

1 UNITED STATES OF AMERICA  
2 NUCLEAR REGULATORY COMMISSION

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4 MEETING WITH ACMUI AND  
5 NRC STAFF

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7 Nuclear Regulatory Commission  
8 One White Flint North  
9 Rockville, Maryland

10

11 Tuesday,  
12 March 2, 2004

13

14 The Commission met in open session, pursuant to  
15 notice, Chairman Nils Diaz, presiding.

16

17 COMMISSIONERS PRESENT:

18 NILS J. DIAZ, Chairman of the Commission

19 EDWARD MCGAFFIGAN, JR., Member of the Commission

20 JEFFREY MERRIFIELD, Member of the Commission

21 (This transcript produced from electronic caption  
22 media and audio and video media provided by the  
Nuclear Regulatory Commission.)

1 STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

2 Secretary

3 General Counsel

4 DR. CARL PAPERIELLO

5 DR. CHARLES MILLER, NMSS

6 PAMELA HENDERSON

7 THOMAS ESSIG

8 DR. MANUEL CERQUEIRA, Chairman, ACMUI

9 MR. RALPH LIETO

10 DR. LEON S. MALMUD, Subcommittee Chairman

11 DR. JEFF WILLIAMSON

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## 1 PROCEEDINGS

2 CHAIRMAN DIAZ: Today we are meeting to  
3 hear from the Staff and from ACMUI regarding their  
4 programs. We are obviously very pleased to have this  
5 meeting and learn all the things, good things that  
6 are going on.

7 We will hear from the Staff first, I  
8 understand, and then from ACMUI. This is one of the  
9 annual briefings the Commission holds. We try to  
10 become fully and currently informed with all of the  
11 details.

12 And I think there are issues that keep  
13 coming up. Some of them are old issues that have a  
14 life of their own and others are new issues. We look  
15 forward to hearing from the staff and ACMUI on these  
16 issues.

17 With that, Mr. Paperiello, unless my fellow  
18 Commissioners have a comment, please go ahead.

19 MR. PAPERIELLO: Good morning, Chairman,  
20 Commissioners.

21 The Staff are pleased to have an  
22 opportunity to brief the Commission on aspects

1 relating to Revised Part 35, the medical use of  
2 byproduct material. And specifically, the Staff is  
3 going to be presenting the NRC's experience  
4 implementing this rule.

5 This medical regulation has evolved over  
6 the years and the latest revision that was completed  
7 in October of 2002 incorporates a risk-informed and  
8 performance-based philosophy.

9 The Commission is also going to be briefed  
10 on the status of follow-up actions related to dose  
11 reconstruction pertaining to an event which occurred  
12 at an NRC licensed medical facility involving an  
13 overexposure to a member of the public.

14 You are going to be briefed by both the  
15 staff as well as members of the Advisory Committee on  
16 the Medical Use of Isotopes on this subject.

17 And the advisory committee will also brief  
18 you on the revisions of Part 35 with respect to  
19 training and experience.

20 And with your permission, I would like to  
21 turn the presentation over to Dr. Miller.

22 DR. MILLER: Good morning, Chairman,

1 Commissioners McGaffigan and Merrifield.

2 I wanted to make a couple of opening  
3 remarks before I turned the microphone over to our  
4 presenters this morning.

5 Over the course of the one year that I have  
6 been the director of the Division for Industrial and  
7 Nuclear Medical Safety, I and my staff have taken on  
8 a challenge for continual improvement of our medical  
9 regulatory program. There are three near term goals  
10 that I have set for myself and my staff to work on.

11 The first is to enhance our working  
12 relationship and the utilization and effectiveness of  
13 the Advisory Committee for the Medical Use of  
14 Isotopes to advise the NRC.

15 The second is to complete the Part 35  
16 training and experience rulemaking which we currently  
17 have undergoing.

18 And the third is to provide technical  
19 support to the regions on the implementation of the  
20 revised Part 35.

21 What we doing now, these next two days, is  
22 we are in our current meetings with the advisory

1 committee. We do that twice a year.

2 We have broken from those meetings to meet  
3 with the Commission this morning and will resume our  
4 meetings with the advisory committee this afternoon.

5 We had some fruitful discussions. And  
6 today we will focus on two subjects that Carl spoke  
7 about. And I would like to turn the microphone over  
8 to Pam Henderson from Region I to give the regional  
9 perspective on the implementation of Part 35 revised  
10 program to date.

11 Pam.

12 MS. HENDERSON: Good morning.

13 The NRC's approach to regulation of medical  
14 uses of byproduct material has undergone a profound  
15 change. It is less prescriptive. It is  
16 risk-informed and performance-based.

17 What we are seeing in the field. We no  
18 longer require submittal of detailed procedures for  
19 limited diagnostic programs. And licensees are still  
20 adjusting to this idea.

21 Licensees frequently have questions  
22 concerning interpretation of the regulations and the

1 expectations of the NRC. To that end, we have  
2 questions and answers on Part 35 on the NRC website.  
3 This has provided a wealth of information for  
4 licensees and for NRC license reviewers.

5       One of the most significant licensing  
6 challenges is to encourage licensees to use NUREG  
7 1556, Volume 9, the "Program Specific Guidance About  
8 Medical Use Licenses."

9       This streamlines the licensing process both  
10 for licensee and the license reviewer. We are still  
11 seeing licensees submitting procedures from the old  
12 Regulatory Guide 10.8, Revision 2. But we are making  
13 a lot of progress because licensees are becoming  
14 aware of the ease of submitting an application under  
15 Volume 9.

16       COMMISSIONER MCGAFFIGAN: Mr. Chairman,  
17 could I ask a clarifying question?

18       This NUREG-1556, Volume 9, is that the NRC  
19 staff product? I also know we endorsed a Reg Guide  
20 that was submitted to us for diagnostic users. Is  
21 this your product or the other product?

22       MS. HENDERSON: That is the staff product.

1           COMMISSIONER MCGAFFIGAN: This is a staff  
2 product. But the other product is consistent with  
3 this staff product?

4           MS. HENDERSON: Yes.

5           COMMISSIONER MCGAFFIGAN: And we have found  
6 it as such.

7           Are people using that other product if they  
8 are diagnostic?

9           MS. HENDERSON: I don't know the answer to  
10 that question.

11          Inspectors are finding that most licensees  
12 express a preference for the earlier, more  
13 prescriptive approach to Part-35.

14          When we visit facilities, we find that  
15 radiation safety committee meetings are still being  
16 held quarterly.

17          Daily surveys are still being done in  
18 diagnostic use areas.

19          Dose calibrators are still being used to  
20 measure unit dosages prior to administration.

21          And licensees are still doing linearity,  
22 geometry and accuracy tests on their dose calibrator



1 at the same frequency and following the same  
2 procedures that were provided in Regulatory Guide  
3 10.8, Revision 2.

4 Licensees continue to submit items that are  
5 no longer required. Quality management programs are  
6 still coming in but these are tapering off.

7 We are still getting detailed procedures  
8 for diagnostic use of byproduct material.

9 We need to improve licensee understanding  
10 of the details that need to be submitted for 35.600  
11 technologies such as high dose rate after loaders and gamma  
12 knives, specifically for the safety procedures and  
13 spot checks that are required.

14 COMMISSIONER MERRIFIELD: Mr. Chairman, can  
15 I ask a clarifying question regarding the  
16 presentations on five, six and seven?

17 Why? Why are -- you said what the  
18 licensees are doing. Why are they doing that?

19 MS. HENDERSON: They feel comfortable.  
20 This is the reaction that we are getting. They feel  
21 safe doing it the old way because they know it meets  
22 the regulations and then some.

1           We need to improve licensee understanding  
2 of the 35.1000 emergent technology procedures. To  
3 that end, on the NRC website, we have posted guidance  
4 on the 35.1000 technologies. And this has been very  
5 helpful to licensees in understanding how they can  
6 meet the regulations and also to license reviewers  
7 who are reviewing license applications for these  
8 technologies.

9           The regions are updating medical licenses  
10 as the licensees come in for amendments and not  
11 waiting until renewal of the license, which can be up  
12 to ten-year renewal.

13           Updates include user authorizations. One  
14 example of this is under the new Part 35 regulations,  
15 35-200 now deals with diagnostic procedures that do  
16 not require a written directive.

17           Under old Part 35, it included all  
18 diagnostic procedures whether or not they required a  
19 written directive.

20           We have had to go to the licenses and  
21 ensure that we are not taking away any authorizations  
22 for users.

1           We are also removing old license conditions  
2 that are now covered by the regulations such as HDR.  
3 Where we had five or more added conditions to  
4 licenses in order to allow them to use this  
5 equipment.

6           These conditions are now part of the  
7 regulations and are no longer necessary on the  
8 licenses.

9           COMMISSIONER MCGAFFIGAN: The licensee  
10 understands that?

11          MS. HENDERSON: Yes. Very well.

12          COMMISSIONER MCGAFFIGAN: You have given  
13 the lack of understanding about the new rule. I just  
14 want to be clear on that.

15          Thank you.

16          MS. HENDERSON: We have added new  
17 conditions to the licensees to permit them greater  
18 flexibility.

19          Inspectors agree that new Part 35 focuses  
20 inspections on more safety significant areas of  
21 medical programs.

22          We are ensuring that inspectors do a

1 performance-based inspection. That they do not do a  
2 record-keeping inspection. That they only look at a  
3 representative sample of the records.

4       The labor rates for inspection and  
5 management accompaniments of inspectors confirm that  
6 inspectors are implementing this new approach.

7       COMMISSIONER MERRIFIELD: In what way?

8       MS. HENDERSON: We are seeing that the  
9 labor rates are going down. And on management  
10 accompaniments, we are seeing that the inspectors  
11 are, in fact, doing risk-informed, performance-based  
12 inspections and not spending a lot of time reviewing  
13 records or looking at any prescriptive commitments  
14 the licensees may have made.

15       For most licensees, the first inspection  
16 under new Part 35 includes education about the  
17 details of the new regulation and guidance about  
18 program changes that may be needed.

19       Finally, the staff actions to address the  
20 challenges.

21       We are continuing dialogue with the  
22 licensee community. This is especially important

1 during licensing and inspection when we deal directly  
2 with the licensees.

3       There is close coordination of the regions  
4 and headquarters, specifically every other week the  
5 regions meet with the Part 35 working group to  
6 discuss various issues coming in from licensing and  
7 inspections.

8       These issues are able to be resolved very  
9 quickly and additional questions and answers are  
10 added to the website as we come up with these  
11 solutions.

12       The NRC public website has provided  
13 guidance to licensees with regard to 35.1000  
14 procedures. This guidance can be updated whenever  
15 necessary.

16       And again, the questions and answers posted  
17 on the website provide a wealth of information for  
18 licensees.

