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NUCLEAR REGULATORY COMMISSION

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BRIEFING ON PROPOSED RULE ON BASIC QUALITY ASSURANCE

IN RADIATION THERAPY

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PUBLIC MEETING

Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Tuesday, June 13, 1989

The Commission met in open session, pursuant to notice, at 2:00 p.m., Lando W. Zech, Jr., Chairman, presiding.

COMMISSIONERS PRESENT:

Lando W. Zech, Jr., Chairman of the Commission
Thomas M. Roberts, Commissioner
Kenneth M. Carr, 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

DR. BILL MORRIS, Director
Division of Regulatory Applications
Office of Research

ROBERT BERNERO, Director
NMSS

HUGH THOMPSON, Deputy Executive Director
Material Safety and Support

JOHN TELFORD, Section Leader
Rulemaking Section
Regulation Development Branch, DRA, RES

JOHN GLENN, Chief of Medical, Acadamic, and Commercial Use Branch

DR. ERIC BECKJORD, Director
Nuclear Regulatory Research

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

2:00 p.m.

CHAIRMAN ZECH: Good afternoon, ladies and gentlemen.

The purpose of the briefing this afternoon is to discuss the status of the Proposed Rule on Basic Quality Assurance in Radiation Therapy. As many of you know, the Nuclear Regulatory Commission is proposing to amend its regulations concerning the medical use of byproduct material.

The proposed amendment would require medical licensees to implement certain quality assurance steps that would reduce the chance of misadministrations. This proposed rule will result in a regulatory reform that will focus on quality assurance and will permit enforcement action to be taken when breakdowns occur, breakdowns that create an increased risk to public health and safety.

The staff recently forwarded for Commission review and approval SECY-89-171, which contains the proposed amendments to 10 CFR Part 35. This paper also responds to other related Commission directives in the medical use area. Today we'll discuss in more detail the contents of the staff's paper. After consideration of these matters, the Commission will be

in a position to vote.

I understand that representatives from the Office of Research will make the key presentation today.

Do any of my fellow Commissioners have any opening comments to make before we begin?

If not, Mr. Thompson, you may proceed.

MR. THOMPSON: Thank you, Mr. Chairman.

As you know, this is an area that the Commission has been providing increased attention to over the past few years, both in the upgrading of some of our regulations as well as increased resources both for attention and policy development areas.

The one item that we'd like to focus your attention to today as we go through this is that the failure rates that we see in the application of the nuclear medicine activities is about as good as we see in any area of the medical application, as well as almost any of the areas that we regulate. So their performance, as we see it, is pretty good, and the proposals that we have before you we think will improve that.

But the rate and the numbers and the improvements that we see are going to be a small number, or are likely to be a small number, and the

resulting benefits in the quantification as we do our cost/benefit analysis may be difficult to see in the precise terms as we normally see, that you would normally see the cost/benefit of this type of rulemaking activity. So just bear that in mind as we go through the briefing today. That's one of the challenges that the staff faces. I think we identified it in the Commission paper. It's something that you may want to explore with us as we go through.

Before I turn it over to Eric to introduce the speakers today, I would just like to note that at the table joining me is John Glenn, for the first time. John is recently selected for the Branch Chief of the Nuclear Medical, Academic, and Industrial Safety Area. He joins us from Region I and he will be instrumental in implementing the rules that the Commission puts out in this area and I just thought that this would be an opportunity for him to be here today. Obviously, he adds some of that field experience that we value to have back here in Headquarters with us.

So with that, Eric?

CHAIRMAN ZECH: Doctor Beckjord, you may proceed.

DOCTOR BECKJORD: Thank you, Mr. Chairman.

I don't have any additional comments to make on that. The presentation on the Basic Quality Assurance Program will be made by Doctor Bill Morris, Division Director of the Division of Regulatory Application. He's accompanied by John Telford, who's Section Leader in the Rulemaking Section of the Regulation Development Branch; and Anthony Tse, who is the Project Manager for this project.

CHAIRMAN ZECH: All right. Fine.

Doctor Morris, you may proceed.

DOCTOR MORRIS: Thank you.

(Slide) On the first page of the handout, we have an outline of the briefing. We'll cover the background that led us to this point in the rulemaking effort, go back over some of the misadministration rates that have occurred through the years, discuss the regulatory objectives of this action, a summary of the amendments that we're proposing, discuss the regulatory guide that would support that amendment, including also the amendments that would involve the modification to the reporting and recordkeeping requirements. I'll talk about the benefits and impacts of the rule and then our recommendations.

Turn to page 2 of the handout, please.

(Slide) In October of 1987, the NRC

published two proposed rulemakings on quality assurance for medical use of byproduct material, a notice of proposed rulemaking on basic quality assurance and a notice of proposed rulemaking on comprehensive quality assurance.

The Commission was briefed on progress of the rulemakings by the staff in March of 1988 and at the briefing the staff described a draft final rule that it was proposing on basic quality assurance that would embody a number of rather prescriptive requirements that would be embodied in that rule.

The Commission subsequently met with representatives of the medical community in April of 1988 to discuss the proposed rule with those individuals. At that meeting, some of the representatives expressed concern that the draft final rule would have an adverse impact on medical practice because it would either interfere with the medical practice or because the cost of the rule would divert resources from more important areas of medical care.

The staff was then directed by the Commission to prepare an options paper providing rulemaking alternatives. In that paper, which was submitted as SECY-88-156 in June of 1988, the staff recommended that a performance based quality assurance

rule be developed, supported by a regulatory guide, so that the formerly prescriptive requirements in the earlier draft rule would now be relegated to the regulatory guide, and would therefore be less intrusive on the medical practice.

The Commission, in its SRM dated July 12th of 1988, approved that recommendation, along with other recommendations the staff had made. Subsequently, the staff went to work on this project and had a series of meetings with medical organizations as had been directed by the Commission, and solicited comments from agreement states and other interested groups.

