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Ann Riley & Associates
Court Reporters
1625 I Street, N.W., Suite 921
Washington, D.C. 20006
(202) 293-3950

D I S C L A I M E R

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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BRIEFING ON STATUS OF PROPOSED RULEMAKING

ON BASIC QA IN RADIATION THERAPY AND RELATED ACTIVITIES

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PUBLIC MEETING

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Nuclear Regulatory Commission

Room 1130

1717 H Street, N.W.

Washington, D.C.

March 22, 1988

The Commission met in open session, pursuant to notice, at 2:04 p.m., the Honorable LANDO W. ZECH, JR., Chairman of the Commission, presiding.

Commissioners Present:

LANDO W. ZECH, Chairman

THOMAS M. ROBERTS, Commissioner

FREDERICK M. BERNTHAL, Commissioner

KENNETH ROGERS, Commissioner

KENNETH M. CARR, Commissioner

Staff and presenters seated at table:

S. CHILK - SECY
S. PETTIJOHN
N. McELROY
J. TAYLOR
B. MORRIS
B. BERNERO
W. PARLER - OGC

Audience Speakers:

H. THOMPSON

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

CHAIRMAN ZECH: Good afternoon, ladies and gentlemen. The purpose of this afternoon's briefing is to discuss the rulemaking initiatives underway for quality assurance for medical uses of isotopes.

This is an information briefing and no vote is expected.

Many of you know that the Nuclear Regulatory Commission is proposing to amend its regulations concerning the medical use of by-product material.

The proposed amendments would require medical licensees to implement quality assurance steps that would reduce the chance of misadministrations.

The Commission is also considering a more comprehensive program for quality assurance in medical use and in the standard of care.

To discuss these issues, we have with us today representatives from the Office of Nuclear Materials Safety and Safeguards, the Office of Research, and the Office for Analysis/Evaluation of Operational Data.

Before we begin, do any of my fellow Commissioners have any opening comments to make?

[No response.]

CHAIRMAN ZECH: If not, Mr. Taylor, will you begin, please.

MR. TAYLOR: Mr. Chairman, I'll begin by introducing the presenters today. On my immediate left is Mr. Norm McElroy from NMSS, Mr. Sam Pettijohn from AEOD; my immediate right, Mr. Billy Morris from research and Bob Bernero, the Deputy Director of NMSS.

The basic introduction and discussion will be led by Mr. Bernero. Bob.

MR. BERNERO: Thank you. Gentlemen, just to put this presentation today in some context, I'd like to point out to you that on March 8th you received a Commission paper which contained an advanced notice of proposed rulemaking regarding training and experience criteria for the medical use of by-products. That is a separate initiative from what we're talking about today, and that is a Commission directive to get public comment on such criteria.

Secondly on March 14th you received a Commission paper on the medical use program. This is a broad plan which grew out of the strategic planning process which you have reviewed, and which is consistent with our FY '88, '89 budget and that covers a five-point program for the overall enhancement of the regulatory oversight of medical uses, the by-product material.

Neither of these two papers is the subject today, but today's subject is of course related to them and can

be related to them.

They all fit together in our broad plan to improve the regulatory oversight of medical uses of by-product material.

As the Chairman said, we're in the midst of a basic QA rule which goes toward the quality assurance for procedures in radiation therapy and in diagnostic procedures where there's a potential for high dose.

We also have an advanced notice for a broader more comprehensive QA program that would cover everything that we regulate.

Now we're going to talk now as an interim discussion. We don't have the final rule. You'll hear shortly that it is in the final review process and you can expect to see it at the end of April. This is an excellent opportunity for discussion of it before it's submitted, and we're going to have first some context in the trends in misadministration that we're aware of recently; we'll have Sam Pettijohn of AEOD present those.

Then Billy Morris of Research is going to cover the QA rule itelf, the public comments on it.

Norm McElroy of NMSS is going to discuss the recent meeting of the Advisory Committee on the Medical Uses of Isotopes, and lastly I will address briefly the regulatory alternatives that we face now. So let me turn

it over to Sam right now.

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

MR. PETTIJOHN: Viewgraph No. 2, please.

[Slide.]

MR. PETTIJOHN: Mr. Chairman, the viewgraph by the AEOD of the data on misadministration covers therapy misadministrations and diagnostic misadministrations that involve greater than 100 microcuries of iodine.

The 100 microcuries of iodine limit was set in order to capture a specific type of diagnostic misadministration. Viewgraph No. 3, please.

[Slide.]

MR. PETTIJOHN: That AEOD data covers November 1980 through 1987 when the rule -- the effective date of the rule was November 1980. There has been a variation over the years in the number of misadministrations reported, both therapy and diagnostic; however, we're not able to attribute anything specifically or to determine any specific trend.

The only milestone in this period was in 1986 when NRC sent a copy of the therapy misadministration report that AEOD wrote out to the licensees.

We categorized two types of errors for these misadministrations and they had to do with the lack of

redundancy and inadequate communications of instructions to personnel. Viewgraph No. 4, please.

[Slide.]

MR. PETTIJOHN: Based on the reported data, we calculated an error rate for both -- this is an error rate per patient for both therapy and the diagnostic ones that involve iodine, and the error rates are 10 to minus 4, 10 to 5 and based on the number of NRC licensed facitilites. Viewgraph No. 5, please.

[Slide.]

MR. PETTIJOHN: In addition to looking at the error rate, we also looked at other factors that we considered significant in regard to misadministrations. And one is we noted that since 1976, there have been five events in which -- therapy events that involved multiple patients -- the number of patients would range from 8 to about 400, and we also looked at 1984 through 1987 data in regard to abnormal occurrences.

1984 through 1987 was selected because the abnormal occurrence reporting was changed in 1984 to specifically address misadministrations.

COMMISSIONER BERNTHAL: Let's see, you said the numbers ranged from what again? To 400?

MR. PETTIJOHN: The number of patients. In other words these were single events that involved multiple

patients, and the first was in 1976 at Riverside that involved the 400 patients, and so the lowest number of patients involved was 8.

COMMISSIONER BERNTHAL: But we have not had a reporting requirement before 1980 so we really don't know what happened between '76 and '80, I would assume, except for the most egregious cases; isn't that true?

MR. PETTIJOHN: Well, except for the fact that these cases were ones that were reported to NRC and that --

COMMISSIONER BERNTHAL: Right. Right.

MR. TAYLOR: That became known to us.

MR. PETTIJOHN: But we don't have the number -- we don't have the total --

COMMISSIONER BERNTHAL: Right, but we don't know how many weren't reported.

MR. PETTIJOHN: That's correct.

COMMISSIONER BERNTHAL: Okay.

MR. PETTIJOHN: All right.

COMMISSIONER CARR: Well, even now we don't have the agreement states reporting to us yet, do we?

MR. PETTIJOHN: That's correct.

COMMISSIONER ROGERS: Well, can you just say something about that error rate table so that these numbers fall into -- the error rate for misadministrations

table. Those are all small numbers. What period of time does this cover? When, was this one year or --

MR. PETTIJOHN: Well, it covers a seven year period from November 1980 through 1987, and it really just takes --

COMMISSIONER ROGERS: This is for that whole period since 1980 then?

MR. PETTIJOHN: That's correct. In fact, very quickly -- back up to Slide No. 1. There is a slide here that shows the calculation in error rate.

COMMISSIONER CARR: If you want to title that properly, it should be "Error Rate for Reported Misadministrations", right?

MR. PETTIJOHN: That's correct. Essentially it's the number of patients in a seven year period over the number of events that were reported taking into consideration that this is only for NRC licensees.

COMMISSIONER ROGERS: So this one -- or so that involves 400 patients, that must have been prior to 1980, then?

MR. PETTIJOHN: It was prior to 1980, that is correct.

COMMISSIONER ROGERS: Was that a teletherapy --

MR. PETTIJOHN: It was a teletherapy misadministration.

COMMISSIONER ROGERS: Because all the others are a one-to-one relationship between the number of patients and the number.

MR. PETTIJOHN: Except for one. And in the 1980 through 1987 data, there was one misadministration that involved 53 patients and that's why in teletherapy we have 83 patients and 31 events.

