the technical training center. They're not actually offered at Chattanooga, but are contracted through the technical training center. We've had good reports on those courses.

For headquarters people, we have arranged for them to spend some time at local hospitals and refresh their memory and their skills in terms of what's going on in the hospitals.

In addition, we've had rotations between headquarters and the regions in letting our people get experience on the front line and certainly here in headquarters. We've had people come in and act and --

MR. BERNERO: I might add, Doctor Glenn is a veteran of the front lines. We brought him up here last year.

DOCTOR GLENN: Okay. Another thing we've

done recently is to turn over the membership a little bit in the ACMUI. Those letters have just gone out, and just mention that we do use the ACMUI in somewhat analogous fashion to the ACRS, as a technical group of experts who can advise us on the issues that come before us.

In a separate Commission paper, we're sending up to you a list of alternatives for a visiting fellows program. The idea would be to bring outside expertise into the Commission to make it available to the staff as a part of this visiting fellows program.

(Slide) If we could have the next slide, please.

Having been out in the field and on the firing line, I think certainly an important aspect of our medical program is the oversight function that we exercise both in terms of here in headquarters, tracking trends, looking at -- reviewing enforcement cases, looking at the licensing statistics and the misadministration reports. But a big emphasis since '88 has been to increase our presence at medical institutions. As a result, in 1989, the inspection frequencies for the larger types of medical institutions were increased. I think you can notice

here in terms of the statistics that there was a large jump in the number of medical inspections that were performed between '88 and '89.

So, we have seen the effects of that change in our priorities and I think particularly I'm pleased that these increased inspections have occurred in the area of teletherapy and our larger research and medical licensees, the broad scope programs, where they do medical research, as well as ordinary diagnostic and therapy procedures.

COMMISSIONER ROGERS: On those inspections, from '88 to '89 you nearly doubled the number of inspections. How did you do that? How could you do that so quickly in terms of manpower availability?

DOCTOR GLENN: Okay. Well, we did bring on -- we started recruiting, I guess, in the summer of '88. So, by the time we got into FY'89, we already had a fair number of these people on board. So, we were able to, by the end of '89, really see those extra people being out there and --

COMMISSIONER ROGERS: How many additional people did you add?

DOCTOR GLENN: Basically five people.

COMMISSIONER ROGERS: Five? To what -- how large a base of people were doing inspections?

DOCTOR GLENN: We'll be getting to that in a later slide. So, if we can delay that one just a little bit.

MR. BERNERO: A dozen and a half or so.

DOCTOR GLENN: (Slide) Okay. The next slide, please.

The fourth area of the five point plan was to make sure that we were communicating more often, having more information exchange with licensees and professional groups. During '89, we were very active, I think, compared to what we had been in the past. There were 31 presentations to professional groups. Approximately 50 percent of those were given by headquarters staff and 50 percent by regional staff.

In addition, the regions presented 15 workshops. These workshops varied from large two day groups to in one region they offered a series of half day workshops, mainly for medical technologists, to train them essentially in what was in the regulations and what were the most common kinds of noncompliance that we were seeing.

I think for some of the bigger workshops, particularly note that participation by some of the Commissioners and by senior staff I think heightened the interest and improved the attendance. So, we had

a very good response for these workshops.

COMMISSIONER ROGERS: What were these professional groups? How many different ones were there, just to get a feeling about what --

DOCTOR GLENN: Well, they varied from the Society of Nuclear Medicine --

(Slide) Maybe if we could have slide 7.3, that will give us some of the listing of some of the groups that we've been interacting with, such as the American Association of Physicists in Medicine.

Oops.

COMMISSIONER ROGERS: Interesting, but wrong slide.

DOCTOR GLENN: Okay. We'll skip 7.3.

The American College of Medical Physicists, the American College of Radiology, Society of Nuclear Medicine, American College of Nuclear Physicians, the American Society of Radiation Oncologists and the College of American Pathologists. There were other smaller groups I think that we also made presentations to.

COMMISSIONER ROGERS: I'm just interested to see how these things worked. Were these regionally presented or they were all in this area? I mean how did --

DOCTOR GLENN: Oh, they were pretty much across the country. Certainly the workshops were regionally based and the presentations tended to be wherever the societies or groups were having their national meetings and so forth.

COMMISSIONER ROGERS: I see. Okay. Good.

DOCTOR GLENN: They're actually quite interested in having us make presentations at their national meetings. So, we usually don't have to try too hard to get on the schedule.

In addition to meetings and workshops, we continued to communicate through our NMSS newsletter, keeping licensees informed of significant enforcement actions, rule changes that were taking place and other special topics as they came up through the year.

Another thing to note is that professional groups and association newsletters quite often use our press releases of significant enforcement actions, put those in their own journals so that the word gets spread a little more quickly and a little more widely than perhaps through our own organ. So, there is interest out there in terms of what we're doing and the word is getting out.

(Slide) The next slide. The next slide, please.

As I mentioned before, there are some areas of concern or opportunity or problems, whatever, that are coming up in the area of nuclear medicine. One thing is that it's a growing technology and apparently with a shrinking work force. We're told that it's hard to recruit people to work in this field, that the turnover is high. And so with more demands and fewer people to do it, it's obviously an area that we have to keep our eyes on and see if there's anything that we have to do in order to maintain the quality that already exists as well as improving it.

We're also told that the current efforts to maintain costs as low as reasonably achievable work against improvements in terms of quality of programs at medical institutions. This is another area where we're trying to learn more, keep our eyes open and see if there is an interaction that we have to be aware of in terms of our regulatory program.

And finally, there are new developments in medical technology. One that's been just around the corner for several years now, and I guess has not fully realized its potential and we're not sure when it will, is the use of things called monoclonal antibodies where you use the antigen antibody reaction to aim magic bullets, so to speak, at tumors within

the body.

So far, the success has been more in the diagnostic area. You are able to label these antibodies and get them to the cancer sites, but to get the kind of ratio you want in order to be effective in therapy and have it be effective before -- sometimes there's some reactions to the mouse serum. It's a mouse antigen that's being used. They have not been fully successful in that area. However, it's one of those things that if the technology is perfected, we could see a large increase in the use of iodine 131, in curie quantities in hospitals and it would have a major impact.

So, we do have studies going on and I'll just mention that one of the people we didn't bring on last year but who we hope to bring on this year, we've made an offer, is a person who has been doing research in the monoclonal antibody area.

(Slide) Another new technology is high-dose-rate brachytherapy. If we could have the first of the 35 millimeter slides.

What you see on the left of the screen is a device that is -- the device that transfers the sources from a shielded position into the treatment area. This particular device has 18 tubes associated

with it and you can run a source into any one of those 18 tubes and it can be stepped through 48 different positions within those tubes. Now, the sources that are being used here are much larger than the sources that are usually -- have in the past been used for brachytherapy for implanting into tumors. Rather than being ten to 20 millicuries, we're talking about up to a ten curie iridium 192 source. That means that you can cut the amount of time that the patient has to be irradiated significantly.

So, in this particular treatment, each one of those tubes, the source can be run automatically and remotely in and out of the tube, stepped through a programmed set of positions and treat the whole area on the leg that is the site for the treatment.

This means that brachytherapy can now be done on an outpatient basis. So it expands the potential number of patients who will use brachytherapy as a treatment mode, whereas hospitals that are doing it only implants using the small sources, are doing maybe one or two of these a week. I've been along on inspections where I was told that they were doing 300 to 400 patients with this kind of technology because it can now be used on an outpatient basis as an adjunct to teletherapy. So, it's

technology that has a lot of promise.