These meetings included a meeting in November with the Quality Assurance Subcommittee of the Advisory Committee on the medical uses of isotopes and they reviewed the process of developing a performance based rule and regulatory guide.

Later, the staff held a public workshop in January of 1989 in which the revised basic QA rule and regulatory guide were discussed with various medical use licensee personnel, including physicians, physicists and technologists. That was a round table discussion between those individuals and members of the staff.

In March, the staff also met with the American College of Radiology to discuss the NRC's draft regulatory guide and the ACR's draft Quality Assurance Program. The American College of Radiology is in the process of developing a comprehensive Quality Assurance Program that would be designed to be adopted in whole or in part by the members of the American College of Radiology.

Now, the NRC staff has used this information gathered in these meetings and conducted a lot of analysis itself in developing the rule and regulatory guide that has been transmitted to you in the SECY paper.

(Slide) Let's move on to page 3. If I can assess for a moment the misadministration experience that has been the concern that would be addressed by the rule.

During the period from 1980 to 1988, there were a total of 88 therapy related events reported to the NRC and approximately 3200 diagnostic related events. Those therapy related events included 23 reports that involved administration of Iodine 131 originally intended to be in the diagnostic range of dosage, but which turned out, through error, to actually have resulted in doses in the therapy range.

So, those events have been included as therapy categorized events in this analysis.

If you extend these rates of misadministration per year that were reported based on NRC licensees to include a projected rate for all licensees, the NRC licensees and the agreement state licensees, it turns out that you might estimate approximately 30 therapy related events and 1200 diagnostic related events per year.

To give some perspective on the significance of these events, there would be approximately 180,000 therapy administrations in a year and approximately 7 million diagnostic administrations in a year, to get some feeling for the actual error rate or the number of events per administration that would be occurring.

COMMISSIONER ROGERS: Excuse me. Just before you leave that, those numbers don't seem to connect together exactly. How did you get the 30 and the 1200? What's the basis for those numbers?

DOCTOR MORRIS: Okay. You'd take the 88 and the 3200 and divide by eight, each of those by eight. There are essentially -- let's see. There are --

COMMISSIONER ROGERS: And I get 11.

MR. THOMPSON: Remember, this is all licensees --

DOCTOR MORRIS: Yes, this is all licensees.

MR. THOMPSON: -- which includes agreement states as well as NRC. So they're about three times the number or two times the number in the agreements states that they are NRC licensees. So, we have about one-third and they have about two-thirds.

COMMISSIONER ROGERS: Okay.

DOCTOR MORRIS: Approximate number is 2500 NRC licensees and 5000 agreement state licensees.

COMMISSIONER ROGERS: Fine. Sure. Okay.

DOCTOR MORRIS: Now, this sense of what the rate of administrations is needs to be supplemented by some thought about the possibility for harm to patients from these misadministrations. There are a variety of situations that can arise in medical treatment and errors can lead to doses either above or below what was intended. It's been difficult to develop any simple assessment of the potential safety and health implications of misadministrations.

So far, the best that the staff has been able to do is to refer to case by case assessments of past administrations by NRC medical consultants or by the licensees themselves to indicate something about whether those misadministrations involving overdoses to patients might have resulted in some adverse health

effects. Some analysis of this was indicated in the Enclosure 5 to SECY paper 88-156, of the potential harm that could occur.

One other point that we need to keep in mind is that there is also a potential adverse health effect to patients who erroneously receive doses below the level necessary for effective treatment of their condition. So, we shouldn't ignore that possibility either as we look at this potential. But we just have not been able to come up with some criterion or some quantitative way to weigh in these health effects. It seems to be necessary to do it on a case by case basis.

(Slide) Well, going on to page 4 of the handout, and having recognized that there are some uncertainties involved of these error rates and understanding how large they are and what the health effects are, the bottom line we believe is that there would be a net benefit to patient safety if the rate of errors and medical use of byproduct material can be reduced. We just simply can't quantify it very well. This is the basic health and safety objective of the proposed regulatory actions to reduce that rate.

Now, it should be emphasized that although it would be desireable to eliminate such errors

altogether, this should not be expected. There will probably be a residual number of errors that will occur and we probably can't devise any means to eliminate and eradicate those errors altogether.

Also, while we want to reduce the error rate as much as we can, we want to do so at a reasonable cost and with a minimal intrusion into the way licensees might want to conduct their medical practice. So, we have to balance these factors too as we proceed.

So, because of the concerns that had been expressed, and these concerns I just mentioned to you, the approach that we've adopted is to state the Commission's requirements for licensees to implement basic quality assurance programs in a general rule and provide through a regulatory guide the more specific criteria that would be acceptable in developing such programs. By allowing this flexibility, we would hope to have a minimal intrusion into the conduct of medical practice.

And also we've noted that there has been some difficulty experienced by licensees and by our inspection enforcement staff in interpreting the current requirements on reporting on misadministrations. And so an additional objective of

the action is to approve the ability to detect and correct a breakdown in QA programs by revising the reporting and recordkeeping requirements.

(Slide) Move on to page 5 of the handout.

CHAIRMAN ZECH: Before you go to page 5, let me just note that your reference to reducing the rate of errors in medical use of byproduct material, we appreciate the fact that the errors are not very high and we appreciate the fact that the medical profession does a generally excellent job in not only diagnosis but also treatment while using byproduct material.

We do not want to intrude in the medical profession business of health care, but we do feel that there's room for improvement. That's the important message we're trying to give to the medical community and we would hope that the medical community would also recognize that -- we recognize the errors are small, but we would like to think that there is room for improvement and we'd like to think that they recognize that also.

DOCTOR MORRIS: Yes.

CHAIRMAN ZECH: All right. You may proceed.

DOCTOR MORRIS: Okay. Page 5 again.