COMMISSIONER ROGERS: Yes, that's right. Okay. Thank you.

MR. PETTIJOHN: Okay. You're welcome. Viewgraph No. 5, please.

[Slide.]

MR. PETTIJOHN: To complete the Viewgraph No. 5, in regard to abnormal occurrences we looked at those for 1980 through 1987. There were 50 misadministrations during that period and 29 of those were reported as abnormal occurrences.

We also looked at some evaluations by medical consultants of adverse effects on patients, and roughly out of the group that were abnormal occurrences, 11 of the patients could likely, based on consultant reports, have some adverse health effects.

Overall, the misadministrations accounted for about 25 percent of abnormal occurrences reported for that period. Viewgraph No. 6, please.

[Slide.]

COMMISSIONER BERNTHAL: How did they determine how somebody could likely suffer adverse health effects?

MR. PETTIJOHN: Well, in the cases involving -- these cases involving iodine, there are cases where people got several thousand rads dose to the thyroid, and the reporting requirements for misadministrations required licensees to indicate an estimate of health effects on the patient, and these are based on the fact that there's a probability the patient would be hypothyroid -- the patient's thyroid would be ablated and therefore that being the health effect.

In other cases where the medical consultant did a more in-depth study, they based it mostly on similar cases in which patients had received light doses of radiation and then looked at what the outcome was for those patients.

COMMISSIONER BERNTHAL: Well, I don't know what the threshold might be, and somebody here must know, for physical effects to the thyroid which may be a different thing than adverse health effects. I do know that roughly speaking for whole-body doses, I believe around 20 R you begin to detect -- it's detectable in the -- the effects on the blood. It's somewhere in that neighborhood; and certainly at 50 R, it's easily detectable and one could as

well define that then as being an adverse health effect.

I don't know that the threshold is so tidy in the case of the thyroid, but I'm wondering how you made the determination. If it's detectable, then one could argue that's an adverse health effect, whether or not they end up with nodules or cancer of the thyroid, it seems to me.

MR. PETTIJOHN: That's correct. Except the cases again -- well, the consultant and licensees reports were based on a fairly high likelihood, in other words in the case of thyroid. Doses given to patients to ablate thyroids are roughly these same doses so that per patient, yet in five millicuries of iodine --

COMMISSIONER BERNTHAL: Well, that's a huge dose and therefore my point that that's a very high threshold to be using to make the determination for adverse health effects it seems to me -- I would tend to choose, and we certainly elsewhere in our regulatory actitivities tend to choose, levels at which -- well, let's see. What was the -- I'm trying to remember the context, this came up a long time ago, but we certainly tend to view clear health effects threshold for whole body dose as being that point at which it's a detectable effect on the blood without reaching the question over the long term anything truly nasty is going to happen.

MR. PETTIJOHN: I guess these were more acute

effects versus --

COMMISSIONER BERNTHAL: Exactly. So it seems to me you're not using quite, I don't know whether you or who decided, but it seems to me the threshold being used here does not really comport with the threshold that we're using elsewhere to determine adverse health effects.

But I just wanted to make that point. Let's go ahead.

MR. PETTIJOHN: Okay. In summary, the conclusions, in fact the error rate as we saw was very low; however, we thought that that notwithstanding that misadministrations are potentially injurious to patients, that there are this potential for -- or there is a potential for events that involve multiple patients and we also noted that a substantial number of misadministrations are reported as abnormal occurrences.

That concludes the AEOD presentation.

CHAIRMAN ZECH: All right. Thank you very much.

MR. TAYLOR: Mr. Morris.

COMMISSIONER BERNTHAL: Let me ask one other question before we get off the AEOD tabulations here of data, and I understand that that's essentially what you do.

MR. PETTIJOHN: Correct.

COMMISSIONER BERNTHAL: You also indicate on the

last point that misadministration AOs were 25 percent of the total. Is that really representative of the trend in the last -- in the more recent past? It was my impression that it was pressing on and up during the times --

MR. PETTIJOHN: Well, this is up through 1987, in other words 1984 through 1987 data on the misadministrations as well as the abnormal occurrence reports for that period.

Prior to 1984, the abnormal occurrence reporting did not specifically address the types of events that occurred in misadministrations, so you know I'd say if you look at '85 through '87 it looks about the same.

COMMISSIONER BERNTHAL: '86 and '87, though, the numbers that I have been given seem to indicate more like 45 percent.

MR. PETTIJOHN: If you take the -- well, then the earlier years and numbers are lower than they are in the latter.

COMMISSIONER BERNTHAL: And granted, there has been more attention focused on this in recent times. '86 and '87, that's a little bit reminiscent of fitness for duty programs, there's no problem until you start looking and then you find some.

COMMISSIONER CARR: Well, I think it's shaky to draw any conclusions on these numbers if you don't have

all the reports in, and if we're not getting reports from the agreement states, and we haven't gotten reports since '74 to '80 from anybody, why, I'm not sure our database is any good. Having said that, let's proceed.

COMMISSIONER BERNTHAL: That's my concern. I agree.

CHAIRMAN ZECH: Let's proceed.

MR. TAYLOR: It's built on the NRC database.

COMMISSIONER BERNTHAL: Yes. Yes.

CHAIRMAN ZECH: Let's proceed.

MR. MORRIS: The purpose of this part of the presentation is to provide you first the status report on the development of the final rule on basic quality assurance in radiation therapy, and then a much more brief discussion of the advance notice of proposed rulemaking on comprehensive quality assurance.

The objective of this rulemaking is to codify the regulations' basic quality assurance requirements that would reduce misadministrations due to human errors, such as those just described in Mr. Pettijohn's presentation.

The proposed rule on basic QA was published last October 2nd for a 60 day comment period ending on December the 1st.

[Slide.]

MR. MORRIS: When the comment period ended, the

Office of Research assumed the lead responsibility for the rulemaking from NMSS.

Mr. Anthony Tse of our office was assigned the task to be the task leader, and in this process, he assumed the efforts -- he had the benefits of the efforts of Mr. McElroy, who is over here, from NMSS; Mr. McElroy has continued to assist Mr. Tse and us in the Office of Research in this project.

Mr. Tse also has had the benefit of assistance from expert consultants in the field of radiation therapy and has visited a number of hospitals to get a first-hand impression of how the rule can be put into practice. Next slide, please.

[Slide.]

MR. MORRIS: This time we have analyzed the public comments and have revised the rule according to the information we gained from those comments, and we have developed a regulatory analysis, and we've sent these documents out for division review both to headquarters and to the regions.

Based on comments from that review, we have revised the package again and I've just sent the rule out for office comments and concurrence. We expect office comments by April the 1st and it's our objective to revolve those comments, achieve office concurrences, and

have a package that EDO can concure in to send to the Commission by the target date of the end of April. And that was the date that we had been directed to have this prepared, and we're on schedule and expect to meet that schedule. Next slide, please.

[Slide.]

MR. MORRIS: We received 69 comment letters on the rule. They came from a variety of sources: 41 from hospitals, 6 from private physicians, 7 from professional associations, 5 from state and regulatory agencies, 2 from an instrumentation manufacturer, and 8 from individuals. Next slide, please.

[Slide.]

MR. MORRIS: The degree of support for the rulemaking varies: 25 percent of those responding supported the rule. Those included the Commission on Radiation Therapy of the American College of Radiology, and the College of American Pathologists.

20 percent opposed the rule, in general terms. Those included the American College of Radiology, and the Society of Nuclear Medicine.

COMMISSIONER ROBERTS: Pardon me. Is the Commission on Radiation Therapy of the American College of Radiology a subset of the American College of Radiology?

MR. MORRIS: That is correct, yes.

COMMISSIONER ROBERTS: All right.

MR. MORRIS: Of the other respondents, 55 percent had specific suggestions for changes to the rule. Some of the representatives in that category included the American Association of Physicists in Medicine, the American College of Medical Physics, and the National Council on Radiation Protection. Next slide, please.

[Slide.]

MR. MORRIS: Just to give you some perspective of the nature of comments we received --

COMMISSIONER BERNTHAL: Bill, excuse me. Commissioner Roberts raises an interesting point that I think needs to be stressed.