There are some problems. Obviously, you're using computers, you have a source that has to move very precisely to within one millimeter. It has to move a lot of times and so we're watching this very carefully. We have had a couple of misadministrations caused by computer programming not being done quite right and so forth. So, it's a promising technology but one that needs some attention paid to it.

COMMISSIONER ROGERS: In this particular one, is it just one source that's moved between these or are there multiple sources?

MR. MYERS: One source.

DOCTOR GLENN: One source and it can be moved into each one of the 18 tubes and then positioned by the computer.

MR. MYERS: If I may, the analogy to this is like a field radiography unit except this is more like a Gattling gun approach where there's multiple lumens or barrels. The source extends out into one, irradiates, retracts and it cocks over to the next channel and then goes out. So, there's several. It can run anywhere from a single time to up to 18 times and there's a total of 864 positions between the 18 channels that it can actually reside in. It's very

sophisticated. The big savings here is one of outpatient care. Obviously, you don't have to hospitalize the patient in some cases.

MR. BERNERO: But you see the complexity of it, the increased intensity of the source. In order to get the power to be able to use this on an outpatient basis, there's a price to pay and that's the complexity and intensity.

DOCTOR GLENN: Okay. The next technology I want to discuss is -- this is sort of the upgrade of brachytherapy into the next century. The next device sort of takes teletherapy to its next logical step.

(Slide) If we could have the second 35 millimeter slide.

This kind of therapy is called stereotactic therapy. The particular device that you're looking at there is called the gamma knife. The gamma knife is used exclusively to treat brain tumors and lesions and you can see that on the patient on the table there that there is this helmet-like thing around the head. The helmet is a very important part of the treatment. Based on x-rays and CAT scans and so forth, the helmet is very carefully positioned on the person's head and then the table that the patient is lying on moves back into that large spherical object in the back and then

the helmet and the device mate in such a way that the person's head is at exactly the right position for the treatment to take place.

Now, this is different from teletherapy in that a teletherapy source you have one large source and you vary the angles and the distances and the size of the fields that you use to treat the person. This device has 201 sources. The next slide will help us see the advantage of that. One of the problems, of course, that you have with 201 sources is that a source exchanges, getting the radioactive material into the device becomes much more complicated. So, quite often they have to build a temporary hot cell at the facility in order to get the sources into the device.

(Slide) If we could have the third 35 millimeter slide.

This is a schematic trying to show what happens with the gamma knife. Imagine the rays of light or the radiation coming through the helmet and from the device, each individual source columnated so you have a pencil-thin beam. And what you notice is that they all come together and cross at one point there towards the bottom. Now, what this means is that on the outside of the head there's very little

radiation being received by healthy tissue. But when you get to the point where all those lines cross, you have 201 radiation beams added together and you get an extremely high radiation field over a very small volume. The volume can be controlled to an accuracy of about plus or minus a millimeter and with a size of the order of millimeters or, at most, centimeters.

It's called the gamma knife because it can be used in lieu of brain surgery. In effect, brain surgery is extremely dangerous, especially certain sites within the brain where it's very hard to get to it. You can deliver a massive enough dose to the tumor to eradicate it, just wipe it out totally, without doing much damage to surrounding tissue. So, it has the precision of a scalpel without a lot of the risks of the scalpel. So, it's a technology again that has a lot of promise. You pay for it in the complexity of loading it up and also it's a rather complex device to use in terms of the preparation of the patient because getting that spot correctly irradiated is tricky.

So, again, complexity and paying a price in terms of the number of sources that have to be jumped is the price you pay for this new technology.

COMMISSIONER CURTISS: Just out of

curiosity, what sort of regulatory review and approval does a new device like this go under?

DOCTOR GLENN: Okay.

COMMISSIONER CURTISS: I take it we're not involved in that, but I'm assuming --

DOCTOR GLENN: Well, we have a role. We do a safety review of the device. But FDA is the one in terms of its medical approval, is in charge of that.

Now, I guess -- one thing I'll mention is that both of the devices that I've discussed here are coming from outside the country. These technologies are coming from Europe currently. So, by the time they get over here, they've been tried out and they have some experience with them. But FDA has the lead role in terms of --

CHAIRMAN CARR: Do we license the 201 sources?

DOCTOR GLENN: Yes, but I guess we don't list them individually on the license or --

MR. BERNERO: We or a state, of course.

DOCTOR GLENN: Yes. Okay. There are currently six of these gamma knife devices installed in the United States and I guess the first one was about five years ago. People are beginning to see how successful they can work, so we expect to see more.

COMMISSIONER ROGERS: Are those sources individually monitored in some way for a period of time unless they were all produced exactly at the same time or something or the same -- very carefully control the amounts of radioactivity? How are they monitored, say, ten years after use? Would there be any drift in how -- what the strength of the individual sources is or not?

DOCTOR GLENN: Actually, that is a problem in terms of how you calibrate this unit. With a one source teletherapy unit, it's relatively simple. Here, of course, you can put a chamber at the point where you expect it to be and see that you're getting the right total dose. White tests, again, are a problem too. So, there is some complexity here. Exactly now they monitor each individual source, I'm not sure. You wouldn't expect, of course, much change to take place, but you do need to worry about the alignment. So, I think that's something that they would check more frequently.

COMMISSIONER CURTISS: To get back to the regulatory review question for a minute, could you expand upon what the relationship is of our review to FDA's, what precisely we look at and how that relates to what FDA looks at?

DOCTOR GLENN: Okay. We look at the device in terms of the shielding that's available with the levels at a certain distance from the outside of the device to be safe for the people who are working in the room. Is the device engineered in such a way that it's not likely that the source could be exposed or the source come out? Are the tolerances correct for the fitting together of the sources and the receptacle within the device? So, our people look at those kinds of things, basically radiation safety associated with use of a device.

FDA is going to look at is the use of this device appropriate from a medical point of view? Does this device -- is it safe to use with humans? Does it benefit humans? Is it effective? So, they're looking at medical safety and efficacy rather than radiation safety and device safety the way we are.

COMMISSIONER CURTISS: Okay.

DOCTOR GLENN: I guess we worry about the-- in terms of transportation, the device may be a transportation container itself. We would be the ones who would be responsible for reviewing that.

(Slide) Okay. The next slide, and this is the final slide, shows the resources that have been allocated or that are being proposed for the medical

program in the next couple of years.

We had a large increase, as I mentioned before, in 1988, increase of five over '89. And '90, we're staying pretty much level. We do anticipate a need for more resources in the medical program, particularly in the inspection and event evaluation area in the regions. That growth is in some measure due to the implementation of the QA Rule.

Also, we have $2 million programmed into FY'91. Most of that $2 million would be used to perform on-site reviews of medical quality assurance programs as the rule becomes effective.

MR. BERNERO: And, of course, the FY'92 resources are simply projected resources you see on that table. You can see we are realizing this increased oversight and we're expecting the QA rule to come in and be picked up there.

DOCTOR GLENN: Now, there's some fluctuation in licensing and so forth. I wouldn't pay too much attention, but these are rounded off numbers and the staff required for licensing fluctuates somewhat based on the number of renewals that are expected to become due each year. So, there's some fluctuation just there. It's not a major programmatic choice that says 8-9-8 there.

COMMISSIONER ROGERS: Just coming back to my earlier question about how big the base was in which you added five, to get some feeling about how big the inspection capability -- how large an increase there was in that, you doubled the number of inspections essentially in one year. You're adding about roughly a third more people. What else happened to allow you to do that many more inspections? Did you have to cut back on something else that you were doing to do that?