The proposed revision of Part 35 now involves a new section, 35.35, which states the

requirement that each licensee should implement a basic Quality Assurance Program. A licensee's program must be designed to meet certain performance objectives which are included in the amendment. That is, the rule would specify or state what the Commission wants to accomplish, but it would not specify how this is to be done. These details would be left to the licensee.

The amendment would also require the licensee to conduct regular audits of the Quality Assurance Program that he would implement and to evaluate these audits so that timely revisions can be made in the program to correct any deficiencies he might detect.

(Slide) Moving on to page 6, on pages 6, 7 and 8, the specific performance objectives that we propose are summarized here. These objectives were selected because they provide a clear indication of Commission expectations for effective medical quality assurance programs and because they address the kinds of human errors which have resulted in reported misadministrations in the past.

If followed, we believe these objectives would help assure, for example, that the medical use of byproduct material is appropriate given the

patient's condition, that prescriptions or other instructions are documented and followed, and the correct patient is treated.

I don't propose to go through each of these in detail. If there are no questions about these objectives, I propose we go on to page 9.

Yes, sir?

COMMISSIONER ROGERS: How is the diagnostic referral procedures manual developed? Who'd develop that?

DOCTOR MORRIS: I believe the licensee would develop that.

COMMISSIONER ROGERS: Then they wouldn't be common then?

DOCTOR MORRIS: Well, I'm sure that there may be some commonality among the various licensees, but I don't think there's any standard manual that I've heard of.

Anyone else know of a standard?

MR. GLENN: Well, let me comment.

DOCTOR MORRIS: Yes?

MR. GLENN: I think it's usually within an institution that they have developed a clinical procedures manual. But it's quite frequent and already exists for most of our licensees that for a

standard procedure such as a liver scan or other kind of imaging study, that they have already prescribed what the normal dose will be for a given clinical indication.

COMMISSIONER ROGERS: As developed by each licensee?

MR. GLENN: By each licensee.

CHAIRMAN ZECH: All right. You may proceed.

DOCTOR MORRIS: (Slide) On slide 9 then, we indicate the proposed implementation of this new Section 35.35. The effective date would be six months after publication of the final amendment in The Federal Register. By that date, we would expect the licensee to submit written certification to the regional office that a Quality Assurance Program meeting the objectives of the Commission's rule had been implemented.

Then, eventually, at the time of license renewal, the licensee would submit the Quality Assurance Program itself for review by the staff. So, the program would be reviewed and approved in a sequence related to the schedule for license renewal for the number of licensees out there.

COMMISSIONER ROBERTS: What is the length of those licenses?

MR. THOMPSON: Five years. There's a sequence, I believe, every five years.

COMMISSIONER CARR: Is it intended that the license renewal be dependent upon approval of that program?

MR. THOMPSON: That would be the intent as part of the license renewal program, that you would, in fact, conduct a review and have yourself from a licensing standpoint that that program met the regulatory requirement.

What we were trying to do is rather than all of a sudden have 2,000 license amendments that have fell on us on one day with a fairly limited staff is to say what we're really trying to do is to get this Quality Assurance Program put in place as best that the hospital knew how to do given the guidance that we'd be developing in the pilot program. Likewise then, complete our full implementation to the licensing process as the hospitals come up for their license renewal.

So, it was kind of a two phased implementation program and then we have a special contractor that we intended that the Commission is giving its resources out to promptly go out when they have certified that they have the program implemented

to audit it just to see how the program and to see that they are implementing the program that they committed to internally, not necessarily just the program precisely as it might finally be in their license after our license review.

COMMISSIONER CARR: Is it intended to audit everybody or just pilot programs?

MR. THOMPSON: The pilot program will be conducted early in the activities and then once the rule goes in place and final, we will audit everybody.

COMMISSIONER CARR: In addition to reviewing the program at the license renewal?

MR. THOMPSON: That's correct. We have to do the license renewal anyway. This will just be one aspect that we look at when we do the license renewal. But the key element there really is the audit of what they're doing at the hospital, and I think that's where the safety improvement's going to occur as opposed to the piece of paper. You know, you can get a great piece of paper and not implement it.

COMMISSIONER CARR: I just wonder if it's going to be worth doing both.

MR. THOMPSON: Well, we've got to do the license amendment anyway.

COMMISSIONER CARR: But that wouldn't have

to be --

MR. THOMPSON: Remember, the license amendment is a piece of paper that they typically would look at it --

COMMISSIONER CARR: Yes, but I mean that part of the program wouldn't have to be -- I mean the license wouldn't have to be contingent upon approving the program if you also looked at it when you went out and did the audit.

MR. THOMPSON: Well, that's certainly something we can look at during the comment period. That may be an appropriate way to --

COMMISSIONER CARR: I'm just trying to cut out some of the manpower intensive part of the problem.

MR. THOMPSON: Well, we stand behind you. But that was the approach taken, to just have them certify that it's in place and that we can go out and audit it.

CHAIRMAN ZECH: All right. Let's proceed.

DOCTOR MORRIS: (Slide) Moving on to page 10, staff has developed a draft regulatory guide which provides an acceptable way to meet the requirements of the proposed amendment. The specific criteria in the guide address each of the performance objectives in

the rule we went over just a few moments ago. However, as stated on page 11 of the handout, the guide is not a Quality Assurance Program in itself, but it provides guidance to assist the licensees in developing their own program.

I point out that now that the pilot program is an essential step in having us learn more about whether we have an effective guide in proposed form and to correct it and make adjustments as we learn more about that guide during the pilot program.

In reference to the previous discussion, I would point out that there will probably be a good chance to learn more about this license renewal and the licensing process during the pilot program because NMSS has requested that we include 12 cases in the pilot program which would give an in depth review of how that process would go, so we'll know more about how the final approval should be engaged because of that program.