MR. MORRIS: I'm sorry. I thought we got the answer. Let's go back to the previous slide.

[Slide.]

COMMISSIONER BERNTHAL: I just wanted to verify that apparently the College of Radiology, I don't know whether it works on a recommendation system or not, but presumably they were well aware of the views and comments of the Commission on Radiation Therapy and yet they chose to take the opposite point of view; is that true?

MR. McELROY: These two organizations, the American College of Radiology and its Commission on Radiation Therapy, may be speaking from different

perspectives in the desire to further quality assurance. The commission -- its Commission on Radiation Therapy is likely to support this endeavor. The Board of Directors of the American College of Radiology may be responding to different concerns of greater magnitude.

COMMISSIONER BERNTHAL: Well, that seems clear, but can you be a little more specific, perhaps?

MR. McELROY: I'd prefer not without reviewing those comment letters again.

MR. MORRIS: I can point out at least one difference between the two. The Commission on Radiation Therapy are essentially oncologists.

COMMISSIONER ROBERTS: Is what?

MR. MORRIS: Oncologist. Those are physicians who treat cancer. The American College of Radiology includes physicists as well physicians, so they do have a slightly different perspective, but it's very difficult -- it would be difficult for us to tell you more than that. That just tells you something different about the make-ups of --

COMMISSIONER BERNTHAL: Medical physicists or --

MR. MORRIS: I think they're physicists.

COMMISSIONER BERNTHAL: Did you say physicists?

MR. MORRIS: Medical physicists and physicians.

COMMISSIONER BERNTHAL: Okay. Okay.

MR. MORRIS: Go on to the next slide now, Joy.

[Slide.]

MR. MORRIS: We've generalized some of those comments that we've received just to give you an idea of the kinds of comments that we are seeing where there is opposition.

We have an assertion, for example, that because the probability of misadministrations is already very low, the rule is not needed; others said that additional regulation would not reduce the frequency of human errors, and there was also a concern that additional requirements would increase the overall costs of radiation therapy.

COMMISSIONER ROBERTS: Does the Staff take a position on that third one?

MR. MORRIS: On the third one, what we have done is taken advantage of the information provided by those commentors who gave us specific comments, and Mr. Tse's advice from his consultants and his visits to the hospitals, and have found ways where we believe we can reduce the burden from the rule without having significant impact on its effectiveness in reducing the frequency of human error in misadministrations.

So our position is simply that where we have been able to discover that there are parts of the originally

proposed rule which we can eliminate without eliminating the benefit of the rule, we've done so. And we've done also a cost -- we've made some estimates of the costs and I'll go on to some of those here later and show you what we believe those costs may be like just to give us all of us a chance to judge for ourselves how much the burden might be.

MR. BERNERO: Mr. Roberts, please keep in mind this is still a fluid situation.

COMMISSIONER ROBERTS: I understand.

MR. BERNERO: There isn't a final Staff position yet.

COMMISSIONER ROBERTS: I understand.

COMMISSIONER CARR: What was the substance of the argument for Bullet 2?

MR. MORRIS: It was the idea that by providing simple redundancy checks, we would not be able to get at the issue of human error and reduce it significantly.

In that regard, as I will be showing you in a moment, Mr. Pettijohn and Mr. Tse have done an analysis in which they have analyzed those events that have occurred and have estimated that maybe 80 percent of the reported events, that's all they've had to operate on, might be eliminated by the rule if it were effectively implemented. That's their judgment at this time, and as Mr. Bernero

said, what I'm telling you today is preliminary. We have judgments by part of the Staff that have not been reviewed completely, but that's our preliminary estimate. But their concern was it just wouldn't be able to do what we wanted to accomplish.

COMMISSIONER CARR: The implication is that they wouldn't pay any attention to it anyway?

MR. MORRIS: That was part of the comment that we got. If someone were insistent, you know, on doing something wrong, you would do it, and the only question --

COMMISSIONER CARR: I would say it's less likely that two would do it wrong than one.

MR. MORRIS: If you're doing a calculation, is it likely that both are going to make the same error, and that would be the basis for the effect of the rule.

COMMISSIONER BERNTHAL: Well, without commenting on the details, and I understand there's concern over the proposed rule as it sits and there may be elements of it that aren't quite the way they need to be, it just seems to me, while I accept the proposition that you may never reduce the frequency of human errors, that's almost a given. Of course people are going to make mistakes and they'll probably continue to make them at roughly the same frequency as they have throughout human history; but the question is, how do you try and minimize the effects of

those mistakes? And that really is, it seems to me, the purpose of any additional requirements one might place on here, that is really a quality assurance.

You aren't going to assure that there aren't mistakes, people will continue to make mistakes; but as somebody here said, if you got two people checking in the simple sense, then the odds are considerably reduced that they'll make the same mistake at the same time.

COMMISSIONER ROGERS: We're looking at and analyzing these 69 comments very assiduously, but 69 is a very small number, it seems to me.

What's the base of hospitals that might be affected by this that we would expect some response from? 41 doesn't look to me like a very large number nationally.

MR. McELROY: We have about 250 teletherapy licensees under NRC jurisdiction and there are about 800 nationwide if this were applied as a matter of compatibilty.

I believe we would capture approximately 800 hospitals that provide the high level brachy therapy which is implanting a radioactive seed inside the patient, and of course there's overlap in those populations.

Moving to nuclear medicine, virtually every hospital in the coutry provides iodine therapy for its patient class.

COMMISSIONER ROGERS: Well, could you comment on why there seems to be so few responses on this? Is there any feeling about that?

MR. MORRIS: The only thing I would comment on, if you will remember there were a number of these comments that came from groups and so they -- to some extent they are representing groups of individuals to the extent they can speak for those groups, and a larger portion of the community may be represented and shown by the BEIR number.

COMMISSIONER ROGERS: Well, are any of these groups really representing hospital groups? I don't see any that read that way to me particularly.

MR. McELROY: I believe most of the associations that commented are representing either a particular group of physicians or the physicists, and I know two of the organizations did form ad hoc comment groups to respond to these notices, so the membership perceived that their invidual comments were reflected in those association comments.

COMMISSIONER ROGERS: Okay.

CHAIRMAN ZECH: All right. Let's proceed.

MR. MORRIS: Next slide, please.

[Slide.]

MR. MORRIS: As I mentioned, we are looking at the rule carefully based on the comments received, and

looking at where we need to modify the rule or think it would be prudent to do so, and we've identified a number of areas where we think some changes are warranted.

As I said before, the basis for this is that we think in most of these cases that they would have minimal impact in having diluted the effectiveness of the rule from the proposed version of our current version, and in one case we would have added the requirement on patient identification and we would have perhaps eliminated one or more of the misadministrations that occurred.

Let's move to the next slide, please.

CHAIRMAN ZECH: Go ahead.

[Slide.]

MR. MORRIS: Again, I mention that these are preliminary numbers. We've tried to get some estimates of the benefits and the costs where we could quantify them to the extent the database allows us to do that, and we have also looked at some of the potential impacts that are difficult to quantify.

Based on that analysis that I spoke of that has been done of the potential impact or effectiveness of the quality assurance measures, we believe that of the 75 misadministrations reported to the NRC over the last seven years, about 80 percent of those could have been averted to effective implementation of the revised rule; that's a

preliminary estimate. It's subject to some change.

If one scales that up to count for all licensees including the NRC licensees and the agreement state licensees, it comes out about to be about 20 misadministrations per year that would have been averted.

Remember, that's a scaled effect and doesn't account for real misadministrations that have been reported.

We evaluated the costs of the rule based on primarily the cost of the redundant checks of calculations by separate individuals. That's the major contribution of costs, and another large contribution is the requirement that if parameters in the radiation therapy fall outside the range of the calibration issue, we should recheck that.

And when we sum these up, we come to about $1.7 million per year as a total estimated cost. What one has -- what we hear from the comments is, that a large number of the commenters believe that most hospitals already follow many of these quality assurance measures. So we believe that the incremental costs from the rule would be to something less than the 1.7 million per year; we've just taken it as an assumption, and that's all it is now, it's an assumption that about 80 percent of the hospitals already are implementing such measures so that

the incremental costs might be $400,000 a year.