DOCTOR GLENN: To the best of my knowledge, we didn't. I have to admit, I was a little surprised at how big the jump was myself. I think it may have been because we were putting particular attention and focus on this that people made sure that the medical inspections got done and that --

MR. BERNERO: There's a hidden loss that we got out of the way in here. Hugh Thompson rightly points out in '88 we had the static eliminator exercise that took a great deal of the resources --

COMMISSIONER ROGERS: I see.

MR. BERNERO: -- away from other programs. We had very severe impact, especially in the two regions, I and III, Region I and Region III, which have a large number of licensees. So, you aren't paying that in this time period. You aren't paying

that hidden tax.

COMMISSIONER CURTISS: I'm curious on the resources. Are we seeing a similar kind of trend in the agreement states that have these programs and would we expect the same kind of wrapping up in resources there for the QA rule? What's happening there?

MR. MILLER: I don't think so at the moment. I think primarily here in the regions is a matter of training, get the proper type of people to do the job. That's where they seem to have more of the problem. They haven't seemed to have many problems yet on a short staff. It's a matter of getting the qualified people. That seems to be their problem.

Now, the gamma knife that you just saw up there, for an example, we had our special topics workshop back in December in Chicago. It was an agreement state that demonstrated how to do the licensing for that device. They took us downtown. They showed us the device being used and there was very good training for the regions and for the other agreement states. But we find though that we're just going to have to do something to get more people trained for the agreement states in these high tech areas that you just had discussed before you.

CHAIRMAN CARR: Well, I read you as saying the agreement states do a better job in inspecting their hospitals than we do probably.

MR. MILLER: Well --

MR. TAYLOR: Did you say that?

CHAIRMAN CARR: Is that not what you said?

MR. MILLER: No, I did not say that.

CHAIRMAN CARR: Well, maybe you'd better say it again.

MR. MILLER: At some time ago, we showed you on a document, on a memo, that we were pretty much ahead of the NRC and the agreement states as far as how often we do inspections. So, they've been doing more inspections on a lot of these program areas. But now I would say they're pretty much par, you know. In other words, the NRC has picked up doing more frequency inspections and some of the states were already doing those kind --

COMMISSIONER CURTISS: So we're catching up with them? Is that what you're saying?

MR. MILLER: Yes, that's correct.

MR. BERNERO: Yes. But I think it would be fair to say that as we see a pulse of activity associated with the QA rule out in the field, that the agreement states will see pretty much the same thing.

COMMISSIONER CURTISS: Sure.

COMMISSIONER ROGERS: Yes.

MR. BERNERO: And so, it's a forecast right now of what we would expect to see. I think the agreement states will see it just as we do and I hope with equally good effect.

Just one other thing on the resource. I'd just like to remind you, this program, the medical program tends to be a very asymmetric one. As you know, we were just discussing the agreement states are very heavily into it with a lot more licensees than we have. And our regional distribution varies according to the number of regional agreement states, to the extent that we have a lot of medical program activity in some regions and very little in others. And so it's very asymmetric.

MR. TAYLOR: That concludes the presentations.

CHAIRMAN CARR: Questions, Commissioner Roberts?

COMMISSIONER ROBERTS: No.

CHAIRMAN CARR: Commissioner Rogers?

COMMISSIONER ROGERS: Yes, a couple. On chart 4, if we could go back to that, I see that the I-131 misadministrations account for most -- well,

certainly more than half of the therapy misadministrations that you're counting in both diagnostic and therapy, apparently. Is there any targeted program that one might address there for I-131 use.

DOCTOR GLENN: I think one thing you might notice, if you look at the QA rule as it was published, is that it does treat therapy and iodine on an equal footing, whether it's iodine for diagnostic or iodine for therapy.

Certainly, we're trying to sensitize the medical community to the problems we've been seeing with iodine, and in these workshops that was one of the items that was stressed, that we were seeing problems in this area.

COMMISSIONER ROGERS: How many of these misadministrations do you think were truly significant?

DOCTOR GLENN: I would say I think most of the iodine 131 and therapy are significant. I guess, there may have been an example where the iodine was given to someone who didn't have a thyroid or something like that, but that would only be one or two. And all the rest of them, when you're talking thousands of rads to the thyroid, you're talking about

potential loss of function at least, whether it is more serious than that.

COMMISSIONER ROGERS: What about the diagnostic use, do you think you could make a comment on those?

DOCTOR GLENN: I would say probably in none of them, except the ones that involved iodine, was there any kind of an immediate health effect such as loss of function of an organ, death, or something of that nature, that we're talking here really in the same realm as we're talking about for occupational safety. We're talking about increased risk of cancer induction at a later time. So we're out of the realm of direct harm into the area of risk.

MR. BERNERO: I think it's worth noting, generally in diagnostic procedures you're talking about exposures of the order of a couple of hundred millirem, whereas when you get into therapy -- or for instance, there's one that comes to mind. Instead of was it 1,000 microcuries of I-131, the patient got 1,000 millicuries. And it ablated the thyroid. And that's a pretty significant safety impact on the patient.

Therapy patients are sick people. They're undergoing radiation therapy because they've got

severe tumors or something. But nevertheless, it's fairly significant if you hit the wrong organ or miss the mark either too high or too low in the dose that's prescribed.

MR. TAYLOR: Some of the diagnostics are relatively benign.

MR. BERNERO: Yes, they're fairly mild. It's undesirable. It's unnecessary radiation exposure to do a brain scan when really you're trying to do a kidney scan or something, but it's not the sort of thing that you could put in a class of heavy safety significance.

COMMISSIONER CURTISS: I was actually intrigued by that same question, because I've seen the chart before and the statistics are kind of a funny thing. The frequency here looks fairly low, but if you take, for example, the reports that we send out to Congress, if you measure significance by whether it's an abnormal occurrence, it looks like we've had about a dozen of those a year. And then if you take a look at the percentage of AOs that are medical in the context of the whole, it looks like about a third to over a half of the AOs that we report come from the medical community.

So I guess I'd be interested when you use

this chart to have a comparison that elicits that fact, the significant ones that we report to Congress. If that's a measure of Commissioner Roger's question of significance, there ought to be a column on here that says one-third to one-half of those for any given year actually are medical misadministrations in the context of the way we --

MR. BERNERO: Abnormal occurrences.

COMMISSIONER CURTISS: That's right.

MR. BERNERO: Again, a word of caution. The frequency is always a difficult number for us to get, because the denominator of the equation is a very, very crude estimate. We don't have accurate data on how many procedures or patients.

CHAIRMAN CARR: Well, when did we start requiring all of them to be reported to us? Always?

MR. McELROY: All what reported to us?

MR. MILLER: The agreement states.

CHAIRMAN CARR: Misadministrations.

MR. McELROY: In about 1981.

CHAIRMAN CARR: So as of now, we know all the ones in the agreement states as well as the ones we license?

MR. McELROY: No.

CHAIRMAN CARR: We don't. This number

excludes agreement states?

COMMISSIONER CURTISS: That's correct, sir.

CHAIRMAN CARR: That's the point I thought we ought to make.

MR. BERNERO: But even for us, we don't know the denominator. And for them, we don't know the denominator.

CHAIRMAN CARR: Well, but they license twice as many as we do.