(Slide) Moving on to slide 12, please.

I just wanted to mention, as I mentioned before, there have been comments of representatives in the medical community and the staff members who have been involved in the inspection enforcement process that there could be some benefit from clearer

reporting and recordkeeping requirements. The staff has developed and is proposing to the Commission a modification to the reporting and recordkeeping requirements which has the objective of better identifying events indicating breakdown in the quality assurance.

Two kinds of events are included, procedural errors that might not necessarily result in an erroneous dose to a patient, and those errors that could result in erroneous doses to patients. So, the procedural errors might be thought of as a precursor to more serious breakdowns. But they would be included in these new types of events.

(Slide) Slide 13.

We note that among those new reporting and recordkeeping requirements, we've added some to insure that the performance objectives in the new 35.35 are being addressed by the licensee, and the structure would have been changed to account for the fact that we would replace the single term "misadministration" by terms now called "therapy events" and "diagnostic events." This is going to, we believe, clarify some of those efforts by our licensees and the inspectors in determining the nature of these events more clearly.

(Slide) Moving on to page 14.

These more specific reporting requirements would clarify certain circumstances that have arisen to better inform people as to what kind of reports are required and the basis for these reports, for example, it would now be clear that a lost brachytherapy source is to be reported under Part 35, whereas in the past this has been a matter of some question and took some deliberation finally to determine that that was appropriate when in the past it would have seemed more appropriate to just simply report it under Part 20.26.

Also, there would now be a graded approach to the reporting requirements. There would be a series of reports that would be required to go to the licensee management and certainly provide him perspective on whether his Quality Assurance Program is having problems or not. Another series of reports at another level of significance would come to the NRC.

(Slide) Page 15, we turn to the issue of trying to look at the benefits and the impacts of the proposed amendment. First, we need to go back, I believe, and look at an analysis of those past misadministrations that have occurred.

The staff has analyzed the 88 therapy events

reported to NRC between 1980 and 1988. This analysis was performed by Anthony Tse of the Office of Research and Sam Pettijohn who was then with AEOD. What they did was they considered the degree to which specific provisions of the regulatory guide would have been effective in preventing each of these 88 events that occurred, assuming that these provisions would have been effectively implemented by the licensees.

They made a judgment on each event regarding the degree of certainty they would attach to the prevention of the event by implementing the regulatory guide. These judgments appear in some detail in Appendix A of the regulatory analysis that accompanies the amendment. What their judgment was was that essentially 59 of the 88 events they felt pretty strongly could have been prevented. Fourteen other events, they believed it would be likely to be prevented, and the remaining 14 events they could not determine or they were felt that they would not be prevented.

Now, this is a retrospective analysis and there's just a limited amount of assurance that we can get about what will happen in the future from it. But it's the best we can come up with to try to get some insight as to the effectiveness of these new measures.

The result of that analysis, when you just assume that of those 14 events that were likely to be preventable, just assume 50 would have been and 50 would not have been and you come up with about 75 percent of the past events may have been prevented.

I want to point out that there are others who might perform this analysis and then could arrive at different judgments. We've tried to document enough information in the regulatory analysis so that various people could make their own assessments, just from a rather superficial reading of what those events were like.

But those analyses appear fairly reasonable to me. I think that one could be optimistic that there would be a potential for reducing the rate of errors in medical use based on that analysis.

(Slide) Moving on to page 16.

However, we need to consider that there are other factors that could somewhat change this picture about the actual reduction error rate that might occur. It could depend on several factors. One factor is the Quality Assurance Programs adopted by the licensees. These programs may include measures different from those in the regulatory guide. We're giving them flexibility to do something -- you know,

to make their own judgments about what would be effective.

Even if they adopted the measures in the regulatory guide, the guide does not include provisions for independent checks of every step of the medical adminstration process. In other words, there's not always a second technician around to watch over the first during each step of the process. And while we have provisions for over checks of calculations by physicists, we don't do everything with redundancy.

Also, even when provisions for human redundancy are included, it's possible that both individuals involved can make the same error from some common cause ~~and~~ effect that might exist.

So, these kinds of factors might have a bearing on how effective the measures would be. In other words, the point is that when you're at a very low human error rate already, it may be difficult to attain some substantial reduction in error and we can't be sure about this.

Also, we need to remember that there would be varying degrees of effectiveness of implementation of the programs by the licensees. To achieve this error -- let's call it a theoretical error rate, it

would require some diligence and care on the part of the licensee staff to achieve what we think is the goal.

Finally, when you compound these certainties that I've just mentioned with the difficulties mentioned earlier in quantifying the impacts on patient health for misadministration, the fact that we have difficulty characterizing that in a clear way, it means that it's somewhat difficult for us to quantify the degree to which patient safety would be approved by the proposed amendment. This does not mean that a qualitative judgment cannot be made that there will be a benefit, however. It's just difficult to quantify.

(Slide) Continuing on page 17, we want to point out that there is that benefit also that comes from an improved ability to detect and report through the revised reporting and recordkeeping requirements that should improve our basis for inspection and enforcement.

One other point to remember is that there are measures that are in the proposed rule, such as the annual audit by the licensee in evaluation of his program and feedback to correct errors, that could find errors that we have not been able to pinpoint in our regulatory guide that could also have a beneficial

effect in reducing errors also.

(Slide) Moving on to page 18, pointing out that we attempted to quantify the cost to licensees of the various steps in this process. The cost of developing and implementing the basic Quality Assurance Program required by this amendment will depend on the mixture of medical administrations of various types that would be conducted by licensees.

That is, some licensees have combinations of different kinds of practices, diagnostics, teletherapy, brachytherapy and radiopharmaceutical therapy. We don't have a detailed breakdown of how this works out for the licensees, so we've just tried to characterize the cost to the licensees in terms of simplified categories.

MR. THOMPSON: Is that per year?