19       Thank you.

20       DR. MILLER: Next I would like to have Tom  
21 Essig. He is going to brief the Commission on the  
22 status of the dose reconstruction effort in St.

1 Joseph Mercy Hospital that you had asked us to brief  
2 you on today.

3 Tom.

4 MR. ESSIG: If I could have the second  
5 slide, please.

6 First, in the way of background, St. Joseph  
7 Mercy Hospital is a 529-bed teaching hospital located in Ann  
8 Arbor, Michigan. On July 1st, 2002, a female patient  
9 was administered 285 millicuries of I-131 for  
10 treatment of thyroid cancer.

11 The patient's daughter was observed  
12 following the treatment to be frequently at her  
13 mother's bedside. The licensee did not allow anyone  
14 in the patient's room during the first 24 hours.  
15 However, no stay time restrictions were imposed after  
16 that.

17 The daughter was, as part of the  
18 reconstruction, noted to be present days two through  
19 four about 50 percent of the time. And days five and  
20 six, when her mother's condition worsened, was there  
21 essentially there all but four hours during the last  
22 two days. The patient died on July 7th.

1 With regard to the inspection activities,  
2 the inspection report documented the daughter may  
3 have received a total effective dose equivalent of 15 REM.

4 The licensee did not collect the bio-assays  
5 sample from the daughter. Thus, the TEDE explicitly  
6 assumes no internal exposure.

7 Approximately 20 other members of the  
8 public were exposed. Of these, ten individuals  
9 received an estimate dosage between 100 and 500  
10 milligrams. The remaining ten received doses of less  
11 than 100 milligrams.

12 The inspection report also noted that the  
13 licensee did not take measures to ensure the doses  
14 were as low as reasonably achievable.

15 With regard to enforceable action, on May  
16 7, 2003, a letter from Region III, regional  
17 administrator imposed a civil penalty in the amount  
18 of \$6,000.

19 The civil penalty consisted of two parts,  
20 first for licensee activities which caused members of  
21 the public to receive doses in excess of the public  
22 limit of 100 milligram per year; and second, for the

1 failure of licensee to investigate and implement  
2 corrective action when it became known that a  
3 relative of the patient was not following the  
4 licensee's radiation safety practices.

5 If I could have the next slide, please.

6 Slide three.

7 Regarding other actions taken to date. In  
8 December of 2003, the letter signed by the President of  
9 Society of Nuclear Medicine and the President of the  
10 American College of Nuclear Physicians forwarded a  
11 critique of the dose evaluation that was contained in  
12 the region's inspection report.

13 This critique, authored by Dr. Carol Marcus  
14 and Dr. Jeffrey Siegel, offered that the NRC's dose  
15 evaluation was as much as a factor of 17 higher than  
16 it should be, in their view. The NMSS's staff's  
17 preliminary evaluation addresses the five principal  
18 issues raised in the critique.

19 We will finalize our evaluation when we  
20 receive the ACMUI's views.

21 Further actions taken to date --

22 COMMISSIONER MCGAFFIGAN: Mr. Chairman,



1 could we get them to tell us what their preliminary  
2 views are? I know that they want to wait for ACMUI  
3 to finalize. But they could tell us -- there were  
4 five things where Carol Marcus and Dr. Siegel said  
5 you guys were conservative up to a factor of 17.

6 Do you agree or don't you?

7 CHAIRMAN DIAZ: If their preliminary  
8 evaluation is complete enough that they can stick  
9 their neck out?

10 COMMISSIONER MERRIFIELD: I do wonder, we  
11 did ask ACMUI to take a look at it. And any time you  
12 have a preliminary view out there, it starts to  
13 solidify themselves into a position. Whereas our  
14 purpose was to have ACMUI take a look at it and try  
15 to see if there was a basis for asking some  
16 questions.

17 I think the argument is it might weaken the  
18 value that we have placed on having ACMUI take a look  
19 at it if the staff solidifies its view too much.

20 MR. ESSIG: We have not shared that with  
21 the subcommittee.

22 COMMISSIONER MCGAFFIGAN: I am going to let

1 it go. This is not rocket science. It is stuff that  
2 you can calculate relatively quickly. So it is  
3 either true or it isn't.

4 COMMISSIONER MERRIFIELD: But keep in mind,  
5 the process that we going through right now is a  
6 reflection on the debate that has been engendered  
7 from the comments we received from outside  
8 stakeholders who have a very different view.

9 And I think, I leave it to Chairman  
10 Diaz, but I think that there is a utility if the  
11 staff has its view -- preliminary view that it has  
12 come to, it would be in an in-camera way without  
13 having access to that same information, ACMUI would  
14 come to its own conclusion and it would interesting  
15 to seeing how those two would conflict, if they do  
16 conflict.

17 They might come to the exact same  
18 conclusion despite not sharing that information.

19 COMMISSIONER MCGAFFIGAN: My personal view  
20 was that what Carol Marcus and Jeff Siegel laid out  
21 reflected that the Chairman's desire for realistic  
22 conservatism as opposed to ultra conservatism. But I

1 look forward to whatever happens in this process that  
2 we go through.

3 I mean, our doses models -- I mean, as a  
4 regulator, we should be realistically conservative  
5 but not ultraconservative.

6 CHAIRMAN DIAZ: I do agree. However, there  
7 is the fact that dose reconstruction is not as simple  
8 as it looks if you want to do it right. It is really  
9 a much more difficult process.

10 I think one time in my life I did try to  
11 teach dose assessments and I was having a real hard  
12 time with it. So it is not as straightforward.  
13 Simple calculations, yes. But a complete calculation  
14 requires a significant amount of detail and effort,  
15 considerations of everything from back scattering -- to all of  
16 those factors that actually come.

17 So why don't we let the process go.

18 COMMISSIONER MERRIFIELD: This distracts  
19 from the Staff's direction at this point. But I  
20 would like make additional comment.

21 I think -- and this is only my own view.

22 But I think -- we suggested a notion of having ACMUI

1 taking a second look at this. What it does provide  
2 you is an opportunity for the potential to have three  
3 separate ways of looking at it.

4 Having done that, I think the next step in  
5 the process -- and I'm in agreement with you on the  
6 concern about over conservatism.

7 If they come up with three separate ways  
8 of looking at it, I think the next step would be a  
9 good rigorous dialogue between our staff, ACMUI and  
10 outside stakeholders to try to figure out how do you  
11 reconcile those differences of opinion to the extent  
12 that we can, so that we can come, perhaps, to some  
13 convergence in terms of agreeing on a principle for  
14 dose reconstruction as difficult as it may be.

15 CHAIRMAN DIAZ: We going to get three  
16 different answers.

17 COMMISSIONER MCGAFFIGAN: What struck me  
18 from the incoming letter was at one point and the  
19 response that Chairman Diaz had signed, we said that  
20 this was arithmetic. A person is here, so much time,  
21 you multiply a couple of numbers and it is finished.  
22 That was our assertion.

1           They came back and said, I don't think so  
2 and for the following reasons. It is more  
3 complicated than that. You are assuming -- that  
4 arithmetic -- the allegation that this is arithmetic  
5 is making a bunch of assumptions which we hereby  
6 challenge.

7           I'm just interested in -- I think it's  
8 right. We will have three different answers as to  
9 whether these simplifying assumptions were  
10 appropriate or not.

11           CHAIRMAN DIAZ: Like Commissioner  
12 Merrifield said, the idea is how do we achieve a  
13 certain amount of convergence in the methods to be  
14 followed so the answers will be reasonable.

15           COMMISSIONER MERRIFIELD: And a better  
16 understanding of everyone about the assumptions that  
17 we are making. So that we can be more a transparent  
18 regulator.

19           CHAIRMAN DIAZ: All right. Thank you.

20           MR. ESSIG: Could we return to slide four,  
21 please.

22           I believe I mentioned that in the January

1 12th letter from Chairman Diaz to the presidents of SNM  
2 and ACNP that ACMUI had been tasked to provide an  
3 independent analysis, as we have just discussed, and  
4 to provide us recommendations, if appropriate,  
5 regarding the ultimate dose reconstruction offered by  
6 the SNM.

7       We formed a subcommittee within the ACMUI  
8 on January 29th of this year to review the dose  
9 evaluation contained in the inspection report and the  
10 critique of it prepared by Drs. Marcus and Siegel.

11       The subcommittee was specifically requested  
12 to review each aspect of the dose evaluation and the  
13 critique offering the alternative methodology and to  
14 determine whether or not it agrees with the  
15 approaches, each approach and why.

16       COMMISSIONER MCGAFFIGAN: I would add, as  
17 Commissioner Merrifield just said, they can come up  
18 with an alternative approach.

19       MR. ESSIG: Yes.

20       COMMISSIONER MCGAFFIGAN: That should be  
21 within the scope of what they are doing.

22       MR. ESSIG: Yes.

1 On slide 5.

2 We are expecting ACMUI's report in about a  
3 month. We are sensitive to the committee's need for  
4 additional discussions at this time since the effort  
5 is just underway. That is our best estimate, about a  
6 month. We expect the subcommittee will deliver to  
7 the full committee in about that time frame. And  
8 then the full committee will have to deliberate and  
9 furnish a final product to us.

10 And we plan to use the Region III  
11 assessment, our own evaluations, the ACMUI report in  
12 forming conclusions regarding the merits of the SNM  
13 critique. And hopefully to use the results of this  
14 evaluation to inform future evaluations of this type.

15 And lastly, then, on slide six.

16 We will prepare a report which would be  
17 appended to the final response letter that is sent to  
18 the SNM and the American College of Nuclear  
19 Physicians.

20 That concludes my presentation.

21 DR. MILLER: Thank you.

22 Chairman, just to embellish a couple of

1 things that Tom said. One of the things we are  
2 trying to take this opportunity to do, both we and  
3 ACMUI, is to take a step back and look at what we got  
4 submitted by SNM, what the licensee did, what the  
5 staff calculations are, what ACMUI comes up and look  
6 for reasonable ways to proceed here. What can we  
7 learn from this?

8         And reasonable people can disagree. And I  
9 think in -- how should we be doing it in the future?  
10 Is there a better way to do it? I think we should  
11 always strive for that.

12         Also I would like to just note that  
13 regardless if you take Carol Marcus' calculations or  
14 the staff calculations or the licensee's calculations  
15 and whatever, in the case -- of this particular case,  
16 it would not have affected the outcome with regard to  
17 the action that the NRC took.

18         MR. PAPERIELLO: That concludes the Staff's  
19 presentation.

20         CHAIRMAN DIAZ: Thank you so very much.  
21 It's always interesting to look at the variability of  
22 results. And with this, Commissioner Merrifield?



1           COMMISSIONER MERRIFIELD: Going back to the  
2 point that Dr. Miller made at the end. It's good for  
3 you to bring us back to the point that it would not  
4 have changed the conclusion that we had.