MR. BERNERO: Yes. That itself is a rough estimate. See, the number of procedures per year in which a patient receives radiation therapy or radiation diagnosis, that number is unknown. It's just estimated from a variety of sources, about the approximate level of such activity in the United States.

COMMISSIONER CURTISS: That's what I thought.

MR. BERNERO: It's pretty hard to be accurate on that.

CHAIRMAN CARR: Give or take 100,000 in 7 million.

MR. BERNERO: Give or take maybe a couple of million.

DOCTOR GLENN: In fact, I think a few years

ago we thought the right number was ten million.

MR. BERNERO: Yes. We used to use a number closer to ten million.

CHAIRMAN CARR: Well, are the agreement states now telling us when -- are we getting a tally on those?

MR. MILLER: I was just getting ready to address that, sir. The compatibility regulation for the agreement states become effective 1 April.

CHAIRMAN CARR: Of this year?

MR. MILLER: But this does not mean, though, that some of the agreement states have not been reporting all ready.

CHAIRMAN CARR: No, I understand. But they weren't required to?

MR. MILLER: They won't be required until 1 April. That's when it becomes the compatibility regulation of this year.

CHAIRMAN CARR: Excuse me, Ken.

COMMISSIONER ROGERS: That's okay, no, fine. They're all good questions. Interesting to hear the answers.

Still, I'd like to turn to chart 6 for a couple questions there. Could you say something about the pilot program? I didn't hear anything much about

that. Have you received any response to our request for voluntary participation yet?

DOCTOR GLENN: Does Research want to answer that?

DOCTOR BAHADUR: Mr. Chairman, I'm Sher Bahadur. I'm the Branch Chief of Laboratory Development Branch, and it's under my branch that we are developing the QLU. The pilot program is also under our responsibility.

What we did was we have sent some letters to the NRC licensees and also to the state program, agreement state licensees. The first week of January, we sent about 72 letters. About 24 invitations were sent to -- let me just see -- to the NRC licensees, and 48 to the agreement state licensees. We got 12 responses from the NRC licensees and 16 from the agreement states.

What we did was at that time we moved to the second round of invitations, and we again sent 24 invitations to the NRC, this time different licensees, and 48 to the agreement state licensees. To date, we have got the positive response from 22 NRC licensees and -- yes, sir -- and 38 from the agreement state licensees.

CHAIRMAN CARR: That's totals?

DOCTOR BAHADUR: That's total to date. Our goal has been to get --

COMMISSIONER ROGERS: Oh, this is totals. I see.

DOCTOR BAHADUR: -- 24 from NRC and 48 from the agreement states.

So what we have done is we have moved to the third stage of invitations. As you see, our success rate has been more like one in three. So we have sent 30 additional letters to the agreement state licensees, hoping that about ten would be -- so by March 9th, we are hoping to put a cap on this process, and at that time hoping that 24 NRC licensees and 48 agreement state licensees would have volunteered.

CHAIRMAN CARR: Thank you.

COMMISSIONER ROGERS: It looks pretty promising, though, so far, doesn't it?

DOCTOR BAHADUR: It is going on a very great success rate, and we have all the hopes that it will be a good program.

COMMISSIONER ROGERS: Do you have any feeling about the results of the contract study on training and experience criteria so far?

DOCTOR GLENN: It's really too -- we just had that a couple of weeks and --

COMMISSIONER ROGERS: I see.

DOCTOR GLENN: -- we're just reading it, so --

COMMISSIONER ROGERS: Okay. Too early on that.

Have you got anything from the QA questionnaires that looks at all to you as important with respect to a decreased need for a QA rule?

DOCTOR GLENN: We really haven't analyzed it yet.

COMMISSIONER ROGERS: We've heard a great deal of -- many responses, negative responses, but is there something in there that gives us a significant basis for reviewing this need?

DOCTOR GLENN: Okay. The actual analysis of that is being folded into another QA contract.

I don't know. Have we done any sort of informal --

MR. MYERS: Sir, in just looking at these as they come in, in a very superficial way, I don't see anything there that's remarkable one way or the other. The form is very complex. Some of the narrative will take a little while to interpret, and then to somehow collate the narratives into something meaningful. And just, like I say, on a superficial basis, I don't see

anything remarkable in one -- positive or negative, whether or not, you know, a QA is needed or not.

It appears that almost all of the responses do seem to indicate some type of QA awareness and, in fact, some types of QA programs. That's about the only thing I could say. I haven't seen anyone that I know of who comes back and says, "This fellow doesn't have anything." They all seem to have something. But what that all means, I think it's just far too early to say.

DOCTOR GLENN: Yes. And I guess I would just mention that's not really surprising to us that they all have some kind of QA program, because the Joint Commission on the Accreditation of Hospitals has required for several years that they be developing QA programs.

MR. MYERS: And many of them appear to participate in voluntary programs that are beyond our purview, but certainly necessary in terms of their overall medical quality programs and even in the operation of their facilities.

COMMISSIONER ROGERS: Well now, we've heard a number of times that the medical community seems to think that the misadministration rate is as low as possible, given human error. And does that say that

the QA rule should be something which is particularly designed to make some improvements in that human error rate, and make some improvements along --

DOCTOR GLENN: Yes, I guess, as I remember, when the Commission paper came up, basically, we couldn't make that statement that in terms of the frequency that we might expect a large difference. However, again, when you look at the types of things that cause misadministrations, it certainly appears that any kind of effective QA program would catch most of the ones that were reported to us. But they are relatively simple errors. Some of them I guess maybe would be harder to catch than others, but it certainly appears that if the QA rule that we have proposed were implemented, that we could eliminate a good fraction of the ones that have occurred. Now how successful we'll be, that we don't know.

COMMISSIONER ROGERS: Chart 7 lists the inter-organization cooperation. How effective has been our interactions with FDA, in particular?

DOCTOR GLENN: We've had an extensive amount of discussion with them -- in particular, having to do with the petition for rulemaking -- to relax some of the requirements that we have on the compounding or the preparation of radiopharmaceuticals. And we've

had several meetings. We've had some good discussions. I won't say we have any answers yet, but the cooperation there has been excellent. The fact is, they have volunteered a member of their staff who's worked on some of their rules to help us in the composing and writing of any rules that we develop as a result of this review.

MR. BERNERO: I think it's worth saying we have a pretty good relationship with FDA, although that particular issue, which will be discussed with the Commission shortly, is a fairly complex one and sensitive one for FDA. And the Food and Drug Administration is not a monolith, like many agencies. They have different groups, different agenda. And as a result, they don't sing with one voice just as other agencies.

CHAIRMAN CARR: I thought all groups did.

MR. TAYLOR: Always hoping.

MR. BERNERO: But in general --

COMMISSIONER ROGERS: Isn't that the beauty of a choir?

MR. BERNERO: Now in general, our relationship with FDA is a very good one, a very healthy one, and we have interactions on the scientific level and administrative level frequently.

CHAIRMAN CARR: Let me piggyback on that a minute. Are the respective authorities clear and distinct, or is there a lot of overlap in our area versus theirs?

MR. BERNERO: I think they are clear and distinct, but they do overlap, just as the line of questioning a little while ago about a medical device and a medical practice using a medical device. We have had instances where the NRC, due to its more intense scrutiny in the field, will go into a situation, an event in a hospital, as if it were an NRC issue, and it is an FDA issue. And due to the overlap of jurisdiction, we can pass the baton to them and do when we need to.

I think people generally within the NRC and within the FDA understand the distinction. There is not a blur about who --

CHAIRMAN CARR: We don't need some kind of formal MOU or --

MR. BERNERO: No, no. I think --

CHAIRMAN CARR: -- agreement that separates the functions?