DOCTOR MORRIS: This is annual.

Let me point out on page 18 that what we're talking about here on this page when you look at the figures are annual costs then of the development for the various licensee types.

The other factor that we've considered is whether or not the licensee might be already implementing good basic quality assurance practices. We think a large number of the licensees are already

implementing the provisions of this rule and reg. guide and that there would be some fraction -- we're estimating 20 percent in our cost analysis would have to take significant measures to upgrade their programs to what's in the rule and reg. guide.

So, the range then that we estimate is it went from maybe as low as $100.00 a year that would be averaged over the first ten years of experience to develop and put into place and have the review conducted of the QA Program up to $4,000.00. The better licensees would have a smaller cost and those licensees who had a combination, say, of different therapy type practices and were not currently adopting these QA practices would have to bear the higher cost.

When you total this up for all the 7500 licensees NRC and agreement states, it would come to approximately $4 million a year and that's assuming this 80 percent are already doing most of the good things and 20 percent would have to upgrade.

(Slide) On page 19, we also mentioned that there would be some increased costs just for the revised reporting and recordkeeping requirements. Those costs could go for -- taking into account all 7500 licensees, from $270,000 per year currently to $344,000 a year after the revisions.

I should point out here that of course only those licensees who experience misadministrations or errors would have to make these reports to the NRC and make the reports to the licensee's management.

Well, upon considering the uncertainties that we've mentioned here in quantifying the benefits and the impacts of the proposed amendment, the staff, as Mr. Thompson mentioned, is unable to determine whether the increases in patient safety will outweigh the economic or other impacts. It's been our intention to develop a rule and reg. guide that would cause little or no intrusion in the licensee's ability to practice medicine as he chooses.

And we've also had an objective of minimizing unnecessary demands on personnel or staffing. However, the degree to which we've been successful that I believe will be determined to some extent through the public comment process and the pilot program.

During that time, we will be taking the initiative to continue interacting with representatives in the medical community and to continue to learn how to improve the rule and the reg. guide in our assessment of the benefits and the impacts from it.

(Slide) So, in that spirit, on page 21, we've noted our recommendation that the Commission direct the staff to issue The Federal Register notice and proceed with the pilot program.

That concludes my presentation.

CHAIRMAN ZECH: All right. Thank you very much.

MR. THOMPSON: We're prepared to respond to any questions, Mr. Chairman, that you or the Commissioners have.

CHAIRMAN ZECH: Thank you very much.

Questions of my fellow Commissioners?

Commissioner Roberts?

COMMISSIONER ROBERTS: No.

CHAIRMAN ZECH: Commissioner Carr?

COMMISSIONER CARR: On your replacing the word "misadministration" with "therapy events" and "diagnostic events," I don't have any problem with that as far as the reporting system goes, but I think when it comes time for citations or enforcement, we ought to call a spade a spade. If it's a misadministration, we should state it. It's obviously an error that got the wrong patient or the wrong dose. I don't think we ought to try to gild it over a little bit by just calling it an event.

MR. THOMPSON: I think that's the way we see it. In fact, that puts it in the enforcement arena where we can take enforcement action as opposed to --

COMMISSIONER CARR: That's okay with me. I mean there ought to be some levels like we got in 1, 2, 3, 4, 5.

MR. THOMPSON: Absolutely. Yes, sir.

COMMISSIONER CARR: If it's a misadministration, that's what we ought to tag them with, I think.

MR. THOMPSON: And the severity levels, if you've got the wrong patient -- you know, there are all sorts of -- the development of that type of enforcement program is just not available to us today and would actually be part of what we would develop on this program.

COMMISSIONER CARR: It seems to me that it would be a better use of manpower to just -- I guess you're going to look at this program in our hospital inspections that we make now that are unannounced. It seems to me that after they certify it, since they're certifying that they've got it in place, that we should pick it up in those inspections and maybe make more of those rather than use our manpower to sit and look at paper because you're going to -- you won't

really know whether that program is working or not by auditing the paperwork until you get there and look at it and see how it's working.

So, you can take that suggestion and meld it in with the pilot program and see what flops out.

MR. THOMPSON: I think that, in essence, is our intent. There is going to be some difficulties maybe with those who are right at the renewal borderline and the inspection borderline time frame. So, we'll look at that. But that is the concept --

COMMISSIONER CARR: I assume if they've applied for a license renewal and we're still looking at the paperwork, their license is extended automatically like --

MR. PARLER: It does as a matter of law. Whether or not they want to change it as a matter of policy is another question. If they don't change it as a matter of policy, as a matter of law, if it's the time of renewal, the license continues in effect.

COMMISSIONER CARR: That's still going to be the case.

MR. BERNERO: The sheer number of licensees means we have to focus the resources on the most effective use. That we see as catching the licensees nominally 20 percent at a time in the renewal process,

and that's the opportune time to have the program, look at the program, audit it, and renew.

COMMISSIONER CARR: Oh, yes. I wasn't suggesting -- I would think that a criteria for renewing their license is that they certify they have the program in place. All I was doing was saying why bother to take a hard look at it then when you can look at it as you go out and inspect the hospital?

MR. THOMPSON: I think, John, you may want to add this in discussions with the regions. We've shifted to a performance based program which really means these programs are going to really vary by the programs that hospitals have in place and the skills of the hospital people in developing programs. So, some of them may not have to do much work and some of them may need to do a lot of work. But, John, I think one of the things the regions were concerned of is what was really going to be there when they implemented these new programs and possibly not having a background and experience level with that type of program.

John, do you have anything you want to add on that?

MR. GLENN: Yes. I think probably the pilot program will give us some valuable insights into this.

One thing we may find is that there are classes of licensees who have trouble actually implementing the rule and that in-office review will serve a valuable function there in making sure that they have correctly interpreted our intent. It may be less resource intensive than doing it only through the inspection process. But I think we intend to throw the resources into the inspection area first, especially through the contractor and certainly through our routine inspection program as well.

