

ORIGINAL

**UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION**

Title: Briefing on Status of Proposed Rulemaking on
Basic QA in Radiation Therapy and Related Activities
(Public Meeting)

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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

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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

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

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

6 This is an information briefing and no vote is
7 expected.

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

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

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

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

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

23 [No response.]

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

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

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

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

17 Secondly on March 14th you received a Commission
18 paper on the medical use program. This is a broad plan
19 which grew out of the strategic planning process which you
20 have reviewed, and which is consistent with our FY '88,
21 '89 budget and that covers a five-point program for the
22 overall enhancement of the regulatory oversight of medical
23 uses, the by-product material.

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

1 be related to them.

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

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

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

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

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

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

1 it over to Sam right now.

2 CHAIRMAN ZECH: All right. Thank you very much.

3 You may proceed.

4 MR. PETTIJOHN: Viewgraph No. 2, please.

5 [Slide.]

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

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

13 [Slide.]

14 MR. PETTIJOHN: That AEOD data covers November
15 1980 through 1987 when the rule -- the effective date of
16 the rule was November 1980. There has been a variation
17 over the years in the number of misadministrations
18 reported, both therapy and diagnostic; however, we're not
19 able to attribute anything specifically or to determine
20 any specific trend.

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

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

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

3 [Slide.]

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

10 [Slide.]

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

19 1984 through 1987 was selected because the
20 abnormal occurrence reporting was changed in 1984 to
21 specifically address misadministrations.

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

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

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

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

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

11 COMMISSIONER BERNTHAL: Right. Right.

12 MR. TAYLOR: That became known to us.

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

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

17 MR. PETTIJOHN: That's correct.

18 COMMISSIONER BERNTHAL: Okay.

19 MR. PETTIJOHN: All right.

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

22 MR. PETTIJOHN: That's correct.

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

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

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

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

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

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

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

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

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

23 COMMISSIONER ROGERS: Was that a teletherapy --

24 MR. PETTIJOHN: It was a teletherapy
25 misadministration.

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

4 MR. PETTIJOHN: Except for one. And in the 1980
5 through 1987 data, there was one misadministration that
6 involved 53 patients and that's why in teletherapy we have
7 83 patients and 31 events.

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

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

12 [Slide.]

13 MR. PETTIJOHN: To complete the Viewgraph No. 5,
14 in regard to abnormal occurrences we looked at those for
15 1980 through 1987. There were 50 misadministrations
16 during that period and 29 of those were reported as
17 abnormal occurrences.

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

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

1 [Slide.]

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

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

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

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

1 well define that then as being an adverse health effect.

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

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

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

25 MR. PETTIJOHN: I guess these were more acute

1 effects versus --

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

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

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

17 That concludes the AEOD presentation.

18 CHAIRMAN ZECH: All right. Thank you very much.

19 MR. TAYLOR: Mr. Morris.

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

24 MR. PETTIJOHN: Correct.

25 COMMISSIONER BERNTHAL: You also indicate on the

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

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

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

13 COMMISSIONER BERNTHAL: '86 and '87, though, the
14 numbers that I have been given seem to indicate more like
15 45 percent.

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

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

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

1 all the reports in, and if we're not getting reports from
2 the agreement states, and we haven't gotten reports since
3 '74 to '80 from anybody, why, I'm not sure our database is
4 any good. Having said that, let's proceed.

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

7 CHAIRMAN ZECH: Let's proceed.

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

9 COMMISSIONER BERNTHAL: Yes. Yes.

10 CHAIRMAN ZECH: Let's proceed.

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

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

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

24 [Slide.]

25 MR. MORRIS: When the comment period ended, the

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

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

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

14 [Slide.]

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

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

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

6 [Slide.]

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

13 [Slide.]

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

19 20 percent opposed the rule, in general terms.
20 Those included the American College of Radiology, and the
21 Society of Nuclear Medicine.

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

25 MR. MORRIS: That is correct, yes.

1 COMMISSIONER ROBERTS: All right.

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

8 [Slide.]

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

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

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

16 [Slide.]

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

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

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

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

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

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

13 COMMISSIONER ROBERTS: Is what?

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

21 COMMISSIONER BERNTHAL: Medical physicists or --

22 MR. MORRIS: I think they're physicists.

23 COMMISSIONER BERNTHAL: Did you say physicists?

24 MR. MORRIS: Medical physicists and physicians.

25 COMMISSIONER BERNTHAL: Okay. Okay.

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

2 [Slide.]