5           But I'm also glad to hear you talk about  
6 the value of understanding how we got through that  
7 process.

8           Clearly, how we go about doing dose  
9 reconstruction is an item which does have a -- does  
10 engender a significant amount of debate among some of  
11 our external stakeholders.

12          And to the extent that we can use the St.  
13 Mercy case as a case study, to really in a  
14 transparent way explain to people how is it that we  
15 do these reconstructions and what are the assumptions  
16 that we would make in this case, similar to the ones  
17 we would make in other cases that we need to be more  
18 guarded about providing private information.

19          I think there is a utility matter. And I  
20 think part of my vision and I think others would  
21 agree that the hope is having gone through this  
22 exercise, hopefully, we can lower the tone and volume

1 of the debate so that when we are making our  
2 decisions, that these people even if they don't agree  
3 with us, they know what our operating assumptions are  
4 in going ahead and doing that.

5       Hopefully we can come to some convergence  
6 and deal with this in total.

7       Going back to the first presentation by  
8 Ms. Henderson. You talked about a significant  
9 education effort that your inspectors have been  
10 undertaking and folks in the region have been  
11 undertaking.

12       What is this -- has this driven an increase  
13 in the staff resources to conduct the inspections?  
14 I want to get some sense of that.

15       And also how long do you think this  
16 education effort is going to need to continue until  
17 we get to a point where people, although they may  
18 prefer the old way, will at least understand what we  
19 are doing with the new way?

20       MS. HENDERSON: I don't think it adds  
21 significantly to the amount of time spent on  
22 inspection because the inspectors do this as they are

1 going along as part of their inspection. They will

2 explain the differences.

3 So I don't really think it adds a lot of

4 time, nothing really significant.

5 As far as how long. Based on the last

6 change to Part 35, I would say five years.

7 COMMISSIONER MERRIFIELD: Five years?

8 MS. HENDERSON: Yes. That would be my best

9 estimate.

10 DR. MILLER: Commissioner, if I could also

11 add, we have to remind ourselves that the Agreement

12 States have three years to come to full compatibility

13 on the revised regulations. So along with that,

14 there is still the effort to work with the states as

15 they come to compatibility on this so that we reach

16 some consensus, not only in NRC-regulated facilities

17 but in state-regulated facilities also.

18 COMMISSIONER MERRIFIELD: And presumably,

19 they would require the five-year type of a cycle to

20 educate the users and their licensees in their state

21 as well.

22 DR. MILLER: Hopefully, you can learn from

1 what's happened in the ensuing period.

2 COMMISSIONER MERRIFIELD: We use currently

3 in enforcement -- well, in taking a look at the issue

4 of mis-administration, our old definition verses

5 medical event, we now have our new definition in Part

6 35. We use a 20 percent number as the kickoff point.

7 If you go outside of the 20 percent figure, that's

8 where you fall into what is now our medical events.

9 How is it that we derived this number? I

10 know this is one that we used for a very long time.

11 How is it that we derived this number? And to the

12 extent we have gone from a deterministic to a

13 risk-informed framework, have we rigorously taken a

14 look at that figure in a risk-informed way to see

15 whether it still makes sense?

16 DR. MILLER: I can't speak to the ancient

17 history of where the 20 percent came from. But it

18 was revisited when the revised Part 35 was

19 promulgated. And it was visited by both the Staff

20 and ACMUI. And it was debated during the public

21 comment period. We received public comments on it

22 that were divergent.

1           The Staff finally -- the NRC finally  
2 decided to retain the 20 percent from the old rule,  
3 not necessarily because it indicated there was a  
4 deficiency in a licensee's program, but more  
5 because it might indicate -- well, let me correct  
6 that -- that it could indicate a deficiency in a  
7 licensee's program.

8           Not necessarily that in every specific case  
9 there was an absolute risk to the patient.

10          So there was a lot of debate on that. And  
11 it was included in the risk-informing of the revised  
12 Part 35.

13          I can't speak -- as I said, I don't know if  
14 Carl remembers where it initially came from. It was  
15 well before my time.

16          MR. PAPERIELLO: I'm going to speak on  
17 teletherapy and external beam. My understanding of  
18 external beam therapy, of course what you are trying  
19 to do is give the maximum amount of dose where you  
20 can generally for tumor suppression and not affect  
21 healthy tissue. Or at least affect healthy tissue to  
22 the point where it can recover.

1           When you start looking at the curves, a 20  
2 percent increase in that dose would be significant.  
3 How you would translate that to all other modalities  
4 of therapy, I'm not sure.

5           I know we looked at it years ago when we  
6 selected the number.

7           But I want to make one point here. This is  
8 one of the reasons we changed the term from  
9 mis-administration to medical event. There is a  
10 number of things that happen, that occur because  
11 machinery that we licensed or an Agreement State  
12 licensed failed to perform as expected. On board  
13 micro processors failed. We licensed the machine.

14          So one way of -- one value in getting  
15 reported medical events is it gives us information to  
16 identify generic issues. And it seems like every  
17 time you get a new modality with a new type of  
18 device, unexpected failures show up. And then with  
19 time, they are eliminated.

20          In answering your question, 20 percent was  
21 looked at and was decided to be, with a lot of  
22 advice, reasonable when we adopted it. If you ask me

1 sitting here that every possible modality of therapy  
2 20 percent means the same thing, I can't say that.  
3 And it probably does not.

4       COMMISSIONER MERRIFIELD: I know it is --  
5 obviously, from a regulator standpoint, it is easier  
6 to use a single number. But given the range of  
7 modalities and the impact that that 20 percent may  
8 have, seems to be some variation.

9       So I think it is at least worth thinking  
10 about again.

11       I would say, Mr. Chairman, this is one of  
12 those examples. We dealt with Part 35, the meat of  
13 what the Commission was doing, a few years ago.  
14 Frankly, I know a little bit more about the topic now  
15 than I used to. In the main, we have made very, very  
16 positive changes as a result of Part 35. But I think  
17 it is good for the Commission to continue asking the  
18 questions and perhaps even taking a look back at a  
19 few of the things that we did then because there may  
20 be further -- I know Carl is wincing at the thought  
21 of that, but there may be further things we may want  
22 to think about or not.

1 MR. PAPERIELLO: Commissioner, actually, it  
2 is more complicated than that. This is the fastest  
3 changing technological changing area we regulate.  
4 This is moving faster than reactors are.

5 We think of reactors as being -- the fact  
6 is this is where the technology changes the most. I  
7 been with medical now, in one aspect or another, for  
8 over 20 years. What was done in 1978 when I first  
9 got involved to now has changed significantly.

10 So it is appropriate to have to change our  
11 regulations as modalities change. That's why we  
12 wrote 35.1000, because you can't put square pegs into  
13 round holes and then revisit what you done. It is  
14 the way it's going to be.

15 I have no problem with that. That is not a  
16 reflection on anybody. It is just a reflection that  
17 it is a very rapidly changing technology.

18 COMMISSIONER MERRIFIELD: Thank you, Mr.  
19 Chairman.

20 CHAIRMAN DIAZ: Thank you, Commissioner  
21 Merrifield.

22 That is a very good statement. I could



1 spend a lot of time on that but I will let it go.

2       Again, I think when we look at the issues  
3 with medical uses of radio isotopes, we have to  
4 come to grips with a realization that we do this  
5 thing to improve the health of patients in many  
6 different ways.

7       So there is always a little bit of risk and  
8 there is a little bit of that. But I think the  
9 overall sense that I always get is that these things  
10 are doing well and that there are errors, and those  
11 errors we learn from them.

12       But fundamentally, to me it is always a  
13 fact that people are really -- here in this agency  
14 are always concerned with how much radiation somebody  
15 gets because of the potential health effects of  
16 radiation. And this case we are using radiation for  
17 the purpose of healing or the purpose of determining  
18 what something is.

19       So those things always come back and say  
20 well, this is voluntary use and there is a difference  
21 in how we see it. And eventually, there is no doubt  
22 that things are going to be changed because the

1 technology change. And even we change, slowly but  
2 surely.

3         With that, let me just go back to this  
4 issue of the staff finding that continuation of items  
5 that are submitted that are no longer required.  
6 There already was discussion about it. This is not a  
7 new thing in this area. We see this in many of our  
8 licensees. They do want to have new things but when  
9 they come in, they say I don't want to change. I  
10 like what I had. I'm comfortable with it. I know  
11 how to do it.

12         And I think it gets into this issue of the  
13 concern with enforcement space.

14         Now, have we done enough as a matter of  
15 training when we go and train people on Part 35 which  
16 we do it during the first inspection, right? When  
17 the first inspection comes, we make sure there is  
18 some training.

19         To have people understand that  
20 enforcement, in many ways, has also changed as the  
21 way and that there is no real -- there is not that  
22 much significance in continuing to do items or where

1 prescribed because now we have them in a complete  
2 different plane of reference.

3 MS. HENDERSON: Absolutely. We point them  
4 towards 1556, Volume 9 which is much more  
5 streamlined. But it is just going to take a while  
6 for them to let go of their older procedures. And  
7 they are generally more prescriptive and they meet  
8 the regulations and then some.

9 CHAIRMAN DIAZ: And you know, this issue  
10 that you see, is this something that we should  
11 address more aggressively when we actually provide  
12 training and instruction, or you believe the level of  
13 which we are doing is sufficient to take them where  
14 we want go in a smooth path, not drastic steps?

15 MS. HENDERSON: I think that what we are  
16 doing in inspection and also when licensees come in  
17 for amendment or renewal of their licenses is enough.  
18 I think that they are slowly getting the message.

19 CHAIRMAN DIAZ: When you go from the Part  
20 35 to the actual special application and the special  
21 licensee, do we make an effort to, again in this same  
22 vein, to understand whether particular issues or the

1 particular capabilities are to make sure that we get  
2 a good match between what they are actually required  
3 of the new Part 35 and what the capabilities are? Do  
4 we actually listen to make sure that we can  
5 communicate on what the requirements are in the  
6 manner that there is a good path forward?

7 MS. HENDERSON: I think so. I think we are  
8 doing that 35.1000 would be a very good example  
9 because this is new guidance for these modalities on  
10 the website. We work with the licensees. It is  
11 guidance so they may propose something as an  
12 alternative. And we go back to the regulations at  
13 that point to make sure that they are meeting them.

14 CHAIRMAN DIAZ: This five years, that's  
15 where you would think will get us to a place where  
16 significant fraction of them -- is there something  
17 that we could be doing extra that will help us get  
18 there?

19 Is the Staff looking at whether there are  
20 additional amount of training information,  
21 communications when we go on and especially during  
22 the inspections, or additional things we can put on

1 the website?

2 What is it that we can do to ease this

3 transition forward?