COMMISSIONER BERNTHAL: Now again your analysis is based on those incidents reported, and we have established that we do not have the agreement states in that database; is that correct?

MR. MORRIS: Yes.

MR. PETTIJOHN: That's correct.

COMMISSIONER BERNTHAL: That's a pretty big chunk, it seems to me.

MR. MORRIS: But, remember, we scaled up the reported number based on the ratio of the number of agreement states and non-agreement states to the number of non-agreement states.

COMMISSIONER BERNTHAL: Number of states or number of hospitals and institutions in each?

MR. MORRIS: It would be the reports from hospitals and institutions and states of different sorts: First, the non-agreement states, and the agreement states.

COMMISSIONER BERNTHAL: Okay. So the scaling was based on the --

MR. MORRIS: It's just a ratio.

COMMISSIONER BERNTHAL: Okay.

MR. MORRIS: We were looking for some figure of merit, and it's a qualified figure, as you understand, and we found that if we assume that $400,000 costs to all

licensees and that 20 misadministrations were averted, it would be about $20,000 per misadministration averted. That would be a figure of merit that one could use to look at the effectiveness of the -- the cost effectiveness of the rule.

One thing that we have also learned from the comments and from the comments of the advisory group to NMSS, is that there may be other impacts that flow from this burden of effort, and those would be things like the following: Less flexibility in medical practice, difficulty in ensuring timely availability of quality personnel, that is to do the second check. If you're a small hospital, it might be difficult to find someone to make that overcheck.

Because hospitals are not able to simply pass on their expenses to their patients because of the new federal guidelines, the cost increment from this kind of regulation may result in a re-allocation of resources in quality assurance in radiation therapy which may not optimize the effectiveness of overall medical care.

Now when you look at the total cost of the industry and think of the total number of licensees involved, the cost per licensee doesn't come to very large numbers; it's in the order of a few thousands per year, say. So that's another perspective that we will -- one

needs to keep in mind to evaluate all of this. We're trying to factor all of this together in looking at our regulatory analysis in giving you our analysis.

CHAIRMAN ZECH: All right. Fine. Let's go on.

MR. MORRIS: I think I just will spend a brief moment to mention to you -- next slide, please -- that we do have an advanced notice of proposed rulemaking on comprehensive quality assurance, and this was issued at the same time as the basic quality assurance rule, but the comment period ended a month later to give more time for commenters to think about this much more broad set of questions, questions related to the adoption of existing industry standards, training, and certification, and accreditation of Staff involvment in administration of radiation therapy, the need for limitations on case load of the Staff members, verification of computer software and so forth.

[Slide.]

MR. MORRIS: For that particular rulemaking, we got 20 letters of comment, and 15 percent stated that certain actions might be needed, others answered questions raised in the notice, others opposed any additional rules that NRC might consider promulgating.

According to the original schedule given to us by the Commission, our schedule would be to evaluate those

comments and draft the proposed rule for Commission review in September. The final slide, Joy.

[Slide.]

MR. MORRIS: Just to give you an impression of the kinds of comments we received here, not greatly different from the ones that we received on the basic QA rule. The current QA training and certification are adequate, additional NRC regulations will not further improve the situation, and hospital QA programs are reviewed and evaluated by the Joint Commission on Accreditation of Health Care Organizations, are some of the kinds of comments that we've received.

MR. TAYLOR: Norm McElroy.

CHAIRMAN ZECH: You may proceed. Thank you.

MR. McELROY: In accordance with your original Staff requirements memorandum, the Staff convened a meeting of the Advisory Committee on the Medical Use of Isotopes in January to discuss this topic.

We remind you that the committee members collectively represent a wide-range of experience in the medical use of all kinds of radiation and not just by-product material.

And the committee members are reminded that they are not there to represent a particular faction when they provide counsel to the NRC.

The committee members discussed the subject rulemaking. They also heard presentations from the Society of Nuclear Medicine, the American College of Radiology, and some physicians working at a variety of hospitals throughout the country.

There were four general comments made by the Committee: First, they believe that there's already good support for quality assurance, and they believe this is best demonstrated by the very low misadministration rate of by-product material particularly when compared to a misadministration rate of non-radioactive drugs of about 15 percent.

COMMISSIONER ROBERTS: How much?

MR. McELROY: 15 percent. If you go into a hospital, there is about one chance in six that you will be given an incorrect pill.

COMMISSIONER BERNTHAL: I think we ought to move us out of this room to another agency in town.

COMMISSIONER CARR: I believe one doctor says about one in three in her testimony.

MR. McELROY: It depends on whose study you read, the values ranges from about 3 percent to 20 percent.

MR. BERNERO: A word of caution about the standards of adverse health effects or simply misadministration, you know the wrong pill; the wrong pill

might not hurt you.

COMMISSIONER CARR: But it's still wrong.

MR. TAYLOR: If you're lucky.

MR. McELROY: If you're lucky. It was pointed out that quality assurance procedures must vary throughout hospitals simply because they serve different patient loads. There are military hospitals under our jurisdiction, Veterans hospitals, there are hospitals in affluent suburban communities, university research hospitals, and county or city general hospitals, all potentially subject to this regulation.

COMMISSIONER BERNTHAL: Let me turn this around just a moment. Why would one believe that if the error rate and misadministrations rate is 30 percent, pick your number, in general administration of drugs, that it really is as low, and we understand that there is some problems with the numbers we're getting, but are the procedures that much better for us or for things involving nuclear materials, or does it lead one to worry a bit more about the numbers?

MR. McELROY: Part of that much lower rate stems from the nature of the business, when you're doing a diagnostic nuclear medicine study or radiation therapy process, it's a very labor and capital equipment intensive process and you don't want to do it for the wrong patient

or provide the wrong process.

MR. MORRIS: And of course we take enforcement when we don't -- we find out that they haven't reported, that's --

MR. McELROY: Secondly, already for the diagnostic dosages of radiopharmaceuticals, we already apply safety measures virtually equivalent to those that are applied to narcotics and dangerous drugs that are occasionally used in hospitals.

The Committee felt that the QA program that we impose should be compatible with the overall hospital quality assurance program. There are lots of quality assurance programs in hospitals, and there was some feeling that this was not developed in close coordination with those other programs.

There's the Joint Commission on Accreditation of Health Care Organizations that you've heard of, there is also an organization called Peer Review Organizations that examines quality of care for cases that are being reimbursed by the Federal Government under Medicare.

And there is also an organization called Radiologic Physics Center that does quality assurance for hospitals that are participating in NIH clinical trials.

Finally the Committe felt there are less prescriptive ways such as participating in standards

development or assisting in the development of training programs.

CHAIRMAN ZECH: Who are the members of the Advisory Committee?

MR. McELROY: We have NMSS -- back up one. As you can see here, there are a variety of physicians representing several specialties, they are in different clinical environments and they come from all over the country.

CHAIRMAN ZECH: These are the advisors to the NRC?

MR. McELROY: This is our Advisory Committee that has assisted us on policy and technical matters for several years.

CHAIRMAN ZECH: All right. Thank you.

MR. McELROY: Okay. Returning to Page 17, specifically commenting on the rules that were circulated for their review, the Committee was unanimous in stating that they do not feel the rulemaking would significantly or measurably reduce the misadministration rate.

CHAIRMAN ZECH: Well, what would? Did they have any other alternatives?

MR. McELROY: They perceived that mistakes that are made to cause misadministrations are human error mistakes and --

CHAIRMAN ZECH: No way to improve, is that what they're saying?

MR. McELROY: They were able to offer no alternative for improvement.

CHAIRMAN ZECH: Okay. Not very helpful, it sounds to me.

MR. McELROY: The mistakes that are made are not peculiar to the medical setting, they're the human mistakes that all of us make.

CHAIRMAN ZECH: Well, they make them too, and ordinarily people who make mistakes try to improve, try to make fewer mistakes. It's kind of surprising to me that this group doesn't think -- that they don't like the rule, Then I would hope that they would think of some alternative. How can they improve?

What they're saying, I think, if I hear you right, is that they're doing about as good as they can do and can't do any better.