CHAIRMAN ZECH: Commissioner Rogers?

COMMISSIONER ROGERS: Yes. I found the statements of reporting of errors in the administration of fractional doses, Section 35.34, somewhat confusing. On page 14 of the SECY, there's some statements at the last paragraph of the page that I really don't quite understand and I wonder if you could clarify that a little bit. There's a statement, "For any treatment fraction, the administered fractional dose differs from the prescribed fractional dose by more than 20 percent of the prescribed fractional dose, that's reportable." And then, "For any treatment fraction the administered fractional dose is greater than twice or less than one-half the prescribed fractional dose is another reportable

situation."

I don't understand what's the difference there between those situations that are being described. Why isn't it just 20 percent rather than 50 percent, greater than twice or less than half of the fractional dose? Do they apply to different kinds of administrations or what?

MR. THOMPSON: We'll let John Glenn try it first. If that doesn't work, we'll try the other John.

MR. GLENN: There are actually two different problems that we were trying to address here. One is where there is an error in the delivery of a single fraction which is outside the bounds of what we consider to be reasonable. That's where the twice or less than one-half would come in. That would be reportable to the NRC purely on the merits of one administration given on one day.

Now, there's also the problem of when the plan is written down incorrectly and there's going to be an accumulation of errors in the fractions that are being given. So, let's say that it's not going to be off by 50 percent, but each of the fractions it's going to be off by 20 percent. It would be reportable when the error that has accumulated in terms of the

dose delivered to what was really prescribed initially is equal to ten percent of the total dose to be delivered --

COMMISSIONER ROGERS: Yes, I understood that. But then I didn't understand the other two differences. Now, I don't want to take a lot of time to pursue this right here because maybe everyone else isn't interested in it. But I found it confusing and I just hope that someone who has to apply this does understand what those differences are.

So, it looks to me like the same words are describing two different kinds of fractional errors and I don't see what's different. The language is all the same. "For any treatment fraction, the administered fractional dose differed from the prescribed fractional dose by more than 20 percent of the prescribed fractional dose. For any treatment fraction," same words, "the administered fractional dose, same words, is greater than twice or less than one-half the prescribed fractional dose."

COMMISSIONER CARR: You can see the last column because if you only report the more ones, you don't get the guy that didn't get enough treatment.

COMMISSIONER ROGERS: Yes, but why not just the less --

COMMISSIONER CARR: But now whether the 20 percent makes into more than 50 percent, I don't know.

MR. BERNERO: -- derive from the -- the one is the total and one is the per treatment. If you go to --

CHAIRMAN ZECH: Let's just one at a time here for the reporter, please.

All right. Who is on?

MR. TELFORD: If I could direct your attention to page 28 and 29 of the SECY paper, you can see how the 20 percent times two is used. In the case of the 20 percent, that report goes to licensee management and quality assurance, since that's a warning level.

COMMISSIONER ROGERS: Okay. All right.

MR. TELFORD: At the 2 level in Item B there on the page --

COMMISSIONER ROGERS: That goes to us.

MR. TELFORD: -- that's the warning-- that's the alarm.

COMMISSIONER ROGERS: Oh, okay. All right. Okay. I see. All right. It's a question of where is it reported to. Yes, all right. I see the point. Yes, it just wasn't clear to me in that particular section.

On your benefit impact comparison, did you consider what the possible benefit would be with respect to insurance rates, medical malpractice insurance rates of putting this in? Would that be a benefit?

DOCTOR MORRIS: We didn't consider it as far as -- I'm pretty sure we didn't consider it.

COMMISSIONER ROGERS: I don't know if there would be an impact on that or not, but you are looking at costs and you are looking at benefits and the only quantitative benefits -- well, I haven't seen any quantitative benefits exactly in this. You don't know how to assess those and then the economic benefit might be as some impact on medical malpractice insurance rates. If this were in effect, they might change. I don't know. Probably go up.

COMMISSIONER CARR: Probably change if we make them reportable.

COMMISSIONER ROGERS: There might be some effect.

MR. BERNERO: Well, excuse me. If I could add, when we edge out of the direct nuclear costs and nuclear benefits, we get into things like this might divert resources from other medical safety uses. By the same token, there could be favorable effects that

the installation of better practices here can instill better practices in adjacent non-nuclear medicine.

COMMISSIONER ROGERS: Right.

MR. BERNERO: And it's extremely difficult to quantify those at all and, of course, to deal with them, they're outside our jurisdiction.

COMMISSIONER ROGERS: It's really a question, not a direction, which is whether you looked at it.

MR. BERNERO: Yes.

COMMISSIONER ROGERS: But just on that matter, the language in the SECY indicates that the efficacy of the proposed QA Program will be determined through the pilot program. But that word "efficacy" is one that we had a little trouble with earlier, I know. In the June '88 SECY, the staff stated that because of the low probability of misadministrations, something that's referred to here repeatedly, a pilot program may not prove the efficacy of the rulemaking. It's just that the data is so meager.

So, is that still an appropriate word? It came out or was disclaimed in an earlier version and now it's back in there again.

DOCTOR MORRIS: I think we may be using it in the latter sense, I believe. What I had in mind

was that just the ability for the licensees to implement these measures and to feel like they were making progress in beefing up their program would be what would be tested in the pilot program.

The idea that you could somehow see in any short-ranged time frame a reduction in the rates may be somewhat optimistic and I'm not sure that that could happen. That may be the difference between the two uses of the word here. I think it may take some time after this rule would be in place before you could go back and reassess the data and see whether the reduction --

COMMISSIONER ROGERS: Really referring to something else, in a sense, in the use of that word.

Do you expect that this petition for rulemaking that came from the Society of Nuclear Medicine, the American College of Nuclear Physicians, will have any effect on the proposed program?