4 I'm getting concerned that we got into this

5 thing and now we are having to manage with a

6 variability that maybe I was not really expecting in

7 this area. I thought they were jump and 80 percent

8 of them are going to say I love this issue. I'm not

9 hearing that.

10 MS. HENDERSON: That's what we thought,

11 too. But that is not case. Sure, there is

12 additional effort that we could make to let licensees

13 know that they do not have to follow the old

14 procedures, that they can move in to use of the new

15 regulations and not fear enforcement action. Sure.

16 CHAIRMAN DIAZ: But are we aggressively

17 addressing those issues in a site-specific basis?

18 MS. HENDERSON: Yes, we are. Because it

19 makes licensing easier for us and inspection easier

20 for us, not only the licensee.

21 So we go in very aggressively. We will

22 bring copies of Volume 9. We will sit down with

1 licensees and go through their program, if they like,  
2 or as we go through inspection will point out you are  
3 using unit doses. You are still assaying them before  
4 you use them. You don't have to do that unless you  
5 voluntarily wish to do that.

6           And they do. They are so used to the  
7 prescriptiveness of Part 35 that it makes them feel  
8 safe to continue using it.

9           CHAIRMAN DIAZ: All right. I think we  
10 discussed the St. Joseph Mercy Hospital case  
11 sufficiently. I believe I understand all I did not  
12 know about it.

13           So Commissioner McGaffigan.

14           COMMISSIONER MCGAFFIGAN: Could I ask  
15 something that was not on the agenda today but I know  
16 you are working on? The endorsement of the  
17 therapeutic guidance that has been submitted to us.  
18 How is that proceeding? When do you foresee being  
19 able to have a staff position as to whether you can  
20 endorse that guidance or endorse the guidance with  
21 modification?

22           MR. ESSIG: We have completed our initial

1 review of it and we have recommended some minor  
2 modifications to it. And it is now being reviewed at  
3 higher management levels within NMSS.

4 COMMISSIONER MCGAFFIGAN: Have you  
5 recommended those changes to the submitters or are  
6 these proposals --

7 MR. ESSIG: These are proposed changes that  
8 we want to make sure our management agrees with. And  
9 then we will recommend back.

10 COMMISSIONER MCGAFFIGAN: Again, I would  
11 urge that process go forward, especially if the Staff  
12 believes they are relatively minor. I hope that the  
13 management can take a look at them and get them back.  
14 And you can have the dialogue and we can get to  
15 conclusion.

16 There is a preface to the question. I know  
17 NUREG-1556, Volume 9 is our bible. But the criticism  
18 that we have gotten of our bible is that it was  
19 fairly complicated especially for diagnostic users.

20 Would it be appropriate when you are  
21 visiting somebody who is just doing diagnostics to  
22 say here is NUREG-1556, Volume 9, and by the way,

1 here is the thing that we have also endorsed that you  
2 may find it easier to use because it focuses just on  
3 diagnostic use? Do we do that?

4 MS. HENDERSON: We don't do that. But that  
5 is a good idea.

6 COMMISSIONER MCGAFFIGAN: It strikes me if  
7 we go through the trouble of endorsing these guidance  
8 documents and saying that they meet our needs, maybe  
9 it is the -- God knows if there were NEI in reactor  
10 space, they would be shouting it from the rooftops  
11 that afternoon and sending out E-mails and whatever.  
12 And maybe the communication with a much more diverse  
13 group of people from the Society of Nuclear Medicine,  
14 the American College of Radiology and all that is  
15 more complicated.

16 But I don't know that we should not also  
17 say, by the way, we have endorsed this and it is  
18 available on the website of blankety-blank  
19 organization or here's a copy. You may want to use  
20 it or once the therapeutic one is endorsed, use it.

21 There is nothing substantively different  
22 between them. They just put the stuff together in a



1 neater way.

2 MR. ESSIG: If I might add. When we did  
3 agree that the guidance prepared on diagnostic  
4 procedures was acceptable to us, we prepared and  
5 promulgated a regulatory issue summary announcing  
6 that. And it is actually on our website with a link  
7 to it.

8 COMMISSIONER MERRIFIELD: The guide is on  
9 our website. If it is on our website, then I think  
10 the inspectors should feel free to sort of say, hey,  
11 you can use this. If you find our stuff complicated,  
12 here is something that may be slightly plainer  
13 English. Not that ours is not plain English.

14 But I urge you to think about that.

15 It is just a question about how this  
16 community works. If it were NEI or a reactor's  
17 owners group, you mentioned it takes 10 years to get  
18 around to relicensing these facilities. But if it  
19 were NEI and there were flexibility involved, they  
20 probably would have a standard change package or  
21 maybe if it were appropriate to a particular reactor  
22 type maybe the owners group would do it.

1 Does anybody put together a standard  
2 license amendment that if you want to move to -- or  
3 maybe it is embedded in these guides -- if you want  
4 to move to the more flexible system that NRC  
5 currently allows, here is a standard license  
6 amendment you might be able to submit or here are  
7 options for a standard license amendment depending on  
8 what you do at your hospital that you can submit?

9 Does anybody do that?

10 MS. HENDERSON: Not specifically but in  
11 Volume 9 there are examples of what you can submit.  
12 And because it is done piecemeal, if they want to  
13 change a location of use, they can go to that area of  
14 the guide and it will tell them exactly what they  
15 need to submit. In the case of diagnostic, they  
16 don't need to submit anything.

17 COMMISSIONER MCGAFFIGAN: They don't have  
18 to submit anything?

19 MS. HENDERSON: Unless you are changing an  
20 address.

21 COMMISSIONER MCGAFFIGAN: Well, that is  
22 good information to have out there.

1           Let me ask one last question about the  
2 Mercy Hospital thing. I understand there was some  
3 good discussion yesterday with ACMUI. But one of the  
4 issues that came up -- and I'm just trying to  
5 understand our philosophy. If it were me and my  
6 mother at that hospital, and our current limit is 500  
7 millirems for patient visitation, I will tell you if  
8 you are sitting out there with your calculator and  
9 telling me, Commissioner, you may be getting close to  
10 500 so I don't think you should visit your mother  
11 tomorrow, I would probably tell you to go to some  
12 place south of here or something.

13           It would be -- I imagine this is in the  
14 medical community. I probably, as a result of having  
15 melanoma four and a half years ago, I probably have  
16 probably gotten 20, 30 REMS through PET scans and CT  
17 scans over the last four and a half years. And  
18 getting an extra couple of hundred millirems is not  
19 the end of the world.

20           So what is our regulatory philosophy if  
21 you have an ornery visitor of a patient and it is not  
22 Commissioner McGaffigan? You may have special rules

1 for me. I hope not. But what is the hospital  
2 supposed do with ornery Patient McGaffigan who says I  
3 don't give a damn what your calculations are saying,  
4 I'm going to visit my mother?

5 COMMISSIONER MERRIFIELD: Before you answer  
6 that, to put to rest any speculation, there is on the  
7 issues that are regulated before the Commission,  
8 there is no separate set of Commissioner standards.

9 That was tongue-in-cheek. I just want to  
10 make sure that the record is clear. No such separate  
11 standards exist.

12 COMMISSIONER MCGAFFIGAN: But it may be  
13 particularly difficult to deal with ornery  
14 McGaffigan. So take me as a typical patient --

15 COMMISSIONER MERRIFIELD: I can comment on  
16 that.

17 COMMISSIONER MCGAFFIGAN: What do you do  
18 with me?

19 MR. ESSIG: You are quite correct. We had  
20 a good lively discussion of this yesterday in the ACMUI  
21 committee meeting. One of the -- in the extreme  
22 case, we were -- we will not, for that case nor any

1 future cases, expect the licensee to take heroic  
2 action such as physically restraining the individual  
3 because we are talking about emotional issues here,  
4 as you noted. But in this case --

5 COMMISSIONER MCGAFFIGAN: Dying mother,  
6 pretty emotional.

7 MR. ESSIG: Yes.

8 In this case we looked at the licensee's  
9 actions to see if they were reasonable.

10 COMMISSIONER MCGAFFIGAN: But do you care  
11 about -- if the person is fully informed, the  
12 hospital did everything they could to try to keep me  
13 from visiting my mother on the fourth day because  
14 they calculated that I was going to exceed 500  
15 millirems that day. And I said, sorry, I understand  
16 your rules. I understand NRC'S rules. Say it is not me.  
17 But I'm going to go visit my mother and I will wear  
18 whatever you want me to wear. But I'm going to visit  
19 my mother.

20 Is that person -- they have done everything  
21 reasonable -- would we take enforcement action in  
22 that case?

1 COMMISSIONER MERRIFIELD: There is an example that Dr. Miller can  
2 tell us about of a counter to what happened at Mercy Hospital.

3 DR. MILLER: Let me use that as an  
4 illustrative example.

5 There was a case, not exactly the same but  
6 similar kind of scenario at St. Joseph Mercy Hospital  
7 that we dealt with in Pennsylvania, University of  
8 Pennsylvania, a year or so ago, where the licensee  
9 did everything right.

10 They trained the individuals. They wrongly  
11 thought they could convert them to occupational  
12 status which would allow them to get higher limits.  
13 But they trained them. They followed their procedures.

14 They came back to the NRC ultimately once  
15 they recognized they could not be occupational status  
16 and asked for some higher limits for the parents.  
17 There was a case of a children's hospital.

18 In that case the region took enforcement  
19 discretion because the licensee did things as well as  
20 could be expected and did it right.

21 Now, with regard to ornery McGaffigan, the  
22 doctors and ACMUI can attest to this, it is the same as if you

1 are a patient in a hospital. The hospital cannot --  
2 my understanding is a hospital cannot legally tell a  
3 patient you can't get up and walk out of here, even  
4 if your doctors are advising you, you better not  
5 leave your bed.

6 So it tugs at an ethical issue. And it is  
7 a very difficult issue to deal with. And we have had  
8 a lot of lively discussion about this, both the Staff  
9 and the staff in ACMUI.

10 Where do we draw the line? If someone --  
11 if the licensee is doing everything that we the  
12 regulators expect the licensee to do, but yet you  
13 have someone who refuses to follow the guidelines --

14 COMMISSIONER MCGAFFIGAN: If you have your  
15 calculator out there and you are saying, gosh, you  
16 have done everything, Mr. McGaffigan, we have asked  
17 to you do, your mother has lived an extra few days  
18 beyond what we have expected and we really tell you,  
19 NRC rules would preclude you going in to see your  
20 mother today.

21 But I can't imagine they would tell me that  
22 very forcefully. I would hope they would not tell me

1 that very forcefully. If they did, I would say thank  
2 you very much. It is apparently within my rights. I  
3 would go visit my mother.

4 But it strikes me that this is an emotional  
5 issue whether it is visiting a mother or visiting a  
6 child. Those are about the two most emotional  
7 things you can do.