MR. BERNERO: I think our functions are necessarily interrelated, but they are understood. And at least in my experience in it, I haven't run

into a situation where somebody in FDA is trying to regulate what we're supposed to regulate or vice versa. It's just that it is a complex thing, and in neither case -- well, certainly -- I would qualify that.

In our case, we are not trying to regulate the practice of medicine directly, and FDA is being very careful about regulating the safety and efficacy of drugs or devices or whatever, and they're being very careful about that. And so we both face that complication of not getting too deeply into the practice of medicine.

MR. PARLER: Mr. Chairman, the Commission, if I may, the Commission in 1979 approved a statement of general policy on the regulation and the medical uses of radioisotopes. I had the occasion to look at that before I came to this meeting. That policy statement explains in some detail and quite clearly in my judgement the respective authorities and roles of the FDA and this Agency. I didn't see anything in that general policy statement that occurred to me to raise any red flags in my mind about there being some ambiguous area that might lead to confusion. If there is such an area which needs expanding, the way to do it, in my judgement, would be to revise that general

policy statement, which, to repeat, seems to me to be comprehensive and clear.

COMMISSIONER ROGERS: Good.

Are there any specific visiting fellowship assignments settled yet?

DOCTOR GLENN: Not settled yet.

COMMISSIONER ROGERS: Or have you gotten to that point yet?

DOCTOR GLENN: There have been discussions, and I guess in the paper that comes up we're providing some alternatives, and perhaps we're recommending that we actually take a little bit of two different possibilities. Because, there's one that we think we can implement in a reliable consistent way and always have a fellow. There's another where we sort of think we have to wait for the right person to come along and be ready and willing to bring that person in, but we can't guarantee we'll always find that person when we go looking.

CHAIRMAN CARR: Commission's already approved the concept.

DOCTOR GLENN: Yes.

CHAIRMAN CARR: Why don't you just go ahead and get it done? I mean, what do you come back to us for?

MR. TAYLOR: We have that --

CHAIRMAN CARR: Did we tell you to?

MR. BERNERO: The paper is up.

MR. THOMPSON: The paper was sent back. It's a question of when they're going to --

MR. TAYLOR: We sent the paper back so you could add when you're going to implement.

Thank you.

MR. BERNERO: The ball is back. We have it, and we can. We have -- in this sort of hybrid sort of approach John spoke of, we have some strong sentiments and feelings.

COMMISSIONER ROGERS: Well, it would seem to me it's gotten a warm reception from the community, I believe. And I would think if you've got the green light from the Commission, you know, try to move quickly.

MR. TAYLOR: The thing that was missing was when you were going to proceed, and we wanted you to have that. If I don't have to bring that up, we'll go ahead.

CHAIRMAN CARR: Just tell us you did already.

COMMISSIONER ROGERS: Right, yes.

MR. BERNERO: We'll bring something with the

past tense.

COMMISSIONER ROGERS: Right. Good news, yes.

MR. BERNERO: Bring the people.

COMMISSIONER ROGERS: And this, finally, on the shrinking work force. Do you have any thoughts on whether there's anything happening to change that? Is it something that we're simply all watching take place, wringing our hands while it occurs, or is somebody doing something about it in some way? It seems as if it's a very serious need, and yet people are not entering the field.

There's shortages all over, and the sources of trained people are drying up, apparently, rather than expanding to meet that need, curious situation. Usually when there's a need, people like to jump in and try to fill that need. Here the need seems to be growing and the solution to meet that need shrinking at the same time.

DOCTOR GLENN: It is troublesome, and I guess some of the forces that are driving it are certainly beyond our control.

COMMISSIONER ROGERS: Well, I'm not suggesting that we necessarily can solve this, but--

DOCTOR GLENN: I guess the thing that I'm

looking to see whether it has an effect is that the shortage has driven salaries up, at least in some areas, and whether the economic incentive is enough to bring people back into the labor market in this area.

CHAIRMAN CARR: Sounds like a ripe area for scholarships from somewhere.

MR. MYERS: Sir, it may be that this is an action like a pendulum. Typically, in medical fields, we see a preeminence or a beginning of a field like computerized tomography, the CT systems, and when they came out about ten years ago, people were getting out the black arm bands for nuclear medicine because they were going to have a funeral for it. That never materialized, although CT went off and did its own thing.

We have magnetic resonance imaging competing against us. There are a lot of things that are out there, such as PET and SPEC scanning, which will be kind of a slow start because it's very expensive. But what will happen is that eventually I think that some of that will kind of draw back in. But we will never see, in terms of the technologist, that great number, perhaps, that we had. It will probably always remain a little bit behind the power curve, because there are a couple of things affecting it. One of them,

obviously, is salaries, and as the technologist and the physician become more dear, their salaries will go up. That will pull some in.

The hazards that are associated with nuclear medicine and therapy are rather unique. We're the only folks that really get exposure in the medical area, because we wade around in the radiation, as opposed to the x-ray and CT folks.

CHAIRMAN CARR: Figuratively speaking, right?

MR. MYERS: Right, sir, figuratively speaking, because basically the x-ray techs can walk behind the shield and we have to be there to inject the isotope to the patient. It can't be done remotely. We have to position the patients and so forth. So there is a perceived hazard.

And because you're also using intravenous injections, there's also a perceived hazard, perhaps, of contracting AIDS and other types of disease, where you just don't have to get into that, in many cases, in other things. So it's an issue that is unresolved.

Schools have also dried up in nuclear technology, simply because a lot of the institutions that funded technologist schools did it out of the extra money that they had in reimbursement costs.

They can no longer do that, and the schools dried up.

COMMISSIONER ROGERS: I wonder whether this shortage, shrinking work force and shortage of resources to meet that need, is getting into the right quarters in the databases of the people that are looking at fields that need attention. You know, these studies are done. Manpower studies are done constantly. I wonder whether this gets lost in something, whether it's so specialized that it doesn't show up in its own right. I don't know. I'm just asking that question, whether there's any way in which those manpower studies that have been done are looking at this with some awareness of the situation.

MR. MYERS: Yes, sir, I would say they are.

NMTCB, one of the certifying boards, has conducted a survey -- I think it was last year-- addressing that same issue, and that covered about 10,000 technologists, approximately, in their base.

I do know that we received some phone calls from, I guess, a Presidential board looking into manpower, that we address some of their concerns, and directed them to the technologist societies for that issue. And I think it is being addressed. You know, the outcome I think is still -- you know, the game is not over.

COMMISSIONER ROGERS: Thank you.

CHAIRMAN CARR: Commissioner Curtiss?

COMMISSIONER CURTISS: Just a couple of questions. The petition for rulemaking, can you tell us what the status of that is, and maybe share with us some preliminary thoughts on what your current thinking is on some of the bigger issues, and maybe talk about the one in particular that -- well, one of the ones that I've heard about. That's the package insert question. Give us a quick run-down on that.

DOCTOR GLENN: I believe Research has the lead.

MR. BERNERO: Okay, yes. Let Research talk to it.

DOCTOR BAHADUR: Well, we had the petition submitted to us in June of '89, and we had published the notice sometime in September. We had lots of comment. Actually, we received 466 comments on that petition. And needless to say, most of the letters were for the petition. Actually, about 60 percent of the letter came as a form letter from the Society of Nuclear Medicine.