MR. McELROY: They would like to improve, I assure you, because it costs them money and loss of base when they --

CHAIRMAN ZECH: Well, what -- they don't have any alternatives, though.

MR. McELROY: They have not posed alternatives.

CHAIRMAN ZECH: All right. Let's go on.

MR. THOMPSON: Mr. Chairman, I do think it would be -- this is Hugh Thompson from NMSS -- I think it would be fair to say at least in my memory of the meeting there that they supported the industry's effort to improve quality assurance activities as opposed to necessarily NRC activity.

I do think that they certainly supported the quality assurance activities and thought that most of the current industry approaches were aimed at that direction. I think we've all had experience, it's the bottom 1 percent of the 2 percent often that our regulations have addressed as opposed to the activities the industry will do voluntarily.

CHAIRMAN ZECH: Well, does industry have an active program to improve?

MR. THOMPSON: The association, I guess -- what is it, the Society of Nuclear Medicine and I think this Joint Committee on Accreditation have recently established some efforts and activities to improve the quality assurances in the area even related to the nuclear programs also.

So I think that's one of the areas that we're evaluating as we consider the various alternatives now before the Staff.

CHAIRMAN ZECH: Okay. Thank you.

COMMISSIONER BERNTHAL: I guess the thing that surprises me a little bit is that you're telling us that the public comment, which included a number of very distinguished groups and individuals, I suppose, that in the public comment on the proposed rule, 25 percent supported it, 55 percent suggested changes which means I gather that they did not oppose issuing a rule, and only 20 percent opposed.

Now I would think that our Advisory group would have taken this under advisement, so to speak, and yet you're saying that even with this public comment, they side with the 20 percent which feel that there should be no rule. Is that what you're saying?

MR. McELROY: I would recharacterize that simply to state that the 55 percent that just recommended changes, may have seen it coming and may not have perceived the possibility that there would be no rulemaking, so they wanted it to be as technically valid as possible.

I'm not certain that you can read into that, that they supported this effort from this organization.

MR. TAYLOR: Norm, don't you get on to the recommendations on the subsequent slide that comes -- some of these questions may be answered.

CHAIRMAN ZECH: Okay. Let's go on.

MR. McELROY: We have some Advisory Committee recommendations --

MR. BERNERO: Excuse me. Just to clarify one point, Norm. I don't think the analysis of comments was fully developed and available for the January meeting, and I think that was part of your question, Mr. Bernthal.

COMMISSIONER BERNTHAL: I see. Okay. Thank you.

MR. McELROY: Still on Page 17, there was concern expressed that in fact this rulemaking could precipitate a decline in the quality of patient care available throughout the hospital simply because it might divert resources from other areas that present greater risk to the patient; for example, in anesthesia, surgery, or the problem of what is referred to as nosocomial infections; an infection that a patient gets that he didn't have when he was admitted to the hospital.

There is about a 3 percent chance that he'll pick up a disease in the hospital that he didn't have when he walked in the front door.

COMMISSIONER BERNTHAL: Don't you think that that 80 percent, though, if they believe that this could result in a decline in patient care would have opposed the rule?

I guess I find it incredible that the Advisory Group thinks that there could be a reduction in the quality of patient care and yet these distinguished panels

that reported, or rather commented on the proposed rule certainly did not reach such a conclusion apparently, because I would have thought their medical principles would have required them to oppose it under those circumstances if they thought there was a significant probability of that occurring.

MR. McELROY: The organizations that commented, I think are very sensitive to the role that NRC has played in this field in the last few years. I think they probably perceived that there was going to be a rulemaking and they simply wanted to be sure it was as good as possible.

MR. TAYLOR: Commissioner, we're going to recommend that you meet with this Advisory Group, and then some of these questions may be able to be answered directly by the participants, but we're acting as the messenger in this sense.

MR. BERNERO: You can tell he's enthusiastic, too.

MR. McELROY: There of course was concern regarding the cost of the rulemaking, and finally on Page 17, there are not the individuals in the pipeline who are needed to perform these quality assurance checks. There is a shortage of health care personnel in this field.

[Slide.]

MR. McELROY: Turning to Page 18, the Advisory Committee did make some general recommendations.

First of all, concerning regulations, if the Commission believes it necessary to proceed with rulemaking, the Advisory Committee felt that perhaps rather than issuing a prescriptive rulemaking as we have currently on our table, that we develop a performance based regulation that would provide for more flexibility and allow each quality assurance program to be site specific; we could inspect against that custom QA program as well as against strong regulations.

There should be more adoption of voluntary standards because they are on-hand and they have peer reviewed; and finally, any rulemaking should be tested with a pilot study to examine its workability in the clinic setting, but --

COMMISSIONER CARR: I think that's a very important point. I was impressed with Dr. Marcus' try at implementing the rule and she said the only thing she could come out with was signing her name to the prescription that didn't interfere with what she was trying to do.

So I would say that's a very important part of whatever we decide to do is to do pilot project.

MR. McELROY: The Committee did caution that such

a pilot project would not likely demonstrate the effectiveness of a rulemaking because of the already low misadministration rate.

COMMISSIONER CARR: But you could -- it would determine the effectiveness of what you tried to get people to do. It might not proves that we have less misadministrations, but it prove whether the rule was workable or unworkable. That's what I would like to see in the pilot project.

MR. McELROY: It would certainly examine the workability of the rulemaking. The Advisory Committee recommended that we continue our interactions with the professional organizations, and that we provide additional training and educational support to licensees and organizations, and that we expand methods of communicating with licensees.

All three of these functions are already in place and will be expanded in the future by the NMSS Staff. That brings us to a variety of regulatory alternatives on Page 19 that Mr. Bernero will address.

MR. BERNERO: Let me wrap this up rather briefly. Would you put up that Page 19.

[Slide.]

MR. BERNERO: We, the NRC, we're moving to improvement in quality assurance, and really there are

three alternatives on the table before us: The first is the revision of the basic QA rule as Billy Morris spoke of it, you know, modified, intelligently changed, promulgating that as a final rule.

The second alternative would recognize or give recognition to the possibility that impact on other medicine or lack of resources, competition of resources, is a difficulty and one would want greater flexibility; an alternative, too, basically is to shift gears a bit and make a performance oriented rule putting the prescriptive character of it into something like a reg guide, and thereby have the flexibility -- the majority of institutions would be expected to adopt the full scale thing, but the lesser institutions, the ones under some constraint or other, could adapt and have a program appropriate to their situation.

The third alternative is to step back altogether and suspend rulemaking and rely instead on the supporting and even the promoting of the industry efforts that Hugh Thompson spoke of; the quality assurance initiatives that the participants have generated themselves.

Right now, the Office of Research has just this week circulated a draft final paper -- Commission paper for Staff review and consensus development. And it covers Alternative One and discusses Alternative Two.

You can expect that at the end of April, we'll come down here giving you the opportunity and the arguments to consider fairly at least the first alternative, the revised rule for promulgation finally, and some variation of one or both of the other alternatives, you can expect that.

We would recommend that you arrange to meet with the Advisory Committee and other experts as well, either in advance of or concurrently with the submission of that paper.

As we said, we expect in our schedule to submit it by the end of April, and we would happily cooperate with scheduling such a meeting.

CHAIRMAN ZECH: All right.

MR. TAYLOR: That concludes our presentation, sir.

CHAIRMAN ZECH: All right. Thank you very much. Any questions, my fellow Commissioners? Commissioner Roberts?

COMMISSIONER ROBERTS: No.

CHAIRMAN ZECH: Commissioner Bernthal?

COMMISSIONER BERNTHAL: Well, I what you're saying, Bob, and I'm certainly receptive to a somewhat less prescriptive type of rule. I guess the question that follows that, however, and we've been been down this path

once or twice before, most notably, I guess, and most recently with the fitness for duty policy statement and ultimately it appears we're moving toward rulemaking there.

But the question then that comes to mind, I have to address toward the end of the table there and ask the general counsel, if we did promulgate the kind of broad performance based quality assurance rule that Mr. Bernero has suggested, could that or would that in your judgment potentially offer all of the enforcement capability and authority that the Commission would be likely to find even under a more prescriptive rulemaking?