8 And we have to have reasonable use of  
9 enforcement discretion. And so describing how you  
10 would use enforcement discretion and what the  
11 hospitals has to do wrong in order to get into  
12 enforcement space where you would not use enforcement  
13 discretion -- I think the discussions you had  
14 yesterday with ACMUI, if they lead to some sort of  
15 clarification, it would be very useful.

16 CHAIRMAN DIAZ: Can they use time  
17 restrictions like or especially the patient is not  
18 sleeping or semiconscious, could they provide some  
19 type of guidance to provide --

20 DR. MILLER: Sure it could be in your procedures. As part of the training,  
21 you are going to want to educate them on the time,  
22 distance and shielding. And if the patient is



1 sleeping.

2 But as the Commissioner McGaffigan has  
3 correctly pointed out, if it gets to the 12th hour  
4 for a patient, it is very difficult to tell their  
5 loved ones, especially if they are in a distraught  
6 state, you can't be there. That gives us a very  
7 difficult situation to deal with as regulators so  
8 that we don't appear as if we are callous, which we  
9 not.

10 COMMISSIONER MCGAFFIGAN: Thank you.

11 COMMISSIONER MERRIFIELD: Just so the  
12 record is clear. I agree with Commissioner McGaffigan in  
13 the struggle on this. And if I were in that person's  
14 shoes, I would do the same thing. I don't really  
15 give a hoot about your regulations. I'm going to do  
16 what is appropriate.

17 And I think as a regulator, we do have to  
18 inject common sense and compassion into what we do in  
19 these kinds of circumstances.

20 If we have got a set of procedures that  
21 the hospital has followed, they done everything they  
22 could despite the person wanting to be in the room to

1 minimize the exposure, and there is some kind of informed  
2 consent or something of that nature, at some point I  
3 think that enforcement description is the right thing  
4 to do.

5 CHAIRMAN DIAZ: Of course, the Commission  
6 struggled with this when we did the patients rule.  
7 We actually had a significant amount of time looking  
8 at what is the approach that we should take when  
9 there is really a need for a visitor to be with a  
10 child or a mother to be with a child or vice versa,  
11 someone to be with their mother.

12 So, I think we all agree this requires a  
13 deeper look and a full understanding of the  
14 circumstances and a good approach from the licensees  
15 to try to match the needs of the patient and the  
16 family with some reasonable guidelines.

17 Thank you, my fellow Commissioners.

18 And with that, I believe I want to thank  
19 the Staff for their presentation. As always, it is  
20 good to see you, Dr. Miller and Ms. Henderson, Mr. Essig. And,  
21 Carl, I see you way too often, I think. Thank you.  
22 I just needed to say that.

1           And would the ACMUI committee please join us.

2           Well, welcome to the Commission. We are  
3 pleased to have you with us today. It is always a  
4 pleasure to see you again, Manny. I hope are you  
5 doing well. I hope the members of the committee are  
6 doing well.

7           We do realize, like Commissioner McGaffigan  
8 said, that the reactors get a lot of the attention,  
9 that this is one area where actually the people of  
10 our country and most other countries are actually  
11 receiving small, medium and sometimes large amounts  
12 of radiation because of health needs. And it is our  
13 purpose to make that as good as possible and your  
14 advice in this issue is very valuable to the  
15 Commission.

16          Thank you for your participation. And with  
17 that, Dr. Cerqueira.

18          DR. CERQUEIRA: Thank you very much,  
19 Chairman Diaz.

20          My name is Manuel Cerqueira. I am the  
21 Chairman of the ACMUI. On behalf of the committee, I  
22 would like to thank you and Commissioner Merrifield

1 and Commissioner McGaffigan to allow us to present  
2 two areas that we think are very important.

3 And the first area is the Part 35 revision  
4 on the proposed rulemaking. And this will be  
5 presented by Ralph Lieto who is a committee member.

6 Ralph.

7 MR. LIETO: Good morning. My name is Ralph  
8 Lieto. I'm the ACMUI member that is representing  
9 nuclear medicine physics. On behalf of the ACMUI  
10 I really appreciate the opportunity to speak to you  
11 on behalf of the proposed rulemaking on Part 35  
12 revision.

13 The NRC published this rule on December  
14 12th of last year seeking comments on the revision of  
15 the training and experience requirements. These  
16 training and experience requirements affect  
17 authorized users, authorized medical physicists,  
18 which is a new designation, authorized nuclear  
19 pharmacists and radiation safety officers.

20 The NRC proposed amendments to the training  
21 and experience affect the approval of these  
22 authorized individuals via both current mechanisms

1 which is board certification recognition and what is  
2 called the alternate pathway.

3       The proposed rules involve significant work  
4 by the ACMUI with NRC staff as well as NRC staff  
5 discussions with representatives of the affected  
6 boards and professional societies.

7       On behalf of the ACMUI, I would like to  
8 bring to the Commissioners' attention, three  
9 particular aspects that we feel need to be commented  
10 on that relate to this proposed published rule.

11       These have been raised in ACMUI meetings  
12 since the committee last met with the Commission, as  
13 well as were raised during the drafting of the  
14 proposed rule.

15       The three aspects involve board  
16 certification, the preceptor statement and transition  
17 issues in going from the current regulations to the  
18 proposed.

19       One of the questions, however, that was  
20 raised during the published proposed rule during the  
21 comment period was that should the word "attestation"  
22 be used to replace word the word "certification" in

1 preceptor statements.

2           The ACMUI would like to strongly reaffirm  
3 its recommendation to use the word "attest" or  
4 "attestation" in place of certification in the  
5 revised Part 35.

6           It should be noted that the comment period  
7 expired or ended last week on February 23rd. There  
8 may be some additional comments by ACMUI members on  
9 these issues after my presentation.

10           The criteria regarding board certification.  
11 The criteria for board certification to be recognized  
12 and listed in Part 35 is one that we feel is the crux  
13 of the proposed rulemaking. The importance of board  
14 certification cannot not be emphasized enough.

15           Board certification provides a means to  
16 assess and document the comprehension of a body of  
17 knowledge and/or basic skills of an individual. It  
18 does not determine the training program content nor  
19 its adequacy, nor does it determine the competence to  
20 supervise safety programs.

21           NRC expects that medical events can be  
22 related to board certification. We feel that this is

1 a misunderstanding of the board process.

2         Now, relating to the training and  
3 experience for a radiation safety officer which is  
4 found in Section 50 of Part 35, repeatedly during the  
5 rule revision process, the ACMUI stated that the  
6 training and experience revision should not exclude  
7 existing recognized boards that provide radiation  
8 safety officers.

9         Particularly in the new paragraph, which  
10 is Section 50(d)(2)(i) is a new paragraph that was  
11 added to allow medical physicists to serve as RSOs if  
12 they were certified in a board specialty whose  
13 certification process has been recognized by either  
14 the Commission or an Agreement State.

15         It appears that it was intended to  
16 authorize RSOs who were board certified medical  
17 physicists but were not AMP's. However, the proposed  
18 rule as currently written appears to disqualify  
19 certification categories in the American Board of  
20 Radiology and the American Board of Science and Nuclear  
21 Medicine from which many currently certified medical  
22 physicists serve as radiation safety officers.

1           Now, we feel this probably was not  
2 intentional. But we want to bring it to the  
3 attention of the Commission so that it is rectified  
4 before the final rulemaking process occurs.  
5 Otherwise, we are concerned that a shortage will be  
6 created of qualified radiation safety officers  
7 via this mechanism.

8           COMMISSIONER MERRIFIELD: Mr. Chairman,  
9 clarification. Would the change be so that the  
10 individuals who currently are, in effect, given a  
11 grandfather or would it also be inclusive of allowing  
12 those boards in the future to certify as well -- or  
13 to attest as well under your new proposal?

14           MR. LIETO: This would be for future.  
15 Because the grandfathering would take care of those  
16 currently. The way it is written is for future RSOs.

17           For example, in the American Board of  
18 Radiology, there is a certification speciality in  
19 medical nuclear physics which the way the tie-in  
20 currently, it appears it would preclude any future  
21 applicants from being recognized as radiation safety  
22 officers that were board certified via that



1 mechanism.

2           COMMISSIONER MERRIFIELD: One further  
3 clarification.

4           In the dialogue that you have had with our  
5 staff, was that an intended action, or do you believe  
6 that that was an oversight?

7           MR. LIETO: I believe it was oversight in  
8 the rewrite and the emerging of all the suggested  
9 changes that have occurred since the training and  
10 experience requirements have been discussed within,  
11 let's say, the last seven to eight months.

12           The advisory committee also would like to  
13 suggest that the process for a board to be recognized  
14 and listed on the NRC website is -- well, the  
15 suggestion is an entirely new concept and  
16 requirement. But the fact that this is occurring is going to  
17 to be a new requirement on  
18 the boards.

19           And we feel that while a formal  
20 application, regardless -- will be required  
21 regardless of the length of time that a board has  
22 existed that the current plan that NRC has to notify

1 boards via a letter or official notice needs to be  
2 supplemented.

3         The ACMUI would suggest that a notice go to  
4 the major societies whose diplomats comprise members  
5 of the various board such as the American College of  
6 Radiology, Society of Nuclear Medicine, American  
7 Society of Therapeutic Radiation Oncologists and the  
8 Health Physicists Society as well as the American  
9 Association of Physicists in Medicine also be  
10 notified about this.

11         In addition, we would like to suggest that  
12 a workshop be set up so that as this process goes  
13 forward, a workshop with the stakeholders which would  
14 include NRC as well as the boards, professional  
15 societies and maybe ACMUI members would occur.

16         The purpose is to address the specifics and  
17 finalization of the process for being listed in the  
18 boards -- for the boards being listed on the NRC  
19 website as well as creating a two-way dialogue to  
20 affect this listing process between the NRC and the  
21 affected groups.

22         COMMISSIONER MERRIFIELD: Mr. Chairman, one

1 further clarification.

2           The two items you have listed in slide 3,  
3 written notice and workshop with stakeholders, are  
4 those issues that you have raised with our staff yet?

5           MR. LIETO: Yes.

6           COMMISSIONER MERRIFIELD: Was there a  
7 response from the staff?

8           MR. LIETO: Well, I would say that there  
9 has not any opposition to it.

10          The formal letter process and formal notice  
11 process, I think, was always the accepted process  
12 from the get-go. There was concern raised by the  
13 ACMUI that just a letter going to a board may not be  
14 an adequate way to affect this process but include  
15 them in a two-way dialogue so that they understand  
16 what's going on.

17          But also trying to make the staff recognize  
18 maybe some of the difficulties in getting listing  
19 that might need to be overcome so that we are not  
20 setting out here maybe a year or so and everybody at  
21 the last minute is trying to get things done in terms  
22 of a listing on the NRC website for recognition.