And right now, what we are doing is we have broken down that into various issues that we are analyzing, and we are discussing the safety concerns

mostly with the FDA, which John was mentioning earlier. We had had closed meetings with them and tried to resolve some of the issues beforehand, before we go in and go the proposed rule route.

What we have done so far is we have published the rule for comments, and the public comment will last until April of '90. And so far --

COMMISSIONER CURTISS: Go ahead.

DOCTOR BAHADUR: But actually, after meeting with the FDA, we have broken that down into two routes. There's a fast track and a slow track. And we went through that for some time, and then we have revised the approach.

COMMISSIONER CURTISS: And the two tracks hinge upon the perceived immediacy of the issues that are being raised? Is that the distinction?

DOCTOR BAHADUR: More than the simplicity of the issues, talking with the FDA. And based on that, right now we're talking about the generic exemption on certain issues. So there is a rulemaking activity progressing normally, and then we are talking about generic exemptions are some of the issues which we are dealing with FDA.

COMMISSIONER CURTISS: All right.

CHAIRMAN CARR: I noticed in the last

regulatory agenda report that the resolution date for that thing has changed to undetermined, which doesn't give me a warm feeling. Have you got any better data than that?

DOCTOR BAHADUR: The reason for rulemaking date being undetermined is because right now all energies are focused towards the generic exemption.

CHAIRMAN CARR: Okay.

DOCTOR BAHADUR: Which will take care of at least five of the six items which were included in the petition. So the idea is to put all the efforts, all the concentration in this generic exemption, and then go back to the rulemaking activity.

CHAIRMAN CARR: So five of six in the generic exemption?

DOCTOR BAHADUR: Is what we are trying to achieve at this time.

CHAIRMAN CARR: And what's the date you're shooting for on that?

DOCTOR BAHADUR: Bob, would you like to --

MR. BERNERO: Yes. The only remaining thing is --

CHAIRMAN CARR: Want to hang your --

MR. BERNERO: Yes, well, let me tell you. I was a little oblique in talking about FDA. And on

this particular issue, we're -- well, to put it in a simple comparison, when FDA has a recipe, a package insert, they say that within that framework a drug is safe and efficacious. When it is outside that, they are no longer saying it is safe and efficacious, but that is not necessarily unsafe. And our regulations have tended to implement it as if it were unsafe the minute it's outside the recipe.

We had hoped on the generic exemption to have unequivocal FDA endorsement of our action, and they're being very cautious about it. We've had repeated meetings. And basically, the intent is I hope to communicate with FDA this week at a high management level to tell them, "Look, we really don't want to draw you out as an agency and have you endorse everything we're doing here officially, but we're satisfying ourselves that there isn't a major obstacle to going forward, and we're going to come forward with it that way."

CHAIRMAN CARR: So we're looking for at least a no objection.

MR. BERNERO: Yes. It's a no objection, a speak now or forever hold your peace sort of thing. And it's just we had hoped --

COMMISSIONER CURTISS: The nature of the

problem, we have construed the FDA requirements on the package inserts more strictly and more conservatively than they would construe them.

MR. BERNERO: That appears to be the essence of the issue.

COMMISSIONER CURTISS: Now we are seeking to adjust through the exemption process our interpretation to permit the kind of latitude that FDA envisions, and seeking FDA's endorsement which they're reluctant to give us.

MR. BERNERO: Pending the long-range resolution of the issue through some rulemaking. This is really like a discretionary enforcement, our generic exemption process, and that's why your attention was needed.

CHAIRMAN CARR: But the intent would be to draft up our exemption statement and get their no objection to it, at least?

MR. BERNERO: That's the intent.

CHAIRMAN CARR: Okay.

COMMISSIONER CURTISS: And that would come back here to the Commission?

MR. BERNERO: Yes, we'll be coming to you. Because, in effect, we're saying on a generic basis we're exempting a whole class of activities.

COMMISSIONER CURTISS: And then the sixth issue, I take it, would be addressed on the slow track or the rulemaking track? That would be the subject of less immediate concern?

CHAIRMAN CARR: I think I understood them to say they dropped the fast track, slow track.

DOCTOR BAHADUR: And I'd like to say that slow track may not be the right characterization of it. Right now we have the exemption policy on one route, and the normal usual rulemaking on the other route.

MR. PARLER: Mr. Chairman, I have a comment.

We have exemption provisions in the regulations, which kind of like acts as a safety valve whenever a need for a safety valve comes up from time to time. But if we have a regulation on the books, and then somebody wants to come out with a generic exemption of unknown time dimensions that would cover five out of the six points in a petition for rulemaking, at least in my mind the distinction between the generic exemption approach, which presumably could be on a fast track, and a rulemaking approach which would be on a slower track, becomes rather blurred to say the least.

I don't know whether I made myself clear or

not.

CHAIRMAN CARR: Sounds like you're saying you might as well just cancel the rule.

COMMISSIONER CURTISS: Or to make an interim change to the rule effective immediately. What you're saying is that through the generic exemptions you effectively amend the rule.

MR. PARLER: You asked the question earlier about a time deadline for changing the rule in the regulatory agenda. If you can in effect short-circuit or bypass existing rules by calling something a generic exemption, it seems to me that from the legal standpoint that would be troublesome. Certainly, it would be troublesome to me.

MR. THOMPSON: Mr. Chairman, we did have --

CHAIRMAN CARR: Identify yourself.

MR. THOMPSON: Excuse me. Hugh Thompson, Deputy Director for Nuclear Materials Safety, Safety Nuclear Materials Operations and Operational Support, or something like that. I'm not sure.

We had some clear debate on which approach to go with the staff, amongst the staff members, whether to go with an exemption as a fast track rulemaking or just go with enforcement discretion. And that discussion we had involved various members of

the staff, and at that time we originally had enforcement discretion. But based on the concerns that were expressed by, I guess, members of the Office of General Counsel, we did figure that it was a cleaner approach, rather than having violations that we were faced with not enforcing, rather than having exemptions. And that was the basis.

Mr. Parler was not part of that meeting, but in order to describe the differences between the two, it was to not have violations on the books which we were not enforcing and going through a process of trying to grant multiple enforcement discretions when those violations were documented. And it was more of a policy question on what the inspectors did when they went out in the field and identified a particular practice which was inconsistent with that current regulation.

MR. PARLER: I didn't mean to say anything any different from what Mr. Thompson just described. He's introduced another policy consideration. Obviously, depending upon how many policy considerations you have on the table, you can have, relatively speaking, preferred options.

What I was suggesting in a broader context is perhaps the preferred option, or perhaps even the

legal requirement may be to go through a rulemaking directly, rather than to change in effect the substance of the rule by a generic exemption approach.

COMMISSIONER CURTISS: If the problem is a generic one and if it's a problem with the rule itself and if, as General Counsel has indicated, there may be some infirmities with the generic exemption approach and distinct from the enforcement discretion approach, Hugh, that you've raised, isn't there -- is there any reason we couldn't address that problem as quickly as the generic exemption by simply going forward with an interim final rule and address the problem with a rule?

MR. THOMPSON: Certainly. That's exactly the place I started off with. I mean, I wanted to be there. I tried to get there, and every door I knocked on there seemed to be a reason not to get there. But if we got the support, that is the best way to go, without any question in my mind. But each time we went through the process, there was always some objection with proceeding in that direction. And the direction that we're headed now I thought had finally reached unanimous consent of the staff to do that.

But I certainly would agree that if we can take the approach to go and have the basis for

supporting a rulemaking immediately effective, that that's the best way to go.