MR. PARLER: Well, I think the answer to that is fairly obvious, if I may say so. With respect, if you have a prescriptive rule that offers more immediate enforcement opportunities than a less prescriptive rule -- I'm kind of like surprised to find that we're talking about a prescriptive rule here because I thought that the policy that the Commission or at least prior Commissions generally adopted, was to stay away from prescriptive rules if not absolutely needed.

However, in response to your question, I can tell you that a performance standard based rule would be better for enforcement purposes than no rule at all because under a policy statement, you first have to find something that

is bad and issue the order. You don't have anything to cite, such as a violation of a regulation.

And, of course, only one agency that I know of is responsible for assuring that actions that are needed to protect the public health and safety in this area are taken, and that's this Agency and the Agreement States who have been given the authority in this area, and not any of these other organizations, whose views I'm sure are very important and whose views should be respected.

But only this Agency has the regulatory authority that serves well as a trustee for the American people that undergo these treatments.

COMMISSIONER BERNTHAL: Well, clearly a policy statement does not give us the authority, but I gather then there would be a difference between a prescriptive rule and a qualitative rule.

Let me ask this question: If you had a performance based rule and there is a misadministration, some sort of clear breach of the procedures -- if something happens, whether or not there is a clear breach of procedures, there's a serious misadministration, is that in and of itself evidence sufficient to indicate then that they have violated a performance based broadly worded rule?

MR. PARLER: Probably, but we'd have to look at

the specifics. Presumably if there's a performance based rule -- and Mr. Taylor, of course, is the expert here -- that would be a program that we would look at and would approve that would flesh out the performance based rule.

The performance based rule would give us the entree for the enforcement action. It would not be just a performance based rule standing alone, I wouldn't think.

MR. TAYLOR: Sir, I might say, as a an example, verifications and signatures of verification -- if you had are performance based rule and it drew up procedures that would impose that within their own hospital, and they had a misadministration, and we went in and found that they hadn't followed their own rules --

COMMISSIONER BERNTHAL: Right.

MR. TAYLOR: -- then we'd have a sufficient bridge to take enforcement. He didn't even follow the rules that you thought were necessary.

COMMISSIONER BERNTHAL: Right.

MR. PARLER: And I agree with that, sir.

MR. TAYLOR: We do that.

COMMISSIONER BERNTHAL: Okay. Thank you.

CHAIRMAN ZECH: Commissioner Carr?

COMMISSIONER CARR: Should we go with Alternative Two instead of Alternative One in your fleshed-out piece of paper, what's the time delay in getting Two out in lieu

of One?

MR. BERNERO: I really don't think it would be a very significant time delay. In fact we've discussed that with the Office of Research a little bit because essentially the material is at hand, it's basically shifting it, converting it. I don't think anyone has identified a specific time.

COMMISSIONER CARR: We wouldn't have to have another comment period?

MR. BERNERO: We did mention the possibility that General Counsel might call for a republication for comment, at lest for a short time.

MR. PARLER: It all depends on whatever is put out, but the interested members of the public are on fair orders so that they could get comments.

If Alternative Two goes beyond that, there is case law which suggests that you have to go out for another round of comments, but that's another thing that we would have to take a look at, at the Alternative Two and how close it is to the alternative that went out.

COMMISSIONER CARR: Well, personally I'd certainly lean to the performance based rule concept, but I hesitate to take another two or three years to get anything on the street.

COMMISSIONER BERNTHAL: Oh, no.

CHAIRMAN ZECH: Commissioner Rogers?

COMMISSIONER ROGERS: Well, just that I would hope that in presenting something on a performance based rule, which is the approach I tend to favor, that considerable thought be given to the teeth that would be put into enforcement.

It seems to me that you have to balance that flexibility that comes with performance based rule with some clear enforceability thoughts that really make it meaningful.

MR. BERNERO: Well, I'd like to remind Staff that there are two kinds of performance based rule: One is be kind to your mother, and the other is be kind to your mother in these seven respects following or satisfying the following list of criteria; and some specificity to it, you know. We would think in terms of the latter.

We have the material, there's no question of that, we --

COMMISSIONER ROGERS: I'm in favor of specifying regular meals and things like that.

[Laughter.]

CHAIRMAN ZECH: Let me just say too, I think that as regards the prescriptive performance based rule, we're just really trying to address our responsibilities, and the performance based rule will satisfy them. I think

that would certainly be something the Commission could entertain.

But I think, as the General Counsel has pointed out, this Agency has the responsibility for public health and safety in these areas of medical isotopes, and we take this very seriously.

We have great respect for the medical communities, medical associations, and individual physicians in our country, and we will certainly listen to their comments, but we ultimately have the responsibility for public health and safety and that is our responsibility that we can't ignore.

So what we're doing is asking for their assistance and their good professional assistance as we move into this area of trying to meet our responsibilities to the American people and carry those responsibilities out in a better manner.

We want to do what we can to protect the public, we don't want to intrude in the practice of medicine. And certainly we don't want to do anything that would have a negative impact on the health care of our country.

My view, though, is that there is always room for improvement. As good as these associations are and these people are, as good as these physicians are, I think there is room for improvement. I think they should recognize

that, I think they do. And I believe a rule for quality assurance is what we're talking about has merit in some form or another, but we're not putting out a rule just for rule's sake. We're trying to improve public health and safety and our responsibility in carrying that out.

So even if the rule would only heighten consciousness of those who use medical isotopes, I think perhaps that would have merit.

But in any case, I would hope that the Staff would continue to work with the health care community of our country with those professionals involved in nuclear medicine.

There is a lot of talent out there that I think we could be perhaps a little more innovative than we've been, and try to see how we can better carry out our responsibilities in public health and safety as regards by-product material and medical use of isotopes.

So I just think -- it's kind of frustrating to think we've been at this so long. I know there's not many misadministrations, but we don't have a good handle on the numbers, even, it looks like, and that's certainly not as good as we'd like.

But we have responsibility in this area and as far as I'm concerned we are going to do something about it, and we're asking for help from those communities that

certainly should be able to help us.

You know, it's one of those things if they don't help us, they might wish they would or might wish they did. We're liable to do something that's, you know, not as smart as we'd like to do, but we're asking for their help.

I think we feel obligated to try to improve, that's all we're trying to do, trying to improve and I hope they would help us do that.

I do think there is room for improvement and I would hope that the Staff will continue to work in this area with those professionals who also have responsibilities for public health and safety in their chosen professions.

Are there any other comments, my fellow Commissioners?

COMMISSIONER ROGERS: Yes.

COMMISSIONER BERNTHAL: I want to-- excuse me.

COMMISSIONER ROGERS: Well, just that -- I wonder if thought shouldn't be given here in relationship with the states and how -- after all, we're talking about radiation therapy of some sort and part of that is not under our regulation, namely that that's created by X ray machines and devices of that sort, and yet the patient effects are the same.

I would hope that some thought is given in working with the professional community on this, that somehow both aspects of therapy are somehow or another at least discussed together. Even though we may not have full responsibility with all of that, that somehow there's a linking together, because I think that there's a difference in perception of things like probabilities and how low is low.

What we're doing here in some way, some of these numbers don't look so low to us in terms of event probabilities that we're trying to drive for with respect to nuclear power plants. They look very low compared to the 5 to 15 percent of misadministrations of medicine, and the X ray people are probably some place in the middle there between these.

I would think that in the national interest, it would make a lot of sense to try to work together with those groups that are responsible at the state level for the licensing and control of radiation from X ray devices in connection with our own developement of a rule here for other sources.

CHAIRMAN ZECH: Good point. Commissioner Bernthal, do you have one comment?

COMMISSIONER BERNTHAL: I just wanted to request that the Staff make a best effort here to get out the best

possible numbers whether it's through the Agreement States or -- we discussed the number of areas in which those statistics might be improved and I understand that AEOD doesn't necessarily even have the data at its disposal, but perhaps you, working with someone else -- for example in other areas, this question of threshold, how do you decide likely health effects? I would like something a little bit better nailed down so that we can make a better judgment on the seriousness of the problem, although there seems to be a consensus developing here on how to proceed.