1           One aspect of the revision to the training  
2 and experience rulemaking has been the NRC  
3 requirement for our preceptor statement. Based on  
4 input from the ACMUI the requirement for a preceptor  
5 statement was decoupled from board certification  
6 pathway to meet this NRC directive.

7           This is a new regulatory requirement for  
8 both board certified and alternate pathways for  
9 obtaining authorization from the Nuclear Regulatory  
10 Commission.

11          Now each new applicant bears the burden  
12 for obtaining this preceptor statement. The ACMUI  
13 believes that the definition of a preceptor will  
14 greatly impact the implementation of this  
15 requirement. The current definition listed in the  
16 slide is "an individual who provides or directs the  
17 training and experience required for an individual to  
18 become an authorized user, authorized medical  
19 physicist, authorized nuclear pharmacist or RSO."

20          We feel that the preceptor statement must  
21 be flexible, practical and minimize implementation  
22 burden, yet allow that a preceptor who is not the one

1 providing the direct training and experience, such as  
2 a program director who has knowledge of the training  
3 and experience as well as skills for that specific  
4 modality or use, to sign the preceptorship.

5         Also we feel and -- this has been  
6 addressed, as pointed out earlier today by staff, for  
7 accommodating multiple preceptor statements. The  
8 ACMUI feels that possibly there may need to be a  
9 change in the definition of the preceptor. A  
10 suggestion of modification might be, as indicated in  
11 the slide, would be an individual who provides or  
12 directs training and experience.

13         It would basically eliminate the article  
14 "the" between directs and training. This is just a  
15 suggestion for NRC consideration. We feel that it is  
16 important that the definition be flexible for its  
17 implementation.

18         Several questions have arisen and concerns  
19 raised in the ACMUI discussion on implementing this  
20 preceptor statement requirement. The ACMUI does not  
21 expect any answers at this meeting with the  
22 Commission but wishes to express these issues for

1 resolution during the final rulemaking process.

2           The question is: Who can be a preceptor?

3 What documentation is required for an individual to  
4 be recognized by the NRC as a preceptor? And what  
5 information does that preceptor need or require to  
6 make an attestation of training and experience? What  
7 is his or her recordkeeping requirements to document  
8 this decision?

9           In grandfathering with respect to 35.57,  
10 for example, when changing from one licensee to  
11 another licensee, does a second preceptor statement  
12 need to be submitted? And must it be updated every  
13 seven years to address the recentness of training  
14 rule that is in Part 35?

15           How will it be handled if the preceptor is  
16 unwilling to provide, for personal reasons or  
17 perceived liability concerns, a preceptor statement?

18           What liability exists with a preceptor in  
19 making a statement? Especially if NRC is looking at  
20 relationships between medical events and training and  
21 experience, there may be these perceived liability  
22 concerns.

1           If the preceptor's unavailability is due to  
2 the fact that the preceptor died, the program  
3 terminated or there is some length between the  
4 program and a preceptor statement being obtained.

5           Ideally, a generic statement that would be  
6 acceptable, most acceptable and practical. However,  
7 can a single statement language exist that would be  
8 appropriate for an authorized user, RSO, nuclear  
9 pharmacist, medical physicist, as well as applicants  
10 who may not have achieved board certification yet.

11           There may arise situations where an  
12 individual may receive multiple modality training at  
13 different institutions or receive training at one  
14 licensee and complete that training at a second  
15 licensee.

16           Multiple preceptor statements would be  
17 most acceptable in this case because otherwise, it  
18 would be very problematic for a single individual to  
19 get a single preceptor statement that would cover the  
20 complete training and experience requirement.

21           Another issue is licensees whose radiation  
22 safety committees are authorized to approve

1 authorized users and authorized medical physicists  
2 such as broad scope licensees. They currently are  
3 capable of expedited approval process because of their  
4 committee authorizations, yet, may experience delays  
5 in this approval process because of the need to get  
6 -- for the delay incurred by getting this preceptor  
7 statement.

8        Obviously, we have raised many questions  
9 and concerns such as the preceptor statement itself  
10 sounds like it may create a bureaucracy of its own.  
11 Based on the past experience with Part 35 licensing,  
12 many problems arose when regulatory guidance became  
13 de facto regulations.

14        The preference at times -- with Part 35 has  
15 been that if it is a requirement, it should be in the  
16 rules. However, the ACMUI suggests that the  
17 implementation of the preceptor statement occur in  
18 guidance space and via the frequently asked questions  
19 on the NRC website to allow maximum flexibility in  
20 addressing the many issues raised regarding the  
21 preceptor statement implementation.

22        In the last slide, as the NRC goes forward



1 in transitioning to the revised Part 35, there have  
2 been few issues of concern that licensees and other  
3 members of the regulated community have raised. One  
4 has to do with individuals currently in training  
5 programs. They have not had the opportunity to  
6 document their training and experience because it was  
7 not a requirement.

8       The individuals in training need to be  
9 given this opportunity to document their training and  
10 experience. And possibly, a recommendation for  
11 consideration is that these training and experience  
12 requirements should be applied to individuals who are  
13 entering training programs after some time period in  
14 the year 2004 as opposed to trying to retroactively  
15 implement this with individuals in training who are  
16 nearing the end of that training phase.

17       The authorized medical physicist is a new  
18 definition which did not exist previously. Some  
19 Agreement States do not explicitly list approved  
20 physicists on their license.

21       In order to ensure that the current  
22 shortage of authorized medical physicists is not made

1 worse, a mechanism is needed to assure that not only  
2 is the initial pool of AMPs not compromised, but also  
3 to provide as a source of preceptor for future  
4 authorized medical physicists.

5       Lastly, the transition issue involves  
6 nuclear medicine authorized users.

7       Part 35 was revised -- before Part 35 was  
8 revised, I-131 use was based on therapy versus  
9 diagnostic applications, rather than the activity  
10 limits that are in the current regulations.

11       In other words, an authorized user who was  
12 authorized under Section 200 of Part 35 could use  
13 I-131 for diagnostic imaging and localization studies  
14 with more than 30 microcuries. This application is  
15 used to assess patients prior to thyroid cancer  
16 treatment and usually does not exceed a few  
17 millicuries.

18       Now it requires that that physician meet  
19 the training and experience requirements for therapy  
20 applications requiring a written directive in Section  
21 392.

22       Some method needs to be found so that

1 authorized users currently providing this study for  
2 patients are permitted to continue providing this  
3 diagnostic application.

4 Because of the comment period that just  
5 closed, additional issues may be raised before the  
6 final rulemaking period occurs. The ACMUI can  
7 provide valuable assistance and will definitely make  
8 itself available to staff during the review and  
9 implementation of these changes.

10 So again, on behalf of the ACMUI, we  
11 appreciate the opportunity to comment and present our  
12 views on these changes.

13 DR. CERQUEIRA: Should we go on to the next  
14 presentation?

15 CHAIRMAN DIAZ: Yes.

16 DR. CERQUEIRA: The next presentation is  
17 going to be the ACMUI review of the NRC method of  
18 dose reconstruction. The presentation will be made by  
19 Dr. Leon Malmud.

20 DR. MALMUD: Good morning, Chairman Diaz  
21 and members of the Commission.

22 I'm Leon Malmud, a board certified nuclear

1 physician and dean emeritus at Temple University  
2 School of Medicine serving as the representative of  
3 health care administration on the ACMUI.

4         The Chairman of the ACMUI, Dr. Cerqueira,  
5 appointed a subcommittee consisting of a patient  
6 advocate, a medical physicist, radio pharmacist, a  
7 therapy physicist and myself as chair to review  
8 material relating to the radiation dose estimates in  
9 the St. Joseph Mercy Hospital incident.

10         Briefly, a patient with metastatic thyroid  
11 cancer who was also in renal failure was treated on  
12 an in-patient basis with 285 millicuries of I-131. The  
13 renal failure is a relevant issue because in patients  
14 with impaired renal failure there is delayed  
15 excretion of the I-131. And therefore, a retained  
16 I-131 dose in the patient given to any visitors a  
17 prolonged exposure to the I-131 in the patient.

18         The patient succumbed to her illness six  
19 days following the I-131 therapy. During that  
20 six-day period, the patient's daughter, whom we are  
21 told was given radiation protection guidelines in  
22 order to minimize the radiation burden that she would

1 receive from her mother, chose to ignore the  
2 guidelines so that she could be physically close to  
3 her terminally-ill mother.

4       As a result of the daughter's  
5 noncompliance, she received a higher than allowed  
6 radiation burden to herself.

7       The NRC's methodology for calculating the  
8 radiation burden to the daughter is being called into  
9 question. Not the fact that in this instance that  
10 the radiation burden to the daughter was even in the  
11 best case scenario, exceeding the 100 millirem  
12 limit -- remember the public for the guidelines --  
13 what was called into question was the methodology for  
14 calculating the radiation burden.

15       We are still in the process of collecting  
16 data and questioning the assumptions presented. For  
17 example, did the daughter actually sit by the  
18 patient's bed for 12 hours a day for 3 days with her  
19 arms physically on the bed and then, for 20 hours a  
20 day for the fifth and sixth days? What was the real  
21 half life of the I-131 in the patient. How was it  
22 measured?

1           It is the assumptions that are being  
2 questioned. The calculation, method of calculation  
3 is not that which is being brought into question.

4           In the absence of adequate contemporaneous  
5 records, and there were inadequate contemporaneous  
6 records, what assumption should be made before  
7 calculating the radiation burden to the daughter?

8           Also, how should a similar situation be  
9 addressed in the future? What guidelines would be  
10 helpful to RSOs and to licensees in addressing in a  
11 humane and compassionate manner noncompliance by  
12 people that we refer to as public visitors?

13           Would more timely notification of the  
14 regional office be appropriate? Would some other  
15 techniques for alerting the individuals who has  
16 refused to comply be effective?

17           We hope to have a final report for  
18 submission to the ACMUI within four weeks. At which  
19 point it will be reviewed by the total ACMUI and  
20 prepared for presentation to the NRC.

21           Thank you.

22           CHAIRMAN DIAZ: Thank you, Dr. Malmud. We

1 appreciate your very, very good summary of this  
2 situation.

3 Any other comments?

4 DR. CERQUEIRA: Those are the only two  
5 issues that we wanted to present to the  
6 Commissioners.

7 CHAIRMAN DIAZ: Okay. Thank you.

8 Commissioner Merrifield?

9 COMMISSIONER MERRIFIELD: Mr. Chairman, I  
10 guess, first, discussing the presentation that we  
11 first had by Mr. Lieto.