DOCTOR MORRIS: The standard that they're developing?

COMMISSIONER ROGERS: Well, there is now a petition for rulemaking that was received last week. Do you expect that that would have any impact on the program or its reporting requirements?

MR. BERNERO: I wouldn't think so. Not the

QA rule. No, I don't think it would impact it. If we proceed favorably, this is what I call the FDA petition, that the FDA authorizes.

COMMISSIONER ROGERS: Yes, right.

MR. BERNERO: If we proceed in favor of that position, there's a little more of their practice-- they have more flexibility. In a sense, there's a broader range for the QA internal process to work for them. But that's a second order effect, I would think. I don't see a direct link.

COMMISSIONER ROGERS: Fine. Thank you very much.

CHAIRMAN ZECH: All right. Commissioner Curtiss?

COMMISSIONER CURTISS: Just one quick question. If your figure of 75 percent is in the ballpark, roughly 75 percent of the events would be prevented by this rule. Do you have a feel for what the overall dose reduction would be from this rule?

DOCTOR MORRIS: No. The overdoses -- we've got some experience from the past and I suppose we could go back and calculate those doses that would have been averted if we assume those events had not occurred. We have not done that. But in general, our feeling is that the variety of situations is so large

that it would be difficult to try to project into the future.

COMMISSIONER CARR: Some are under doses.

MR. BERNERO: Yes. I would like to just interject. We've just gone through this process in another arena. It's very difficult in medical administration to separate the good radiation from the bad radiation from the missing radiation, the under doses. The figure of merit or demerit, you know, averted dose, just breaks down. It's very difficult to use.

COMMISSIONER CURTISS: That's all I have.

CHAIRMAN ZECH: In the pilot program that you developed, how have you determined who will participate in this program? Did you go for volunteers or what did you do in that regard?

DOCTOR MORRIS: Once the Commission decides to move forward --

CHAIRMAN ZECH: Yes. Have you thought about that?

DOCTOR MORRIS: -- we will begin to contact the various potential volunteers. There would be a Federal Register notice that would accompany the rule that would describe the pilot program and ask for volunteers. And also there would be another process we

would go through to make sure that we have a balance of different kinds of licensees. So, there would be two different mixes in the pilot program. We will be making an effort to get volunteers through The Federal Register.

CHAIRMAN ZECH: All right. Thank you.

Well, unless there are any further questions from my colleagues, I would just like to thank the staff for a very useful, informative briefing. Frankly, I'm encouraged by the progress that has been made in this very important rulemaking effort and I commend the staff and others who have assisted you in contributing to development of this rule.

I note that the staff has worked very closely with the medical community and we appreciate their support for this rule, recognizing that there are those who don't think it's necessary, but at least they have helped, I understand, in this development. We have tried to develop a performance based rule, making it a reasonable rule. I know that you're developing this pilot program and you've put a lot of effort into this whole initiative.

We want a good rule. But I think as much as anything, we do recognize that the importance of this rule is to enhance public health and safety. We do

think there's room for improvement in spite of the excellent record that we see. But in all human endeavor, improvement is usually possible. We expect the medical community to strive for improvement.

During my time on the Commission, I've had a chance to visit a number of hospitals. I've been impressed by the hospitals I've visited, with their dedication to professionalism of the medical community, those who are striving to diagnose and treat patients. My observation is that they are doing this in a very commendable manner and the rule certainly is not meant to intrude on that continued fine performance of the medical community.

But the rule is intended to see if we can't make some improvement and even make an excellent record even better because we're dealing with human lives and it's important that we and the medical community do what we can to seek improvement. I believe that with the medical community's continue dedication to the safety of their patients, that this improvement is possible.

I would ask my fellow Commissioners to reflect the next few days on today's discussions and the paper before us in SECY-89-171 and vote when you feel you are ready.

Before we -- let me ask my fellow Commissioners for any additional comments before we conclude.

But before we conclude the day, let me congratulate Commissioner Carr on his selection by President Bush to be the Chairman of the Nuclear Regulatory Commission and to relieve me on the lst of July. I know Commissioner Carr will receive the continued fine support of the Commission that I've received and also the continued fine support of our staff.

So, Commissioner Carr, you have my very sincere congratulations and best wishes for your success as Chairman of the Nuclear Regulatory Commission.

COMMISSIONER CARR: Thank you.

CHAIRMAN ZECH: Are there any other comments to make? If there are not, we thank you very much.

Again, we stand adjourned.

(Whereupon, at 2:57 p.m., the hearing 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: BRIEFING ON PROPOSED RULE ON BASIC QUALITY ASSURANCE IN RADIATION THERAPY
PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: JUNE 13, 1989

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

PROPOSED AMENDMENT TO 10 CFR 35

BASIC QUALITY ASSURANCE PROGRAM

AND REPORTING REQUIREMENTS

STAFF PRESENTATION TO THE COMMISSION

JUNE 13, 1989

OUTLINE OF BRIEFING

- BACKGROUND
- MISADMINISTRATION RATES
- REGULATORY OBJECTIVES
- SUMMARY OF AMENDMENTS TO PART 35
- REGULATORY GUIDE
- MODIFICATIONS OF REPORTING AND RECORDKEEPING REQUIREMENTS
- BENEFITS AND IMPACTS
- RECOMMENDATIONS

BACKGROUND

- Proposed Medical QA Rulemaking of 1987
- Response of Medical Licensees
- Staff Options Paper & Recommendations (SECY-88-156)
- Commission Decision (SRM of 7/12/88)
- Staff Interaction with Industry

MISADMINISTRATION RATES

- Misadministrations reported to NRC (1980-1988)
  - 88 Therapy related events
  - ~ 3200 Diagnostic related events
- Estimated misadministration rate - all licensees
  - 30 Therapy and 1200 diag. events/yr