Other than that, I would just comment, going back to the case of fitness for duty where the Commission put out a policy statement, one which went a little beyond be kind to your mother, and of course it was only a policy statement, but there did turn out to be a little bit of a list of particulars there; I always felt that it probably could have been stated in about one sentence: Nuclear power plant sites shall be free of drugs and alcohol, and you've got to be able to demonstrate it, a sort of period.

And that kind of a statement, it seems to me, translated into the proper scenario here for the subject that we're discussing today might very well be the kind of rule that we would be looking at here.

In other words, I'm a little concerned about a terribly long bill of particulars following that "be kind

to your mother" and I'm not sure we need that. If you say that you must have a quality assurance program that's effective, that's part of it, but being able to demonstrate that it should be effective at least when somebody walks in and looks at it is another part of it, or "please don't take my top-of-the-head words" here as guidance.

If you understand what I'm saying, somewhere between a broad qualitative ill-defined statement that may be unenforceable, and dotting all the i's and crossing the t's, there ought to be something that makes sense, it seems to me, and I would hope that we would work toward that.

CHAIRMAN ZECH: Are there any other comments? Commissioner Carr.

COMMISSIONER CARR: What you ought to write is don't do anything to harm your mother, then we could do something.

CHAIRMAN ZECH: Is that it?

COMMISSIONER CARR: That's it.

CHAIRMAN ZECH: And adjourned.

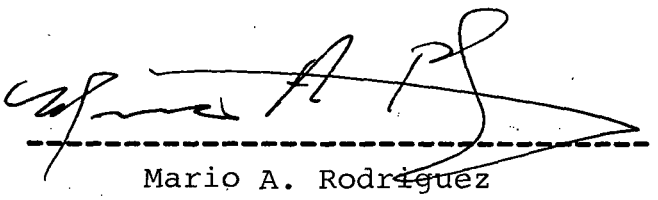
[Whereupon, at 3:20 p.m., the meeting was adjourned.]

REPORTER'S CERTIFICATE

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

TITLE OF MEETING: Briefing on Status of Proposed Rulemaking on Basic QA in Radiation Therapy and Related Activite
PLACE OF MEETING: Washington, D.C.
DATE OF MEETING: March 22, 1988

were held as herein appears, and that this is the original transcript thereof for the file of the Commission taken stenographically by me, thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing events.



Mario A. Rodriguez

Ann Riley & Associates, Ltd.

PREPARED ON
MARCH 14, 1988

COMMISSION BRIEFING

PROPOSED RULEMAKING
ON
BASIC QUALITY ASSURANCE IN RADIATION THERAPY

BY

AEOD, RES, AND NMSS
MARCH 22, 1988

TOPICS

1. Introduction (NMSS)

2. Report on Recent Trends in Misadministrations (AEOD)

3. Basic QA Rule (RES)

4. Overview of Comprehensive QA (RES)

5. The Advisory Committee on the Medical Uses of Isotopes (NMSS)

6. Regulatory Alternatives (NMSS)

ANALYSIS OF MISADMINISTRATION DATA

FOR

THERAPY MISADMINISTRATIONS

AND

DIAGNOSTIC MISADMINISTRATIONS INVOLVING GREATER THAN 100 MICROCURIES OF IODINE - 131

MISADMINISTRATIONS REPORTED TO NRC

YEAR	THERAPY* MISADMINISTRATIONS	DIAGNOSTIC (I-131)** MISADMINISTRATIONS
NOVEMBER 1980 - DEC 1981	10	2
1982	4	3
1983	4	2
1984	14	3
1985	4	3
1986	7	5
1987	9	5
TOTAL	52	23
ANNUAL AVERAGE	7	3

* THE PRIMARY CONTRIBUTING FACTORS FOR THESE MISADMINISTRATIONS WERE:
  - LACK OF REDUNDANCY IN VERIFYING THE ACCURACY OF IMPORTANT MEASUREMENTS AND CALCULATIONS
  - INADEQUATE COMMUNICATION OF INSTRUCTIONS TO PERSONNEL

** THE PRIMARY CONTRIBUTING FACTOR FOR THESE MISADMINISTRATIONS WAS INADEQUATE COMMUNICATION OF INSTRUCTIONS TO PERSONNEL

ERROR RATE FOR MISADMINISTRATIONS

TYPE	NUMBER OF THERAPY/STUDIES*	NUMBER OF EVENTS	NUMBER OF PATIENTS	PATIENT ERROR RATE
THERAPY:				
TELETHERAPY	308,000	31	83	3E-4
BRACHYTHERAPY	154,000	12	12	8E-5
RADIOPHARMACEUTICAL THERAPY	92,400	9	9	1E-4
DIAGNOSTIC (MISADMINISTRATIONS INVOLVING 100 MICRO-CURIES OF IODINE-131)	1,540,000	23	23	2E-5

* NRC LICENSED FACILITIES ONLY

SIGNIFICANCE OF MISADMINISTRATIONS

- SINCE 1976 FIVE THERAPY MISADMINISTRATION EVENTS KNOWN TO NRC HAVE INVOLVED MULTIPLE PATIENTS. THE NUMBER OF PATIENTS INVOLVED RANGED FROM 8 TO 400.

- FOR MISADMINISTRATIONS REPORTED FOR 1984 - 1987:

  - 29 OF THE 50 MISADMINISTRATIONS THAT WERE REPORTED FOR THAT PERIOD WERE ABNORMAL OCCURRENCES

  - EVALUATIONS BY NRC MEDICAL CONSULTANTS AND/OR LICENSEES INDICATE THAT 11 OF THE 29 PATIENTS COULD LIKELY SUFFER ADVERSE HEALTH EFFECTS

  - MISADMINISTRATION AOs WERE 25% OF THE TOTAL AOs

CONCLUSIONS

- ERROR RATE FOR MISADMINISTRATIONS IS LOW
- THE LOW ERROR RATE FOR MISADMINISTRATIONS NOTWITHSTANDING, MISADMINISTRATIONS ARE:
  - POTENTIALLY INJURIOUS TO PATIENTS
  - POTENTIALLY INVOLVE MULTIPLE PATIENTS
  - A SUBSTANTIAL FRACTION ARE ABNORMAL OCCURRENCES

BASIC QA RULE

THE PROPOSED RULE

- OBJECTIVE: TO REDUCE MISADMINISTRATIONS DUE TO HUMAN ERRORS.
- PUBLISHED ON 10/2/87.
- COMMENT PERIOD ENDED ON 12/1/87.

BASIC QA RULE

CURRENT STATUS

- PUBLIC COMMENTS ANALYZED AND RULE REVISED.
- DIVISION REVIEW COMPLETE.
- REGULATORY ANALYSIS REFINED.
- DRAFT RULE SENT FOR OFFICE CONCURRENCE/COMMENT.
- OFFICE CONCURRENCE/COMMENTS DUE 4/1/88.
- SUBMIT DRAFT FINAL RULE TO COMMISSION BY 4/29/88.

BASIC QA RULE

PUBLIC COMMENTS ON THE PROPOSED RULE

- TOTAL NUMBER OF COMMENT LETTERS RECEIVED - 69

- SOURCES OF THE COMMENT LETTERS
  - 41 FROM HOSPITALS
  - 6 FROM PRIVATE PHYSICIANS
  - 7 FROM PROFESSIONAL ASSOCIATIONS
  - 5 FROM STATE REGULATORY AGENCIES
  - 2 FROM AN INSTRUMENTATION MANUFACTURER
  - 8 FROM INDIVIDUALS (DID NOT INDICATE PROFESSION)

BASIC QA RULE

SUPPORT OF THE PROPOSED RULE

- 25% SUPPORTED, INCLUDING:
  - COMMISSION ON RADIATION THERAPY OF THE AMERICAN COLLEGE OF RADIOLOGY
  - COLLEGE OF AMERICAN PATHOLOGISTS
- 20% OPPOSED, INCLUDING:
  - AMERICAN COLLEGE OF RADIOLOGY
  - SOCIETY OF NUCLEAR MEDICINE
- 55% SUGGESTED CHANGES, INCLUDING:
  - AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE
  - AMERICAN COLLEGE OF MEDICAL PHYSICS
  - NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS

BASIC QA RULE

PUBLIC COMMENTS ON THE PROPOSED RULE

MOST SIGNIFICANT OPPOSING COMMENTS

- BECAUSE THE PROBABILITY OF MISADMINISTRATION IS ALREADY VERY LOW, THE RULE IS NOT NEEDED.