12 You have raised, I think, a lot of issues  
13 you got under consideration and then are, obviously,  
14 also being considered by our staff. I'm not really  
15 in a position to directly comment on my agreement or  
16 lack of agreement with the individual things you  
17 proposed. But certainly would hope that the staff in  
18 its dialogue can continue discussions with all of you  
19 and be able to explain to everyone where they are  
20 coming from and why they decided to make the  
21 recommendation they are going to be making to us.

22 On the issue of dose reconstruction, I

1 would agree with the Chairman, Dr. Malmud, that this  
2 is a very good presentation and I appreciate it. The  
3 issue of dose reconstruction we talked about, I  
4 think, quite well earlier on.

5 I do think it's going to be very helpful to  
6 get your independent views of how we went about  
7 conducting this effort. And certainly, as we go  
8 forward in the future, you talked about guidance  
9 documents, I think also having -- we ought to think  
10 about in the future having a very clear set of  
11 operating instructions for our own staff that  
12 everybody will be aware of as to how we go about  
13 making some of those judgment calls. To the extent  
14 we can.

15 Sometimes you have to make judgment calls  
16 on the spot. But to the extent we can be more  
17 transparent about our thinking on some of that,  
18 that's helpful. I certainly would recommend your  
19 continued dialogue on that issue as well.

20 In terms of additional questions, I guess  
21 I would -- I did raise an issue with our staff  
22 regarding the 20 percent number that we utilized



1 regarding medical events. I would be interested, if  
2 you did have any observations you want to make on  
3 that particular topic, given the dialogue that I had  
4 with Dr. Miller.

5 DR. CERQUEIRA: Dr. Williamson would like  
6 to make a comment.

7 DR. WILLIAMSON: Good morning, Chairman  
8 Diaz and Commissioners. I am Jeff Williamson, the  
9 therapy physics representative to the ACMUI.

10 Well, I think from the perspective of a  
11 working physicist in radiation therapy, to a great  
12 extent, our committee, the medical event criteria are  
13 not firstly criteria or harbingers necessarily of  
14 patient injury or risk. They were negotiated based  
15 on what our overall views were regarding the  
16 capability of the equipment now being used to deliver  
17 doses with a given precision, the kinds of QA  
18 guidelines we use which in radiation therapy we  
19 normally try to administer doses with a five percent  
20 accuracy.

21 So they, in essence, serve, I think, more  
22 as a harbinger of there is a problem with the

1 delivery or planning system that needs to be looked  
2 at. So it is kind of a performance end point that  
3 may be the ultimate goal of the new performance-based  
4 regulation to reduce.

5         And as our discussions evolved regarding  
6 the need for patient notification, the notification  
7 needs to be made because once one knows -- a federal  
8 agency knows of an infraction or avoidable error that  
9 was made and could possibly have consequences for the  
10 health of the patient, then there is an obligation to  
11 tell the patient.

12         But it is not firstly from our perspective  
13 a criterion that means harm or potential harm to the  
14 patient.

15         So it is set several -- you know a  
16 multiple of three to four above the normal operating  
17 procedure. It is certainly true that depending on  
18 the modality, the requirement may not always be easy  
19 to apply.

20         For example, permanent seed implants for  
21 prostate cancer is an area where -- or an application  
22 where the user, despite his or her best efforts and

1 the best quality control implanting, once the seeds  
2 are implanted, you really don't have control how much  
3 the prostate is going to reduce in volume as edema  
4 resolves.

5 Seeds may move. In some patients, the  
6 prostate may be more difficult to visualize on post  
7 implant imaging procedures than others.

8 So there is a whole range of things that  
9 could happen. You really have limited control. And  
10 20 percent may not be completely reasonable.

11 So that is an issue we are now struggling  
12 with with the staff to give them guidance on how to  
13 apply the medical event criteria in a reasonable way  
14 to prostate implants that does not penalize well done  
15 procedures but helps identify the tails of the  
16 distribution of practice quality so that events that  
17 really are significant deviations from acceptable  
18 quality assurance practices are identified.

19 I guess that's in summary how we have  
20 tended to look at it as a committee and we thought  
21 that the 20 percent was reasonable on that basis.

22 CHAIRMAN DIAZ: I believe that one of your

1 colleagues wants to make a comment.

2           MR. NAG: I am Subir Nag. I'm a member of the ACMUI. I am  
3 also a clinician, a radiation oncologist practicing  
4 at Ohio State University. I would like to make  
5 additional comments. Dr. Williamson had given a physician  
6 perspective. I would in addition like to give a clinician  
7 perspective.

8           This would be on the definition of medical event. Also  
9 what the perception of the public becomes when you  
10 figure this medical event.

11           Where did this number, 20 percent, come  
12 from? I believe the number 20 percent came from the  
13 external beam, but there is a big difference between  
14 external beam and brachytherapy. An external beam, the  
15 volume that radiates is quite large. The volume that  
16 it radiates is outside the pocket is also very large.  
17 And therefore, I think 20 percent makes a significant  
18 difference in external beam because the colorings of  
19 the body is not only dose dependent but more  
20 importantly, is volume dependent.

21           And therefore, when you are radiating a big  
22 volume, 20 percent above what you wanted to give, you

1 can figure adverse consequences.

2         In brachytherapy, it is totally different. The

3 volume within your target is much, much smaller.

4         Secondly, the volume radiates to the

5 outside in extraneous mode. And therefore, the body

6 would volume out probably a much more than a 20 percent

7 difference.

8         I think this 20 percent that automatically

9 permits an external beam needs to be examined. The

10 reason is. When you label something as a medical

11 event, you think of fear in the patient when there

12 may be no abnormal consequences at all.

13         If I gave the target not 20 percent more

14 but 100 percent more, I probably would not cause any

15 damage because that is within the tumor area unless

16 there was abnormal tissue within the area.

17         So what we need to figure out is what does

18 the surrounding normal tissue get. Even that, it is

19 not very easy because the volume, the dose mode that

20 it may be only one CC and getting a much bigger dose

21 and that may be a very minimal consequence.

22         The problem is once you have now labeled

1 something as a medical event, you have informed the  
2 patient. The patient perception is something went  
3 wrong. I am now overdosed. And even if they have  
4 minor side effects, this is because the doctor did  
5 something wrong and it may trigger adverse consequences, legal  
6 action -- when none of this should have happened.

7         So I think we need to either form a  
8 subcommittee or get the views of members of the  
9 American Bachytherapy Society, et cetera, and as to  
10 whether this 20 percent is set in stone or is  
11 ill-advised. Or it can be linked to what the normal  
12 tissue dosage are rather than what did the human get.

13         CHAIRMAN DIAZ: Thank you.

14         COMMISSIONER MERRIFIELD: If I could ask a  
15 follow-up question on that.

16         One of the issues that was raised by our  
17 staff -- Dr. Paperiello, I think, spoke to this  
18 issue, and that is: Using that trigger level as our  
19 identification of new modalities that may have some  
20 teething pains when they are first applied. Is the  
21 response that you have articulated different in that  
22 cases?

1 Does 20 percent make more sense?

2 MR. NAG: Probably not. I think it should  
3 be more risk based. I think you can use that 20 percent value  
4 to apply to the other information but not make  
5 enforcement based on 20 percent. Twenty percent may  
6 be a way to gather or let's check what is happening.  
7 But to use that 20 percent to enforce, make it a  
8 medical event, report it to everybody, may be a  
9 problem in my mind or in the clinician's mind.

10 COMMISSIONER MERRIFIELD: Chairman, I  
11 appreciate this dialogue. Obviously, like many of  
12 our boards, there are some differences of opinion and  
13 that's healthy. And I think it's good to see that as  
14 there are differences of opinion on this side of the  
15 table, too. And that's healthy.

16 But I think this is worthy of a further  
17 dialogue from my own part. I'm speaking for myself.  
18 It may be yet something else we may wish to consider  
19 having ACMUI either in the whole or as a subcommittee  
20 take a look at and see if we are doing this in the  
21 risk-informed way -- risk-informed not risk based --  
22 risk-informed way that we like to do business around here.

1 Thank you, Mr. Chairman.

2 CHAIRMAN DIAZ: Thank you, Commissioner  
3 Merrifield.

4 That was a significant part of what I was  
5 going to do. So you guys have already preempted me  
6 which I resent. But that's okay. I'll live with  
7 that.

8 I do believe -- maybe you want to comment  
9 on it -- that there is a need now that we know more  
10 and we know some of this variations that exist and  
11 that we have to deal with it. Whether ACMUI could  
12 provide some additional recommendations to the  
13 Commission on what is a medical event that -- what  
14 are the issues that need to be dealt with? When does  
15 a medical event become an abnormal occurrence?

16 I think these are issues that you might  
17 want to look at because we deal with those issues all  
18 the time. And your expertise -- we normally tell  
19 the regions and the residents that you're where the rubber  
20 meets the road, that's where you are. We will value  
21 any recommendations or suggestions in how to go a  
22 little further, a path forward, and how we deal with



1 these issues.

2 I invite your comments, Dr. Cerqueira.

3 DR. CERQUEIRA: I think certainly, we can  
4 look that and then, in the area of therapeutics, it  
5 is certainly a very important issue. I think with  
6 diagnostics, again, if we sort of risk informed, it  
7 is certainly not as much of an issue.

8 But we certainly will be happy to look at  
9 that and come back to the Commissioners with further  
10 recommendations.

11 CHAIRMAN DIAZ: We report abnormal  
12 occurrences to the Congress. And we canvas all of  
13 these issues. And I think on certain occasions the  
14 difference between a non-medical event and a medical  
15 event, and an abnormal becomes important to us.

16 Any additional comments?

17 Okay. And I did hear very well the issue  
18 on the Part 35, especially the preceptor seems to  
19 require some additional pre-analysis before the final  
20 rule is made. And we value your comments on it.

21 I think that your comments, Dr. Lieto, on  
22 the transition. It is a very important issue.

1           Every time there is a transition there are  
2 issues. And those interfaces need to be addressed.  
3 And what I'm hearing is that we need to put a little  
4 more effort into those areas.

5           Any additional comments on that?

6           DR. CERQUEIRA: No. We appreciate the  
7 Commission's support on this. And obviously, the  
8 ACMUI will be available and make itself available to assist the  
9 staff in this manner.

10          CHAIRMAN DIAZ: I look forward to the  
11 completion of the report. With that, Commissioner  
12 McGaffigan.

13          COMMISSIONER MCGAFFIGAN: Thank you,  
14 Mr. Chairman.

15          On this issue of the 20 percent, I will  
16 just give you the perspective, may indicate some  
17 differences in this side of this table. I have no  
18 problem with you all looking at how we could  
19 communicate better about it.

20          Having just gone through a multi-year  
21 rulemaking where we ended up at 20 percent again the  
22 notion of launching a rulemaking to change the

1 definition of a medical event, given all the other  
2 rulemakings we have to do, given the budget  
3 stringency that we are facing, particularly in NMSS  
4 rulemaking space, that may not be the best use.