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

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

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

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

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

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

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

10 COMMISSIONER ROBERTS: I understand.

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

13 COMMISSIONER ROBERTS: I understand.

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

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

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

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

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

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

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

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

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

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

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

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

12 What's the base of hospitals that might be
13 affected by this that we would expect some response from?
14 41 doesn't look to me like a very large number nationally.

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

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

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

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

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

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

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

20 COMMISSIONER ROGERS: Okay.

21 CHAIRMAN ZECH: All right. Let's proceed.

22 MR. MORRIS: Next slide, please.

23 [Slide.]

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

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

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

11 Let's move to the next slide, please.

12 CHAIRMAN ZECH: Go ahead.

13 [Slide.]

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

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

1 preliminary estimate. It's subject to some change.

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

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

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

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

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

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

6 MR. MORRIS: Yes.

7 MR. PETTIJOHN: That's correct.

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

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

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

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

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

21 MR. MORRIS: It's just a ratio.

22 COMMISSIONER BERNTHAL: Okay.

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

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

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

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

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

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

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

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

18 [Slide.]

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

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

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

3 [Slide.]

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

13 MR. TAYLOR: Norm McElroy.

14 CHAIRMAN ZECH: You may proceed. Thank you.

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

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

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

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

6 There were four general comments made by the
7 Committee: First, they believe that there's already good
8 support for quality assurance, and they believe this is
9 best demonstrated by the very low misadministration rate
10 of by-product material particularly when compared to a
11 misadministration rate of non-radioactive drugs of about
12 15 percent.

13 COMMISSIONER ROBERTS: How much?

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

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

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

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

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

1 might not hurt you.

2 COMMISSIONER CARR: But it's still wrong.

3 MR. TAYLOR: If you're lucky.

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

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

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

1 or provide the wrong process.

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

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

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

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

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

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

1 development or assisting in the development of training
2 programs.

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

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

10 CHAIRMAN ZECH: These are the advisors to the
11 NRC?

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

15 CHAIRMAN ZECH: All right. Thank you.

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

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

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

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

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

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

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

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

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

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

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

24 MR. McELROY: They have not posed alternatives.

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

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

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

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

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

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

25 CHAIRMAN ZECH: Okay. Thank you.

1 COMMISSIONER BERNTHAL: I guess the thing that
2 surprises me a little bit is that you're telling us that
3 the public comment, which included a number of very
4 distinguished groups and individuals, I suppose, that in
5 the public comment on the proposed rule, 25 percent
6 supported it, 55 percent suggested changes which means I
7 gather that they did not oppose issuing a rule, and only
8 20 percent opposed.

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

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

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

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

25 CHAIRMAN ZECH: Okay. Let's go on.

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

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

7 COMMISSIONER BERNTHAL: I see. Okay. Thank you.

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

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

20 COMMISSIONER BERNTHAL: Don't you think that that
21 80 percent, though, if they believe that this could result
22 in a decline in patient care would have opposed the rule?

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

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

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

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

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

20 MR. McELROY: There of course was concern
21 regarding the cost of the rulemaking, and finally on Page
22 17, there are not the individuals in the pipeline who are
23 needed to perform these quality assurance checks. There
24 is a shortage of health care personnel in this field.

25 [Slide.]

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

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

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

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

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

25 MR. McELROY: The Committee did caution that such

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

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

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

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

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

23 [Slide.]

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

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

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

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

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

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

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

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

14 CHAIRMAN ZECH: All right.

15 MR. TAYLOR: That concludes our presentation,
16 sir.

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

20 COMMISSIONER ROBERTS: No.

21 CHAIRMAN ZECH: Commissioner Bernthal?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 COMMISSIONER BERNTHAL: Right.

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

18 COMMISSIONER BERNTHAL: Right.

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

20 MR. TAYLOR: We do that.

21 COMMISSIONER BERNTHAL: Okay. Thank you.

22 CHAIRMAN ZECH: Commissioner Carr?

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

1 of One?

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

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

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

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

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

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

25 COMMISSIONER BERNTHAL: Oh, no.

1 CHAIRMAN ZECH: Commissioner Rogers?

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

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

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

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

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

21 [Laughter.]