MR. TAYLOR: The staff will leave here and take a look at that. We've been anxious to get this thing settled, so we'll take a look and come back.

COMMISSIONER CURTISS: Let me get on to my other two questions. I didn't mean to --

CHAIRMAN CARR: Well it seems that if we know where we want to go, we ought to be able to find a way to get there.

MR. TAYLOR: Right. We want to get there soonest.

COMMISSIONER CURTISS: On the increased inspections that you've conducted, I guess I'd be interested in the flavor of what you've found and in particular whether the kinds of things that you're finding square with the kinds of problems that the proposed QA rule would address. Is there a match there? Is there an overlap?

DOCTOR GLENN: I guess I have not seen a different finding as a result of the increased inspection effort. I would say, though, that we're going to those facilities where we see the most serious problems occurring more often. And perhaps I guess what we hope is that in the future we'll see a

drop-off because of that increased attention. But this first go around, I don't think we can comment.

COMMISSIONER CURTISS: Okay. Final question on the workshops. Can you give us a little bit of a flavor of what you're hearing, what you've heard from folks in the workshops? What's the temperature of people generally out there in terms of the concerns that they're raising and the questions that they're asking, in addition to the material that we're imparting to them?

DOCTOR GLENN: Okay. There were sort of two types of response. One was the group of people who appreciated the fact that we were out there, that we were talking to them. We were explaining our positions. They understood where we were coming from better and they appreciated it just from that point of view. "Hey, we know what you're talking about now, and that's good."

Certainly we also heard from those groups who felt that we were going too far too fast in certain areas, in the area of QA in terms of enforcing the package insert rule, in terms of strong enforcement on a compounding case. We got a lot of comments from a particular group who felt that we were not in touch with what the Commissions position should

be in terms of keeping out of the practice of medicine and the practice of pharmacy. They felt that we'd intruded too far into that area.

So we got two separate groups, one very positive and the other one not necessarily negative but telling us they thought that we were on the wrong track in that particular area.

COMMISSIONER CURTISS: All right. That's all I have.

CHAIRMAN CARR: I recently talked to Doctor Welinsky, the Administrator of the Health Care Financing Administration, and my concern was whether they gave consideration if we throw in a rule for QA that increases the cost to the hospitals, how do they take that into account in figuring out their financing. She said that she thought they had QA programs in place, but she'd take a look at that.

What kind of interaction do you expect to have with the HCFA over the next year?

DOCTOR GLENN: We've just started making the contacts, really. I guess, one thing is that we've got several initiatives going on. One is a contract that's going to help us understand a little bit better what HCFA's role in this whole area of quality assurance is, and we would expect, I guess, those

findings by late summer. But we do intend to, at a middle management level, to institute some contacts and begin to explore with them some of these issues.

MR. BERNERO: Some of these other issues appear to be germane to their scope of responsibility. Just talking about the training and qualifications, if we press for expenditure of resources and better training and qualifications, as well as in general on QA, are those costs recoverable? Do they know? Does HCFA know of the shortage of trained personnel? There are many things there and I think we need a more open and more active communication with --

CHAIRMAN CARR: Well, along that line, when you're looking at the Advisory Committee on Medical Uses, you might consider whether we need somebody from HCFA on that committee.

MR. TAYLOR: We're going to be meeting on that --

CHAIRMAN CARR: If it's going to cost somebody money, they ought to know up front what we're doing and why we're doing it. I don't know -- have you decided yet on whether we ought to expand that committee to take in a state representation or not?

MR. BERNERO: We've talked about that. We're looking there. The Advisory Committee on the

Medical Use of Isotopes is much more in the vein of an ACRS, looking at it from a diverse technical background, a medical use of isotopes. And so far we're less inclined to look for a diverse viewpoint or a diverse position in the society, broad society not something like Society of Nuclear Medicine or anything like that.

So, therefore, public interest groups or state governmental groups wouldn't ordinarily find their way into such a group.

CHAIRMAN CARR: Yes. I'm concerned. What we do has an impact on both of those groups though.

MR. BERNERO: Oh, yes, yes.

CHAIRMAN CARR: How and when do we bring them in best, I guess is the question.

MR. BERNERO: Yes. Should they be a member of the committee or should there be an orderly process to discuss with them the broad issues as well as the advice of the committee? We have in the past tended to look at the advisory committee as experts in the medical use, practitioners, radiologists and medical physicists, people like that.

COMMISSIONER ROGERS: Well, perhaps you could get some kind of representation of expertise in these impact questions, financial impact questions

without actually being faced with the dilemma of simply a spokesman for the state --

MR. BERNERO: Yes.

COMMISSIONER ROGERS: -- point of view. Presumably there are some organizations in which people develop an expertise at analyzing funding impacts of certain kinds of practices of various kinds and regulations and know what the different state scenes are. We know this is very much the case in the nuclear power industry where there are lots of industry experts out there who can tell you what the costs are going to be of various regulatory alternatives, and I wonder whether that might not be a way of getting that kind of dimension into the committee without necessarily simply providing a slot on the committee for an exertion of power, politics.

MR. TAYLOR: We owe the Commission response on that. In fact, I've set up a meeting with the staff tomorrow just to explore these kind of questions. But the first position of the staff was we ought to stick with the medical. We're going to be talking about that and we'll be coming to the Commission. I believe we owe you a recommendation in that area.

COMMISSIONER ROGERS: Well, I'd just like to

say that I think what you need on your committees are experts, not representatives.

MR. TAYLOR: There's a difference.

COMMISSIONER ROGERS: You could go outside of the purely scientific and technical as long -- it seems to me, quite valuably, if you keep that as a guiding principle.

COMMISSIONER ROGERS: Understand.

CHAIRMAN CARR: Did we do a study on therapy misadministrations? Did somebody do a study on that?

DOCTOR GLENN: I think that on April 9th, AEOD will probably be discussing that in their briefing.

CHAIRMAN CARR: And on your NMSS newsletter, do you include the ACMUI members on the distribution list and the representatives of those professional organizations, are they on it too? If not, may I suggest we put them on it?

MR. BERNERO: Let's check. I thought they were, but --

DOCTOR GLENN: Yes, I'll have to check.

MR. TAYLOR: We'll verify that.

Will you do that?

CHAIRMAN CARR: The more people we can send that out to, I think the better off we'll be because

it's a --

MR. BERNERO: Yes. I think we've tried to spread that out as much as possible.

CHAIRMAN CARR: It looks like a pretty good effort to me.

Well, I want to thank the staff for the informative briefing and commend them for their efforts over the last year to further improve NRC's regulation of medical uses of byproduct and material to ensure adequate protection of the public from unnecessary radiation exposures.

Staff efforts to communicate with the licensees, the professional organizations, states and other federal agencies in the medical use area through workshops, conferences and training courses are particularly commendable.

Also, I commend the staff for pursuing innovative efforts to improve medical use regulations such as the two step licensing program recently implemented in Region I.

I encourage the staff to implement the visiting fellows program; to seek opportunities to conduct extended facility visits and develop first-hand understanding of safety needs, which you've been doing; to solicit constructive comments from all those

outside organizations and states on how we can do a better job. You are going to provide your paper on the membership of the Advisory Committee on Medical Uses. I think, if you can afford it, continue to conduct the workshops. I think they're valuable and be sure that you get your needs into the five year plan so that we have enough resources to carry out the program.

I think the NRC, the agreement states and the licensees share the responsibility to take care of the public and the medical uses and we must continue to pursue this goal by improving the regulatory program within the available resources.

Any additional comments?