5       But in terms of trying to communicate  
6 better with the public, including the Congress, that  
7 a medical event does not mean an adverse effect on  
8 the patient. Rarely does it mean that. I think that  
9 was clear in the statements of consideration at the  
10 time we did the rule but maybe we fall back.

11       And I know there were reporting  
12 requirements that come with it. And they may have  
13 some baggage. And I understand the baggage. But I  
14 think it is more a communication issue than it is a  
15 rulemaking issue.

16       The number was chosen not because it is,  
17 as everybody have said, it is a point at which the  
18 patient is harmed. So we need to think about  
19 rulemaking versus communicating better and having...

20       The other issue I'm going to raise does not  
21 have to do with your presentation today. One  
22 clarification I was going to make.

1           On the Mercy Hospital case I was using 500  
2 millirems for an ornery Commissioner that I hope is  
3 never in the position that that young lady was in.  
4 But at the time of the event, 100 millirems was the  
5 rule.

6           Because we first changed the patient  
7 release rule to 500 millirems several years ago. And  
8 then when we redid Part 35, we stayed with 500  
9 millirems for patient release and adopted a proposed  
10 petition for rulemaking from one of the hospitals  
11 that we go to 500 millirems for patient visitation as  
12 well.

13          So there may be some confusion out there  
14 about the 100 versus 500. Five hundred is the rule  
15 today. And I'm very happy that 500 is the rule  
16 today. At the time of the Mercy Hospital event, the  
17 number was 100, the one that we are reconstructing  
18 the doses on.

19          The issue that I am going to bring up that  
20 was not on the agenda but was on your agenda  
21 yesterday is the issue that we brought you into  
22 security and got you a safeguard's briefing

1 yesterday. But what I am going to say at the moment, it  
2 is not safeguard information, it is national policy.

3       We have a commitment to -- our Ambassador  
4 to the IAEA has made a commitment to the IAEA code of  
5 conduct, the enhanced code of conduct on the safety and  
6 security of high risk sources.

7       One of the things we have to do under that  
8 commitment is have -- be able to have cradle to grave  
9 controls on high risk sources. And we have launched  
10 an effort with very strong support from the top of  
11 the Commission and strong support from elsewhere in  
12 the Executive Branch and the Congress that we get our  
13 initial inventory of who has high risk radioactive  
14 sources and get that in our hands, preferably  
15 yesterday.

16       We been at this now for a couple of  
17 months. We have told the Congress, I think in the  
18 Chairman's previous letter to Congress that we had  
19 launched this effort. And I just tell you that we  
20 want to get that data. Oak Ridge is our contractor.  
21 If Oak Ridge contacts you and says -- it is perfectly  
22 fair for to you call back to the NRC and say is this

1 person doing this on your behalf. And I don't have  
2 the name of the Oak Ridge contractor. But Oak Ridge  
3 is doing this.

4 Your Agreement States -- if your Agreement  
5 State is doing this, for the most part -- some of  
6 them asked us to do it. But for the most part, the  
7 Agreement State is doing it for us. But we want to  
8 have a pretty darn accurate inventory of who has what  
9 the IAEA has defined in the annex to the code of conduct  
10 to be high risk sources.

11 And that does not mean we are going to have  
12 reactor type security at your facilities. What it  
13 means is because these sources are largely  
14 self-protecting in your facilities, somebody isn't going  
15 to walk into a brachytherapy machine, take the source out  
16 and go off and do something with it probably without  
17 killing themselves fairly rapidly most days of the  
18 week.

19 We need to know where they are. And then  
20 we are going to separately figure out -- and you  
21 heard some of that probably yesterday as well --  
22 where they stand, what additional security measures,

1 if any, are needed at various facilities.

2           We have decided that additional security  
3 measures are needed for large irradiators. We had  
4 decided that additional security measures are needed  
5 for manufacturers and distributors of high risk  
6 sources. That you have significant numbers of them.  
7 And the staff is working on additional categories,  
8 lower risk categories of folks and trying to decide  
9 whether we need additional things.

10           But the inventory is very important to us.  
11 I don't think you will be involved because I think it  
12 is your distributor that will be involved.

13           But we will also, I suspect, by the end of  
14 this year, certainly by some time next year, we are  
15 likely to have an export/import regime for these  
16 sources so that every high risk source that enters or  
17 exits the country requires a license.

18           And I think we are trying to lead the world  
19 in this effort. And I think we are leading the world  
20 in both of these areas in terms of getting an  
21 inventory and in terms of having an export and import  
22 regime that is implemented.

1           But I understand there was some concern.  
2   And it may show that we are not -- again  
3   communication is a lot of our problem around here.  
4   We may not have communicated well with people why  
5   we are doing this, why we are doing it and how we  
6   doing it. But it is terribly important that we get  
7   full cooperation from your community as we do this.

8           So if you have any comments, that's fine.  
9   Otherwise, everything I said is public information  
10   and is the sort of thing that's been in Chairman  
11   letters to the Congress.

12           CHAIRMAN DIAZ: I think it will be  
13   important that you see this information, that we  
14   receive the benefits of any guidance regarding the  
15   differences in this potential security requirements.  
16   That might be -- we are looking for simple things  
17   that people do to safeguard the sources.

18           COMMISSIONER MCGAFFIGAN: That latter stuff  
19   may be for their own deliberation. Not right in  
20   front of us.

21           DR. WILLIAMSON: Not on this topic. I wanted to  
22   before the close of the meeting make a couple of



1 comments on the dose reconstruction.

2 DR. CERQUEIRA: Do you have a comment related o this specific --

3 MR. LIETO: Is there something specifically that we can do to --

4 COMMISSIONER MCGAFFIGAN: You should have

5 already, theoretically, we should have the data from

6 all of you already. It was not an order that went

7 out. It was an information request. But, if

8 necessary, there's discussion among us as to whether

9 orders will be issued to those who do not comply

10 voluntarily.

11 DR. CERQUEIRA: It did come up during the

12 discussion yesterday that perhaps there is a

13 communication problem that some of the licensees were

14 contacted without having any idea who was contacting

15 them and what the information was going to be used

16 for.

17 So I think the license community is not

18 necessarily aware that this is ongoing or who was

19 doing it. So I think that communication issue should

20 be addressed.

21 COMMISSIONER MCGAFFIGAN: We are having to

22 make an awful lot of follow-up phone calls. And I

1 appreciate -- one of the comments I understand was  
2 made yesterday was that you all are very reluctant to  
3 give somebody who calls you up your list of high risk  
4 sources.

5 I commend you for that. I absolutely and  
6 totally commend you for that.

7 So we have to make sure that you understand  
8 that the person contacting you is legitimate. But we  
9 also need the information.

10 And it is my understanding that the staff  
11 has been making hundreds of follow-up calls. And  
12 that may be because we didn't adequately communicate  
13 at the outset and give this person a bona fide that  
14 said this person is acting for NRC and this is a  
15 legitimate thing we are doing in response to a  
16 national commitment to the code of conduct.

17 Commissioner Merrifield usually makes  
18 speeches about communications being at the heart of  
19 all problem. And this may have been the case here.

20 CHAIRMAN DIAZ: Very good. Well, I think  
21 that this is an issue that concerns all of us and we  
22 want to find simple and good solutions to it. I

1 appreciate it.

2 COMMISSIONER MCGAFFIGAN: I think there was  
3 one comment.

4 CHAIRMAN DIAZ: I'm sorry. Go ahead.

5 DR. WILLIAMSON: Thank you very much.

6 I'm a member of the dose reconstruction  
7 subcommittee and two issues we were planning to  
8 follow-up on that may take longer than our month  
9 deadline would be to consider the general issue of to  
10 what extent do the rules allow compassionate  
11 dispensation to give a loved one or a caregiver a  
12 higher limit than would normally be accorded to the  
13 general public.

14 For example, NCRP has procedures and  
15 recommendations that will allow, in extraordinary  
16 circumstances, an individual to get up to a REM.

17 This is widely used for parents in managing  
18 pediatric patients who are getting x-ray examination.  
19 So we would like to make some recommendations on this  
20 and not sort of have the -- force hospitals to be in  
21 the position of actively discouraging always such  
22 patient visitation. Is that reasonable?

1 I think the second, the last comment I  
2 would like to make is also in the dose reconstruction  
3 subcommittee. We would maybe like to, if we possibly  
4 can, come up with some more general recommendations  
5 on how the scientific integrity of NRC dose  
6 reconstructions in general can be improved.

7 So we will use our examination of this  
8 incident to try to see if we can make some  
9 improvements along that line. It does in this case  
10 seem to be kind of a crisis of confidence of the  
11 regulated community. And these calculations may be  
12 more than it is any kind of a technical issue.

13 Finally, with regard to the Part 35 RSO  
14 certification, there is a lot of concern in the  
15 community. Many small licensees who do nuclear  
16 medicine, for example, the certified diagnostic x-ray  
17 physicist or nuclear medical physicist may be, by far  
18 and away, the most expert and qualified person to  
19 take on the RSO duties on behalf of a licensee,  
20 provided that the individual has work experience in  
21 those areas.

22 So it is not -- I don't think we are

1 trying to propose that the requirement for broad  
2 scope licensee RSOs be rewritten. But I think it is  
3 an issue of the smaller more limited scope licensees.

4 CHAIRMAN DIAZ: Well, thank you,  
5 Dr. Williamson. And I want to thank the staff and  
6 the committee for their presentation.

7 COMMISSIONER MERRIFIELD: I have one.  
8 This is a response to a comment made by Commissioner  
9 McGaffigan.

10 I share your concern about costs of  
11 rulemaking and things of that nature. I certainly  
12 would express a similar sentiment.

13 It would seem to me and I think my desire  
14 to have ACMUI take a look at the 20 percent  
15 figure, is reflective of what we went through on the  
16 reactor side relative to getting away from level four  
17 violations and going to non-cited violations.

18 We still are effectuating the right  
19 outcomes. We are getting our licensees to change  
20 their way of doing business.

21 But the degree of emotion involved in  
22 that, like going from a penalty to a non-penalty, was

1 reduced significantly. We are getting the kind of  
2 outcomes we want.

3       And I'm wondering even if we didn't change  
4 the 20 percent figure, if the issue of what do we  
5 enforce on and when do we enforce, might be looked at  
6 to see if in this area we may be able to turn  
7 the temperature down some as well. As long as we  
8 continue to get the same outcomes I think we would  
9 all agree on that.

10       CHAIRMAN DIAZ: Thank you. On the public  
11 health and safety basis that is certainly an issue.

12       Again, I want to thank you for joining us  
13 today as we being very valuable. We do appreciate  
14 and value your contributions to the Commission. We  
15 look forward to continuing our interactions.

16       And with that, we are adjourned.

17       (Thereupon, the briefing was adjourned.)

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