- ADDITIONAL REGULATION WOULD NOT REDUCE THE FREQUENCY OF HUMAN ERRORS.

- PATIENT CARE COST WOULD BE SIGNIFICANTLY INCREASED.

BASIC QA RULE

MODIFICATIONS BEING CONSIDERED

BASED ON SPECIFIC PUBLIC COMMENTS

- ELIMINATE SMALL DOSAGES OF SODIUM IODIDE AND DIAGNOSTIC DOSAGES OF OTHER IODINE COMPOUNDS FROM THE QA REQUIREMENTS.

- ELIMINATE REQUIREMENT THAT LICENSEE MAY NOT ORDER RADIOPHARMACEUTICALS WITHOUT APPROVAL OF AUTHORIZED USER.

- ELIMINATE THE REQUIREMENTS FOR MEASURING BRACHYTHERAPY SOURCES BY LICENSEES.

- ELIMINATE INDEPENDENT CHECK OF OUTPUT OF ANNUAL FULL CALIBRATIONS FOR TELETHERAPY MACHINES, BUT MAINTAIN INDEPENDENT CHECK FOR FULL CALIBRATION RESULTING FROM SOURCE CHANGE OR OTHER PROBLEMS WITH THE SOURCE. PERMIT THE USE OF TLD.

- ADD REQUIREMENT ON PATIENT IDENTIFICATION.

BASIC QA RULE

BENEFIT-IMPACT ANALYSIS

BENEFITS

- Preliminary Analysis Indicates that 60 (80%) of the 75 misadm. reported to NRC between 11/80 and 12/87 could have been averted through effective implementation of revised rule.

- For all licensees, about 20 misadm./yr. could have been averted.

IMPACTS

- Estimated Costs
  - to all licensees for Basic QA ---------- $1.7M/yr
  - Incremental assuming most licensees (80%) already follow most Basic QA measures ---------- $0.4M/yr
  - Incremental Cost Per misadministration averted --- $20,000

- Other Potential Impacts (For those not already practicing Basic QA)
  - Less Flexibility in Medical Practice
  - Difficulty In Assuring Timely Availability of Qualified Personnel
  - Reallocation of Resources to QA In Radiation Therapy May Not Optimize Effectiveness of Overall Medical Care.

ADVANCE NOTICE ON COMPREHENSIVE QA

1. PURPOSE
   - o TO SEEK PUBLIC COMMENTS ON COMPREHENSIVE QA PROGRAMS

2. THE ADVANCE NOTICE OF PROPOSED RULEMAKING
   - o PUBLISHED ON 10/2/87.
   - o COMMENT PERIOD ENDED ON 12/31/87.

3. PUBLIC COMMENTS
   - o 20 LETTERS WERE RECEIVED.
   - o 3 (15%) STATED CERTAIN ACTIONS MIGHT BE NEEDED.
   - o 12 (60%) ANSWERED QUESTIONS RAISED IN THE NOTICE.
   - o 5 (25%) OPPOSED ANY ADDITIONAL RULES.

4. FUTURE ACTIONS
   - o DRAFT PROPOSED RULE DUE COMMISSION ON 9/30/88.

ADVANCE NOTICE ON COMPREHENSIVE QA

MOST SIGNIFICANT OPPOSING COMMENTS

- CURRENT QA, TRAINING, AND CERTIFICATION ARE ADEQUATE.
- ADDITIONAL NRC REGULATIONS MAY NOT FURTHER IMPROVE QA.
- HOSPITAL QA PROGRAMS ARE REVIEWED AND EVALUATED BY JCAHO.*

*JCAHO - JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS

THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
GENERAL COMMENTS FROM THE MEETING

- THERE IS GOOD GENERAL SUPPORT FOR QA IN NUCLEAR MEDICINE DIAGNOSIS AND THERAPY.

- QA PROCEDURES VARY BECAUSE OF DIFFERENCES IN PATIENT COMMUNITIES BEING SERVED AND PATIENT LOADS.

- NRC QA REQUIREMENTS SHOULD BE COMPATIBLE WITH OVERALL HOSPITAL WIDE QA PROGRAMS.

- THERE ARE LESS PRESCRIPTIVE WAYS, WHICH WOULD ULTIMATELY BETTER SERVE PATIENT CARE, FOR NRC TO ENHANCE AND ENFORCE QA THAN THE PROPOSED RULE.

THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
COMMENTS ON BASIC QUALITY ASSURANCE RULES

- THE PROPOSED RULES ARE UNLIKELY TO SIGNIFICANTLY CHANGE MISADMINISTRATION RATE.

- THE RULES COULD CAUSE A REDUCTION IN THE QUALITY OF PATIENT CARE
  - DIVERSION OF RESOURCES FROM OTHER HIGHER RISK PROGRAMS
  - DELAYED PATIENT CARE IN CERTAIN SITUATIONS.

- THE PROPOSED RULES ARE COSTLY.

- SUFFICIENTLY TRAINED PERSONNEL NEEDED FOR IMPLEMENTATION ARE NOT AVAILABLE.

THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES RECOMMENDATIONS ON BASIC QUALITY ASSURANCE RULES

REGULATORY RECOMMENDATIONS

- Obtain QA Program Commitment & Description in License Application.
- Inspect and Enforce Licensee's QA Program.
- Adopt Appropriate Voluntary Standards.
- Test Proposed Rules With Pilot Studies.

NON-REGULATORY RECOMMENDATIONS

- Seek Cooperative Interaction With Professional Organizations.
- Provide Additional Training and Educational Support to Licensees.
- Expand Methods of Communicating Information to Licensees.

NRC REGULATORY ALTERNATIVES

ALTERNATIVE 1:

PROMULGATE PRESCRIPTIVE BASIC QA RULE.

ALTERNATIVE 2:

DEVELOP PERFORMANCE-BASED RULE AND

- DEVELOP REGULATORY GUIDE.
- ADOPT VOLUNTARY STANDARDS.

ALTERNATIVE 3:

DO NOT ISSUE RULE, INSTEAD EMPHASIZE

- TRAINING AND ASSISTANCE.
- INDUSTRY STANDARDS DEVELOPMENT.

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

RICHARD E. CUNNINGHAM, CHAIRMAN

VINCENT P. COLLINS, M.D., HOUSTON, TX -- RADIATION ONCOLOGY

SALLY J. DENARDO, M.D., SACRAMENTO, CA -- NUCLEAR MEDICINE

JACK K. GOODRICH, M.D., ERIE, PA -- NUCLEAR MEDICINE

MELVIN L. GRIEM, M.D., OGDEN DUNES, IN -- RADIATION ONCOLOGY

NILO E. HERRERA, M.D., DANBURY, CT -- NUCLEAR MEDICINE

B. LEONARD HOLMAN, M.D. BOSTON, MA -- CARDIOLOGY AND NUCLEAR MEDICINE

GERALD M. POHOST, M.D., BIRMINGHAM, AL -- CARDIOLOGY AND NUCLEAR MEDICINE

EDWARD W. WEBSTER, PH.D., BOSTON, MA -- RADIOLOGICAL PHYSICS

DAVID H. WOODBURY, M.D., WESTLAND, MI -- NUCLEAR MEDICINE

CONSULTANTS TO THE COMMITTEE

PETER R. ALMOND, PH.D. LOUISVILLE, KY -- RADIOLOGICAL PHYSICS

WILLIAM H. BRINER, CAPT, USPHS (RET), DURHAM, NC -- NUCLEAR PHARMACY

CALCULATION OF ERROR RATE

$$\text{PATIENT ERROR RATE} = \frac{\text{TOTAL NUMBER OF PATIENTS INVOLVED IN MISAD (7 YR PERIOD)}}{\text{(THERAPIES/STUDIES)/YEAR)*(22 NRC ST/50 AGREEMENT ST) *7}}$$