COMMISSIONER ROGERS: Well, just to reinforce what we already, I think, agreed on, to get on very expeditiously with this question of deciding whether a generic exemption or an interim rule is the most appropriate way to go, but to clear that up quickly and get on with it because it is a very sensitive sore point out there with the community.

CHAIRMAN CARR: We stand adjourned.

(Whereupon, at 3:32 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 20, 1990

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

BRIEFING ON MEDICAL USE OF
BYPRODUCT MATERIALS

FEBRUARY 20, 1990

JOHN E. GLENN
NORMAN L. MCELROY

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TOPICS

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

INDUSTRY CHARACTERIZATION

- ANNUAL CLINICAL PROCEDURES
  - 7 MILLION DIAGNOSTIC
  - 150 THOUSAND THERAPY
- MEDICAL USE LICENSEES

	NRC STATES	AGREEMENT STATES
HOSPITALS	2200	4400
PRIVATE PRAC.	400	600

MISADMINISTRATIONS REPORTED BY NRC LICENSEES

	CY86	CY87	CY88	EST CY89*	FREQ
DIAGNOSTIC	433	409	393	338	.0002
I-131	5	5	7	11	
THERAPY	7	9	12	10	.0002
LICENSEES INVOLVED	369	348	344	310	15%

* REPORTED AS OF JANUARY 1990

NRC'S MEDICAL USE PROGRAM

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

PROGRAM DEVELOPMENT

GOAL: IMPROVED QUALITY IN MEDICAL USE

- DEVELOP QA RULE & REGULATORY GUIDE
- DEVELOP TECHNICAL BASIS FOR DETERMINING WHETHER CHANGES ARE NEEDED IN TRAINING CRITERIA
- QA QUESTIONNAIRE
- PROPOSED PRICE-ANDERSON FOR RADIO-PHARMACEUTICAL LICENSEES TERMINATED
- HUMAN FACTORS
- RADIOPHARMACY PETITION

INTER-ORGANIZATION COOPERATION

GOAL: USE EXISTING FRAMEWORK

- HHS
  - FDA
  - HCFA
- EPA
- DOT
- DOI
  - OSHA
- DVA
- PROFESSIONAL
- SCIENTIFIC
- ADMINISTRATIVE
- CREDENTIALING
- ACCREDITATION

STAFF DEVELOPMENT

GOAL: INCREASED MEDICAL USE EXPERIENCE

- RECENTLY HIRED PERSONNEL HAVE MEDICAL USE BACKGROUNDS
- PROVIDING REFRESHER TRAINING
  - TTC COURSES ON NUCLEAR MEDICINE, RADIATION THERAPY WERE REVISED
  - HELD OBSERVATION DETAIL FOR STAFF AT A NEARBY HOSPITAL
  - HEADQUARTERS/REGION ROTATION
- ROTATION OF MEMBERSHIP IN ACMUI
- VISITING FELLOWS PROGRAM UNDER DEVELOPMENT

OVERSIGHT

GOAL: EARLY NOTICE OF DEVELOPING PROBLEMS

- TRACK TRENDS IN LICENSING, INSPECTION, AND MISADMINISTRATION REPORTS
- INSPECTIONS
  - CY 87 608
  - CY 88 570
  - CY 89 1030

INFORMATION EXCHANGE

GOAL: WIDESPREAD NOTICE OF NRC ACTIVITIES

- 31 PRESENTATIONS TO PROFESSIONAL GROUPS
- 15 WORKSHOPS FOR LICENSEES
- NMSS NEWSLETTER
- ASSOCIATION NEWSLETTERS USE NRC PRESS RELEASES OF SIGNIFICANT ENFORCEMENT ACTIONS

AREAS OF CONCERN IN MEDICAL USE

- SHRINKING WORKFORCE
- STRINGENT REIMBURSEMENT CONTROLS
- MEDICAL TECHNOLOGY
  - MONOCLONAL ANTIBODIES
  - HIGH-DOSE-RATE BRACHYTHERAPY
  - STEREOTACTIC THERAPY
  - COMPUTERIZATION

RESOURCES FOR MEDICAL USE PROGRAM

FUNCTIONAL AREAS	FY89 $	FY89 FTE	FY90 $	FY90 FTE	FY91 $	FY91 FTE	FY92 $	FY92 FTE
PROGRAM DEVELOPMENT & EVENT EVALUATION (HQ)	2	8	1	7	2	7	1	7
INSPECTION AND EVENT EVALUATION (REGIONS)		19		19		22		23
LICENSING (REGIONS)		7		8		9		8
SUPERVISION (HQ & REGIONS)		5		5		5		5
TOTALS	2	39	1	39	2	43	1	43

RESERVE SLIDES FOR

BRIEFING ON MEDICAL USE OF

BYPRODUCT MATERIALS

FEBRUARY 20, 1990

QA RULEMAKING

- Performance-oriented QA Rule
  - Pilot Program to Test Implementation
  - Final Rule to Commission March 1991
  - Expanded Reporting Requirement

RADIOPHARMACY PETITION

- ACNP/SNM PETITIONED FOR CHANGES IN RADIOPHARMACY RULES
- NOTICE OF RECEIPT PUBLISHED
- INITIAL STAFF EFFORTS DIRECTED TOWARD PROVIDING INTERIM RELIEF
- STAFF CONTINUES TO WORK ON RESOLUTION

HUMAN FACTORS

- TELETHERAPY
- BRACHYTHERAPY
- TREATMENT PLANNING

RADIOPHARMACY PETITION

- PETITION RECEIVED FROM ACNP/SNM
- NOTICE OF RECEIPT PUBLISHED
- INITIAL WORK DIRECTED TOWARD RELIEF FROM CERTAIN RESTRICTIONS
- LONG TERM WORK DIRECTED TOWARD RESOLUTION OF THE REQUEST

ORGANIZATIONS AFFECTING LICENSEES

- FEDERAL AGENCIES - 5
- SCIENTIFIC OR PROFESSIONAL - 12
- CREDENTIALING OR ACCREDITING
  - PHYSICIANS - 4
  - TECHNOLOGISTS - 5
  - TRAINING PROGRAMS - 3

FEDERAL AGENCIES

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

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

SCIENTIFIC

- RADIOLOGIC SOCIETY OF NORTH AMERICA
- UNITED STATES PHARMACOPEIA
- NATL COUNCIL ON RADN PROT AND MSMNTS
- AMER ROENTGEN RAY SOCIETY
- AMER SOC OF RADN THERAPY ONCOLOGIST

ADMINISTRATIVE

- ASSO OF COMMUNITY CANCER CENTERS
- ASSO OF HOSPITAL RADIOLOGY ADMIN
- SOC OF RADN ONCOLOGY ADMIN

CREDENTIALING FOR PHYSICIANS

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

CREDENTIALING FOR SCIENTISTS AND TECHNOLOGISTS

- o AMER COLL OF RADIOLOGY
- o AMER BD OF SCIENCE IN NUC MEDICINE
- o AMER REGISTRY OF RADIOLOGIC TECHS
- o NUC MED TECHNOLOGY CERT BD
- o STATE LICENSING (14)

PROGRAM ACCREDITATION

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

INSPECTION FREQUENCY (YEARS)

	FY88	FY89	FY90	BASIS
HOSPITALS				
- BROAD SCOPE	2	1	1	RISK
- COMMUNITY	3	3	3	RESOURCES
COBALT THERAPY	3	1	1	RISK
PRIVATE PRACTICE	5	4	4	PRESENCE