REGULATORY OBJECTIVES

- Reduce Rate of Errors in Medical Use of Byproduct Material
- Establish General Requirement for Basic Quality Assurance Programs for Medical Use
- Provide Guidance on QA Program Elements Acceptable to the NRC
- Improve Detection and Correction of Breakdown in QA in Medical Use

SUMMARY OF NEW SECTION 35.35

- Requires Implementation of NRC Approved Basic QA Program
- Specifies Objectives of QA Program
- Requires Regular Program Audits to Verify Compliance
- Requires Evaluation of Audits by Licensee Management
- Requires Prompt Modification of Program to Prevent Recurrence of Errors

SPECIFIC OBJECTIVES OF MEDICAL QA PROGRAM

To Ensure That

- Any medical use is indicated for patient's medical condition.
- Prescriptions or Diagnostic Referrals are Documented & understood.
- Medical use is in accordance with the prescription or the Diagnostic Referral and Clinical Procedures Manual

SPECIFIC OBJECTIVES OF MEDICAL QA PROGRAM

To Ensure That

- Patient Identity is Verified.
- Unintended Deviations from Prescriptions or Diagnostic Referrals and Procedures Manual are identified & evaluated.

SPECIFIC OBJECTIVES OF MEDICAL QA PROGRAM

To Ensure That

° Brachytherapy & Teletherapy treatment planning is in accordance with the prescription.

IMPLEMENTATION OF 35.35

- THE EFFECTIVE DATE IS 6 MONTHS AFTER PUBLICATION OF FINAL AMENDMENT.
- BY THE EFFECTIVE DATE, SUBMIT WRITTEN CERTIFICATION THAT A PROGRAM HAS BEEN IMPLEMENTED.
- SUBMIT PROGRAM TO REGIONAL OFFICES AT TIME OF LICENSE RENEWAL.

REGULATORY GUIDE

- PROVIDES AN ACCEPTABLE WAY TO MEET THE REQUIREMENTS IN PROPOSED SECTION 35.35 FOR BASIC MEDICAL QA PROGRAM.
- ADDRESSES EACH OF THE PERFORMANCE OBJECTIVES OF THE QA PROGRAM REQUIRED BY SECTION 35.35.

REGULATORY GUIDE

- PROVIDES GUIDANCE FOR LICENSEE TO DEVELOP BASIC QA PROGRAM.
- WILL BE EVALUATED THROUGH PILOT PROGRAM.

MODIFICATION TO REPORTING AND RECORDKEEPING REQUIREMENTS

- Objective is to better identify events indicating breakdown in Quality Assurance.
  - Procedural errors.
  - Erroneous doses to patients

MODIFICATION TO REPORTING AND RECORDKEEPING REQUIREMENTS

- Requirements added to assure each of performance objectives in 35.35 is addressed.
- Structure revised to account for replacing single term "Misadministration" with "Therapy Events" and "Diagnostic Events."

MODIFICATION TO REPORTING AND RECORDKEEPING REQUIREMENTS

- Clarifications (e.g. lost brachytherapy sources)
- Graded approach to reporting
  - To licensee management
  - To NRC

ANALYSIS OF PAST MISADMINISTRATIONS

- STAFF ANALYZED 88 THERAPY EVENTS REPORTED FROM 1980-1988.
- CONSIDERED EFFECTIVENESS OF SPECIFIC PROVISIONS OF REG. GUIDE IN PREVENTING THESE EVENTS.
- ANALYSIS SUGGESTS APPROXIMATELY 75% OF EVENTS COULD HAVE BEEN PREVENTED BY BASIC QA.

BENEFITS

- PROPOSED AMENDMENTS AND R.G. HAVE POTENTIAL TO REDUCE LIKELIHOOD OF MISADMINISTRATIONS DUE TO SIMPLE HUMAN ERROR.
- ACTUAL REDUCTION IN ERROR RATE DEPENDENT ON EFFECTIVENESS OF QA MEASURES AND THEIR IMPLEMENTATON.
- INCREASE IN PATIENT SAFETY DIFFICULT TO QUANTIFY.

BENEFITS

° REVISED REPORTING AND RECORDKEEPING SHOULD PROVIDE AN IMPROVED BASIS FOR INSPECTION AND ENFORCEMENT.

IMPACTS

° ANNUAL COSTS OF DEVELOPMENT AND IMPLEMENTATION OF BASIC QA PROGRAM
  - DEPEND ON TYPE OF LICENSEE.
  - DEPEND ON DEGREE TO WHICH LICENSEE ALREADY IMPLEMENTS GOOD BASIC QA PRACTICES.
  - RANGE FROM ~ $100 TO ~ $4000 PER LICENSEE.
  - FOR ALL 7500 LICENSEES ~ $4M.

IMPACTS

° INCREASED COSTS OF REPORTING & RECORDKEEPING REQUIREMENTS

- TOTAL FOR 7500 LICENSEES

  $270,000/YEAR ⟶ $344,000/YEAR

- FOR AVG. LICENSEE

  $36/YEAR ⟶ $46/YEAR

BENEFIT-IMPACT COMPARISON

- UNCERTAINTIES IN QUANTIFYING BENEFITS AND IMPACTS.
- STAFF UNABLE TO DETERMINE WHETHER INCREASES IN PATIENT SAFETY WILL OUTWEIGH ECONOMIC AND OTHER IMPACTS.
- PUBLIC COMMENT PROCESS AND PILOT PROGRAM PROVIDE OPPORTUNITY TO LEARN MORE ABOUT BENEFIT-IMPACT BALANCE.

RECOMMENDATIONS

THAT THE COMMISSION APPROVE

- PUBLICATION OF PROPOSED REVISION TO PART 35.
- PUBLICATION OF REGULATORY GUIDE.
- STAFF PLANS TO CONDUCT PILOT PROGRAMS