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

1 that would certainly be something the Commission could
2 entertain.

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

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

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

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

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

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

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

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

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

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

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

1 certainly should be able to help us.

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

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

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

15 Are there any other comments, my fellow
16 Commissioners?

17 COMMISSIONER ROGERS: Yes.

18 COMMISSIONER BERNTHAL: I want to-- excuse me.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 CHAIRMAN ZECH: Is that it?

20 COMMISSIONER CARR: That's it.

21 CHAIRMAN ZECH: And adjourned.

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

24

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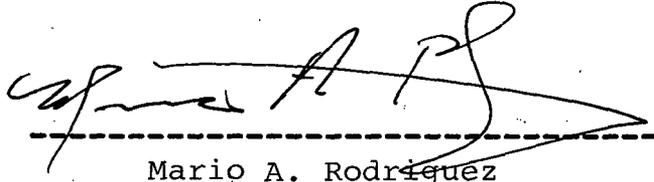
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REPORTER'S CERTIFICATE

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 Activities
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

<u>YEAR</u>	<u>THERAPY*</u> <u>MISADMINISTRATIONS</u>	<u>DIAGNOSTIC (I-131)**</u> <u>MISADMINISTRATIONS</u>
NOVEMBER 1980 - DEC 1981	10	2
1982	4	3
1983	4	2
1984	14	3
1985	4	3
1986	7	5
1987	<u>9</u>	<u>5</u>
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

<u>TYPE</u>	<u>NUMBER OF THERAPY/STUDIES*</u>	<u>NUMBER OF EVENTS</u>	<u>NUMBER OF PATIENTS</u>	<u>PATIENT ERROR RATE</u>
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

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

BASIC QA RULE

CURRENT STATUS

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

BASIC QA RULE

PUBLIC COMMENTS ON THE PROPOSED RULE

- 0 TOTAL NUMBER OF COMMENT LETTERS RECEIVED - 69

- 0 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

0 25% SUPPORTED, INCLUDING:

- COMMISSION ON RADIATION THERAPY OF THE AMERICAN COLLEGE OF RADIOLOGY
- COLLEGE OF AMERICAN PATHOLOGISTS

0 20% OPPOSED, INCLUDING:

- AMERICAN COLLEGE OF RADIOLOGY
- SOCIETY OF NUCLEAR MEDICINE

0 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

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

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

- O PATIENT CARE COST WOULD BE SIGNIFICANTLY INCREASED.

BASIC QA RULE
MODIFICATIONS BEING CONSIDERED
BASED ON SPECIFIC PUBLIC COMMENTS

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

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

- 0 ELIMINATE THE REQUIREMENTS FOR MEASURING BRACHYTHERAPY SOURCES BY LICENSEES.**

- 0 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.**

- 0 ADD REQUIREMENT ON PATIENT IDENTIFICATION.**

BASIC QA RULE
BENEFIT-IMPACT ANALYSIS

BENEFITS

- 0 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.

- 0 FOR ALL LICENSEES, ABOUT 20 MISADM./YR. COULD HAVE BEEN AVERTED.

IMPACTS

- 0 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

- 0 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

- O CURRENT QA, TRAINING, AND CERTIFICATION ARE ADEQUATE.**
- O ADDITIONAL NRC REGULATIONS MAY NOT FURTHER IMPROVE QA.**
- O 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

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

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

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

- O 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**

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

- O 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.**

- O THE PROPOSED RULES ARE COSTLY.**

- O 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

- 0 OBTAIN QA PROGRAM COMMITMENT & DESCRIPTION IN LICENSE APPLICATION.
- 0 INSPECT AND ENFORCE LICENSEE'S QA PROGRAM.
- 0 ADOPT APPROPRIATE VOLUNTARY STANDARDS.
- 0 TEST PROPOSED RULES WITH PILOT STUDIES.

NON-REGULATORY RECOMMENDATIONS

- 0 SEEK COOPERATIVE INTERACTION WITH PROFESSIONAL ORGANIZATIONS.
- 0 PROVIDE ADDITIONAL TRAINING AND EDUCATIONAL SUPPORT TO LICENSEES.
- 0 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

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

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CALCULATION OF ERROR RATE

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